Official Meeting Summary – Date Drafted: February 13, 2008

Meeting type – CDISC - HL7 Stage II

Meeting date & time – February 13, 2008, 11-12 noon (Eastern time)

Meeting format – Webinar / Conference call

Meeting Leader(s) – Jason Rock

Meeting Recorder – Erik Henrikson

Attendees – Name / Affiliation -

Jason Rock / GlobalSubmit
Erik Henrikson / FDA
Terry Harden / IBM
Bill Friggle / Sanofi
Jay Levine / FDA
Mary Lenzen / Octagon
Joyce Nyland / City of Hope Medial Center
Marti Velezis / BAH
Scott Getzin / Lilly
Wayne Kubick / Lincoln Technologies

Background and Objectives

a. History of events leading up to the meeting –

FDA wishes to receive, in regulatory submissions, standard clinical study information content developed by the Clinical Data Interchange Standards Consortium in an HL7 message exchange format. This is key to the FDA strategic initiatives to improve public health and patient safety.

This project is currently broken in to two stages requirements analysis and message development.

b. Meeting was requested by – FDA

c. Purpose of the meeting – RCRIM **(**HL 7 Listserve) members to discuss develop consensus necessary for a path forward on CDISC-HL7 Stage II activities

Discussion

Participant members were noted and discussion ensued.

Unfinished business included the need to finalize the January 23, 2008 Meeting Minutes

Presentation

Jason Rock provided an overview of the base clinical statement pattern and how to use templates off of the clinical statement.
A clinical statement is an HL7 V3 artifact that describes information relevant to the care of a patient.
The clinical statement has been worked on by several different people from different countries and is in production use in the UK and Canada.
The clinical statement can capture information about observation (e.g. lab test, physical exams), Substance Administration (e.g. drug, radiotherapy), Supply (e.g. dispense 30 tablets with 5 refills), procedure (e.g. surgical procedure, massage) and encounter (e.g. field visit, telephone call). The clinical statement also supports relationships between clinical statement (e.g. cause, reference, reason for).
Templates were also discussed. A template is a set of constraints/extensions to a model. Templates can further define a clinical statement. For example, a clinical statement can represent almost any relevant information to the care of a patient; however, a template could define exactly how you would capture a barthel index. This barthel index template would be put on top of a clinical statement to better enforce validation.

Decisions/agreements reached

a. Action items ownership –

- Jason will make available to everyone the .ppt slides used for this presentation, a information web link which also explains these slides and a related Technical manual
- Next meeting will be a presentation on "ASPIRE"

Date(s) for follow-up - February 20, 2008

Related Documents

- Meeting Minutes from January 9, 2008 & January 23, 2008
- Basic info about clinical statement pattern standard:

http://www.hl7.org/v3ballot/html/domains/uvcs/uvcs.htm
http://www.hl7.org/v3ballot/html/domains/uvcs/uvcs_ClinicalStatementTopics.htm

- Clinical Statement .ppt slide presentation

Other

Meeting Minutes Drafted/Author – Erik Henrikson

Clinical Statement Pattern

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Agenda

- Review Clinical Statement
  - What it is?
  - Basics of the clinical statement (act choice box)
  - Relationships between clinical statements
- Using the clinical statement - Templates

Clinical Statement - Definition

- An expression of a discrete item of clinical (or clinically related) information relevant to the care of a patient.
- Clinical information can be expressed with different levels of granularity
- The detail conveyed in a single statement may vary.

Goals

- A ‘pattern’ to convey clinical information
- Designed to be used with other HL7 V3 models
  - not capable of being implemented 'as is‘
- Should be refined for specific needs
  - Through constraints and/or extensions
- does not represent a physical structure for storing data

Stewards

- Informed by many individuals from many countries
- Including but not limited to:
  - UK National Programme for Information Technology (NPfIT)
  - HL7 Structured Documents Technical Committee
  - Clinical Statement Task Force
- Currently used in production
  - Canada
  - UK

Parts of the Model

- Clinical Statement Act Choice Box
- Relationships between Clinical Statements
- Participations surrounding the Acts (not going to be reviewed today)
- Acts and relationships outside the Choice Box (not going to be reviewed today)

Clinical Statement Act Choice Box

- This part of the model is used to convey detailed clinical information
- Can be used to group clinical statements
- Can be used to relate clinical statement
  - Can refer to previously sent clinical statement (i.e. no duplicate information is sent) or send full statement
- Can specify order of activities
- Can specify the absence of an activity

Clinical Statement Act Choice Box

- Observation
- Substance Administration
- Supply
- Procedure
- Encounter
- Organizer
- Act

Observation

- What was actually observed ("results" or "answers")
  - Can also be a request, recommendation, promise, refusal, a goal or risk to be avoided
- Many observations are name-value-pairs
- May consist of “child” observations
  - a white blood cell count consists of the sub-observations for the counts of the various granulocytes, lymphocytes and other normal or abnormal blood cells (e.g., blasts)
- Can be 'Subjective' and 'Objective' findings
- Can also be an ‘Assessment’
  - establishment of a diagnosis is an Observation

Examples of Observations

- Recording the results of a Family History Assessment
- Laboratory test and associated result
- Physical exam test and associated result
- Device temperature
- Soil lead level
- An assertion of a clinical finding, such as left femur fracture

Substance Administration

- Involves introducing or otherwise applying a material into or to the subject
  - also includes requesting, instructing the patient, recommending, promising, prohibiting or refusing to administer a substance, as well as the actual act of personally administering the drug
- Photons and other models of radiation or light energy are considered substances
- Performers may be a person, device, plant
  - e.g. poison ivy, animal, mosquito bite, self-administration

Examples of Substance Administration

- Administration of a measurable quantity of an external force (e.g. radiotherapy)
- Administration of a measurable quantity of a substance or force as part of an investigative procedure (e.g. glucose administered in a glucose tolerance test).
- Chemotherapy regimens (multiple substance administrations)
- Drug prescription
- Vaccination record
- Tube feeding of a patient
- Agricultural field spraying
- Oiling a machine
- Medicating a herd in a feedlot via food additives

Supply

- Providing a material (dispensing)
  - Includes requesting, recommending, promising, prohibiting or refusing such a supply
- Associated to a product
- Precise identification of the Material (manufacturer, serial numbers, etc.) is important
- Examples:
  - Ordering bed sheets
  - Dispensing of a drug
  - Issuing medical supplies from storage
- Note: an outpatient prescription typically includes both a recommendation for Substance Administration (e.g. take digoxin 0.125mg by mouth once per day) and a request to Supply (e.g. dispense 30 tablets, with 5 refills)

Procedure

- Goal is to alter the physical condition of the subject
  - includes requesting, recommending, promising, prohibiting or refusing to carry out a procedure
  - X-Rays are not a procedure (in HL7 terms) because the goal is not to alter the condition of the patient
- Most procedure have associated observations
  - interventional radiology (e.g., catheter directed thrombolysis) does both observing and treating
- Examples:
  - Surgical procedure
  - Massage
  - Acupuncture

Encounter

- Interaction with a patient for the purpose of providing healthcare-related service
  - Includes requesting, proposing, promising, prohibiting or refusing an encounter
  - Includes admissions, discharges and transfers of care, single discrete office visit
- Examples
  - outpatient visit to multiple departments
  - home health support (including physical therapy)
  - inpatient hospital stay
  - emergency room visit
  - field visit (e.g., traffic accident)
  - office visit
  - occupational therapy
  - telephone call

Organizer

- Represents a heading in a heading structure, or "organizer tree“
- Does not itself have any semantic content
- Can be uses as a component relationship
  - "hemoglobin measurement" is a component of a "complete blood count"
- Organizer typically can be assigned a concept identifier
  - category might be identified as 'investigations‘
  - a battery might be identified as 'Full blood count'

Act (Generic)

- Used when more specific classes are not appropriate
- This is a catch all

Relationships between Clinical Statements

- The model provides three mechanisms that allow Clinical Statements to be linked:
  - Containment
  - Reference
  - Direct relationship

Containment

- Grouping of clinical data (Organizer)
- Example:
  - an Antenatal exam may comprise individual observations of maternal weight, maternal BP, fetal size, fetal heart rate etc
  - Linking statements relating to a specific 'Problem' (or adverse event)

Reference

- To assert a link to a Clinical Statement that is already in the communication instance for another purpose, thus avoiding unnecessary duplication
- To assert a link to a Clinical Statement that is directly related to the purpose of the communication but has been sent as part of a prior notification
- To link to a Clinical Statement that is already available as a result of an unrelated communication

Direct Relationship

- When one clinical statement explains or supports another clinical statement
  - if a previous condition explains an observation made during a visit
- Note: If the supporting Clinical Statement is already available from a previous communication, the link by reference approach may be used

Relationship Include

- Cause (is etiology for)
  - Observation, Procedure, or Substance Administration CAUSES an Observation
  - Used to show that the source caused the target observation (for instance, source "diabetes mellitus" is the cause of target "kidney disease").
- evaluates (goal)
  - Observation EVALUATES an Observation
  - Used to link an observation (intent or actual) to a goal to indicate that the observation evaluates the goal (for instance, a source observation of "walking distance" evaluates a target goal of "adequate walking distance").
- Is manifestation of
  - Observation IS A MANIFESTATION OF an Observation
  - Used to say that the source is a manifestation of the target (for instance, source "hives" is a manifestation of target "penicillin allergy").
- Refers to
  - Observation, Procedure , Substance Administration , Supply REFERS TO an Observation, Procedure, Substance Administration
  - Used to show a general relationship between the source and the target, when the more specific semantics of the relationship isn't known.

Relationships Cont.

- Has reason
  - Encounter, Observation, Procedure, Substance Administration, Supply HAS REASON for Encounter, Observation, Procedure, Substance Administration, Supply
  - Used to show the reason or rational for a service (for instance source "treadmill test" has reason "chest pain").
- Starts after start
  - Encounter, Observation, Procedure, Substance Administration, Supply STARTS AFTER [the] START of Encounter, Observation, Procedure, Substance Administration, Supply
  - The source Act starts after the start of the target Act (for instance source "diaphoresis" starts after the start of target "chest pain").
- Has support
  - Observation HAS SUPPORT for an Observation
  - Used to show that the target provides supporting evidence for the source (for instance source "possible lung tumor" has support target "mass seen on chest-x-ray").
- Has Subject
  - Observation HAS SUBJECT for an Observation
  - Used to relate a source region of interest to a target image, or to relate an observation to its subject observation (for instance, source "moderate severity" has subject target "chest pain").

Relationships Cont.

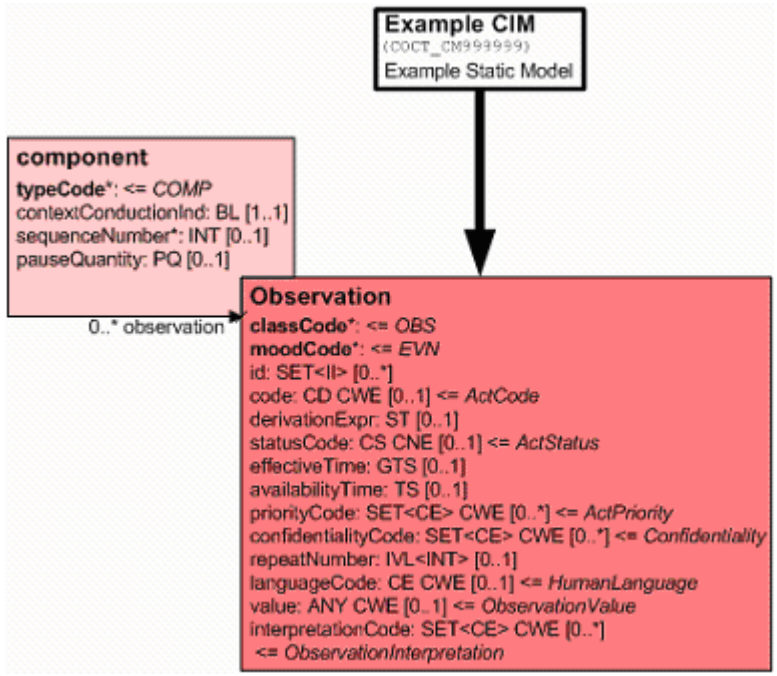
- Is excerpt of
  - Observation IS [an] EXCERPT OF an Observation, Procedure, Substance Administration, Supply
  - Used to show that the source is excerpted from the target (for instance source "hemoglobin value of 12" is an excerpt of target "complete blood count").
- Episode link
  - Observation [is the same] EPISODE [as] an Observation
  - Used to show that the source and the target are part of the same episode (for instance, a diagnosis of "pneumonia" can be linked to an external problem list entry of "pneumonia" to show that the current diagnosis is part of the ongoing episode of pneumonia).
- Replace
  - Encounter , Observation, Organizer, Procedure, Substance Administration, Supply [is] REPLACED [by] an Encounter , Observation, Organizer, Procedure, Substance Administration, Supply
  - Used to indicate that the source statement is a replacement for the target external act.

Templates

- Definition: Set of constraints / extensions on a particular model
- Templates are used to further refine existing models to specify a narrower scope
- In other words, take a broad model like the clinical statement and define a particular use case definitively

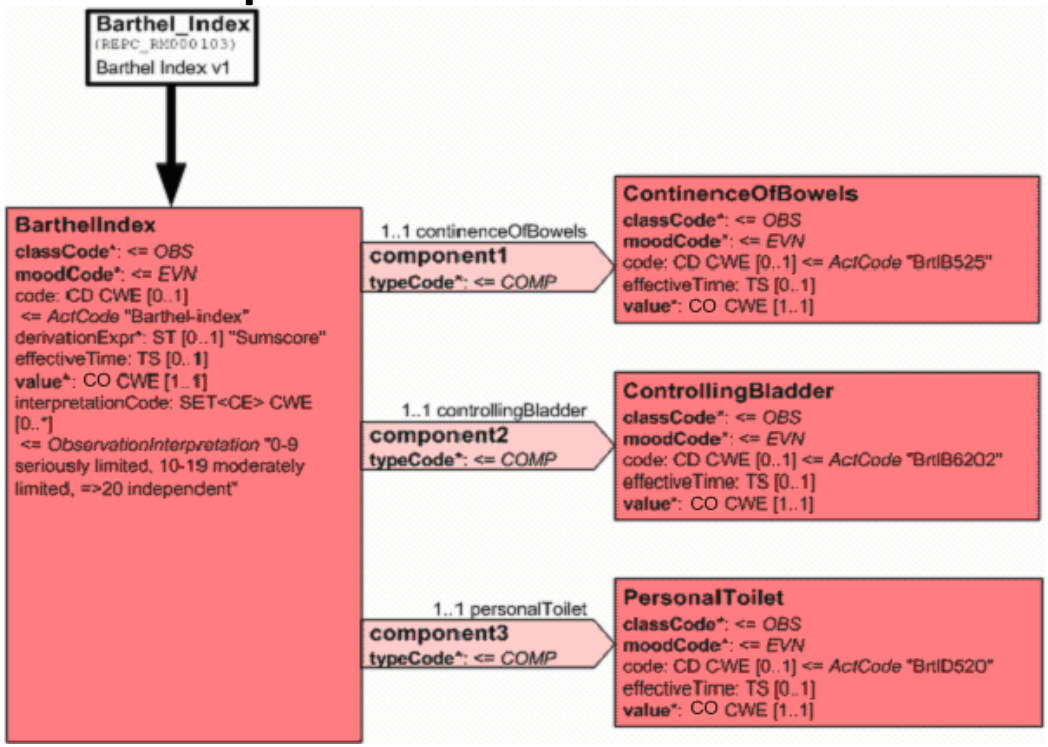
Template Example

Example below is based on a Clinical Statement Pattern. The below diagram is generic. The example shows an observation that can have zero or many "child" observation



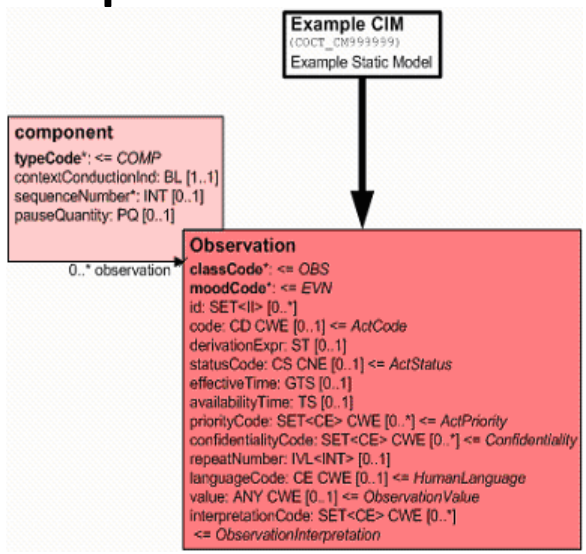
Templates Cont.

- Templates will take the generic structure and allow one to define a specific structure.
- For example:



Template Cont.

- The Barthel Index is one observation, a component relationship with three child observations
- By creating a Barthel Index template we have better validation of a Clinical Statement.



Templates In Use

- Templates can be stored in a registry
- When a template is created other can use it
- When templates exist for a particular need, the template should be used, otherwise the generic structure should be used

Thank You