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HL7 Clinical Document Architecture: Overview and Applications

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A Bit About Myself...

2003 M.D. (Ramathibodi)

2009 M.S. in Health Informatics (U of MN)

2011 Ph.D. in Health Informatics (U of MN)

2012 Certified HL7 CDA Specialist

- **Lecturer, Department of Community Medicine**
- **Deputy Executive Director for Informatics (CIO/CMIO), Chakri Naruebodindra Medical Institute**
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<http://groups.google.com/group/ThaiHealthIT>

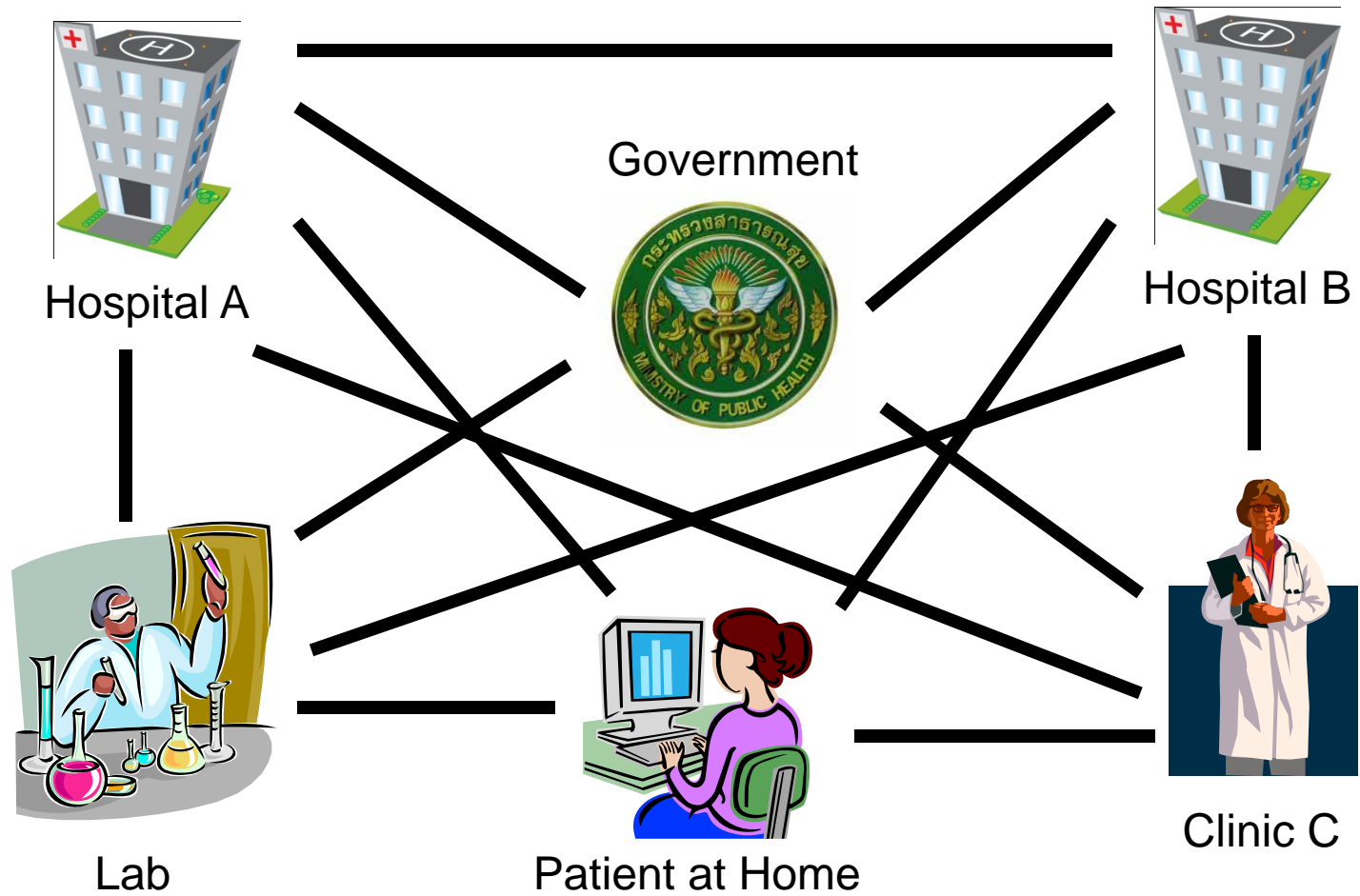
Research interests:

- EHRs & health IT applications in clinical settings
- Health IT adoption & eHealth development
- Health informatics education & workforce development



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Health Information Exchange (HIE)





Why Health Information Standards?

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Objectives

- Interoperability
- Inter-operable systems

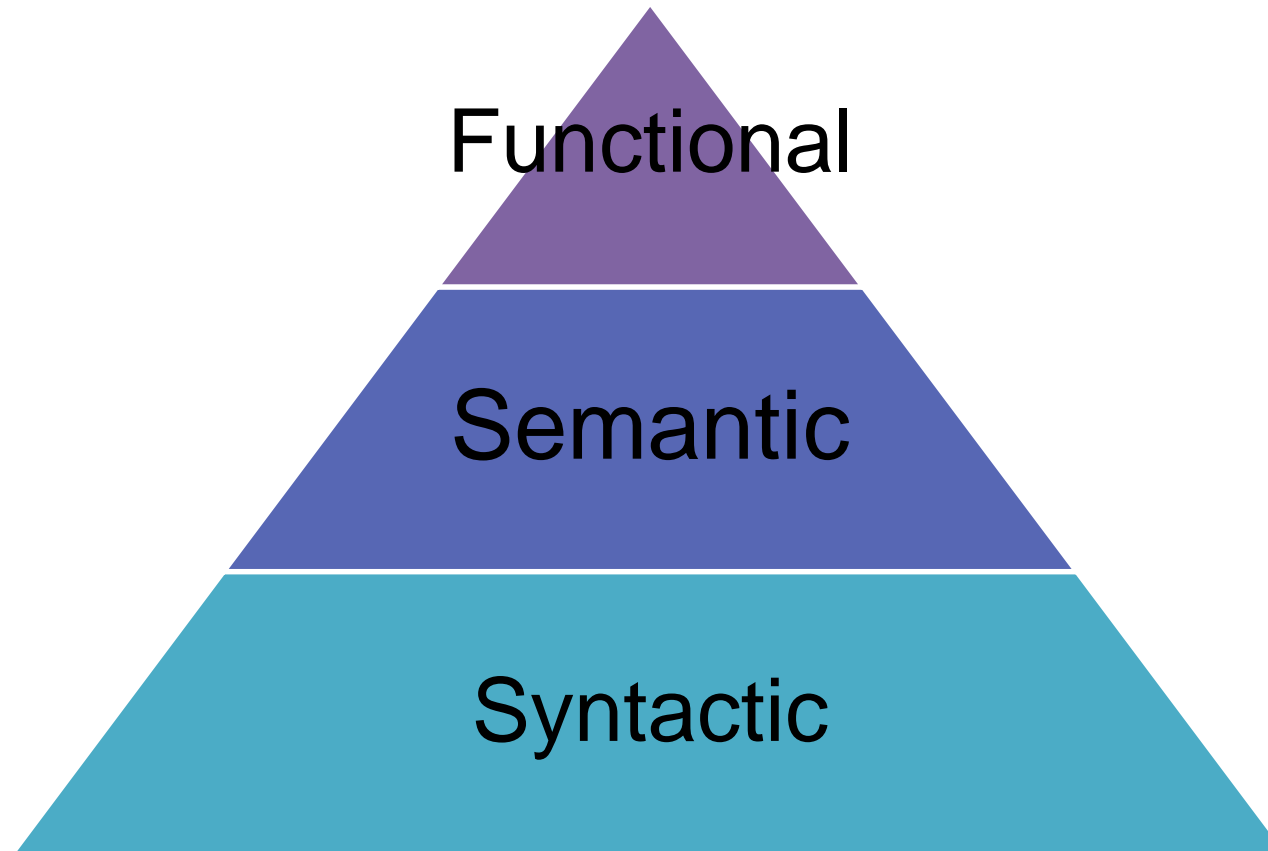
Ultimate Goals

- Continuity of Care
- Quality
 - Safety
 - Timeliness
 - Effectiveness
 - Equity
 - Patient-Centeredness
- Efficiency



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Levels of Interoperability





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How Standards Support Interoperability

Functional

Functional Standards (HL7 EHR
Functional Specifications)

Vocabularies, Terminologies,
Coding Systems (ICD-10, ICD-9,
CPT, SNOMED CT, LOINC)

Semantic

Information Models (HL7 v.3 RIM,
ASTM CCR, HL7 CCD)

Standard Data Sets
Unique ID

Syntactic

Exchange Standards (HL7 v.2,
HL7 v.3 Messaging, HL7 CDA,
DICOM)

Technical Standards
(TCP/IP, encryption,
security)

Some may be hybrid: e.g. HL7 v.3, HL7 CCD



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Exchange Standards

Message Exchange

- Goal: Specify format for exchange of data
- Internal vs. external messages
- Examples
 - HL7 v.2
 - HL7 v.3 Messaging
 - DICOM
 - NCPDP

Document Exchange

- Goal: Specify format for exchange of “documents”
- Examples
 - HL7 v.3 Clinical Document Architecture (CDA)
 - ASTM Continuity of Care Record (CCR)
 - HL7 Continuity of Care Document (CCD)



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Exchange Standards

Messages

- Human Unreadable
- Machine Processable

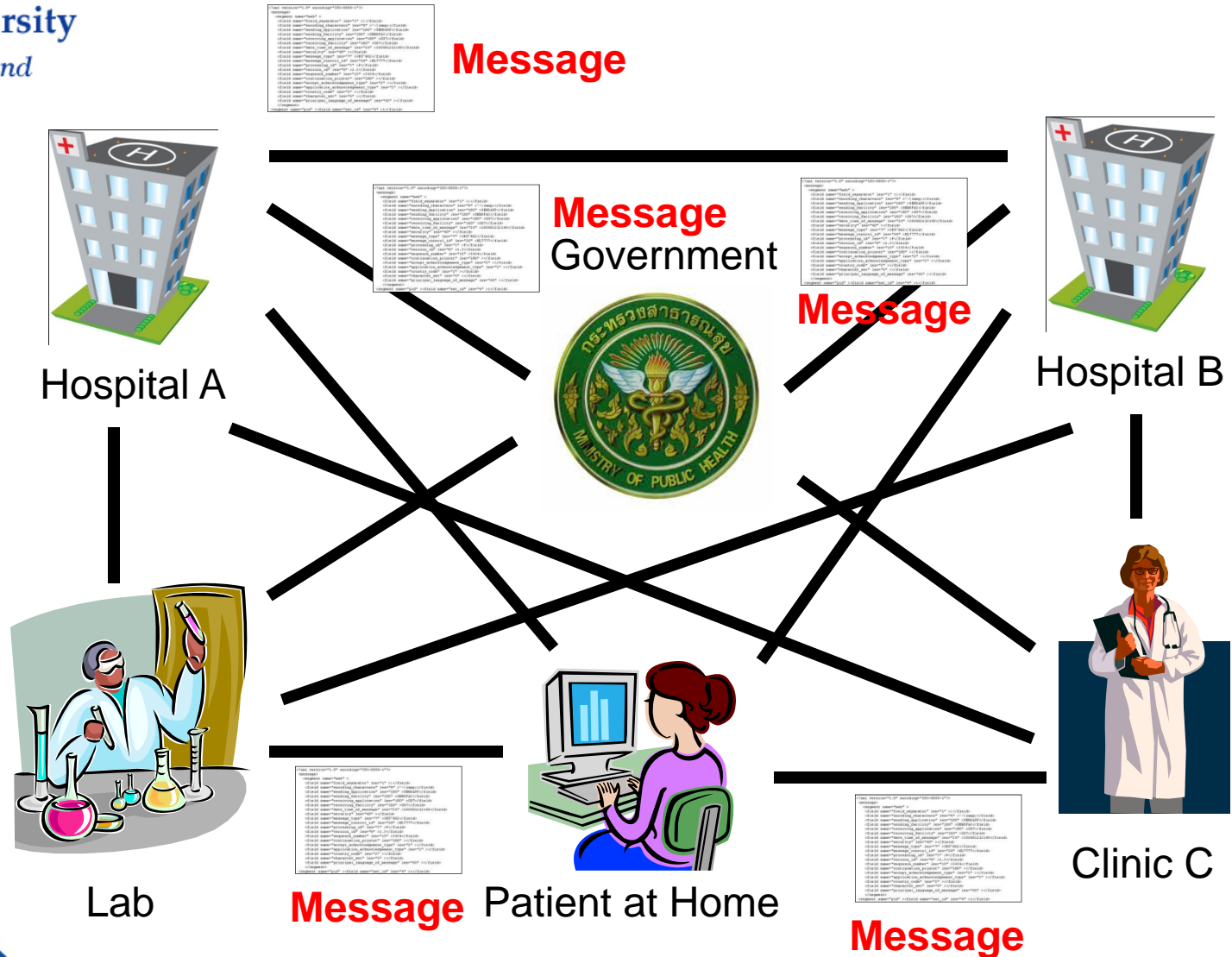
Clinical Documents

- Human Readable
- (Ideally) Machine Processable



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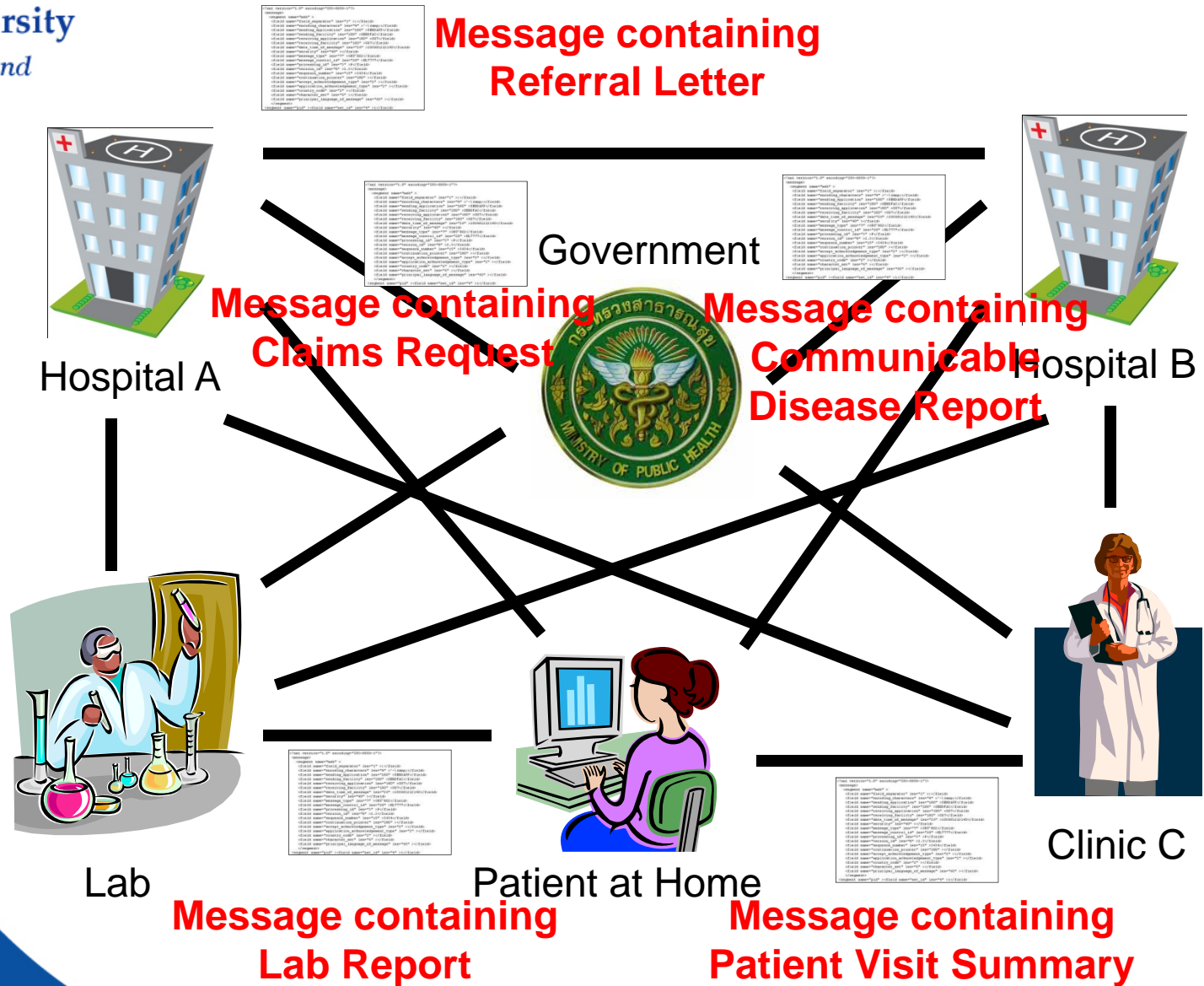
Message Exchange





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Clinical Document Exchange





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Sample HL7 v.2 Message (Lab Result)

```
OBX|1|NM|10839-9^TROPONIN-I^LN||5|ng/ml|  
0-1.3|H||H|F|19980309...
```



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Sample HL7 v.3 Message (Patient Registration)

```
<?xml version="1.0" encoding="UTF-8"?>
<PRPA_IN101311UV02 xmlns="urn:hl7-org:v3"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  ITSVersion="XML_1.0" xsi:schemaLocation="urn:hl7-org:v3
  ../schemas/PRPA_IN101311UV02.xsd">
  ...
  <name use="SYL" >
    <given>นวนรรน</given>
    <family>ธีระอัมพรพันธุ์</family>
  </name>
  <name use="ABC">
    <given>Nawanan</given>
    <family>Theera-Ampornpunt</family>
  </name>
    <administrativeGenderCode code="M"/>
  ...
</PRPA_IN101311UV02>
```

Message source adapted from Ramathibodi HL7 Project by Supachai Parchariyanon,
Kavin Asavanant, Sireerat Srisiratanakul & Chaiwiwat Tongtaweekhaikit



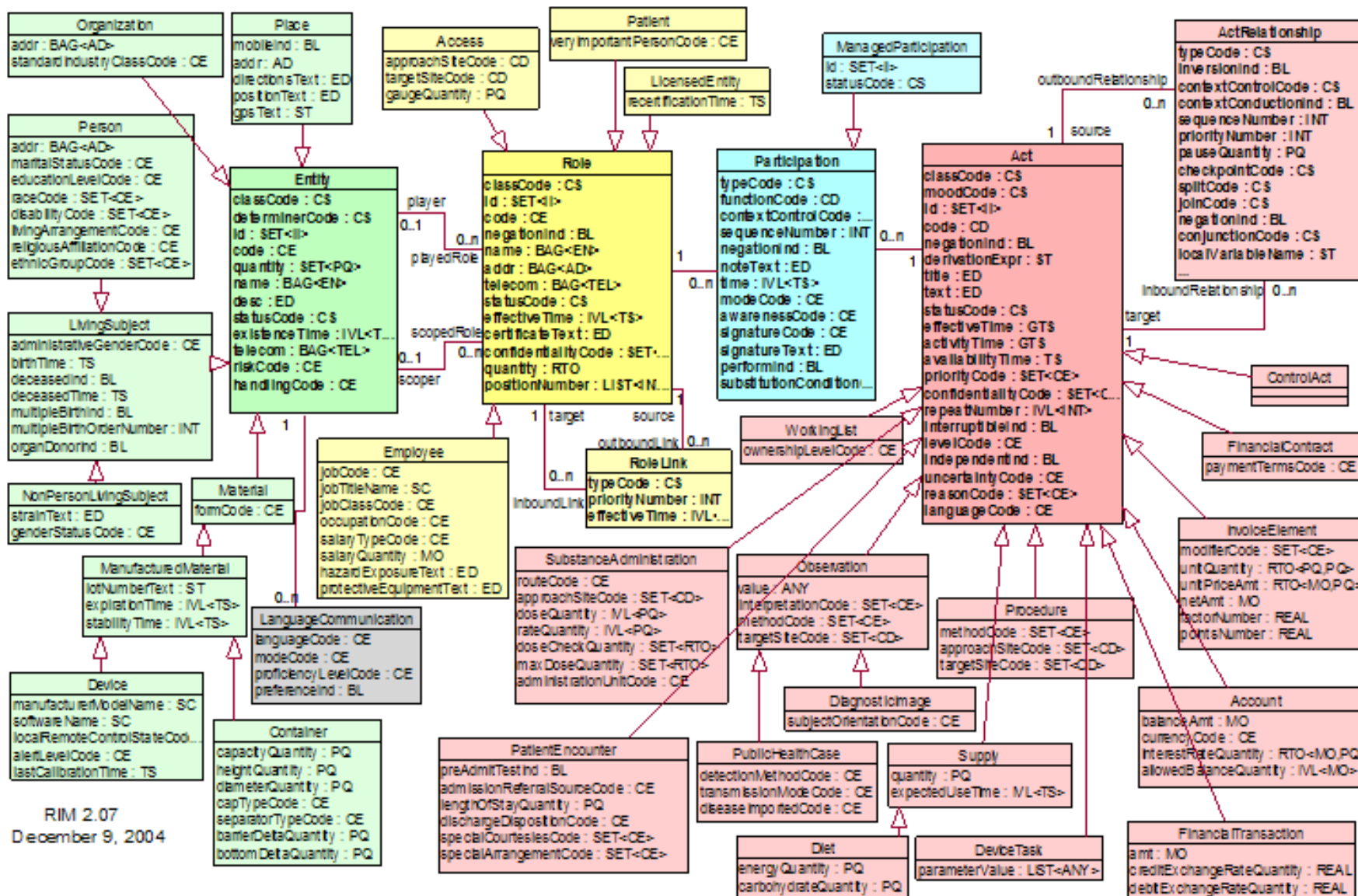
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HL7 V3 Standards

- A family of standards based on V3 information models and development methodology
- Components
 - HL7 V3 Reference Information Model (RIM)
 - HL7 V3 Messaging
 - HL7 Development Framework (HDF)



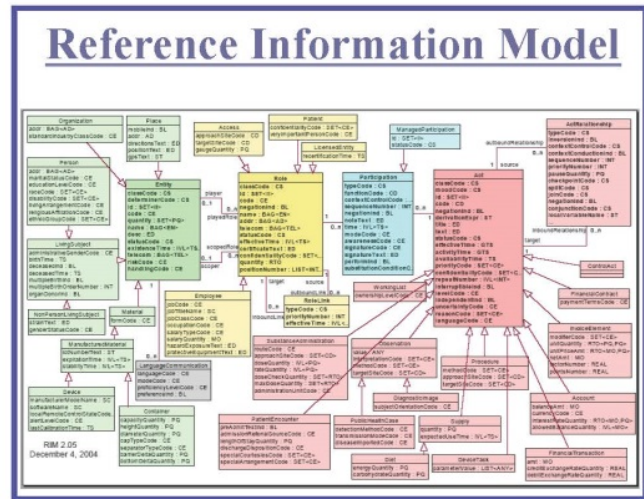
HL7 Reference Information Model (RIM)



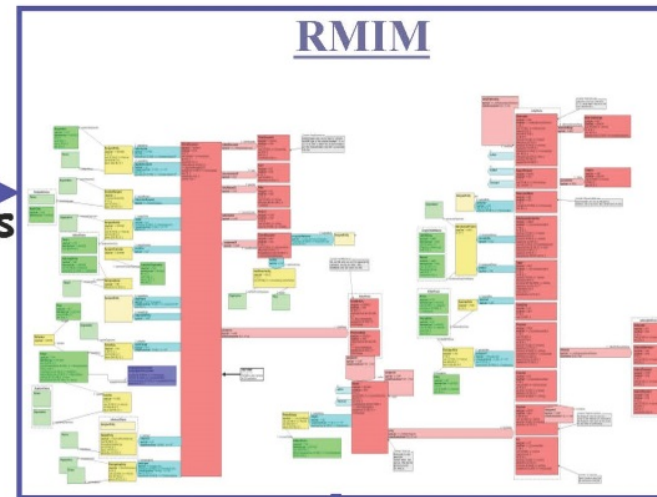
RIM 2.07
December 9, 2004

Source: HL7 CDA R2

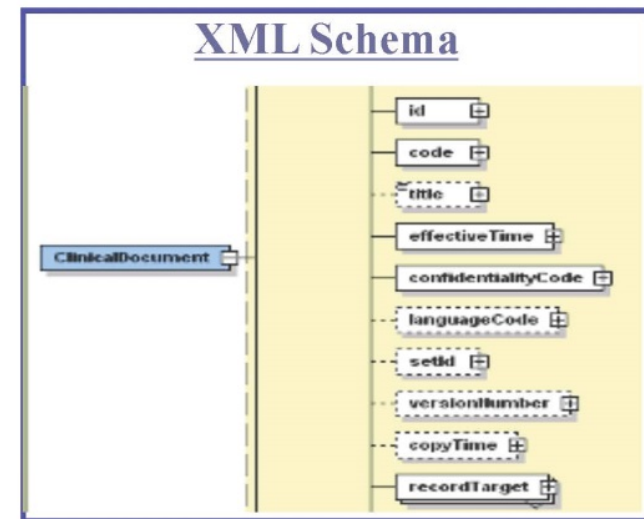
How V3 Models are developed and maintained: with *just enough* HL7 Development Framework



subset of RIM
tighten constraints



linearization
additional constraints



algorithmic

Hierarchical Description

id	name	card	type	role	parent	children	notes
1	ClinicalDocument					Document	ClinicalDocument N
2	typeId	1..1	M	R	InfrastructureRoot	II	N
3	classCode	1..1	M	R	Act	CS	D DOCCLIN
4	moodCode	1..1	M	R	Act	CS	D EVN
5	id	1..1	R	Act	II		D DocumentType
6	code	1..1	R	Act	CE		D
7	title	0..1	R	Act	ST		D
8	effectiveTime	1..1	R	Act	TS		D
9	confidentialityCode	1..1	R	Act	CE		D x_BasicConfid
10	languageCode	0..1	R	Act	CS		D HumanLangu
11	setId	0..1	R	ContextStructure	II		D
12	versionNumber	0..1	R	ContextStructure	INT		D
13	copyTime	0..1	R	Document	TS		D
14	authenticator	0..*	R	Act	SET<Authenticator>		N
15	typeCode	1..1	M	R	Participation	CS	D AUTHEN
16	time	1..1	R	Participation	TS		D
17	signatureCode	1..1	R	Participation	CS		D ParticipationS
18	assignedEntry	1..1	M	R	Participation	AssignedEntry	D ASSIGNED
19	classCode	1..1	M	R	Role	CS	D
20	id	1..*	R	Role	SET<ID>		D
21	code	0..1	R	Role	CE		D RoleCode
22	addr	0..*	R	Role	SET<AD>		D

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



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HL7 V3 Messaging

- V3 provides messaging standards for
 - Patient administration
 - Medical records
 - Orders
 - Laboratory
 - Claims & Reimbursement
 - Care provision
 - Clinical genomics
 - Public Health
 - Etc.



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How HL7 V3 Works

- Message sent from sending application to receiving application
- Mostly triggered by an event
- Typical scenario portrayed in a storyboard
- Message in XML with machine-processable elements conforming to messaging standard
- Data elements in message conform to RIM
- Not designed for human readability



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What Is HL7 CDA?

- “A document markup standard that specifies structure & semantics of “clinical documents” for the purpose of exchange”
[Source: HL7 CDA Release 2]
- Focuses on document exchange, not message exchange
- A document is packaged in a message during exchange
- **Note:** CDA is not designed for document storage. Only for exchange!!



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A Clinical Document (1)

- A documentation of clinical observations and services, with the following characteristics:
 - **Persistence** - continues to exist in an unaltered state, for a time period defined by local and regulatory requirements
 - **Stewardship** - maintained by an organization entrusted with its care
 - **Potential for authentication** - an assemblage of information that is intended to be legally authenticated



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A Clinical Document (2)

- A documentation of clinical observations and services, with the following characteristics:
 - **Context** - establishes the default context for its contents; can exist in non-messaging contexts
 - **Wholeness** - Authentication of a clinical document applies to the whole and does not apply to portions of the document without full context of the document
 - **Human readability** - human readable



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A Clinical Document (3)

- A CDA document is a defined & complete information object that can include
 - Text
 - Images
 - Sounds
 - Other multimedia content



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Some Possible Use Cases of CDA

- Intra-institutional
 - Exchange of parts of medical records (scanned or structured electronic health records)
 - Lab/Imaging requests & reports
 - Prescriptions/order forms
 - Admission notes
 - Progress notes
 - Operative notes
 - Discharge summaries
 - Payment receipts
 - Other forms/documents (clinical or administrative)



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Some Possible Use Cases of CDA

- **Inter-institutional**
 - Referral letters
 - Claims requests or reimbursement documents
 - External lab/imaging reports
 - Visit summary documents
 - Insurance eligibility & coverage documents
 - Identification documents
 - Disease reporting
 - Other administrative reports



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CDA Releases

- CDA Release 1 (ANSI-approved in 2000)
 - First specification derived from HL7 RIM
- CDA Release 2 (2005) - Current Release
 - Basic model essentially unchanged from R1
 - Document has a header & a body
 - Body contains nested sections
 - Sections can be coded using standard vocabularies and can contain entries
 - Derived from HL7 RIM Version 2.07



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Key Aspects of CDA

- CDA documents are encoded in XML
 - When alternative implementations are feasible, new conformance requirements will be issued
- CDA documents derive their machine processable meaning from HL7 RIM and use HL7 V3 Data Types
- CDA specification is richly expressive & flexible
 - Templates can be used to constrain generic CDA specifications



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Scope of CDA

- Standardization of clinical documents for exchange
- Data format of clinical documents outside of exchange context (such as data format used to store clinical documents) is **out-of-scope**



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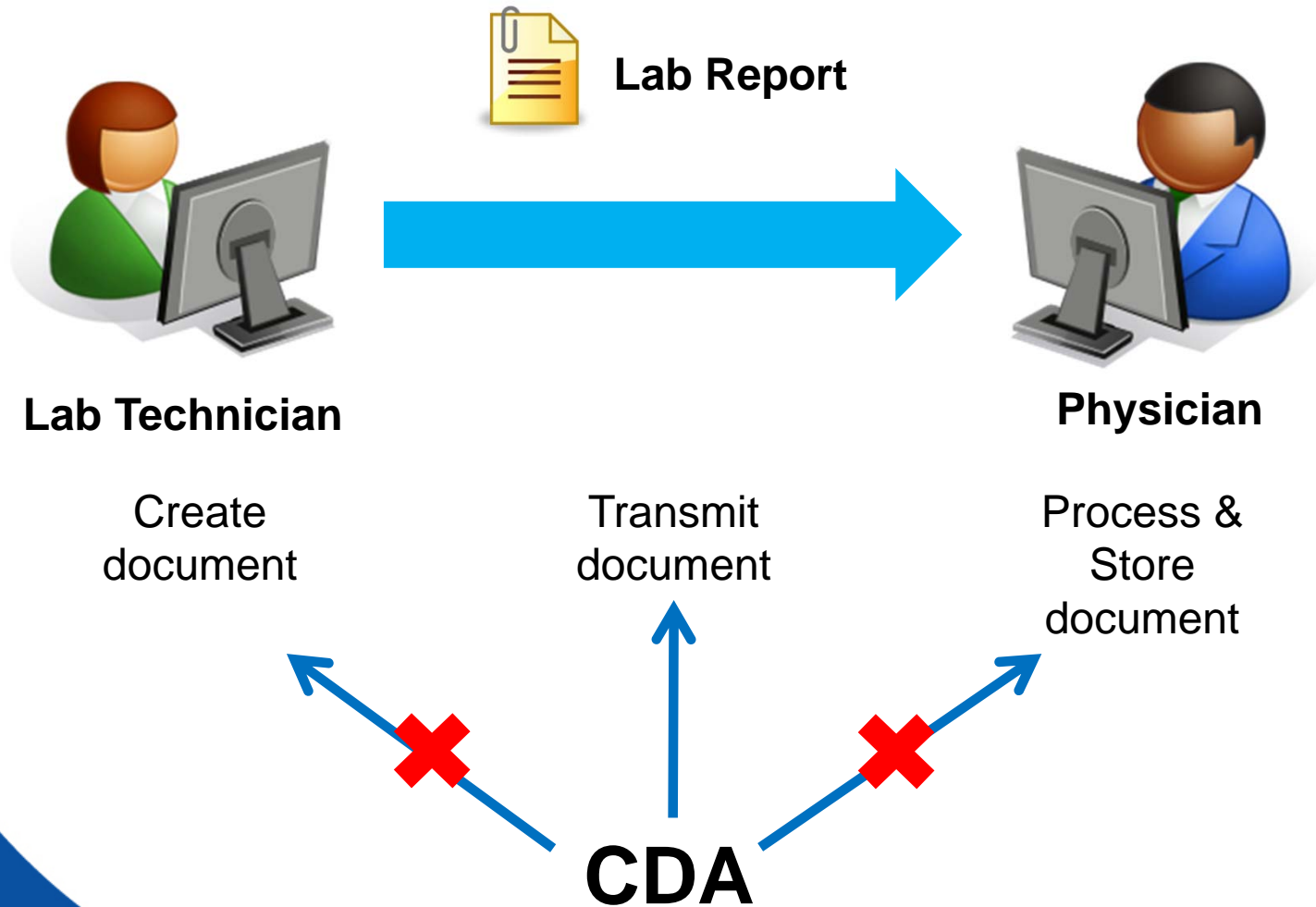
Scope of CDA

- CDA doesn't specify creation or management of documents and messages related to document management
- Instead, **HL7 V3 Structured Documents WG** provides specifications on standards for document exchange within HL7 V3 messages (where CDA clinical documents can become contents of the messages)



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Scope of CDA





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CDA & HL7 Messages

- Documents complement HL7 messaging specifications
- Documents are defined and complete information objects that can exist outside of a messaging context
- A document can be a MIME-encoded payload within an HL7 message

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



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CDA & Message Exchange

- CDA can be payload (or content) in any kind of message
 - HL7 V2.x message
 - HL7 V3 message
 - EDI ANSI X12 message
 - IHE Cross-Enterprise Document Sharing (XDS) message
- And it can be passed from one kind to another

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



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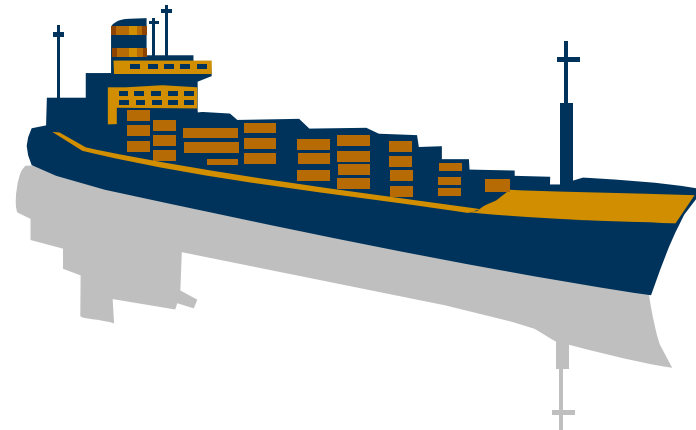
CDA & Message Exchange



Clinical Document
(Payload)



HL7 V3 Message
(Message)



HL7 V2 Message
(Message)

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



CDA As Payload

Relationship to HL7 messages

Documents can be encapsulated within HL7 messages as MIME packages

HL7 V2.x

MSH | ...
EVN | ...
PID | ...
PV1 | ...
TXA | ...
OBX | 1 | ED | ...



| ...

HL7 V3

```
<Act.Code code="11488-4"
codeSystem="2.16.840.1.113883.6.
1" displayName="Consultation
note"/>

<Act.text type="multipart/
related"> MIME-Version: 1.0
Content-Type: multipart/related;
boundary="HL7-CDA-boundary";
type="text/xml";
start="10.12.45567.43" Content-
Transfer-Encoding: BASE64
```



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



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MIME

- Multipurpose Internet Mail Extensions
- An Internet standard that extends the format of e-mail to support
 - Text in non-ASCII character sets
 - Non-text attachments
 - Message bodies with multiple parts
 - Etc.
- Often used in e-mails & some HTTP data
- Encoding: e.g. base64 (converting bits into 64 ASCII characters)



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Base64 Encoding

- TWFuIGlzIGRpc3Rpbmd1aXNoZWQsIG5vdCBvbmx5IGJ5IGhpcyByZWZzb24sIGJ1dCBieSB0aGlzIHNpbmd1bGZyIHh3c3Rpb24gZnJvbSBvdGh1ciBhbm1tYWxzLCB3aGljaCBpcyBhIGx1c3Qgb2YgdGh1IG1pbmQsIHRoYXQgYnkgYSBwZXJzZXZlcmFuY2Ugb2YgZGVsaWdodCBpb3I0aGUgY29udGluZGVkIGFuZCBpbmR1ZmF0aWdhYm91dGdlbmVyYXRpb24gb2Yga25vd2x1ZGdlLCBleGN1ZWRzIHRoZSBzaG9ydCB2ZWwhbWVudG9yY2Ugb2YgYW55IGNhcm5hbCBwbGVhc3VyZS4=
- Man is distinguished, not only by his reason, but by this singular passion from other animals, which is a lust of the mind, that by a perseverance of delight in the continued and indefatigable generation of knowledge, exceeds the short vehemence of any carnal pleasure.



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Components of CDA Document

- Header
- Body
 - Section
 - Entry (machine processable)
 - Narrative Block (human readable)



A Closer Look at a CDA Document

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```
<ClinicalDocument> ... CDA Header ...  
<structuredBody> <section> <text>... Single  
Narrative Block ...</text>  
<observation>...</observation> Human Readable Part  
<substanceAdministration>  
<supply>...</supply>  
</substanceAdministration> <observation>  
<externalObservation>... Machine Processable Parts  
</externalObservation> </observation>  
</section> <section> <section>...</section>  
</section> </structuredBody>  
</ClinicalDocument>
```



Rendering CDA Documents (1)

Ma
W

```
*****
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



Rendering CDA Documents (2)

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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



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Rendering CDA Documents (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



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Human Readability & Rendering CDA Documents

```
<ClinicalDocument> ... CDA Header ...  
<structuredBody> <section> <text>... Single  
Narrative Block ...</text>  
<observation>...</observation> Text to be rendered  
<substanceAdministration>  
<supply>...</supply>  
</substanceAdministration> <observation>  
<externalObservation>...  
</externalObservation> </observation>  
</section> <section> <section>...</section>  
</section> </structuredBody>  
</ClinicalDocument>
```



XML Markup of CDA Documents

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- CDA instances are valid against CDA Schema
- May be subject to additional validation
- No prohibition against multiple schema languages (W3C, DTD, RELAXNG, etc.) as long as conforming instances are compatible



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Security, Confidentiality & Data Integrity

- Application systems sending and receiving CDA documents are responsible for meeting all legal requirements for
 - Document authentication
 - Document confidentiality
 - Document retention
- Encryption & source/recipient authentication may be necessary but is not part of CDA specs
- Confidentiality status is available within CDA



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CDA & Document Management

- CDA focuses on document exchange, not storage or processing
- Clinical documents are used for various reasons
 - Clinical care
 - Medico-legal reasons (as evidence)
 - Auditing
 - Etc.
- Clinical documents may contain errors or need data updates (e.g. preliminary lab results vs. final results)



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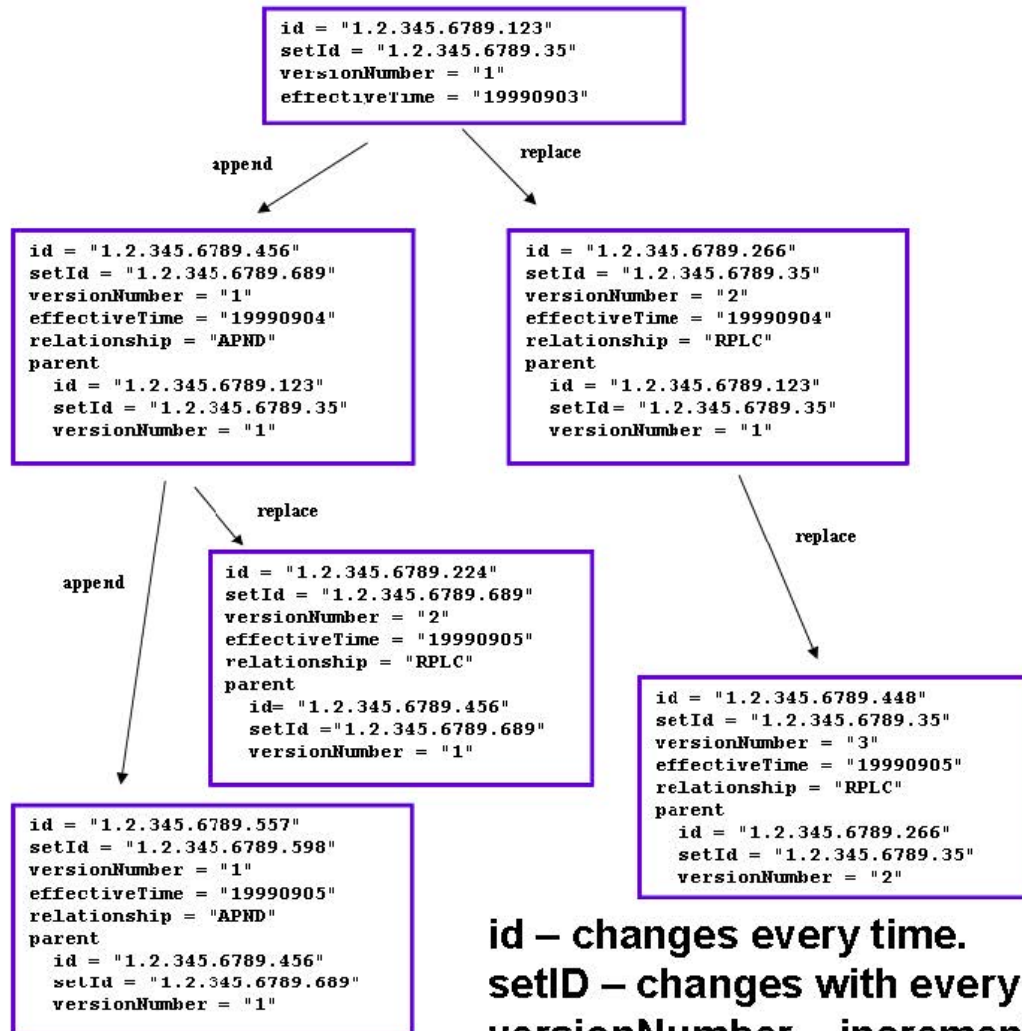
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CDA & Document Management

- CDA supports appending and replacement of documents through use of Document ID, setID, versionNumber & parent document
 - Supports version control of documents
 - Both old (replaced) and new versions of documents can be stored in and retrieved from document management systems depending on situation
 - Addendum is possible through append
 - Addendum itself can also be replaced with same version control mechanism
 - Document management system (not CDA) is responsible for keeping track of most up-to-date documents



Document Management Examples



id – changes every time.
setId – changes with every append.
versionNumber – increments with a replacement
and is reset to 1 with an append.

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



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Achieving Interoperability

- CDA is a general-purpose, broad standard
- Use in each use case or context requires **implementation guides** to constrain CDA
- Examples
 - Operative Note (OP)
 - Consultation Notes (CON)
 - Care Record Summary (CRS)
 - Continuity of Care Document (CCD)
 - CDA for Public Health Case Reports (PHCRPT)
 - Quality Reporting Document Architecture (QRDA)



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CDA Extensibility

- Locally-defined markup possible when local semantics have no corresponding representation in CDA specification
- Additional XML elements & attributes that are not included in CDA Schema are permitted in local **extensions**



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Summary

- CDA is a markup standard for document exchange
 - Not message exchange
 - Not document storage or processing
- CDA is a general-purpose standard
 - Use in specific context requires **Implementation Guides** (and possibly **Extensions**)



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Summary

- CDA is XML-based and RIM-based
- CDA documents can be exchanged as encapsulated data (**payload**) in any message (HL7 V2, HL7 V3, etc.)
- CDA is not dependent on using HL7 V3 messages
- CDA consists of
 - Header
 - Body
 - Section
 - Entry (machine processable)
 - Narrative Block (human readable)



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Next

- HL7 RIM & Data Types
- Navigating HL7 CDA Normative Edition
- Implementation Workshop