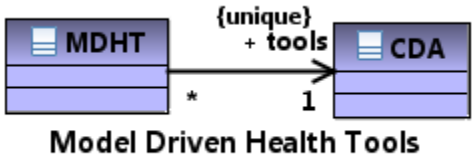
Implementation Guide for CDA Release 2
Toxic Shock Syndrome Case Report CDA R2
Optional Subtitle



Model Driven Health Tools

PROTOTYPE: FOR DISCUSSION AND DEMONSTRATION USE ONLY

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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*
- *Approach*
- *Scope*
- *Audience*
- *Organization of This Guide*
- *Use of Templates*
- *Conventions Used in This Guide*

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:

- *Toxic Shock Syndrome Case Report*

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

Toxic Shock Syndrome Case Report

[ClinicalDocument: templateId `2.16.840.1.113883.10.20.15.1.6`]

1. **SHALL** conform to *PHCR Public Health Case Report* template (templateId: `2.16.840.1.113883.10.20.15`)
2. **SHALL** contain exactly one [1..1] **`title`** = "Public Health Case Report - Toxic Shock Syndrome"
3. **SHALL** contain exactly one [1..1] **`component`**, such that
   a. Contains exactly one [1..1] *Tss Phcr Clinical Information Section* (templateId: `2.16.840.1.113883.10.20.15.2.42`)
4. **SHOULD** contain zero or one [0..1] **`component`**, such that
   a. Contains exactly one [1..1] *Tss Phcr Relevant Dx Tests Section* (templateId: `2.16.840.1.113883.10.20.15.2.43`)

Toxic Shock Syndrome Case Report example

Chapter 3

SECTION TEMPLATES

Topics:

- *Tss Phcr Clinical Information Section*
- *Tss Phcr Relevant Dx Tests Section*

Tss Phcr Clinical Information Section

[Section: templateId `2.16.840.1.113883.10.20.15.2.42`]

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`**, such that
   a. Contains **`@typeCode="DRIV"`** *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Tss Case Observation* (templateId: `2.16.840.1.113883.10.20.15.3.99`)

Tss Phcr Clinical Information Section example

Tss Phcr Relevant Dx Tests Section

[Section: templateId `2.16.840.1.113883.10.20.15.2.43`]

1. **SHALL** conform to *PHCR Phcr Relevant Dx Tests Section* template (templateId: `2.16.840.1.113883.10.20.15.2.3`)
2. **MAY** contain zero or more [0..*] **`entry`**, such that
   a. Contains **`@typeCode="DRIV"`** *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Tss Result Organizer* (templateId: `2.16.840.1.113883.10.20.15.3.101`)
3. **SHOULD** contain zero or more [0..*] **`entry`**, such that
   a. Contains **`@typeCode="DRIV"`** *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Tss Result Observation* (templateId: `2.16.840.1.113883.10.20.15.3.102`)

Tss Phcr Relevant Dx Tests Section example

Chapter 4

CLINICAL STATEMENT TEMPLATES

Topics:

- *Tss Case Observation*
- *Tss Result Observation*
- *Tss Result Organizer*
- *Tss Signs And Symptoms Observation*

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.

Tss Case Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.99`]

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..*] **`entryRelationship`**, such that
   a. Contains **`@typeCode="MFST"`** *MFST (is manifestation of)*
   b. Contains exactly one [1..1] *Tss Signs And Symptoms Observation* (templateId: `2.16.840.1.113883.10.20.15.3.100`)
3. **SHALL** contain exactly one [1..1] **`value/@code`**`="240450004"` (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`), where its data type is CD (CONF:1874)

Tss Case Observation example

Tss Result Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.102`]

1. **SHALL** conform to *PHCR Result Observation* template (templateId: `2.16.840.1.113883.10.20.15.3.58`)
2. **SHALL** contain exactly one [1..1] **`code`**, which **SHALL** be selected from ValueSet *`Lab Test Result Name (Tss)`* **DYNAMIC**

Tss Result Observation example

Tss Result Organizer

[Organizer: templateId `2.16.840.1.113883.10.20.15.3.101`]

1. **SHALL** conform to *PHCR Result Organizer* template (templateId: `2.16.840.1.113883.10.20.15.3.59`)
2. **SHALL** contain at least one [1..*] **`component`**, such that
   a. Contains exactly one [1..1] *Tss Result Observation* (templateId: `2.16.840.1.113883.10.20.15.3.102`)
3. **SHALL** contain exactly one [1..1] **`code`**, which **SHALL** be selected from ValueSet *`Lab Test Result Name (Tss)`* **DYNAMIC**

Tss Result Organizer example

Tss Signs And Symptoms Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.100`]

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`**, which **SHALL** be selected from ValueSet *`Signs and Symptoms (Tss)`* **DYNAMIC**, where its data type is CD

Tss Signs And Symptoms 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:

- *Lab Test Result Name (Tss)*
- *Signs and Symptoms (Tss)*

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

Lab Test Result Name (Tss)

Value Set	Lab Test Result Name (Tss) - (OID not specified)
Code System	LOINC - 2.16.840.1.113883.6.1
Source	PHIN VADS

Concept Code	Concept Name	Code System	Description
11468-6	Bacillus anthracis Ab:ACnc:Pt:XXX:Qn:IF	LOINC	
33697-4	Bacillus anthracis Ag:ACnc:Pt:Isolate:Ord:IF	LOINC	
22866-8	Bacillus anthracis Ag:ACnc:Pt:Tiss:Ord:IF	LOINC	
22867-6	Bacillus anthracis Ag:ACnc:Pt:XXX:Ord:IF	LOINC	
51976-9	Bacillus anthracis capsule Ag:Prid:Pt:XXX:Nom:IF	LOINC	
44269-9	Bacillus anthracis cell wall Ag:Prid:Pt:XXX:Nom:IF	LOINC	
33698-2	Bacillus anthracis:ACnc:Pt:Isolate:Ord:Phage lysis	LOINC	
44270-7	Bacillus anthracis spore Ag:Prid:Pt:XXX:Nom:IF	LOINC	
11469-4	Bacillus anthracis:ACnc:Pt:XXX:Ord:Organism specific culture	LOINC	
17928-3	Bacteria identified:Prid:Pt:Bld:Nom:Aerobic culture	LOINC	
17915-0	Bacteria identified:Prid:Pt:Wound.shlw:Nom:Aerobic culture	LOINC	
622-1	Bacteria identified:Prid:Pt:Sputum:Nom:Aerobic culture	LOINC	
21020-3	Bacteria identified:Prid:Pt:XXX:Nom:Anaerobic +Aerobic culture	LOINC	
41622-2	B anthracis DNA XXX PCR	LOINC	

Signs and Symptoms (Tss)

Value Set	Signs and Symptoms (Tss) - (OID not specified)
Source	PHIN VADS

Concept Code	Concept Name	Code System	Description
21522001	Abdominal pain	SNOMEDCT	
84387000	Asymptomatic	SNOMEDCT	
29857009	Chest pain	SNOMEDCT	
43724002	Chill	SNOMEDCT	
PHC819	Cutaneous ulcer with edema and black eschar	PHIN VS (CDC Local Coding System)	
62315008	Diarrhea	SNOMEDCT	
230145002	Difficulty breathing	SNOMEDCT	
267038008	Edema	SNOMEDCT	
386661006	Fever	SNOMEDCT	
25064002	Headache	SNOMEDCT	
30746006	Lymphadenopathy	SNOMEDCT	
409596002	Non-productive cough	SNOMEDCT	

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*