Global Health Informatics Standards for Patient Safety

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What's happening in the world ?

What's happening in the world?

- Aged Population
- Chronic diseases care
- Dispersed medical records
- Popular physical fitness activities
- Preventable medical errors
- Technological advancement – pull
  - Evidence based medicine
  - Individual based medicine
  - e-Health
  - u-Health

Medical Error

Estimated annual mortality:

Air travel deaths	300
AIDS	16,500
Breast cancer	43,000
Highway fatalities	43,500
Preventable medical errors (*1 jet crash/day*)	44,000 - 98,000

Costs of Preventable Medical Errors:
US$29 billion/year overall

[1999 Institute of Medicine (IOM) Report]

Issues

- Health care industry is not taking advantage of IT
- EHR/data should be shared, data should be integrated.
- Protect person's privacy and security of system
- Shareable EHR should be readily available at point of care and time of care, public health setting and national policy making

New Paradigm of Health Informatics

"Connection and Integration"

New Paradigm

- Consumer focused healthcare
  - empowerment : self govern
  - connect healthcare : integrated records
  - integrate care information
  - safety and risk management
  - quality of care information
  - consumer health information
  - consumer health education

New Paradigm (2)

- Health Informatics
  - lifelong health/care records : interoperable
  - clinical decision support system
  - knowledge management system
  - care process enhancement : workflow
    quality and
    reimbursement

New Systems Needed

- Integrated and comprehensive EHR/EHRS
  - data capture : documents, bio-signals, images, sound, etc
  - data integration
  - data filing
  - data viewing
  - data sharing
  - messaging and communication
  - workflow and process management

New Systems Needed (2)

- Anytime, anywhere, any line, any device
  - web based, wired and wireless
  - portable
  - eHealth, uHealth
  - telehealth
- Decision support
- Knowledge management

Electronic Health Records

- EHR and EHRS
  - Institutional EHRS
  - Sharable EHRS
  - Public Health or Population EHRS
  - Personal EHRS

Global Interoperable EHRS Development

"Examples"

"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

Global Health Informatics Standards Development

"Interoperable 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.

source : IEEE Standard Computer Dictionary : A Compilation of IEEE Standard Computer Glossaries, IEEE, 1990

Functional interoperability
Semantic interoperability

Interoperability (2)

- Interoperability
  - Functional interoperability
    Message format and content
  - Semantic interoperability
    Terms (SNOMED-CT, LOINC) and units
- Vision : PnP (Plug and Play)

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"

Influential Party

- User
- Industry, Vendor
- Standards Developing Organizations(SDO)
- Government
- ISO – one of major SDOs

Global SDOs

ISO (International Organization for Standardization) – Health informatics in general
IEC (International Electrical Commission) – Computer
ITU (International Telecommunication Union) – Telecom.
HL7 (Health Level 7) – EHR, Messaging and Commu.
UN/EDIFACT (UN/EDI Finance, Administration, Commerce and Transportation) – EDI
UN/CEFACT(UN/Center for Electronic FACT) – XML and OASIS ebXML

Global SDOs(2)

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

WHO – Classification of diseases (ICD)

SNOMED (Systematized Nomenclature of Medicine)

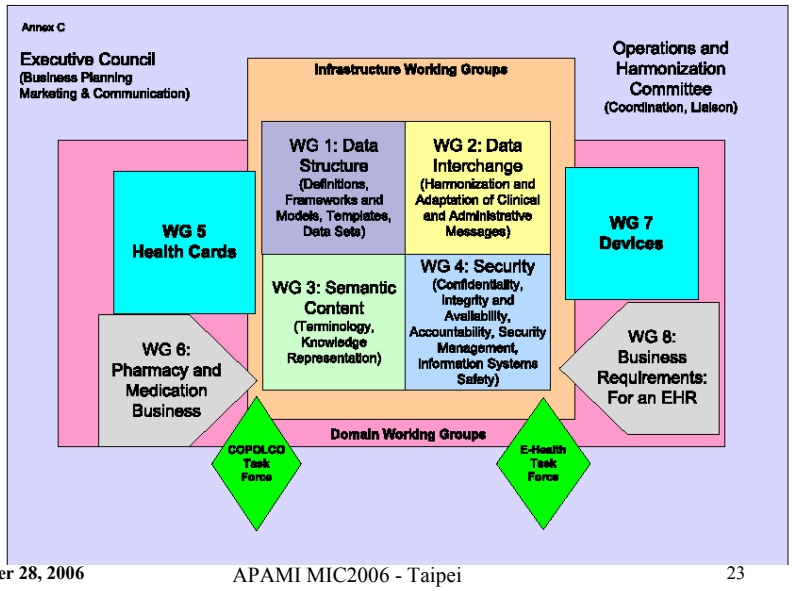
LOINC (Logical Object Identifier Nomenclature Codes)

Standards Conformance Testing Organizations

IHE (Integration of Healthcare Enterprise) –
"Connect-a-thone" demonstration of interoperability
XDS-Rad., Lab., Cardiol., Eyecare, Patientcare Device, Patientcare Coordination, IT Infrastructure

HIMSS (Health Information Management Systems Society) – CCHIT Project
CCHIT=Commission on Certification of Health Information Technology

ISO/TC 215, Health Informatics



SDOs Working Together

CEN/TC 251, Health Informatics

Health Level 7

DICOM

IHE

WHO

Health Level Seven (HL7)

V2.5 Messaging
V3.0
Reference Information Model (RIM)
Clinical Document Architecture (CDA) R2
Arden Syntax
Clinical Context Object Working group (CCOW)
EHR Functionality (DSTU)

Health Level Seven (HL7)

Common Terminology Services R1
Structured Product Labeling
Individual Case Safety Report
Electronic Submission of Stability Data
Annotated ECG for Clinical Trial submissions

Global Health Informatics Standards for Patient Safety

GHTF Risk Management Push

- After 9.11 event Global Harmonization Task Force (GHTF) requested all global SDOs should develop standards for risk management.
- All port safety with airlines and shipping risk management against terrorism

GHTF Risk Management Push (2)

- ISO/TC 215, Health Informatics looked at patient safety issues
  - accurate data/information transmission
  - medical device data safety
  - system security and privacy protection
  - bioterrorism alert

Patient Safety

- Assuring interoperability
  - Data structure
  - Terminology and coding
  - Messaging and communication
  - Medical device interoperability
- Security and privacy protection
- Conformance
- Testing - QoS

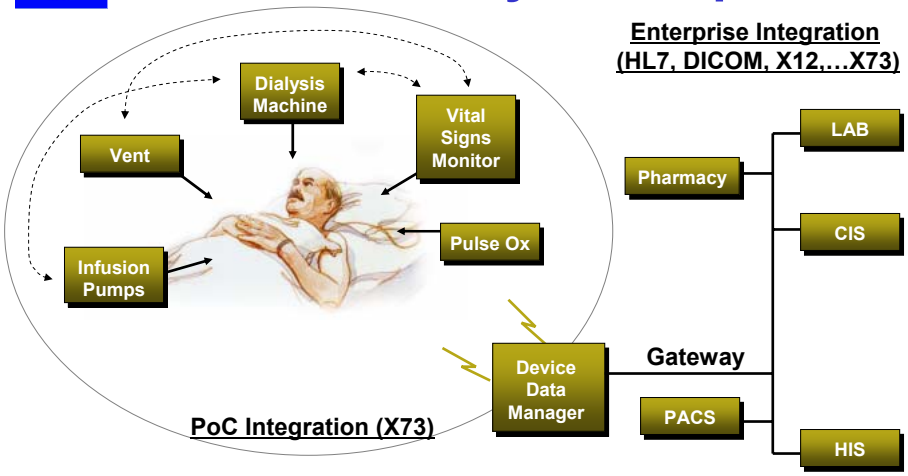
Patient Safety (2)

- ISO/TR 21730 Health informatics - Use of mobile wireless communication and computing technology in healthcare facilities - Recommendations for electromagnetic compatibility with medical devices
- ISO/TC 215/WG4 TR Health Informatics – Measures for assuring patient safety of health information program

Point-of-Care Medical Device Informatics & Interoperability

Key Concepts

PoC MDI² Key Concepts



Multi-vendor environment

Requires both semantic & technical interoperability

PoC MDI² Key Concepts

Specifically which devices are we looking at?

- *Vital signs monitors*
- *Infusion pumps*
- *Ventilators*
- *Dialysis devices (acute & chronic)*
- *Implantable cardiac devices*
- *Glucometers*
- *Blood gas analyzers*
- *Pulse oximeters*
- *… (hospital beds?)*

PoC MDI² Key Concepts

PoC integration characterized by…

- ✓ Real-time (milliseconds to seconds)
- ✓ Device-to-device "peer" interoperability
- ✓ Device external control…local & remote
- ✓ Regulated environment – *Direct* Patient Safety concerns!
- ✓ High precision semantics – greater than at clinical level
- ✓ Resource sensitive (memory/bandwidth/processor/…)

PoC MDI² Key Concepts

Key Benefits of device interoperability:

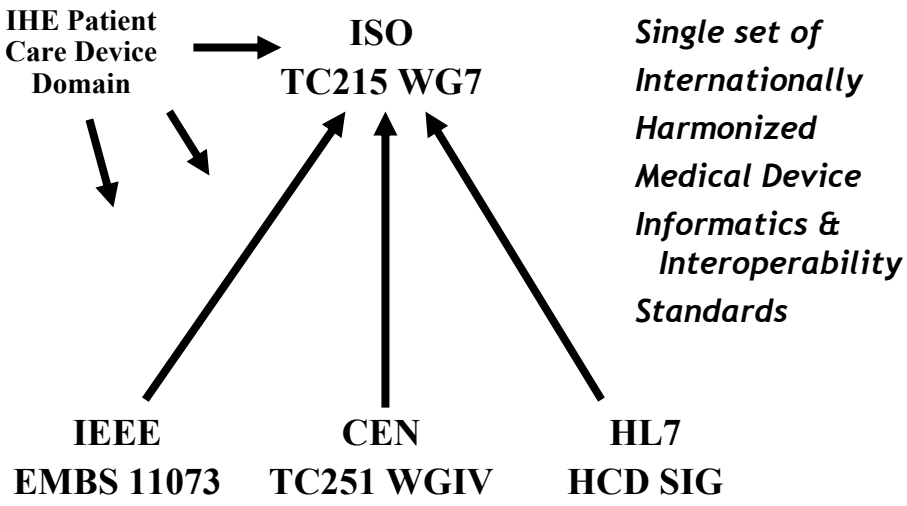
- Heterogeneity – Multiple manufacturers + multiple device modalities coexisting over a shared infrastructure
- Semantic Interoperability (comparability) – shared terminology and data models, interpret data based on the clinical context, compare information from different healthcare facilities, and interrogate systems across enterprises and regions.
- Real-Time Availability – ability to provide data in a time frame appropriate to the physiologic function being measured, displayed or affected (controlled).

PoC MDI² Key Concepts

Innovation from interoperability…

- ✓ *Smart alarms / alarm management systems*
- ✓ *OR Dashboards*
- ✓ *Acute dialysis "fluids management"*
- ✓ *Smart Pumps / ADE Detection & Intervention*
- ✓ *Mobile patient monitoring / Remote viewing*
- ✓ *Anesthesia record data mining*
- ✓ *Shared Infrastructure (Security, QoS, Services…)*
- ✓ *Home monitoring (wellness … chronic)*
- ✓ *EHR / PHR Integration!*

PoC MDI² Organizations



Single set of Internationally Harmonized Medical Device Informatics & Interoperability Standards

Point of Care Device Interface - Working Trends

- Multiple devices and multiple vendors
- ISO/TC215 WG7, IEEE X73, CEN/TC251 WG IV and HL7 Health Care Device SIG develop and harmonize standards together
- Terminology maybe SNOMED-CT, LOINC and ??

PoC MDI² X73 Standards

11073-1xxxx	Device Data & Services
11073-2xxxx	General Application Services
11073-3xxxx	Transport & Physical Layers
11073-5xxxx	Internetworking Support
11073-6xxxx	Application Gateways

Point-of-Care Medical Device Informatics & Interoperability

Networked Medical Device Risk Management

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"

Q & A

Contact Information

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

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