

Slide 1

## Networking and Health Information Exchange

Unit 7d  
Supporting Standards for EHR Application

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Slide 2

### Unit 7 Objectives

- Understand other standards that help to support networking and reporting requirements as well as functionality to optimize the connectivity among heterogeneous systems deployed within a single enterprise
  - Understand single sign-on standards and the HL7 Clinical Context Object Workgroup (CCOW) standard
- Understand regulatory standards
- Understand issues relating to person identifiers, master patient indexes, and record locator services

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Slide 3

### Regulatory and Regulated Standards

- Domain: **Public Health**
  - Individual Case Safety Report (ICSR)
  - Generic Incident Notification (GIN)
- Domain: **Regulated Products**
  - Structured Product Labeling (SPL)
  - Regulated Product Submission (RPS)
  - Common Product Model (CPM)
- Domain: **Regulated Studies**
  - Annotated ECG (aECG)
  - Clinical Trial Laboratory (CT Lab)
  - Stability Study

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Slide 4

### Structured Product Labeling

- Business Driver: US HHS Directive -
  - Develop standard for communicating the content of drug product labelling in both a human and machine-readable format to serve as the basis of a national repository
  - Create national repository of all current approved labelling on National Library of Medicine DailyMed website
- DailyMed serves as the official source of approved labelling for prescribing physicians, patients and healthcare providers
- Based on HL7 Clinical Document Architecture (CDA)
- SPL Version 3 complies with new FDA Physician Labelling Rule, and includes encoded Highlights section, among other features.
- V3 mandatory in US for all new indications and efficacy supplements (with multi-year phase-in for remaining types of labelling applications)

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Slide 5

### Regulated Product Submission

- Messaging standard for submitting product information to regulatory authorities
- Can carry an ICH CTD submission and other submission types for drugs, device, veterinary products, food additives and other regulated products.
- RPS Storyboards include initial submissions, updates, amendments, withdrawals, referencing other submissions, etc.

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Slide 6

### Common Product Model

- Domain information model relating to modeling of any kind or instance of a "product"
- Examples
  - Medication, including vaccines
  - Devices used in medical services
  - Anything else a person can be exposed to

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Slide 7

**Clinical Context Object Workgroup (CCOW)**

- Enables disparate applications to synchronize in real-time at the user interface level
- Provides two discrete functions
  - Facilitates a process called context management- links subjects to applications
  - Provides single sign on that enables secure access of disparate applications by a user

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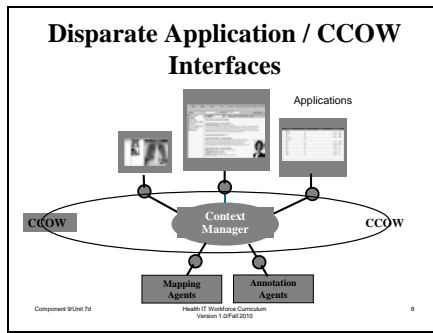
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Slide 9

**Why CCOW ?**

- Multiple disparate applications:
  - labs, meds, cardiology, scheduling, billing, etc.
- Users in need of easy access to data and tools:
  - physicians, nurses, therapists, administrators, etc.
- Kiosk as well as personal workstations:
  - hospitals, clinics, offices, homes, etc.

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Slide 13

**Entity Identifiers**

- Person Identifier
  - Debate: Unique identifier vs identifying parameters
- Provider Identifier
  - National Provider Identifier [HIPAA] [NPI]
  - ISO
- Facility Identifier
- Employer Identifier
- Health Plans Identifier
  
- Master Patient Index (local, regional, national)
- Record Locator Service

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Slide 14

**Elements for Patient Identifiers**

- Medical Record Number
- Patient Surname
- Patient Given name
- Gender
- Telephone Number
- Zip code
- City
- Date of Birth year, month, day
- Next of kin surname, given name
- Physician surname, given name

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**Master Patient Index (MPI)**

- Contains required data to identify and distinguish patient across healthcare facilities and levels
- Includes some patient demographic data
- May include multiple identifiers the patient is assigned across various facilities
- Has a primary identifier

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### Other services

- Genomic and proteomic data as part of EHR
- Rule-based data exchange
- Filters for data presentation
- Consent management
- Identifying candidates for clinical trials
- Record linkages
- Notification services
- Natural language processes
- Mapping services in transition (real word inclusion)

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Slide 17

### Clinical Genomics – Family Tree

- Clinical genomic standard – HL7 Clinical Genomics Work Group
  - Family history (pedigree) topic
  - Genetic variations topic
  - Gene expressions topic
  - CMETS defined by the domain
  - Messages for the exchange of family history and genetic information

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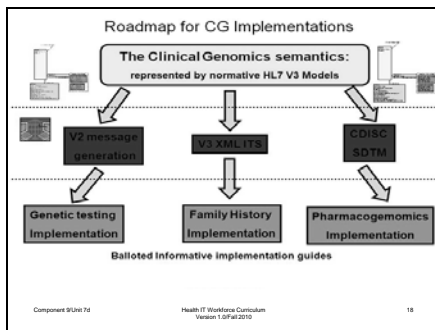
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Slide 18



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Slide 19

## Summary

This last subunit identified a few of the additional standards required to support networking and the exchange of data. CCOW is an important and powerful standard that has great value in today's world of disparate systems. The other standards represent more domain specific activities. Many standards have yet to be developed to support the full requirements for networking and data sharing.

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