Overview of Clinical Data Standards

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Overview

• Background
  – Data representation, knowledge exchange

• Clinical data representation
  – Terminologies, Documents, Information models

• Clinical knowledge exchange
  – Infobuttons, Order Sets, CDS Services

• Conclusions
  – Opportunities, forms of participation
Data & Knowledge interoperability

Home

Data + Knowledge

Rehabilitation Phase

Interoperability

Ambulatory Visit

Data + Knowledge

Hospital Procedure

Data + Knowledge
Definitions (1/2)

• **Standard** - “A document, established by *consensus* and approved by a *recognized body*, which provides rules, guidelines, or characteristics for activities”
• **Interoperability** - “The ability of two or more systems or components to **exchange** information and to **use** the information that has been exchanged.”
Development of standards

• SDO: Standards Developing Organization
• Many national and international organizations
  – Interdependencies and overlapping efforts
• Several with specific focus on Healthcare
  – Examples: HL7, IHE, DICOM, CDISC, ...
CLINICAL DATA REPRESENTATION
Clinical data representation (4/18)

- Define “data points” (elements and values) using available standards
- Define logical models that combine data points and provide meaningful clinical information
- Obtain detailed provenance to understand how and when data was acquired, and also who provided the data
- Represent semantic and temporal linkages between data instances
Clinical data: standards

- Data elements and data values
  - Available: reference terminologies and ontologies

- Information models
  - Work in progress: isolated efforts and collections
  - Available: clinical documents (multiple types)

- Provenance models
  - Work in progress: competing models

- Semantic and temporal linkages
  - Preliminary work

Additional work is needed → opportunities
LOINC

• Logical Observation Identifiers Names and Codes
• Organization: LOINC Committee
• Purpose: identification of laboratory and clinical observations (HL7 messages)
• Content: laboratory tests, clinical measurements, documents, etc.
• Information:
  – http://loinc.org
<table>
<thead>
<tr>
<th>LOINC</th>
<th>Description</th>
<th>Component</th>
<th>Attribute</th>
<th>Time</th>
<th>System</th>
</tr>
</thead>
<tbody>
<tr>
<td>24372-5</td>
<td>Peak systolic blood pressure during right ventricular septal defect maximum velocity measurement</td>
<td></td>
<td>压力或压强</td>
<td>时间点</td>
<td>动脉系统,XXX</td>
</tr>
<tr>
<td>11378-7</td>
<td>Systolic blood pressure at First encounter</td>
<td></td>
<td>压力或压强</td>
<td>就医过程持续时间*第一</td>
<td>动脉系统</td>
</tr>
<tr>
<td>20185-5</td>
<td>End systolic blood pressure by US</td>
<td></td>
<td>压力或压强</td>
<td>时间点</td>
<td>循环系统,XXX</td>
</tr>
<tr>
<td>20186-3</td>
<td>Peak systolic blood pressure by US</td>
<td></td>
<td>压力或压强</td>
<td>时间点</td>
<td>循环系统,XXX</td>
</tr>
<tr>
<td>24370-9</td>
<td>Peak systolic blood pressure during mitral regurgitation maximum velocity measurement</td>
<td></td>
<td>压力或压强</td>
<td>时间点</td>
<td>动脉系统,XXX</td>
</tr>
<tr>
<td>24371-7</td>
<td>Peak systolic blood pressure during aortic stenosis maximum velocity measurement</td>
<td></td>
<td>压力或压强</td>
<td>时间点</td>
<td>动脉系统,XXX</td>
</tr>
<tr>
<td>45372-0</td>
<td>Blood pressure systolic and diastolic—post phlebotomy</td>
<td>收缩期与舒张期血压*在静脉采血之后</td>
<td>压力或压强</td>
<td>时间点</td>
<td>动脉系统</td>
</tr>
<tr>
<td>50402-7</td>
<td>Blood pressure systolic and diastolic—after transfusion</td>
<td>收缩期与舒张期血压*在输血之后</td>
<td>压力或压强</td>
<td>时间点</td>
<td>动脉系统</td>
</tr>
<tr>
<td>50403-5</td>
<td>Blood pressure systolic and diastolic—before transfusion</td>
<td>收缩期与舒张期血压*在输血之前</td>
<td>压力或压强</td>
<td>时间点</td>
<td>动脉系统</td>
</tr>
<tr>
<td>55294-4</td>
<td>Blood pressure systolic and diastolic</td>
<td>收缩期与舒张期血压</td>
<td>—</td>
<td>时间点</td>
<td>动脉系统</td>
</tr>
</tbody>
</table>
SNOMED CT

• **Systematized Nomenclature of Medicine – Clinical Terms**

• *Organization*: International Health Terminology Standards Development Organisation (IHTSDO)
  – SNOMED Terminology Solutions - College of American Pathologists

• *Purpose*: Encoding of multiple clinical domains

• *Content*: Comprehensive (diseases, signs, symptoms, living organisms, chemicals, body parts, morphology, occupations, modifiers, etc.)

• Information:
  – [http://www.ihtsdo.org](http://www.ihtsdo.org)
Many others (incomplete list)

- **RxNorm**: clinical drugs and drug delivery devices (NLM)
  

- **NDF-RT**: National Drug File - Reference Terminology (VA)
  

- **IIS**: Vaccination code sets (CDC)
  

- **HL7 Vocabulary domains** (messaging, documents, services)
  
Document standards

• Clinical Document Architecture (CDA)
• Organization: HL7 International
• Purpose: document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange between healthcare providers and patients
• Content:
  – Continuity of care, procedure note, patient assessments, etc.
  – Clinical oncology treatment plan, PHR plans, genetic testing reports, public cancer registries, etc.
  – Data Provenance
• Information:
Information models

- **Clinical Information Modeling Initiative (CIMI)**
- Organization: HL7 International
- Purpose: Improve the interoperability of healthcare systems through shared implementable clinical information models - a **single curated collection** with bindings to reference terminologies
- Content: laboratory test results, vital signs, diagnoses, procedures, patient measures, etc.
- Information:
  - [http://www.hl7.org/Special/Committees/cimi/index.cfm](http://www.hl7.org/Special/Committees/cimi/index.cfm)
  - [http://www.opencimi.org](http://www.opencimi.org)
CLINICAL KNOWLEDGE EXCHANGE
Implementation of CDS modalities

<table>
<thead>
<tr>
<th>CDS modality</th>
<th>Types of Knowledge Assets</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Information selection and retrieval</td>
<td>Reference</td>
</tr>
<tr>
<td>2. Information aggregation and presentation</td>
<td>Actionable</td>
</tr>
<tr>
<td>3. Data entry assistance</td>
<td>Executable</td>
</tr>
<tr>
<td>4. Event monitors</td>
<td></td>
</tr>
<tr>
<td>5. Care workflow assistance</td>
<td></td>
</tr>
<tr>
<td>6. Descriptive or predictive modeling</td>
<td></td>
</tr>
</tbody>
</table>

Complexity

Cost

Availability

Maintainability
## Standards-based implementations?

<table>
<thead>
<tr>
<th>CDS modality</th>
<th>Relevant Interoperability Standards (data &amp; knowledge representation and exchange)</th>
</tr>
</thead>
</table>
| 1. Information selection and retrieval | Guideline Elements Model (GEM): ASTM  
Context-aware Info Retrieval (Infobutton): HL7  
Structured Product Label (medications): HL7 |
| 2. Information aggregation and presentation | Clinical Document Architecture (CDA): HL7  
Health Quality Measures Format (eMeasures): HL7  
Order sets: HL7 |
| 3. Data entry assistance           |                                                                                   |
| 4. Event monitors                  |                                                                                   |
| 5. Care workflow assistance        | Arden Syntax for Medical Logic Systems: HL7  
GELLO - A Common Expression Language: HL7  
Decision Support Services: HL7  
Virtual Medical Record (vMR): HL7 |
| 6. Descriptive or predictive modeling |                                                                                   |

### Problem List infobuttons

#### Information about “Depression”

- **Problem Description:**
  - Type: Acute
  - Severity: Major
  - Condition: Worse
  - Comments: No changes, patient still depressed...

- **Additional Details:**
  - Onset: 04/04/2011
  - Comments: Must reduce their stress an...
  - Type: Chronic
  - Onset: 11/30/2007
  - Comments: Upgrading a problem that was...
  - Type: Acute
  - Onset: 09/15/2001
  - Comments: Updating a problem that was...
  - Type: Chronic
  - Onset: 02/16/2011
  - Resolution: 05/09/2011
  - Comments: Stress of high school
  - Onset: 07/07/2010
  - Comments: Stress of high school
  - Onset: 04/05/2011
  - Comments: Stress of high school
  - Onset: 05/15/2011
HL7 Infobutton standard

Integration across repositories

- **Common Terminology Services – Release 2 (CTS2)**
- Organization: HL7 + Object Management Group (OMG)
- Purpose: standardized interface for the use and management of terminologies (extensible to knowledge assets)
- Content: concepts, value sets, code systems, entities, information models, APIs, etc.
- Information:
Content Consumers
(e.g., Clinical applications and services, EHR systems, etc.)

CKMS

EXPORT
(same XML format used for Import)

Publication

Review & Vetting

Authoring

Validation

Linking

IMPORT
(XML format compatible with available standards – e.g., CTS2)

Content Sources
(e.g., EHR content, Open source content, Licensed content, etc.)
CONCLUSIONS
Known challenges with standards

- **Widespread use** of the standard
  - Measurement of **acceptance** (success)
  - Implementation **costs** versus **benefits** obtained

- **Standards usually define a non-prescriptive model**
  - Formal document, precise definitions, well-defined problems (scenarios)
  - **Conformance, variability, evolution**

- **High degree of complexity and dynamism**
  - Wide spectrum of scenarios and approaches
  - Continuous **evolution** (dynamic): domain + technology
  - Extensive (cumbersome) documentation
Participate!

• Most SDOs welcome open and **broad** participation
  – Healthcare providers, government stakeholders, payers, pharmaceutical companies, system vendors, consultants

• Understand the scope and applicability of existing standards
  – Gain **access** to available standards
  – Decide how each standard **applies** to your organization

• Contribute to and influence the development of standards
  – Bring your **specific needs** and discuss implementation options
  – Seek information from other stakeholders to make **informed decisions**

• Achieve industry leadership by demonstrating interoperability
  – Learn about industry **best practices**
  – Understand implementation **timeline** and **costs**
  – Improve the **quality** and **sustainability** of your local systems
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