Clinical Observation Modeling

VA Informatics Architecture
SOLOR Meeting

Walter Sujansky
January 31, 2013
Goals of Clinical Observation Modeling

- Create **conceptual-level models** of the discrete statements about patients that can be stored in, processed by, and retrieved from an information system
  - E.g., blood pressure, lab result, exam finding, symptom

- **Standardize** the capture, retrieval, and exchange of clinical observations within and between information systems
  - Different software modules use the same clinical obs. models

- **De-couple** the creation and maintenance of clinical domain-specific objects from their technical implementation in software code and database structures
  - *Domain objects* => *Diverse, complex, frequently changing*
  - *Technical implementation* => *Brittle, costly to update*
Clinical Observation Modeling – Example
Clinical Observation Models for Interoperability

Data Capture
(Data-Entry Forms, EDI Messages, XML Documents)

Data Query
(UI Displays, CDS Rules, Quality Measures)

Data Exchange
(APIs, EDI Messages, XML Documents)

Meta-Data Models
(flexible, extensible)

DB Schema & Code
(invariant)

“Model-Driven Development” (MDD)
OpenEHR: Example MDD Framework
### OpenEHR Reference Model

<table>
<thead>
<tr>
<th>Layer</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EHR</strong></td>
<td>The electronic health record for one person</td>
</tr>
<tr>
<td><strong>Folders</strong></td>
<td>High-level organisation of the EHR eg per episode, per clinical speciality</td>
</tr>
<tr>
<td><strong>Compositions</strong></td>
<td>Set of entries comprising a clinical care session or document eg test result, letter</td>
</tr>
<tr>
<td><strong>Sections</strong></td>
<td>Clinical headings reflecting the workflow and consultation/reasoning process</td>
</tr>
<tr>
<td><strong>Entries</strong></td>
<td>Clinical “statements” about Observations, Evaluations, and Instructions</td>
</tr>
<tr>
<td><strong>Clusters</strong></td>
<td>Compound entries, test batteries eg blood pressure, full blood count</td>
</tr>
<tr>
<td><strong>Elements</strong></td>
<td>Element entries: leaf nodes with values eg reason for encounter, body weight</td>
</tr>
<tr>
<td><strong>Data values</strong></td>
<td>Date types for instance values eg coded terms, measurements with units</td>
</tr>
</tbody>
</table>
OpenEHR Reference Model
## OpenEHR Reference Model

<table>
<thead>
<tr>
<th>Structure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>EHR</td>
<td>The electronic health record for one person</td>
</tr>
<tr>
<td>Folders</td>
<td>High-level organisation of the EHR eg per episode, per clinical speciality</td>
</tr>
<tr>
<td>Compositions</td>
<td>Set of entries comprising a clinical care session or document eg test result, letter</td>
</tr>
<tr>
<td>Sections</td>
<td>Clinical headings reflecting the workflow and consultation/reasoning process</td>
</tr>
<tr>
<td>Entries</td>
<td>Clinical “statements” about Observations, Evaluations, and Instructions</td>
</tr>
<tr>
<td>Clusters</td>
<td>Compound entries, test batteries eg blood pressure, full blood count</td>
</tr>
<tr>
<td>Elements</td>
<td>Element entries: leaf nodes with values eg reason for encounter, body weight</td>
</tr>
<tr>
<td>Data values</td>
<td>Date types for instance values eg coded terms, measurements with units</td>
</tr>
</tbody>
</table>
Result of a clinical evaluation or test – includes previous results and current observations
Although most clinical content is modelled directly in archetypes, the underlying openEHR reference model ‘class’ provides a small number of universal attributes which will always be available as if they were part of the archetype itself. A brief description of the parent archetype class and clinically important attributes are listed below.

### OBSERVATION

**Used to record information from a direct observation or measurement, or may be a record the perspective of the subject eg history-taking.**

#### Attributes

<table>
<thead>
<tr>
<th><strong>Events</strong></th>
<th>One or more individual timed events during the Observation. Can represent either a specific point-in-time or an interval event.</th>
</tr>
</thead>
</table>
| (RM: events) | **Event**
| Occurrences: 0..* |
| **Information Provider** | A record of the person or agent who provided the information. This could include the patient; a patient agent, e.g. parent, guardian; the clinician or a device/software. It is generally only used when the information provider needs to be made explicit - that is, it is NOT the overall Composition Author/composer or other identified individuals/parties participating in the event. |
| (RM: provider) | **Party Proxy**
| Occurrences: 0..1 |
| **Subject** | The human subject referred to in this Admin Entry. This is usually the Subject of the EHR, that is the patient. However in certain circumstances it may refer to others, for example an organ donor, a fetus, or a family member. |
| (RM: subject) | **Party Proxy**
| Occurrences: 1..1 |
OpenEHR: Archetypes
OpenEHR Example Archetype

**Archetype ID**
openEHR-EHR-OBSERVATION.blood_pressure.v1

**Status**
Published

**Data**

- **Systolic**
  - Quantity
- **Diastolic**
- **Mean arterial (SHAPED-CT[2003]:163030003)**
  - (On examination - Systolic BP reading (finding))
- **Pulse pressure**

**Description**

- **Position**
  - Coded Text
  - The position of the subject at the time of measurement.
  - Assumed value: Sitting

- **Cuff**
  - **Location**
  - **Method**
  - **Mean arterial pressure formula**
  - **Systolic pressure formula**
  - **Diastolic pressure formula**
  - **Diastolic endpoint**
  - **Device**
  - **Extension**

**Protocol**

- at1000::Standing [Standing at the time of blood pressure measurement.]
- at1001::Sitting [Sitting (for example on bed or chair) at the time of blood pressure measurement.]
- at1002::Racning [Racning at the time of blood pressure measurement.]
- at1003::Lying [Lying flat at the time of blood pressure measurement.]
- at1014::Lying with tilt to left [Lying flat with some lateral tilt, usually angled towards the left side. Commonly required in the last trimester of pregnancy to relieve aorticav compression.]

- Optional

- **Units:**
  - 0.0..<1000.0 mm[Hg]; Limit decimal places: 0..0
OpenEHR Example Archetype
OpenEHR Example Archetype - Documentation

Use to record details about findings on physical examination of the subject of care. This may include a narrative description of the findings, a framework in which to nest detailed CLUSTER examination archetypes, and a clinical interpretation of the findings.

Examples of detailed CLUSTER examination archetypes include those that describe inspection, palpation, auscultation, percussion and movement of body systems or anatomical structures, such as CLUSTER.exam_pupils.

Narrative descriptions of clinical findings from existing clinical systems may be captured using the 'Description' data element.

Clinicians may sometimes want to record a summative phrase such as 'chronic otitis media' as an Interpretation of the physical examination. In the context of the physical examination archetype this should only be understood as 'physical signs are consistent with chronic otitis media'. While the summative phrase may appear to represent a diagnosis, safe and consistent querying requires a diagnosis to be recorded using the EVALUATION.problem_diagnosis archetype, even if the phrases are identical.

Misuse

Not to be used for recording history-taking observations - use specific OBSERVATION and CLUSTER archetypes. For example OBSERVATION.story and CLUSTER.symptom.

Not to be used to record stand-alone clinical observations - use specific OBSERVATION archetypes. For example OBSERVATION.blood_pressure, OBSERVATION.body_weight, or OBSERVATION.height.
Clinical Observation Models for Interoperability

Data Capture
(Data-Entry Forms, EDI Messages, XML Documents)

Data Query
(UI Displays, CDS Rules, Quality Measures)

Data Exchange
(APIs, EDI Messages, XML Documents)

Clinical Models

Reference Model

Core Database Implementation

Sujansky & Associates, LLC
OpenEHR Example Archetype

Structured detail
Cluster
Optional, repeating

Structured detail about the individual’s story or patient’s history.

For example: a specific symptom such as nausea or pain; an event such as a fall off a bicycle; or an issue such as a desire to quit using tobacco.

Include:
openEHR-EHR-CLUSTER.health_event.v1 and specialisations Or
openEHR-EHR-CLUSTER.issue.v1 Or
openEHR-EHR-CLUSTER.symptom_sign.v1

Symptom/Sign name
Text

The name of the reported symptom or sign.

First ever?
Symptom name should be coded with a terminology, where possible.
OpenEHR: Templates
OpenEHR Example Template

Concept name: Blood Pressure
Archetype ID: openEHR-EHR-OBSERVATION.blood_pressure.v1
Path: /items
OpenEHR Example Template: Use of Archetypes
OpenEHR Example Template
OpenEHR Example Template: Use of Archetypes

Archetype ID: openEHR-EHR-OBSERVATION.exa.m.v1
Status: Published

Confounding Factors
- Any event

State
- Events

Physical Examination Findings
- Data
  - Examination Detail
    - Cluster
      - Optional, repeating
      - Structured details of the physical examination
    - Include:
      - All not explicitly excluded archetypes

Archetype ID: openEHR-EHR-CLUSTER.oedema.v0
Status: Draft

Description
- Oedema
  - Items
    - Character
    - Extent
    - Degree
    - Comments
  - Attribution

Degree
- Ordinal
  - Optional
  - The degree of oedema.
    1: at0007::Mild + [Mild oedema.]
    2: at0008::Moderate ++ [Moderate oedema.]
    3: at0009::Severe +++ [Severe oedema.]
OpenEHR Example Archetype

Screen Forms  Message Schemas  Document Schemas  APIs

Templates

Archetypes

Reference Model

Terminology Bindings

Queries

Terminologies

Generated artefacts
Clinical Observation Model (OpenEHR)
Clinical Observation Model (OpenCEM)
Clinical Observation Model (CIMI)
Clinical Observations – Design Patterns

- Observation = “A Discrete Patient Descriptor”
  - E.g.,
    - Diagnosis, LDL level, Systolic BP, Apgar Score, Reported Symptom, Father’s Diagnoses

- Facets of a patient descriptor
  1. What **Aspect** of the patient is being described?
     - Explicitly (“Patient’s systolic BP is 130 mmHg” : aspect = Systolic BP) or
     - Implicitly (“Patient has asthma” : aspect = Diagnosis)
  2. What is the **Value/Magnitude** of the descriptor?
     - “Fatigue”, “185, with units = mg/dL”, “Asthma, with type= intrinsic”
  3. “**Context**”
     - When did the descriptor apply to the patient? Who reported it? Was patient sitting or standing at the time? What technique was used?
     - (Sometimes fuzzy distinction between Context and Aspect)
Multiple Valid Representations of Same Observation

“Patient has fasting LDL cholesterol of 185”

1. Aspect = Serum LDL cholesterol measurement
   Value = (185, with units-of-measure = mg/dL)
   Context = Fasting

2. Aspect = Lab Test Result
   Value = (Test type = Fasting Serum LDL cholesterol, mg/dL
   Test result = 185)

“Patient’s Father had Heart Failure”

1. Aspect = Diagnosis
   Value = Heart Failure
   Context = (Family History, with Relation = Father)

2. Aspect = Family History
   Value = (Heart Failure, with Relation = Father)
Clinical Observations – Patterns in Question
Clinical Observations – Patterns in Question

- “Assertion” Pattern
  - Aspect = NULL
    Value = (Asthma, with type=intrinsic, severity = mild, …)
    Context = (Time of observation, person responsible, …)

- “Evaluation” Pattern
  - Aspect = Serum LDL cholesterol ("the question")
    Value = (185, with units-of-measure=mg/dL, …) ("the answer")
    Context = Fasting

- “Belief” Pattern (??)
  - Aspect = Diagnosis
    Value = (Asthma, with type=intrinsic, severity = mild, …)
  - Aspect = LDL cholesterol, with Fasting-State = true
    Value = (185, with units-of-measure=mg/dL)
Clinical Observation Patterns: Why does it matter?

- Desiderata for terminologies and concept models
  - **Understandable**
    - Definitions should be understandable by average clinicians [and others who use the definitions], given brief explanations
  - **Reproducible**
    - Retrieval and representation of the same concept should not vary according to the nature of the interface, user preferences, or the time of entry
  - **Usable**
    - We should ignore concepts or distinctions for which there is no current use in healthcare
Clinical Observation Models for Interoperability

Data Capture
(Data-Entry Forms, EDI Messages, XML Documents)

Data Query
(UI Displays, CDS Rules, Quality Measures)

Data Exchange
(APIs, EDI Messages, XML Documents)

Clinical Models

Reference Model

Core Database Implementation
Clinical Observation Patterns: Why does it matter?

- Desiderata for terminologies and concept models
  - **Understandable**
    - Definitions should be understandable by average clinicians [and others who use the definitions], given brief explanations
  - **Reproducible**
    - Retrieval and representation of the same concept should not vary according to the nature of the interface, user preferences, or the time of entry
  - **Usable**
    - We should ignore concepts or distinctions for which there is no current use in healthcare
Reproducible Clinical Observation Models

- Avoid arbitrary variation
  1. Aspect = NULL
     Value = Regular pulse vs.
  2. Aspect = Skin Turgor
     Value = Normal vs.
  3. Aspect = Physical Exam Finding
     Value = Brisk Knee Reflex

- Explicitly represent clinically relevant distinctions
  1. Aspect = Patient-Reported Symptom
     Value = Weakness in Right Arm vs.
  2. Aspect = Physical Exam Finding
     Value = Weakness in Right Arm
Possible Perspectives

1. **Standardize on a single pattern for observations**
   - Easier for data analysts and software developers to remember the pattern for all clinical models and use them in applications, CDS rules, clinical measures, etc.
   - Most general pattern is “Belief” pattern
     - Aspect = <the relationship to the patient, possibly with modifiers>
     - Value = <value of the relationship, possible with modifiers>

2. **Allow multiple patterns, specific to individual types of observations, or even to specific observations**
   - Clinical models, themselves, will be quite complex and extensive, so the basic “pattern” of the model will comprise the least of the variations among models
   - Hence, doesn’t matter if there is one pattern or multiple patterns, as long as they are clearly documented
OpenEHR Example Archetype

Archetype ID: openEHR-EHR-OBSERVATION.blood_pressure.v1
Status: Published

Data
- Systolic
- Diastolic
- Mean arterial pressure
- Pulse pressure
- Comment

State
- Position
- Confounding factors
- Exertion
- Sleep status
- Tilt
- Any event
- 24 hour average

Events
- Attribution

Protocol
- Cuff size
- Location of measurement
- X - Specific location
- Structured measurement location
- Method
- Mean arterial pressure formula
- Systolic pressure formula
- Diastolic pressure formula
- Diastolic endpoint
- Device
- Extension

Description
OpenEHR Example Archetype
BAD – violates “Reproducible” criterion
OpenEHR Example Template
OpenEHR Example Template: Use of Archetypes

Structured detail
Cluster

Optional, repeating

Structured detail about the individual’s story or patient’s history.

For example: a specific symptom such as nausea or pain; an event such as a fall off a bicycle; or an issue such as a desire to quit using tobacco.

Include:
openEHR-EHR-CLUSTER.health_event.v1 and specialisations or
openEHR-EHR-CLUSTER.issue.v1 or
openEHR-EHR-CLUSTER.symptom_sign.v1

Symptom/Sign name
Text

The name of the reported symptom or sign.

Symptom name should be coded with a terminology, where possible.
OpenEHR Example Template – Form View

3. Presentation and symptoms

- Reason for Encounter [0..*]
- Medical history
  - Co-morbidity
  - Other medical history
  - Allergies and Other Adverse Reactions

Symptoms

- Symptom:
  - Breathlessness on mild exercise
    - Symptom name [1..1]: SNOMEDCT:161940008:breathlessness - mild exertion
    - Absent
  - Breathlessness on moderate exercise
    - Symptom name [1..1]: SNOMEDCT:161939006:breathlessness - moderate exertion
    - Absent
  - Breathlessness lying flat
    - Symptom name [1..1]: SNOMEDCT:62744007:orthopnoea
    - Intensity
      - Degree: Not present [0]