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Health Intersections

# POSITION STATEMENT: CLINICAL DOCUMENTS AND FHIR

*Adopted August 1, 2014; revised April 10, 2015*

This position statement addresses the relationship between HL7's Clinical Document Architecture (CDA) product line and the Fast Health Interoperability Resource (FHIR) product line. It was prepared jointly by Lantana Consulting Group—a recognized leader in the CDA community—and Grahame Grieve, Health Intersections, the FHIR project lead. This statement is not official policy. It is our hope that it will stimulate discussion and possibly guide policy makers, architects, and implementers as well as standards developers.

This April 10, 2015 revision updates the position in light of progress under the second FHIR ballot as a Draft Standard for Trial Use and Project Argonaut. *In short, we find that the gaps between DSTU 1 and CDA have been identified, many addressed, and that we are on track to meet the objectives laid out here through the coming round of ballot reconciliation.*

## Position:

*CDA addresses interoperability for clinical documents, mixing narrative, and structured data. FHIR provides granular access to data, a contemporary, streamlined approach to interoperability, and is easy to implement. FHIR can be the future of CDA, it is making great progress, but it is not there yet.*

## Call to Action:

- Recognize the duality and interdependence of data and narrative in clinical information
- Understand the gaps in support for clinical documents in the current FHIR Draft Standard for Trial Use (DSTU)
- Ensure that FHIR 2.0 addresses clinical document requirements
- Establish, publish, and test CDA/FHIR, FHIR/CDA mapping
- 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

## Rationale:

Presently, CDA is HL7's leading specification for exchange of clinical data, embodied in regulation in the United States and worldwide. FHIR has been identified as a better option because of its API-centric nature, streamlined syntax, use of contemporary Internet protocols, and overall ease of use and simplicity. This raises several questions: How do these specifications relate to each other today, and how will they do so in the

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future? Is FHIR a complement to CDA or a replacement? How does it affect the next iteration of HL7 clinical document exchange?

We address these broad issues through three specific questions:

- What's the right relationship between documents and APIs?
- What are the success criteria for using FHIR as a clinical document specification?
- Can "CDA on FHIR" replace "CDA on HL7 V3" (the current specification) for all clinical documents?

The answers to these questions suggest a general roadmap for the future of HL7's clinical document product line.

## 1. What's the right relationship between documents and APIs?

All-encompassing interoperability of a patient's medical record must accommodate a combination of data and narrative:

"The medical record is not data. It contains data, as do many forms of writing, but it is not data, nor is it simply a repository into which data are poured. Although its raw material is information—some of which, importantly, can only be expressed with words and not with numbers—a finished medical record is information that has been transformed by the knowledge, skill, and experience of the physician, motivated by the healing impulse, into an understanding of human experience that makes the care of the patient possible." [1]

This dual nature of a medical record—the combination of data and narrative—runs deeply through the clinical process and, consequently, through the clinical record.

HL7 offers two widely implemented, normative specifications, Version 2 (V2) messaging and CDA documents, using two separate syntaxes and data models. V2 provides limited support for combining data and narrative. CDA provides strong support for combining data and narrative. Formal obligations about persistence, stewardship, authentication, and context define the clinical document use case. These aspects of clinical information exchange are relevant, and important when information is shared between disparate teams—different disciplines, contexts, or clinical systems.

In contrast to documents, APIs provide highly granular access to the data-centric parts of the clinical record. This kind of access is typical in the context of tightly integrated systems that rely on trust, often inferred, in the practices around the data. Clinical content received from an external team, however, must be assimilated into the record, and made available along with other data to establish interoperability at the clinical level.

Documents package data in a persistent format during exchange between disparate parts of the healthcare system, while APIs access data within clinical and administrative applications. Documents are and should remain the correct way to exchange information between clinicians in disparate parts of the healthcare system, while APIs will integrate access to the data between applications where the context is unambiguous.

***It follows, then, that both the document and API should seamlessly use the same syntax and semantics, and both should reflect and support the duality between narrative and data.***

In FHIR, both the API and the document are built using one set of resources, and all resources include both narrative and data. This extends and improves on the ten year old vision of CDA as an HL7 Version 3 standard, sharing syntax and semantics with Version 3 messages. If or when FHIR can accommodate the full

[1] Foote RS. The Challenge to the Medical Record. JAMA Intern Med. 2013;173(13):1171-1172.

CDA use case, the future holds the promise of seamless integration and information sharing between clinical documents and APIs.

## 2: What are the success criteria for clinical documents on FHIR?

FHIR defines a framework for exchanging documents that offers strong advantages over the current HL7 Reference Information Model (RIM)-based CDA XML architecture. These advantages will only be realized, however, if the FHIR framework proves to be practical for the full use case for clinical documents.

The following criteria will determine whether the FHIR document framework meets this goal.

### Document Creation

- Applications reliably extract unambiguous data from their persistent stores and/or other applications using APIs and can build conformant documents automatically.
- Human authors create CDA on FHIR documents using a variety of tools equal to or greater than available for CDA or unstructured notes.
- Human authors attest to the document contents (both Narrative and Data) of auto-generated and authored notes with confidence.

### Reading

- Human readers are confident in the fidelity of the document.
- Applications reliably extract unambiguous data from the document and integrate the data into their persistent data store, and make data available through APIs.
- Caveat: Narrative will exceed the expressivity and nuance of coded entries in most cases where not auto-generated from structured data.

### Framework

- Projects can publish implementation guides with formal conformance statements that represent the proper contents of a document.
- Applications can leverage the formal descriptions to create proper documents.
- HL7's clinical documents use contemporary interoperability approaches.
- Clinical documents can contain a variable level of coded information, including documents designed primarily for human processing and documents designed for increasing levels of machine processing.

## 3. Can "CDA on FHIR" replace "CDA on HL7 V3" (the current specification) for all clinical document use cases?

Yes, it can. But here's what needs to happen. Several activities currently under way are assessing the readiness of FHIR for clinical documents:

- General CDA/FHIR Mapping taskforce
- Consolidated CDA (C-CDA)/FHIR Mapping work for specific resources
- "CDA on FHIR" project to define full CDA use case on FHIR framework
- Prototype work with electronic health record (EHR) and other clinical system vendors
- Collaborations with clinical communities and clinical connectathons

- These projects are evaluating both the general approach of using FHIR resources for documents and the suitability of specific resources, including both infrastructure and core clinical resources.
- Although these projects are works in progress, we are on track to meet our objectives and can draw provisional conclusions:
    - No fundamental issues with the overall approach have been identified
    - More work is needed to find the most effective way to bind narrative content with the associated machine readable data contained in the document
    - Many minor issues existing in the current FHIR resources are being addressed
    - Clinical documents—including C-CDA—cover some subject areas for which no suitable FHIR resources have yet been defined. The scope of the 1st FHIR DSTU was limited to Personal Health Records / Summaries. C-CDA Release 2 covers twelve distinct document types plus unstructured documents drawing from over 70 section-level and 100 entry-level templates.

## Road Map to Prepare FHIR for CDA:

FHIR DSTU 1 is not a replacement for CDA or C-CDA. Building out the specification so that it can represent existing documents as FHIR resources, and ensuring that FHIR resources can be integrated into CDA documents remains a key focus of the on-going work on DSTU 2. To complete this work, the following are needed:

1. Complete work on the "CDA on FHIR" project, now under Project Argonaut[2].
    a. Resolve remaining issues such that full CDA functionality is attainable
    b. Test against C-CDA requirements and through translation of samples across a range of document types
    c. Test in connectathons, report on results, and augment the specification until compliant
2. Complete and publish formal mapping expressions under DSTU 2
    a. Determine formats that would be useful
    b. Determine extent of CDA templates to be mapped
    c. Test through connectathons
3. Governance
    a. Define measurable success criteria within formal project scope statements
    b. Create a formal progress reporting mechanism so that interested parties are able to be well informed about overall progress

[2] http://www.hl7.org/documentcenter/public_temp_D91EC83A-1C23-BA17-0C83F7BB045C984F/pressreleases/HL7_PRESS_20141204.pdf

## Road Map for Implementation:

In the future, we envision a changed standards landscape where:

- Clinical documents and APIs share a common syntax and set of resources;
- Data can be acquired through an API and incorporated into a document or pulled from a document and made available in an API.

*To achieve this future state*, policy and implementation architectures should:

1. Use FHIR where
    a. Some change in the specification is tolerable as the specification is still in flux
    b. The full breadth of healthcare use cases are not required
2. Use CDA where
    a. Stability is critical for investment in clinical information
    b. The range of use cases required is broad
3. Use FHIR as an implementation strategy to extract and transform data to populate CDA R2 documents, similar to the approach of "greenCDA" which was one inspiration for FHIR
4. Distinguish between API and document use cases, and retain flexibility while the FHIR specification develops