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



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



Contents

Acknowledgments	5
Revision History	
·	
CI 4 A TAMPO O DATOTA O N	
Chapter 1: INTRODUCTION	
Overview	
Approach	
Scope	
Audience	
Organization of This Guide	
Templates	
Vocabulary and Value Sets	10
Use of Templates	
Originator Responsibilities	11
Recipient Responsibilities	11
Conventions Used in This Guide	
Conformance Requirements	11
Keywords	
XML Examples	
	4.0
Chapter 2: DOCUMENT TEMPLATES	13
Salmonellosis Case Report	14
	4=
Chapter 3: SECTION TEMPLATES	
Salmonellosis PHCR Clinical Information Section	
Salmonellosis PHCR Relevant Dx Tests Section	
Salmonellosis PHCR Social History Section	19
	IDEC 41
Chapter 4: CLINICAL STATEMENT TEMPLA	
HIV Status Observation	
Salmonellosis Case Observation	
Salmonellosis Possible Exposure Location And Type Act	
Salmonellosis Result Observation	
Salmonellosis Result Organizer	
Salmonellosis Signs And Symptoms Observation	26
Chanton 5. OTHER CLASSES	20
Chapter 5: OTHER CLASSES	
Chapter 6: VALUE SETS	21
Disease Type (Salmonellosis)	
HIV Status (PHCR)	
Lab Test Name (Salmonellosis)	
Signs and Symptoms (Salmonellosis)	
REFERENCES	



Acknowledgments

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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



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 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

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.

2

DOCUMENT TEMPLATES

Topics:

• Salmonellosis Case Report

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

Salmonellosis Case Report

```
[ClinicalDocument: templateId 2.16.840.1.113883.10.20.15.1.9]
```

- 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 Salmonellosis"
- **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:742, CONF:674), such that
 - **a.** Contains exactly one [1..1] *Pher Treatment Information Section* (templateId: 2.16.840.1.113883.10.20.15.2.4)
- 13. SHOULD contain zero or one [0..1] component (CONF:643, CONF:609), such that
 - **a.** Contains exactly one [1..1] *Pher Encounters Section* (templateId: 2.16.840.1.113883.10.20.15.2.2)
- **14. 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)
- **15. SHOULD** contain zero or one [0..1] **component**, such that
 - **a.** Contains exactly one [1..1] *Salmonellosis PHCR Social History Section* (templateId: 2.16.840.1.113883.10.20.15.2.36)
- **16. SHOULD** contain zero or one [0..1] **component**, such that
 - **a.** Contains exactly one [1..1] *Salmonellosis PHCR Relevant Dx Tests Section* (templateId: 2.16.840.1.113883.10.20.15.2.38)
- 17. SHALL contain exactly one [1..1] component, such that
 - **a.** Contains exactly one [1..1] *Salmonellosis PHCR Clinical Information Section* (templateId: 2.16.840.1.113883.10.20.15.2.37)
- **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())
- **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..*] 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())
- **33.** Author / AssignedAuthor **SHALL** contain [1..1] addr (CONF:562)
 - [OCL]: self.author.assignedAuthor.addr->one(addr : datatypes::AD | not addr.oclIsUndefined())
- **34.** Author / Assigned Author **SHALL** contain [1..1] telecom (CONF:564)
 - [OCL]: self.author.assignedAuthor.telecom->one(tel: datatypes::TEL | not tel.oclIsUndefined())
- **35.** 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())
- 36. The custodian of a public health case report SHALL be the reporting organization. (CONF:1616)
- **37. SHALL** contain [1..1] legalAuthenticator (CONF:1854)
 - [OCL]: self.legalAuthenticator->one(legalAuthenticator: cda::LegalAuthenticator | not legalAuthenticator.oclIsUndefined())
- **38.** LegalAuthenticator **SHALL** contain [1..1] time (CONF:1855)
 - [OCL]: self.legalAuthenticator.time->one(time : datatypes::TS | not time.value.oclIsUndefined())
- **39.** LegalAuthenticator **SHALL** contain [1..1] assignedEntity (CONF:1856)
 - [OCL]: self.legalAuthenticator.assignedEntity->one(assignedEntity: cda::AssignedEntity | not assignedEntity.oclIsUndefined())
- **40.** 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())
- **41.** Legal Authenticator / Assigned Entity **SHALL** contain [1..1] addr (CONF:1857)
 - [OCL]: self.legalAuthenticator.assignedEntity.addr->one(addr: datatypes::AD | not addr.oclIsUndefined())
- **42.** LegalAuthenticator / AssignedEntity **SHALL** contain [1..1] telecom (CONF:1859)
- 43. Legal Authenticator / Assigned Entity SHALL contain [1..1] assigned Person/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())
```

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)

Salmonellosis Case Report example

3

SECTION TEMPLATES

Topics:

- Salmonellosis PHCR Clinical Information Section
- Salmonellosis PHCR Relevant Dx Tests Section
- Salmonellosis PHCR Social History Section

Salmonellosis PHCR Clinical Information Section

[Section: templateId 2.16.840.1.113883.10.20.15.2.37]

- **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] *Pher 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] *Salmonellosis Case Observation* (templateId: 2.16.840.1.113883.10.20.15.3.116)
- 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))
```

Salmonellosis PHCR Clinical Information Section example

Salmonellosis PHCR Relevant Dx Tests Section

[Section: templateId 2.16.840.1.113883.10.20.15.2.38]

- 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] *Salmonellosis Result Organizer* (templateId: 2.16.840.1.113883.10.20.15.3.118)
- **8. SHOULD** contain zero or more [0..*] **entry**, such that
 - a. Contains @typeCode="DRIV" DRIV (is derived from)
 - **b.** Contains exactly one [1..1] *Salmonellosis Result Observation* (templateId: 2.16.840.1.113883.10.20.15.3.119)
- 9. SHOULD satisfy: Contains a case-insensitive language-insensitive string containing 'results'. (CONF-392)
 - UNIMPLEMENTABLE

Salmonellosis PHCR Relevant Dx Tests Section example

Salmonellosis PHCR Social History Section

[Section: templateId 2.16.840.1.113883.10.20.15.2.36]

- 1. SHALL conform to CCD Social History Section template (templateId: 2.16.840.1.113883.10.20.1.15)
- **2. SHALL** conform to *PHCR Phcr Social History Section* template (templateId: 2.16.840.1.113883.10.20.15.2.22)
- **3. SHALL** contain exactly one [1..1] **code/@code**="29762-2" *Social History* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:1894)
- **4. SHALL** contain exactly one [1..1] **title** = "Social History" (CONF:1895)
- 5. SHALL contain exactly one [1..1] text (CONF:1896)
- **6. SHOULD** contain zero or more [0..*] **entry**, such that
 - a. Contains exactly one [1..1] Social History Observation (templateId: 2.16.840.1.113883.10.20.1.33)
- 7. SHOULD contain zero or more [0..*] entry (CONF:1897, CONF:1898, CONF:1899), such that
 - a. Contains @typeCode="DRIV" DRIV (is derived from)
 - **b.** Contains exactly one [1..1] *Geotemporal History Observation* (templateId: 2.16.840.1.113883.10.20.15.3.3)
- 8. SHOULD contain zero or one [0..1] entry (CONF:1900, CONF:1901, CONF:1902), such that
 - a. Contains @typeCode="DRIV" DRIV (is derived from)
 - **b.** Contains exactly one [1..1] *Most Recent Time Arrived In USA Observation* (templateId: 2.16.840.1.113883.10.20.15.3.6)
- 9. SHOULD contain zero or more [0..*] entry (CONF:1903, CONF:1904, CONF:1905), such that
 - a. Contains @typeCode="DRIV" DRIV (is derived from)
 - **b.** Contains exactly one [1..1] *Race Observation* (templateId: 2.16.840.1.113883.10.20.15.3.9)
- 10. SHOULD contain zero or more [0..*] entry (CONF:1906, CONF:1907, CONF:1908), such that
 - a. Contains @typeCode="DRIV" DRIV (is derived from)
 - **b.** Contains exactly one [1..1] *Occupation Observation* (templateId: 2.16.840.1.113883.10.20.15.3.7)

- 11. MAY contain zero or more [0..*] entry (CONF:1909, CONF:1910, CONF:1911), such that
 - a. Contains @typeCode="DRIV" DRIV (is derived from)
 - **b.** Contains exactly one [1..1] *Pregnancy Observation* (templateId: 2.16.840.1.113883.10.20.15.3.8)
- **12. SHOULD** contain zero or more [0..*] **entry**, such that
 - a. Contains @typeCode="DRIV" DRIV (is derived from)
 - **b.** Contains exactly one [1..1] *Salmonellosis Possible Exposure Location And Type Act* (templateId: 2.16.840.1.113883.10.20.15.3.115)
- **13. SHOULD** contain zero or one [0..1] **entry**, such that
 - a. Contains @typeCode="DRIV" DRIV (is derived from)
 - **b.** Contains exactly one [1..1] *HIV Status Observation* (templateId: 2.16.840.1.113883.10.20.15.3.4)
- 14. SHOULD satisfy: Contains a case-insensitive language-insensitive string containing 'social history'. (CONF-236)
 - UNIMPLEMENTABLE
- **15.** Marital status **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / maritalStatusCode. Additional information **MAY** be represented as social history observations (CONF-250)
 - [OCL]: self.getClinicalDocument().recordTarget->select(r | not r.patientRole.patient.maritalStatusCode.hasContent())->isEmpty()
- **16.** Religious affiliation **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / religiousAffiliationCode. Additional information **MAY** be represented as social history observations (CONF-251)
 - [OCL]: self.getClinicalDocument().recordTarget->select(r | not r.patientRole.patient.religiousAffiliationCode.hasContent())->isEmpty()
- **17.** A patients race **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / raceCode. Additional information **MAY** be represented as social history observations (CONF-252)
 - [OCL]: self.getClinicalDocument().recordTarget->select(r | not r.patientRole.patient.raceCode.hasContent())->isEmpty()
- **18.** The value for ClinicalDocument / recordTarget / patientRole / patient / raceCode **MAY** be selected from codeSystem 2.16.840.1.113883.5.104 (Race) (CONF-253)
 - [OCL]: self.getClinicalDocument().recordTarget->forAll(r | r.patientRole.patient.raceCode.codeSystem = '2.16.840.1.113883.5.104')
- 19. A patients ethnicity SHOULD be represented as ClinicalDocument / recordTarget / patientRole / patient / ethnicGroupCode. Additional information MAY be represented as social history observations. (CONF-254)
 - [OCL]: self.getClinicalDocument().recordTarget->select(r | not r.patientRole.patient.ethnicGroupCode.hasContent())->isEmpty()
- **20.** The value for ClinicalDocument / recordTarget / patientRole / patient / ethnicGroupCode **MAY** be selected from codeSystem 2.16.840.1.113883.5.50 (Ethnicity). (CONF-255)

Salmonellosis PHCR Social History Section example

4

CLINICAL STATEMENT TEMPLATES

Topics:

- HIV Status Observation
- Salmonellosis Case Observation
- Salmonellosis Possible Exposure Location And Type Act
- Salmonellosis Result Observation
- Salmonellosis Result Organizer
- Salmonellosis 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.

HIV Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.15.3.4]

- 1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
- 2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
- 3. SHALL contain exactly one [1..1] code/@code="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode)
- **4. SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus)
- 5. SHALL contain exactly one [1..1] value, which SHALL be selected from ValueSet 2.16.840.1.114222.4.11.3232 HIV Status (PHCR) STATIC 1, where its data type is CD

HIV Status Observation example

Salmonellosis Case Observation

[Observation: templateId 2.16.840.1.113883.10.20.15.3.116]

- 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)
- SHALL contain exactly one [1..1] value, which SHALL be selected from ValueSet
 2.16.840.1.114222.4.11.6024 Disease Type (Salmonellosis) STATIC, where its data type is CD (CONF:1874)
- **10. SHOULD** contain zero or more [0..*] **targetSiteCode**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.9 Body Site **DYNAMIC**
- 11. 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)
- 12. 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)
- 13. 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)

```
14. 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:
```

15. SHOULD contain zero or more [0..*] entryRelationship, such that

a. Contains exactly one [1..1] *Salmonellosis Signs And Symptoms Observation* (templateId: 2.16.840.1.113883.10.20.15.3.117)

16. SHALL contain one or more sources of information. (CONF-161)

2.16.840.1.113883.10.20.1.50)

```
(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'))
```

17. MAY contain exactly one Patient Awareness (CONF-180)

```
• [OCL]: self.participant->one(partic : cda::Participant2 | partic.oclIsKindOf(ccd::PatientAwareness))
```

18. SHOULD contain [0..1] effectiveTime/low (CONF:1873)

```
• [OCL]: self.effectiveTime->exists(time : datatypes::IVL_TS | not time.low.oclIsUndefined())
```

19. SHOULD contain [0..1] author (CONF:1875)

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

20. Author **SHALL** contain [1..1] time (CONF:1876)

21. Author **SHALL** contain [1..1] assignedAuthor (CONF:1877)

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

22. Author / Assigned Author **SHALL** contain [1..*] id (CONF:1878)

23. Author / AssignedAuthor **MAY** contain [0..*] addr (CONF:1879)

24. Author / AssignedAuthor **MAY** contain [0..*] telecom (CONF:1880)

25. Author / AssignedAuthor **MAY** contain [0..1] assignedPerson (CONF:1881)

26. Author / Assigned Author / Person **MAY** contain [0..1] name (CONF:1882)

27. Author / AssignedAuthor MAY contain [0..1] representedOrganization (CONF:1883)

Salmonellosis Case Observation example

Salmonellosis Possible Exposure Location And Type Act

```
[Act: templateId 2.16.840.1.113883.10.20.15.3.115]
```

- 1. SHALL contain exactly one [1..1] @classCode="ACT" Act (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
- 2. Contains exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)
- **3. SHALL** contain exactly one [1..1] **code/@code**="413350009" *Finding with explicit context* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT)
- **4. SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus)
- **5. SHALL** contain [1..1] qualifier

- **6. SHALL** contain [1..1] qualifier
- 7. SHALL contain [1..*] participant
- 8. MAY contain [0..*] participant
- **9.** MAY contain [0..*] participant

Salmonellosis Possible Exposure Location And Type Act example

Salmonellosis Result Observation

[Observation: templateId 2.16.840.1.113883.10.20.15.3.119]

- 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 2.16.840.1.114222.4.11.4198 Lab Test Name (Salmonellosis) DYNAMIC (CONF-412)
- 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'))
```

Salmonellosis Result Observation example

Salmonellosis Result Organizer

[Organizer: templateId 2.16.840.1.113883.10.20.15.3.118]

- 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 2.16.840.1.114222.4.11.4198 Lab Test Name (Salmonellosis) DYNAMIC (CONF-397, CONF:1999)
- 7. SHALL contain exactly one [1..1] statusCode/@code="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (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. SHALL contain at least one [1..*] component, such that
 - **a.** Contains exactly one [1..1] *Salmonellosis Result Observation* (templateId: 2.16.840.1.113883.10.20.15.3.119)
- **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)
```

19. MAY contain [0..1] specimen, which if present SHOULD contain [0..1] specimenRole, which if present SHOULD contain [0..1] id SHALL contain [1..1] specimenPlayingEntity, which SHALL contain [1..1] code/@code, which SHALL be selected from ValueSet 2.16.840.1.114222.4.11.946 Specimen DYNAMIC

Salmonellosis Result Organizer example

Salmonellosis Signs And Symptoms Observation

[Observation: templateId 2.16.840.1.113883.10.20.15.3.117]

- **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 2.16.840.1.114222.4.11.6023 Signs and Symptoms (Salmonellosis) STATIC, 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)

Salmonellosis Signs And Symptoms Observation example

5

OTHER CLASSES

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



VALUE SETS

Topics:

- Disease Type (Salmonellosis)
- HIV Status (PHCR)
- Lab Test Name (Salmonellosis)
- Signs and Symptoms (Salmonellosis)

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

Disease Type (Salmonellosis)

Value Set	Disease Type (Salmonellosis) - 2.16.840.1.114222.4.11.6024	
Source	SNOMED CT	
Definition	Salmonellosis disease types - from SNOMED CT	

Concept Code	Concept Name	Code System	Description
186134009	Infection of gastrointestinal tract by Salmonella enterica subspecies arizonae (disorder)	SNOMEDCT	
47375003	Localized Salmonella infection (disorder)	SNOMEDCT	
397503006	Salmonella enterica subspecies arizonae infection (disorder)	SNOMEDCT	
302229004	Salmonella food poisoning (disorder)	SNOMEDCT	
42338000	Salmonella gastroenteritis (disorder)	SNOMEDCT	
302231008	Salmonella infection (disorder)	SNOMEDCT	
420764009	Salmonella infection associated with AIDS (disorder)	SNOMEDCT	
402962004	Salmonella infection with skin involvement (disorder)	SNOMEDCT	
77645007	Salmonella meningitis (disorder)	SNOMEDCT	
6803002	Salmonella osteomyelitis (disorder)	SNOMEDCT	
2523007	Salmonella pneumonia (disorder)	SNOMEDCT	
49786009	Salmonella septicemia (disorder)	SNOMEDCT	
90974009	Salmonellosis (except human typhoid and paratyphoid) (disorder)	SNOMEDCT	

HIV Status (PHCR)

Version	1
Definition	HIV Status value set has concepts that expresses the status of HIV such as HIV negative or HIV positive. This value set is based upon SNOMED CT finding domain.

Concept Code	Concept Name	Code System	Description
165815009	HIV negative	SNOMEDCT	
165816005	HIV positive	SNOMEDCT	

Lab Test Name (Salmonellosis)

Value Set	Lab Test Name (Salmonellosis) - 2.16.840.1.114222.4.11.4198
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.4198
Definition	lab tests associated with Salmonellosis

Signs and Symptoms (Salmonellosis)

Value Set	Signs and Symptoms (Salmonellosis) - 2.16.840.1.114222.4.11.6023
Source	PHIN VADS
Definition	Salmonellosis signs and symptoms list from CSTE position statement

Concept Code	Concept Name	Code System	Description
84387000	Asymptomatic (finding)	SNOMEDCT	
422587007	Nausea (finding)	SNOMEDCT	
422400008	Vomiting (disorder)	SNOMEDCT	
21522001	Abdominal pain	SNOMEDCT	
62315008	Diarrhea (finding)	SNOMEDCT	
62479008	Acquired immune deficiency syndrome (AIDS) (disorder)	SNOMEDCT	
161891005	Backache	SNOMEDCT	
95545007	Bloody diarrhea	SNOMEDCT	
50177009	Body temperature above reference range	SNOMEDCT	
84229001	Fatigue	SNOMEDCT	
386661006	Fever	SNOMEDCT	
25064002	Headache	SNOMEDCT	
51197009	Stomach cramps (finding)	SNOMEDCT	
13791008	Weakness (asthenia)	SNOMEDCT	

REFERENCES

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- 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*