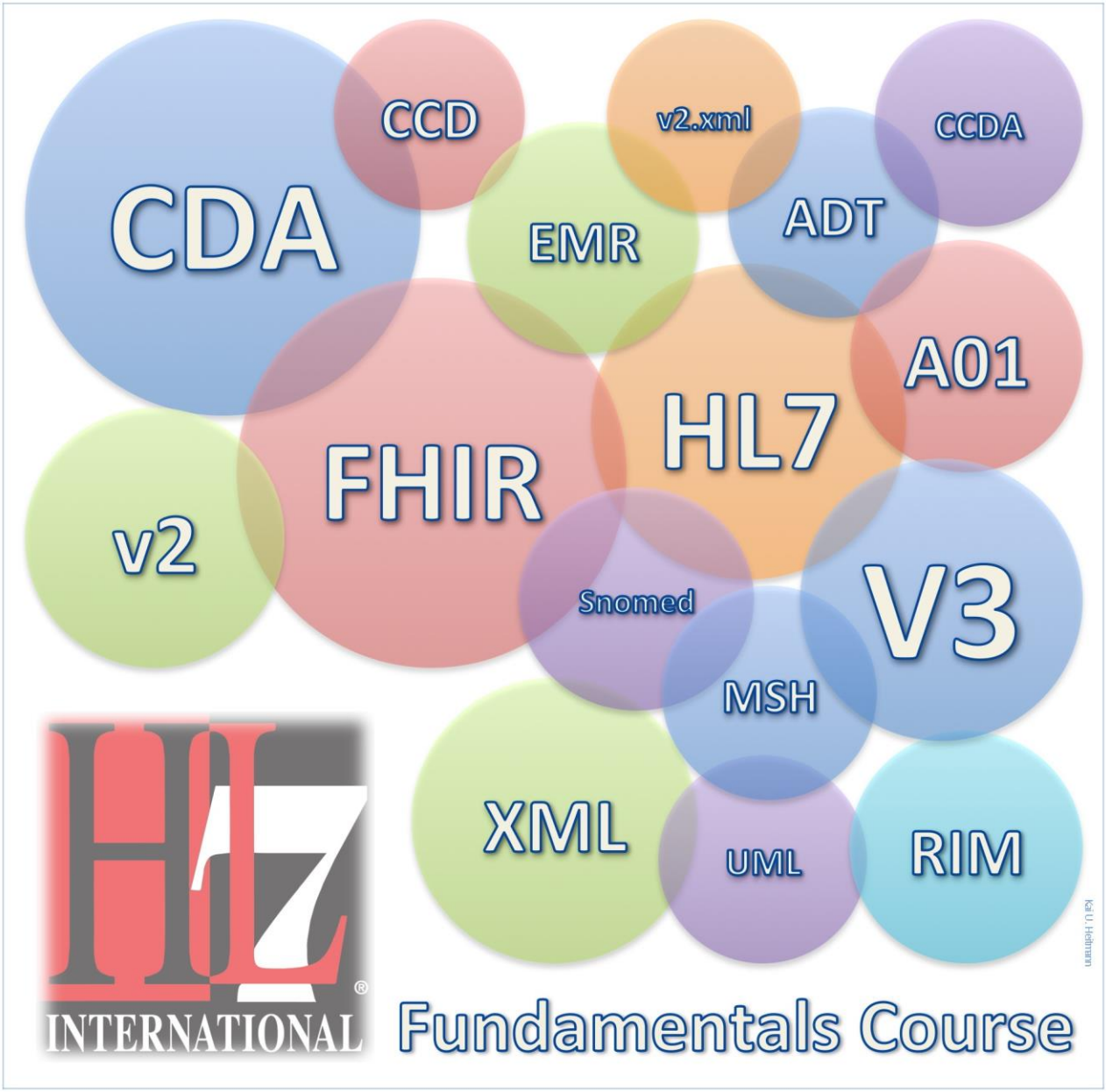

CDA Module, Unit 4:

CDA R2 Entries: Clinical Statements

Reading Material

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Unit Content and Learning Objectives

In this Unit, we will bring an overview of the CDA R2 entries (clinical statements)

1. Definitions

What is a "Clinical Statement"?

A Clinical Statement is an expression of a discrete item of clinical, clinically related or public health information that is recorded because of its relevance to the care of a patient.

Clinical or public health information can be expressed with different levels of granularity and therefore the **extent and detail conveyed** in a single statement may vary.

To be a clinical statement, a concept must be associated with a patient and be specific with respect to:

1. It's temporal context
2. It's relationship to the entity
3. It's mood and presence, absence or value (for observations)
4. It's mood and status (for procedures)

What is "Clinical Information"?

Clinical information is used primarily as part of the process of providing a health care service to an individual patient. Its form can be human-readable and/or computer-processable. It also may be used for epidemiological, research, and public health-care. However, it excludes information outside the clinical domain (for example billing information, logistics, etc.)

Medical Records as Collection of Statements

A medical record consists of an agent's (e.g.: physicians, nurses, etc.) direct observations (**statements**) about the patient.[1] The medical record allows the agent to naturally express and according to their understanding, information about the direct observation. These include desirable features such as:

- accepting uncertain and negative statements
- allowing expression at their natural level of abstraction
- allowing descriptions to an arbitrary level of detail
- including the context of observations

[1] Foundations for an Electronic Medical Record, Rector and Nolan, 1991

An Example

This is a patient story:

> Patrick Pump examined Adam Everyman in consultation on January 15, 2008 at the GHH. He is a 37-year-old man from Ann Arbor, Michigan. He complains of occasional palpitations and racing heart beats, with occasional dizziness. He underwent cardiac angiography at the Good Health Hospital, yesterday, which revealed normal coronaries. His Blood pressure is 88/62. X-Ray consis-tent with cardiomegalia. No known drug allergies. The patient currently is on Nexium 40 mg p.o. daily. Diagnosis is Congestive heart failure. Patient referred for an electrophysiology study.

The same story structured with Clinical Statements:

> 1-Context
> Patient: Adam Everyman
> Age: 37 Years
> Date: January 15, 2008
> Location: GOOD HEALTH HOSPITAL
> Physician: Patrick Pump, Cardiologist - Attending Physician
>
> 2-Clinical Statements
> a_1. observation: complains of occasional palpitations
> a_2. observation: complains of racing heart beats
> a_3. observation: complains of occasional dizziness
> b_1. procedure: cardiac angiography (Completed: Jan 14, 2008)
> b_2. observation: normal coronaries, ejection fraction: 10%
> c. observation: blood pressure: Systolic 88mm/Hg - Diastolic 62 mm/Hg
> d. observation: radiology: cardiomegalia
> e. observation: no allergies
> f. substance administration: Nexium 40 mg p.o. daily
> g. observation: diagnosis: Congestive heart failure
> h. procedure: electrophysiology study (planned)

There are different ways to represent the same clinical meaning; an application can represent clinical meaning in different ways from free text to codes:

Simple Textual

Date	Observation
01/14/2008	normal coronaries

Simple Coded

Date	Code
01/14/2008	NC

Code & Value

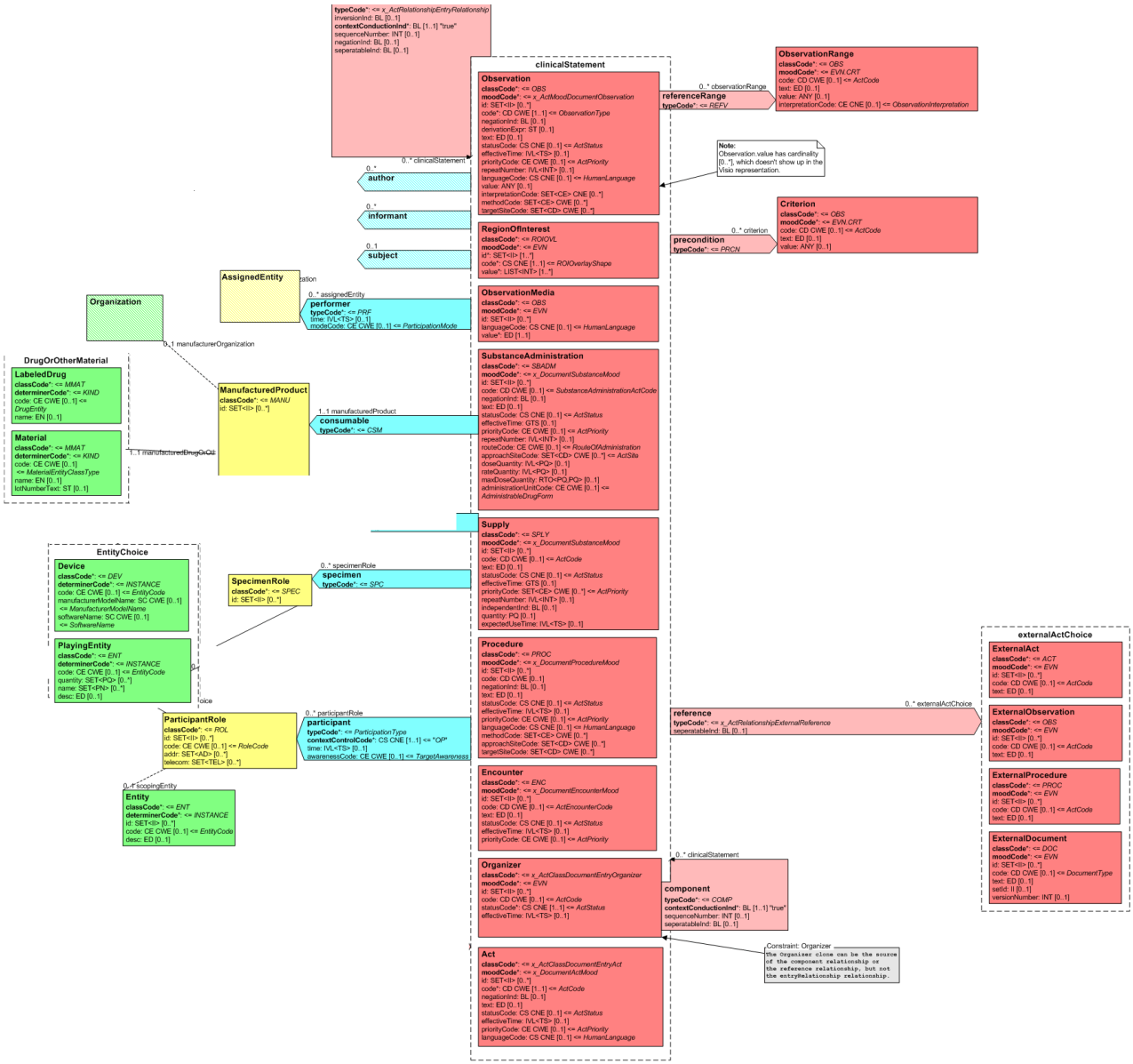
Date	Code	Value
01/14/2008	Coronaries	Normal

Fixed Record

Date	Coronaries	Ejection
01/14/2008	Normal	10

2. Why Entries in CDA R2

For CDA R2, the Clinical Statement pattern is used to convey clinical statements through coded entries for each narrative section:



3. Review of the Clinical Statement in CDA R2

We will not cover *everything* in the model, just the most relevant aspects

Common Attributes of Clinical Statements:

Attribute	Description	Datatype	Cardinality
classCode	Kind of Clinical Statement	CS	1..1 (structural)
moodCode	Determines whether the statement is about an actual event (EVN), order (RQO), promise (PRMS), appointment (APT)	CS	1..1 (structural)
id	unique identifier for a clinical statement	II	0…n
code	Classifies the nature of the information conveyed by the statement	CD (code+ translation +qualifiers)	Observation - 1...1 Others - optional
value	Information assigned by the observation action	ANY	Depends on the domain and use
priorityCode	Code or set of codes specifying the urgency	CE	0..1

Clinical Statement CDA R2 Act Choice Box

The Clinical Statement has the choice box structure to allow any clinically relevant selection, duplication, and ordering of Acts to be included in the communication:

ACT_CHOICE
Observation ObservationMedia
SubstanceAdministration
Procedure
Supply
Encounter
Act
Organizer

4. Review of Entry Choices

Observation Statement

Represent observations in different moods:

- EVN: Actual
- RQO: Requested

Attribute	Description	Datatype	Cardinality
classCode	Kind of Clinical Statement	CS->"OBS"	OBS
moodCode	Determines whether the statement is about an actual event (EVN), order (RQO), promise (PRMS), appointment (APT)	CS->"EVN" or "RQO" or "GOAL"	1..1 (structural)
id	unique identifier for the observation	II	0..n
code	*Clinical or radiological Finding*, diagnosis, clinical concept, LOINC code for lab analytes, etc.	CD (code+ translation +qualifiers)	1..1
value	Used when there is distinct value (numeric, nominal, text or coded)	ANY	
effectiveTime	Period or timestamp of finding or observation	TS	0..1
negationInd	Negates the observation	BL	0..1

SubstanceAdministration Statement

Represents substance administration in different moods:

- EVN: Actual
- RQO: Requested

The capture of medication-related information also involves the interrelationship of SubstanceAdministration with several other classes.

An outpatient prescription typically includes both a recommendation for SubstanceAdministration and a request to Supply. The Supply class represents dispensing, whereas the SubstanceAdministration class represents administration.

Prescriptions are complex activities that involve both an administration request to the patient (e.g. "*take digoxin 0.125mg by mouth once per day*") and a supply request to the pharmacy (e.g. "*dispense 30 tablets, with 5 refills*/repeats").

This should be represented by a SubstanceAdministration statement that has a component Supply statement. The nested Supply statement can have Supply.independentInd set to "false" to signal that the Supply cannot stand alone, without containing SubstanceAdministration.

Attribute	Description	Datatype	Cardinality
classCode	Kind of Clinical Statement	CS->"SBADM"	1..1 (structural)
moodCode	Determines whether the statement is about an actual event (EVN), order (RQO)	CS->"EVN" or "RQO"	1..1 (structural)
effectiveTime	Timing of administration	GTS	0..1
negationInd	Negates the administration	BL	0..1
doseQuantity	How much medication is given per dose	IVL(PQ)	0..1
rateQuantity	At what rate the medication is administered	IVL(PQ)	0..1
maxDoseQuantity	Maximum dose of the medication that can be given over a stated time interval	RTO(PQ,PQ)	0..1

Procedure Statement

The procedure statement represents an act whose immediate and primary outcome (post-condition) is the alteration of the physical condition of the subject.

This includes requesting, recommending, promising, prohibiting or refusing to carry out a procedure as well as the actual act of undertaking the procedure.

Attribute	Description	Datatype	Cardinality
classCode	Kind of Clinical Statement	CS->"PROC"	1..1 (structural)
moodCode	Determines whether the statement is about an actual event (EVN), order (RQO), intent, appointment, etc.	CS->"EVN" or "RQO"	1..1 (structural)
effectiveTime	Time of the procedure	GTS	0..1
negationInd	Negates the procedure	BL	0..1
methodCode	The means or technique used to perform the procedure.	SET(CE)	0..n
approachSiteCode	The anatomical site or system through which the procedure reaches its target.	SET(CE)	0..n
targetSiteCode	The anatomical site or system that is the focus of the procedure.	SET(CE)	0..n

Supply Statement

The supply statement is used for representing the provision of a material by one entity to another. It includes requesting, recommending, promising, prohibiting or refusing such a supply, as well as the actual supply event.

Attribute	Description	Datatype	Cardinality
classCode	Kind of Clinical Statement	CS->"SPLY"	1..1 (structural)
moodCode	Determines whether the statement is about an actual event (EVN), order (RQO), intent, appointment, etc.	CS	1..1 (structural)
effectiveTime	Time of the procedure	GTS	0..1
quantity	Quantity supplied	PQ	0..1
expectedUseTime	Time expected	IVL(TS)	0..1

Encounter Statement

The encounter statement represents an interaction between a patient and care provider(s) for the purpose of providing healthcare-related service(s). This type of statement covers admissions, discharges and transfers of care, as well as the more usual understanding of a single discrete clinical office visit.

It further deals with a plan for regular visits, such as preventive care during pregnancy, or monitoring of chronically ill patients. It includes requesting, proposing, promising, prohibiting or refusing an encounter as well as an actual encounter event.

This is used to represent related encounters, such as follow-up visits or referenced past encounters.

Attribute	Description	Datatype	Cardinality
classCode	Kind of Clinical Statement	CS->"ENC"	1..1 (structural)
moodCode	Determines whether the statement is about an actual procedure (EVN), order (RQO), intent, appointment, etc.	CS	1..1 (structural)

5. Relationships between Clinical Statements

The model provides two mechanisms that allow Clinical Statements to be linked:

- . Containment
- . Direct relationship

These links may be achieved by the patterns described below:

- component
- entryRelationship

These are all refinements of the same general structure and share the following facilities:

- **inversionInd**: when 'true' reverses the direction of the relationship e.g. **'Cause of' becomes 'Caused by'**
- **negationInd**: when 'true' allows the sender to specifically state that the relationship does not apply e.g.. **An observation was not caused by a medication**

Containment

Grouping of classes of clinical data is achieved using collector classes such as the Organizer Class, associated with a 'Component' Act Relationship that supports recursion of the Clinical Statement structure.

Grouping can be used for many purposes, including:

- **Relating statements:** For example, an Antenatal exam may comprise individual observations of maternal weight, maternal BP, fetal size, fetal heart rate etc.
- **Organizer:** The type of grouping permitted is restricted by the vocabulary used in the Organizer.code attribute.

Direct Relationship

This linkage type is supported by the recursion on the Clinical Statement with ActRelationship.typeCode specifying the nature of the link between the statements. It is used to include a Clinical Statement in a communication that relates to another included Clinical Statement but is not directly pertinent to the Focal Act, source Act or purpose of the communication.

An example of this relationship would be if a previous condition explains an observation made during an encounter. In this case the previous condition is only being included in the communication to explain the observation and not because it was identified during the encounter.

Where the supporting Clinical Statement is already available from a previous communication, the link by reference approach may be used to convey this type of linkage.

Component

The component relationship is used to link the organizer class to one or more ActChoice Acts. The component.typeCode value is fixed to COMP (is component of) and is used to show that the target is a component of the source Organizer act.

For Example; "hemoglobin measurement" is a component of a "complete blood count".

The source Organizer can contain other Organizers and/or other entries.

The following table is a guideline for **reasonable relationships** between Clinical Statement Acts and is not a conformance constraint:

ActRelationship Type	Reasonable Source and Target classes	Comments
CAUS (is etiology for)	[Act | Observation | Procedure | SubstanceAdministration] CAUS [Observation]	Used to show that the source caused the target observation (for instance, source "diabetes mellitus" is the cause of target "kidney disease").
COMP (has component)	[Act | Observation | Procedure | SubstanceAdministration | Supply] COMP [Act | Observation | Procedure | SubstanceAdministration | Supply]	Used to show that the target is a component of the source (for instance "hemoglobin measurement" is a component of a "complete blood count").
GEVL (evaluates (goal))	[Observation] GEVL [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").
MFST (is manifestation of)	[Observation] MFST [Observation]	Used to say that the source is a manifestation of the target (for instance, source "hives" is a manifestation of target "penicillin allergy").
REFR (refers to)	[Act | Observation | Procedure | SubstanceAdministration | Supply] REFR [Act | Observation | ObservationMedia | Procedure | RegionOfInterest | SubstanceAdministration | Supply]	Used to show a general relationship between the source and the target, when the more specific semantics of the relationship isn't known.
RSON (has reason)	[Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply] RSON [Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply]	Used to show the reason or rational for a service (for instance source "treadmill test" has reason "chest pain").
SAS (starts after start)	[Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply] SAS [Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply]	The source Act starts after the start of the target Act (for instance source "diaphoresis" starts after the start of target "chest pain").
SPRT (has support)	[Observation] SPRT [Observation | ObservationMedia | RegionOfInterest]	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").
SUBJ (has subject)	[Observation | RegionOfInterest] SUBJ [Observation | ObservationMedia]	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"). The ActRelationshipType "has subject" is similar to the ParticipationType "subject". Entries that primarily operate on physical subjects use the Participation, whereas entries that primarily operate on other entries use the ActRelationship.

ActRelationship Type	Reasonable Source and Target classes	Comments
XCRPT (is excerpt of)	[Act | Observation] XCRPT [Act | Observation | Procedure | SubstanceAdministration | 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"). The distinction between an excerpt and an informant participant can be unclear. For example, as in the case of recording a patient's medication history where the clinician may obtain the information from an informant or may excerpt the information from another computer system. An informant (or source of information) is a person who provides relevant information. An informant class is in the header, and can be overridden in the body. An excerpt is a sub portion of some other act.

6. Participations Surrounding the Acts

Clinical statements may have various participations, including:

- author
- informant
- subject
- performer
- consumable
- specimen
- participant

subject

The patient is considered the Subject of each Clinical Statement in the communication unless it is explicitly indicated that this is not the case for some statement(s). This can be shown by indicating an additional subject participation that provides details of the specific entity to which the statement relates.

author

This class represents the humans and/or machines authoring the statements. This may be an assigned person or organization such as a healthcare provider, a related party such as a family member or the patient themselves.

consumable

The consumable participation is used to describe the administered substance. The manufactured material identifies the drug that is consumed in the substance administration. The Material entity is used to identify non-drug administered substances such as vaccines and blood products.

informant

An informant (or source of information) is a person that provides relevant information to the participation. For example, the parent of an incapacitated patient who describes the patient's behavior prior to the onset of the incident.

An informant may also be an assigned person or organization such as a healthcare provider, a related party such as a family member or the patient themselves.

The RelatedEntity role is used to represent an informant without a role.id (e.g. a parent or person on the street). The informant in this case bears some formal or personal relationship to the patient. RelatedEntity.code can be used to specify the nature of the relationship.

performer

The performer is a person who carries out or will carry out a particular act. The performer need not always be the principal responsible participant, e.g. a surgery resident operating under supervision of attending surgeon is a performer.

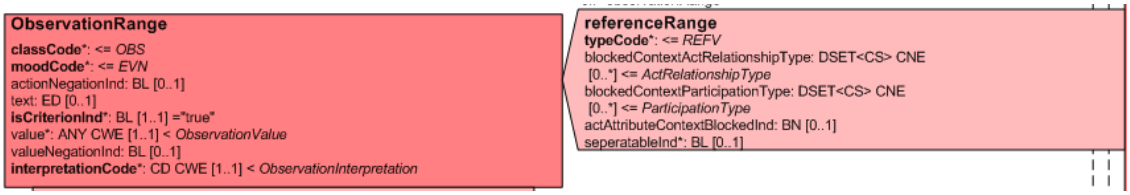
consumable

The dispensed product associates the Supply act to a ManufacturedProduct. This may be a LabeledDrug entity or a Material.

7. Acts and Relationships outside the Choice Box

referenceRange

The referenceRange relationship (see the Observation statement) has a source of an Observation-Range.



8. Examples of Use of the Clinical Statement in CDA R2

substanceAdministration/direct entryRelationship example

This example is from the HL7 New Zealand CDA Implementation for e-Prescription: "CAL.D.FORTE 1.25mg Tablets, Take ONE tablet at 8am once monthly. 1 tablet dispensed on Oct 22, 2008"):

```
<entry>
 <substanceAdministration classCode="SBADM" moodCode="EVN">
  <id extension="1234.7099521"
   root="2.16.840.1.113883.2.18.10"/>
   <effectiveTime xsi:type="PIVL_TS">
    <period value="24" unit="h"/>
   </effectiveTime>
   <doseQuantity value="1" unit="tablets"/>
   <consumable>
    <manufacturedProduct>
     <manufacturedMaterial>
      <code code="2193000"
       codeSystem="2.16.840.1.113883.2.18.4"
       codeSystemName="NZ Pharmac" displayName="CAL.D.FORTE
        1.25mg  Tablets">
        <originalText>Colecalciferol</originalText>
      </code>
      <name>CAL.D.FORTE</name>
     </manufacturedMaterial>
   </manufacturedProduct>
  </consumable>
  <entryRelationship typeCode="REFR">
   <supply classCode="SPLY" moodCode="EVN">
    <effectiveTime value="20081022092604"/>
    <quantity value="1" unit="Tablets"/>
   </supply>
  </entryRelationship>
 </substanceAdministration>
</entry>
```

procedure example

This example is from the HL7 CCD:
Total hip replacement prosthesis-1998

```
<entry typeCode="DRIV">
 <procedure classCode="PROC" moodCode="EVN">
  <id root="e401f340-7be2-11db-9fe1-0800200c9a66"/>
  <code code="52734007" codeSystem="2.16.840.1.113883.6.96" d
   displayName="Total hip replacement">
   <originalText><reference value="#Proc1"/></originalText>
   <qualifier>
  <name code="272741003" displayName="Laterality"/>
  <value code="7771000" displayName="Left"/>
   </qualifier>
  </code>
  <statusCode code="completed"/>
  <effectiveTime value="1998"/>
 </procedure>
</entry>
```

observation (lab result with reference range) example

This example is from the HL7 CCD:
PLT (ref.range : 150-350 10+3/ul) : 123 [LOW]

```
<component>
  <observation classCode="OBS" moodCode="EVN">
  <id root="80a6c740-67a5-11db-bd13-0800200c9a66"/>
    <code code="26515-7" codeSystem="2.16.840.1.113883.6.1"
    displayName="PLT"/>
  <statusCode code="completed"/>
  <effectiveTime value="200003231430"/>
  <value xsi:type="PQ" value="123" unit="10+3/ul"/>
  <interpretationCode code="L"
    codeSystem="2.16.840.1.113883.5.83"/>
  <referenceRange>
  <observationRange>
   <value xsi:type="IVL_PQ">
     <low value="150" unit="10+3/ul"/>
     <high value="350" unit="10+3/ul"/>
   </value>
  </observationRange>
  </referenceRange>
 </observation>
</component>
```

encounter (with location) example

This example is from the HL7 CCD:

Checkup examination at Good Health Clinic

```
<encounter classCode="ENC" moodCode="EVN">
  <id root="2a620155-9d11-439e-92b3-5d9815ff4de8"/>
  <code code="GENRL" codeSystem="2.16.840.1.113883.5.4"
        displayName="General">
   <originalText>Checkup Examination</originalText>
  </code>
  <effectiveTime value="20000407"/>
  <participant typeCode="LOC">
   <participantRole classCode="SDLOC">
    <id root="2.16.840.1.113883.19.5"/>
    <playingEntity classCode="PLC">
     <name>Good Health Clinic</name>
    </playingEntity>
  </participantRole>
   </participant>

</encounter>
```

Unit Summary and Conclusion

This Unit concludes the CDA R2 Module. You now have an overview over CDA R2, its Implementation Guides, data types and the use of Clinical Statements.

References

Clinical Statement Working Group:
http://wiki.hl7.org/index.php?title=Clinical_Statement_Work_Group

Clinical Templates:
http://wiki.hl7.org/index.php?title=List_of_template_registries