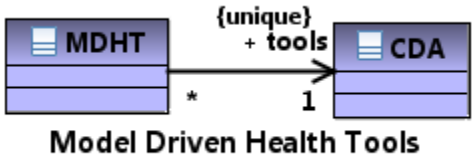
Implementation Guide for CDA Release 2
Silicosis Case Report CDA R2
Optional Subtitle



Model Driven Health Tools

PROTOTYPE: FOR DISCUSSION AND DEMONSTRATION USE ONLY

Contents

Acknowledgments

This document contains an example of healthcare standards and specifications publication generated from UML models, using the OHT Model Driven Health Tools (MDHT). Some portions of this document may not be publicly available but are included for demonstration purposes only, therefore this version of the document is to be treated as CONFIDENTIAL by the project participants.

This demonstration document contains informtion from the following sources:

Revision History

Rev	Date	By Whom	Changes
New	July 2010	Dave Carlson	
First draft for posting	December 2010	Dave Carlson	Updated model content and publication format

Chapter 1

INTRODUCTION

Topics:

Overview

This implementation guide is generated from UML models developed in the Open Health Tools (OHT) Model-Driven Health Tools (MDHT) project. The data specifications have been formalized into computational models expressed in UML. These models are used by automated tooling to generate this publication, plus validation tools and Java libraries for implementers.

Approach

Working with specifications generated from formal UML models 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).

Conventions Used in This Guide

Conformance Requirements

Conformance statements are grouped and identified by the name of the template, along with the templateId and the context of the template (e.g., ClinicalDocument, section, observation), which specifies the element under constraint. If a template is a specialization of another template, its first constraint indicates the more general template. In all cases where a more specific template conforms to a more general template, asserting the more specific template also implies conformance to the more general template. An example is shown below.

Template name

`[<type of template>: templateId <XXXX.XX.XXX.XXX>]`

Description of the template will be here .....

1. Conforms to <The template name> Template (templateId: XXXX<XX>XXX>YYY).
2. **SHALL** contain [1..1] @classCode = <AAA> <code display name> (CodeSystem: 123.456.789 <XXX> Class) **STATIC** (CONF:<number>).
3. .....

Figure 1: Template name and "conforms to" appearance

The conformance verb keyword at the start of a constraint (**SHALL** , **SHOULD** , **MAY**, etc.) indicates business conformance, whereas the cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within an instance. Thus, " **MAY** contain 0..1" and " **SHOULD** contain 0..1" both allow for a document to omit the particular component, but the latter is a stronger recommendation that the component be included if it is known.

The following cardinality indicators may be interpreted as follows:

0..1 as zero to one present
1..1 as one and only one present
2..2 as two must be present
1..* as one or more present
0..* as zero to many present

Value set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (**SHALL** , **SHOULD** , **MAY,** etc.) and an indication of **DYNAMIC** vs. **STATIC** binding. The use of **SHALL** requires that the component be valued with a member from the cited value set; however, in every case any HL7 "null" value such as other (OTH) or unknown (UNK) may be used.

Each constraint is uniquely identified (e.g., "CONF:605") by an identifier placed at or near the end of the constraint. These identifiers are not sequential as they are based on the order of creation of the constraint.

1. **SHALL** contain [1..1] component/structuredBody (CONF:4082).
    a. This component/structuredBody **SHOULD** contain [0..1] component (CONF:4130) such that it
        a. **SHALL** contain [1..1] Reporting Parameters section (templateId:2.16.840.1.113883.10.20.17.2.1) (CONF:4131).
    b. This component/structuredBody **SHALL** contain [1..1] component (CONF:4132) such that it
        a. **SHALL** contain [1..1] Patient data section - NCR (templateId:2.16.840.1.113883.10.20.17.2.5) (CONF:4133).

Figure 2: Template-based conformance statements example

CCD templates are included within this implementation guide for ease of reference. CCD templates contained within this implementation guide are formatted WITHOUT typical **KEYWORD** and **XML** element styles. A WIKI site is available if you would like to make a comment to be considered for the next release of CCD: *http://wiki.hl7.org/index.php?title=CCD_Suggested_Enhancements* The user name and password are: wiki/wikiwiki. You will need to create an account to edit the page and add your suggestion.

1. The value for "Observation / @moodCode" in a problem observation SHALL be "EVN" 2.16.840.1.113883.5.1001 ActMood STATIC. (CONF: 814).
2. A problem observation SHALL include exactly one Observation / statusCode. (CONF: 815).
3. The value for "Observation / statusCode" in a problem observation SHALL be "completed" 2.16.840.1.113883.5.14 ActStatus STATIC. (CONF: 816).
4. A problem observation SHOULD contain exactly one Observation / effectiveTime, to indicate the biological timing of condition (e.g. the time the condition started, the onset of the illness or symptom, the duration of a condition). (CONF: 817).

Figure 3: CCD conformance statements example

Keywords

The keywords SHALL, SHALL NOT, SHOULD, SHOULD NOT, MAY, and NEED NOT in this document are to be interpreted as described in the *HL7 Version 3 Publishing Facilitator's Guide*:

- **SHALL**: an absolute requirement
- **SHALL NOT**: an absolute prohibition against inclusion
- **SHOULD/SHOULD NOT**: valid reasons to include or ignore a particular item, but must be understood and carefully weighed
- **MAY/NEED NOT**: truly optional; can be included or omitted as the author decides with no implications

XML Examples

XML samples appear in various figures in this document in a fixed-width font. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (…) as shown in the example below.

```
<ClinicalDocument xmlns='urn:h17-org:v3'>
  ...
</ClinicalDocument>
```

Figure 4: ClinicalDocument example

XPath expressions are used in the narrative and conformance requirements to identify elements because they are familiar to many XML implementers.

Chapter 2

DOCUMENT TEMPLATES

Topics:

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

Silicosis Case Report

[ClinicalDocument: templateId `2.16.840.1.113883.10.20.15.1.8`]

1. **SHALL** conform to *PHCR Public Health Case Report* template (templateId: `2.16.840.1.113883.10.20.15`)
2. **SHOULD** contain zero or one [0..1] **`component`**
   a. Contains exactly one [1..1] *Silicosis PHCR Social History Section* (templateId: `2.16.840.1.113883.10.20.15.2.33`)
3. **SHALL** contain exactly one [1..1] **`component`**
   a. Contains exactly one [1..1] *Silicosis PHCR Clinical Information Section* (templateId: `2.16.840.1.113883.10.20.15.2.34`)
4. **SHALL** contain exactly one [1..1] **`title`** = "Public Health Case Report - Silicosis"
5. **SHOULD** contain zero or one [0..1] **`component`**
   a. Contains exactly one [1..1] *Silicosis PHCR Relevant Dx Tests Section* (templateId: `2.16.840.1.113883.10.20.15.2.35`)

Silicosis Case Report example

Chapter 3

SECTION TEMPLATES

Topics:

Silicosis PHCR Clinical Information Section

[Section: templateId `2.16.840.1.113883.10.20.15.2.34`]

1. **SHALL** conform to *PHCR Phcr Clinical Information Section* template (templateId: `2.16.840.1.113883.10.20.15.2.1`)
2. **SHALL** contain exactly one [1..1] **`entry`**
   a. Contains exactly one [1..1] *Silicosis Case Observation* (templateId: `2.16.840.1.113883.10.20.15.3.111`)
3. **SHOULD** contain zero or one [0..1] **`entry`**
   a. Contains exactly one [1..1] *Silicosis History Of Tuberculosis Observation* (templateId: `2.16.840.1.113883.10.20.15.3.107`)

Silicosis PHCR Clinical Information Section example

Silicosis PHCR Relevant Dx Tests Section

[Section: templateId `2.16.840.1.113883.10.20.15.2.35`]

1. **SHALL** conform to *PHCR PhcrRelevantDxTestsSection* template (templateId: `2.16.840.1.113883.10.20.15.2.3`)
2. **MAY** contain zero or more [0..*] **`entry`**
   a. Contains exactly one [1..1] *Silicosis Imaging Observation* (templateId: `2.16.840.1.113883.10.20.15.3.108`)

Silicosis PHCR Relevant Dx Tests Section example

Silicosis PHCR Social History Section

[Section: templateId `2.16.840.1.113883.10.20.15.2.33`]

1. **SHALL** conform to *PHCR Phcr Social History Section* template (templateId: `2.16.840.1.113883.10.20.15.2.22`)
2. **SHOULD** contain zero or one [0..1] **`entry`**
   a. Contains exactly one [1..1] *Silicosis Socio Behavioral Boolean Risk Factor Observation* (templateId: `2.16.840.1.113883.10.20.15.3.110`)
3. **SHOULD** contain zero or more [0..*] **`entry`**
   a. Contains exactly one [1..1] *Silicosis Possible Exposure Location And Type Act* (templateId: `2.16.840.1.113883.10.20.15.3.109`)

Silicosis PHCR Social History Section example

Chapter 4

CLINICAL STATEMENT TEMPLATES

Topics:

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.

Silicosis Case Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.111`]

1. **SHALL** conform to *PHCR Case Observation* template (templateId: `2.16.840.1.113883.10.20.15.3.54`)
2. **SHOULD** contain zero or more [0..*] **`targetSiteCode`**, where the @code **SHOULD** be selected from ValueSet `Body Site 2.16.840.1.113883.3.88.12.3221.8.9` **DYNAMIC**
3. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:1874), where the @code **SHALL** be selected from ValueSet *`Disease Type (silicosis)`* `2.16.840.1.114222.4.11.6018` **STATIC**
4. **SHOULD** contain zero or more [0..*] **`entryRelationship`**
   a. Contains **`@typeCode="MFST"`** *MFST*
   b. Contains exactly one [1..1] *Silicosis Signs And Symptoms Observation* (templateId: `2.16.840.1.113883.10.20.15.3.112`)

Silicosis Case Observation example

Silicosis History Of Tuberculosis Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.107`]

1. **SHALL** conform to *CCD Problem Observation* template (templateId: `2.16.840.1.113883.10.20.1.28`)
2. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
3. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from ValueSet `ProblemTypeCode 2.16.840.1.113883.1.11.20.14` **STATIC** 20061017 (CONF-159)
4. **SHALL** contain exactly one [1..1] **`value`** with data type CD, where the @code **SHALL** be selected from ValueSet **STATIC**

Silicosis History Of Tuberculosis Observation example

Silicosis Imaging Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.108`]

1. **SHALL** conform to *PHCR Imaging Observation* template (templateId: `2.16.840.1.113883.10.20.15.3.5`)
2. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:825), where the @code **SHALL** be selected from ValueSet *`Chest Imaging Tests`* `2.16.840.1.114222.4.11.6019` **STATIC**

Silicosis Imaging Observation example

Silicosis Possible Exposure Location And Type Act

[Act: templateId `2.16.840.1.113883.10.20.15.3.109`]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)

3. **SHALL** contain exactly one [1..1] **`code/@code`**`="413350009"` *Finding with explicit context* (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`)
4. **SHALL** contain zero or one [0..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`)
5. code **SHALL** contain [1..1] qualifier
6. code **SHALL** contain [1..1] qualifier
7. **SHALL** contain [1..*] participant
8. **MAY** contain [0..*] participant

Silicosis Possible Exposure Location And Type Act example

Silicosis Signs And Symptoms Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.112`]

1. **SHALL** conform to *PHCR Signs And Symptoms Observation* template (templateId: `2.16.840.1.113883.10.20.15.3.53`)
2. **SHALL** contain exactly one [1..1] **`value`** with data type CD (CONF:1867), where the @code **SHALL** be selected from ValueSet *`Signs and Symptoms (silicosis)`* `2.16.840.1.114222.4.11.6017` **STATIC**

Silicosis Signs And Symptoms Observation example

Silicosis Socio Behavioral Boolean Risk Factor Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.110`]

1. **SHALL** conform to *CCD Social History Observation* template (templateId: `2.16.840.1.113883.10.20.1.33`)
2. **SHALL** contain zero or one [0..1] **`@negationInd`**
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="ASSERTION"` (CodeSystem: `2.16.840.1.113883.5.4 HL7ActCode`)
4. **SHOULD** contain zero or one [0..1] **`effectiveTime`**
5. **SHALL** contain exactly one [1..1] **`value`** with data type CD**`/@code`**`="102445001"` *Exposure to toxic dust* (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`)

Silicosis Socio Behavioral Boolean Risk Factor Observation example

Chapter 5

OTHER CLASSES

This section of the Implementation Guide describes other classes that are not CDA Clinical Documents, Sections, or Clinical Statements.

Chapter 6

VALUE SETS

Topics:

The following tables summarize the value sets used in this Implementation Guide.

Chest Imaging Tests

Value Set	Chest Imaging Tests - 2.16.840.1.114222.4.11.6019
Source	PHIN VADS
Definition	Value set provides imaging tests that are used to diagnose Silicosis. Codes are from LOINC.

Concept Code	Concept Name	Code System	Description
24642-1	Chest XR AP+PA Upr	LOINC	
36687-2	Chest XR AP+Lat	LOINC	
30745-4	Chest XR	LOINC	
37439-7	Chest CT High Res	LOINC	
37441-3	Chest CT High Res WO contr	LOINC	
39341-3	Chest XR Lat+PA W insp+exp	LOINC	
42272-5	Chest XR PA+Lat	LOINC	

Disease Type (silicosis)

Value Set	Disease Type (silicosis) - 2.16.840.1.114222.4.11.6018
Source	PHIN VADS
Definition	Silicosis disease type value set has problems or disease related to Silicosis. This value set is based upon SNOMED CT

Concept Code	Concept Name	Code System	Description
196009005	massive silicotic fibrosis	SNOMEDCT	
233760007	acute silicosis	SNOMEDCT	
233761006	subacute silicosis	SNOMEDCT	
233762004	chronic silicosis	SNOMEDCT	
233763009	silicotuberculosis	SNOMEDCT	
33548005	anthracosilicosis	SNOMEDCT	
34004002	siderosilicosis	SNOMEDCT	
40640008	massive silicotic fibrosis of lung	SNOMEDCT	
47515009	simple silicosis	SNOMEDCT	
49840000	complicated silicosis	SNOMEDCT	
805002	pneumoconiosis due to silica	SNOMEDCT	

Signs and Symptoms (silicosis)

Value Set	Signs and Symptoms (silicosis) - 2.16.840.1.114222.4.11.6017
Source	PHIN VADS
Definition	Signs and symptoms related to silicosis disease. Codes from SNOMED CT

Concept Code	Concept Name	Code System	Description
267036007	Dyspnea (finding)	SNOMEDCT	
49727002	Cough (finding)	SNOMEDCT	
284523002	Persistent cough (finding)	SNOMEDCT	
84229001	Fatigue (finding)	SNOMEDCT	
271823003	Tachypnea (finding)	SNOMEDCT	
89362005	Weight loss (finding)	SNOMEDCT	
79890006	Loss of appetite (finding)	SNOMEDCT	
29857009	Chest pain (finding)	SNOMEDCT	
386661006	Fever (finding)	SNOMEDCT	
3415004	Cyanosis (finding)	SNOMEDCT	
83291003	Cor pulmonale (disorder)	SNOMEDCT	
409623005	Respiratory insufficiency (disorder)	SNOMEDCT	

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- 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*