Clinical Data Definitions
Agenda

• Purpose of the Clinical Data Definition project

• Clinical Data Definition constructs
  • Associated standards
  • Templated Reference Information Model

• Example of the approach

• Participants

• Summary
Why Clinical Data Definitions

• A fundamental need to accurately describe data in the healthcare and life-science environment
  • Transactional and analytic

• Need to support meaningful data storage and exchange

• Alternative approaches to creating Clinical Data Definitions
  • Proprietary or copyrighted development
  • Proprietary knowledge or codes
  • Not compliant with existing healthcare standards
  • Require users to purchase a tool set to develop/edit
Clinical Data Definitions

• Clinical data definitions are *not* a replacement for
  • Concept codes
  • Concept maps
  • UMLS or other terminologies

  → Clinical data definitions leverage terminologies

• Clinical data definitions are *not* a replacement of informatics standards, such as
  • HL7 RIM, C-DISC, IHE, HL7 messaging or BRIDG

  → Clinical data definitions use informatics standards
Clinical Data Definitions

- Existing healthcare standards provide
  - Abstract concepts (e.g., HL7 RIM, C-DISC and IHE)
  - Structures for data exchange (e.g., HL7, IHE and X12)
  - Structures for organization (e.g., CCR, CDA and CCD)

- Existing standards do not define content

- Clinical Data Definitions define
  - A specific instance of an object (e.g., Pulse)
  - Primary attribute and data types (e.g., Rate)
  - Constraints (e.g., Beats per Minute)
  - Terminology (e.g., UMLS code or other code translation)
Clinical Data Definitions

• Common methodology for representing data

• Enables a message or document to contain
  • Defined content that is semantically interoperable
  • Re-usable data across business processes
  • Coded data that can support rules and workflow

• Simplifies the building and maintenance of
  • Simple data objects (e.g., a clinical finding)
  • Complex data collection (e.g, assessments and CRFs)
  • Rules and workflow
### Example CDD: Blood Pressure

**Description**

Blood pressure is the pressure exerted by the blood at right angles to the walls of the blood vessels. Blood pressure values are universally stated in millimetres of mercury (mmHg).

<table>
<thead>
<tr>
<th>Short Name</th>
<th>BP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Name</td>
<td>Blood Pressure - Complete</td>
</tr>
<tr>
<td>TemplateID</td>
<td></td>
</tr>
<tr>
<td>UMLS Concept Code</td>
<td>C0436781</td>
</tr>
<tr>
<td>Synonym</td>
<td>O/E-blood pressure reading NOS; O/E - blood pressure; On examination - blood pressure reading NOS (context-dependent category); On examination - blood pressure reading NOS (finding)</td>
</tr>
<tr>
<td>Type</td>
<td>Observation</td>
</tr>
<tr>
<td>Revision</td>
<td>11008</td>
</tr>
</tbody>
</table>

#### Relationships

<table>
<thead>
<tr>
<th>Type</th>
<th>Category or CDD</th>
<th>Cardinality</th>
<th>Rule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contains</td>
<td>Blood Pressure - Systolic</td>
<td>0..1</td>
<td></td>
</tr>
<tr>
<td>Contains</td>
<td>Blood Pressure - Diastolic</td>
<td>0..1</td>
<td></td>
</tr>
</tbody>
</table>

#### Attributes

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Value</th>
<th>Cardinality</th>
<th>Data Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Name or Code</td>
<td>Lying</td>
<td>C0444334</td>
<td>CD</td>
</tr>
<tr>
<td>Device Name or Code</td>
<td>Reclining</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Name or Code</td>
<td>Sitting</td>
<td>C0277814</td>
<td></td>
</tr>
<tr>
<td>Device Name or Code</td>
<td>Standing</td>
<td>C0231472</td>
<td></td>
</tr>
</tbody>
</table>

**Description**

The diastolic pressure is a component of the complete blood pressure and is defined as the lowest pressure (at the resting phase of the cardiac cycle). Values are universally stated in millimeters of mercury (mmHg).

<table>
<thead>
<tr>
<th>Short Name</th>
<th>Diastolic Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Name</td>
<td>Blood Pressure - Diastolic</td>
</tr>
<tr>
<td>Template ID</td>
<td></td>
</tr>
<tr>
<td>UMLS Concept Code</td>
<td>C0436794</td>
</tr>
<tr>
<td>Synonym</td>
<td>O/E - Diastolic BP reading; On examination - Diastolic BP reading (context-dependent category); On examination - Diastolic BP reading (finding)</td>
</tr>
<tr>
<td>Type</td>
<td>Observation</td>
</tr>
<tr>
<td>Revision</td>
<td>6954</td>
</tr>
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</table>

#### Attribute

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Value</th>
<th>Cardinality</th>
<th>Data Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value</td>
<td>Diastolic Pressure</td>
<td>01/01/08</td>
<td>PQ</td>
</tr>
</tbody>
</table>

---

On one attribute shown for Blood Pressure to simplify slide and because of space available on slide. Blood Pressure has many attributes see [http://www.wikihit.org/wiki/index.php/Blood_Pressure_-_Complete](http://www.wikihit.org/wiki/index.php/Blood_Pressure_-_Complete)
Clinical Data Definition Process

- Developed using public wiki
  - www.wikiHIT.org

- Community Validation

- Transformed into XML representations
  - Constrained templates

- Available for implementation in any platform

- Vendor neutral
<relationship name="systolic" direction="OUT" typeCode="COMP">
  <act xsi:type="Act" classCode="OBS" moodCode="E VN">
    <!--templateId>urn:wikihit-org:PATIENT-ACT:0</templateId-->
    <code>
      <CD codeSystemName="UMLS" codeSystemVersion="2006AC" code="C0017594"/>
    </code>
    <title>
      <ST>Systolic BP</ST>
    </title>
    <observation>
      <value>
        <label>Systolic</label>
        <PQ>
          <value>0</value>
          <unit>mm/Hg</unit>
        </PQ>
      </value>
    </observation>
  </act>
</relationship>
Participants

- Provider organizations
- Research centers
- Medical institutes
- Federal agencies
- Commercial software companies
Future Development

• End user tool for the development and management of Clinical Data Definitions
  • Remove the need to learn wiki mark-up language
  • Ensure compliance with standards
  • Engage clinicians and domain experts in the process

• Publish definitions to public wiki for
  • Community validation
  • Community commentary
  • Free download

• Change management through CVS
Summary

• Clinical Data Definitions are a fundamental requirement for health informatics

• Collaborative development of CDD will
  • Accelerate the development process
  • Ensure commonality and compliance with standards
  • Encourage public comment
  • Prevent multiple standards developing
  • Support clinical and research data management

• Creative commons approach is essential for adoption