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

PROTOTYPE: FOR DISCUSSION
AND DEMONSTRATION USE ONLY
(Consolidated Developer Documentation)
# Contents

Acknowledgments ................................................................................................................. 5  
Revision History .................................................................................................................... 7  

Chapter 1: INTRODUCTION ........................................................................ 9  
  Overview................................................................................................................................................ 10  
  Approach................................................................................................................................................ 10  
  Scope...................................................................................................................................................... 10  
  Audience.................................................................................................................................................10  
  Organization of This Guide.................................................................................................................... 10  
    Templates................................................................................................................................... 10  
    Vocabulary and Value Sets........................................................................................................ 10  
  Use of Templates...................................................................................................................................11  
    Originator Responsibilities........................................................................................................ 11  
    Recipient Responsibilities.......................................................................................................... 11  
  Conventions Used in This Guide........................................................................................................ 11  
    Conformance Requirements....................................................................................................... 11  
    Keywords................................................................................................................................... 12  
    XML Examples.......................................................................................................................... 12  

Chapter 2: DOCUMENT TEMPLATES.....................................................13  
  Toxic Shock Syndrome Case Report..................................................................................................... 14  

Chapter 3: SECTION TEMPLATES .......................................................... 17  
  Tss Phcr Clinical Information Section................................................................................................... 18  
  Tss Phcr Relevant Dx Tests Section...................................................................................................... 18  

Chapter 4: CLINICAL STATEMENT TEMPLATES .............................. 21  
  Tss Case Observation............................................................................................................................. 22  
  Tss Result Observation......................................................................................................................... 23  
  Tss Result Organizer.............................................................................................................................. 24  
  Tss Signs And Symptoms Observation................................................................................................. 25  

Chapter 5: OTHER CLASSES ..................................................................... 27  

Chapter 6: VALUE SETS ............................................................................. 29  
  Lab Test Result Name (Tss)................................................................................................................... 30  
  Signs and Symptoms (Tss).................................................................................................................. 31  

REFERENCES ....................................................................................................................33
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 information from the following sources:

© 2010 ANSI. This material may be copied without permission from ANSI only if and to the extent that the text is not altered in any fashion and ANSI's copyright is clearly noted.

SNOMED CT® is the registered trademark of the International Health Terminology Standard Development Organization (IHTSDO).

This material contains content from LOINC® (http://loinc.org). The LOINC table, LOINC codes, and LOINC panels and forms file are copyright © 1995-2010, Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC) Committee and available at no cost under the license at http://loinc.org/terms-of-use.

Certain materials contained in this Interoperability Specification are reproduced from Health Level Seven (HL7) HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), HL7 Implementation Guide for CDA Release 2: History and Physical (H&P) Notes, HL7 Implementation Guide for CDA Release 2: Consult Notes, or HL7 Implementation Guide for CDA Release 2: Operative Notes with permission of Health Level Seven, Inc. No part of the material may be copied or reproduced in any form outside of the Interoperability Specification documents, including an electronic retrieval system, or made available on the Internet without the prior written permission of Health Level Seven, Inc. Copies of standards included in this Interoperability Specification may be purchased from the Health Level Seven, Inc. Material drawn from these standards is credited where used.
## Revision History

<table>
<thead>
<tr>
<th>Rev</th>
<th>Date</th>
<th>By Whom</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>New</td>
<td>July 2010</td>
<td>Dave Carlson</td>
<td></td>
</tr>
<tr>
<td>First draft for posting</td>
<td>December 2010</td>
<td>Dave Carlson</td>
<td>Updated model content and publication format</td>
</tr>
</tbody>
</table>
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 templateIds 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 templateIds).

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

CD 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).
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.

```xml
<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. Contains exactly one [1..1] typeId, where its data type is InfrastructureRootTypeId
3. Contains exactly one [1..1] id, where its data type is II
5. SHALL contain exactly one [1..1] title = "Public Health Case Report - Toxic Shock Syndrome"
6. Contains exactly one [1..1] effectiveTime, where its data type is TS
7. Contains exactly one [1..1] confidentialityCode, where its data type is CE
8. Contains at least one [1..*] recordTarget, where its type is Record Target
9. Contains at least one [1..*] author, where its type is Author
10. Contains exactly one [1..1] custodian, where its type is Custodian
11. Contains exactly one [1..1] component, where its type is Component2
12. SHOULD contain zero or one [0..1] component (CONF:914, CONF:915), such that
   a. Contains exactly one [1..1] Phcr Social History Section (templateId: 2.16.840.1.113883.10.20.15.2.22)
13. SHOULD contain zero or one [0..1] component (CONF:742, CONF:674), such that
    a. Contains exactly one [1..1] Phcr Treatment Information Section (templateId: 2.16.840.1.113883.10.20.15.2.4)
14. SHOULD contain zero or one [0..1] component (CONF:643, CONF:609), such that
    a. Contains exactly one [1..1] Phcr Encounters Section (templateId: 2.16.840.1.113883.10.20.15.2.2)
15. MAY contain zero or one [0..1] component, such that
    a. Contains exactly one [1..1] CCD Immunizations Section (templateId: 2.16.840.1.113883.10.20.1.6)
16. 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)
17. 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)
18. SHALL contain [1..1] recordTarget (CONF:547)
   • [OCL]: self.recordTarget->one(recordTarget : cda::RecordTarget | not recordTarget.oclIsUndefined())
19. RecordTarget SHALL contain [1..1] patientRole (CONF:548)
   • [OCL]: self.recordTarget.patientRole->one(patientRole : cda::PatientRole | not patientRole.oclIsUndefined())
20. RecordTarget / PatientRole SHALL contain [1..*] id (CONF:549)
   • [OCL]: self.recordTarget.patientRole.id->exists(id : datatypes::II | not id.root.oclIsUndefined() or not id.extension.oclIsUndefined() or not id.nullFlavor.oclIsUndefined())
21. RecordTarget / PatientRole SHOULD contain [0..*] addr (CONF:550)
22. RecordTarget / PatientRole SHOULD contain [0..*] telecom (CONF:551)
23. RecordTarget / PatientRole SHOULD contain [0..1] patient (CONF:552)
24. RecordTarget / PatientRole / Patient SHOULD contain [0..*] name (CONF:553)
25. RecordTarget / PatientRole / Patient SHOULD contain [0..1] administrativeGenderCode/@code, which SHALL be selected from ValueSet 2.16.840.1.113883.1.11.1 Administrative Gender (HL7 V3) DYNAMIC (CONF:554)
26. RecordTarget / PatientRole / Patient SHOULD contain [0..1] birthTime (CONF:555)
27. RecordTarget / PatientRole / Patient SHOULD contain [0..1] ethnicGroupCode, which SHALL be selected from ValueSet 2.16.840.1.114222.4.11.837 Ethnicity group DYNAMIC (CONF:556)
28. RecordTarget / PatientRole / Patient SHOULD contain [0..1] birthplace/place, which SHALL be selected from ValueSet 2.16.840.1.114222.4.11.3200 Birth Country DYNAMIC (CONF:557)
29. SHALL contain [1..*] author (CONF:1853)
   • [OCL]: self.author->exists(author : cda::Author | not author.oclIsUndefined())
30. Author SHALL contain [1..1] time (CONF:560)
   • [OCL]: self.author.time->one(time : datatypes::TS | not time.value.oclIsUndefined() or not time.nullFlavor.oclIsUndefined())
31. Author SHALL contain [1..1] assignedAuthor (CONF:561)
   • [OCL]: self.author.assignedAuthor->one(assignedAuthor : cda::AssignedAuthor | not assignedAuthor.oclIsUndefined())
32. Author / AssignedAuthor SHALL contain [1..1] addr (CONF:562)
   • [OCL]: self.author.assignedAuthor.addr->one(addr : datatypes::AD | not addr.oclIsUndefined())
33. Author / AssignedAuthor SHALL contain [1..1] telecom (CONF:564)
   • [OCL]: self.author.assignedAuthor.telecom->one(tel : datatypes::TEL | not tel.oclIsUndefined())
34. Author / AssignedAuthor SHALL contain [1..1] assignedPerson/name (CONF:565)
   • [OCL]: self.author.assignedAuthor.assignedPerson->one(assignedPerson : cda::Person | not assignedPerson.oclIsUndefined()) and self.author.assignedAuthor.assignedPerson.name->one(name : datatypes::PN | not name.oclIsUndefined())
35. The custodian of a public health case report SHALL be the reporting organization. (CONF:1616)
36. SHALL contain [1..1] legalAuthenticator (CONF:1854)
   • [OCL]: self.legalAuthenticator->one(legalAuthenticator : cda::LegalAuthenticator | not legalAuthenticator.oclIsUndefined())
37. LegalAuthenticator SHALL contain [1..1] time (CONF:1855)
   • [OCL]: self.legalAuthenticator.time->one(time : datatypes::TS | not time.value.oclIsUndefined() or not time.nullFlavor.oclIsUndefined())
38. LegalAuthenticator SHALL contain [1..1] assignedEntity (CONF:1856)
   • [OCL]: self.legalAuthenticator.assignedEntity->one(assignedEntity : cda::AssignedEntity | not assignedEntity.oclIsUndefined())
39. LegalAuthenticator / AssignedEntity SHALL contain [1..*] id (CONF:1857)
   • [OCL]: self.legalAuthenticator.assignedEntity.id->exists(id : datatypes::II | not id.root.oclIsUndefined() or not id.extension.oclIsUndefined() or not id.nullFlavor.oclIsUndefined())
40. LegalAuthenticator / AssignedEntity SHALL contain [1..1] addr (CONF:1859)
   • [OCL]: self.legalAuthenticator.assignedEntity.addr->one(addr : datatypes::AD | not addr.oclIsUndefined())
41. LegalAuthenticator / AssignedEntity SHALL contain [1..1] telecom (CONF:1859)
42. LegalAuthenticator / AssignedEntity SHALL contain [1..1] assignedPerson/name (CONF:1860)
   • [OCL]: self.legalAuthenticator.assignedEntity.assignedPerson->one(assignedPerson : cda::Person | not assignedPerson.oclIsUndefined())
44. Where a Public Health Case Report CDA R2 document contains any of the section or clinical statement templates defined in this implementation guide, such section or clinical statement **SHALL** include a templateId/@root valued with the corresponding template's identifier. (CONF:2017)

**Toxic Shock Syndrome Case Report example**
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] code/@code="55752-0" Clinical Information (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:540)
3. SHALL contain exactly one [1..1] title = "Clinical Information" (CONF:541)
4. SHALL contain exactly one [1..1] text (CONF:542)
5. SHOULD contain zero or more [0..*] entry, such that
   a. Contains @typeCode="DRIV" DRIV (is derived from)
   b. Contains exactly one [1..1] Phcr Relevant Medical Condition History Observation (templateId: 2.16.840.1.113883.10.20.15.3.62)
6. MAY contain zero or one [0..1] entry (CONF:1912, CONF:1913, CONF:1914), such that
   a. Contains @typeCode="DRIV" DRIV (is derived from)
   b. Contains exactly one [1..1] Patient Condition Alive Observation (templateId: 2.16.840.1.113883.10.20.15.3.42)
7. MAY contain zero or one [0..1] entry (CONF:1915, CONF:1916, CONF:1917), such that
   a. Contains @typeCode="DRIV" DRIV (is derived from)
   b. Contains exactly one [1..1] Patient Condition Deceased Observation (templateId: 2.16.840.1.113883.10.20.15.3.17)
8. 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)
9. TemplateId 2.16.840.1.113883.10.20.15.3.42 (Patient condition alive) and templateId 2.16.840.1.113883.10.20.15.3.17 (Patient condition deceased) SHALL NOT be present together in a CDA PHCR instance. (CONF:1918)
   
   [OCL]: self.getObservations()->exists(obs3 : cda::Observation | obs3.oclIsKindOf(phcr::PatientConditionAliveObservation) and not self.getObservations()->exists(obs4 : cda::Observation | obs4.oclIsKindOf(phcr::PatientConditionDeceasedObservation)) or self.getObservations()->exists(obs1 : cda::Observation | obs1.oclIsKindOf(phcr::PatientConditionDeceasedObservation) and not self.getObservations()->exists(obs2 : cda::Observation | obs2.oclIsKindOf(phcr::PatientConditionAliveObservation)) or self.getObservations()->forAll(obs : cda::Observation | not obs.oclIsKindOf(phcr::PatientConditionAliveObservation) and not obs.oclIsKindOf(phcr::PatientConditionDeceasedObservation))

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 CCD Results Section template (templateId: 2.16.840.1.113883.10.20.1.14)
2. SHALL conform to PHCR Phcr Relevant Dx Tests Section template (templateId: 2.16.840.1.113883.10.20.15.2.3)
3. SHALL contain exactly one [1..1] code/@code="30954-2" Relevant diagnostic tests and/or laboratory data (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-389)

4. SHALL contain exactly one [1..1] title = "Relevant diagnostic tests and/or laboratory data" (CONF-391)

5. SHALL contain exactly one [1..1] text (CONF-388, CONF:737)

6. MAY contain zero or more [0..*] entry (CONF:2014, CONF:2015, CONF:2016), such that
   a. Contains @typeCode="DRIV" DRIV (is derived from)
   b. Contains exactly one [1..1] Imaging Observation (templateId: 2.16.840.1.113883.10.20.15.3.5)

7. 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)

8. 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)

9. SHOULD satisfy: Contains a case-insensitive language-insensitive string containing 'results'. (CONF-392)
   • UNIMPLEMENTABLE

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 **CCD Problem Observation** template (templateId: 2.16.840.1.113883.10.20.1.28)
2. SHALL conform to **PHCR Case Observation** template (templateId: 2.16.840.1.113883.10.20.15.3.54)
3. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:1868)
4. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:1869)
5. MAY contain zero or more [0..*] id (CONF:1870)
6. SHALL contain exactly one [1..1] code/@code="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) (CONF:1871)
7. SHALL contain exactly one [1..1] statusCode/@code="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF:1872)
8. SHOULD contain zero or one [0..1] effectiveTime (CONF:1873)
9. 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)
10. MAY contain zero or one [0..1] entryRelationship (CONF-162), such that
    a. Contains @typeCode="REFR" REFR (refers to)
    b. Contains exactly one [1..1] Problem Status Observation (templateId: 2.16.840.1.113883.10.20.1.50)
11. MAY contain zero or one [0..1] entryRelationship (CONF-165), such that
    a. Contains @typeCode="REFR" REFR (refers to)
    b. Contains exactly one [1..1] Problem Health Status Observation (templateId: 2.16.840.1.113883.10.20.1.51)
12. MAY contain zero or one [0..1] entryRelationship (CONF-160), such that
    a. Contains @typeCode="SUBJ" SUBJ (has subject)
    b. Contains exactly one [1..1] Age Observation (templateId: 2.16.840.1.113883.10.20.1.38)
13. SHOULD contain zero or one [0..1] entryRelationship (CONF:1884, CONF:1885, CONF:1886), such that
    a. Contains @typeCode="REFR" REFR (refers to)
    b. Contains exactly one [1..1] CCD Problem Status Observation (templateId: 2.16.840.1.113883.10.20.1.50)
14. 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)
15. SHALL contain one or more sources of information. (CONF-161)
    - [OCL]: not self.informant->isEmpty()
      or not self.getSection().informant->isEmpty()
      or not self.getClinicalDocument().informant->isEmpty()
      or self.reference->exists(ref : cda::Reference | ref,typeCode = vocab::x_ActRelationshipExternalReference::XCRPT)
      or (self.entryRelationship->exists(rel : cda::EntryRelationship | rel.typeCode = vocab::x_ActRelationshipEntryRelationship::::REFR
        and rel.observation.code.code = '48766-0'))
16. MAY contain exactly one Patient Awareness (CONF-180)
    - [OCL]: self.participant->one(partic : cda::Participant2 | partic.oclIsKindOf(cda::PatientAwareness))
17. SHOULD contain [0..1] effectiveTime/low (CONF:1873)
   • [OCL]: self.effectiveTime->exists(time : datatypes::IVL_TS | not time.low.oclIsUndefined())

18. SHOULD contain [0..1] author (CONF:1875)
   • [OCL]: self.author->exists(author : cda::Author | not author.oclIsUndefined())

19. Author SHALL contain [1..1] time (CONF:1876)
20. Author SHALL contain [1..1] assignedAuthor (CONF:1877)
   • [OCL]: self.author.assignedAuthor->exists(assignedAuthor : cda::AssignedAuthor | not assignedAuthor.oclIsUndefined())

21. Author / AssignedAuthor SHALL contain [1..*] id (CONF:1878)
22. Author / AssignedAuthor MAY contain [0..*] addr (CONF:1879)
23. Author / AssignedAuthor MAY contain [0..*] telecom (CONF:1880)
24. Author / AssignedAuthor MAY contain [0..1] assignedPerson (CONF:1881)
25. Author / AssignedAuthor / Person MAY contain [0..1] name (CONF:1882)
26. Author / AssignedAuthor MAY contain [0..1] representedOrganization (CONF:1883)

Tss Case Observation example

Tss Result Observation

[Observation: templateId 2.16.840.1.113883.10.20.15.3.102]

1. SHALL conform to CCD Result Observation template (templateId: 2.16.840.1.113883.10.20.1.31)
2. SHALL conform to PHCR Result Observation template (templateId: 2.16.840.1.113883.10.20.15.3.58)
3. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:1967)
4. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF-408)
5. SHALL contain at least one [1..*] id (CONF-409)
6. SHALL contain exactly one [1..1] code, which SHALL be selected from ValueSet Lab Test Result Name (Tss) DYNAMIC
7. SHALL contain exactly one [1..1] statusCode/@code="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF:1971)
8. SHOULD contain exactly one [1..1] effectiveTime (CONF-411)
   • Represents the biologically relevant time (e.g. time the specimen was obtained from the patient).
9. SHALL contain exactly one [1..1] value (CONF-416)
10. SHOULD contain zero or more [0..*] interpretationCode (CONF-418)
   • Can be used to provide a rough qualitative interpretation of the observation, such as 'N' (normal), 'L' (low), 'S' (susceptible), etc. Interpretation is generally provided for numeric results where an interpretation range has been defined, or for antimicrobial susceptibility test interpretation.
11. MAY contain zero or one [0..1] methodCode (CONF-414)
   • Included if the method isn't inherent in code or if there is a need to further specialize the method in code.
12. MAY contain zero or more [0..*] entryRelationship (CONF:1990), such that
   a. Contains @typeCode="REFR" REFR (refers to)
   b. Contains exactly one [1..1] Specimen Collection Procedure (templateId: 2.16.840.1.113883.10.20.15.3.2)
13. **MAY** contain zero or more [0..*] `entryRelationship` (CONF:1993), such that
   a. Contains `@typeCode="COMP" COMP (has component)`
   b. Contains exactly one [1..1] `Susceptibility Result` (templateId: 2.16.840.1.113883.10.20.15.3.10)

14. The value for 'code' **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and **MAY** be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12). (CONF-413)
   - `[OCL]: self.code.codeSystem = '2.16.840.1.113883.6.1' xor self.code.codeSystem = '2.16.840.1.113883.6.96' xor self.code.codeSystem = '2.16.840.1.113883.6.12'`

15. The methodCode **SHALL NOT** conflict with the method inherent in code (CONF-415)
   - **UNIMPLEMENTABLE**

16. Where value is a physical quantity, the unit of measure **SHALL** be expressed using a valid Unified Code for Units of Measure (UCUM) expression. (CONF-417)
   - **UNIMPLEMENTABLE**

17. **SHOULD** satisfy: Contain one or more `referenceRange` to show the normal range of values for the observation result (CONF-419)
   - `[OCL]: not self.referenceRange->isEmpty()`

18. **SHALL NOT** contain `referenceRange` / `observationRange` / `code`, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models. (CONF-420)
   - `[OCL]: self.referenceRange->forAll(range : cda::ReferenceRange | range.observationRange.code.code.oclIsUndefined())`

19. **SHALL** satisfy: Contains one or more sources of information. (CONF-421)
   - `[OCL]: not self.informant->isEmpty() or not self.getSection().informant->isEmpty() or not self.getClinicalDocument().informant->isEmpty() or self.reference->exists(ref : cda::Reference | ref.typeCode = vocab::x_ActRelationshipExternalReference::XCRPT) or (self.entryRelationship->exists(rel : cda::EntryRelationship | rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR and rel.observation.code.code = '48766-0'))`

---

**Tss Result Observation example**

**Tss Result Organizer**

[Organizer: templateId 2.16.840.1.113883.10.20.15.3.101]

1. **SHALL** conform to **CCD Result Organizer** template (templateId: 2.16.840.1.113883.10.20.1.32)
2. **SHALL** conform to **PHCR Result Organizer** template (templateId: 2.16.840.1.113883.10.20.15.3.59)
3. **SHALL** contain exactly one [1..1] `@classCode="BATTERY"` (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)(CONF:1996)
5. **SHALL** contain at least one [1..*] `id` (CONF-395, CONF:1998)
6. **SHALL** contain exactly one [1..1] `code`, which **SHALL** be selected from ValueSet **Lab Test Result Name (Tss) DYNAMIC**
8. **SHALL** contain exactly one [1..1] `effectiveTime` (CONF:2001)
9. **SHOULD** contain at least one [1..*] specimen (CONF-399), such that
   • Should be included if the specimen isn't inherent in code value.
10. **MAY** contain zero or one [0..1] component (CONF:2009, CONF:2010), such that
    a. Contains exactly one [1..1] Specimen Collection Procedure (templateId:
       2.16.840.1.113883.10.20.15.3.2)
11. **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)
12. The value for 'code' in a result organizer **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1)
    or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and **MAY** be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12) or ValueSet 2.16.840.1.113883.1.11.20.16 ResultTypeCode STATIC. (CONF-398)

    • [OCL]: self.code.codeSystem = '2.16.840.1.113883.6.1' xor self.code.codeSystem = '2.16.840.1.113883.6.96' xor self.code.codeSystem = '2.16.840.1.113883.6.12' xor self.code.codeSystem = '2.16.840.1.113883.1.11.20.16'
13. The specimen element **SHALL NOT** conflict with the specimen inherent in code (CONF-400)
    • UNIMPLEMENTABLE
14. specimen / specimenRole / id **SHOULD** be set to equal a Procedure / specimen / specimenRole / id to indicate that the Results and the Procedure are referring to the same specimen. (CONF-401)
    • UNIMPLEMENTABLE
15. **SHALL** satisfy: Contains one or more component (CONF-402)
    • [OCL]: not self.component->isEmpty()
16. The target of one or more result organizer component relationships **MAY** be a procedure, to indicate the means or technique by which a result is obtained, particularly if the means or technique isn't inherent in code or if there is a need to further specialize the code value. (CONF-403)
    • UNIMPLEMENTABLE
17. A result organizer component / procedure **MAY** be a reference to a procedure described in the Procedure section. (CONF-404)
    • UNIMPLEMENTABLE
18. **SHALL** satisfy: Contains one or more sources of information. (CONF-406)
    • [OCL]: not self.informant->isEmpty()
      or not self.getSection().informant->isEmpty()
      or not self.getClinicalDocument().informant->isEmpty()
      or self.reference->exists(ref : cda::Reference | ref.typeCode = vocab::x_ActRelationshipExternalReference::XCRPT)

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] @classCode="OBS" Observation (CodeSystem:
   2.16.840.1.113883.5.6 HL7ActClass) (CONF:1861)
3. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem:
   2.16.840.1.113883.5.1001 HL7ActMood) (CONF:1862)
4. SHALL contain exactly one [1..1] `@negationInd` (CONF:1863)

5. SHALL contain exactly one [1..1] `code/@code="ASSERTION"` (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) (CONF:1864)

6. SHALL contain exactly one [1..1] `statusCode/@code="completed"` (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF:1865)

7. SHOULD contain zero or one [0..1] `effectiveTime` (CONF:1866)

8. SHALL contain exactly one [1..1] `value`, which SHALL be selected from ValueSet `Signs and Symptoms (Tss) DYNAMIC`, where its data type is CD

9. PHCR Case Observation SHOULD contain zero or more [0..*] `entryRelationship` (CONF:1887, CONF:1888, CONF:1890), such that Contains `@typeCode="MFST" MFST (is manifestation of)`, such that Contains `@inversionInd="true"`, and Contains exactly one [1..1] Signs And Symptoms Observation (templateId: 2.16.840.1.113883.10.20.15.3.53) (CONF:1889)

Tss Signs And Symptoms Observation example
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)

<table>
<thead>
<tr>
<th>Code</th>
<th>Concept Name</th>
<th>Code System</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11468-6</td>
<td>Bacillus anthracis</td>
<td>LOINC</td>
<td></td>
</tr>
<tr>
<td>33697-4</td>
<td>Bacillus anthracis</td>
<td>LOINC</td>
<td></td>
</tr>
<tr>
<td>22866-8</td>
<td>Bacillus anthracis</td>
<td>LOINC</td>
<td></td>
</tr>
<tr>
<td>22867-6</td>
<td>Bacillus anthracis</td>
<td>LOINC</td>
<td></td>
</tr>
<tr>
<td>51976-9</td>
<td>Bacillus anthracis capsule</td>
<td>LOINC</td>
<td></td>
</tr>
<tr>
<td>44269-9</td>
<td>Bacillus anthracis cell wall</td>
<td>LOINC</td>
<td></td>
</tr>
<tr>
<td>33698-2</td>
<td>Bacillus anthracis:ACnc:Pt:Isolate:Ord:Phage lysis</td>
<td>LOINC</td>
<td></td>
</tr>
<tr>
<td>44270-7</td>
<td>Bacillus anthracis spore</td>
<td>LOINC</td>
<td></td>
</tr>
<tr>
<td>11469-4</td>
<td>Bacillus anthracis:ACnc:Pt:XXX:Ord:Organism specific culture</td>
<td>LOINC</td>
<td></td>
</tr>
<tr>
<td>17928-3</td>
<td>Bacteria identified:Prid:Pt:Bld:Nom:Aerobic culture</td>
<td>LOINC</td>
<td></td>
</tr>
<tr>
<td>17915-0</td>
<td>Bacteria identified:Prid:Pt:Wound.shlw:Nom:Aerobic culture</td>
<td>LOINC</td>
<td></td>
</tr>
<tr>
<td>622-1</td>
<td>Bacteria identified:Prid:Pt:Sputum:Nom:Aerobic culture</td>
<td>LOINC</td>
<td></td>
</tr>
<tr>
<td>21020-3</td>
<td>Bacteria identified:Prid:Pt:XXX:Nom:Anaerobic +Aerobic culture</td>
<td>LOINC</td>
<td></td>
</tr>
<tr>
<td>41622-2</td>
<td>B anthracis DNA XXX PCR</td>
<td>LOINC</td>
<td></td>
</tr>
</tbody>
</table>
## Signs and Symptoms (Tss)

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


• LOINC®: Logical Observation Identifiers Names and Codes, Regenstrief Institute.

• SNOMED CT®: SNOMED Clinical Terms SNOMED International Organization.

• Extensible Markup Language, www.w3.org/XML.


• 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.