Slide 1

Curriculum Development
Centers Program

Awardee of The Office of the National Coordinator for
Health Information Technology

Component 9 – Networking and
Health Information Exchange

Unit 3–2 - National and
International Standards
Developing Organizations

This material was developed by Duke University, funded by the Department of Health and Human Services, Office of the National Coordinator for Health Information Technology under Award Number IU24OC000024.

_____

_____

_____

_____

_____

_____

Slide 2

Objectives

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

Component 9/Unit 3-2   Health IT Workforce Curriculum
Version 2.0/Spring 2011   2

_____

_____

_____

_____

_____

_____

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

Component 9/Unit 3-2   Health IT Workforce Curriculum
Version 2.0/Spring 2011   3

_____

_____

_____

_____

_____

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

_____

_____

_____

_____

_____

_____

Slide 5

Significant Relationships

- Vienna Agreement
- HL7 Pilot Agreement
- IEEE Partnership Agreement

_____

_____

_____

_____

_____

_____

Slide 6

Harmonization of International Standards

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

_____

_____

_____

_____

_____

_____

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

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

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

Slide 10

Health Level 7 International

- 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

_____

_____

_____

_____

_____

_____

Slide 11

HL7 Steering Divisions

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

_____

_____

_____

_____

_____

_____

Slide 12

Domain Experts

- Anatomic Pathology
- Anesthesiology
- Attachments
- Child Health
- Clinical Interoperability Council
- Community Based Health Services
- Emergency Care
- Government Projects

- Health Care Devices
- Imaging Integration
- Laboratory
- Patient Care
- Patient Safety
- Public Health Emergency Response (PHER)
- Pharmacy
- Regulated Clinical Research (RCRIM)
- Information Management

_____

_____

_____

_____

_____

_____

Slide 13

Foundation and Technology

- Conformance & Implementation
- Infrastructure & Messaging
- Implementable Technology Specifications (ITS)
- Java

- Modeling & Methodology
- Security
- Service Oriented Architecture (SOA)
- Templates
- Vocabulary

_____

_____

_____

_____

_____

_____

_____

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
- Scheduling & Logistics
- Structured Documents

_____

_____

_____

_____

_____

Slide 15

Technical and Support Services

- Education
- Electronic Services
- Implementation
- Marketing Committee

_____

_____

_____

_____

_____

Slide 16

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

_____

_____

_____

_____

_____

_____

_____

Slide 17

HL7 Products

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

_____

_____

_____

_____

_____

_____

Slide 18

HL7 Products

- Application
  - Electronic Health Record
    - Functional EHR-S Standard
    - 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

_____

_____

_____

_____

_____

_____

Slide 19

HL7 Products

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

_____

_____

_____

_____

_____

_____

Slide 20

HL7 Products

- Regulated Studies
  - Structured Product Labeling (SPL)
  - Annotated ECG
  - Individual Case Safety Report 9ICSR0
  - Drug Stability Study
  - Regulated Product Submission
  - Common Product Model (CPM)
  - Periodic Reporting of Clinical Trials Laboratory Results

_____

_____

_____

_____

_____

_____

Slide 21

HL7 Products

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

_____

_____

_____

_____

_____

_____

Slide 22

Implementations Guide

- 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 Messaging Profiling Specification
- Continuity of Care Document (CCD)
- *And growing…*

_____

_____

_____

_____

_____

_____

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 v2.5.1
- Messaging Standard v2.3.1

_____

_____

_____

_____

_____

_____

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

_____

_____

_____

_____

_____

_____

Slide 25

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 systems at the same time
- EPCglobal – use RFID technology to track items in real time

_____

_____

_____

_____

_____

_____

_____

Slide 26

Summary

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

_____

_____

_____

_____

_____

_____