

### **Communication protocols and norms in healthcare**

# HL7 Norm Continuation – HL7v3 and HL7 CDA

Course: Biomedical Informatics

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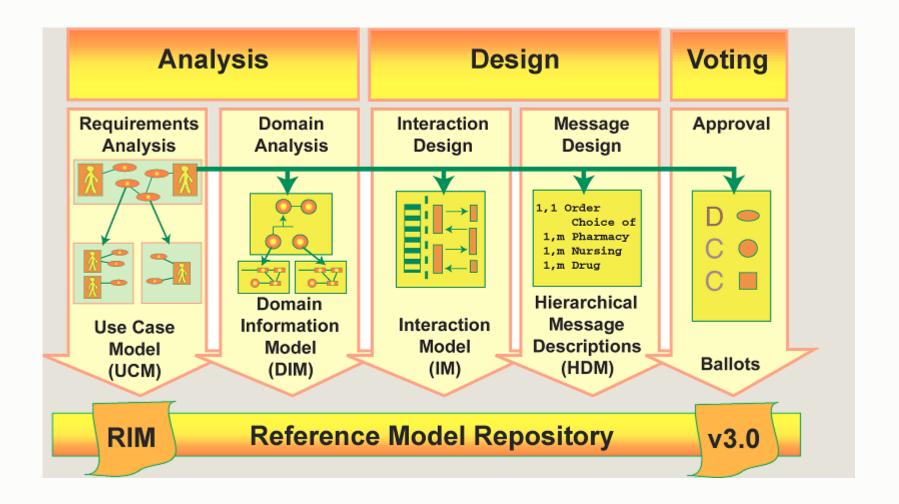
### HL7v3 approach



- The key challenges of HL7v2 relate to wide optionality and the lack of a robust methodology for creating the messages themselves
- Unlike HL7v2, the process of creating messages and specifications is presented asexplicitly documented methodology
  - Creation of use case models (Model Driven Approach)
  - Definition of information models using UML notation
  - Includes reference model, vocabulary and data type specifications
  - Detailed definition of standard support by specification (part) of the HL7 application interface
- The main goal is not to replace HL7v2, but to support implementations at regional and national levels, and the creation of an electronic health record through a stable system design methodology and messaging interface.

## **HL7v3** methodology





## Main features of HL7v3 methodology



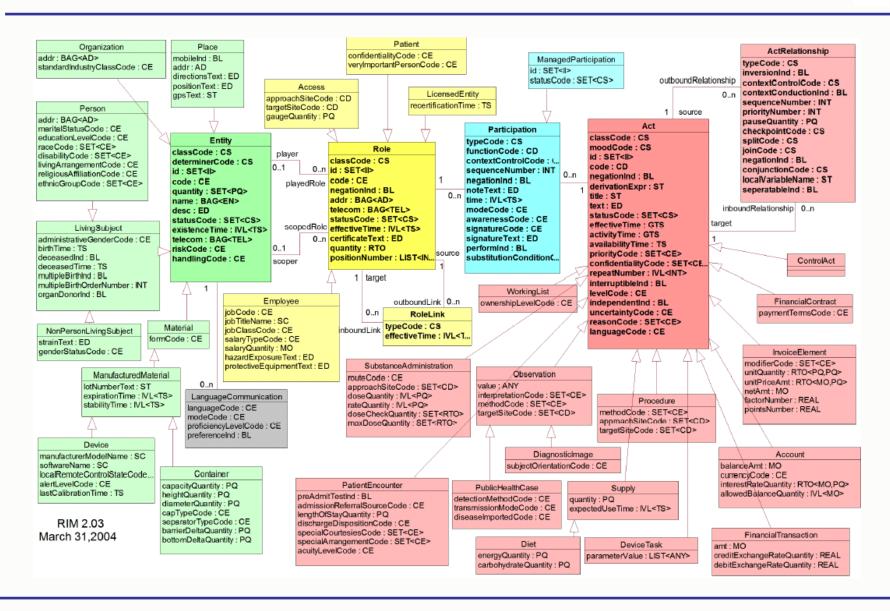
- Standardization of the "language" of all HL7v3 messages
  - Syntactic level information models (RIM) and objects
  - Semantic level standardization of vocabulary set
- Detailed description of events in healthcare
  - Definition of the responsibility of the sender and recipient of the message through interaction models
  - Description of the HL7 application interface
- Communication mechanisms and syntax
  - Using XML as message syntax XML Implementation Technology Specification (ITS)
  - Requirements specifications for information transfer transport mechanisms (Minimum Lower Layer Protocol (MLLP), SOAP/Web Services, ebXML)

### **HL7 RIM - Reference Information Model**



- A static model that includes health information in the area of HL7 norm standardization
- RIM is modeled using UML notation (Object Management Group).
- The source of all information models in use
  - DMIM Domain Message Information Model
  - RMIM Refined Message Information Model
  - HMD Hierarchical Message Description
  - MT Message Types

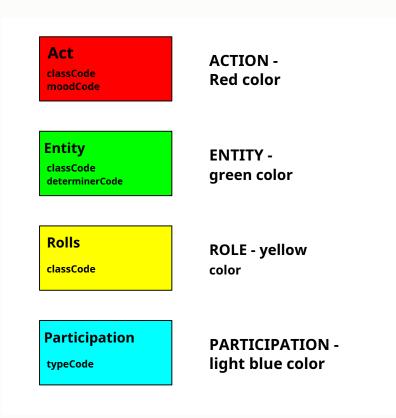




## **HL7v3 RIM - methodology**



- All models are based on 4 basic types of objects
  - Action(English Act) describes a case that occurs in the domain of healthcare
  - Participation(English Participation) describes the context of the action
  - Entity(English Entity) describes
     physical things and persons who
     participate in the said action
  - the role(English Rolls) defines the roles of individual entities



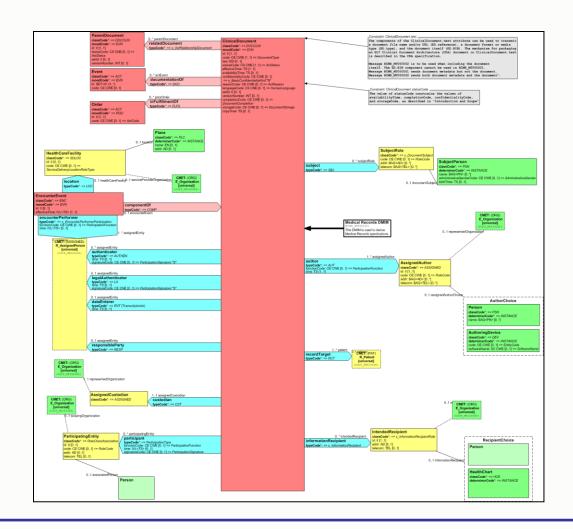
### **HL7v3** information models



- DMIM (Domain Message Information Model) includes information of interest to a particular technical committee, special interest group or project (e.g. laboratories, pharmacies, health record)
- RMIM (Refined Message Information Model) describes a connected group of messages using HL7 modeling rules (analogy – use case)
- HMD tabular representation of the sequence of elements contained in the RMIM





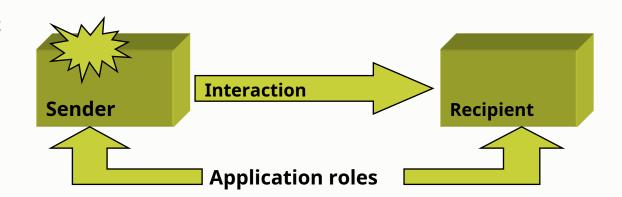


## **HL7v3 dynamics**



- HL7 Interaction key normative dynamic artifact
- HL7 interaction defined by three components
  - Trigger Event
  - Composite Message Type
  - Receiver Responsibility

## The causing event interaction



## HL7v3 methodology in application



- Example sending an invoice from the doctor's office to the insurance company
- Process analysis, information model, transport:
  - Ivan Ivić, doctor: "After every examination, I have to send a bill to the insurance company."
  - Insurance company: "The invoice must contain identification of the doctor and patient, medical procedures, date and signature of the doctor"

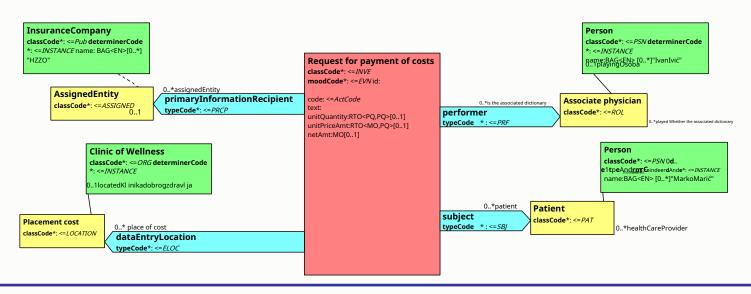
- Computer scientist: "How much work..."







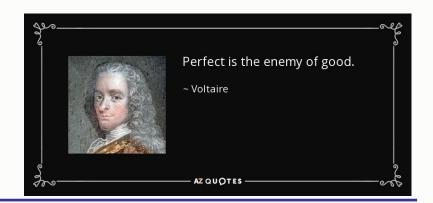
- Sending an invoice Use Case
- HL7v3 modeling methodology
  - Action sending invoice
  - Entities and roles Marko Marić in the role of patient, Ivan Ivić in the role of doctor, the Clinic of Good Health in the role of cost center, HZZO in the role of insurance company



### **HL7v3 Challenges**



- A series of problems in practice
  - Very complex and demanding implementations
  - A long learning process
  - Localization, especially outside the US
  - Lack of stable development tools
  - Complexity of modeling, dynamics, communication protocols, transport
  - Message size
- The result
  - Very low level of acceptance in the industry





## **HL7 CDA**

### **HL7 CDA**



- HL7 CDA Clinical Document Architecture
- HL7v2.xi v3 are primary *messaging* specifications data transition, communication in treatment processes
- Why the need for CDA?
  - Documents are actually the most natural method of expressing health status
  - Healthcare workers are used to communicating with documents
  - All health records (including electronic ones) include documents registers and repositories
  - Fragments of data are useful for a certain time and in a certain context; to ensure persistence, the system asks for (signed) documents

### **HL7 CDA – Objectives and application**



- 6 key characteristics of CDA specifications and documents
  - Persistence the clinical document exists in its original state as long as the rules and/or regulations require it
  - Manageability the clinical document is maintained by the organization providing the care
  - Possibility of authentication a collection of information that is intended for legal authentication
  - Preservation of context
  - Completeness document authentication refers to the entire content
  - Human readability level

- Examples in application
  - Dismissal letter
  - The recipe
  - Referral



## **HL7 CDA – Key settings**



- Interoperability
  - Human readability level
    - Mapping the paper world into the electronic one
  - Computer level
    - Storage and management of clinical data
    - Preservation of context
    - Archiving in a consistent manner enables documents to be reused
- The idea of meeting requirements on both levels
  - Guaranteed human processing preservation of the basic form of the document
  - Iterative addition tags according to XML notation so that the document can be computerized
- HL7 CDA is the same as the ISO standard ISO/HL7 27932:2008



## HL7 CDA – key settings cont'd



- HL7 CDA documents are
  - Encoded using XML
  - Based on HL7 RIM and HL7v3 data types, which then represent the basis for computer processing of information
  - Specifications are broad and comprehensive
    - The basic specification is limited and adapted to a particular use case using templates. *Templates*)
- CDA does not specify or condition
  - Transport mechanisms, i.e. the way in which the document is transferred from point A to point B
    - It can also be part of an HL7 message, with additional mapping requirements. In this case, the CDA document is transmitted as multimedia content
  - The way the document is physically stored
  - Creation and management of documents, but defines exclusively the architecture and format for exchange

### Structure of the CDA document



#### Header

structured and coded

### Body

structured content with coded "sections"

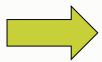
- Salutation
- Problem/Subjective
- History
  - •Family History
  - Past Medical History
- Physical/Objective
- Diagnoses
  - Admit diagnoses
  - Intermediate diagnoses
  - Discharge diagnoses

coded (e.g. ICD 10)

- Epicrise
- Plan
- •.........



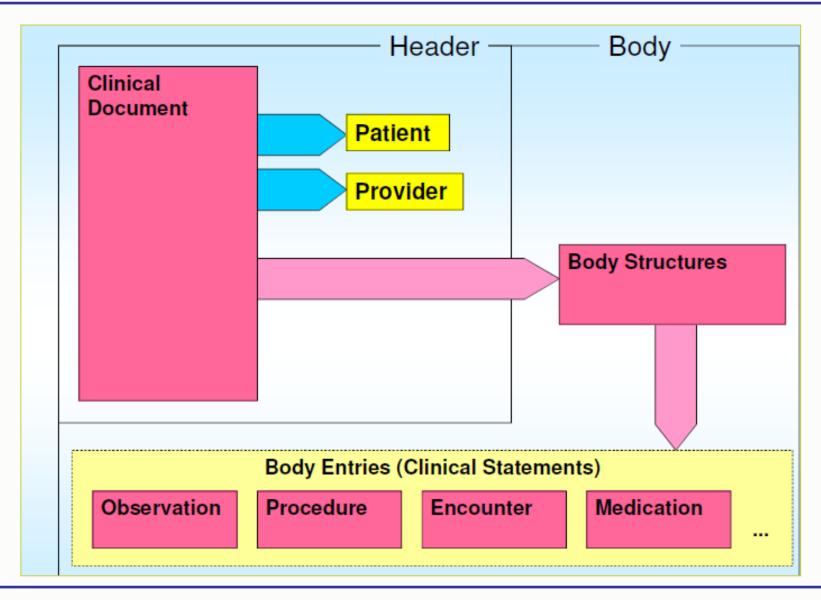
- the context in which the document is located
- key data for document changes



- clinical data about the patient
- XML hierarchy data divided into sections, paragraphs, lists and tables







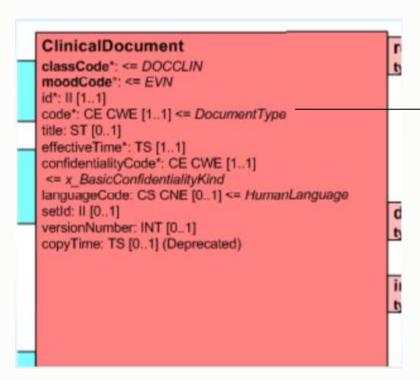
### **HL7 CDA Header**



- Document identification and classification (see example on the next page)
  - ID, category, title, date, version
- Language, confidentiality, authorization, patient consent
- Digital signatures
- Content recipient
- Document manager
- Register of the document (the person who physically entered the data in the document)
- Responsible persons
- The patient
- Author

### **Clinical Document**



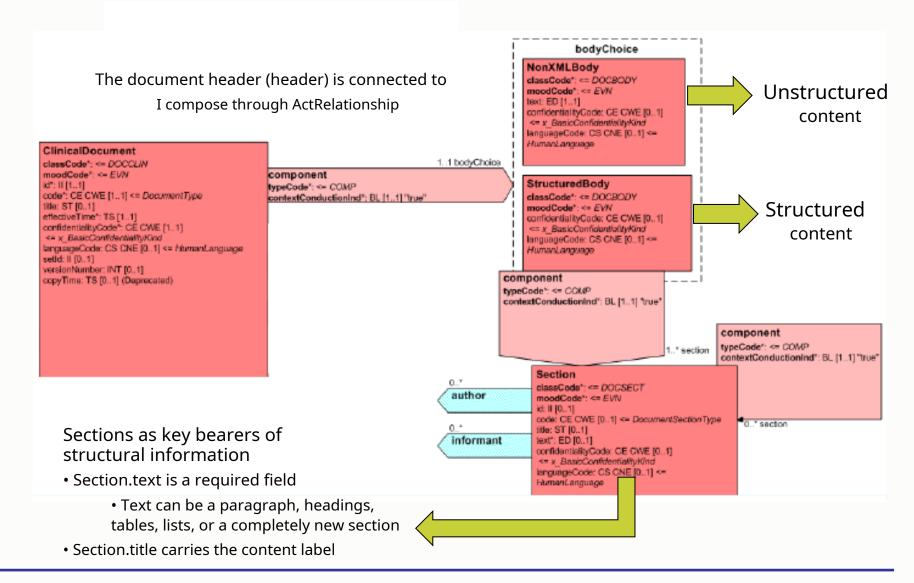


# Types of clinical documents (LOINC codes)

Code Document-Type Authoring Com			Context
code	Document-Type	Provider	Context
34133-9	Summarization of Episode Note	Practicioner	
18842-5	Discharge summarization note	Provider	
11490-0	Discharge summarization note	Physician	
34745-0	Discharge summarization note	Nurse	
34105-7	Discharge summarization note	Provider	Hospital
34106-5	Discharge summarization note	Physician	Hospital
18761-7	Transfer summarization note	Provider	
28616-1	Transfer summarization note	Physician	
28651-8	Transfer summarization note	Nurse	
18733-6	Ambulatory visit note		
18742-7	Arthroscopy report		
18743-5	Autopsy report		
18745-0	Cardiac catheterization report		
11488-4	Consultation note		
18747-6	CT report		
11520-4	Echocardiogram report		
15507-7	Emergency visit note		
11492-6	History and physical note		

## **HL7 CDA Body**





## **CDA Body**



- Clinical content, either in the form of unstructured BLOB or structured markup text
- Body is composed of a number of Section components. Each Section component contains
  - Unique narrative block for each section (Section.text)
  - Section.text is crucial for human readability and interoperability
  - Zero, one or more clinical elements (Entries) and extension
- CDA Entries
  - Structured clinical content intended for further computer processing
  - As a rule, they encode what is in the corresponding Section.text part
  - Can be nested (*Entries within Entries*)
  - I can reference external objects

### **CDA Entries**



- Types of clinical content within CDA Entry
  - Observations (text content and multimedia)
  - Region of interest (multimedia)
  - Administration of medicines
  - Procurement of materials (Supply)
  - Procedures
  - Relationships between individual treatment episodes (Encounter)
  - Class organizer organization of multiple clinical contents in a group according to context
  - Generic Act

#### clinicalStatement Observation classCode\*: <= OBS moodCode\*: <= x ActMoodDocumentObservation id: SET<II> [0..\*] code\*: CD CWE [1..1] <= ObservationType negationInd: BL [0..1] derivationExpr: ST [0..1] text: ED [0..1] statusCode: CS CNE [0..1] <= ActStatus effectiveTime: IVL<TS> [0..1] priorityCode: CE CWE [0..1] <= ActPriority repeatNumber: IVL<INT> [0..1] languageCode: CS CNE [0..1] <= HumanLanguage value: ANY [0..1] interpretationCode: SET<CE> CNE [0..\*] methodCode: SET<CE> CWE [0..\*] targetSiteCode: SET<CD> CWE [0..\*]

# RegionOfInterest classCode\*: <= RO/OVL moodCode\*: <= EVN id\*: SET<||> [1.\*] code\*: CS CNE [1.1] <= RO/OverlayShap

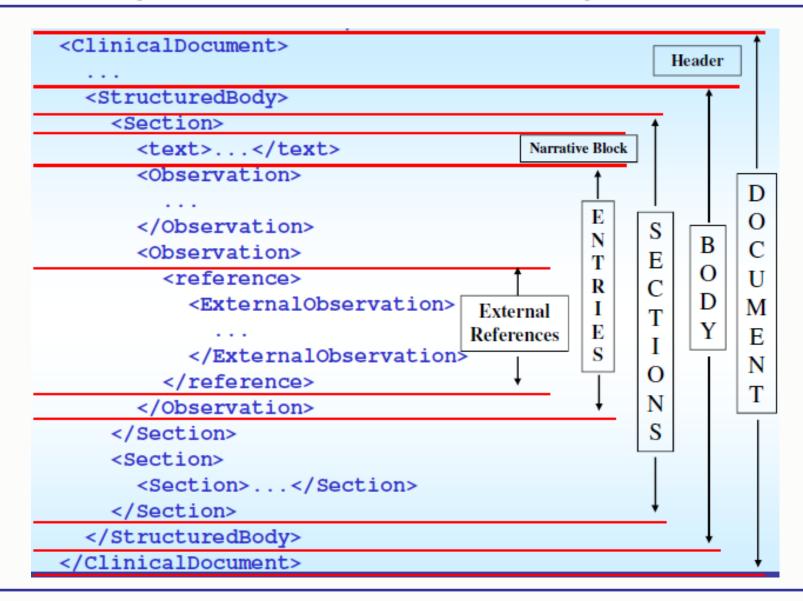
code\*: CS CNE [1..1] <= ROIOverlayShape value\*: LIST<INT> [1..\*]

```
ObservationMedia
classCode*: <= OBS
moodCode*: <= EVN
id: SET<||> [0..*]
languageCode: CS CNE [0..1] <= HumanLanguage
value*: ED [1..1]
```

```
SubstanceAdministration
classCode*: <= SBADM
moodCode*: <= x_DocumentSubstanceMood
id: SET<||> [0..*]
code: CD CWE [0..1] <= SubstanceAdministrationActCode
negationInd: BL [0..1]
text: ED [0..1]
statusCode: CS CNE [0..1] <= ActStatus
effectiveTime: GTS [0..1]
```



### XML representation of basic CDA components





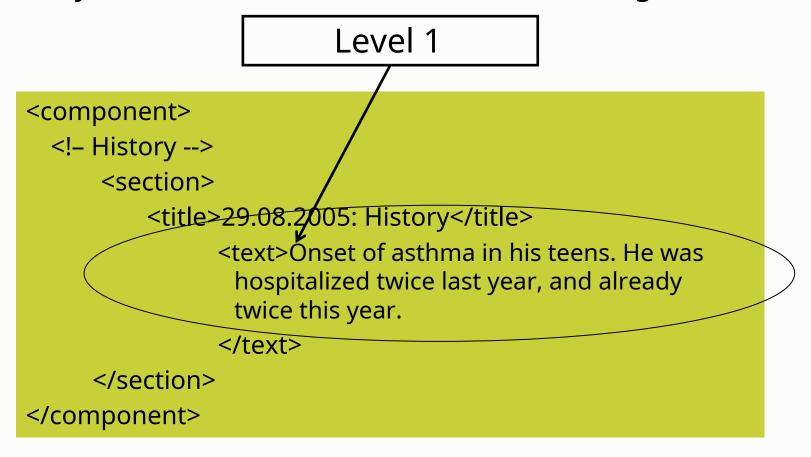
## **HL7 CDA levels (Levels = Sections)**

CDA Release 2	
CDA Level 1	The unconstrained CDA specification.
CDA Level 2	The CDA specification with section-level templates applied.  "My discharge letter has the following structure"
CDA Level 3	The CDA specification with entry- level (and optionally section-level) templates applied. "My discharge letter contains the following granular data"

### HL7 CDA - Level 1



ordinary narrative text with additional formatting



### HL7 CDA - Level 2



Coding sections within the CDA body for computer

processing

```
Level 2
```

### HL7 CDA - Level 3



 Coding of individual keywords within section of the CDA body for additional computing processing

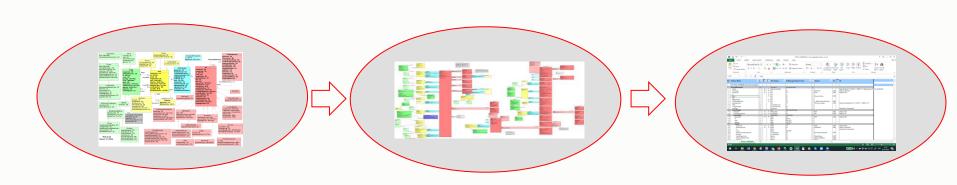
### Level 3

```
<component>
    <section>
           <code code="10164-2" codeSystemName="LOINC"
                      codeSystem="2.16.840.1.113883.6.1" />
           <title>29.08.2005: History</title>
           <text>Onset of <content ID="a1">asthma</content> in
his teens. He was hospitalized twice last year, and already twice this
year. </text>
           <entry typeCode="COMP">
           <observation>
           <code code="195967001"
odeSystem="2.16.840.1.113883.6.96"
         codeSystemName="SNOMED CT"
           displayName="Asthma">
           <originalText>
                      <reference value="#a1"/>
           </originalText>
           </code>
           </observation>
           </entry>
    </section>
</component>
```

### **CDA RMIM - HMD**



- CDA structured content intended for computer interoperability is based on HL7v3 RIM and HL7v3 data types
- CDA R-MIM is created by standard processes of cloning classes from RIM
- CDA Hierarchical description of the message (Hierarchical Message Description HMD) is a tabular representation of the contents of R-MIM



ROME CDA R-ROM CDA HMD

### **CDA HMD**



- Key artifact for validating and conforming CDA documents to modeling rules
- Source for CDA scheme (XSL stylesheet)
- Document conformance to the schema is checked and measured at the level of each HL7 RIM attribute
- RIM Attributes can be defined as
  - Mandatory\*(in the HMD tabular display "bold" text and star) the sender must send a value (NULL is not allowed)
    - An example is ClinicalDocument.typeId
  - Required\* (asterisk) the sender must fill in the value where it is known, regardless of the allowed number of repetitions (cardinality)
    - An example is Section.text
    - All attributes whose cardinality is 1 or greater

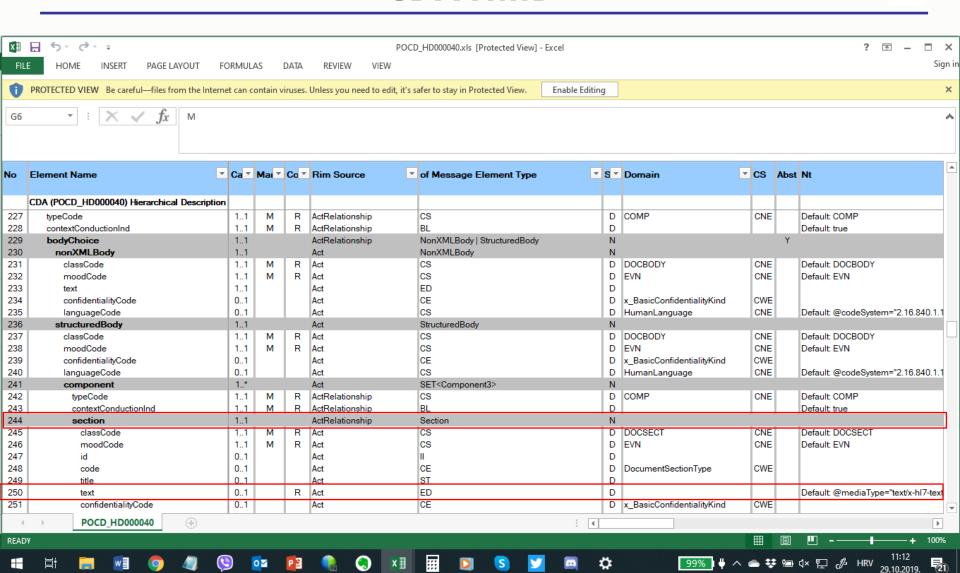
## **HL7 CDA Human readability**



- The standard guarantees that the recipient of the CDA document can present clinical content on a standard WEB browser
- Printable content is located inSection.textfield
- Taking into account the combination of narrative part and CDA*entries* , this implies the following settings
  - The recipient must have a clear deterministic way of presenting the document
  - It is not necessary for the sender to send a separate XSL document to print the document
  - Applies exclusively to authentic content
    - The CDA document may contain additional information that is exclusively for computer processing, but which are not authentic, and thus are not displayed on the browser
  - When structured content is derived from a narrative part, there must be a mechanism that describes that process (e.g. Author, human or computer coding), and vice versa

### **CDA HMD**





### **CDA Validation and Conformance**



- A CDA document is considered valid ifminimally validates in accordance with the scheme, although uses coded elements from associated vocabularies
- IMPORTANT –the computer cannot process the validity for the human readability part, and additional rules are introduced for the sender and receiver of the message, as follows:
  - 1. Recipient of the document
  - He assumes *default* values where they are defined, and the CDA document instance itself does not contain a value
  - Must process the entire CDA Header (but not necessarily display it!)
  - It must process the CDA Body to the level where it can be displayed in a web browser
    - If it is non-XML content, it must use/include a tool that can display the default content (according to MIME type)
    - If it is structured XML content
      - Must display the content found in Section.title, to clearly indicate the content tag. Lack of this value signals an unmarked section
      - Must display Section.text content according to formatting rules (text, HTML, multimedia, etc.)
  - 2. Sender of the document
  - Must construct the narrative block (Section.title and Section.text) in such a way that the recipient can display it in the browser

## CDA Validation and Conformance Cont'd



- The recipient does not necessarily have to
  - Know how to process all the Entries that are inside the CDA message
  - Validate the entire document according to the templates
- The above functions may be part of additional requirements for local implementations

## **Exchange of CDA documents**



- The CDA document is a defined and complete information object that can
  - Exist outside the messaging context is sent as a single information object
  - To be transmitted as content within an HL7 message
- Exchange of CDA document within HL7 message is also supported
  - In that case, the CDA document is actually a multimedia MIME object, encoded using ED (encapsulated data type).
  - In HL7V2, CDA documents are transferred within OBX (*Observation/Result*) of a segment within any message that implies the exchange of documents (e.g. *Medical Document Management, MDM*). The CDA Header is mapped to the TXA (Transcription Document Header) segment that precedes the OBX segment (see slide behind)
  - In HL7v3, CDAs can be transmitted in any message that exchanges documents (eg HL7v3 Medical Records Messages)
  - The standard includes the definition of the mapping between the fields within the segment and the CDA Header



### HL7 CDA in HL7 V2 message

## MDM Segment - CDA Mapping example

TXA Field	CDA Component	
TXA-2 Document type	ClinicalDocument.code	
TXA-4 Activity date/time	ServiceEvent.effectiveTime	
TXA-5 Primary activity provider code/name	ServiceEvent performer	
TXA-6 Origination date/time	ClinicalDocument.effectiveTime	
TXA-7 Transcription date/time TXA-9	dataEnterer.time	
Originator code/name TXA-11	author	
Transcriptionist code/name TXA-12	dataEnterer	
Unique document number TXA-13	ClinicalDocument.id	
Parent document number TXA-14 Placer	ParentDocument.id	
order number	Order.id	
TXA-18 Document confidentiality	ClinicalDocument.confidentiality	
status	Code	
TXA-22 Authentication person, time	authenticator,	
stamp	legalAuthenticator	
TXA-23 Distributed copies	informationRecipient	

#### Mapping CDA Header content to

TXA segment in the MDM message

```
MSH | ...
EVNÍ...
PV1 | ...
OBX | 1 | ED | 11492-6 "History and Physical "LN | |
  ^multipart^related^A^
  MIME-Version: 1.0
  Content-Type: multipart/related; boundary="HL7-CDA-boundary";
  type="text/xml"; start="10.12.45567.43"
  Content-Transfer-Encoding: BASE64
  --HL7-CDA-boundary
  Content-Type: text/xml; charset="US-ASCII"
  Content-ID: &lt:10.12.45567.43>
   ... Base 64 of base CDA document, which contains
      <observationMedia classCode="OBS" moodCode="EVN">
         <id root="10.23.4567.345"/>
        <value mediaType="image/jpeg">
            <reference value="left hand image.jpeg"/>
         </observationMedia>
   -- HL7-CDA-boundary
   Content-ID: <10.23.4567.345>
  Content-Location: canned left hand image.jpeg
   Content-Type: image/JPEG
   ... Base64 image ...
   --HL7-CDA-boundary--
```

Example message

### **Consolidated CDA**



- A CDA document often results in a very complex structure. Therefore, templates are introduced in practice to profile the basic specification for easier use -> Consolidated CDA
- C-CDA is a set of templates that facilitate the implementation of a series of clinical documents based on CDA
- The idea of templates is to enable the following advantages:
  - Reusable building blocks
  - Faster implementations
  - Modularity (e.g. Blood pressure, diagnosis at discharge), which enables repackaging and use of the same in several different guidelines and implementations
  - Incremental interoperability
- Templates can be used at the following levels
  - Level 1 template at the level of the document itself (e.g. discharge letter)
  - Level 2 template at the section level within the document (e.g. Allergies or drug therapy)
  - Level 3 template at the data level (entry) within the document (e.g. specific observations or procedures)
- C-CDA V2.1 supports 11 types of documents (2020)



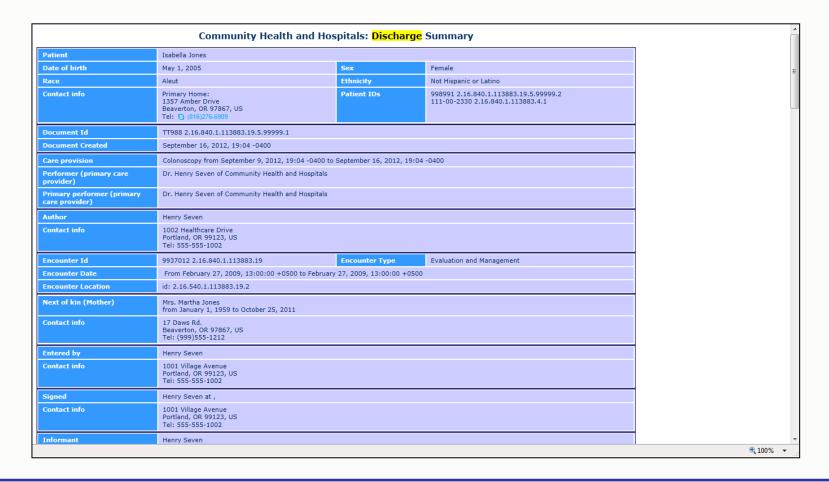


```
<?xml version="1.0" encoding="UTF-8"?>
- <ClinicalDocument xsi:schemaLocation="urn:hl7-org:v3 infrastructure/cda/CDA_SDTC.xsd" xmlns="urn:hl7-org:v3"</p>
 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
        <!--RealmCode, TypeID and templateID are inherited from the InfrastructureRoot class -->
     <realmCode code="KZ"/>
     <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
     <templateId root="1.2.398.7.1.4.10.1.1.10"/>
     <templateId root="1.2.398.7.1.4.10.1.1.11"/>
     <id root="1.2.398.7.1.14.1.1.1467203468544"/>
     <code code="100" displayName="Document Name" codeSystemName="Document Type" codeSystem="1.2.398.7.1.10.3.1"/>
        <!-- Код и отображаемое наименование приведены только для примера, реальные значения могут отличаться -->
        <!-- Заголовок документа -->
     <title>Анализ крови на гепатит</title>
        <!-- Заголовок документа приведен для примера -->
     <effectiveTime value="20160629125600+0100"/>
     <confidentialityCode code="N" codeSystemName="Конфиденциальность" codeSystem="1.2.398.7.1.10.3.4"/>
     <languageCode code="RU-RU"/>
     <setId root="1.2.398.7.1.14.1.2.79745468654346"/>
     <versionNumber value="1"/>
   + <recordTarget>
        <!-- Author of the document, author -->
   + <author contextControlCode="OP" typeCode="AUT">
        <!-- System that generated the document -->
   + <author contextControlCode="OP" typeCode="AUT">
   + <custodian>
        <!-- Работник здравоохранения или система -->
   + <authenticator typeCode="AUTHEN">
   + <inFulfillmentOf typeCode="FLFS">
        <!-- VISIT -->
   + <componentOf>
   - <component>
      - <nonXMLBody>
            <text representation="B64"
               mediaType="application/pdf">JVBERi0xLjQKJaqrrK0KNCAwIG9iago8PAovQ3JlYXRvciAoQXBhY2hlIEZPUCBWZ
        </nonXMLBody>
     </component>
 </ClinicalDocument>
```



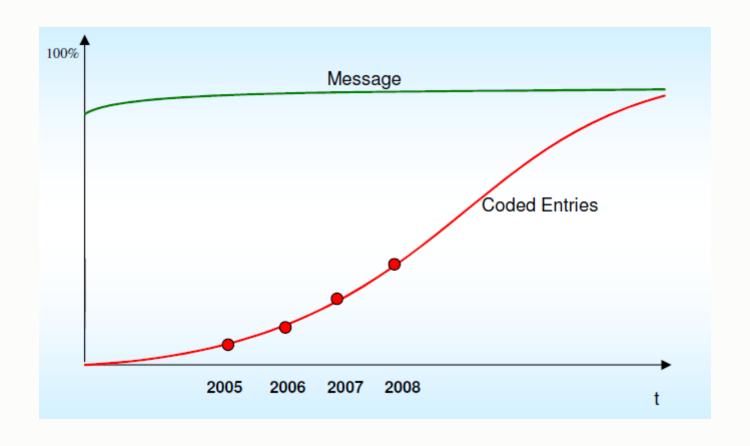


### Consolidated CDA -link





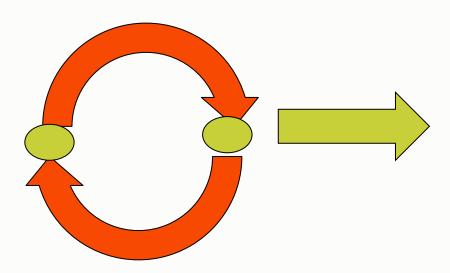




## **HL7: Message or Document????**



### Message



It reflects the state of affairs in at a given moment
Support of ongoing processes

### **Document**



Summary information of someone complete process

Formal data transfer for providing care

### Conclusion



- HL7v3 as a response to the shortcomings of HL7v2, and the option to implement national systems and electronic health records over time turned out to be quite complicated in practice
- HL7 CDA, due to its document management nature, has found a good response in practice
  - The challenge is still the complexity of the design and the variety of documents
  - Mostly in practice we meet Level 1 or Level 2 very rarely Level 3
- Robustness of design vs speed of implementation as a rule, inversely proportional
- In the next lecture HL7 FHIR

### Literature



- HL7v3 Normative content
  - https://www.hl7.org/implement/standards/product\_brief.cfm?product\_id= 186
- HL7 CDA Normative content
  - http://www.hl7.org/implement/standards/product\_brief.cfm?product\_id=7
- HL7 Document vs. Messaging Paradigm
  - http://www.ringholm.de/docs/04200\_en.htm
- Consolidated CDA Review
  - https://en.wikipedia.org/wiki/Consolidated\_Clinical\_Document\_Architecture e
  - https://www.hl7.org/implement/standards/product\_brief.cfm?product\_id= 492
- Online tools for validation and testing of HL7 CDA (and others)
  - https://www.art-decor.org/mediawiki/index.php/Main\_Page