CDA Tools Design Pilot

Contents

Acknowledgments

TODO: Add acknowledgments specific to this project team.

We acknowledge the foundational work on HL7 Version 3 and the Reference Information Model (RIM), the HL7 domain committees, especially Patient Care, and the work done on Clinical Document Architecture (CDA) itself.

We also acknowledge the collaborative effort of the American Society for Standards and Materials (ASTM) and HL7, which produced the Continuity of Care Document (CCD). All these efforts were critical ingredients to the development of this Draft Standard for Trial Use (DSTU), and the degree to which the DSTU reflects these efforts will foster interoperability across the spectrum of health care.

INTRODUCTION

Purpose

The purpose of this Implementation Guide (IG) is to specify a standard for ...

Approach

Working with an initial portion of the data provides the opportunity to work with the data from the perspective of the underlying model and electronic format and to explore many design issues thoroughly. Taking this as an initial step ensures that the data set developers and standards community can reach consensus prior to the larger commitment of time that would be required to bring the full data set into standard format.

This project supports reusability and ease of data collection through a standard data representation harmonized with work developed through Health Information Technology Expert Panel (HITEP), balloted through Health Level Seven (HL7) and/or recognized by the Health Information Technology Standards Panel (HITSP).

This implementation guide (IG) specifies a standard for electronic submission of NCRs in a Clinical Document Architecture (CDA), Release 2 format.

Scope

TODO: scope of this implementation guide.

Audience

The audience for this document includes software developers and implementers who wish to develop...

Organization of This Guide

The requirements as laid out in the body of this document are subject to change per the policy on implementation guides (see section 13.02" Draft Standard for Trial Use Documents" within the HL7 Governance and Operations Manual, *http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf*).

Templates

Templates are organized by document (see Document Templates), by section (see Section Templates), and by clinical statements (see Clinical Statement Templates). Within a section, templates are arranged hierarchically, where a more specific template is nested under the more generic template that it conforms to. See Templates by Containment for a listing of the higher level templates by containment; the appendix Templates Used in This Guide includes a table of all of the templates Organized Hierarchically.

Vocabulary and Value Sets

Vocabularies recommended in this guide are from standard vocabularies. When SNOMED codes are used, rules defined in Using SNOMED CT in HL7 Version 3 are adhered to. In many cases, these vocabularies are further constrained into value sets for use within this guide. Value set names and OIDs are summarized in the table Summary

of Value Sets. Each named value set in this summary table is stored in a template database that will be maintained by CHCA.

Use of Templates

When valued in an instance, the template identifier (`templateId`) signals the imposition of a set of template-defined constraints. The value of this attribute provides a unique identifier for the templates in question.

Originator Responsibilities

An originator can apply a `templateId` to assert conformance with a particular template.

In the most general forms of CDA exchange, an originator need not apply a `templateId` for every template that an object in an instance document conforms to. This implementation guide asserts when `templateId`s are required for conformance.

Recipient Responsibilities

A recipient may reject an instance that does not contain a particular `templateId` (e.g., a recipient looking to receive only CCD documents can reject an instance without the appropriate `templateId`).

A recipient may process objects in an instance document that do not contain a `templateId` (e.g., a recipient can process entries that contain Observation acts within a Problems section, even if the entries do not have `templateId`s).

DOCUMENT TEMPLATES

This section contains the document level constraints for CDA documents that are compliant with this implementation guide.

Tuberculosis Follow Up Progress Note

[ClinicalDocument: templateId `2.16.840.1.113883.10.20.15.2.6.1.1.1.1.1.2.3`]

The CDA for Tuberculosis Follow Up Progress Note constrains CDA to express the data elements identified by the CRSWg as specific to a follow-up report of tuberculosis. Tuberculosis (TB) is a contagious and potentially life-threatening infectious disease caused by a bacterium called Mycobacterium tuberculosis. The tuberculosis bacteria are spread from person to person through the air.

1. Conforms to *CDA Clinical Document*
2. **SHALL** contain [1..1] `component` such that it
    a. **SHALL** contain [1..1] *TB Results Section* (templateId: `2.16.840.1.113883.10.20.15.2.6`)
3. **SHALL** satisfy: There can be any number of patient names, but at least one of them must include a given and family name.

```
TODO: XML document snippet
```

Figure 1: Tuberculosis Follow Up Progress Note example

SECTION TEMPLATES

TB Results Section

[Section: templateId `2.16.840.1.113883.10.20.15.2.6`]

The tuberculosis results section represents the name of the laboratory tests, the date that the specimens for the laboratory tests were taken from the subject of the case report, and the date that the tests were performed on the specimen. It represents the result of the laboratory tests and observation ranges and susceptibility results. In addition, it captures the name of organization where the specimens were collected.

1. Conforms to *CCD Results Section* template (templateId: `2.16.840.1.113883.10.20.1.14`)
2. **MAY** contain [0..*] `entry` such that it
   a. **SHALL** contain [1..1] @typeCode="DRIV" *DRIV (is derived from)*
   b. **SHALL** contain [1..1] *TB Result Organizer* (templateId: `2.16.840.1.113883.10.20.15.3.21`)
3. **SHALL** contain [1..1] `code/@code` = "30954-2" *Relevant diagnostic tests and/or laboratory data* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
4. **SHALL** contain [1..1] `text`
5. **SHALL** contain [1..1] `title` = "Relevant diagnostic tests and/or laboratory data"
6. **MAY** contain [0..*] `entry` such that it
   a. **SHALL** contain [1..1] @typeCode="DRIV" *DRIV (is derived from)*
   b. **SHALL** contain [1..1] *TB Result Observation* (templateId: `2.16.840.1.113883.10.20.15.3.13`)

```
TODO: XML document snippet
```

Figure 2: TB Results Section example

CLINICAL STATEMENT TEMPLATES

This section of the Implementation Guide details the clinical statement entries referenced in the document section templates. The clinical statement entry templates are arranged alphabetically.

TB Result Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.13`]

This clinical statement represents the name of the laboratory test, the date that the specimen for the laboratory test was taken from the subject of the case report, the date that the laboratory test was performed on the specimen, and the result of the laboratory test. If applicable, it may capture the physical body location from where the specimen for the lab report was taken from the subject. In addition, it captures the name of organization where the specimen was collected. This tuberculosis result observation also contains a susceptibility clinical statement.

1. Conforms to *CCD Result Observation* template (templateId: `2.16.840.1.113883.10.20.1.31`)
2. **SHALL** contain [1..1] `@classCode` = "OBS"
3. **SHALL** contain [1..1] `code`, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3205 Lab Test Result Name (TB) DYNAMIC
4. **SHALL** contain [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)

```
TODO: XML document snippet
```

Figure 3: TB Result Observation example

TB Result Organizer

[Organizer: templateId `2.16.840.1.113883.10.20.15.3.21`]

The tuberculosis result organizer identifies an observation set, contained within the result organizer as a set of result observations. It contains information applicable to all of the contained result observations. It is particularly useful to group a number of tests, such as culture results, that are performed on a common specimen.

1. Conforms to *CCD Result Organizer* template (templateId: `2.16.840.1.113883.10.20.1.32`)
2. **SHALL** contain [1..1] `code`, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3205 Lab Test Result Name (TB) DYNAMIC
3. **SHALL** contain [1..1] `component` such that it
    a. **SHALL** contain [1..1] *TB Result Observation* (templateId: `2.16.840.1.113883.10.20.15.3.13`)

```
TODO: XML document snippet
```

Figure 4: TB Result Organizer example

CLASSES

This section of the Implementation Guide details the non-template classes, i.e. those that do not have a templateId.

REFERENCES

- HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD) A CDA implementation of ASTM E2369-05 Standard Specification for Continuity of Care Record© (CCR) April 01, 2007 available through *HL7* .
- HL7 Implementation Guide for CDA Release 2 Quality Reporting Document Architecture (QRDA) Draft Standard for Trial Use March 2009. Available at: *Quality Reporting Document Architecture (QRDA)*
- HL7 Implementation Guide for CDA Release 2 CDA for Public Health Case Reports (PHCR) Informative Standard October 2009. Available through *HL7* .
- HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection (HAI) Reports, Release 2 Draft Standard for Trial Use January 2009 Available at: *NHSN Healthcare Associated Infection (HAI) Reports*
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A, (Editors). HL7 Clinical Document Architecture, Release 2.0. ANSI-approved HL7 Standard; May 2005. Ann Arbor, Mich.: Health Level Seven, Inc. Available through *HL7* or if an HL7 member with the following link: *CDA Release 2 Normative Web Edition.*
- *LOINC®* : Logical Observation Identifiers Names and Codes, Regenstrief Institute.
- *SNOMED CT®* : SNOMED Clinical Terms SNOMED International Organization.
- Extensible Markup Language, *www.w3.org/XML* .
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A., HL7 Clinical Document Architecture, Release 2. J Am Med Inform Assoc. 2006;13:30-39. Available at: *http://www.jamia.org/cgi/reprint/13/1/30* .
- Using SNOMED CT in HL7 Version 3; Implementation Guide, Release 1.5. Available through *HL7* or if an HL7 member with the following link: *Using SNOMED CT in HL7 Version 3*