



HL7 Clinical Document Architecture

Bob Dolin, MD, FACP, FACMI
Chair, HL7

What is the CDA?

- The CDA is a document markup standard for the structure and semantics of an exchanged "clinical document".
- A clinical document is a documentation of observations and other services with the following characteristics:
 - Persistence
 - Stewardship
 - Potential for authentication
 - Context
 - Wholeness
 - Human readability
- A CDA document is a defined and complete information object that can exist outside of a message, and can include text, images, sounds, and other multimedia content.



CDA Business Case

- **CDA hits the “sweet spot”** – CDA encompasses all of clinical documents. A single standard for the entire EHR is too broad. Multiple standards and/or messages for each EHR function may be difficult to implement. CDA is “just right”.
- **Implementation experience** - CDA has been a normative standard since 2000, and has been balloted through HL7's consensus process. CDA is widely implemented.
- **Gentle on-ramp to information exchange** - CDA is straight-forward to implement, and provides a mechanism for incremental semantic interoperability.
- **Improved patient care** - CDA provides a mechanism for inserting evidence-based medicine directly into the process of care (via templates), making it easier to do the right thing.
- **Lower costs** – CDA's top down strategy let's you implement once, and reuse many times for new scenarios.



CDA provides a gentle on-ramp to information exchange

■ A minimally conformant CDA document:

```
<ClinicalDocument>
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
  <id root="2.16.840.1.113883.19.4"/>
  <code code="11488-4" codeSystem="2.16.840.1.113883.6.1"/>
  <effectiveTime value="20000407"/>
  <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>
  <recordTarget>
    <patientRole><id root="2.16.840.1.113883.19.5"/></patientRole>
  </recordTarget>
  <author>
    <time value="2000040714"/>
    <assignedAuthor><id root="2.16.840.1.113883.19.5"/></assignedAuthor>
  </author>
  <custodian>
    <assignedCustodian>
      <representedCustodianOrganization>
        <id root="2.16.840.1.113883.19.5"/>
      </representedCustodianOrganization>
    </assignedCustodian>
  </custodian>
  <legalAuthenticator>
    <time value="20000408"/>
    <signatureCode code="S"/>
    <assignedEntity><id root="2.16.840.1.113883.19.5"/></assignedEntity>
  </legalAuthenticator>
  <component>
    <nonXMLBody>
      <text mediaType="text/plain"><reference value="1598765.txt"/></text>
    </nonXMLBody>
  </component>
</ClinicalDocument>
```



Key aspects of the CDA

- CDA documents are encoded in Extensible Markup Language (XML).
- CDA is derived from HL7's central Reference Information Model (RIM), thereby enabling data reusability - with lab or pharmacy messages, with claims attachments, clinical trials, etc.
- The CDA specification is richly expressive and flexible. Templates, conformance profiles, and implementation guides can be used to constrain the generic CDA specification.



CDA Guiding Principles

- Give priority to documents generated by clinicians involved in direct patient care.
- Minimize the technical barriers needed to implement the Standard.
- Promote longevity of all information encoded according to this architecture.
- Promote exchange that is independent of the underlying transfer or storage mechanism.
- Enable policy-makers to control their own information requirements without extension to this specification.



Major Components of a CDA Document

- A CDA document has a Header and a Body.
- A CDA document Body is comprised of Sections.
- A CDA Section contains one Narrative Block and zero to many Entries.
 - [1..1] Header
 - [1..1] Body
 - [1..*] Sections
 - [1..1] Narrative block
 - [0..*] Entries



Major Components of a CDA Document

```
<ClinicalDocument>
```

```
...
```

```
<structuredBody>
```

```
<section>
```

```
<text>...</text>
```

```
<observation>...</observation>
```

```
<substanceAdministration>
```

```
<supply>...</supply>
```

```
</substanceAdministration>
```

```
<observation>
```

```
<externalObservation>
```

```
...
```

```
</externalObservation>
```

```
</observation>
```

```
</section>
```

```
<section>
```

```
<section>...</section>
```

```
</section>
```

```
</structuredBody>
```

```
</ClinicalDocument>
```

Header

Narrative Block

ENTRIES

SECTIONS

BODY

DOCUMENT

External
References

CDA, Release One

Allergies and Adverse Reactions

- Penicillin - Hives
 - Aspirin - Wheezing
 - Codeine – Itching and nausea
-

ANSI/HL7 CDA R1.0-2000

```
<section>
  <caption>
    <caption_cd V="48765-2" S="LOINC"/>
      Allergies and Adverse Reactions
  </caption>
  <list>
    <item><content ID="A1">Penicillin - Hives</content></item>
    <item><content>Aspirin - Wheezing</content></item>
    <item>
      <content>Codeine - Itching and nausea</content>
    </item>
  </list>
  <coded_entry>
    <coded_entry.value ORIGTXT="A1"
      V="DF-10074" S="SNOMED" DN="Allergy to Penicillin"/>
  </coded_entry>
</section>
```

CDA, Release Two

```
<section>
  <code code="48765-2" codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC"/>
  <title>Allergies and Adverse Reactions</title>
  <text>
    <list>
      <item><content ID="A1">Penicillin - Hives</content></item>
      <item>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"
        codeSystemName="SNOMED CT" displayName="Hives">
        <originalText><reference value="#A1"/></originalText>
      </code>
      <entryRelationship typeCode="MFST">
        <observation classCode="OBS" moodCode="EVN">
          <code code="91936005" codeSystem="2.16.840.1.113883.6.96"
            codeSystemName="SNOMED CT"
            displayName="Allergy to penicillin"/>
          </observation>
        </entryRelationship>
      </observation>
    </entry>
  </section>
```

CDA is based on a principle of *Incremental Interoperability*

- *Incremental Interoperability* means that an implementer can begin with a simple CDA, and then add structured data elements over time.
- CDA R2 consists of a single CDA XML Schema, and the “architecture” arises from the ability to apply one or more “templates” which serve to constrain the richness and flexibility of CDA.
- Professional society recommendations, national clinical practice guidelines, standardized data sets can be expressed as CDA templates.
- There are many kinds of templates that might be created. Two are particularly relevant for documents:
 - Those that constrain the document sections based on the type of document (section-level templates);
 - Those that constrain the entries within document sections (entry-level templates).

