Università degli Studi di Trieste Corso di Laurea Magistrale in **INGEGNERIA CLINICA HEALTH INFORMATICS STANDARD** Corso di Informatica Medica **Docente Sara Renata Francesca MARCEGLIA**





HL7 v3

- Change in the HL7 philosophy → from message definition to data exchange model definition
- Creation of the HL7 Reference Information Model (RIM) data model
 - Object oriented (attributes and methods)
 - In 2006 the RIM became the standard ISO/HL7 21731;
- Data format → from ASCII-delimited messages to XML messages.

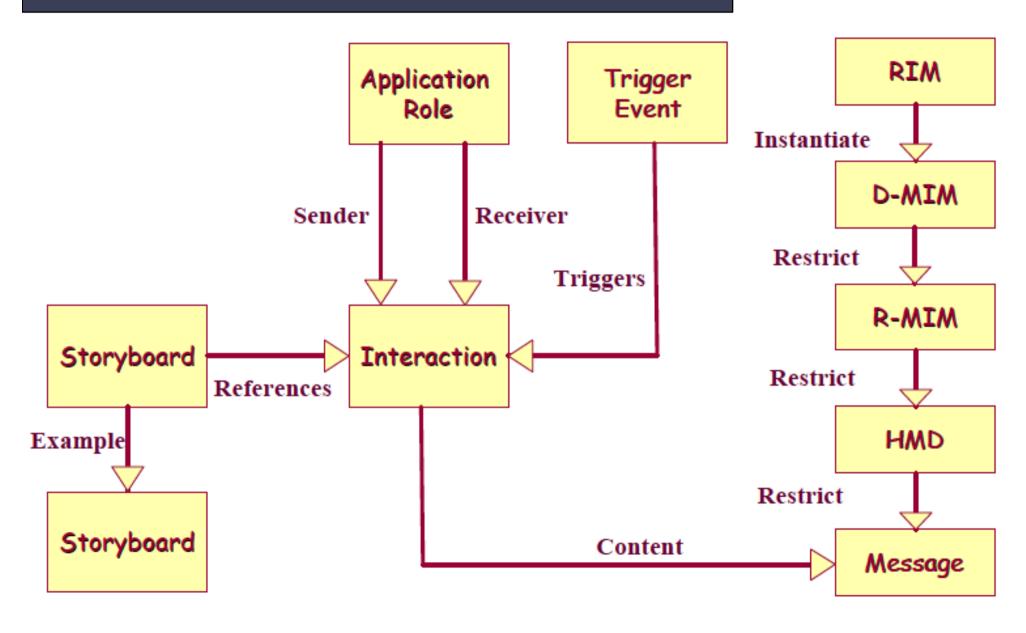


HL7 v3-based system implementation pathway (1/2)

- 1. Define a consensus Reference Information Model (RIM)
- Assemble the terminology/vocabulary and data types necessary to express the attributes of the RIM
- 3. Design the technology to implement the interactions (XML)
- Develop supporting structures (Storyboards, Trigger events, application roles) that reflect the business model in healthcare
- Apply the RIM, Vocabulary and Data Types and supporting information to define interactions
- 6. Publish, Verify, Localize and Implement

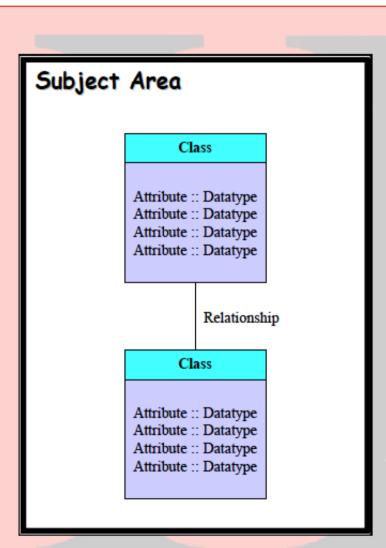


HL7 v3-based system implementation pathway (2/2)





RIM components



Subject Area: a major partition of a

information model.

Class: something about which

information is collected.

Relationship: an affiliation between two

classes.

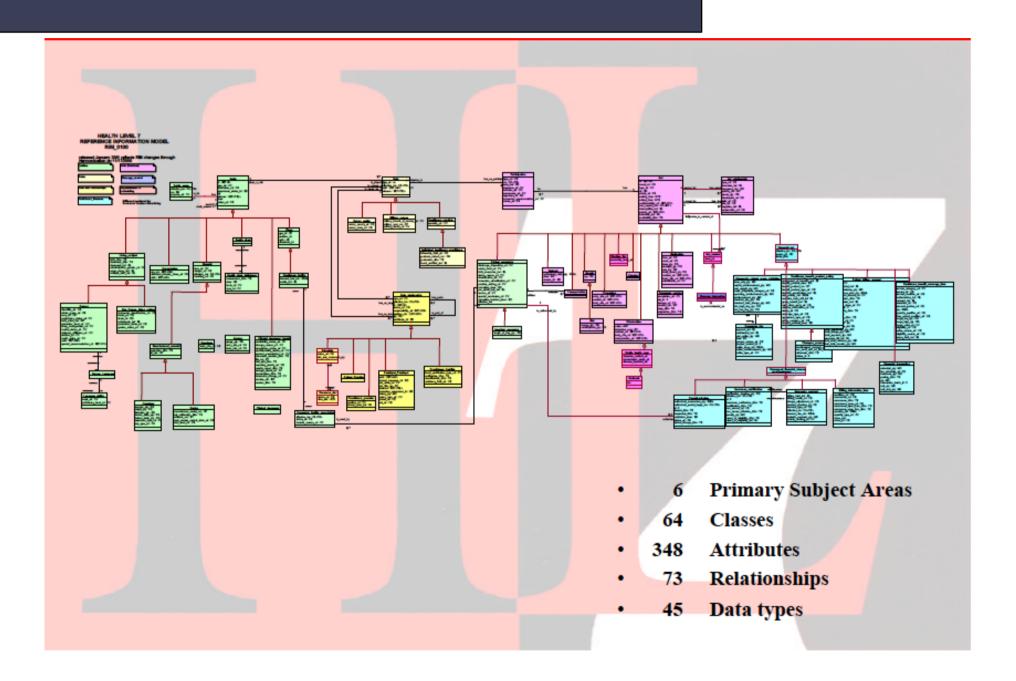
Attribute: information about a class.

Data Type: a specification of the format

of an attribute.

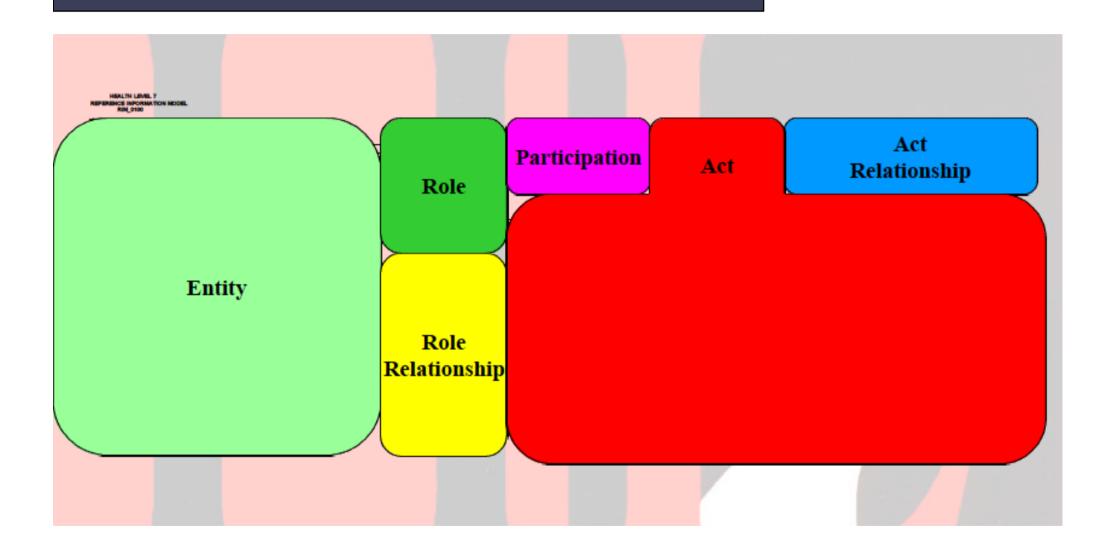


RIM class diagram



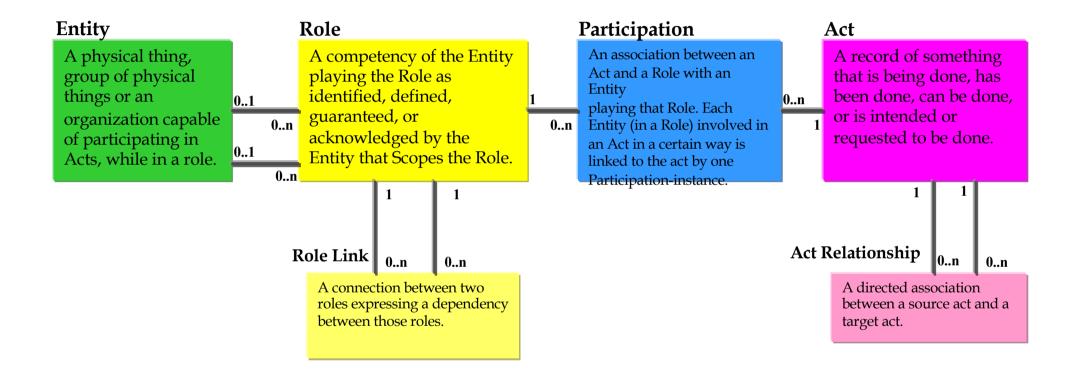


Primary subject areas





RIM Core classes





Entity

Entity

classCode: CS

determinerCode: CS

id : SET<II> code : CE

quantity: SET<PQ> name: BAG<EN>

desc: ED

statusCode: SET<CS>

existenceTime: IVL<TS>

telecom: BAG<TEL>

riskCode: CE

handlingCode: CE

Entity: a person, animal, organization or thing A collection of classes related to the Entity class, its specializations and related qualifying classes. The classes represent health care stakeholders and other things of interest to health care.

Entity has the following sub-classes:

Container

Device

LanguageCommunication

LivingSubject

ManufacturedMaterial

Material

NonPersonLivingSubject

Organization

Person

Place



Role

Role

classCode : CS
id : SET<II>
code : CE

negationInd : BL
addr : BAG<AD>

telecom : BAG<TEL>
statusCode : SET<CS>
effectiveTime : IVL<TS>

certificateText : ED

quantity: RTO

positionNumber: LIST<INT>

Roles:

A responsibility or part played by an entity (e.g. Person in a role of patient, employee, etc.) – different faces of an Entity A collection of classes related to the Role class and its specializations. These classes focus on the roles participants may play in health care.

Role has the following sub-classes:

Access

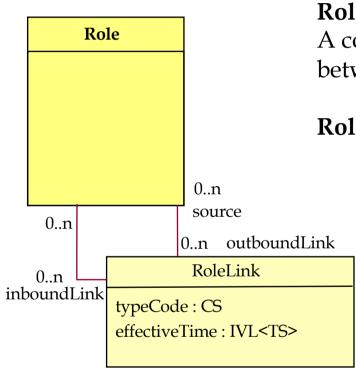
Employee

LicensedEntity

Patient



RoleLink



RoleLink:

A connection between two roles expressing a dependency between those roles.

RoleLink has no sub-classes.



Participation

Participation

typeCode : CS

functionCode: CD

context Control Code: CS

sequenceNumber : INT

negation Ind: BL

noteText : ED time : IVL<TS> modeCode : CE

awarenessCode : CE signatureCode : CE

signatureText : ED

performInd: BL

substitutionConditionCode: CE

Participation:

An association between an Act and a Role with an Entity playing that Role.

Participation has the following sub-class:

ManagedParticipation

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Act

Act

classCode : CS moodCode : CS id : SET<II> code : CD

negationInd : BL derivationExpr : ST

text : ED title : ST

statusCode : SET<CS>
effectiveTime : GTS
activityTime : GTS
availabilityTime : TS
priorityCode : SET<CE>

confidentialityCode : SET<CE>
repeatNumber : IVL<INT>

interruptibleInd: BL

levelCode: CE

independentInd : BL
uncertaintyCode : CE
reasonCode : SET<CE>
languageCode : CE

Act:

A collection of classes including the Act class and its specializations. These relate to the actions and events that constitute health care services. A record of something that is being done, has been done, can be done, or is intended or requested to be done.

Among Act sub-classes:

Account Observation ControlAct Participation

DeviceTask PatientEncounter

DiagnosticImage Procedure

Diet PublicHealthCase

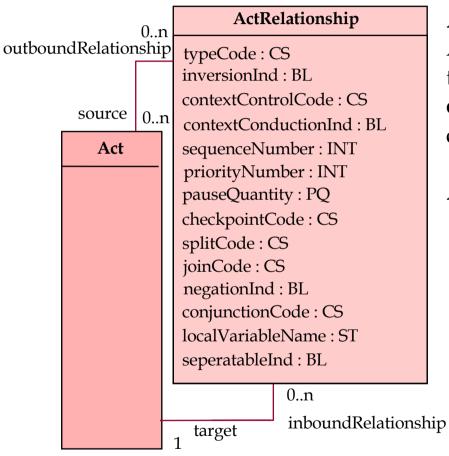
FinancialContract SubstanceAdministration

FinancialTransaction Supply

InvoiceElement WorkingList



ActRelationship



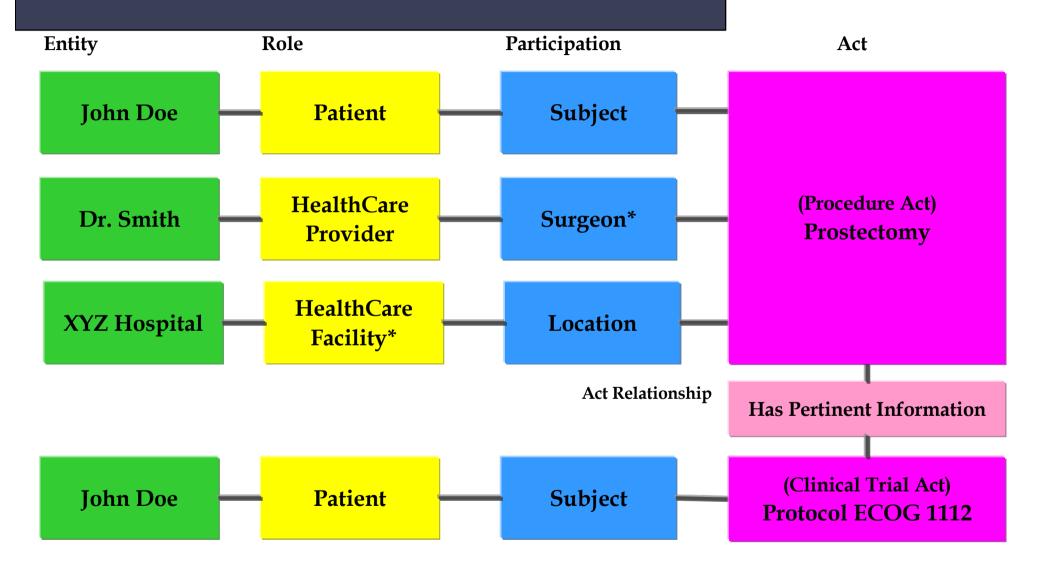
ActRelationship:

A directed association between a source Act and a target Act. A point from a later instance to a earlier instance OR point from collector instance to component instance.

ActRelationship has no sub-classes.

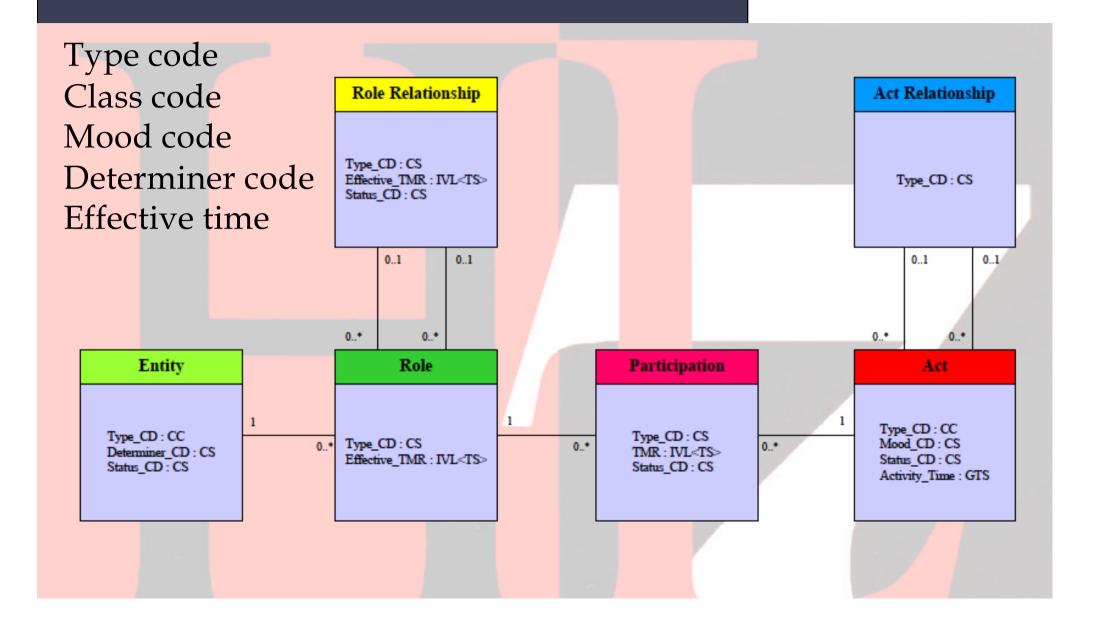


HL7 RIM instance example



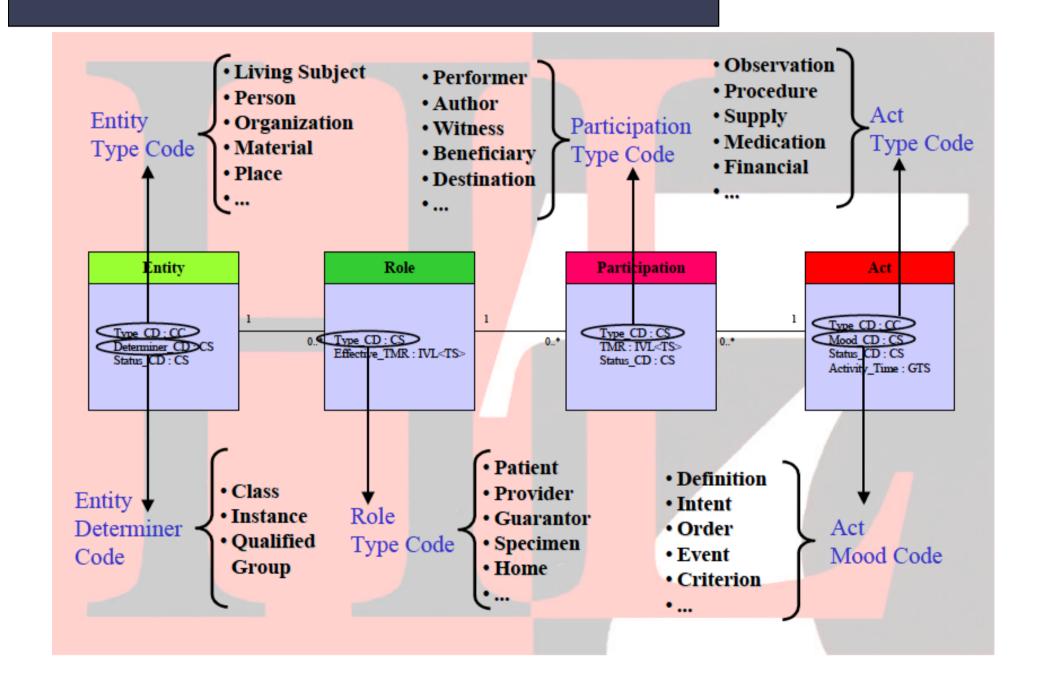


Core attributes





Core attributes value set





The "mood codes"

- - Why don't you clean your room today?
- - Clean your room!
- ✓ Intent (INT)
 - ∠ I promise to clean my room
- Event (EVN)
 - The room is cleaned
- - "Cleaning your room" means make the bed, put toys away...
- Event Criterion (EVN.CRT)
 - ∠ If you want ice cream you must clean your room



Vocabulary domains and codes

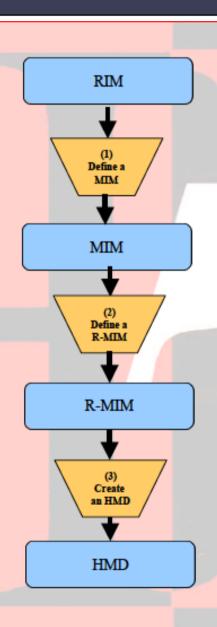
- Coded attributes in the RIM must be associated with one and only one Vocabulary Domain prior to being used in a message specification.
- A vocabulary domain is "The set of all concepts that can be taken as valid values in an instance of a coded field or attribute."
- Each concept in the vocabulary domain is represented using a code from a specific vocabulary.
- A vocabulary is a defined set of coded concepts.
- A vocabulary may be specified as an enumerated list of coded concepts (HL7 defined) or as a reference to an externally maintained list of coded concepts (e.g., SNOMED, LOINC, CPT, . . .).



RIM implementation process

Reference Information Model Message Information Model R-MIM Refined Message Information Model

Hierarchical Message Definition



- Select a subset of the RIM classes.
- Select a subset of class relationships
- Select a subset of class attributes
- Select a subset of attribute datatypes
- Select a subset of attribute domains and value sets
- Created clones of classes and attributes
- Assign alias class and attribute names
- Eliminate unnecessary class hierarchies
- Finalize class relationships and multiplicity
- Finalize attribute domains and value sets
- Select a root class for the message
- Arrange classes and attributes hierarchically
- Declare inclusion and repetition constraints
- Declare domain value constraints
- Assign message element names



HL7 - references

Introduction To HL7 Version 3

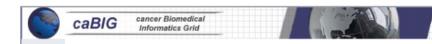
Gavin Tong, Consultant, HL7 Canada





Introduction to Health Level Seven (HL7)

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www.hl7.org



Health Level Seven Version 3.0 and the Reference Information Model









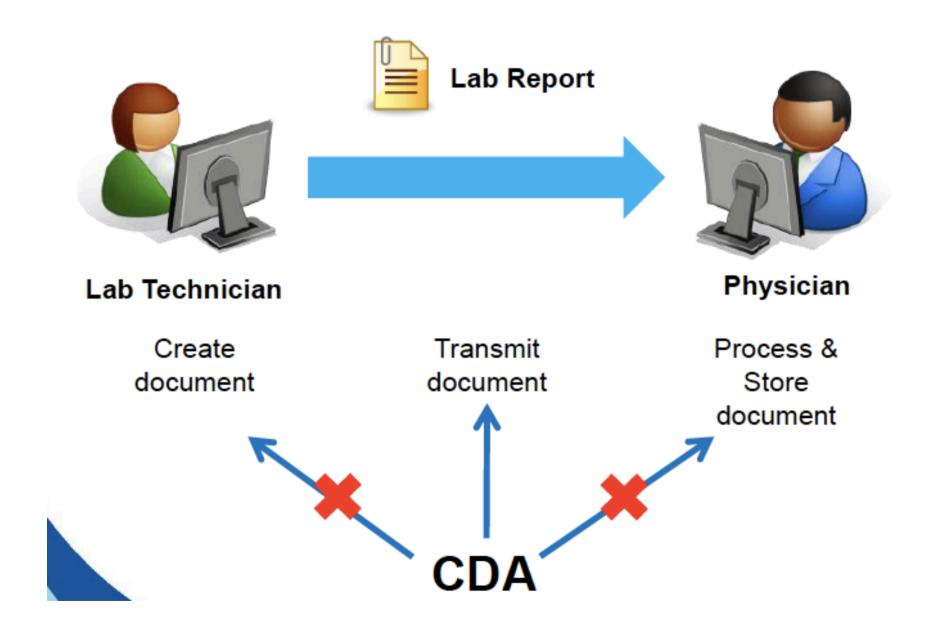
WHAT IS THE CDA

 The HL7 CDA is a document markup standard that specifies the structure and semantics of a clinical document (such as a discharge summary, progress note, procedure report) for the purpose of exchange.

- Defined and complete information object that can include text, images, sounds, and other multimedia content.
- It can be transferred within a message, and can exist independently, outside the transferring message.
- CDA documents are encoded in Extensible Markup Language (XML).
- CDA documents incorporate concepts from standard coding systems such as Systemized Nomenclature of Medicine Clinical Terms (SNOMED CT) and Logical Observation Identifiers Names and Codes (LOINC).



SCOPE OF THE CDA





XML

- XML is Extensible Markup Language (www.w3c.org)
- In XML, structure and format are conveyed by markup which is embedded into the information

<markup>text</markup>

<section>

<title=Hospital Course</title>

<text> The patient was admitted and started on Lovenox and mirroglycerin paste. The patient had serial cardiac enzymes and was ruled out for myocardial infarction. The patient underwent a dual isotope stress test. There was no evidence of reversible ischemia on the Cardiolite scan. The patient has been ambulated.

</text>

</section>



HL7 DOCUMENT vs HL7 MESSAGE

HL7 MESSAGE

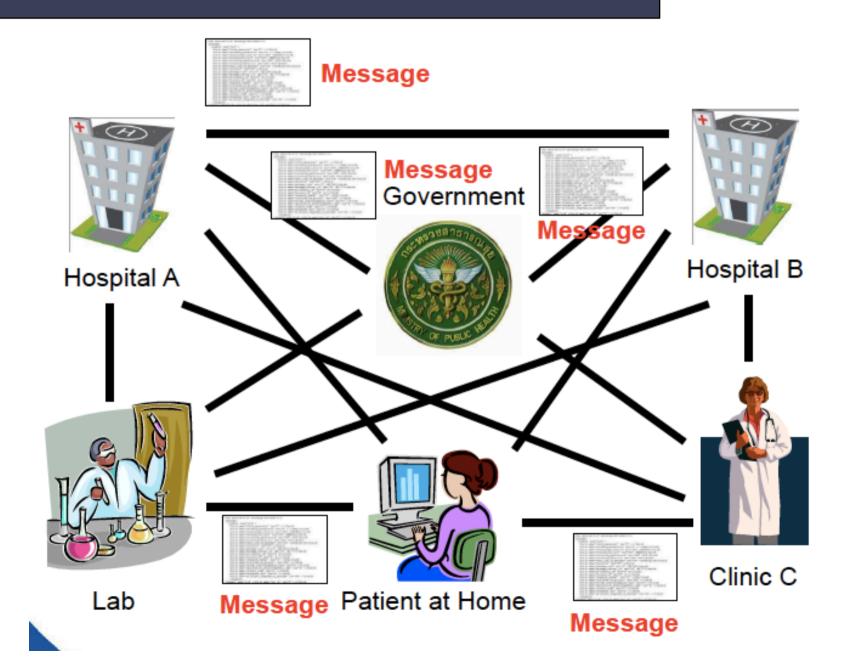
- Transient
- Trigger-based there are events that induce the message creation
- Non-persistent Once received, the message can be deleted

HL7 DOCUMENT

- Persistence –A clinical document continues to exist in an unaltered state, for a time period
- Stewardship –A clinical document is maintained by an organization entrusted with its care
- Potential for authentication -A clinical document is an assemblage of information that is intended to be legally authenticated
- Context -A clinical document establishes the default context for its contents
- Wholeness -Authentication of a clinical document applies to the whole
- Human readability –A clinical document is human readable

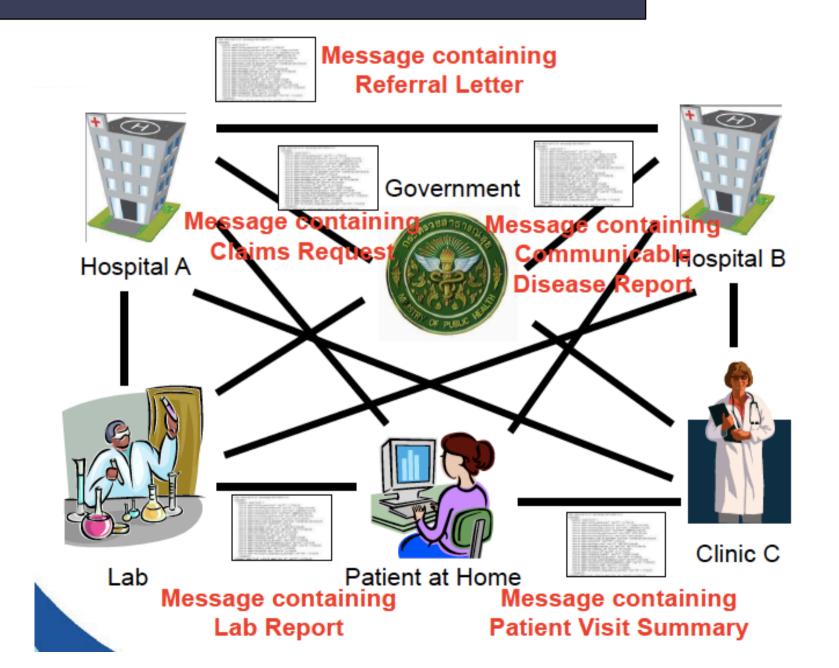


EXCHANGING MESSAGES





EXCHANGING DOCUMENTS





CDA-2 DOCUMENT EXCHANGE

- CDA documents can be exchanged in HL7 messages or exchanged using other transport solutions.
- To exchange a CDA Document:
 - All components of a CDA document that are integral to its state of wholeness (such as attested multimedia) can be exchanged as a unit;
 - Content needing to be rendered or additional files associated with a CDA document (such as a style sheet) can be included in the exchange package;
 - There is **no need to change any of the references** (e.g., a reference to attested multimedia in a separate file) within the base CDA document when creating or extracting the exchange package (indeed, they cannot be changed);
 - There are no restrictions on the directory structure used by receivers—
 receivers can place the components of the CDA document into directories of
 their choosing;
 - Critical metadata about the CDA instance needed for document management (e.g., document state, document archival status) must be included in the exchange package.

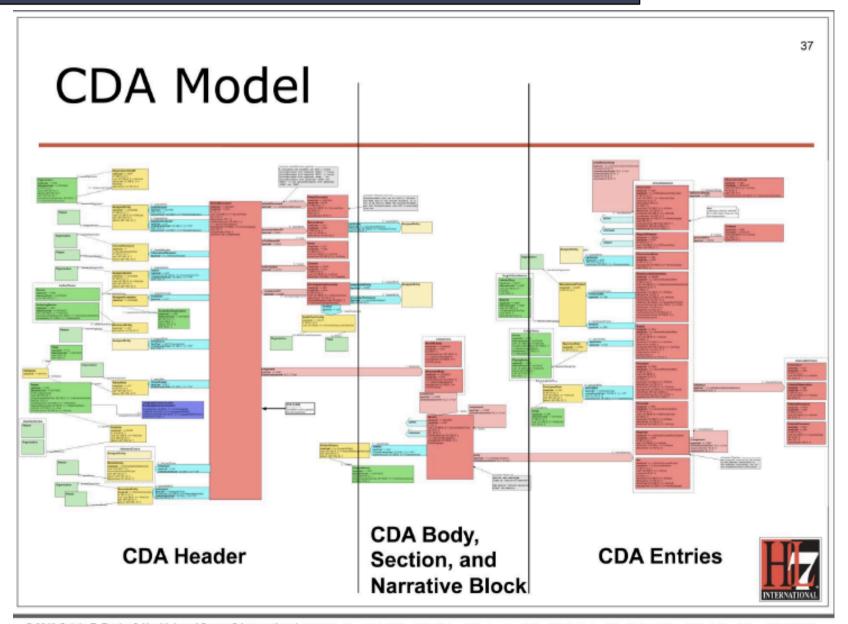


CDA-2 EXTENSIBILITY

- Locally defined markup can be used to extend CDA when local semantics have no corresponding representation in the CDA specification.
- To support local extensibility requirements, it is permitted to include additional XML elements and attributes that are not included in the CDA schema.
- These extensions should not change the meaning of any of the standard data items, and receivers must be able to safely ignore these elements.
- Document recipients must be able to faithfully render the CDA document while ignoring extensions.



CDA-2 OBJECT MODEL





CDA-2 COMPONENTS

```
<ClinicalDocument>
                    Header
  ... CDA Header ...
  structuredBody>
   <section>
      <text>(a.k.a. "narrative block")</text>
     <observation>...
      <substanceAdministration>
       <supply>...</supply>
     </substanceAdministration>
                                 Body
      <observation>
       <externalObservation>...
       </externalObservation>
     </observation>
    </section>
   <section>
       <section>...</section>
    </section>
   /structuredBody>
</ClinicalDocument>
```



CDA2 HEADER

- Metadata about the document
- Focused on data for:
 - Document Indexing
 - Document authentication
 - Document context
- Supports document management

id : Identificativo univoco del documento

code : Codifica LOINC

effectiveTime : Data di creazione del documento author : Persona che valida il documento custodian : Struttura che ha generato il referto

recordTarget : Anagrafica Paziente

title : Testo d'intestazione del documento

setId : Identificativo comune ad ogni revisione del documento

versionNumber : Versione del documento
 legalAuthenticator : Firmatario del referto
 informationRecipient : Unità di consegna

dataEnterer : Rappresenta la persona che inserisce i dati nel sistema
 responsibleParty : Primario della struttura che ha generato l'atto

relatedDocument : Collegamento tra due documenti
 documentationOf : Motivo della richiesta di indagine

inFulfillmentOf : Order Filler

componentOf : Order Placer e Unità richiedente



CDA-2 HEADER EXAMPLE (1)

```
<ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
    xsi:schemaLocation="urn:hl7-org:v3 ..\..\0.Standards\HL7\CCD\CDASchemas\cda\Schemas\CDA.xsd">
    <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
    <templateId root="2.16.840.1.113883.10.20.9"/>
    <id root="db734647-fc99-424c-a864-7e3cda82e703"/>
        <code code="53576-5" codeSystem="2.16.840.1.113883.6.1"/>
        <title>Good Health Personal Healthcare Monitoring Report</title>
        <effectiveTime value="20080501123333-0500"/>
        <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>
        <languageCode code="en-US"/>
```



CDA-2 HEADER EXAMPLE (2)

```
<recordTarget>
    <patientRole>
        <id extension="996-756-495" root="2.16.840.1.113883.19.5"/>
        <!-- The following tag was modified in Release 2-->
        <addr>
            <streetAddressLine>6666 Home Street</streetAddressLine>
            <city>Ann Arbor</city>
            <state>MI</state>
            <postalCode>99999</postalCode>
            <country>USA</country>
        </addr>
        <telecom value="tel:555-555-5001"/>
        <patient>
            <name>
                <qiven>Ned</qiven>
                <family>Nuclear</family>
                <suffix/>
            </name>
            <administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1"/>
            <birthTime value="19320924"/>
        </patient>
    </patientRole>
</recordTarget>
```

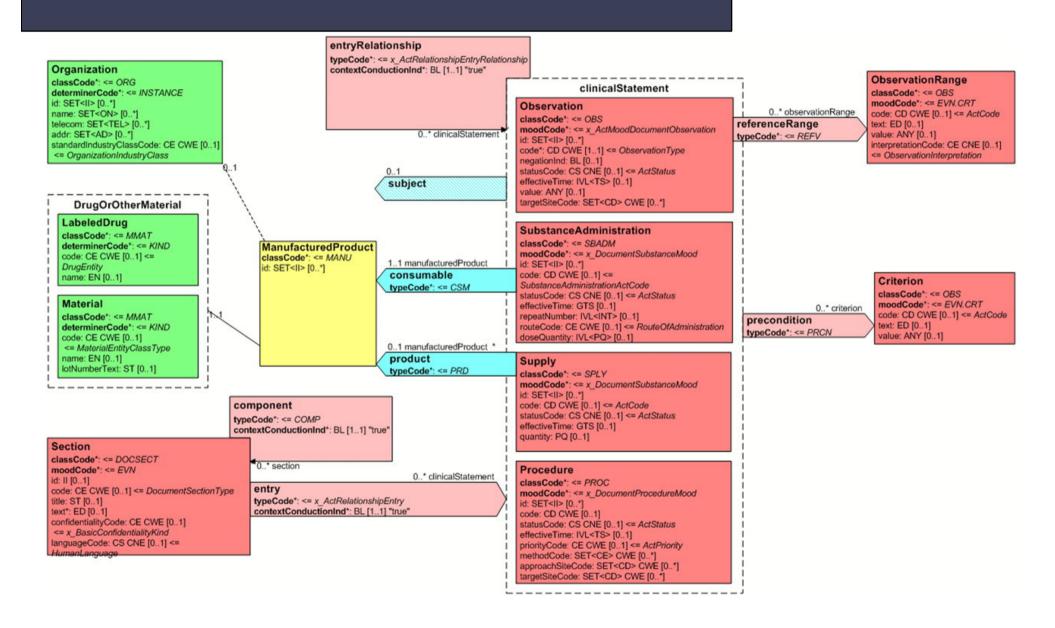


CDA BODY

- Unstructured Body provides a container for non-XML content
- Structured Body that provides both structured human readable narrative as well as machine readable content
 - Narrative block that provides the human readable content and represents the authenticated content of the document
 - **Entries** that optionally provide a discrete, machine readable representation of the document content



CDA ENTRIES





ENTRY RELATIONSHIP

Table 1 ■ CDA entryRelationship Types

entryRelationship. typeCode	Reasonable Source and Target Acts	Comments
CAUS (is etiology for)	[Act Observation Procedure Substance Administration] 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 Substance Administration Supply] COMP [Act Observation Procedure Substance Administration 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").
RSON (has reason)	[Act Encounter Observation Procedure SubstanceAdministration Supply] RSON [Act Encounter Observation Procedure SubstanceAdministration Supply]	Used to show the reason or rationale 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 of the source (for instance, source "possible lung tumor" has support target "mass seen on chest -x-ray").



CDA 2 BODY EXAMPLE (1/4)

Figure 4. An example of a simple observation.



CDA 2 BODY EXAMPLE (2/4)

```
<section>
  <code code="10164-2" codeSystem="2.16.840.1.113883.6.1"</pre>
   codeSystemName="LOINC"/>
  <title>History of Present Illness</title>
  <text>Henry Levin, the 7<sup>th</sup> is a 67 year old male
   complaining of disabling <content ID="SX1">osteoarthritis
   of the right knee</content>.
  </text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <code code="396275006" codeSystem="2.16.840.1.113883.6.96"</pre>
       codeSystemName="SNOMED CT" displayName="Osteoarthritis">
        <originalText><reference value="#$X1"/></originalText>
        <qualifier>
          <name code="363698007" codeSystem="2.16.840.1.113883.6.96"</pre>
           displayName="finding site"/>
          <value code="6757004" codeSystem="2.16.840.1.113883.6.96"</pre>
           displayName="right knee"/>
        </gualifier>
      </code>
    </observation>
  </entry>
</section>
```

Figure 5. An example of a more complex observation.



CDA 2 BODY EXAMPLE (3/4)

```
<section>
 <code code="10157-2" codeSystem="2.16.840.1.113883.6.1"</pre>
  codeSystemName="LOINC"/>
 <title>Family history</title>
 <text>
   st>
     <item>Father had fatal MI in 1970.</item>
     <item>No cancer or diabetes.</item>
   </list>
 </text>
 <entry>
   <observation classCode="OBS" moodCode="EVN">
     <code code="22298006" codeSystem="2.16.840.1.113883.6.96"</pre>
       codeSystemName="SNOMED CT" displayName="Myocardial infarction"/>
      <effectiveTime value-"1970"/>
     <subject>
       <relatedSubject classCode="PRS">
          <code code="FTH" codeSystem="2.16.840.1.113883.5.111"</pre>
           codeSystemName="PersonalRelationshipRoleType"
           displayName="Father"/>
        </relatedSubject>
      <entryRelationship typeCode="CAUS" contextConductionInd="true">
        <observation classCode="OBS" moodCode="EVN">
          <code code="399347008" codeSystem="2.16.840.1.113883.6.96"</pre>
           codeSystemName="SNOMED CT" displayName="death"/>
          <effectiveTime value="1970"/>
        </observation>
      </entryRelationship>
      </observation>
 </entry>
 <entry>
    <observation classCode="OBS" moodCode="EVN" negationInd="true">
      <code code="275937001" codeSystem="2.16.840.1.113883.6.96"</pre>
       codeSystemName="SNOMED CT"
       displayName="Family history of cancer"/>
   </observation>
 </entry>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
     <code code="160274005" codeSystem="2.16.840.1.113883.6.96"</pre>
      codeSystemName="SNOMED CT"
      displayName-"No family history of diabetes"/>
    </observation>
  </entry>
</section>
```

FAMILY HISTORY



CDA 2 BODY EXAMPLE (4/4)

```
<section>
  <code code="101155-0" codeSystem="2.16.040.1.113003.6.1"</pre>
  codeSystemName="LOINC"/>
  <title>Allergies and Adverse Reactions</title>
    <11iat>
      <iten>Penicillin - Hives</item>
      <iten>Aspirin - Wheezing</item>
      <item>Codeine - Itching and nausea</item>
    </list>
  </text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <code code="247472004" codeSystem="2.16.840.1.113883.6.96"</pre>
       displayName="Hives"/>
      <entryRelationship typeCode~"MFST">
        <observation classCode="OBS" moodCode="EVN">
          <code code="91936005" codeSystem="2.16.840.1.113883.6.96"</pre>
           codeSystemName="SNOMED CT" displayName="PCN Allergy"/>
        </observation>
      </entryRelationship>
    </observation>
  </entry>
</section>
```

Figure 7. An example of allergies and adverse reactions.

```
<section>
  <text>Take captopril 25mg PO every 12 hours.</text>
  <entry>
    <substanceAdministration classCode="SBADM" moodCode="RQO">
      <effectiveTime xsi:type="PIVL TS">
        <period value="12" unit="h"/>
      </effectiveTime>
      <routeCode code="PO" codeSystem="2.16.840.1.113883.5.112"</pre>
       codeSystemName="RouteOfAdministration"/>
      <doseQuantity value="1"/>
      <consumable>
        <manufacturedProduct>
          <manufacturedLabeledDrug>
            <code code="318821008" codeSystem="2.16.840.1.113883.6.96"</pre>
             codeSystemName-"SNOMED CT"
             displayName="Captopril 25mg tablet"/>
          </manufacturedLabeledDrug>
        </manufacturedProduct>
      </consumable>
    </substanceAdministration>
  </entry>
</section>
```

Figure 8. An example of a substance administration.



CDA RENDERING (1/3)

```
History of Present Illness section
                        <component>
                                <section>
                                        <code code="10164-2"
codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
                                        <title>History of Present Illness</title>
                                        <text>
                                                <content styleCode="Bold">Henry Levin,
the 7<sup>th</sup>
                                                </content> is a 67 year old male
referred for further asthma management. Onset of asthma in his <content
revised="delete">twenties</content>
                                                <content
revised="insert">teens</content>. He was hospitalized twice last year, and already
twice this year. He has not been able to be weaned off steroids for the past several
months.
                                                </text>
                                </section>
                        </component>
                        <!--
 Past Medical History section
                        <component>
                                <section>
```

Source: From "What is CDA R2? by Calvin E. Beebe at HL7 Educational Summit in July 2012



CDA RENDERING (2/3)

Good Health Clinic Consultation Note

Patient: Henry Levin, the 7th MRN: 12345

Birthdate: September 24, 1932 Sex: Male

Consultant: Robert Dolin, MD Created On: April 7, 2000

History of Present Illness

Henry Levin, the 7th is a 67 year old male referred for further asthma management. Onset of asthma in his teens. He was hospitalized twice last year, and already twice this year. He has not been able to be weaned off steroids for the past several months.

Past Medical History

- Asthma
- · Hypertension (see HTN.cda for details)
- · Osteoarthritis, right knee

Medications

- Theodur 200mg BID
- Proventil inhaler 2puffs QID PRN

Source: From "What is CDA R2? by Calvin E. Beebe at HL7 Educational Summit in July 2012



CDA RENDERING (3/3)

- Different recipients may use different style sheets to render the same CDA document, and thus may display it differently (but the same content is presented)
- This can help facilitate display of CDA documents with specific preferences or local requirements



CDA TEMPLATES

- Templates and/or implementation guides can be used to constrain the CDA specification within a particular implementation and to provide validating rule sets that check conformance to these constraints.
- Templates

 formal definition of a set of constraints on the model
- Templates are set of instructions for a CDA instance of a particular use case
- A template has two parts
 - Metadata → identifier, version, description, etc
 - Body → actual constraints



SIMPLE OBJECT ACCESS PROTOCOL (SOAP)

- CDA-2 implementation relies on the SOAP architecture
- SOAP is an XML-based protocol for accessing web services over HTTP. It has some specification which could be used across all applications.
- SOAP was developed as an intermediate language so that applications built on various programming languages could talk easily to each other and avoid the extreme development effort.
- SOAP is designed to be platform independent and is also designed to be operating system independent. So the SOAP protocol can work any programming language based applications on both Windows and <u>Linux</u> platform.



SOAP MESSAGE

SOAP Envelope

SOAP Header

Header Block

Header Block

SOAP Body

Message Block

The Envelope element identifies the XML document as a SOAP message

The Header element contains header information such as authentication credentials which can be used by the calling application or the definition of complex types which could be used in the SOAP message

The Body element contains call and response information



EXAMPLE: REQUEST CDA2

```
<soap:Envelope xmlns:soap="http://www.w3.org/2003/05/soap-envelope"</pre>
xmlns:urn="urn:ihe:iti:xds-b:2007" xmlns:wsa="http://www.w3.org/2005/08/addressing">
    <soap:Header>
         <wsa:To>http://appsrv-
    unix.sancarlo.pz.it:9090/DocumentRepository/DocumentRepositoryXDSBService?wsdl</ws
    a:To> <wsa:MessageID>urn:uuid:566EAD10FEBB55C5A61257193478400</wsa:MessageID>
         <wsa:Action>urn:ihe:iti:2007:RetrieveDocumentSet</wsa:Action>
         <wsa:ReplyTo>
         <wsa:Address>http://www.w3.org/2005/08/addressing/anonymous</wsa:Address>
         </wsa:ReplyTo>
    </soap:Header>
         <soap:Body>
<urn:RetrieveDocumentSetRequest> <!--1 or more repetitions:--> <urn:DocumentRequest>
<urn:RepositoryUniqueId>2.16.840.1.113883.2.9.3.33.4.3/urn:RepositoryUniqueId>
<urn:DocumentUniqueId>2.16.840.1.113883.2.9.3.170.4.3.1.1.3^R1000000000_3</urn:Docume</pre>
ntUniqueId> </urn:DocumentRequest>
</urn:RetrieveDocumentSetRequest>
         </soap:Body>
</soap:Envelope>
```