HL7 **Clinical Document Architecture Today and Tomorrow** COPYRIGHT (c) 2004 Mayo Foundation for Medical Education and Research

CDA - Today and Tomorrow

- HL7, Home of the CDA
- CDA, What is it?
- Mayo's use of CDA
- Acceptance of CDA World Wide
- CDA Release 2 What is planned?





What is Health Level 7?

 Health Level 7 or HL7 is one of several ANSI-accredited Standards Developing Organizations responsible for national standards used by the health care industry today.

It's name is taken in part from the OSI model which represents the 7 layers of a communication stack.

HL7 has focused on the application layer or layer 7 of healthcare applications.





HL7 is a Global Standard!

- Argentina
- Australia

Brazil

• Canad *

China

Croatia

- Czech Republic
 Denmark

Lithuania

- Finland
- **HL7 Organizations in 27 Countries!**
- Ireland







- Korea (Str.)
- Poland



- Southern fina Spain
- Switzerland
 - Taiwan

Turkey

- The Netherlands ted Kingdom• US^



What sort of standards?

HL7 Messaging Standards

	Chapter Title	Chapter Content
1	Introduction	Overview of HL7
2	Control	Message Definitions, Interchange Protocols
3	Patient Administration	Admit, Discharge, Transfer, and Demographics
4	Order Entry	Observations, Pharmacy, Dietary, and Supplies
5	Query	Rules applying to queries and to their responses
6	Financial Management	Patient Accounting and Charges
7	Observation Reporting	Observation Report Messages
8	Master Files	Health Care Application Master Files
9	Medical Records /	Document Management Services and Resources
	Information Management	
10	Scheduling	Appointment Scheduling and Resources
11	Patient Referral	Primary Care Referral Messages
<i>12</i>	Patient Care	Problem-Oriented Records.
13	Laboratory Automation	Equipment status, specimen status, equipment
		inventory, equipment comment, equipment response,
1		equipment notification, equipment test code settings,
		equipment logs/service
14	Application Management	Application control-level requests, transmission of
		application management information
15	Personnel Management	Professional affiliations, educational details, language
		detail, practitioner organization unit, practitioner detail,
	DICHT (-) 2004 M E d: f M	staff identification



What sort of standards?

- HL7 Messaging Standards and ...
- Clinical Context Management (CCOW)
- Arden Syntax for Medical Logic Systems
- Reference Information Model (RIM)
- Clinical Document Architecture (CDA)
- Electronic Healthcare Records (EHR)



My area of focus...

- HL7 Messaging Standards
- Clinical Context Management (CCOW)
- Arden Syntax for Medical Logic Systems
- Reference Information Model (RIM)
- **ØClinical Document Architecture (CDA)**
- Electronic Healthcare Records (EHR)



Clinical Document Architecture

An XML markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange.

Originally presented at the HL7 Plenary meeting in Sept of 1998, CDA Release 1.0 was approved as an ANSI standard on November of 2000.



Structured Documents TC

Currently there are 4 Co-Chairs to the SDTC:

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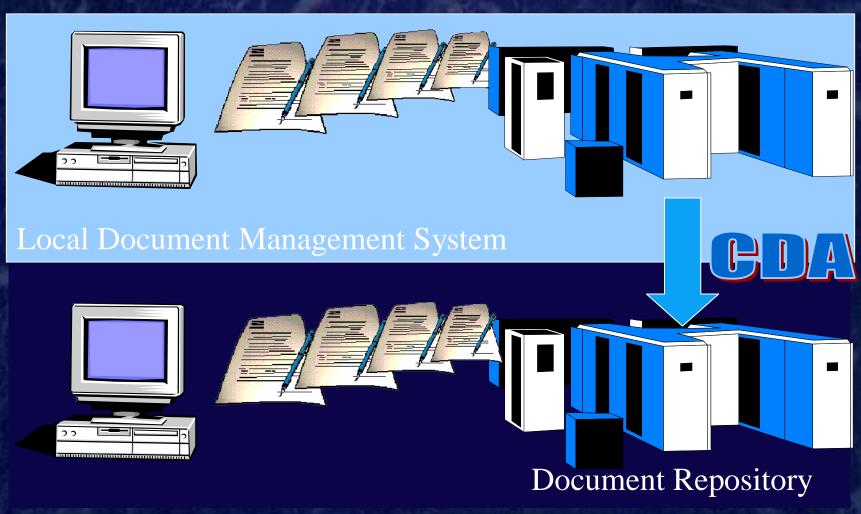
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Document Exchange Standard



Key Aspects of CDA

 CDA documents are encoded in Extensible Markup Language (XML).

 CDA documents derive their meaning from the HL7 Reference Information Model (RIM) and use the HL7 Version 3 Data Types.

 The CDA specification is richly expressive and flexible. Document-level, section-level and entry-level templates can be used to constrain the generic CDA specification.



What is XML?

- XML eXtensible Markup Language is a simplified subset of SGML that has been optimized for use on the World Wide Web.
 - HTML is an example of an SGML compliant specification, where the tags are predefined.
 - XML is extensible, in that it allows you to define your own vocabulary or <tags> which can be used to describe the abstract structure of a document.



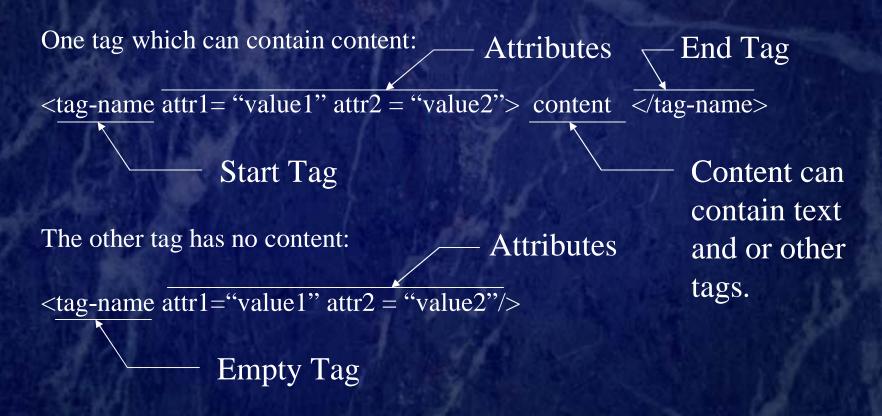
Why use XML?

- If you carefully define your tags, in the future you can go back and read those documents.
 - Word changes file format with each release.
 - RTF is owned by Microsoft and expresses only presentation format not meaning.
 - XML allows you to define a document format that expresses meaning that can last!



What is XML?

XML is composed of two types of tags:





Document VS Message

- Persistence
 - A clinical document continues to exist in an unaltered state, for a time period defined by local and regulatory requirements.
- Stewardship
 - A clinical document is maintained by a person or organization entrusted with its care.
- Potential for authentication
 - A clinical document is an assemblage of information that is intended to be legally authenticated.



Document VS Message

- Wholeness
 - Authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document.
- Human readability
 - A clinical document is human readable, guarantees that a receiver of a CDA document can readily display the clinical content of the note on a standard Web browser.
- Context

(Release 2.0)

 A clinical document establishes the default context for its contents.



CDA - Header

- The CDA Header is derived from the HL7 Reference Information Model (RIM) and contains:
 - Document information
 - Encounter data
 - Service actors (such as providers)
 - Service targets (such as patients)
 - Local markup



CDA Release 1.0

- CDA Release 1.0 specifies a highly structured header, yet utilizes generic clinical document body markup.
 - Supporting
 - Multiple sections containing:
 - Tables
 - List
 - Which can contain text, links to other
 Paragraphs documents or images, coded_entries and
 - Sections local markup.



CDA Release 1.0 at Mayo **MICS Notes Editor** COPYRIGHT (c) 2004 Mayo Foundation for Medical Education and Research

Goals for MICS Notes

- Strong desire to maintain:
 - Templated document entry
 - Entry automation
 - Digital dictation compatibility
 - Standards compliance
- Support to work with HL7 on Structured Documents Standards (CDA).
- Replacement of Notes-I & CDM Reports with a integrated document management system.



MICS Notes Editor

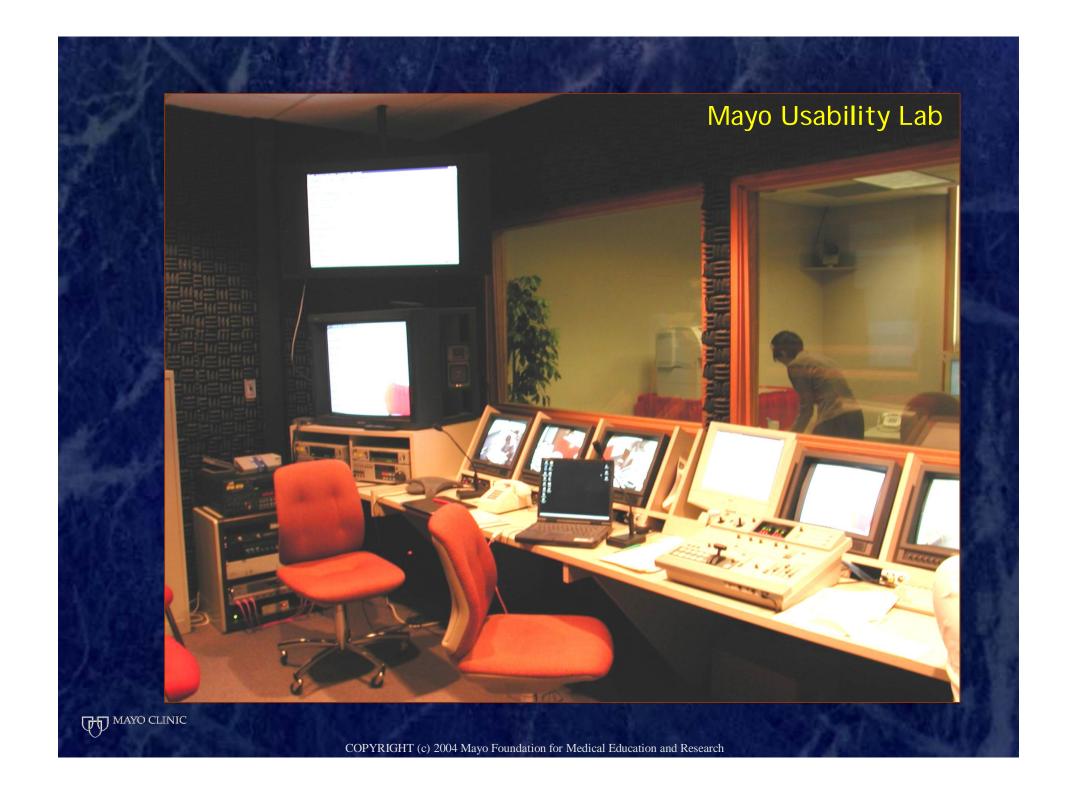
- MICS Notes Editor [xmIDP]
 - Co-developed with Pen!etics Development Inc www.penetics.com
 - Java-based text editor
 - Derived from a history of PDA and tablet entry
 - Writes "pure" XML documents (Unicode)
 - Powerful knowledge base (KB) and KB manager behind editor



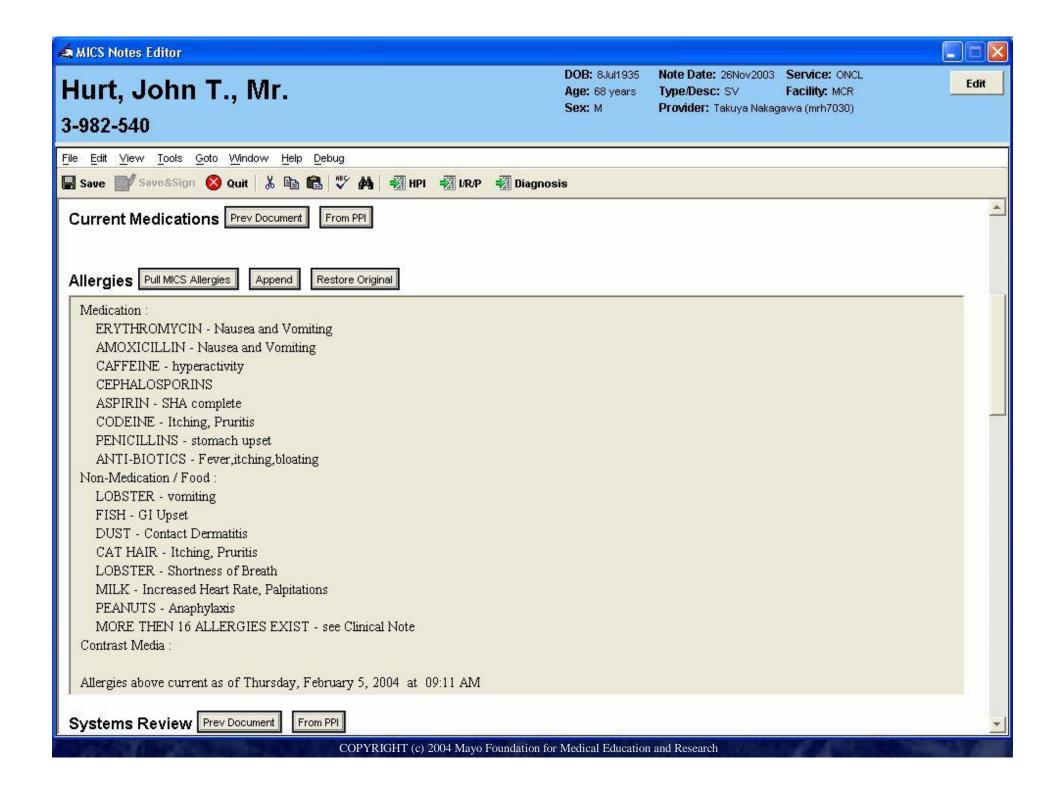
MICS Notes Editor

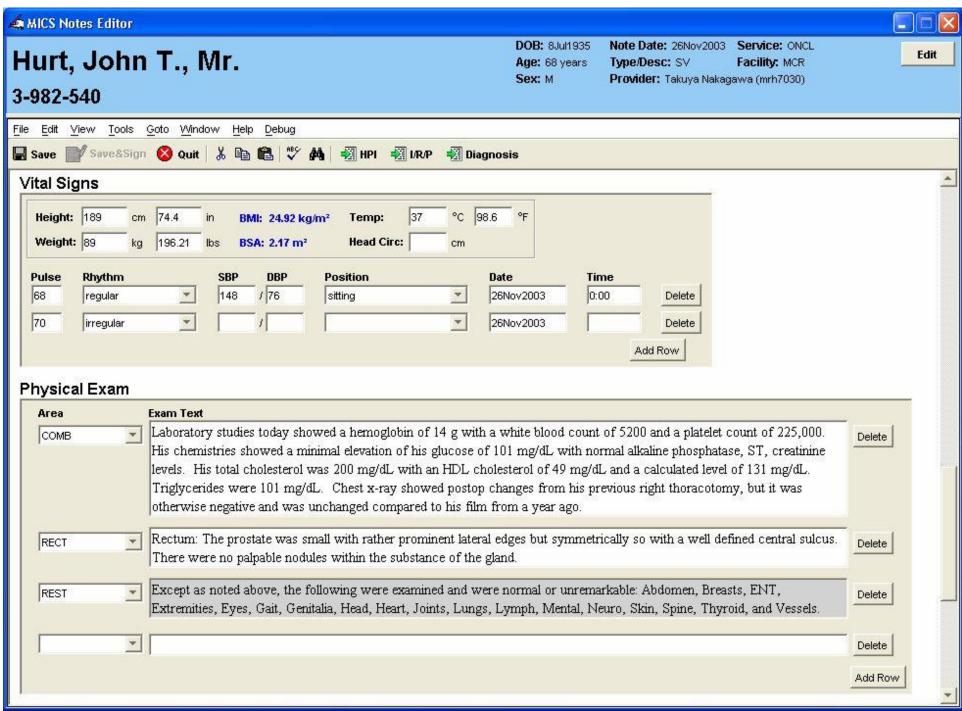
- Use case analysis identified a need to support both:
 - Transcriber
 - Self-entry provider
- 3 Usability & Process labs for Notes-II XML editor were used to refined the design.











New Approaches

- Generating Structured Content
 - One of the significant challenges in creating structured documents is the development of an efficiently means to create content.
 - For the MICS Notes editor, a mixture of custom dialogs and an integrated knowledge base are our principle solutions to this problem.



Vital Signs Panel

 MICS Editor uses panels like these to capture highly structured content.



Vital Signs data is needed for Growth Charts.



RIM - Act & Observation

 The Act and Observation classes are found in the HL7 Reference Information Model (RIM). These classes are used to model findings in the RIM and are useful references when considering the modeling of clinical findings within the Vital Signs table.



RIM - Act & Observation

Required Act Attributes:

ü 1. activity_time The time when the action happened.

2. availability_dttm The time at which a receiving system obtained information.

ü 3. confidentiality_cd A code that limits disclosure of information about this act.

4. critical_time The biologically relevant time of the action.

ü **5. id** The instance identifier for the act.

7. max_repeat_nmr This is the maximum number of repetitions of an act.

8. mood_cd Set for observation mood, as opposed to ordered, master reference or goal.

9. orderable ind Used in master reference mood for orderable acts.

10. priority_cd Specifies the urgency under which an act is scheduled or performed.

11. status_cd State of an action, pending, active, completed, cancelled or deleted.

12. txt Description of the act.

ü 13. type_cd A code to specify the act conceptually.

FT MAYO CLINIC

RIM - Act & Observation

Required Observation Attributes:

- 1. body site cd

2. derivation_expr

3. interpretation_cd

 4. method_cd used. Focus on a particular anatomic site, body part or body system.

Supports construction of associative expression based relationships.

Allows for a very rough interpretation of the course or outcome.

Several methods maybe used to obtain results, this says which was

ü 5. value

The result value of an observation action, finding.

In addition to the act / observation attributes identified, a number of classes related to Act are required to define the context of the observation. They include:

has service target has a service actor has a service actor for Patient for Originator for Legal Authenticator



Vital Signs Elements

Id

Value

Activity time

Type code

Patient

Authentication

ÜConfidentiality

üOriginator

Instance Identifier

The quantity or text associated

The time of the observation

LOINC concept code

Context required

Context required

Level One

Level One



Table Caption Code

<caption_cd> - The caption code element

- The caption code in the CDA / Notes II DTD is used to identify the concept associated with a container in the document. At CDA Level 1, no safe context can be assume, outside human readability.
- For Notes II, a locally defined table caption_cd will be assigned to the Vital Signs table. This code will identify Vital Sign tables and by policy, establish the Patient and Authenticator context.
 - For the Vital Signs table, the patient and authenticator contexts will assumed to be the document's.
- In addition, assignment of this code to a table stipulates that the table honor the **XPATH constraints** that have been defined for later machine processing.



Vital Signs Markup



Identifiers

<id> - The identifier element

- The <id> element is not required if the observation was originally entered into this document. In these cases, the identifier is assumed to be the document's identifier.
- If the content of the observation was obtained from another source such as a findings table in the LastWord system, then the <id> could be assigned the key value for the observation in the LastWord relational database.



Vital Signs Markup

```
<section>
  <caption>
    <caption cd V="12345-0" S="LOINC-OID-value"/> VITAL SIGNS
  </caption>
  <caption><caption cd V="2000-1" S="MAYO-OID-</pre>
value"/></caption>
    Date / Time
        18-Apr-2000 14:30
    Height
        <id EX="id-value" RT="OID-value"/>
           177.0 cm (69.7 in)
    Weight
        <id EX="id-value" RT="OID-value"/>
            88.0 kg (194.0 lbs.)
  </section>
```



Value

<value> - The value element

- The <value> element is used to provide a structured representation of the observations found within the Vital Signs table. Value is derived from the Observation class in the RIM and is used when the content of the observation is a Quantity, I.E. a measure with a unit. The reference for units is taken from "The Unified Code for Units of Measure", which can be obtained from : http://aurora.rg.iupui.edu/UCUM/
- In the situation where the observation is free text, we propose that we use PCDATA within the <content> element.
- When English measures and units are to be depicted within the table, a second optional <value> element will be included for its representation.



Vital Signs Markup

```
<section>
  <caption>
    <caption cd V="12345-0" S="LOINC-OID-value"/> VITAL SIGNS
  </caption>
  <caption><caption_cd V="2000-1" S="MAYO-OID-value"/></caption>
    Date / Time
        18-Apr-2000 14:30
    Height
        <id EX="id-value" RT="OID-value"/>
           <value V="177.0" U="cm"/>177.0 cm
           <value V="69.7" U="[in i]"/> 69.7 in
    Weight
        <id EX="id-value" RT="OID-value"/>
           <value V="88.0" U="kg"/>88.0 kg
           <value V="194.0" U="[lb-av]"/>194.0 lbs.
  </section>
```



Activity Time

<activity_tmr> - The activity time

- The Vital Signs table will be defined with date / time entries running across the top, in the first row. The date and time specification is the activity time associated with the individual reading. The activity times will run in chronological order, with oldest entries occurring in the second column, just after the heading entries for each of the vitals and proceeding to the most current entry recorded in the right most column.
- The choice between ACT.activity_time Vs ACT.critical_time needs to be discussed. For now we will specify activity time, however critical time maybe more appropriate. I will review at HL7 with other experts.



Vital Signs Markup

```
<section>
  <caption>
     <caption_cd V="12345-0" S="LOINC-OID-value"/> VITAL SIGNS
  </caption>
  <caption><caption cd V="2000-1" S="MAYO-OID-value"/></caption>
    Date / Time
        <activity tmr V="20000418T1430"/>
           18-Apr-2000 14:30
     Height
        <id EX="id-value" RT="OID-value"/>
           <value V="177.0" U="cm"/>177.0 cm
           <value V="69.7" U="[in i]"/> 69.7 in
     Weight
        <id EX="id-value" RT="OID-value"/>
           <value V="88.0" U="kq"/>88.0 kq
           <value V="194.0" U="[lb-av]"/>194.0 lbs.
  </section>
```

Vital Type

<caption_cd> - The type specification

- Within the Vital Signs table the <caption_cd> element is used to identify the concept of the observation that is recorded in the following cells of the table row. The concept will be encoded using the LOINC coding system.
- This carries the concept of the container encoding to its lowest level. The container that is being coded is the
 or table row.
- The presentation name for the concept is displayed redundantly as PCDATA in the > element. Although, not absolutely required, it simplifies the task of viewing the caption text within the editor that we are using to create and update the document.



Vital Signs Markup

```
<section>
  <caption><caption cd V="2000-1" S="MAYO-OID-value"/></caption>
     Date / Time
        <activity tmr V="20000418T1430"/>
           18-Apr-2000 14:30
     <caption cd V="3137-3" S="LOINC-OID-value"
                     DN="BODY HEIGHT"/>Height
        <id EX="id-value" RT="OID-value"/>
            <value V="177.0" U="cm"/>177.0 cm
            <value V="69.7" U="[in i]"/> 69.7 in
     <caption cd V="3141-9" S="LOINC-OID-value"</th>
                    DN="BODY WEIGHT"/>Weight
        <id EX="id-value" RT="OID-value"/>
            <value V="88.0" U="kq"/>88.0 kq
            <value V="194.0" U="[lb-av]"/>194.0 lbs.
  </section>
```

CDA Level 3 -

Vital Signs

18-Apr-2000 14:30

Date / Time

```
Height
                                                  177 cm (69.7 in)
   <section>
                                        Weight
                                                  88.0 kg (194.0 lbs.)
     <caption>
        <caption cd V="12345-0" S="LOINC-OID-value"/> VITAL SIGNS
     </caption>
     <caption><caption cd V="2000-1" S="MAYO-OID-</pre>
   value"/></caption>
        Date / Time
            <activity tmr V="20000418T1430"/>
               18-Apr-2000 14:30
        <caption cd V="3137-3" S="LOINC-OID-value"
                         DN="BODY HEIGHT"/>Height
            <id EX="id-value" RT="OID-value"/>
               <value V="177.0" U="cm"/>177.0 cm
               <value V="69.7" U="[in i]"/> 69.7 in
        <caption cd V="3141-9" S="LOINC-OID-value"
                         DN="BODY WEIGHT"/>Weight
            <id EX="id-value" RT="OID-value"/>
               <value V="88.0" U="kg"/>88.0 kg
               <value V="194.0" U="[lb-av]"/>194.0 lbs.
     F M * Section>
```

Vital Signs - Presentation

Vital Signs

Date / Time	18-Apr-2000 14:30	18-Apr-2000 15:30
Height	177 cm (69.7 in)	177 cm (69.7 in)
Weight	88.0 kg (194.0 lbs.)	88.0 kg (194.0 lbs.)
ВМІ	28.1 kg/m²	28.1 kg/m²
BSA	2.05 m²	2.05 m²
Temperature	36.9 °C (98.5 °F)	36.9 °C (98.5 °F)
Head Circ	61 cm	61 cm
Pulse	76 /minute	74 /minute
Rhythm	Regular	Regular
Systolic	132 mmHg	135 mmHg
Diastolic	86 mmHg	88 mmHg
Position / Cuff	Left Arm	Left Arm

Activity time use to record the ACT.Activity_time of the service act.

Caption code used to record Act.type_cd for the vital entries on current row.

Value use to encode the Observation.value (finding) of the activity.

Id use to identify the Act.id of the vital in an external source.

Vital Signs - Conformance

XPATH Access Methods

- To ensure proper machine processing of the Vital Signs entries within tables with caption_cd = 2000-1. A series of XPATH expressions have been created as a conformance specification.
- Implementations at Mayo will need to be validated using these expressions and certified before being allowed to create Vital Sign tables.



Vital Signs - Conformance

Entries	XPath Expression	Notes	
Vitals Table	/table[caption/caption_cd/@V = "2000-1"]	Only one vital signs table is assumed.	
Activity Time	tr/th [n]/@activity_tmr	n = vitals column + 1	
Observation(s)			
Height	tr[th/caption_cd/@V="3137-3"]/td [m]	m = vitals observation column	
Weight	tr[th/caption_cd/@V ="3141-9"]/td [m]	m = vitals observation column	
BMI	tr[th/caption_cd/@V ="?????-?"]/td [m]	m = vitals observation column	
BSA	tr[th/caption_cd/@V ="?????-?"]/td [m]	m = vitals observation column	
Temperature	tr[th/caption_cd/@V = '8310-5']/td [m]	m = vitals observation column	
Respiratory	tr[th/caption_cd/@V ="?????-?"]/td [m]	m = vitals observation column	
Pulse	tr[th/caption_cd/@V ="?????-?"]/td [m]	m = vitals observation column	
Rhythm	tr[th/caption_cd/@V ="?????-?"]/td [m]	m = vitals observation column	
Systolic	tr[th/caption_cd/@V ="?????-?"]/td [m]	m = vitals observation column	
Diastolic	tr[th/caption_cd/@V ="?????-?"]/td [m]	m = vitals observation column	
Position / Cuff	tr[th/caption_cd/@V ="?????-?"]/td [m]	m = vitals observation column	
ID / Value / Unit			
${ m I\!D}$	id/@id		
Metric Value	value/@V[1]		
Metric Unit	value/@U[1]		
English Value	value/@V[2]	AUDINOUS DESIGNATION	
English Unit	value/@U[2]	STATISTICAL PROPERTY OF THE PARTY OF THE PAR	



Vital Signs Conformance

Üld Optionally in elements.

ÜValue Found in elements.

ÜActivity time Found in row = 1, column > 1

ÜType code Found in column =1, row > 1

ÜPatient Context taken from doc header

ÜAuthentication Context taken from doc header

ÜConfidentiality Level One

ÜOriginator Level One



Summary

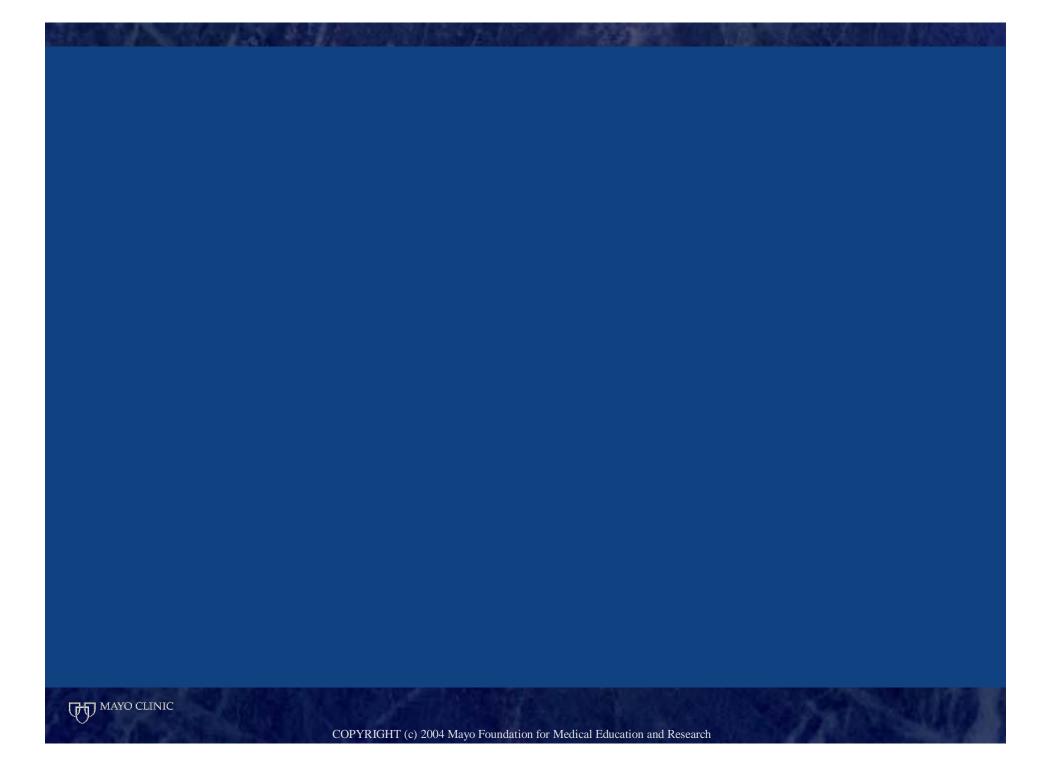
- The Vital Signs representation at Release 1.0 is not directly supported by the CDA standard. Local markup was used to support our machine processing requirements defined at Mayo.
- XPath expressions can be useed in defining conformance expectations for complex XML objects.
- Basing our extensions upon the HL7 Reference Information Model, has assured us a means to transform our content from Release 1.0 to 2.0.



MICS Notes Editor

- In addition, to standardized panels, the new editor supports scripting similar to Shorthand™.
 - Support for End User scripting.
 - Scripting works for some areas.
 - Support placing codes within the text of a document.
 - Leverage KB scripts to enrich content of clinical documents.





MICS Notes Editor

- Notes-II XML Editor Knowledge base
 - Nodes created in KB Admin
 - ü Each node represents atomic info for charting
 - ü Node links are parent : child
 - ü Node display = KB tree
 - Extensive keyboard automation



MICS Notes Editor

- Pilot release, supporting Clinical Notes entry:
 - Standard panels for: Vital Signs, Physical Exams
 - Transcription and Physician entry supported
 - Extensive keyboard automation
 - MS-WordTM like interface
- This year we will be incorporating:
 - Provider KB scripting support
 - Hospital Summaries entry



Regional Use of CDA

• Add graphic here...



Acceptance of CDA World Wide

 Since it's approval in 2000, CDA release 1 has been used world wide at a number of sites.

 HL7 International CDA Conference cosponsored by HL7 Germany and HL7 Finland.

October 7-9, 2002



Conference Presentations

- GMS PICNIC: Ireland, Denmark, Crete
 - Pharmacy Patient Validation & Electronic Claims Reimbursement
- Seamless Care and CDA: Finland
 - Regional Electronic Patient Record System
- SCIPHOX: Germany
 - Standardization of Communication between Information Systems in Physician Offices and Hospitals using XML



Conference Presentations

- HL7 CDA in HYGEIAnet : Crete
 - Regional Health Information Network of Crete
- CDA at the University of Munster
 - Discharge Patient Documentation and more.
- CDA for MERIT-9: Japan
 - Research projects of Japanese Ministry of Health and Welfare to facilitate clinical data exchanges.



Conference Presentations

- CDA in Staffordshire EHR: UK
 - Clinical content for emergency care scenarios
- CDA in Taiwan
 - Discharge Summary Case Study
- CDA at the University of Heidelberg
 - XML based discharge letters in internal medicine using CDA Level One.



2004 Annual HIMSS Conference and Exhibition

- Dictaphone
 - CCR
 - Discharge Summary
 - Imaging Report /Release 1 / Level 1
 - Surgical Report / Release 1 / Level 1
- Epic
 - Discharge Summary
- Microsoft InfoPath
 - CCR referral for admission / Release 2
 - Pathology Report



Overall Interest in CDA continues to grow.

- Over 3000+ Google hits on "HL7 CDA", the number of projects is growing world wide.
- The International HL7 Affiliates have underwritten a 2'nd International CDA Conference in Oct, 2004.

CDA Next Generation – Release 2.0



CDA Release 2

The basic model of CDA is essentially unchanged. A CDA document has a similar header, however it is the body which has been enhanced, it contains a much richer assortment of entries to use within CDA structures.

CDA, Release Two enables clinical content to be formally expressed to the extent that is it modeled in the RIM.

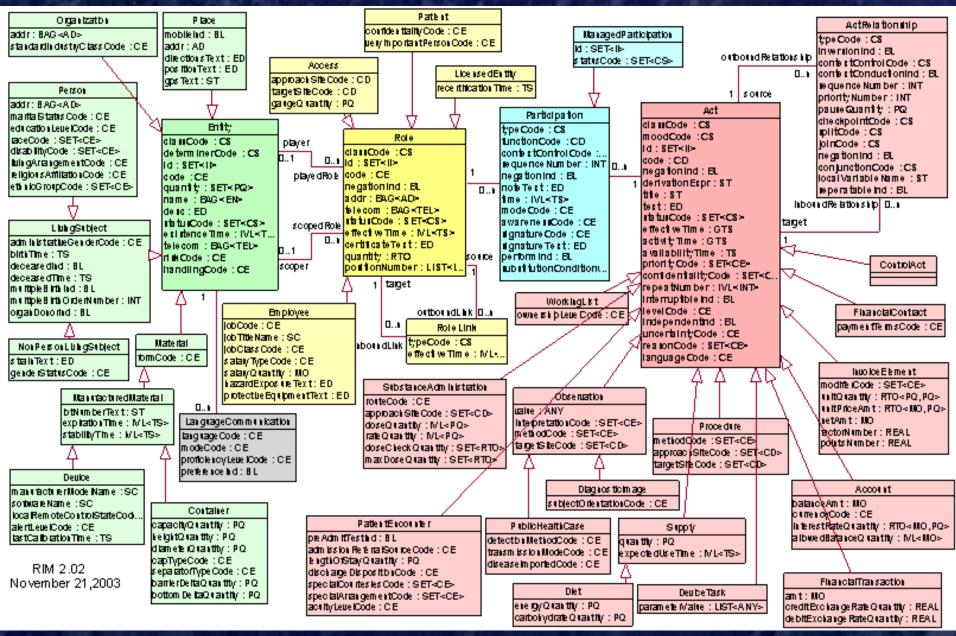


CDA Release 2.0

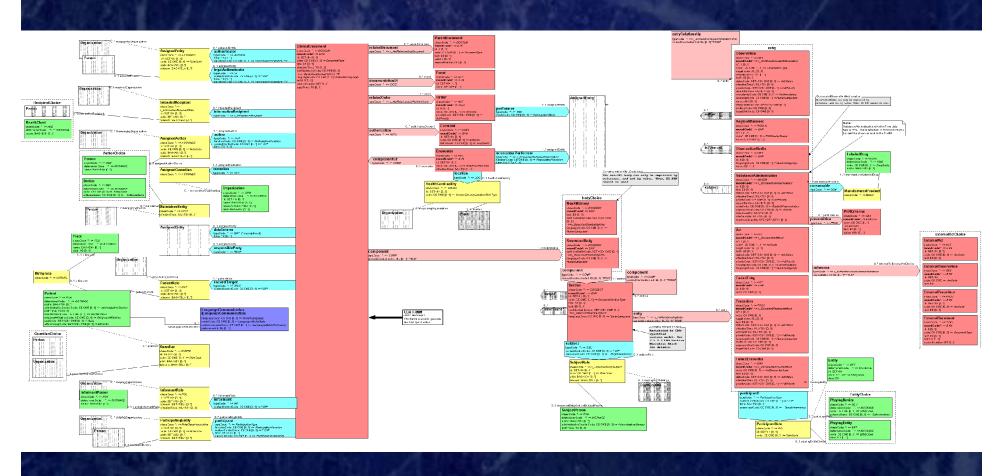
- New Features & Enhancements:
 - Greater structured content support
 - Transform document relationships
 - Authenticated content defined
 - Region of Interest support
 - Delete and Insert support (Revisions)
 - Bold, Italic and Underline support
 - Greater V3 conformance (More RIM)



HL7 RIM Model



CDA – Refined Message Information Mode (R-MIM)



Release 1 à Release 2

Structured Header

Section
w/ paragraphs, tables
and lists containing
text w/ coded entries

Section
w/ paragraphs, tables
and lists containing
text w/ coded entries

Structured Header

Section w/ paragraphs, tables and lists containing text.

CDA R-MIM Entries

Section w/ paragraphs, tables and lists containing text.

CDA R-MIM Entries



CDA Entries

Coded Entry

(Deprecated)

- ACT
 - FutureEncounter
 - Observation
 - ObservationMedia
 - Procedure
 - RegionOfInterest
 - SubstanceAdministration



CDA Entries

An ACT can be expressed in different tenses or MOODS: Order for, Plan to, Occurrence of, ...

- ACT
 - FutureEncounter
 - Observation
 - ObservationMedia
 - Procedure
 - RegionOfInterest
 - SubstanceAdministration

10 types of relationships exist between acts:



Summary of CDA Release 2.0 Goals in the Future...

- Support for a standardized means of modeling structured content for the purposed of exchange.
- Continued enhancement to the standard based upon demonstrated use cases.



Why CDA?

Readable

- CDA Level 1 looked like our documents: narrative, multisectioned
- Version 3 modeling approach promises machine processability

Durable

- Our documents needed to survive technology changes
- Our paper based system has lasted 100 years

Shareable

- Standards based document exchange \$\$ savings
- Developing needs for Regional partners and others

Flexible

- Multi-media & web technology support day one
- An architecture to cover all the documentation needs of Mayo.



MICS Notes II Team

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- Huhn, Jeff
- Rosemark, Jim
- Nakagawa, Takuya
- Mohsin, Mohammad

Implementation Team

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- Krahn, Linda
- Voller, David
- Lucas, Tom



Thank You

- Dr Paul Carpenter,
 - Document Oversight Chair
- Dr David Mohr
 - MICS Oversight Chair



