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Clinical Documents on FHIR

Rick Geimer

Lantana Webinar, June 12, 2018

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Rick Geimer (rick.geimer@lantanagroup.com)

- Member of the HL7 CDA Management Group, FHIR Infrastructure Work Group, Structured Documents Work Group, and Attachments Work Group.
- HL7 CDA R2 Certified Specialist, Certified FHIR Proficient
- Co-Editor, CDA Consolidation and many other implementation guides
- Lead: C-CDA on FHIR project
- Day job: Lantana Chief Innovation Officer

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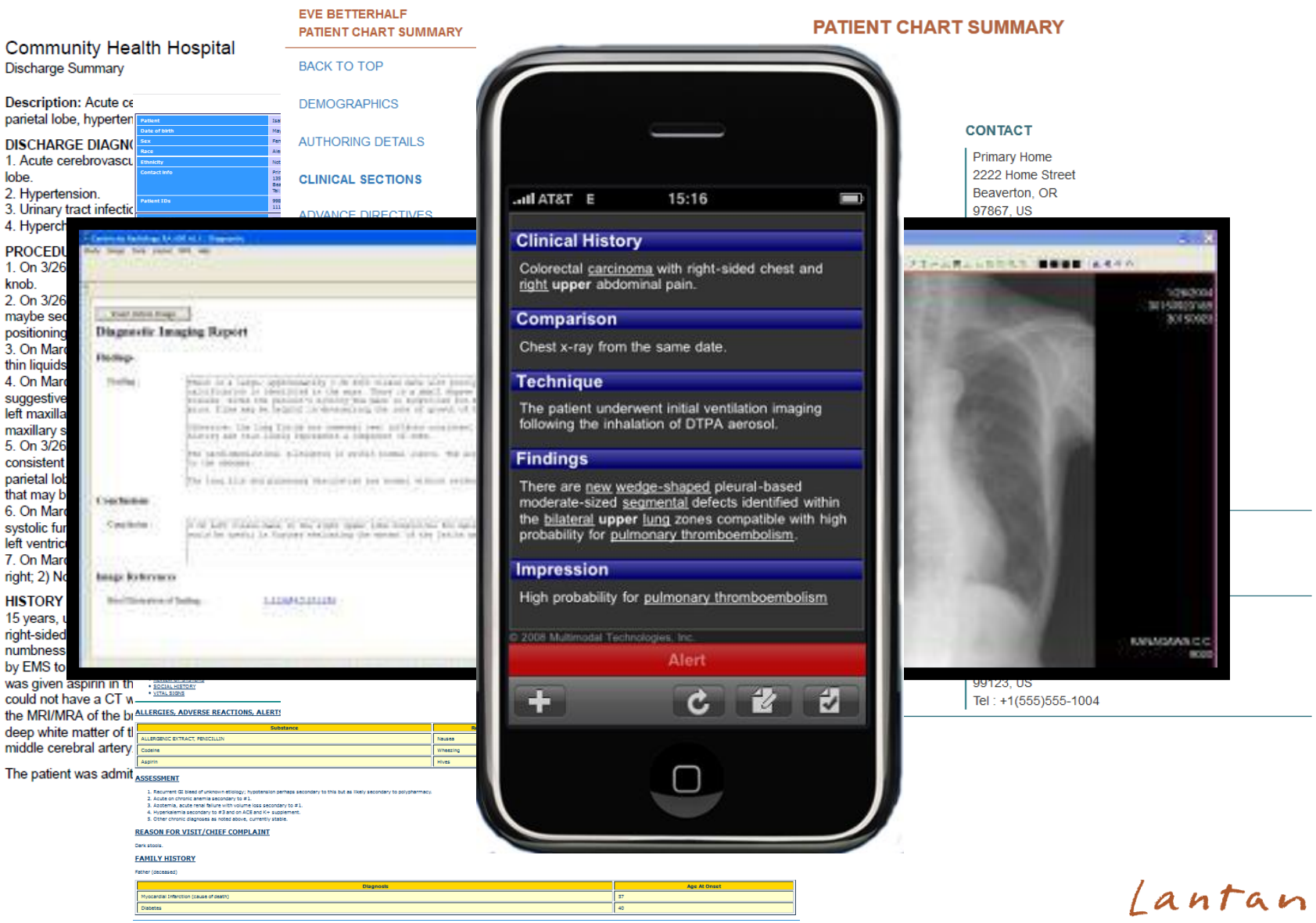
- Our Mission:
  - Improve healthcare through health information technology (IT)
  - Lead the industry through our consulting and volunteer practice
- Our Services:
  - *Strategic advice for health IT planning, design, & purchasing*
  - Development & implementation
  - Terminology, data governance, & education

Outline

- Overview of Electronic Clinical Documents
- FHIR documents
- C-CDA on FHIR and US Core
- Converting data to/from C-CDA and FHIR
- Current/Future Work and Resources

Clinical Documents

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



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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 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)

- HL7 Consult Note
- HL7 Diagnostic Imaging Report
- HL7 Discharge Summary
- HL7 History and Physical
- HL7 Operative Note
- HL7 Procedure Note
- HL7 Unstructured Documents
- HL7 Progress Notes
- HL7 Continuity of Care Document
- HITSP/C84 Consult and History & Physical Note Document
- HITSP/C32 - Summary Documents Using HL7 CCD
- HITSP/C48 Referral and Discharge Summary Document constructs
- HITSP/C62 Scanned document

HL7 INTERNATIONAL HEALTH STORY PROJECT IHE HITSP

Consolidate and harmonize various standalone documents into one master implementation guide for the primary care use case.

Later versions added additional document types such as the Care Plan document type.

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What can be improved?

Grahame's Law:

- You can hide complexity, or **make it worse**, but you can't make it go away.

HL7 V3 was more complex than necessary.

- Simple technical problems became road-blocks for many implementers.

CDA was the stable, simpler part of HL7 V3.

- But inherited much of the V3 complexity
- Never had a viable API complement

FHIR makes many simple problems simple again.

- Lets implementers focus on solving the hard problems.

Many CDAs today are just EHR data dumps.

- FHIR Queries can serve the same purpose with more specificity.
- The future: fewer data dump documents, more clinically relevant documents

F – Fast (to design & to implement)

- Relative – No technology can make integration as fast as we'd like

H – Health

- That's why we're here

I – Interoperable

- Ditto

R – Resources

- Building blocks – more on these to follow

FHIR is like Lego(™) for Healthcare

- Resources = Blocks
- Resources are discrete chunks of clinical information
- Resources can be assembled into larger constructs
- You operate on resources via FHIR's REST APIs - like programming Lego Mindstorms (™)

Similarities

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

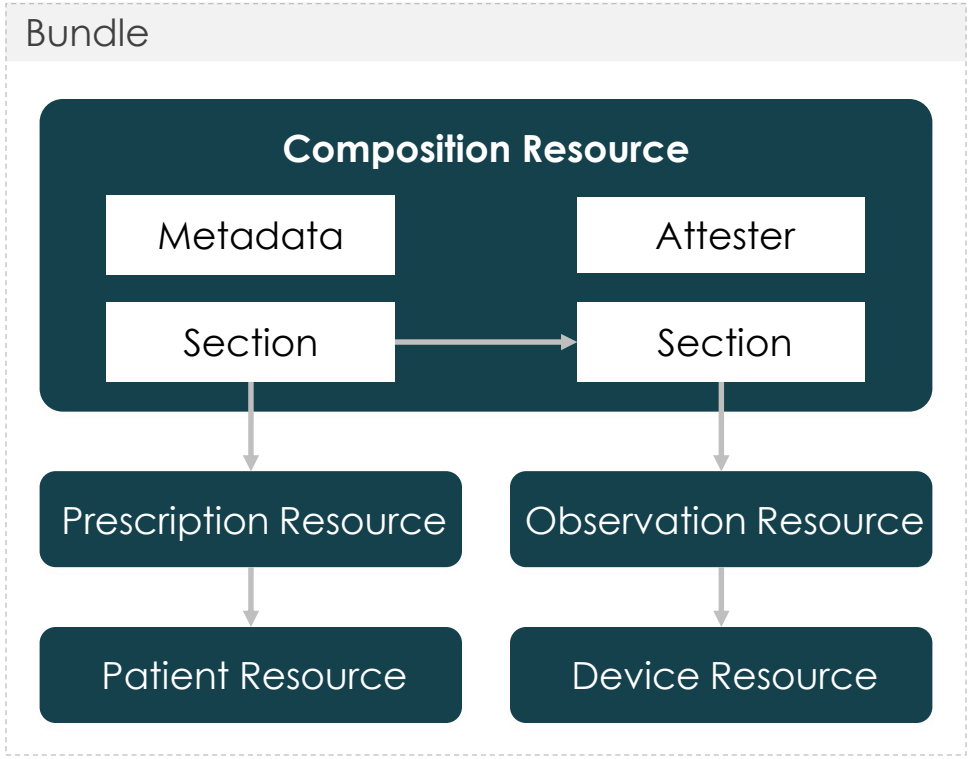
FHIR Differences

- Can use out of the box – no templates required (but profiling still recommended)
- Encompasses documents, resources, messages, and APIs (i.e. not just a document exchange format)
- Implementer tooling generated with spec

FHIR Documents

- Address 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

FHIR Documents: Bundles of Resources




```
<Bundle>
  <entry>
      <Composition />
  </entry>
  <entry>
      <Observation />
  </entry>
  <entry>
      <Device />
  </entry>
  <entry>
      <Prescription />
  </entry>
  <entry>
      <Patient />
  </entry>
</Bundle>
```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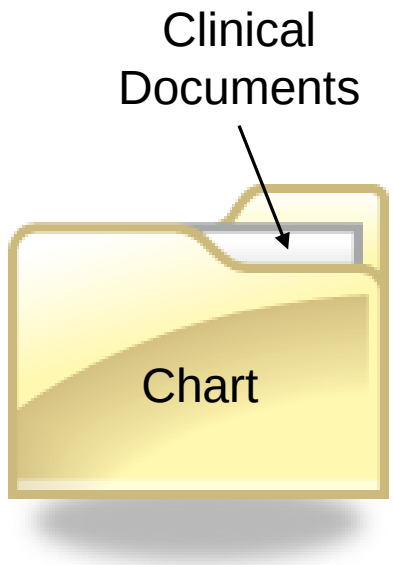
Contains

- 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

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)

First: Human Readable

```
<section>
  <title value="Allergies and Intolerances"/>
  <code>
    <coding>
      <system value="http://loinc.org"/>
      <code value="48765-2"/>
      <display value="Allergies and adverse reactions"/>
    </coding>
  </code>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml">
          <ul>
            <li>Penicillin - Hives</li>
            ...
          </ul>
    </div>
  </text>
  ...
</section>
```

Allergies and Intolerances

- Penicillin - Hives

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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>
```


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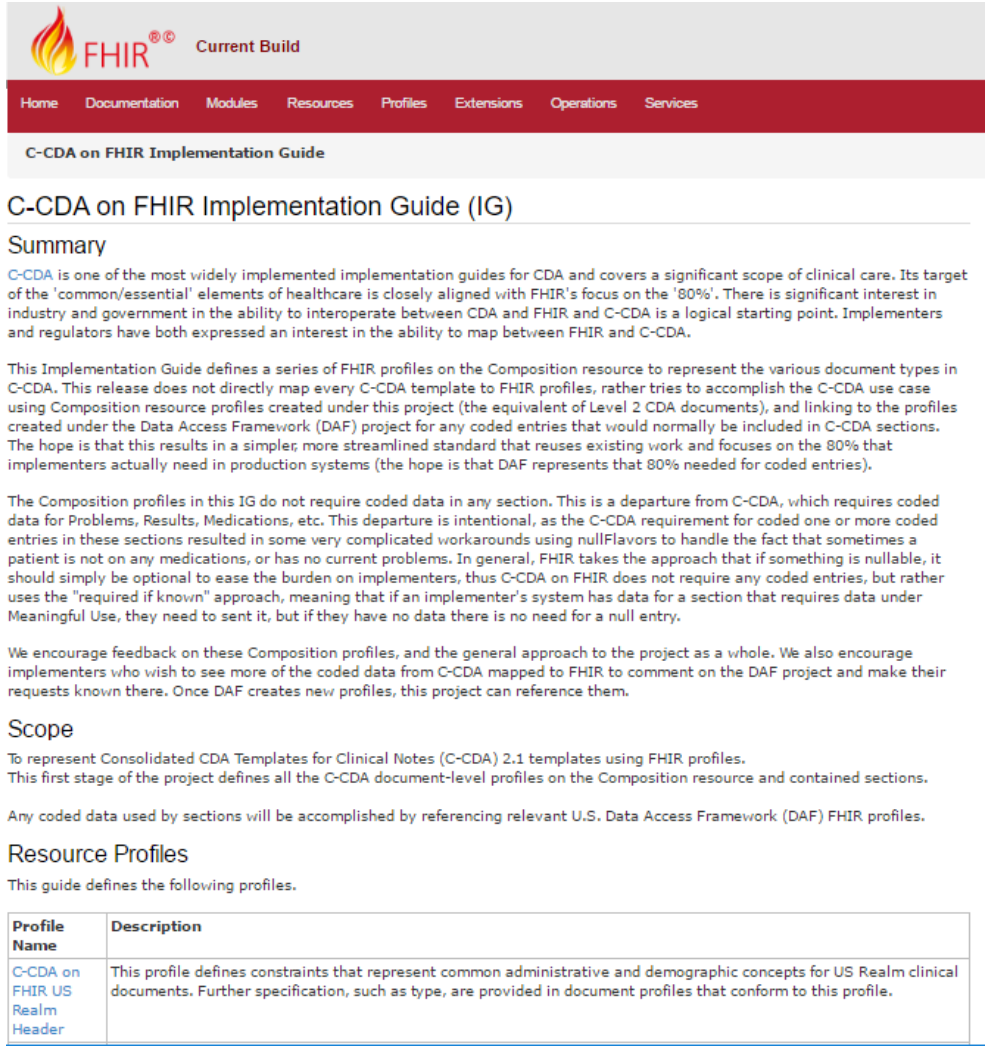
US Realm FHIR Implementation Guide

- Goal:
  - FHIR profiles for the C-CDA use case
- Scope
  - Represent C-CDA templates using FHIR profiles
  - Focus on C-CDA document-level profiles using the Composition Resource
  - Coded entries limited to US Core profiles via the 80/20 rule.



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.

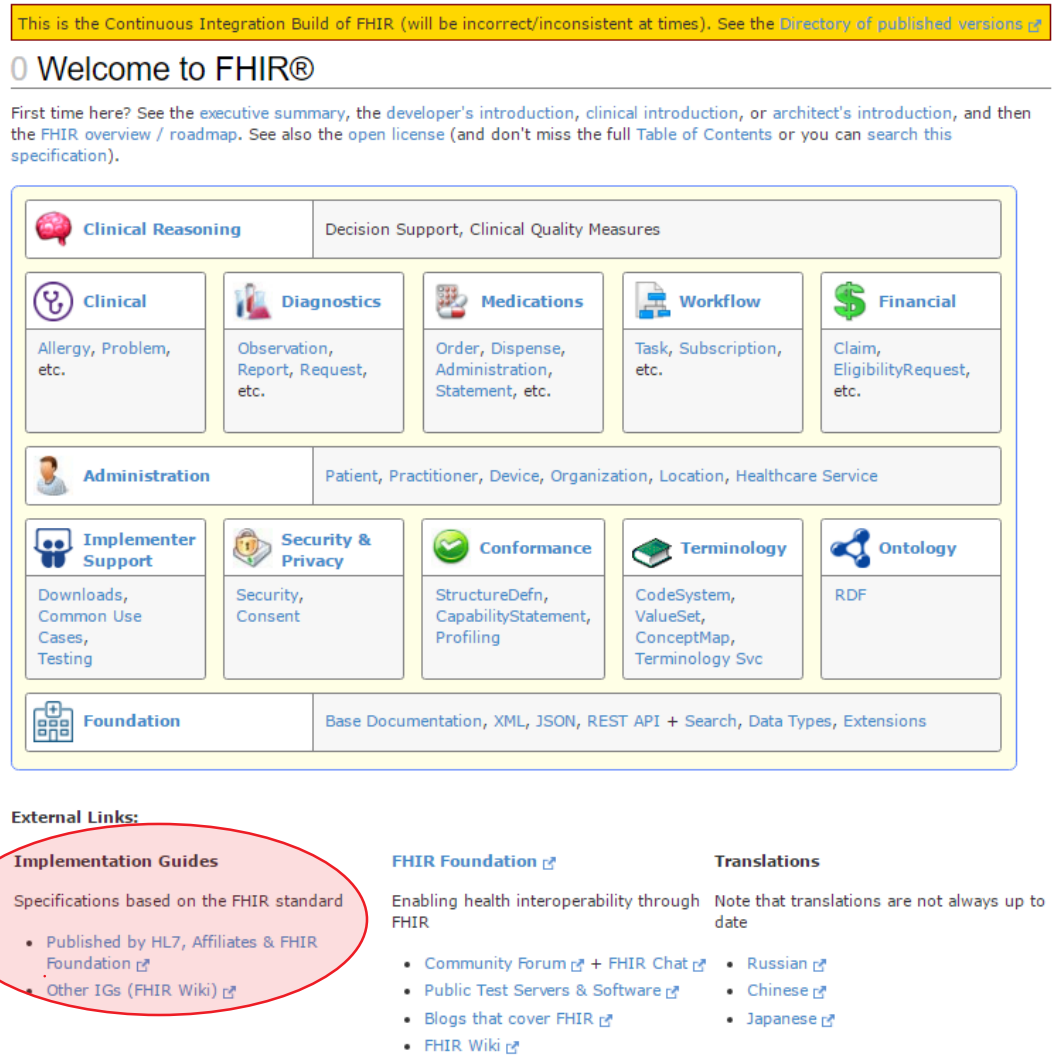
Finding C-CDA on FHIR

Published specification

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

Current build

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



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Location

- http://hl7.org/fhir/us/core/index.html

FHIR Profiles for the Common Clinical Data Set (CCDS)

- CCDS location:
- https://www.healthit.gov/sites/default/files/2015Ed_CCG_CCDS.pdf

- US Core AllergyIntolerance Profile
- US Core CareTeam Profile
- US Core Condition (a.k.a Problem) Profile
- US Core Device Profile
- US Core DiagnosticReport Profile
- US Core Goal Profile
- US Core Immunization Profile
- US Core Location Profile
- US Core Medication Profile
- US Core MedicationRequest Profile
- US Core MedicationStatement Profile
- US Core Practitioner Profile
- US Core Procedure Profile
- US Core Results Profile
- US Core Smoking Status Profile
- US Core CarePlan Profile
- US Core Organization Core Profile
- US Core Patient Profile

- US Core adopts the Vitals Signs Profile from FHIR Core.

C-CDA on FHIR Demo

- Live walkthrough of the specification
- Composition profiles and US Core

Converting between C-CDA and C-CDA on FHIR

Why?

- Quick way to get a critical mass of FHIR documents
- Continuity with existing practice, using better syntax and APIs
- Creating FHIR documents and converting to CDA may be an easier way for developers to comply with today's regulations
- Supports transitional strategies with mixed environments

How?

- Future:
  - C-CDA to FHIR mapping project
    - HL7 sanctioned mappings defined using FHIR Mapping Language
    - Project began in May 2018, completion in Sept 2019
- Current
  - Various non-HL7 solutions (some proprietary, some open)
  - Example: ONC-HIP Pharmacist Care Plan transforms

Live Demo

- ONC-HIP Pharmacist Care Plan (PhCP) transforms using XSLT

Managing FHIR Documents

- Documents are persistent objects
- Thus they must be stored somewhere (or reproduced exactly on demand)
- Options:
  - FHIR server (/Bundle or /Binary endpoint)
  - Document management system
  - Clinical data repository
  - Database
  - File system
  - etc.
- **Important:** documents cannot be generated, transmitted, then disposed of like an message. They are a persistent part of the patient record.

FHIR validation pack

- Includes XML Schema and Schematron files
- http://build.fhir.org/fhir-all-xsd.zip
- FHIR Validator (Java Tool)
- http://build.fhir.org/validator.zip

FHIR server validation

- Most servers do basic resource validation
- Use the $validate operation
  - Can validate profiles like C-CDA on FHIR
  - http://build.fhir.org/operation-resource-validate.html

Future Work

- Unstructured Documents (US Core DocumentReference profile)
- Section entry profiles not covered by US Core
- Other CDA IGs as driven by demand
- C-CDA to FHIR Mapping Project
  - Promises C-CDA to FHIR Mappings using FHIR Mapping Language
  - Starting now, ending close of 2019

Is your roadmap on FHIR?

- FHIR evaporates “V3 messaging”
- V2: if not broke… don’t replace
- CDA
  - FHIR retains CDA document concepts
  - Improves text/data management
  - Unified model/syntax with messages/API
- C-CDA on FHIR
  - Ready for trial use
  - Limited production
  - Needs more testing/implementation

The FHIR spec:

- Updated continuously
- URLs
  - Latest balloted version: http://hl7.org/fhir
  - Continuous build: http://build.fhir.org/

Lantana White Paper co-authored with Grahame Grieve:

- FHIR CDA Position Statement and Roadmap
- Updated April, 2015
- URL: http://www.lantanagroup.com/resources/publications/

Rick:

- Updated continuously, rebooted occasionally
- rick.geimer@lantanagroup.com

Questions?