



Overview of Health Informatics Standardization

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Topics

1. Introduction of ISO TC 215, Health Informatics
2. Issues
3. Future
4. Conclusion



ISO TC 215 Health Informatics

Chair : Yun Sik Kwak (Rep. of Korea)

Secretariat : ANSI (USA)

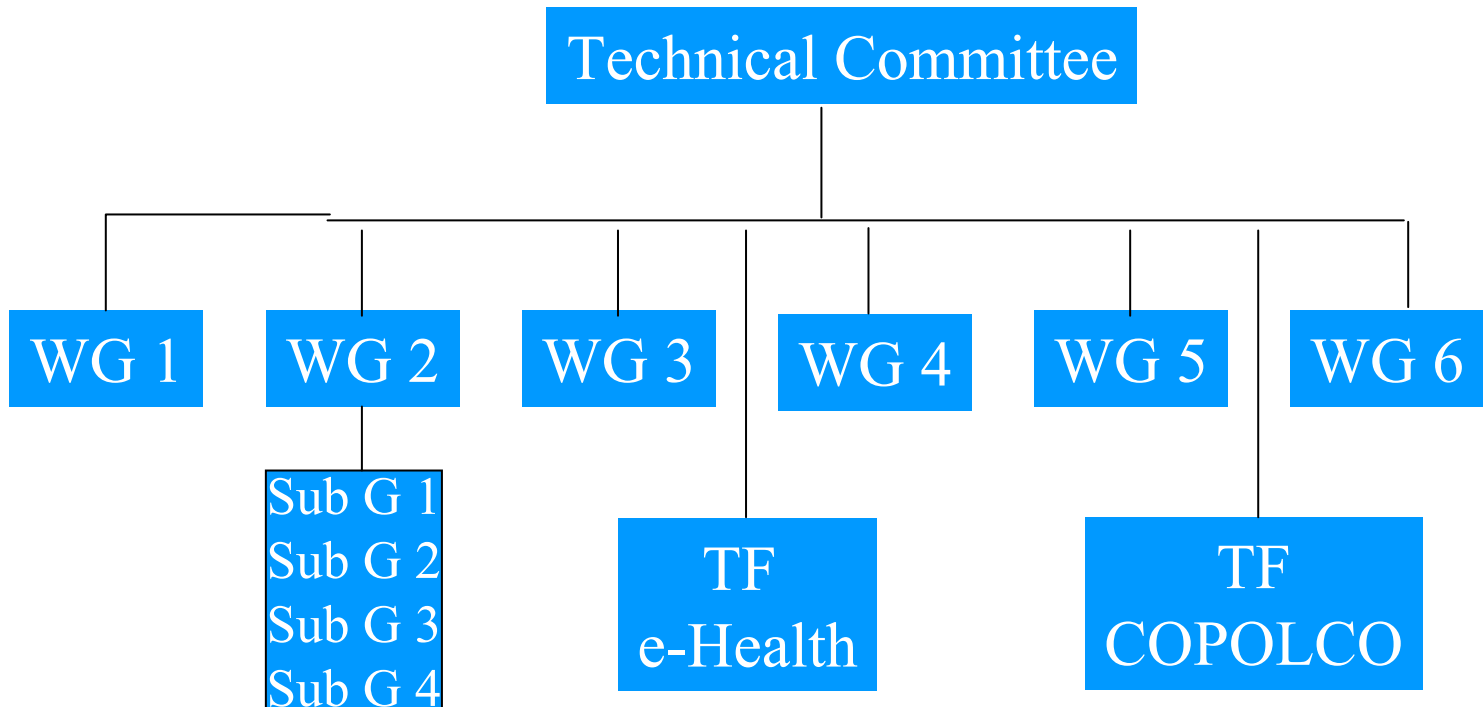
Secretary : Joyce Sensmeier, RN (HIMSS; USA)
Audrey Dickerson, RN

Scope : Standardization in field of information for health, health ICT to achieve compatibility and interoperability between independent systems.

Also to ensure compatibility of data for comparative statistical purpose (eg, classifications), and to reduce duplication of effort and redundancies.



ISO TC215 Structure





ISO TC 215 Membership

'P' Member Bodies = 25

Africa	: S Africa	Kenya	(2)													
N America	: Canada	USA (Secretariat)	(2)													
S America	: None															
Asia	: Israel	Japan	Korea	Turkey	(4)											
Europe	: Austria	Belgium	Denmark	Finland	France	Germany	Ireland	Italy	Netherlands	Norway	Spain	Sweden	Serbia/Croatia	Russian federation	United Kingdom	(15)
Oceania	: Australia	New Zealand	(2)													



ISO TC 215 Membership

'O' Member Bodies = 14

Africa	: Zimbabwe	(1)
C America	: Ecuador	(1)
S America	: Argentina	(1)
Asia	: China India Mongolia Singapore Thailand	(5)
Europe	: Czech Republic Hungary Poland Portugal Switzerland Yugoslavia	(6)

'S' Member Countries

Receive publications



ISO TC 215 WG 1

Health Records and Modelling Coordination

- **Convenor** : Don Newsham (Canada)
- **Scope** : To develop standards to facilitate the capturing, safe communications, and trusted management of information concerning the total health process applied to one subject of care for individual and public health purposes and, furthermore, to coordinate modelling of other relevant standards efforts such as those regarding terminology, messaging, and security
- http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=infostand_ihisd_isowg1_e



ISO TC 215 WG 2

Messaging and communications

- **Convenor** : Edward Hammond (USA)
- **Scope** : effort of the WG 2 is defined as follows:
 - A general statement of the types of standards to be considered (for example, the functional purpose of the interchange and the circumstances in which the interchange should occur)
 - The specific domains of activity (that is, clinical messaging, medical device communication, and business and financial messaging)
 - A set of additional tasks or working principles that will guide the effort
- www.hl7.org/special/committees/tc215
- <http://isotc.iso.ch/livelink/livelink?func=ll&objId=1300702&objAction=browse&sort=name>



ISO TC 215 WG 2

Messaging and

communications(cont')

- **Scope** : A means of implementing that interchange in one or more syntax or communication modalities.
- **Specific Domains** :
 - Clinical messaging
 - Medical device communication
 - Business and financial messaging



ISO TC 215 WG 2

Messaging and

communications(cont')

- Sub-working Groups :
 1. Architecture
 2. Device interface
 3. Methodology
 4. DICOM persistent object



ISO TC 215 WG 3

Health Concept Representation

- **Convenor** : Christopher Chute (USA)
- **Scope** : To develop standards for representation of health concepts. These standards include formal models of representation and description of health concepts; principles of their organization within terminologies and their related systems (including controlled clinical terminologies and classifications); and issues concerning context of their use in electronic health records.
- <http://www.tc215wg3.nhs.uk/>



ISO TC 215 WG 4, Security

- **Convenor** : Gunnar Klein (Sweden)
- **Scope** : Defining standards for technical measures to protect and enhance the confidentiality, availability, and integrity of health information, and also accountability for users, as well as guidelines for security management in healthcare.
- <http://www.medis.or.jp/iso/tc215wg4.html>



ISO TC 215 WG 5 Health Cards

- **Convenor** : Juergen Sembritzki (Germany)
- **Scope** : To develop standards in field of healthcare usage of machine readable cards compliant with physical characteristics, including dimensions defined in ISO/IEC 7810, **Identification cards – Physical characteristics**. The WG shall place special emphasis on standards on technology independent data structure leading to interoperability and compatibility including communication of data.
- http://www.din.de/cgi_ds/dokuser/v/ds_einstieg.init?sprache=en



ISO TC 215 WG 6 e-Pharmacy

- **Convenor** : Ray Roger (UK)
- **Scope** : To be developed.
- ‘P’ members notified to nominate experts.
Need to act soon!
Technical Health Informatician
Pharmacy Informatician
Physician Informatician
Nursing Informatician



ISO TC 215 Liaison

International Council of Nurses	-	Category B
IMIA WG Standard	-	A
UN/EDIFACT D11 Healthcare EWG	-	A
WHO	-	B
World Wide Web Consortium	-	B



ISO/TC 215 Officer Structure

- Chairman
- Secretariat
 - WG Convenors
 - Project Leaders



Chairman

- Responsible for the overall management of the technical committee, including any subcommittees and working groups
- Works closely with the Secretary to ensure effective management of the work programme



Secretary

- Responsible for monitoring, reporting, and ensuring active and timely progress of the work and adherence to the ISO Directives
- Provides administrative support



Working Group Convenor

- Assigned to an individual
 - Convenor shall confirm interest in serving and commitment of time and financial resources
 - ISO/TC 215 convenors have a three year term limit
 - Convenors are responsible for the progress of work items within their respective working group



Project Leaders

- Assigned for the development of each work item
 - Nominated by the proposer of a new project
 - Appointed by the P-members of the TC



ISO/CS Support

- Sophie Clivio, ISO Programme Manager
 - Central Secretariat Contact
 - Coordinates ISO/CS resources for committee's use
 - Procedural questions
 - Work programme
 - Balloting of DIS and FDIS
 - Editing/publication



WEBSITE

- ISO General Site
 - www.iso.ch
- ISO/TC 215 Homepage (LiveLink):
 - <http://isotc.iso.ch/livelink/livelink.exe?func=ll&objId=529136&objAction=browse&sort=name>
- Standards specific information
 - www.iso.ch/sdis
 - Templates
 - Directives
 - Informative articles/*Communiqué*



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 (cont')

- Functional : robust system
- Semantic : data elements, data types
coded terminology
- TC 215 activity :
 - WG 1 - EHR architecture and modeling
 - WG 2 : architecture
interface
methods - ISO/FDIS 17113 MDF
ISO/NWI Data type
ISO/NWI CHICs



ISO/OSI 7 Layers

- Focus is primarily on Level 7 inter-operability
- Medical Device Communications covers all 7 layers.

ISO/OSI Level 7: Application

ISO/OSI Level 6: Presentation

ISO/OSI Level 5: Session

ISO/OSI Level 4: Transport

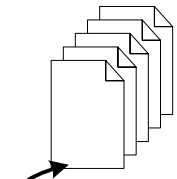
ISO/OSI Level 3: Network

ISO/OSI Level 2: Datalink

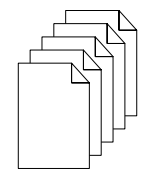
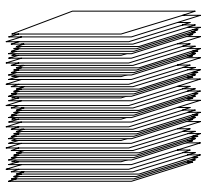
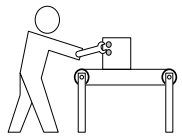
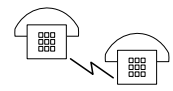
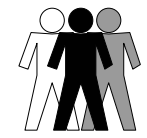
ISO/OSI Level 1: Physical



Use Case Descriptions



Pilot
Projects





Issues

1. Global relevance
2. Inclusiveness and exclusiveness
3. Timeliness of marketing
4. Compliance testing (1-1-1)
One item – one std – one test
5. QoS (Quality of service)



Current Interesting Item

- Health Insurance Claims
 - EDI
 - HL7 Attachment



Current Hot Items

- ITU, WHO are interested in stds:
 - e-Health
 - Telehealth
 - m-Health (u-Health)

(due to usefulness in Africa and other developing countries)
- Emerging healthcare technologies
- Regional cultural diversity
 - APAMI WG



Where do we go to?

1. Inclusiveness of developing countries
2. Multi-cultural representation
3. Clinical users representation
4. Negotiated idealism and realism
5. Market relevance and timeliness
6. Harmonization
CEN and others

**Need your participation through your
country member bodies !**



Where do we go to?(2)

1. Inclusiveness of developing countries
2. Multi-cultural representation
3. Clinical users representation

Twining, Funding, Technology transfer
America, Africa, Asia

4. Negotiated idealism and realism
5. Market relevance and timeliness
6. Harmonization – HL7, CEN and others

**Need your participation through
your country member bodies !**



Future of HI Standards

- Participate in ISO activities.
- Country SDOs localize IS with local language
- Harmonize stds
- Study Ethical, Legal and Social Impact
- Develop experts in HI/NI standards
- Standardization is an essential component of:
 - seamless communication of HI;
 - robust HI system;
 - flawless global interoperability; and
 - global marketing of domestic industry.



Conclusions

- Aim for global participation for consensus
- Remember lessons learned from past experience - interoperability
- New paradigm of intelligent, Web and XML based system, comply with standards for :
 - all healthcare providers' benefit
 - all patients' benefit
 - cost effective solutions
 - “Plug and Play”



Thank you

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ISO/TC215 WG Activities

Working Group 1

- Designation ISO/DIS 17120 Health informatics - Country identifier mechanism in healthcare
- Designation ISO/DTS 18308 Health informatics - Requirements for the electronic health record reference architecture
- Designation ISO/DTS 21667 Health informatics - Health indicators conceptual framework
- Designation ISO/WDTR 17119 Health informatics - A general domain model for health information - profiling framework
- Designation ISO/PWI Health informatics - Emergency data set



ISO/TC215 WG Activities(cont')

Working Group 1

- Designation ISO/PWI Health informatics - Health indicators definitions, attributes and relationships
- Designation ISO/PWI Health informatics - Essential principles of health care documentation
- Designation ISO/DTR Health informatics - EHR definition, scope and context

Working Group 2

- ISO/TR 18307 Health informatics - Key characteristics for interoperability and compatibility in messaging and communications standards (Published in Jan 2002)



ISO/TC215 WG Activities(cont')

Working Group 2

- ISO/IS 18812 Health informatics - Clinical analyzer interfaces to laboratory information systems - Use profiles (Published in Jan 2003)
- Designation ISO/WD 11703-00000 Health informatics - Point-of-care medical device communications - Framework and overview
- Designation ISO/WD 11703-10101 Health informatics - Point-of-care medical device communications - Nomenclature
- Designation ISO/DIS 11703-10201 Health informatics - Point-of-care medical device communications - Domain information model



ISO/TC215 WG Activities(cont')

Working Group 2

- Designation ISO/DIS 11073-20101 Health informatics - Point-of-care medical device communication - Application profiles - Base standard
- Designation ISO/WD 11073-20201 Health informatics - Point-of-care medical device communication - Application profiles - Polling mode
- Designation ISO/WD 11073-20202 Health informatics - Point-of-care medical device communication - Application profiles - Baseline
- Designation ISO/WD 11073-10300 Health informatics - Point-of-care medical device communication - Device specialization - Framework and overview



ISO/TC215 WG Activities(cont')

Working Group 2

- Designation ISO/WD 11073-10301 Health informatics - Point-of-care medical device communication - Device specialization - Infusion device
- Designation ISO/WD 11073-10302 Health informatics - Point-of-care medical device communication - Device specialization - Vital signs monitor
- Designation ISO/WD 11073-10303 Health informatics - Point-of-care medical device communication - Device specialization - Ventilator
- Designation ISO/WD 11073-10304 Health informatics - Point-of-care medical device communication - Device specialization - Pulse oximeter



ISO/TC215 WG Activities(cont')

Working Group 2

- Designation ISO/WD 11073-10305 Health informatics - Point-of-care medical device communication - Device specialization - Defibrillator
- Designation ISO/WD 11073-10306 Health informatics - Point-of-care medical device communication - Device specialization - ECG
- Designation ISO/WD 11073-10307 Health informatics - Point-of-care medical device communication - Device specialization - Blood pressure
- Designation ISO/WD 11073-10308 Health informatics - Point-of-care medical device communication - Device specialization - Temperature



ISO/TC215 WG Activities(cont')

Working Group 2

- Designation ISO/WD 11073-20102 Health informatics - Point-of-care medical device communication - Application profiles - MIB elements
- Designation ISO/DIS 11073-30300 Health informatics - Point-of-care medical device communication - Transport profile - Infrared wireless
- Designation ISO/DIS 11073-30200 Health informatics - Point-of-care medical device communication - Transport profile - Cable connected
- Designation ISO/WD 11073-20301 Health informatics - Point-of-care medical device communication - Application profiles - Optional package, remote control



ISO/TC215 WG Activities(cont')

Working Group 2

- Designation ISO/DTR 21089 Health informatics - Trusted end-to-end information flows
- Designation ISO/PWI 21090 Health informatics - Data types for use in healthcare data interchange
- Designation ISO/PWI 22599 Health informatics - Processes for developing and implementing a message standard
- Designation ISO/DTR 16056-1 Health informatics - Interoperability of telehealth systems and networks -Part 1: Introduction and definitions
- Designation ISO/DTR 16056-2 Health informatics - Interoperability of telehealth systems and networks - Part 2: Real-time systems



ISO/TC215 WG Activities(cont')

Working Group 2

- Designation ISO/DTS 16058 Health informatics - Interoperability of telelearning systems
- Designation ISO/WD 17432 Health informatics - Web access to DICOM persistent objects
- Designation ISO/PWI Health informatics - Stakeholder general purpose information component
- Designation ISO/PWI Health informatics - Methodology for documenting high-level flows (stakeholder to stakeholder) communications
- Designation ISO/PWI Health informatics - Requirements for interoperability and compatibility in messaging and communications standards



ISO/TC215 WG Activities(cont')

Working Group 2

- Designation ISO/PWI 18232 Health informatics - Messages and communication - Procedure result data objects - Unique instance identifiers - Format
- Designation ISO/PNWI Health informatics - Interoperability guidelines for telehealth systems and networks
- Designation ISO/PNWI Health informatics - Quality indicators for health information made available on the Internet
- Designation ISO/PNWI Health informatics - Inventory of healthcare informatics related standards and works in progress
- Designation ISO/PNWI Health informatics - De-identification of health records



ISO/TC215 WG Activities(cont')

Working Group 3

- ISO/TS 17117 Health informatics - Controlled health vocabularies - Vocabulary structure and high-level quality indicators (Published in Jan 2002) - revision proposed
- Designation ISO/CD 17115 Health informatics - Metavocabulary for terminologic systems
- Designation ISO/DIS 18104 Health informatics - Integration of a reference terminology model for nursing

Working Group 4

- ISO/TS 17090-1 Health informatics - Public key infrastructure - Part 1: Framework and overview (in Press)



ISO/TC215 WG Activities(cont')

Working Group 4

- ISO/TS 17090-2 Health informatics - Public key infrastructure - Part 2: Certificate profile (in Press)
- ISO/TS 17090-3 Health informatics - Public key infrastructure - Part 3: Policy management of certification authority (in Press)
- Designation ISO/WD TS 21547-1 Health informatics - Security requirements for archiving and backup - Part 1: Archiving of health records
- Designation ISO/PWI Health informatics - Framework for health information security
- Designation ISO/WD TS 21091 Health informatics - Directory services for security, communications and identification of professionals and patients



ISO/TC215 WG Activities(cont')

Working Group 4

- Designation ISO/DIS 22857 Health informatics - Guidelines on data protection to facilitate trans-border flow of personal health information
- Designation ISO/PWI TS 22600 Health informatics - Privilege management and access control
- Designation ISO/PWI Health informatics - Functional and structural roles

Working Group 5

- Designation ISO/DIS 21549-1 Health informatics - Patient healthcard data - Part 1: General structure
- Designation ISO/DIS 21549-2 Health informatics - Patient healthcard data - Part 2: Common objects



ISO/TC215 WG Activities(cont')

Working Group 5

- Designation ISO/DIS 21549-3 Health informatics - Patient healthcard data - Part 3: Limited clinical data
- Designation ISO/CD 21549-7 Health informatics - Patient healthcard data - Part 7: Electronic prescription
- Designation ISO/PWI 21549-5 Health informatics - Patient healthcard data - Part 5: Identification data
- Designation ISO/PWI 21549-6 Health informatics - Patient healthcard data - Part 6: Administrative data
- Designation ISO/WD 21549-8 Health informatics - Patient healthcard data - Part 8: Links
- Designation ISO/WD 20301 Health informatics - Healthcards - General characteristics



ISO/TC215 WG Activities(cont')

Working Group 5

- Designation ISO/WD 20302 Health informatics - Healthcards - Numbering system and registration procedure for issuer identifiers

Working Group 6 e-Pharmacy

Task Force

- e-Health
- Consumer policy



Thank you

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