

Slide 1

**Networking and Health  
Information Exchange**

Unit 3b  
National and International Standards  
Developing Organizations

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Slide 2

**Objectives**

- To understand the organizations that develop standards for the international community and for the United States.
- To develop an understanding of the kinds of standards being developed and for what purposes.

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Slide 3

**ISO TC 215 Healthcare  
Informatics**

- Standards have national priority
- Members are nations
- Established in 1998
- Products include Technical Reports, Technical Specifications, and International Standards

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Slide 4

**Work groups of TC 215**

- WG1 – Data Structure
- WG2 – Data Interchange
- WG3 – Semantic Content
- WG4 – Security
- WG6– Pharmacy and Medicines – Business
- WG7 – Medical Devices
- WG8 – Business requirements for Electronic Health Records
- WG9 –SDO Harmonization

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Slide 5

**Significant relationships**

- Vienna Agreement
- HL7 pilot agreement
- IEEE partnership agreement

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Slide 6

**Harmonization of international standards**

- Creation of Joint Initiative Council in 2007.
- Founding members – ISO TC 215, CEN TC 251, and HL7. Later members include CDISC, IHTSDO, and GS1.
- Operates as a council of equals and was created to create a single standard for a single business use.

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Slide 7

**CEN TC 251**

- Workgroup within European Union; goal is to achieve compatibility and interoperability between independent systems and to enable modularity in EHR systems.

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Slide 8

**CEN TC 251 work groups**

- WG I – Information Models
- WG II – Terminology and knowledge representation
- WG III – Safety and Quality
- WG IV – Technology for Interoperability.

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Slide 9

**CEN Standard EN 13606**

- An important CEN standard is EN 13606 – Health Informatics – Electronic Health Record communication, published in 5 parts
  - (1) Reference Model
  - (2) Archetypes interchange specification
  - (3) Archetypes and term lists
  - (4) Security
  - (5) Interface specification
- These standards are being used in the European Union and are becoming ISO standards

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Slide 10

**Health Level 7**

- Formed in 1987 as a U.S. SDO; invited international affiliates in the early 1990s
- Now HL7 International with over 40 international country members
- Is an ANSI accredited SDO

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Slide 11

**HL7 steering divisions**

- Domain Experts
- Foundation and Technology
- Structure and Semantic Design
- Technical and Support Services

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Slide 12

**Domain experts**

• Anatomic Pathology	• Health Care Devices
• Anesthesiology	• Imaging Integration
• Attachments	• Laboratory
• Child Health	• Patient Care
• Clinical Interoperability Council	• Patient Safety
• Community Based Health Services	• Public Health Emergency Response (PHER)
• Emergency Care	• Pharmacy
• Government Projects	• Regulated Clinical Research (RCRIM)

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Slide 13

**Foundation and Technology**

- Conformance & Implementation
- Infrastructure & Messaging
- Implementable Technology Specifications (ITS)
- Java
- Modeling & Methodology
- Security
- Service Oriented Architecture (SOA)
- Templates
- Vocabulary

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Slide 14

**Structure and Semantic Design**

- Arden Syntax
- Clinical Context Object Workgroup (CCOW)
- Clinical Decision Support
- Clinical Statement
- Electronic Health Record (EHR)
- Financial Management
- Genomics
- Orders & Observations
- Patient Administration
- Personnel Management
- Scheduling & Logistics
- Structured Documents

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**Technical and Support Services**

- Education
- Electronic Services
- Implementation
- Marketing Committee
- Process Improvement
- Committee (PIC)
- Project Services
- Tooling

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**HL7 products**

- **Messaging Standards**
  - Version 2.x (current is 2.7 published 12/07)
  - XML Encoding Rules for v2 Messages
  - Version 3.0 (2008 Normative Edition in publication)
- **Infrastructure**
  - Master file structure infrastructure
  - Role-Based Access Control

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**HL7 products**

- **Models**
  - Reference Information Model
  - Data Types
  - Common Message Element Type
  - XML Implementation Technology Specification - Structures

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**HL7 products**

- **Application**
  - Electronic Health Record
    - Functional EHR-S Standard today
    - Interactions for EHR-S and Functional PHR-S
    - Profiles
  - EHR Behavioral Health Functional Model
  - EHR Child Health Functional Model
  - Scheduling
  - Notifiable Condition Report
  - Personnel Management
  - Genomics - Pedigree

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**HL7 products**

- Documents
  - Clinical Document Architecture
  - Continuity of Care Document
- Decision Support
  - Arden Syntax
  - Virtual Medical Record
  - GELLO: Common Expression Language
  - Infobutton

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**HL7 products**

- Regulated Studies
  - Structured Product Labeling
  - Annotated ECG
  - Individual Case Safety Report
  - Drug Stability Study
  - Regulated Product Submission
  - Common Product Model
  - Periodic Reporting of Clinical Trials Laboratory Results

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**HL7 products**

- Clinical Context Object Workgroup
  - Clinical Context Management
  - Application Protection Package
  - Manager Protection Package
  - User Authenticator Package

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**Implementations Guides**

- HL7 Claims Attachments
- Secure HL7 Transactions Using Internet Mail
- HL7 Security Service Framework
- CDA R2
- Common Audit Message
- Standard Guide for Implementing HL7 EDI Communication Security
- HL7 Version 2.x Message Profiling Specification
- Continuity of Care Document (CCD)
- *And growing...*

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Slide 23

**HL7 Standards named in HHS  
Final Rule**

- HL7 v2.5.1 Implementation Guide: Electronic Laboratory Results Reporting to Public Health
- Clinical Document Architecture (CDA)
- Continuity of Care Document (CCD)
- Messaging Standard Version 2.5.1
- Messaging Standard Version 2.3.1

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Slide 24

**CDISC standards**

- Study Data Tabulation Model (SDTM)
  - Recommended for FDA regulatory submissions
- Analysis Data Model (ADaM)
  - Complements SDTM submission by detailing statistical analysis performed on clinical trials results
- Operational Data Model (ODM)
- Clinical Data Acquisition Standards Harmonization (CDASH)
- Laboratory Data Model (LAB)
- CDISC Terminology

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**GS1 key standards**

- Barcodes
- eCom – electronic business messaging standards for automatic transmission of data
- GDSN – Global Data Synchronization – allow business partners to have consistent item data in their system at the same time
- EPCglobal – use RFID technology to track items in real time

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**Summary**

- Multiple SDOs = competing and overlapping standards
- Redundancy in work
- Redundancy in people
- Limited resources

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