



FHIR Documents

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Who am I?

- Rick Geimer
- Chief Innovation Officer, Lantana Consulting Group
- Co-Chair FHIR Infrastructure Working Group
- Member of the CDA Management Group

Learning Objectives Tutorial

- Key characteristics of clinical documents
- The FHIR document paradigm
- Example: How to find and navigate the C-CDA on FHIR specification

Clinical Documents

- This is a document
- and this
- and this
- and this
- and this
- and this

The image illustrates a mobile application for viewing clinical documents. The central smartphone screen displays a document titled "PATIENT CHART SUMMARY" for a patient with ID 12345, Henry L. Levin. The document content includes:

- Clinical History:** Colorectal carcinoma with right-sided chest and right upper abdominal pain.
- Comparison:** Chest x-ray from the same date.
- Technique:** The patient underwent initial ventilation imaging following the inhalation of DTPA aerosol.
- Findings:** There are new wedge-shaped pleural-based moderate-sized segmental defects identified within the bilateral upper lung zones compatible with high probability for pulmonary thromboembolism.
- Impression:** High probability for pulmonary thromboembolism.

Surrounding the smartphone are several desktop screens showing different sections of the patient's medical record:

- Top Left:** A table with patient information including Name (EVE BETTERHALF), Date of Birth, Sex, Race, and Insurance ID.
- Top Right:** A header for the "PATIENT CHART SUMMARY" with patient ID 12345 and name Henry L. Levin.
- Middle Left:** A "Diagnostic Imaging Report" with sections for History, Technique, Findings, and Impression.
- Middle Right:** A chest X-ray image with a "CHART SUMMARY" overlay.
- Bottom Left:** A list of "INSURANCE PROVIDERS" and "TREATMENT PLAN".
- Bottom Center:** A list of "PROBLEMS" and "PROCEDURES".
- Bottom Right:** A "CONTACT" section with address: 1004 Healthcare Drive, Portland, OR 99123, US, and phone: +1(555)555-1004.

Key Characteristics

- **Persistence** – A clinical document continues to exist in an unaltered state, for a time period defined by local and regulatory requirements. Note: documents outlive the servers (and often the syntax) on which they are created.
- **Stewardship** – A clinical document is maintained by an organization entrusted with its care.
- **Potential for authentication** – A clinical document is an assemblage of information that is intended to be legally authenticated.
- **Context** – A clinical document establishes the default context for its contents.
- **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.

Clinical Document Standards at HL7

- Clinical Document Architecture (CDA)
- Consolidated CDA (C-CDA) and other CDA Implementation Guides (IGs)
- FHIR Document Paradigm
- C-CDA on FHIR and other FHIR Document IGs

Clinical Document Architecture (CDA)

- A specification for exchange of clinical documents, defining their structure and semantics
- ANSI/ISO standard developed by HL7's Structured Documents Work Group (SDWG)
- Base standard on which many Implementation Guides (IGs) are built:
 - Quality Reporting Document Architecture (QRDA)
 - Healthcare Associated Infection (HAI) Reports
 - Consolidated CDA (C-CDA)
 - ...and many others

Consolidated CDA (C-CDA)

- Care Plan
- Consultation Note
- Continuity of Care Document (CCD)
- Diagnostic Imaging Report
- Discharge Summary
- History and Physical
- Operative Note
- Procedure Note
- Progress Note
- Referral Note
- Transfer Summary
- Unstructured Document

CDAR2_IG_CCDA_CLINNOTES_R1_DSTU2.1_2015AUG_
Vol2_2019JUNwith_errata



**HL7 Implementation Guide for CDA® Release 2:
Consolidated CDA Templates for Clinical Notes
(US Realm)
Draft Standard for Trial Use Release 2.1**

Draft Standard for Trial Use

August 2015

Volume 2 — Templates and Supporting Material

Sponsored by:
Structured Documents Work Group
Patient Care Work Group
Child Health work Group

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FHIR and CDA

Similarities

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

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 – Position Statement

- Position: FHIR is the document future
- Call to action:
 - Define, document, and promote a future where clinical documents and Application Programming Interfaces (APIs) share a common syntax and set of resources
 - Establish, in technical and regulatory policy, a smooth roadmap to the future of clinical document exchange



<http://www.lantanagroup.com/resources/publications/>

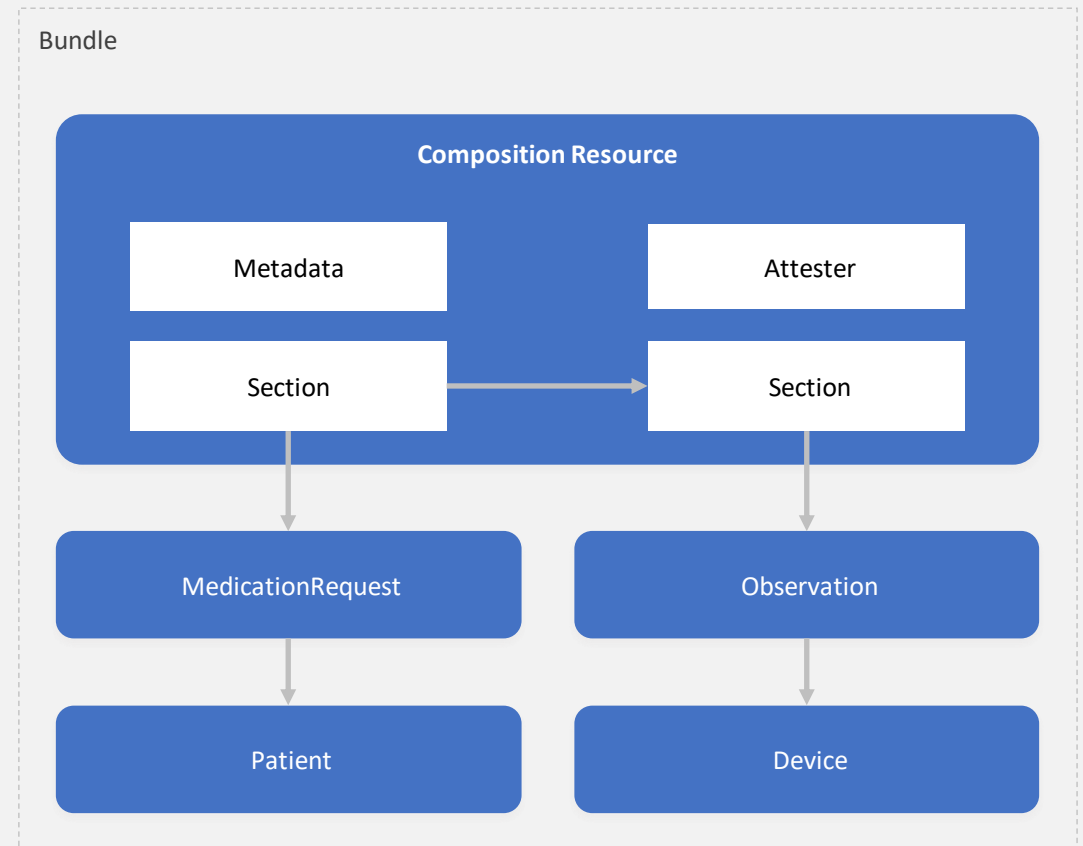
The FHIR Document Paradigm

- 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
- <http://hl7.org/fhir/documents.html>

FHIR Documents are Bundles of Resources

```

<Bundle>
  <entry>
    <Composition />
  </entry>
  <entry>
    <Observation />
  </entry>
  <entry>
    <Device />
  </entry>
  <entry>
    <MedicationRequest />
  </entry>
  <entry>
    <Patient />
  </entry>
</Bundle>
  
```



Composition Resource

- Contains
 - Patient
 - Author
 - Custodian
 - Type of document (e.g., Discharge summary)
 - Attested narrative of the document
- Sufficient for
 - Medical records management
 - Document management
 - Enable clinical document exchange across and within institutions
 - Human readable documents

Name	Flags	Card.	Type	Description & Constraints
Composition	TU		DomainResource	A set of resources composed into a single coherent clinical statement with clinical attestation Elements defined in Ancestors: id , meta , implicitRules , language , text , contained , extension , modifierExtension
identifier	Σ	0..1	Identifier	Version-independent identifier for the Composition
status	?! Σ	1..1	code	preliminary final amended entered-in-error CompositionStatus (Required)
type	Σ	1..1	CodeableConcept	Kind of composition (LOINC if possible) FHIR Document Type Codes (Preferred)
category	Σ	0..*	CodeableConcept	Categorization of Composition Document Class Value Set (Example)
subject	Σ	0..1	Reference(Any)	Who and/or what the composition is about
encounter	Σ	0..1	Reference(Encounter)	Context of the Composition
date	Σ	1..1	dateTime	Composition editing time
author	Σ	1..*	Reference(Practitioner PractitionerRole Device Patient RelatedPerson Organization)	Who and/or what authored the composition
title	Σ	1..1	string	Human Readable name/title
confidentiality	Σ	0..1	code	As defined by affinity domain V3 Value SetConfidentialityClassification (Required)
attester		0..*	BackboneElement	Attests to accuracy of composition
mode		1..1	code	personal professional legal official CompositionAttestationMode (Required)
time		0..1	dateTime	When the composition was attested
party		0..1	Reference(Patient RelatedPerson Practitioner PractitionerRole Organization)	Who attested the composition
custodian	Σ	0..1	Reference(Organization)	Organization which maintains the composition
relatesTo		0..*	BackboneElement	Relationships to other compositions/documents
code		1..1	code	replaces transforms signs appends DocumentRelationshipType (Required)
target[x]		1..1		Target of the relationship
targetIdentifier			Identifier	
targetReference			Reference(Composition)	
event	Σ	0..*	BackboneElement	The clinical service(s) being documented
code	Σ	0..*	CodeableConcept	Code(s) that apply to the event being documented v3 Code System ActCode (Example)
period	Σ	0..1	Period	The period covered by the documentation
detail	Σ	0..*	Reference(Any)	The event(s) being documented

Sections and Narrative

- Composition resources contain sections (which may be nested)
- The section narrative markup is XHTML
- The narrative contains the attested text of the document
- It is ok for sections to consist of only human readable text (i.e., no machine processable resources)

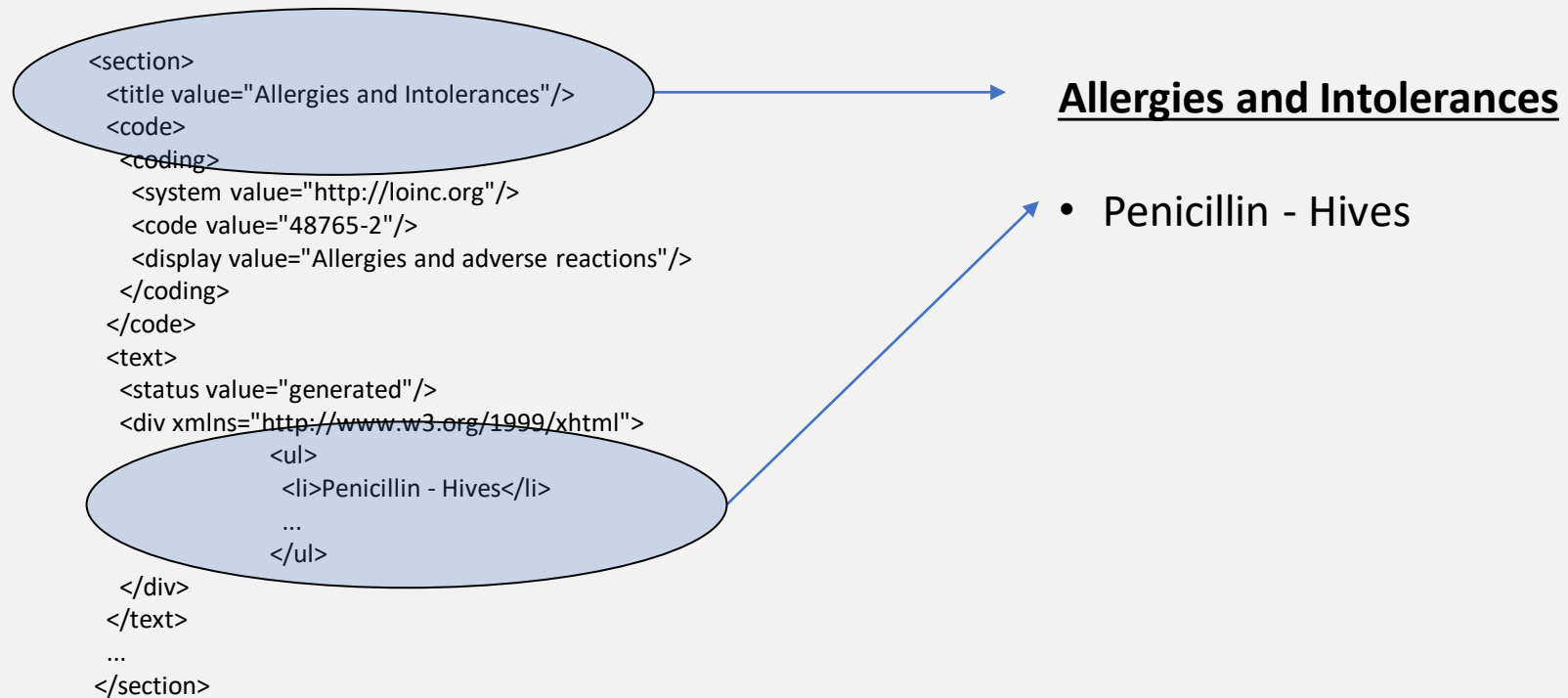
Composition Resource (Cont.)

Key fields

- Identifier
- Date
- Type
- Subject
- Author
- Attester
- Custodian
- Sections and narrative
- Section entries with references to other resources

section	I	0..*	BackboneElement	Composition is broken into sections + Rule: A section must contain at least one of text, entries, or sub-sections + Rule: A section can only have an emptyReason if it is empty
title		0..1	string	Label for section (e.g. for ToC)
code		0..1	CodeableConcept	Classification of section (recommended) Document Section Codes (Example)
author		0..*	Reference(Practitioner PractitionerRole Device Patient RelatedPerson Organization)	Who and/or what authored the section
focus		0..1	Reference(Any)	Who/what the section is about, when it is not about the subject of composition
text	I	0..1	Narrative	Text summary of the section, for human interpretation
mode		0..1	code	working snapshot changes ListMode (Required)
orderBy		0..1	CodeableConcept	Order of section entries List Order Codes (Preferred)
entry	I	0..*	Reference(Any)	A reference to data that supports this section
emptyReason	I	0..1	CodeableConcept	Why the section is empty List Empty Reasons (Preferred)
section	I	0..*	see section	Nested Section

First – Human Readable



Next – Coded Data

```

<AllergyIntolerance xmlns="http://hl7.org/fhir">
  <clinicalStatus value="active"/>
  <verificationStatus value="confirmed"/>
  <category value="medication"/>
  <criticality value="high"/>
  <code>
    <coding>
      <system value="http://snomed.info/sct"/>
      <code value="418038007"/>
      <display value="allergy to penicillin"/>
    </coding>
  </code>
  <patient>
    <reference value="Patient/1"/>
    <display value="Henry Levin"/>
  </patient>
  
```

```

    <assertedDate value="2000"/>
    <reaction>
      <manifestation>
        <coding>
          <system value="http://snomed.info/sct"/>
          <code value="247472004"/>
          <display value="hives"/>
        </coding>
      </manifestation>
      <severity value="mild"/>
    </reaction>
  </AllergyIntolerance>
  
```

A Bit of Bundle

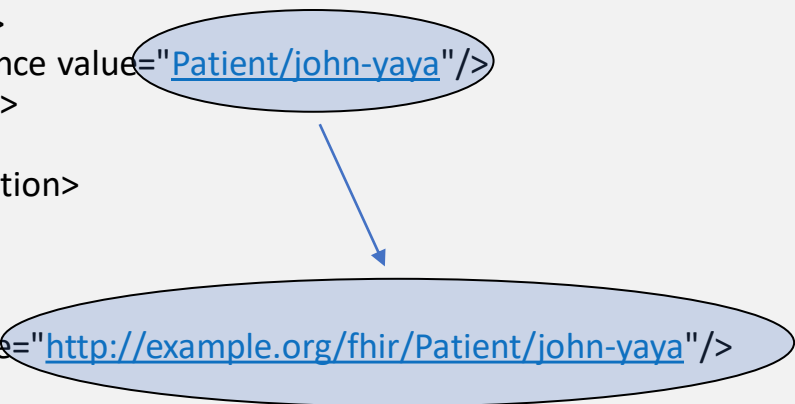
- Type = document
- Bundle.identifier
 - Version dependent
 - Must be globally unique to satisfy the persistence requirement
- First entry is a Composition
- The bundle contains all resources referenced directly or indirectly from the Composition

Name	Flags	Card.	Type	Description & Constraints
Bundle	Σ I N		Resource	Contains a collection of resources + <i>FullUrl</i> must be unique in a bundle, or else entries with the same <i>fullUrl</i> must have different <i>meta.versionId</i> + A document must have an identifier with a system and a value + <i>entry.request</i> only for some types of bundles + <i>entry.response</i> only for some types of bundles + <i>total</i> only when a search or history + <i>entry.search</i> only when a search Elements defined in Ancestors: id , meta , implicitRules , language
identifier	Σ	0..1	Identifier	Persistent identifier for the bundle
type	Σ	1..1	code	document message transaction transaction-response batch batch-response history searchset collection BundleType (Required)
timestamp	Σ	0..1	instant	When the bundle was assembled
total	Σ I	0..1	unsignedInt	If search, the total number of matches
link	Σ	0..*	BackboneElement	Links related to this Bundle
relation	Σ	1..1	string	See http://www.iana.org/assignments/link-relations/link-relations.xhtml#link-relations-1
url	Σ	1..1	uri	Reference details for the link
entry	Σ I	0..*	BackboneElement	Entry in the bundle - will have a resource,

References in Bundle Resources

```

<?xml version="1.0" encoding="UTF-8"?>
<Bundle xmlns="http://hl7.org/fhir">
  <id value="ee5590ab-72c0-4c07-9dc0-cc574729cd0a"/>
  <type value="document"/>
  <entry>
    <fullUrl value="http://example.org/fhir/Composition/1"/>
    <resource>
      <Composition>
        <subject>
          <reference value="Patient/john-yaya"/>
        </subject>
        ...
      </Composition>
    </resource>
  </entry>
  <entry>
    <fullUrl value="http://example.org/fhir/Patient/john-yaya"/>
    <resource>
      <Patient>...</Patient>
    </resource>
  </entry>
</Bundle>
  
```



Displaying FHIR Documents

- When the document is presented for human consumption, applications SHOULD present the collated narrative portions in order:
 - Composition.subject -> Patient.text
 - Composition.text
 - Composition.section.text
- Reference stylesheet (XSLT)
 - Document2HTML.xslt in the XML Tools download
 - <http://hl7.org/fhir/downloads.html>

Documents and the FHIR REST API

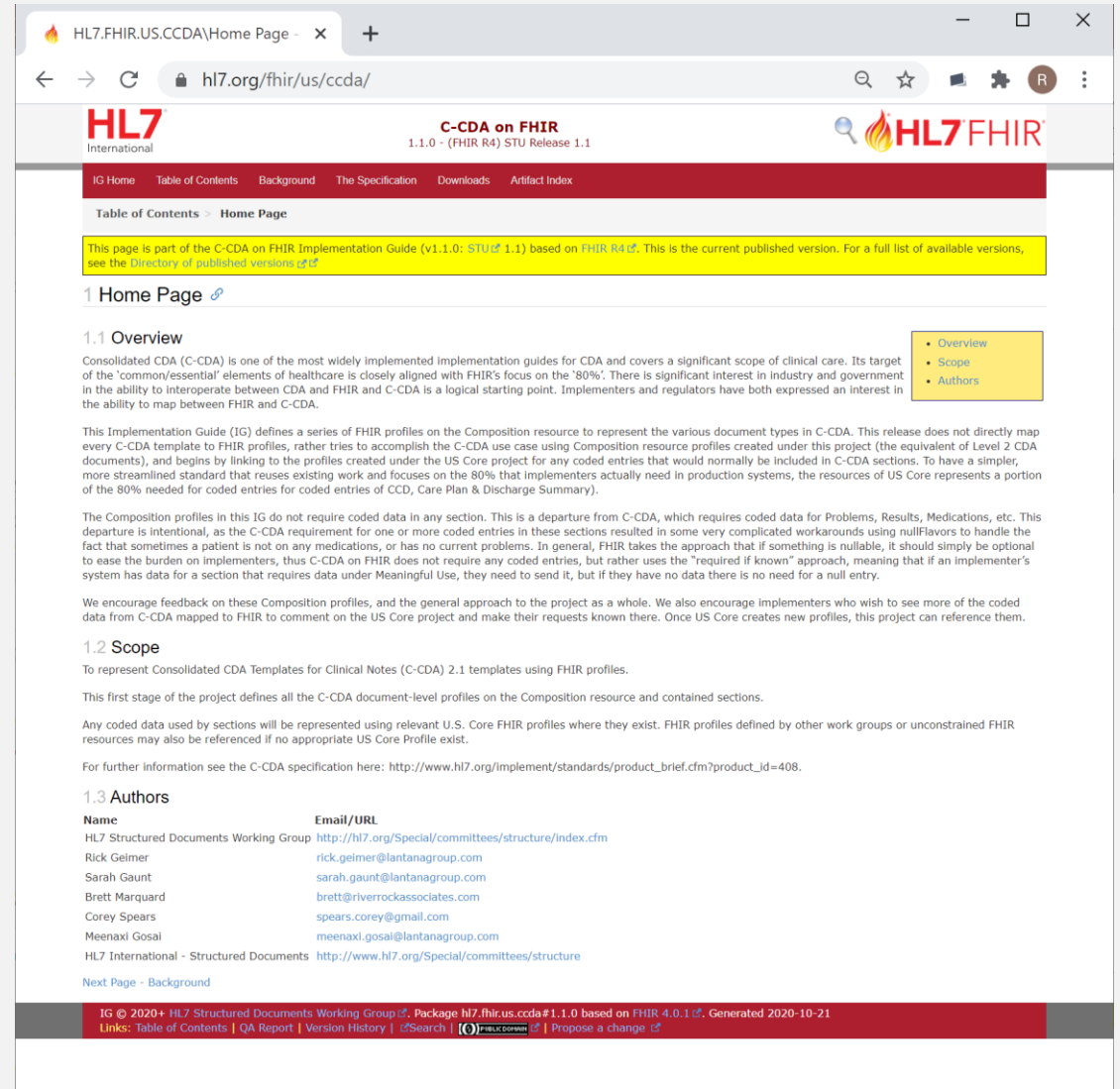
- Generating documents
 - \$document operation
 - Stores at the /Bundle endpoint if persist=true
- Moving documents or storing externally created documents
 - Send to /Bundle or /Binary depending on your use case
 - Use PUT to preserve IDs when sending to /Bundle (first, make sure globally unique)
- Decomposing documents in constituent resources
 - POST to the transaction endpoint (May need to be converted to a transaction bundle first)

FHIR Implementation Guides (IG)

- FHIR IGs are collections of profiles, value sets, examples, resource instances (conformance, etc.) and human readable documentation.
- There is an ImplementationGuide resource that ties it all together
- Publishing FHIR IGs is a rather new and tricky process

C-CDA on FHIR

- US Realm FHIR IG
 - <https://www.hl7.org/fhir/us/ccda/>
- Scope:
 - Consolidated CDA Templates for Clinical Notes (C-CDA) 2.1 templates using FHIR profiles
 - Define all the C-CDA document-level profiles on the Composition resource and contained sections
 - Represent coded data by referencing relevant US-Core FHIR profiles



HL7.FHIR.US.CCDA\Home Page - x +

hl7.org/fhir/us/ccda/

HL7 International **C-CDA on FHIR** 1.1.0 - (FHIR R4) STU Release 1.1

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This page is part of the C-CDA on FHIR Implementation Guide (v1.1.0: STU of 1.1) based on FHIR R4. This is the current published version. For a full list of available versions, see the [Directory of published versions](#).

1 Home Page

1.1 Overview

Consolidated CDA (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 (IG) 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 begins by linking to the profiles created under the US Core project for any coded entries that would normally be included in C-CDA sections. To have a simpler, more streamlined standard that reuses existing work and focuses on the 80% that implementers actually need in production systems, the resources of US Core represents a portion of the 80% needed for coded entries for CCD, Care Plan & Discharge Summary).

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 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 send 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 US Core project and make their requests known there. Once US Core creates new profiles, this project can reference them.

1.2 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 represented using relevant U.S. Core FHIR profiles where they exist. FHIR profiles defined by other work groups or unconstrained FHIR resources may also be referenced if no appropriate US Core Profile exist.

For further information see the C-CDA specification here: http://www.hl7.org/Implement/standards/product_brief.cfm?product_id=408.

1.3 Authors

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Live Walkthrough of C-CDA on FHIR

What did you learn?

Objectives reminder:

- Key characteristics of clinical documents
- The FHIR document paradigm
- Example: How to find and navigate the C-CDA on FHIR specification

Contact

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Q&A