Practical modeling issues: Representing coded and structured patient data in EHR systems

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Stanley M Huff, MD
Chief Medical Informatics Officer
Acknowledgements

- Tom Oniki
- Joey Coyle
- Craig Parker
- Yan Heras
- Cessily Johnson
- Roberto Rocha
- Lee Min Lau
- Alan James
- Many, many, others…
Intermountain Healthcare

- Not-for-profit health care provider
- Serving Utah and Southern Idaho
- 23 Hospitals/ 2105 beds/150 Clinics
- Clinical data on ~2 million people
- Medical Group of ~750 employed physicians
- Insurance plan of 500,000 covered lives
- $130 M/year charitable care exclusive of bad debt
- 27,000 employees
- Partner in the Utah Health Information Network
Homer Warner and HELP

- The first version of the HELP (Health Evaluation through Logical Processing) system was built in 1967.
- From its inception, the HELP system was built primarily to provide advanced decision support.
The complexity of modern medicine exceeds the inherent limitations of the unaided human mind.’
~ David M. Eddy, MD, Ph.D.

‘... man is not perfectible. There are limits to man’s capabilities as an information processor that assure the occurrence of random errors in his activities.’
~ Clement J. McDonald, MD
Intermountain can only provide the highest quality, lowest cost health care with the use of advanced clinical decision support systems integrated into frontline workflow.
Why do we need detailed clinical models?
A diagram of a simplified clinical model

BloodPressurePanel

key BloodPressure

data 120 mmHg

SystolicBloodPressureQn

data 80 mmHg

DiastolicBloodPressureQn

SystolicBP

DiastolicBP
Need for a standard model

• A stack of coded items is ambiguous (SNOMED CT)
  – Numbness of right arm and left leg
    • Numbness (44077006)
    • Right (24028007)
    • Arm (40983000)
    • Left (7771000)
    • Leg (30021000)
  – Numbness of left arm and right leg
    • Numbness (44077006)
    • Left (7771000)
    • Arm (40983000)
    • Right (24028007)
    • Leg (30021000)
What if there is no model?

Site #1
Dry Weight: 70 kg

Site #2
Weight: 70 kg
- Dry
- Wet
- Ideal
Too many ways to say the same thing

• A single name/code and value
  – *Dry Weight* is 70 kg

• Combination of two names/codes and values
  – *Weight* is 70 kg
    • *Weight type* is *dry*
Pre-coordinated representation
<observation>
  <cd>Dry weight (LOINC 8340-2)</cd>
  <value>70 kg</value>
</observation>

Post-coordinated (compositional) representation
<observation>
  <cd>Weight (LOINC 3141-9)</cd>
  <qualifier>
    <cd>Weight type (LOINC 8337-8)</cd>
    <value>Dry (SNOMED CT 13880007)</value>
    <qualifier>
      <value>70 kg</value>
    </qualifier>
  </qualifier>
</observation>
Relational database implications

### How would you calculate the desired weight loss during the hospital stay?

<table>
<thead>
<tr>
<th>Patient Identifier</th>
<th>Date and Time</th>
<th>Observation Type</th>
<th>Observation Value</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>123456789</td>
<td>7/4/2005</td>
<td>Dry Weight</td>
<td>70</td>
<td>kg</td>
</tr>
<tr>
<td>123456789</td>
<td>7/19/2005</td>
<td>Current Weight</td>
<td>73</td>
<td>kg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Identifier</th>
<th>Date and Time</th>
<th>Observation Type</th>
<th>Weight type</th>
<th>Observation Value</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>123456789</td>
<td>7/4/2005</td>
<td>Weight</td>
<td>Dry</td>
<td>70</td>
<td>kg</td>
</tr>
<tr>
<td>123456789</td>
<td>7/19/2005</td>
<td>Weight</td>
<td>Current</td>
<td>73</td>
<td>kg</td>
</tr>
</tbody>
</table>
The essentials of the proposition

- The need for the clinical models is dictated by **what we want to accomplish** as providers of health care.
- The **best clinical care** requires the use of computerized clinical decision support and automated data analysis.
- **Clinical decision support** and **automated data analysis** can only function against **standard structured coded data**.
- The **detailed clinical models** provide the **standard structure and terminology** needed for clinical decision support and automated data analysis.
Another example

• If you use LOINC, and SNOMED
  – You still have many ways to express the same information

• A single name/code and value
  – Left patellar deep tendon reflex intensity is 2+

• Combination of two names/codes and values
  – Patellar deep tendon reflex intensity is 2+
    • Laterality is left

• Combination of three names/codes and values
  – Deep tendon reflex intensity is 2+
    • Body location is patella
    – Laterality is left
More complicated items:

- Signs, symptoms
- Diagnoses
- Problem list
- Family History
- Use of negation – “No Family Hx of Cancer”
- Description of a heart murmur
- Description of breath sounds
  - “Rales in right and left upper lobes”
  - “Rales, rhonchi, and egophony in right lower lobe”
What do we model?

- All data in the patient’s EMR, including:
  - Allergies
  - Problem lists
  - Laboratory results
  - Medication and diagnostic orders
  - Medication administration
  - Physical exam and clinical measurements
  - Signs, symptoms, diagnoses
  - Clinical documents
  - Procedures
  - Family history, medical history and review of symptoms
How are the models used in an EMR?

- Data entry screens, flow sheets, reports, ad hoc queries
  - Basis for application access to clinical data
- Computer-to-Computer Interfaces
  - Creation of maps from departmental/foreign system models to the standard database model
- Core data storage services
  - Validation of data as it is stored in the database
- Decision logic
  - Basis for referencing data in decision support logic
- Does **NOT** dictate physical storage strategy
How Are the Models Used Globally?

• They are the pattern for clinical data in many different contexts
  – Messages for electronic data exchange (HL7, Script, DICOM)
  – Models for EMR data
  – Reference for data used in clinical decision support
  – Payload in standard services (patient data access)
  – Others…
The specific uses that we need to support

- Data sharing
- Real time decision support
- Sharing of decision logic
- Direct assignment of billing codes
- Bio-surveillance

- Data analysis and reporting
  - Reportable diseases
  - HEDIS measurements
  - Quality improvements
  - Adverse drug events

- Clinical research
  - Clinical trials
  - Continuous quality improvement
Real time, patient specific, decision support

- Alerts
  - Potassium and digoxin
  - Coagulation clinic
- Reminders
  - Mammography
  - Immunizations
- Protocols
  - Ventilator weaning
  - ARDS protocol
  - Prophylactic use of antibiotics in surgery
- Advising
  - Antibiotic assistant
- Critiquing
  - Blood ordering
- Interpretation
  - Blood gas interpretation
- Management – purpose specific aggregation and presentation of data
  - DVT management
  - Diabetic report
Clinical modeling activities

- Netherlands/ISO Standard
- CEN 13606
- United Kingdom – NHS
- Singapore
- Sweden
- Australia - openEHR
- Canada
- US Veterans Administration
- US Department of Defense
- Intermountain Healthcare
- Mayo Clinic

- HL7
  - Version 3 RIM, message templates
  - TermInfo
  - CDA plus Templates
  - Detailed Clinical Models
  - greenCDA
- Tolven
- NIH/NCI – Common Data Elements, CaBIG
- CDISC SHARE
Mission

Improve the interoperability of healthcare information systems through shared implementable clinical information models.
Clinical Information Modeling Initiative

Goals

• Shared repository of detailed clinical information models
• Using a single formalism
• Based on a common set of base data types
• With formal bindings of the models to standard coded terminologies
• Repository is open and models are free for use at no cost
Progress on a strategy for open sharing
Goal: Open Sharing of Models and Terms

- GE owns and holds the copyright for the models and terminology.
- Intermountain has a perpetual license to distribute and sublicense the models and terminology for free.
- GE and Intermountain are sharing the models in perpetuity without cost.
- Models are posted to a website for free download (terminology to follow).
- No cost license to protect Intermountain and GE use.
- Anyone is allowed to make and own derivative works.
Access to the models

• Browser and download site
  - http://intermountainhealthcare.org/CEM/Pages/LicenseAgreement.aspx
GE/Intermountain Clinical Element Model Search

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Please enter search criteria to the left. The model name and description are searched. If you are unsure what to search for, please view the Model List.
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Model Search

Systolic

Please enter search criteria to the left. The model name and description are searched. If you are unsure what to search for, please view the Model List.

4 results were found.

- BloodPressurePanel
  BloodPressurePanel is an Associated CEM Panel that groups a systolic blood pressure, diastolic blood pressure, and mean arterial pressure all obtained at the same time.
  Keywords: Blood Pressure Panel

- MeanArterialPressureMeas
  MeanArterialPressureMeas captures a subject's mean arterial pressure, which can be calculated as \( ((2 \times \text{Diastolic}) + \text{Systolic}) / 3 \).
  Keywords: Mean Arterial Pressure

- SystolicBloodPressureMeas
  SystolicBloodPressureMeas captures a subject's systolic blood pressure.
  Keywords: Systolic Blood Pressure
### SystolicBloodPressureMeas

<table>
<thead>
<tr>
<th>Description / Status:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name:</strong></td>
</tr>
<tr>
<td><strong>Definition:</strong></td>
</tr>
<tr>
<td><strong>Status:</strong></td>
</tr>
</tbody>
</table>

### RAW XML

```xml
<ct type="statement" name="SystolicBloodPressureMeas" xmlns="">
  <key code="SystolicBloodPressure_KEY_ECID" />
  <data type="pq" />
  <qual card="0-1" name="methodDevice" type="MethodDevice" />
  <qual card="0-1" name="bodyLocationPrecood" type="BodyLocationPrecood" />
  <qual card="0-1" name="bodyPosition" type="BodyPosition" />
  <qual card="0-1" name="abnormalInterpretation" type="AbnormalInterpretation" />
  <qual card="0-1" name="deltaFlag" type="DeltaFlag" />
  <qual card="0-1" name="referenceRangeNar" type="ReferenceRangeNar" />
  <qual card="0-1" name="relativeTemporalContext" type="RelativeTemporalContext" />
  <mod card="0-M" name="subject" type="Subject" />
  <att card="0-1" name="observed" type="Observed" />
</ct>
```
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Model Search  Model List  Model Detail

SystolicBloodPressureMeas

<table>
<thead>
<tr>
<th>Description / Status:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: SystolicBloodPressureMeas</td>
</tr>
<tr>
<td>Definition: SystolicBloodPressureMeas captures a subject's systolic blood pressure.</td>
</tr>
<tr>
<td>Status: proposed</td>
</tr>
</tbody>
</table>

Details  XML View

<table>
<thead>
<tr>
<th>Kind:</th>
</tr>
</thead>
<tbody>
<tr>
<td>statement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Constraints:</th>
</tr>
</thead>
<tbody>
<tr>
<td>key.code = SystolicBloodPressure_KEY_ECID</td>
</tr>
<tr>
<td>data.type = pq</td>
</tr>
<tr>
<td>data.pq.unit.domain = PressureUnits.DOMAIN_ECID</td>
</tr>
<tr>
<td>data.pq.normal = MillimetersOfMercury_ECID</td>
</tr>
</tbody>
</table>
SystolicBloodPressureMeas

**Description / Status:**

- **Name:** SystolicBloodPressureMeas
- **Definition:** SystolicBloodPressureMeas captures a subject's systolic blood pressure.
- **Status:** proposed

**RAW XML**

```xml
<ctype kind="statement" name="SystolicBloodPressureMeas" xmlns="">
  <key code="SystolicBloodPressure_KEY_ECID" />
  <data type="pq" />
  <qual card="0-1" name="methodDevice" type="MethodDevice" />
  <qual card="0-1" name="bodyLocationPrecoord" type="BodyLocationPrecoord" />
  <qual card="0-1" name="bodyPosition" type="BodyPosition" />
  <qual card="0-1" name="abnormalInterpretation" type="AbnormalInterpretation" />
  <qual card="0-1" name="deltaFlag" type="DeltaFlag" />
  <qual card="0-1" name="referenceRangeNorm" type="ReferenceRangeNorm" />
  <qual card="0-1" name="relativeTemporalContext" type="RelativeTemporalContext" />
  <mod card="0-M" name="subject" type="Subject" />
  <att card="0-1" name="observed" type="Observed" />
</ctype>
```
**SystolicBloodPressureMeas**

**Description / Status:**

<table>
<thead>
<tr>
<th>Name</th>
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</tr>
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  <data type="pq" />
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  <qual card="0-1" name="bodyLocationPrecoord" type="BodyLocationPrecoord" />
  <qual card="0-1" name="bodyPosition" type="BodyPosition" />
  <qual card="0-1" name="abnormalInterpretation" type="AbnormalInterpretation" />
  <qual card="0-1" name="deltaFlag" type="DeltaFlag" />
  <qual card="0-1" name="referenceRangeNar" type="ReferenceRangeNar" />
  <qual card="0-1" name="relativeTemporalContext" type="RelativeTemporalContext" />
  <mod card="0-1" name="subject" type="Subject" />
  <att card="0-1" name="observed" type="Observed" />
</ctype>
```
<?xml version="1.0" encoding="UTF-8" ?>

<ctml>

<!-- This section (the <ctype> element) is the CEType that the modelers create. If one downloads all the models from the zip file link, this is the definition that one will see in each individual model. -->

<ctype kind="statement" name="SystolicBloodPressureMeas">
  <key code="SystolicBloodPressure_KEY_ECID" />
  <data type="pq" />
  <qual card="0-1" name="methodDevice" type="MethodDevice" />
  <qual card="0-1" name="bodyLocationPrecond" type="BodyLocationPrecoord" />
  <qual card="0-1" name="bodyPosition" type="BodyPosition" />
  <qual card="0-1" name="abnormalInterpretation" type="AbnormalInterpretation" />
  <qual card="0-1" name="deltaFlag" type="DeltaFlag" />
  <qual card="0-1" name="referenceRangeNar" type="ReferenceRangeNar" />
  <qual card="0-0M" name="relativeTemporalContext" type="RelativeTemporalContext" />
  <mod card="0-1" name="subject" type="Subject" />
  <att card="0-1" name="observed" type="Observed" />
  <att card="0-1" name="reportedReceived" type="ReportedReceived" />
  <att card="0-1" name="verified" type="Verified" />
  <constraint path="qual.abnormalInterpretation.data.cwe.domain" value="AbnormalFlagNumericNom_DOMAIN_ECID" />
  <constraint path="qual.deltaFlag.data.cwe.domain" value="DeltaFlagNumericNom_DOMAIN_ECID" />
  <constraint path="data.pq.unit.domain" value="PressureUnits_DOMAIN_ECID" />
  <constraint path="data.pq.normal" value="MillimetersOfHgECID" />
  <constraint path="qual.methodDevice.data.cwe.domain" value="BloodPressureMeasurementDevice_DOMAIN_ECID" />
  <link card="0-0M" name="hasPrecondition" relation="hasPrecondition_ECID" />
    <target path="type.domain" value="PreconditionTypes_DOMAIN_ECID" />
  </link>
</ctype>

<!-- This section (the <ctype-c> element) is a de-normalized view of a compiled version of the CEType and includes the content from multiple referenced models. -->

<ctype-c kind="statement" name="SystolicBloodPressureMeas">
  <definition value="SystolicBloodPressureMeas captures a subject's systolic blood pressure." />
  <status value="proposed" />
</ctype-c>
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Model Search  Model List

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

To begin browsing the model list, please choose a letter.
Saccharomonospora Viridis ABACncPtSerOrdLabObs
Saccharomonospora Viridis ABACncPtSerOrdLabObs is the Clinical Element Model for standard laboratory test results/observations ordinal results. LOINC Code: 22572-2.

Saccharomyces Cerevisiae AB Ig AACncPtSerQnLabObs
Saccharomyces Cerevisiae AB Ig AACncPtSerQnLabObs is the Clinical Element Model for standard laboratory test results/observations numeric results. LOINC Code: 31032-6.

Saccharomyces Cerevisiae AB Ig GACncPtSerQnLabObs
Saccharomyces Cerevisiae AB Ig GACncPtSerQnLabObs is the Clinical Element Model for standard laboratory test results/observations numeric results. LOINC Code: 31031-8.

Saccharopolyspora Rectivirga AB A CncPtSerOrdImmuneDiffusionLabObs
Saccharopolyspora Rectivirga AB A CncPtSerOrdImmuneDiffusionLabObs is the Clinical Element Model for standard laboratory test results/observations ordinal results. LOINC Code: 6818-9.
Model Classes Created

- Patient, Employee, Provider, Organization, ContactParty, PatientContact (visit), ServiceDeliveryLocation, AdmitDiagnosis
- HealthIssue (Problem), Allergy, Intolerance, Document
- Order
  - OrderLab, OrderLabMicro, OrderBloodProduct
  - OrderMedAmb, OrderMedCont, OrderMedInt, OrderMedPCA, OrderMedReg
  - OrderNutrition, OrderRadiology, OrderNursing, OrderRepiratory, OrderTherapies
- LabObs, MicroLabObs, Assert, Eval, Meas, Proc
- Qualifiers, Modifiers (Subject), Attributions, Panels
Model Subtypes Created

• Number of models created - 4384
  – Laboratory models – 2933
  – Evaluations – 210
  – Measurements – 353
  – Assertions – 143
  – Procedures – 87
  – Qualifiers, Modifiers, and Components
    • Statuses – 26
    • Date/times – 27
    • Others – 400+
  – Panels – 79
Tools - Browser

• **Browsers/Editors**
  – Daedalus – authoring, real time links to terminology (not finished)

• **Compiler**
  – Syntax check
  – Verification of terminology links (value sets)
  – Outputs
    • Compiled representation for run time use
    • Multiple outputs (future)
Next steps

- Enhance the compiler
- Finish Daedalus
- Continue creating content
  - We estimate that we are about 10% complete
The basic name-value pair strategy
HL7 Result Message (ORU)

MSH|^~\&|||19981105131523||ORU^R01|

PID||100928782^9^M11||Smith^John^J|

OBR|||Z0063-0^BP^LN|

OBX||CE|8361-4^POSITION^LN||SIT^Sitting|

OBX||NM|8479-8^SBP^LN||138|mmHg|
OBX: a name-value pair approach

A code that identifies the *datatype* of OBX-5

Other data fields include: date of observation, identity of provider giving observation, normal ranges, abnormal flags

OBX-5: Data

A code that identifies the data in OBX-5 (Temp Reading)

A code that identifies the units of numerical data in OBX-5

OBX || NM || 11289-6^LN || 38 || C^ISO+ || | | | | F
OBX: with a coded value

A code that identifies the *datatype as a coded element*

The code is from LOINC

The code is from SNOMED

OBX||CE|883-9^Blood Group^LN||58460004^Group O^SCT|

A code that identifies the data in OBX-5 (ABO Blood Group)

OBX-5: Data
A code for Group O
How terminologies fit into the model

• LOINC – attributes/observables
• SNOMED CT – findings/values (many) and observables (some)
• First Data Bank - values
• RxNORM - values
Two (multi?) level modeling
HL7 RIM Class Diagram

Entity

Role

Clinical Acts

Financial Acts

- 5 Primary Subject Areas
- 44 Classes
- 192 Attributes
- 7 Associations
- 39 Generalizations
Specialization by restriction (constraint)

Act
class_cd <= ACT
mood <= ActMood
code <= ActCode

Observation
class_cd <= OBS
mood <= ActMood
code <= ObservationType

ObservationOrder
class_cd <= OBS
mood <= ORD
code <= ObservationType

LabOrder
class_cd <= OBS
mood <= ORD
code <= LabObservation

LabOrder (US)
class_cd <= OBS
mood <= ORD
code <= LOINC

LabOrder (UK)
class_cd <= OBS
mood <= ORD
code <= SNOMED Lab
Examples of reference models

- HL7 RIM
- OpenEHR reference model
- CEN reference model
- Clinical element model
Model & terminology must be done together

- Terminology models and information models
  - models made by data modelers (message standards)
  - models made by terminology groups (maintenance of terms)
- “Impedance mismatch” arises when one group is making terms and another group is making the model
- Post coordination in a single field in the model is just a way of hiding part of the model
The CM-SIG recommends that the IHTSDO establishes a policy that SNOMED be cooperatively integrated with a specific set of information models, such that use of SNOMED with an information model will only be explicitly supported if the information model is included in this set.
Model Centered Data Representation

- SNOMED
- LOINC
- FDB
- RxNorm
- ICD-10
- CPT

Internal Terminology (ECIDS)

Context Specific Mapping Tables

- ECIS Thesaurus
- Mayo Thesaurus
- IH Thesaurus

LexGrid Terminology Server

Models and Concepts
We assume that the model is used in association with a terminology server.
Model and Terminology

**Model**

MedicationOrder ::= SET {
  drug                Drug,  
dose               Decimal,  
route               DrugRoute,  
frequency       DrugFrequency,  
startTime        DateTime,  
endTime         DateTime,  
orderedBy      Clinician,  
orderNumber OrderNumber
}

**Instance data**

MedicationOrder {  
  drug                PenVK,  
dose               250,  
route               Oral,  
frequency       Q6H,  
startTime        09/01/95 10:01,  
endTime         09/11/95 23:59,  
orderedBy      Don Jones, M.D.,  
orderNumber OrderNumber A234567
}

If the medicationOrder.drug is a “antibiotic” then notify the infection control officer.
<table>
<thead>
<tr>
<th>Drugs has-child</th>
<th>Antibiotics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs has-child</td>
<td>Analgesics</td>
</tr>
<tr>
<td>Drugs has-child</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Antibiotics has-child</td>
<td>Penicillins</td>
</tr>
<tr>
<td>Antibiotics has-child</td>
<td>Cephalosporins</td>
</tr>
<tr>
<td>Antibiotics has-child</td>
<td>Aminoglycosides</td>
</tr>
<tr>
<td>Penicillins has-child</td>
<td>Pen VK</td>
</tr>
<tr>
<td>Penicillins has-child</td>
<td>Amoxicillin</td>
</tr>
<tr>
<td>Penicillins has-child</td>
<td>Nafcillin</td>
</tr>
<tr>
<td>Drugs has-member</td>
<td>Antibiotics</td>
</tr>
<tr>
<td>Drugs has-member</td>
<td>Penicillins</td>
</tr>
<tr>
<td>Drugs has-member</td>
<td>Pen VK</td>
</tr>
<tr>
<td>Drugs has-member</td>
<td>Amoxicillin</td>
</tr>
<tr>
<td>Drugs has-member</td>
<td>Nafcillin</td>
</tr>
</tbody>
</table>
Relationships Between Models

- Core Model
  - Observation
    - Clinical Observation
      - Blood Pressure
    - Lab Observation
      - Heart Rate
  - Order
  - Problem
    - Temperature
The Clinical Element Model
A formalism is needed to be able to discuss the modeling issues. However, the particulars of a particular formalism is not the issue. The logical structure of the data and relationships and associations between data elements is the most important thing. What are the issues of “style” that we can agree on?
Basic elements of the core model

- **Type** - The name of a particular model
- **Key** - Links the model to a concept in an external coded terminology.
- **Value Choice** - Possible ways to convey the model’s value.
Value Choice

- **Data** - Value conveyed as an HL7 version 3 data type
- **Items** - Value conveyed by multiple Clinical Elements collectively
A Simple Laboratory Observation

Clinical Element

- type: SerumSodiumMeas
- key: SerumSodium
- data: 140 mEq/L
Simplified Representation

Clinical Element

- type: LabObservationQnXCE
- key: SerumSodium
- data: 140 mEq/L

LabObservationQnXCE

- key: SerumSodium
- data: 140 mEq/L
A Panel containing 2 Observations

- **BloodPressurePanel**
  - **key**: BloodPressure
  - **items**:
    - **SystolicBloodPressureQn**: 120 mmHg
    - **DiastolicBloodPressureQn**: 80 mmHg
Mods and Quals of the Value Choice

- **Mods** - Component CE’s which change the meaning of the Value Choice.
- **Quals** - Component CE’s which give more information about the Value Choice.
The Use of Qualifiers

SystolicBPObs
  - data: 138 mmHg
  - quals
    * BodyLocation
      * data: Right Arm
    * PatientPosition
      * data: Sitting

SystolicBP
The Use of Modifiers (subject)

BloodTypeObs  Blood Type

data  O negative

mods

Subject  Subject

data  Self (patient)

BloodTypeObs  Blood Type

data  O positive

mods

Subject  Subject

data  Fetus
Clinical Element Modeling Language (CEML)
<ctype name="BloodPressurePanel" kind="panel">
  <key code="BloodPressurePanel_KEY_ECID" />
  <item name="systolicBloodPressureMeas" type="SystolicBloodPressureMeas" card="0-1" />
  <item name="diastolicBloodPressureMeas" type="DiastolicBloodPressureMeas" card="0-1" />
  <item name="meanArterialPressureMeas" type="MeanArterialPressureMeas" card="0-1" />
  <qual name="methodDevice" type="MethodDevice" card="0-1" />
  <qual name="bodyLocationPrecoord" type="BodyLocationPrecoord" card="0-1" />
  <qual name="bodyPosition" type="BodyPosition" card="0-1" />
  <qual name="relativeTemporalContext" type="RelativeTemporalContext" card="0-M" />
  <qual name="patientPrecondition" type="PatientPrecondition" card="0-M" />
  <mod name="subject" type="Subject" card="0-1" />
  <att name="observed" type="Observed" card="0-1" />
  <att name="reportedReceived" type="ReportedReceived" card="0-1" />
  <att name="verified" type="Verified" card="0-1" />
  <constraint path="qual.methodDevice.data.cwe.domain" value="BloodPressureMeasurementDevice_DOMAIN_ECID" />
  <constraint path="qual.bodyLocationPrecoord.data.cwe.domain"
    value="BloodPressureBodyLocationPrecoord_DOMAIN_ECID" />
  <link name="hasPrecondition" relation="hasPrecondition_ECID" card="0-M">
    <target path="type.domain" value="PreconditionTypes_DOMAIN_ECID" />
  </link>
</ctype>
Changing from CEML to CDL

- The models are still Clinical Element Models
- Switching to a new modeling language
  - Clinical Element Modeling Language (CEML)
  - Constraint Definition Language
- Semantics are identical
- Type inheritance supported by the compiler
- CDL is context independent language
- The CDL parser uses ANTLR
- CDL was developed by Alan James (GE)
<ctype name="BloodPressurePanel" kind="panel">
  <key code="BloodPressurePanel_KEY_ECID" />
  <item name="systolicBloodPressureMeas" type="SystolicBloodPressureMeas" card="0-1" />
  <item name="diastolicBloodPressureMeas" type="DiastolicBloodPressureMeas" card="0-1" />
  <item name="meanArterialPressureMeas" type="MeanArterialPressureMeas" card="0-1" />
  <qual name="methodDevice" type="MethodDevice" card="0-1" />
  <qual name="bodyLocationPrecoord" type="BodyLocationPrecoord" card="0-1" />
  <qual name="bodyPosition" type="BodyPosition" card="0-1" />
  <qual name="relativeTemporalContext" type="RelativeTemporalContext" card="0-M" />
  <qual name="patientPrecondition" type="PatientPrecondition" card="0-M" />
  <mod name="subject" type="Subject" card="0-1" />
  <att name="observed" type="Observed" card="0-1" />
  <att name="reportedReceived" type="ReportedReceived" card="0-1" />
  <att name="verified" type="Verified" card="0-1" />
  <constraint path="qual.methodDevice.data.cwe.domain" value="BloodPressureMeasurementDevice_DOMAIN_ECID" />
  <constraint path="qual.bodyLocationPrecoord.data.cwe.domain" value="BloodPressureBodyLocationPrecoord_DOMAIN_ECID" />
  <link name="hasPrecondition" relation="hasPrecondition_ECID" card="0-M">
    <target path="type.domain" value="PreconditionTypes_DOMAIN_ECID" />
  </link>
</ctype>
model BloodPressurePanel is panel
{
    key code(BloodPressurePanel_KEY_ECID);

    statement SystolicBloodPressureMeas systolicBloodPressureMeas optional
        systolicBloodPressureMeas.methodDevice.conduct(methodDevice)
        systolicBloodPressureMeas.bodyLocationPrecoord.conduct(bodyLocationPrecoord)
        systolicBloodPressureMeas.bodyPosition.conduct(bodyPosition)
        systolicBloodPressureMeas.relativeTemporalContext.conduct(relativeTemporalContext)
        systolicBloodPressureMeas.subject.conduct(subject)
        systolicBloodPressureMeas.observed.conduct(observed)
        systolicBloodPressureMeas.reportedReceived.conduct(reportedReceived)
        systolicBloodPressureMeas.verified.conduct(verified);
    statement DiastolicBloodPressureMeas diastolicBloodPressureMeas optional
        ...
    statement MeanArterialPressureMeas meanArterialPressureMeas optional
        ...

    qualifier MethodDevice methodDevice optional;
        md.code.domain(BloodPressureMeasurementDevice_DOMAIN_ECID);
    qualifier BodyLocationPrecoord bodyLocationPrecoord optional;
        blp.code.domain(BloodPressureBodyLocationPrecoord_DOMAIN_ECID);
    modifier Subject subject optional;

    attribution Observed observed optional;
    attribution ReportedReceived reportedReceived optional;
    attribution Verified verified optional;
}
Type name and key code (CDL)

model BloodPressurePanel is panel {

key code(BloodPressurePanel_KEY_ECID);

statement SystolicBloodPressureMeas systolicBloodPressureMeas optional
systolicBloodPressureMeas.methodDevice.conduct(methodDevice)
systolicBloodPressureMeas.bodyLocationPrecoord.conduct(bodyLocationPrecoord)
systolicBloodPressureMeas.bodyPosition.conduct(bodyPosition)
systolicBloodPressureMeas.relativeTemporalContext.conduct(relativeTemporalContext)
systolicBloodPressureMeas.subject.conduct(subject)
systolicBloodPressureMeas.observed.conduct(observed)
systolicBloodPressureMeas.reportedReceived.conduct(reportedReceived)
systolicBloodPressureMeas.verified.conduct(verified);

statement DiastolicBloodPressureMeas diastolicBloodPressureMeas optional
....

statement MeanArterialPressureMeas meanArterialPressureMeas optional
....

qualifier MethodDevice methodDevice optional;
md.code.domain(BloodPressureMeasurementDevice_DOMAIN_ECID);

qualifier BodyLocationPrecoord bodyLocationPrecoord optional;
blp.code.domain(BloodPressureBodyLocationPrecoord_DOMAIN_ECID);

modifier Subject subject optional;

attribution Observed observed optional;
attribution ReportedReceived reportedReceived optional;
attribution Verified verified optional;
}

The name of this model

Binding to a single “observable” concept
Binding to a "domain" (value set)

The name of the terminology “domain” that the element is “bound” to

qualifier MethodDevice methodDevice optional;
(BloodPressureMeasurementDevice_DOMAIN_ECID);

modifier Subject subject optional;

qualifier BodyLocationPrecoord bodyLocationPrecoord optional;
(BloodPressureBodyLocationPrecoord_DOMAIN_ECID);

blp.code.domain

methodDevice md.code.domain
Clinical Element Models and the HL7 RIM
CEM and HL7 RIM

<observation classCode="OBS" moodCode="EVN">  
  <code code="ASSERTION">  
  <text>Allergy to PCN manifesting as hives</text>  
  <value xsi:type="CD" code="106190000" (Allergy)  
    <qualifier>  
      <name code="246075003" (Causative agent)  
        <value code="373270004" (Penicillin -class of antibiotic)  
        </value>  
      </name>  
    </qualifier>  
  </value>  
  <actRelationship typeCode="MFST">  
    <observation classCode="OBS" moodCode="EVN">  
      <code code="ASSERTION">  
      <value xsi:type="CD" code="247472004" (Hives)  
      </value>  
    </observation>  
  </actRelationship>  
</observation>
HL7 Allergy as a CEM

- AllergyStatement
  - data: Allergy
  - quals
    - CausativeAgent
      - data: Penicillin
      - Manifestation
        - data: Hives
“Isosemantic” Models
Pre and Post Coordination

Precoordinated Model (User Interface Model)
- SystolicBPRightArmSittingObs
- SystolicBPRightArmSitting
- data 138 mmHg

Post coordinated Model (Storage Model)
- SystolicBPObs
- SystolicBP
- data 138 mmHg
- quals
- BodyLocation
- BodyLocation
- data Right Arm
- PatientPosition
- PatientPosition
- data Sitting
Isosemantic models

• User interface models
  – Convenient for data entry
  – Typically pre-coordinated
  – Many variations

• Storage models
  – Only one model is designated as *the* storage model
  – Comprehensive set of qualifiers and modifiers
  – The storage model is referenced in reports, rules, protocols, data analysis

• Composition – Decomposition mappings
Decomposition Mapping

Precoordinated Model (User Interface Model)

- **SystolicBPRightArmSittingObs**
  - data: 138 mmHg

Post coordinated Model (Storage Model)

- **SystolicBPObs**
  - data: 138 mmHg
  - quals:
    - **BodyLocation**
    - data: Right Arm
    - **PatientPosition**
    - data: Sitting
Requirements for “Good” Models
Requirements for good models

- Accurate – corresponds to the real world
- Unambiguous – only one meaning
- Understandable
  - People recognize the real world referent(s)
- Reproducible
  - Different modelers would model in the same way
- Parsimonious and harmonious use of terminology
  - Semantics of the model and terminology match
- Flexible
  - Evolve gracefully over time
- Consistent across domains – Specimen Collection and I&O Charting
- Practical – implementable in current databases and standard languages
- Minimally complex – cover only what is needed
- Common queries are easy
Ambiguity

Pulse

Present (Present/Absent)
72 beats/minute (Rate)
Thready (Quality)
Irregular (Rhythm)
Specific Cases in Modeling
Disclaimer: This is our current best thinking. Some models have not been used in a production system yet. Some models may change when we have more production experience.
Assertion versus Evaluation Styles
Data Entry Styles

**Hair Color**
- Brown
- Blonde
- Red

**Evaluation Styles**

**Finding**
- Brown hair

**Assertion Style**
- Brown hair
- Blonde hair
- Red hair

**Hair Color**
- Brown
- Blonde
- Red
Assertion Vs Evaluation

**Evaluation Style**

- HairColorObs
- Hair Color
- data
- Brown

**Assertion Style**

- HairColorObs
- Assertion
- data
- Brown Hair Color
Both evaluation and assertion styles are accurate and unambiguous

Evaluation style is more common as a data entry mode

Assertion style allows each assertion to become a present/absent column for statistical analysis

Evaluation style is our preferred storage form when the value represents an attribute of the patient

Storage of assertion style instances is best for reasons, complications, final diagnoses, etc.

**Conclusion:** You need to support both styles and be able to convert between them
Deprecated representation

Only the “code” (HL7) or key (CEM) has a value.

It is implied that this means that “the patient has brown hair color.

Implying meaning is usually a bad idea.
Subject
Subject – Evaluation Style

FetalBloodTypeObs Fetal Blood Type
  data O negative

BloodTypeObs Blood Type
  data O negative
  mods
  Subject
  data Fetus
Subject – Assertion Style #1

- FetalBloodTypeObs: Assertion
  - data: Fetal Blood Type O negative

- BloodTypeObs: Assertion
  - data: Blood Type O negative
  - mods
    - Subject: Subject
      - data: Fetus
Subject – Assertion Style #2

BreastCancerInMotherObs

data Breast Cancer in Mother

BreastCancerObs

data Breast Cancer
mods

Subject

data Mother
Subject as a Compound Statement

Subject

items

Person Identity

Person Name

Relationship

Maternal Aunt

data

Clara Barton
Representation of Family History

Breast Cancer Obs
  data
  mods
  Subject
    items
  Relationship
    data
    Family (ancestor)
Pre Vs Post Coordinated Subject

• Pre coordinated
  – Easier for data entry
  – Can lead to combinatorial explosion

• Post coordinated
  – Easier to coordinate findings between patient and related party
  – Easier to extend model with additional qualifiers
  – Consistent with family history
  – Allows detail on the identity of the subject
  – Easier to misuse data (mistake cancer in mother for cancer in patient)

• Conclusion: Support both pre and post coordinated subject styles, but use post coordinated model for storage
Negation and Uncertainty
## Data Entry Styles

### Medical History

<table>
<thead>
<tr>
<th>Hx Finding</th>
<th>Diabetes</th>
<th>Renal Disease</th>
<th>Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Yes</strong></td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td><strong>No</strong></td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td><strong>Unk</strong></td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

(handles pertinent negatives)

(repeating field)
Negation

(Implicit that this means “diabetes is present.”)
Pre Coordinated Negation

(Leads to combinatorial explosion)
Use of Negation and Certainty are mutually exclusive sets. Negation is only present/absent. All other degrees of probability are represented as values of Certainty.
Possible values for CombinedUncertainty: Not present, present, maybe, maybe not, probably, probably not, might, might not, likely, unlikely, very unlikely, very likely....
Conclusions on Negation

- “Picklist” style selection of findings does not allow for the representation of pertinent negative findings.
- Pre-coordinating negation with findings leads to “combinatorial explosion” in many situations.
- It is difficult to avoid using pre-coordination for some common phrases, “No Salmonella, Shigella, or Campylobacter identified.”
- You can separate pure negation from uncertainty, or combine them into one field.
- Combining negation and uncertainty into one field will probably prevent entry of some nonsensical expressions.
Done and Not Done

(Implicitly this means “appendectomy was done.”)
Done and Not Done

• Recording of whether actions or events occurred or not has a similar structure to negation, but the values are *Done* and *Not Done*.

• Theoretically, it is possible to use both Negation, and Done/Not Done in a single statement. For example: The patient had abdominal surgery but it was *NOT* an appendectomy.”
History Of
“History Of” issues

• A clinician can observe a sign or perform a procedure and record the event in the EHR.
• The patient or family can report a symptom or procedure occurred.
• It is essential to distinguish these two cases.
• When you query for existence of a given disease you want consistency of representation between direct observations and historical observations.
As data ages, the observed information becomes the same as reported information. If you ask the database “Did the patient have vomiting?”, you want “True” to be returned in either case.
Attribution

• Recording the source of information
  – Who, when, where
• Database add/modify/delete timestamps are handled separately from clinical processes
• Attributions pertain to actions or events
• Attributions are represented as a special class of qualifiers
General model for act attribution

- **State the act (action or event)**
  - Observed, reported, ordered, counter signed, transcribed

- **State the attribution information**
  - **Who**
    - Participation (observer, reporter, receiver)
    - Role (mother, physician, nurse, student)
  - **When** (exact or fuzzy time)
  - **Where**
    - Geographical place
    - Network place
    - Could be different for patient than for clinician
  - **Reason for the action**
    - Reason for order, reason for cancel, reason for hold
Differences for Observed and Reported

- **Observed**
  - Action (Observed)
  - Observer
  - Timestamp

- **Reported**
  - Action (Reported)
  - Reporter
  - Receiver
  - Timestamp

- Observer, reporter, and receiver could be programs or electronic data stores
Attribution - Reported

- Action
  - Reported
    - data
    - quals
  - ReportTimeObs
    - ReportTime
      - data
      - 11/09/2007
  - Participant
    - items
    - Role
      - data
      - Mother
    - Receiver
    - items
    - Role
      - data
      - Clinician
Assertion with Attributions

VomitingObs  Assertion

Vomiting      data

Subject       Subject

Patient       data

Observed      Reported

(As previously defined)
Attributions

• Attribution information unifies the historical and observational data.

• Attribution allows status change information to be carried in the instance of data.

• Specific models for particular kinds of attributions allows participants, roles, locations, and reasons to be specified.
Pain and Pain Severity
Pain Observation and Qualifiers

PainObs

Assertion

data Pain

quals

BodyLocation

Body Location

data Abdomen

PainQuality

Pain Quality

data Dull

PainSeverity

Pain Severity

data Moderate
Pain Modeling Issues

- Pain severity is not usually measured unless there is pain.
- A pain severity of (None, 0) is the same as no pain.
- In common practice Pain Severity Scales are thought of as independent observations, not qualifiers of pain.
- **Conclusion:** We allow the pain severity scales as independent observations. However, the pain assertion model is more expressive.
Semantic links
How much data in a single record?

• “Chest pain made worse by exercise”
  – Two events, but very close association
  – Normally would go into a single finding

• “Ate a meal at a restaurant and 30 minutes later he felt nauseated, and then an hour later he began vomiting blood.”
  – Discrete events with known time and potential causal relationships
  – May need to be represented by multiple associated findings

• Semantic links are used to represent relationships between distinct event instances
PA view is compared to the previous examination dated 10-22-91. In comparison to a study of 6.2.92, there has been a slight increase in the degree of cardiomegaly. The previously described area of consolidation in the left upper lobe has improved. Post-operative changes consistent with coronary artery bypass. There is persistent bilateral apical pleural thickening and superior paramediastinal streaky opacities.
### Representation of Semantic Links

<table>
<thead>
<tr>
<th>InstanceId 1</th>
<th>Relationship</th>
<th>InstanceId 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>(123) Nausea</td>
<td>followed-by</td>
<td>(987) Vomiting</td>
</tr>
</tbody>
</table>

- Semantic links can also have certainty and attribution
  - Certainty (certain, possible, probable, not likely)
  - Attribution (who or what asserted the relationship, when, and why?)
Questions?
Information Model Ideas

Repository of Shared Models in a Single Formalism

Initial Loading of Repository

CEMs
DCMs
CDA Templates
openEHR Archetypes
CEN Archetypes
LRA Models
CMETs, HMDs RMIMs

CEM
V2 “|”
LRA
V2 XML
HTML
V3 XML
V3 Next
UML
openEHR
Archetype
CDA
OWL
SOA
Payload

CDISC
SHARE
CEN
Archetype

Standard Terminologies

Translators
Other issues

- Levels of models – boundary between what is in “file” and what we represent in tables or some other kind of knowledge representation. Models in files to the level of different attributes and then further constraints in tables?
- Could these models be represented in OWL, DL and other semantic web tools?
- Examples using coded ordinal data type
- Yes/no questions are really a different user entry style for assertion models
- More examples with Family History
- Better slides for semantic links
- Specific examples of “Hx of”
- Discussion of other modifiers – planned procedures, goals, etc.
- Examples of “Relative Temporal Context”
- Implementation choices in object oriented languages
Other issues

- Show how the hierarchy of CEMs could produce the Act hierarchy in the HL7 RIM
- Inheritance of qualifiers and attributions between panels and statements
- Common qualifiers across models and within the same family of models
  - Status, body location, changes (in vision, appetite, etc.)
  - Don’t want “hard” hierarchies, but want common query and behaviors across different models
- Co-occurrence constraints
- “CHOICE in Qualifiers”
  - Items that could be numeric or conceptual (frequency of “after meals” XOR “every 4 hours”)
- Use of “aggregate data”
Other issues

• Storage of data that does not conform to the model
  – Alternative data (data type does not match)
  – Unrecognized qualifier
  – Too many qualifiers - cardinality of qualifier is not allowed

• Support for calculated values

• Relative temporal context

• Practical compromises
  – Allowing value sets with “low, med, high, not assessed”
Other Issues

• Types of collections
  – Statements
  – Complex statements – orders
  – Panels
  – Apgar scores, Treadmill test
  – Folders, sections, and other arbitrary collections (from CEN 13606)