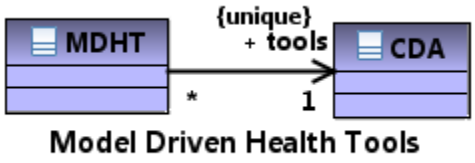
Implementation Guide for CDA Release 2
Meningococcal Case Report CDA R2
Optional Subtitle



Model Driven Health Tools

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

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.

Meningococcal Case Report

[ClinicalDocument: templateId `2.16.840.1.113883.10.20.15.1.15`]

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
4. **SHALL** contain exactly one [1..1] **`code/@code="55751-2"`** *Public Health Case Report* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF:546)
5. **SHALL** contain exactly one [1..1] **`title`** = "Public Health Case Report - Meningococcal"
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] *Meningococcal Phcr Clinical Information Section* (templateId: `2.16.840.1.113883.10.20.15.2.59`)
17. **SHOULD** contain zero or one [0..1] **`component`**, such that
    a. Contains exactly one [1..1] *Meningococcal Phcr Relevant Dx Tests Section* (templateId: `2.16.840.1.113883.10.20.15.2.60`)
18. RecordTarget **SHALL** contain [1..1] patientRole (CONF:548)
    - `[OCL]: self.recordTarget.patientRole->one(patientRole : cda::PatientRole | not patientRole.oclIsUndefined())`
19. 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())`
20. RecordTarget / PatientRole **SHOULD** contain [0..*] addr (CONF:550)
21. RecordTarget / PatientRole **SHOULD** contain [0..*] telecom (CONF:551)
22. RecordTarget / PatientRole **SHOULD** contain [0..1] patient (CONF:552)
23. RecordTarget / PatientRole / Patient **SHOULD** contain [0..*] name (CONF:553)
24. 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)
25. RecordTarget / PatientRole / Patient **SHOULD** contain [0..1] birthTime (CONF:555)

26. 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)

27. 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)

28. **SHALL** contain [1..*] author (CONF:1853)

- `[OCL]: self.author->exists(author : cda::Author | not author.oclIsUndefined())`

29. 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())`

30. Author **SHALL** contain [1..1] assignedAuthor (CONF:561)

- `[OCL]: self.author.assignedAuthor->one(assignedAuthor : cda::AssignedAuthor | not assignedAuthor.oclIsUndefined())`

31. Author / AssignedAuthor **SHALL** contain [1..*] id (CONF:562)

- `[OCL]: self.author.assignedAuthor.id->exists(id : datatypes::II | not id.root.oclIsUndefined() or not id.extension.oclIsUndefined() or not id.nullFlavor.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:1857)

- `[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()) and self.legalAuthenticator.assignedEntity.assignedPerson.name->one(name : datatypes::PN | not name.oclIsUndefined())`

43. 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)

Meningococcal Case Report example

Chapter 3

SECTION TEMPLATES

Topics:

Meningococcal Phcr Clinical Information Section

[Section: templateId `2.16.840.1.113883.10.20.15.2.59`]

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] *Meningococcal Case Observation* (templateId: `2.16.840.1.113883.10.20.15.3.138`)
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))
```

Meningococcal Phcr Clinical Information Section example

Meningococcal Phcr Relevant Dx Tests Section

[Section: templateId `2.16.840.1.113883.10.20.15.2.60`]

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. **SHOULD** contain zero or more [0..*] **`entry`**, such that
   a. Contains **`@typeCode="`**`DRIV"` *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Meningococcal Result Observation* (templateId: `2.16.840.1.113883.10.20.15.3.141`)
8. **MAY** contain zero or more [0..*] **`entry`**, such that
   a. Contains **`@typeCode="`**`DRIV"` *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Meningococcal Result Organizer* (templateId: `2.16.840.1.113883.10.20.15.3.140`)
9. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'results'. (CONF-392)
   - UNIMPLEMENTABLE

Meningococcal Phcr Relevant Dx Tests 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.

Meningococcal Case Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.138`]

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 HL7ActStatus`) (CONF:1872)
8. **SHOULD** contain zero or one [0..1] **`effectiveTime`** (CONF:1873)
9. **SHALL** contain exactly one [1..1] **`value`**, which **SHALL** be selected from ValueSet `2.16.840.1.114222.4.11.6060` *`PHVS_DiseaseType_Meningococcal`* **DYNAMIC**, 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] *Meningococcal Signs And Symptoms Observation* (templateId: `2.16.840.1.113883.10.20.15.3.139`)
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(ccd::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)

Meningococcal Case Observation example

Meningococcal Result Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.141`]

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 `2.16.840.1.114222.4.11.4176` *`Lab Test Name (Meningococcal Disease)`* **DYNAMIC** (CONF-412)
7. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (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'))
      ```

Meningococcal Result Observation example

Meningococcal Result Organizer

[Organizer: templateId `2.16.840.1.113883.10.20.15.3.140`]

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)
4. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-394, CONF:1997)
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 `2.16.840.1.114222.4.11.4176 Lab Test Name (Meningococcal Disease)` **STATIC** (CONF-397, CONF:1999)
7. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF:2000)
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. Contains zero or one [0..1] **`component`**, such that
    a. Contains exactly one [1..1] *Meningococcal Result Observation* (templateId: `2.16.840.1.113883.10.20.15.3.141`)
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)
      ```

Meningococcal Result Organizer example

Meningococcal Signs And Symptoms Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.139`]

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 HL7ActStatus`) (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 `2.16.840.1.114222.4.11.6061` *`PHVS_SignsSymptoms_Meningococcal`* **DYNAMIC**, where its data type is CD (CONF:1867)
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)

Meningococcal 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:

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

Lab Test Name (Meningococcal Disease)

Value Set	Lab Test Name (Meningococcal Disease) - 2.16.840.1.114222.4.11.4176
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.4176

PHV S_ Disease Type_ Meningococcal

Value Set	PHVS_DiseaseType_Meningococcal - 2.16.840.1.114222.4.11.6060
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.6060

PHV S_ Signs Symptoms_ Meningococcal

Value Set	PHVS_SignsSymptoms_Meningococcal - 2.16.840.1.114222.4.11.6061
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.6061

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*