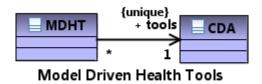
Implementation Guide for CDA Release 2 Salmonellosis Case Report CDA R2 Optional Subtitle



PROTOTYPE: FOR DISCUSSION AND DEMONSTRATION USE ONLY



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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.

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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. 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)
- 3. **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)
- **4. 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)
- 5. SHALL contain exactly one [1..1] title = "Public Health Case Report Salmonellosis"

Salmonellosis Case Report example

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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] **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)
```

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 *PHCR Phcr Relevant Dx Tests Section* template (templateId:
 - 2.16.840.1.113883.10.20.15.2.3)
- 2. MAY contain zero or more [0..*] entry, such that
 - a. Contains @typeCode="DRIV" DRIV (is derived from)
 - **b.** Contains exactly one [1..1] *Salmonellosis Result Organizer* (templateId: 2.16.840.1.113883.10.20.15.3.118)
- **3. 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)

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 *PHCR Phcr Social History Section* template (templateId:

```
2.16.840.1.113883.10.20.15.2.22)
```

- 2. **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)
- 3. 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)

Salmonellosis PHCR Social History Section example

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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 *PHCR Case Observation* template (templateId: 2.16.840.1.113883.10.20.15.3.54)
- 2. 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
- 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)
- **4. 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)

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 *PHCR Result Observation* template (templateId: 2.16.840.1.113883.10.20.15.3.58)
- 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)

Salmonellosis Result Observation example

Salmonellosis Result Organizer

[Organizer: templateId 2.16.840.1.113883.10.20.15.3.118]

- **1. SHALL** conform to *PHCR Result Organizer* template (templateId: 2.16.840.1.113883.10.20.15.3.59)
- 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)
- 3. 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)
- **4. 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)
- 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)

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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)

Value Set

| 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 | |
| İ | 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 | |
| İ | 25064002 | Headache | SNOMEDCT | |
| | 51197009 | Stomach cramps (finding) | SNOMEDCT | |
| | 13791008 | Weakness (asthenia) | SNOMEDCT | |

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