Introduction to Consolidated CDA (C-CDA)

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Instructor

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- ## Lantana Consulting Group
  - Our Mission:
    - Improve healthcare through health information technology (IT)
    - Lead the industry through our consulting and volunteer practice
  - Our Services:
    - Software & standard development & implementation
    - Terminology, data governance, and education
    - Strategic advice for health IT planning, design, and purchasing

Learning Objectives

- History and need for the guide

- Use cases for each document type

- How to read and understand the guide

- Similarities and differences with past work
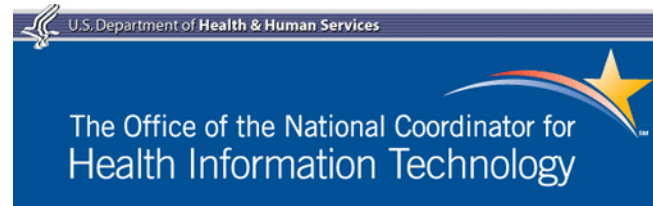
- Available tools and resources

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HISTORY AND NEED

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The 'Situation'

C-CDA

Key Participants

Approximately 140 volunteers participating in weekly calls and offline work

HL7 Consolidated CDA IG (C-CDA)

CDA Consolidation

- 9 Clinical Documents
- 60 Document Sections
- 66 Clinical Statements
- 156 Templates
- 239 Figures
- 285 Tables
- 508 Pages
- ~2100 Conformance Clauses
- **1 PDF Document**
- **1 Source**
- **Model Driven Tools**

Prior State

- ~20 clinical documents
- ~110 Sections
- ~200 Clinical Statements
- 500+ Templates
- 800+ Pages
- 3000+ Conformance Clauses
- 17 PDF Documents
- 3 sources
- No Tools

R1.1 published July 2012

Consolidation Project Goals

- Update and harmonize C32 while addressing known issues (ambiguity, gaps, etc.)
  - Initially, those issues identified by ONC and required for Meaningful Use (open technical issues from HITSP, etc.)
  - Next, those reused in Health Story
  - Finally, if time allows, full set of CCD/C32 templates

- Proof of concept for model-driven, structured tools supporting easy to use developer documentation

- Rapid demonstration of templated CDA as a data element centric paradigm for health information exchange

Consolidation Project Scope

- **Success criteria**
  - Publication as DSTU in time for recognition under the next stage of Meaningful Use
  - Subsequent adoption across the industry
  - Development of related International Guides should follow

- **Note: *revisions to source specifications* not *required by consolidation are out of scope***

DOCUMENTS AND USE CASES

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Clinical Documents

- Continuity of Care Document 1.1
- History and Physical
- Consult Note
- Discharge Summary
- Diagnostic Imaging Report
- Procedure Note
- Operative Note
- Progress Note
- Unstructured Document

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Continuity of Care Document 1.1

- Core data set of the most relevant patient healthcare data, covering one or more encounters.

- Enables aggregation of **pertinent** data about a patient

- Supports continuity of care

- Provide a snapshot in time of patient data

- CCD 1.1 was designed to comply with Stage 1 Meaningful Use and be ready for Stage 2

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History and Physical

- Supports hospital admission, preoperative review, and initial ambulatory patient assessments
  - Current complaint or reason for encounter
  - Past or ongoing medical issues
  - Current medications and allergies
  - Physical examination and vital signs
  - Diagnostic test results
  - Assessment and Care plan

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Consult Note

- Supports consultations (request for advice) from one provider to another. Includes CMS required content for a Consultation Evaluation and Management procedure.

  - Reason for Referral/Visit

  - History of Present Illness

  - Physical Examination

  - Assessment and Plan

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Discharge Summary

- Summarizes a patient's admission to a hospital; it provides pertinent information for the continuation of care following discharge.
  - Conforms to Joint Commission Requirements
  - Includes
    - Reason for Admission
    - Procedures Performed
    - Care, Treatment and Services provided
    - Patient condition and disposition at discharge
    - Information provided to patient and family
    - Provisions for follow-up care

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Diagnostic Imaging Report

- Provides a specialist's interpretation of image data. It conveys the interpretation to the referring (ordering) physician and becomes part of the patient's medical record.

- For use in Radiology, Endoscopy, Cardiology, and other imaging specialties.

- Supports X-Ray, Fluoroscopy, Mammography, CT, MR, Ultrasound, Endoscopic and other imaging techniques

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Procedure Note

- Documents non-operative procedures including interventional cardiology, interventional radiology, gastrointestinal endoscopy, osteopathic manipulation, and many other specialty fields.

- The procedure note must be sufficiently detailed to justify the procedure, describe the course of the procedure, and provide continuity of care

  - Indications for the procedure

  - Post-procedure diagnosis

  - Pertinent events of the procedure

  - Patient's tolerance

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Operative Note

- Documents a surgical procedure. The operative note should be sufficiently detailed to support the diagnoses, justify the treatment, document the course of the procedure, and provide continuity of care.
  - Pre- and post-surgical diagnosis,
  - Pertinent events of the procedure,
  - Post-procedure patient condition.

Progress Note

- Documents a patient's ongoing progress and clinical status during a hospitalization or outpatient visit.
- Not used for a Medicare Progress Report

Unstructured Document

- Documentation captured in an unstructured format encapsulated within an image or unstructured text file.

Text Formats	
MSWord	application/msword*
PDF	application/pdf
Plain Text	text/plain
RTF Text	text/rtf
HTML	text/html

Image Formats	
GIF Image	image/gif
TIF Image	image/tiff
JPEG Image	image/jpeg
PNG Image	image/png

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READING THE GUIDE

Guide Structure

- Conformance Clauses

- Dealing with Unknown and Negation

- Document Templates

- Section Templates

- Entry Templates

Conformance Clauses

1. **SHALL** contain exactly one [1..1] @**classCode**="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:7345).

- Conformance Verb
- Cardinality
- CDA XML element or attribute path
- Value Sets

Conformance Verbs

- **SHALL**
an absolute requirement

- **SHALL NOT**
an absolute prohibition against inclusion

- **SHOULD/SHOULD NOT**
best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course

- **MAY/NEED NOT**
truly optional; can be included or omitted as the author decides with no implications

See HL7 Version 3 Publishing Facilitator's Guide

Cardinality

- In English and numeric:

  - zero or one [0..1]

  - exactly one [1..1]

  - at least one [1..*]

  - zero or more [0..*]

  - at least one and not more than n [1..n]

Value Sets

1. **SHALL** contain exactly one [1..1] **value with @xsi:type="CD"**, where the @code **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.6.8 Problem Severity **DYNAMIC** (CONF:7356).

OID and Name

- Value set identifier and descriptive name

STATIC vs DYNAMIC

- They are bound to a specified version of a vocabulary in value set
- They are bound to the most current version of the vocabulary used for the value set

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Use of nullFlavor

- Use of null values is allowed in elements unless explicitly prohibited.
  - Allowed
    1. **SHALL** contain at least one [1..*] **id**
  - Prohibited
    1. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:5256).
       a. **SHALL NOT** contain [0..0] nullFlavor (CONF:52580).
- Required attributes must be present and cannot be null.
  1. **SHALL** contain exactly one [1..1] **effectiveTime/@value** (CONF:5256).

Unknowns and Negations

- Unknown or Negation is a statement about an occurrence. Did this occur?
  - ➤ Yes
  - ➤ No
  - ➤ I don't know (because …)
- Descriptive properties of the occurrence, date/time, type of occurrence, other features, further refine what has been negated or stated as unknown.

Unknown

Features of an Act

If the sender doesn't know an attribute of an act, that attribute can be null.

```
<substanceAdministration >
...
  <effectiveTime xsi:type="IVL_TS">
     <low value="20140118"/>
     <high nullFlavor="NI"/>
  </effectiveTime>
...
</substanceAdministration>
```

Taken from: Med every 4-6 hours

Entire Section

If the sender doesn't know if an act occurred, the nullFlavor is on the act (detail could include specific allergy, drug, etc.).

```
<!-- nullFlavor of NI indicates No Information.-->
<section nullFlavor="NI">
<!-- conforms to Problems section with entries required -->
  <templateId root="2.16.840.1.113883.10.20.22.2.5.1"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.5.1"
                extension="2015-08-01"/>
  <code code="11450-4"
        codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC"
        displayName="PROBLEM LIST"/>
  <title>PROBLEMS</title>
  <text>No Information</text>
</section>
```

Taken from: General - No Section Information Problems

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No Known

If the sender wants to state 'no known', a negationInd can be used on the corresponding act (substanceAdministration, Procedure, etc.)

```
<substanceAdministration negationInd="true">
…
 <manufacturedProduct classCode="MANU">
            <templateId root="2.16.840.1.113883.10.20.22.4.23" extension="2014-06-09"/>
…
            <manufacturedMaterial>
              <code nullFlavor="OTH" codeSystem="2.16.840.1.113883.6.88">
                <translation code="410942007" displayName="drug or medication"
                    codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>
              </code>
            </manufacturedMaterial>
…
</substanceAdministration>
```

See No Medications example

CDA Example Task Force

- Purpose: collect and share member submitted samples
- Meets every Thursday at noon ET
  - http://wiki.hl7.org/index.php?title=CDA_Example_Task_Force
- Examples from this group populate the HL7 CDA example search tool
  - http://cdasearch.hl7.org/
- Demonstration on the following slide…

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No Known – Allergies

- **No Known Allergies**

- **No Known Medication Allergies**

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Templates

- A template is an expression of a set of constraints on the base CDA model applying additional constraints to a portion of an instance of data.

- Templates are used to further define and refine the CDA model to specify a narrower and more focused scope.

- In other words, a template is a layer of constraints applied to a more generic model to narrow the scope of that model for a specific use case or implementation.

- **Example**: narrow the scope of a CDA observation, which can (theoretically) describe any kind of observation, to a single concept, e.g., an Allergy Observation.

Templates

CDA without Templates

- Like a kitchen full of raw ingredients, with no menu, recipes, cookbooks, or other guidance.

- Very flexible, but hard to use without experience.

- Only the cook understands the meal before it arrives at the table.

- Hard to say something has been prepared incorrectly when there was not agreement on what was being cooked

CDA with Templates

- Same kitchen, but…

- Full menu with recipes.

- Food is prepped.

- Less flexible, but easier for the novice.

- The cook and the diner know what to expect.

- If the dish is prepared incorrectly, the diner can point to the menu description and notify the restaurant that they have a problem

Templates and Conformance Statements

Templates are composed of conformance statements.

Conformance statements express the rules to follow.

2.64.1 Results Section (entries required) (V3)

```
[section: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.2.3.1:2015-08-01
(open)]
```

1. Conforms to Results Section (entries optional) (V3) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.3:2015-08-01).
2. MAY contain zero or one [0..1] @nullFlavor="NI" No information (CodeSystem: HL7NullFlavor urn:oid:2.16.840.1.113883.5.1008) (CONF:1198-32875).
3. SHALL contain exactly one [1..1] templateId (CONF:1198-7108) such that it
   a. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.2.3.1" (CONF:1198-9137).
   b. SHALL contain exactly one [1..1] @extension="2015-08-01" (CONF:1198-32592).
4. SHALL contain exactly one [1..1] code (CONF:1198-15433).
   a. This code SHALL contain exactly one [1..1] @code="30954-2" Relevant diagnostic tests and/or laboratory data (CONF:1198-15434).
   b. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1198-31040).
5. SHALL contain exactly one [1..1] title (CONF:1198-8892).
6. SHALL contain exactly one [1..1] text (CONF:1198-7111).

Open vs. Closed Templates

- **Open**: the template can be extended, everything not explicitly prohibited is allowed.

- **Closed**: the template is fully specified. Anything not explicitly allowed is prohibited.

Instructions
[act: templateId 2.16.840.1.113883.10.20.22.4.20(open)]

Estimated Date of Delivery
[observation: templateId 2.16.840.1.113883.10.20.15.3.1(closed)]

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The General Header Constraints

- Common set of constraints on the CDA Header
  - Identifies it as conforming to US Realm
  - Must have a title
  - Fixes precision of creation date
  - Patient, Author, Custodian required
  - Legal Authenticator recommended
  - Guardian, Data Enterer, Informant, Information Recipient, other Authenticators and participants are optional

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Patient and Person Name

- Adds rules for Patient Name and person name
  - Patient Names must be fielded, and must contain family/given name elements. (PTN.US.FIELDED)
  - Person names may be fielded, or strings, but not a combination (PN.US.FIELDED)

Addresses (AD.US.FIELDED)

- Must be fielded (no mixed content)
- Limited number of address lines (4)
- Street and City required
- State, Postal Code and Country recommended

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Document Template Organization

- **Header Constraints**
  - templateId
  - code
- **Body Constraints (Section Requirements)**
- **Template Containment Table**

Template Title	Template Type	templateId
Continuity of Care Document (CCD)	document	2.16.840.1.113883.10.20.22.1.2
Allergies Section (entries required)	section	2.16.840.1.113883.10.20.22.2.6.1
Allergy Problem Act	entry	2.16.840.1.113883.10.20.22.4.30
Allergy Observation	entry	2.16.840.1.113883.10.20.22.4.7
Allergy Status Observation	entry	2.16.840.1.113883.10.20.22.4.28
Reaction Observation	entry	2.16.840.1.113883.10.20.22.4.9

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Section Template Organization

- ## Context

- ## Common Constraints

  - ➢ templateId

  - ➢ code

  - ➢ title

  - ➢ text

  - ➢ entry

Procedure Activity Act (V2)

[act: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.12:2014-06-09 (open)]

Table 427: Procedure Activity Act (V2) Contexts

Contained By:	Contains:
Procedures Section (entries optional) (V2) (optional)	Service Delivery Location (optional)
Procedures Section (entries required) (V2) (optional)	Medication Activity (V2) (optional)
Planned Intervention Act (V2) (optional)	Indication (V2) (optional)
Intervention Act (V2) (optional)	Instruction (V2) (optional)
	Author Participation (optional)

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General Section Structure

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:1198-7877) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.5" (CONF:1198-10440).
   b. **SHALL** contain exactly one [1..1] **@extension**="2015-08-01" (CONF:1198-32511).
2. **SHALL** contain exactly one [1..1] **code** (CONF:1198-15407).
   a. This code **SHALL** contain exactly one [1..1] **@code**="11450-4" Problem List (CONF:1198-15408).
   b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1198-31141).
3. **SHALL** contain exactly one [1..1] **title** (CONF:1198-7879).
4. **SHALL** contain exactly one [1..1] **text** (CONF:1198-7880).
5. **SHOULD** contain zero or more [0..*] **entry** (CONF:1198-7881) such that it
   a. **SHALL** contain exactly one [1..1] **Problem Concern Act (V3)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.3:2015-08-01) (CONF:1198-15505).
6. **MAY** contain zero or one [0..1] **entry** (CONF:1198-30481) such that it
   a. **SHALL** contain exactly one [1..1] **Health Status Observation (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.5:2014-06-09) (CONF:1198-30482).

```xml
<section>
   <templateId root="2.16.840.1.113883.10.20.22.2.5"
               extension="2015-08-01"/>
   <code code="11450-4"
      codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC"
      displayName="PROBLEM LIST"/>
   <title>PROBLEMS</title>
   <text>
      <list listType="ordered">
      <item>Pneumonia: Resolved in March 1998 </item>
      <item>...</item>
      </list>
   </text>
   <entry typeCode="DRIV">
      <act classCode="ACT" moodCode="EVN">
      <!-- Problem Concern Act template -->
      ...
      </act>
   </entry>
</section>
```

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Entry Template Organization

- Context
- Constraint Overview
- Value Sets
- Example

XPath	Card.	Verb	Data Type	CONF#	Fixed Value
act (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.3:2015-08-01)					
@classCode	1..1	SHALL		1198-9024	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = ACT
@moodCode	1..1	SHALL		1198-9025	urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN
templateId	1..1	SHALL		1198-16772	
@root	1..1	SHALL		1198-16773	2.16.840.1.113883.10.20.22.4.3
@extension	1..1	SHALL		1198-32509	2015-08-01
id	1..*	SHALL		1198-9026	
code	1..1	SHALL		1198-9027	
@code	1..1	SHALL		1198-19184	CONC
@codeSystem	1..1	SHALL		1198-32168	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = 2.16.840.1.113883.5.6

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Value Set Table

Value Set: Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 STATIC 2008-12-18		
Code System(s):	SNOMED CT 2.16.840.1.113883.6.96	
Description:	**This value set indicates the level of medical judgment used to determine the existence of a problem. Value Set Source: https://vsac.nlm.nih.gov/valuesets**	
Code	**Code System**	**Print Name**
404684003	SNOMED CT	Finding
409586006	SNOMED CT	Complaint
282291009	SNOMED CT	Diagnosis
64572001	SNOMED CT	Condition
248536006	SNOMED CT	Functional limitation
418799008	SNOMED CT	Symptom
55607006	SNOMED CT	Problem

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Sample XML

```xml
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.4"/>
  <!-- Problem Observation template -->
  <id root="d11275e7-67ae-11db-bd13-0800200c9a66"/>
  <code code="409586006"
        codeSystem="2.16.840.1.113883.6.96"
        displayName="Complaint"/>
  <text>
        ...
  </text>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="1950"/>
  </effectiveTime>
  <value xsi:type="CD" code="195967001"
         codeSystem="2.16.840.1.113883.6.96"
         displayName="Asthma"/>
</observation>
```

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CCD Document Content

Section	Opt	CCD 1.1	HITSP C32
Allergies	SHALL	2.16.840.1.113883.10.20.22.2.6.1	2.16.840.1.113883.10.20.1.2 2.16.840.1.113883.3.88.11.83.102 1.3.6.1.4.1.19376.1.5.3.1.3.13
Medications	SHALL	2.16.840.1.113883.10.20.22.2.1.1	2.16.840.1.113883.10.20.1.8 2.16.840.1.113883.3.88.11.83.112 1.3.6.1.4.1.19376.1.5.3.1.3.19
Problems	SHALL	2.16.840.1.113883.10.20.22.2.5.1	2.16.840.1.113883.10.20.1.11 2.16.840.1.113883.3.88.11.83.103 1.3.6.1.4.1.19376.1.5.3.1.3.6
Results	SHALL	2.16.840.1.113883.10.20.22.2.3.1	2.16.840.1.113883.10.20.1.14 2.16.840.1.113883.3.88.11.83.122 1.3.6.1.4.1.19376.1.5.3.1.3.28
Procedures	SHOULD	2.16.840.1.113883.10.20.22.2.7.1	2.16.840.1.113883.10.20.1.12 2.16.840.1.113883.10.20.18.2.18 2.16.840.1.113883.3.88.11.83.108 1.3.6.1.4.1.19376.1.5.3.1.3.12
Advance Directives	MAY	2.16.840.1.113883.10.20.22.2.21	2.16.840.1.113883.10.20.1.1 2.16.840.1.113883.3.88.11.83.116 1.3.6.1.4.1.19376.1.5.3.1.3.35
Encounters	MAY	2.16.840.1.113883.10.20.22.2.22	2.16.840.1.113883.10.20.1.3 2.16.840.1.113883.3.88.11.83.127 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.3
Family History	MAY	2.16.840.1.113883.10.20.22.2.15	2.16.840.1.113883.10.20.1.4 2.16.840.1.113883.10.20.18.2.17 2.16.840.1.113883.3.88.11.83.125 1.3.6.1.4.1.19376.1.5.3.1.3.15
Functional Status	MAY	2.16.840.1.113883.10.20.22.2.14	2.16.840.1.113883.10.20.1.5 2.16.840.1.113883.3.88.11.83.109 1.3.6.1.4.1.19376.1.5.3.1.3.17
Immunizations	MAY	2.16.840.1.113883.10.20.22.2.2	2.16.840.1.113883.10.20.1.6 2.16.840.1.113883.3.88.11.83.117 1.3.6.1.4.1.19376.1.5.3.1.3.23
Medical Equipment	MAY	2.16.840.1.113883.10.20.22.2.23	2.16.840.1.113883.10.20.1.7 2.16.840.1.113883.3.88.11.83.128 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5
Payers	MAY	2.16.840.1.113883.10.20.22.2.18	2.16.840.1.113883.10.20.1.9 2.16.840.1.113883.3.88.11.83.101.1 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7
Plan of Care	MAY	2.16.840.1.113883.10.20.22.2.10	2.16.840.1.113883.10.20.2.7 2.16.840.1.113883.10.20.1.10 2.16.840.1.113883.3.88.11.83.124 1.3.6.1.4.1.19376.1.5.3.1.3.31
Social History	MAY	2.16.840.1.113883.10.20.22.2.17	2.16.840.1.113883.10.20.1.15 2.16.840.1.113883.3.88.11.83.126 1.3.6.1.4.1.19376.1.5.3.1.3.16
Vital Signs	MAY	2.16.840.1.113883.10.20.22.2.4	2.16.840.1.113883.10.20.1.16 2.16.840.1.113883.10.20.2.4 2.16.840.1.113883.3.88.11.83.119 1.3.6.1.4.1.19376.1.5.3.1.3.25

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Migration Strategy for older content

- Start with older conforming content (HITSP C32, etc.)

- Fix demographics (names and addresses)

- Add template identifiers for new templates

  - Leave in compatible templates

- Remove incompatible templates

  - Problem Section and Concern

- Address differences in representation of unknowns

Fixing the Content

- Review Sample CDA Documents
  - With Robust content
  - With missing data (problems, allergies, meds, etc.)
  - With missing demographics (gender, DOB, etc.)

- CDA Consolidation Guide
  - Review General Header Compliance
  - Review CCD Header Compliance
  - Review CCD Body Compliance
  - Review Section Compliance
  - Review Entry Compliance

- Validate and fix
  - More on this later…

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C-CDA 2.1

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C-CDA R2.0/R2.1

- **R2.0 November 2014 Draft Standard for Trial Use**
- **R2.1 August 2016 (DSTU)**
- **12 document templates:**

Care Plan (R2.0)	Operative Note
Continuity of Care	Procedure Note
Consultation Note	Progress Note
Diagnostic Imaging Report	Referral Note (R2.0)
Discharge Summary	Transfer Summary (R2.0)
History and Physical (H&P) Note	Unstructured Document

- **80 document sections**
- **112 entry templates**
- **Based on Clinical Document Architecture (CDA)**

C-CDA R2.0

- Added 3 new document types, and made updates to existing R1.1 templates

- A R1.1 receiver is not able to automatically process certain common R2.0 templates (e.g. Allergies, Vital Signs)

- Vendors expressed compatibility concerns on requiring R2.0 in the ONC 2016 Notice for Proposed Rulemaking (NPRM)

With R2.0

2.0 Sender

1.1 Receiver

C-CDA R2.1

- Adds guidance on how to create a R1.1 compatible instance
- Includes new document types (not automatically supported by R1.1 receiver)
- Fastest DSTU update ever completed in HL7 due to broad industry and stakeholder support

With R2.1

2.1 Sender ✓ 1.1 Receiver

Care Plan

- Consensus-driven dynamic plan that represents a patient's and Care Team Members' prioritized concerns, goals, and planned interventions. Enables aggregation of **pertinent** data about a patient.

- The CDA Care Plan represents an instance of this dynamic Care Plan at a point in time. The CDA document itself is NOT dynamic.

- Two required Sections: Health Concerns and Interventions

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Referral Note

- Communicates pertinent information from a provider who is requesting services of another provider of clinical or non-clinical services.

- Includes the reason for the referral and additional information that would augment decision making and care delivery.

Transfer Summary

- The Transfer Summary standardizes critical information for exchange of information between providers of care when a patient moves between health care settings.

- "Uber CCD" – 7 required sections and 20 recommended sections

(CCD 6 required section and 17 Recommended Sections)

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C-CDA Companion Guide

C-CDA Companion Guide

- [Published](#) in March 2017

- Provides guidance to systems implementing C-CDA to meet ONC 2015 Edition rule

- Additional new templates in the appendix

…prior companion guide for [MU Stage 2](#)

What about Volume 3

CDAR2_IG_CCDA_VOL3_R1_D1_2017JAN_
Vol3_Additional Templates_and_Supporting_Material

HL7 CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes; Additional Optional Templates, Release 1 - US Realm

January 2017

HL7 Standard for Trial Use Ballot

Volume 3 — Additional Templates and Supporting Material

Volume 3 No Longer…

- Split into separate guides
- Out for ballot
  - HL7 CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes; Advance Directives Templates, Release 1 - US Realm
  - HL7 CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes; Unique Device Identifier (UDI) Templates, Release 1 - US Realm
- Dispose comments this week in Structured Documents Working Group
- Future – Occupational Data Health

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Tool and Resource Examples

- A subgroup of the Structured Documents Work Group (SDWG) meets weekly to develop and review samples.

- Agenda
  http://wiki.hl7.org/index.php?title=CDA_Example_Task_Force

- Repository of samples
  https://github.com/HL7/C-CDA-Examples

- Beta search tool
  http://cdasearch.hl7.org

C-CDA VALUE SETS

8/21/2018

Value Sets

1. **SHALL** contain exactly one [1..1] **value with @xsi:type="CD"**, where the @code **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.6.8 Problem Severity **DYNAMIC** (CONF:7356).

- ## OID and Name
  - Value set identifier and descriptive name

- ## STATIC vs DYNAMIC
  - They are bound to a specified version of a vocabulary in value set
  - They are bound to the most current version of the vocabulary used for the value set

Looking Up Lists of Codes (Value Sets)

- C-CDA/MU require certain value sets
  - Gender
  - Race/Ethnicity
  - Many others…

- Use the Value Set Authority Center (VSAC)
  - Search or download C-CDA value sets
  - Requires a free UMLS License to access
  - https://vsac.nlm.nih.gov/

VSAC Search Example (Gender)

VSAC Search Results (Example)

Value Set Members

Expanded Code List

View | Toggle | Clear   Page 1 of 1   20 ▾   View 1 - 3 of 3

Code	Descriptor	Code System	Version	Code System OID
F	Female	AdministrativeGen	HL7V3.0_2016-	2.16.840.1.113883.5.1
M	Male	AdministrativeGen	HL7V3.0_2016-	2.16.840.1.113883.5.1
UN	Undifferentiated	AdministrativeGen	HL7V3.0_2016-	2.16.840.1.113883.5.1

View   Page 1 of 1   20 ▾   View 1 - 3 of 3

```
<administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1"/>
```

RENDERING C-CDA DOCUMENTS

8/21/2018

Rendering CDA Documents

- **CDA Stylesheets:**
  - XSLT stylesheets convert CDA to HTML
  - Run directly in a browser for real-time rendering, or run separately to generate a static HTML version of the document
  - HL7 CDA Stylesheet in gForge: https://gforge.hl7.org/svn/strucdoc
  - Lantana stylesheet: https://github.com/lantanagroup/stylesheets
- **CDA Rendering Challenge:**
  - http://www.hl7.org/events/toolingchallenge.cfm

Rendering Options

- **Stylesheet Options:**
  - ➢ Run from browser
    - Requires adding a processing instruction, if not present
    - Security concerns: referencing external software
    - Browser support: browser support for XSLT has varied over time
  - ➢ Run offline
    - Use Xalan, Saxon, etc. to convert to XHTML
    - View transformed HTML result in browser

VALIDATING C-CDA DOCUMENTS

8/21/2018

Validation Overview

- ## Validation
  - Ensures documents are valid according to specifications.
  - Ensures exchanged documents meet external sources' expectations.
  - Prerequisite for many certification criteria
  - Checks structure, syntax, terminology, datatypes, etc.
- ## Senders
  - Validate their own data to ensure they are sending valid attachments
- ## Receivers
  - Validate incoming documents to ensure they can be processed

Base Validation – CDA Specification

All CDA documents must validate against the base CDA specification.

For example:

- CCD is a C-CDA document type.

- All C-CDA documents (US specific use case) are CDA documents (generic, country agnostic)

- Therefore, all CCDs must validate against the base CDA specification
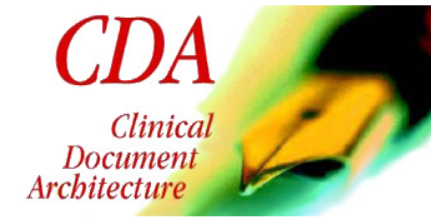
Normative Edition - May, 2005

HL7 Clinical Document Architecture, Release 2.0
CDA Schemas
CDA R2 Sample Documents

CDA Hierarchical Descriptor (Excel)
CDA RMIM (gif)
CDA RMIM (Visio)

HL7 Reference Information Model Vers. 2.07
HL7 Vocabulary Domains
Version 3 Data Types - Abstract Specification
Version 3 Data Types - Implementation Technology Specification for XML

Additional Support Files

HL7 V3 Guide
HL7 V3 Glossary
Package Note to Readers

Web Publication: September 2005
Links will open in a new window

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ANSI/HL7 CDA, R2-2005 (R2010)
HL7 Clinical Document Architecture, Release 2
(reaffirmation of ANSI/HL7 CDA, R2-2005)
6/24/2010

ISO/HL7 27932: 2008
HL7 Clinical Document Architecture, Release 2

The CDA XML Schema

- CDA_SDTC.xsd

- Ensures XML well-formedness

- Ensures the XML conforms to overall CDA structure

- XML parsers should parse the document without issue.

- Does not validate data Implementation Guide constraints

- Only checks parent/child nodes and hard document structure

Schematron

- A language for making assertions about the presence or absence of patterns in XML documents.

- ISO standard

- Declarative, developers express document requirements and structure

- Uses standard XPath (1.1) to "select" nodes based on index, name, name + value, and others

- Reference implementation based on XSLT

- http://schematron.com/

C-CDA Schematron Validation

- Based on C-CDA IG requirements
- Direct correspondence between conformance statements and Schematron assertions
- Triggered off the presence of templateId elements

SHALL contain exactly one [1..1] code (CONF:1198-17180).

a. This code SHALL contain exactly one [1..1] @code="34133-9" Summarization of Episode Note (CONF:1198-17181).

```
<sch:rule context="cda:ClinicalDocument[
cda:templateId[
@root='2.16.840.1.113883.10.20.22.1.4' and
@extension='2015-08-01']]>
    <sch:assert id="a-1198-17180" test="count(cda:code)=1"/>
    <sch:assert id="a-1198-17181" test="cda:code[@code='34133-9']"/>
</sch:rule>
```

Constraint Layering

To validate a CDA document:

➢ Validate against the CDA XML Schema

➢ Validate against any IG specific Schematron schemas

➢ Validate against any additional constraints (e.g. Meaningful Use, etc.)

MU

C-CDA

Base CDA Specification
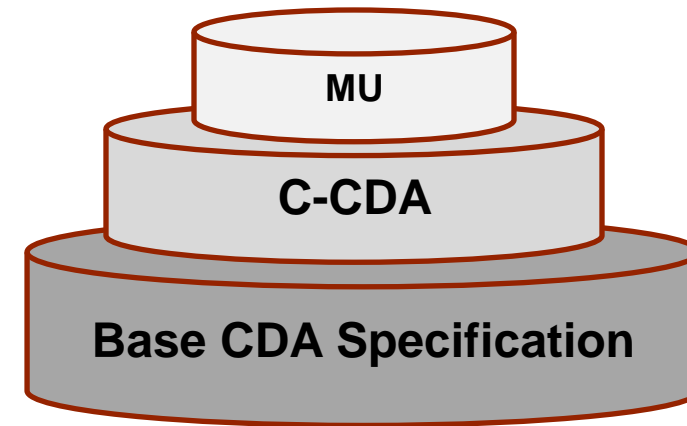
Validation Tooling

- XML Integrated Development Environments (IDEs)

- Online Validators
  - Edge Testing Tool (ETT)
  - C-CDA Scorecard

- Custom validation

XML IDEs

Most popular:

➤ OxygenXML

➤ XML Spy

Both Support:

➤ XML Schema Browsing

➤ XML Schema Validation

➤ Autocorrect

➤ Error highlighting

OxygenXML Only:

➤ Integrated Schematron Validator
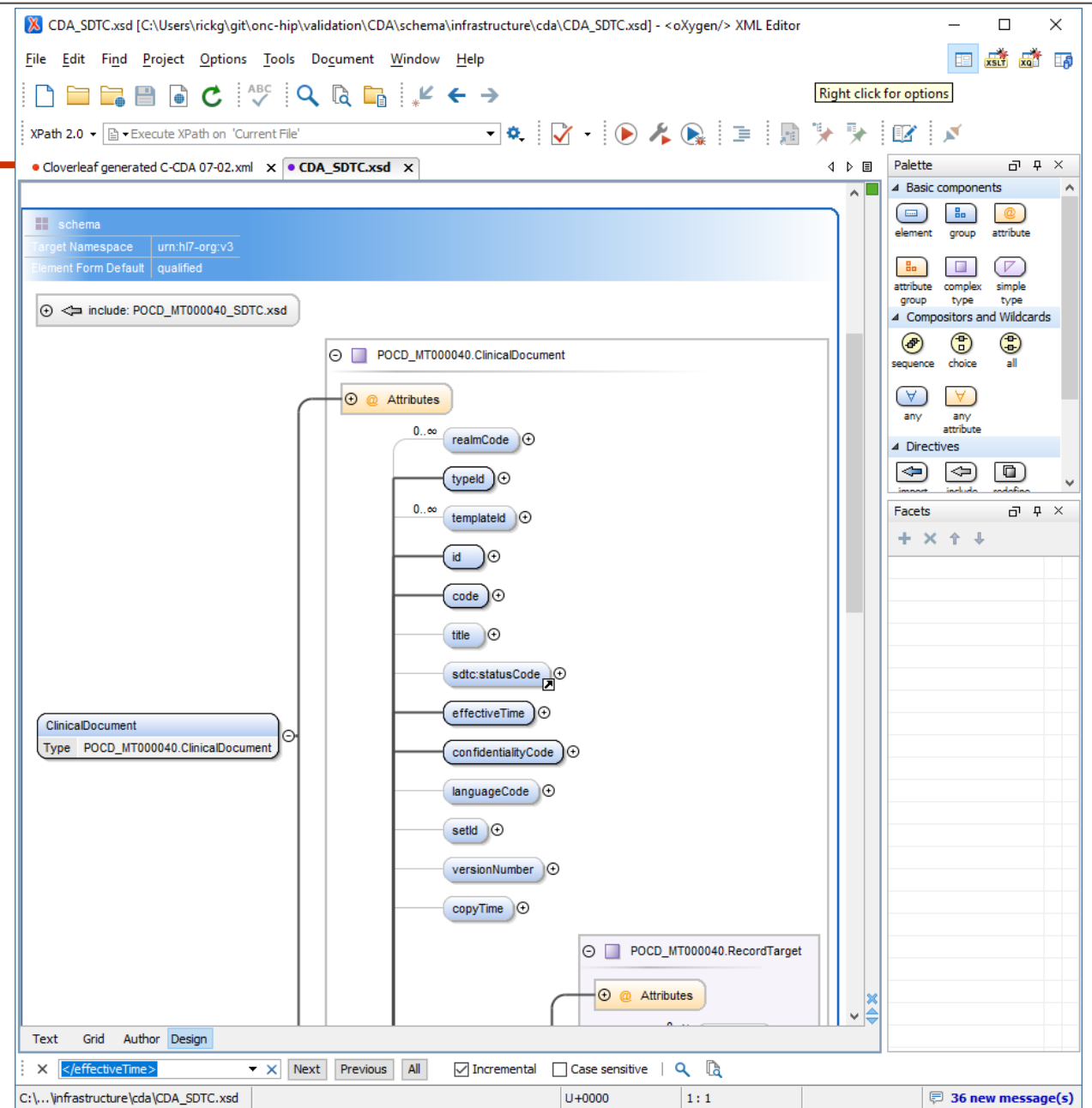
Edge Testing Tool (ETT)

- Message Validators
- C-CDA R2.1 Validator
- XML Schema + Schematron + ONC specific certification criteria
- https://ttpedge.sitenv.org

C-CDA Scorecard

- ONC-sponsored tool
- Combines pass/fail validation with best practice rules to "grade" CDA documents.
  - Any errors result in an F (sections show as black)
  - D and above is passing
- Development still in progress (some bugs)
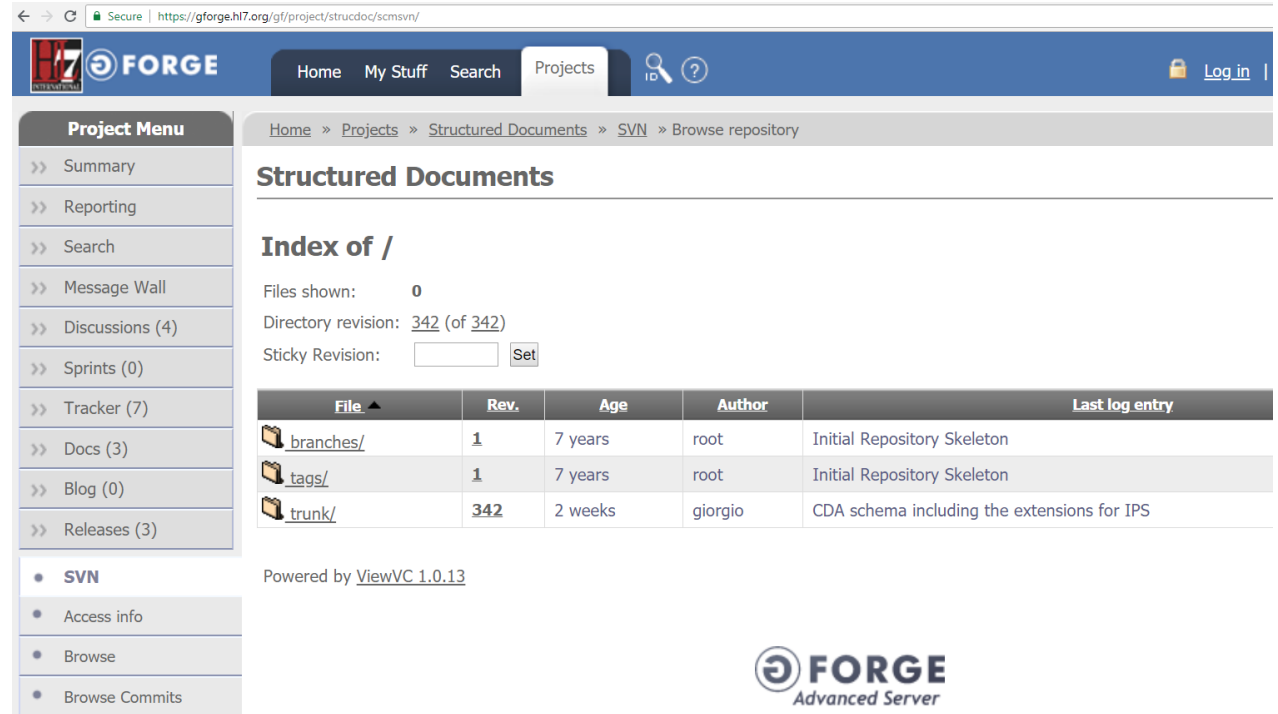- Some of the rules for scoring high are "overkill"
  https://sitenv.org/ccda-smart-scorecard/

C-CDA R1.1 Scorecard For:

lowScoringSample.xml

Grade:	Score:	Issues:
D	62 / 100	91

C-CDA IG Conformance Errors:	2015 Edition Certification Feedback:
0	0

Detailed grades and the number of issues for each of the sections of information present in your document are shown below. You can use it to quickly identify areas within the document that require the most attention. Click on each of the boxes to navigate to the appropriate part of the report that contains additional details on the identified issues.

Miscellaneous: A+ (0)	Immunizations: C (9)	Procedures: D (2)
Patient: A+ (1)	Allergies: D (10)	Encounters: D (5)
Problems: B- (11)	Lab Results: D (21)	Medications: D (5)
Vital Signs: C (20)	Social History: D (7)	

► Click Here For Detailed Results

Custom Validation

- **Implement XML Schema and Schematron validation in source code.**

- **All major software development platforms support XML parsing with XML Schema**

- **Most also support Schematron, though indirectly**

  - Most have XSLT support

  - The reference implementation of Schematron compiles to XSLT

Downloading Schema/Schematron Updates

- Found in HL7 Gforge

- SVN repository:

  - https://gforge.hl7.org/gf/project/strucdoc/scmsvn/

  - CDA XML Schema updates in trunk/CDA_SDTC

  - C-CDA Schematron updates in trunk/C-CDAR2.1/Schematron

- Access Instructions:

  https://gforge.hl7.org/gf/project/strucdoc/scmsvn/?action=AccessInfo

C-CDA ON FHIR

8/21/2018

FHIR and CDA

Similarities

- Support profiling for specific use-cases
- Human readability is minimum for interoperability
- Validation tooling, profile tooling

FHIR Differences
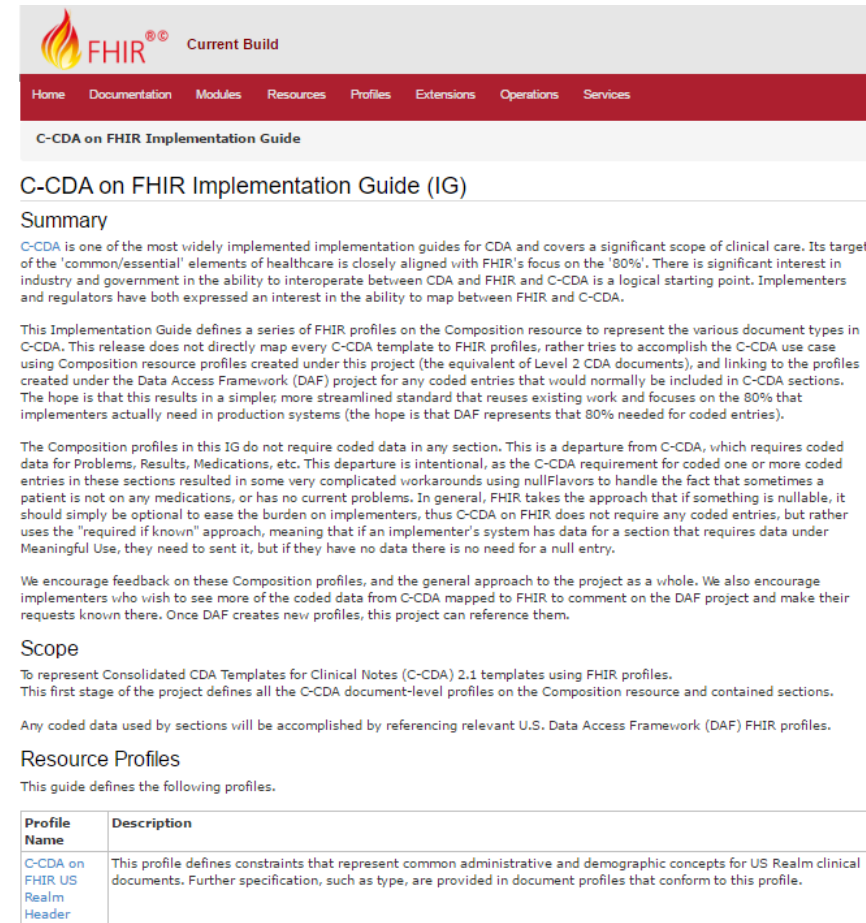
- Can use out of the box – no templates required (but profiling still recommended)
- Not restricted to just documents
- Implementer tooling generated with spec
- Tighter coupling to APIs (RESTful services)

FHIR Documents

- Addresses CDA use case for clinical documents
- Collection of resources bound together
  - Root is a Composition resource
  - Much like the CDA header + narrative
- Sent as a Bundle resource
- Can be signed, authenticated, etc.
- A FHIR document has the same basic obligations as a CDA document
- Full rules: http://build.fhir.org/documents.html

C-CDA on FHIR

- **US Realm FHIR implementation guide**

- **Goal: Implementable FHIR profiles for the C-CDA use case**

- **Scope**
  - ➢ Develop document-level profiles on the Composition resource and contained sections.
  - ➢ Represent coded data using US-Core FHIR profiles.

FHIR®© **Current Build**

Home   Documentation   Modules   Resources   Profiles   Extensions   Operations   Services

C-CDA on FHIR Implementation Guide

C-CDA on FHIR Implementation Guide (IG)

Summary

C-CDA is one of the most widely implemented implementation guides for CDA and covers a significant scope of clinical care. Its target of the 'common/essential' elements of healthcare is closely aligned with FHIR's focus on the '80%'. There is significant interest in industry and government in the ability to interoperate between CDA and FHIR and C-CDA is a logical starting point. Implementers and regulators have both expressed an interest in the ability to map between FHIR and C-CDA.

This Implementation Guide defines a series of FHIR profiles on the Composition resource to represent the various document types in C-CDA. This release does not directly map every C-CDA template to FHIR profiles, rather tries to accomplish the C-CDA use case using Composition resource profiles created under this project (the equivalent of Level 2 CDA documents), and linking to the profiles created under the Data Access Framework (DAF) project for any coded entries that would normally be included in C-CDA sections. The hope is that this results in a simpler, more streamlined standard that reuses existing work and focuses on the 80% that implementers actually need in production systems (the hope is that DAF represents that 80% needed for coded entries).

The Composition profiles in this IG do not require coded data in any section. This is a departure from C-CDA, which requires coded data for Problems, Results, Medications, etc. This departure is intentional, as the C-CDA requirement for coded one or more coded entries in these sections resulted in some very complicated workarounds using nullFlavors to handle the fact that sometimes a patient is not on any medications, or has no current problems. In general, FHIR takes the approach that if something is nullable, it should simply be optional to ease the burden on implementers, thus C-CDA on FHIR does not require any coded entries, but rather uses the "required if known" approach, meaning that if an implementer's system has data for a section that requires data under Meaningful Use, they need to sent it, but if they have no data there is no need for a null entry.

We encourage feedback on these Composition profiles, and the general approach to the project as a whole. We also encourage implementers who wish to see more of the coded data from C-CDA mapped to FHIR to comment on the DAF project and make their requests known there. Once DAF creates new profiles, this project can reference them.

Scope

To represent Consolidated CDA Templates for Clinical Notes (C-CDA) 2.1 templates using FHIR profiles.
This first stage of the project defines all the C-CDA document-level profiles on the Composition resource and contained sections.

Any coded data used by sections will be accomplished by referencing relevant U.S. Data Access Framework (DAF) FHIR profiles.

Resource Profiles

This guide defines the following profiles.

Profile Name	Description
C-CDA on FHIR US Realm Header	This profile defines constraints that represent common administrative and demographic concepts for US Realm clinical documents. Further specification, such as type, are provided in document profiles that conform to this profile.

Finding C-CDA on FHIR

■ **Published specification:**

➢ http://hl7.org/fhir/us/ccda/index.html

■ **Current build:**

➢ http://build.fhir.org/ig/HL7/ccda-on-fhir/

Questions

?

8/21/2018