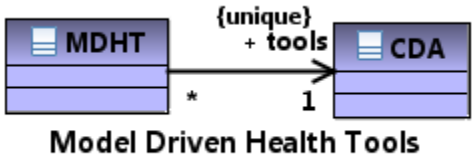
Implementation Guide for CDA Release 2
MDHT Example Project
Optional Subtitle



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.

MTM

[ClinicalDocument: templateId]

1. **SHALL** conform to *Consol General Header Constraints* template (templateId: `2.16.840.1.113883.10.20.22.1.1`)
2. **SHALL** contain exactly one [1..1] **`realmCode/@code`**`="US"` (CONF:5249)
3. **SHALL** contain exactly one [1..1] **`typeId`** (CONF:5361)
4. **SHALL** contain exactly one [1..1] **`id`** (CONF:5363)
5. **SHALL** contain exactly one [1..1] **`code`** (CONF:5253)
6. **SHALL** contain exactly one [1..1] **`title`** (CONF:5254)
7. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF:5256)
8. **SHALL** contain exactly one [1..1] **`confidentialityCode`**, which **SHALL** be selected from ValueSet `2.16.840.1.113883.1.11.16926` *`BasicConfidentialityKind`* **STATIC** (CONF:5259)
9. **SHALL** contain exactly one [1..1] **`languageCode`**, which **SHALL** be selected from ValueSet `2.16.840.1.113883.1.11.11526` *`Language`* **DYNAMIC** (CONF:5372)
10. **MAY** contain zero or one [0..1] **`setId`** (CONF:5261)
11. **MAY** contain zero or one [0..1] **`versionNumber`** (CONF:5264)
12. Contains exactly one [1..1] **`component`**, where its type is *Component2*
13. **SHALL** contain at least one [1..*] **`recordTarget`** (CONF:5266)
    - The recordTarget records the patient whose health information is described by the clinical document; it must contain at least one patientRole element.
14. **MAY** contain exactly one [1..1] **`componentOf`** (CONF:9955)
15. **SHALL** contain at least one [1..*] **`author`** (CONF:5444)
16. **MAY** contain zero or one [0..1] **`dataEnterer`** (CONF:5441)
17. **SHALL** contain exactly one [1..1] **`custodian`** (iv., CONF:5519)
18. **MAY** contain zero or more [0..*] **`informationRecipient`** (CONF:5565)
19. **SHOULD** contain zero or one [0..1] **`legalAuthenticator`** (CONF:5579)
20. **MAY** contain zero or more [0..*] **`authenticator`** (CONF:5607)
21. **MAY** contain zero or one [0..1] **`informant`** (CONF:8001)
22. **MAY** contain zero or more [0..*] **`supportParticipant`** (CONF:10003)
23. **MAY** contain zero or more [0..*] **`inFulfillmentOf`** (CONF:9952)
24. **SHALL** contain exactly one [1..1] **`component`**
    a. Contains exactly one [1..1] *Consol Allergies Section* (templateId: `2.16.840.1.113883.10.20.22.2.6.1`)
25. **SHALL** contain exactly one [1..1] **`component`**
    a. Contains exactly one [1..1] *MTM Medication Section* (templateId: `2.16.840.1.113883.10.20.22.2.1.1`)

MTM example

Chapter 3

SECTION TEMPLATES

Topics:

MTM Medication Section

[Section: templateId `2.16.840.1.113883.10.20.22.2.1.1`]

1. **SHALL** conform to *Consol Medications Section Entries Optional* template (templateId: `2.16.840.1.113883.10.20.22.2.1`)
2. **SHALL** conform to *Consol Medications Section* template (templateId: `2.16.840.1.113883.10.20.22.2.1.1`)
3. **SHALL** contain exactly one [1..1] **`code/@code="10160-0"`** *History of medication use* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF:7569)
4. **SHALL** contain exactly one [1..1] **`title`** = "Medications" (CONF:7793)
5. **SHALL** contain exactly one [1..1] **`text`** (CONF:7571)
6. **SHALL** contain at least one [1..*] **`entry`** (CONF:7572, CONF:7573)
   a. Contains exactly one [1..1] *MTM Medication Activity* (templateId: `2.16.840.1.113883.10.20.22.4.16`)
7. If medication use is unknown, the appropriate nullFlavor **MAY** be present (see unknown information in Section 1)
   - UNIMPLEMENTABLE
8. If medication use is unknown, the appropriate nullFlavor **MAY** be present (see unknown information in Section 1) (CONF-299)
   - UNIMPLEMENTABLE

MTM Medication 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.

MTM Medication Activity

[SubstanceAdministration: templateId `2.16.840.1.113883.10.20.22.4.16`]

1. **SHALL** conform to *Consol Medication Activity* template (templateId: `2.16.840.1.113883.10.20.22.4.16`)
2. **SHALL** contain exactly one [1..1] **`@classCode`**`="SBADM"` (CodeSystem: `2.16.840.1.113883.5.6` `HL7ActClass`) (CONF:7496)
3. **SHALL** contain exactly one [1..1] **`@moodCode`**, which **SHALL** be selected from ValueSet `2.16.840.1.113883.11.20.9.18` *`MoodCodeEvnInt`* **STATIC** 2011-04-03 (CONF:7497)
4. **SHALL** contain at least one [1..*] **`id`** (CONF:7500)
5. **MAY** contain zero or one [0..1] **`code`** (CONF:7506)
6. **SHOULD** contain zero or one [0..1] **`text`** (CONF:7501)
   - Use for optional product-related information, such as additional instructions, product image/identifiers, goals of therapy, pharmacy, etc., and change field title accordingly. This field may be expanded or divided. Delete this field if not used.
7. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF:7507)
8. Contains zero or more [0..*] **`effectiveTime`**
9. **MAY** contain zero or one [0..1] **`repeatNumber`** (CONF:7555)
   - In "INT" (intent) mood, the repeatNumber defines the number of allowed administrations. For example, a repeatNumber of "3" means that the substance can be administered up to 3 times

     In "EVN" (event) mood, the repeatNumber is the number of occurrences. For example, a repeatNumber of "3" in a substance administration event means that the current administration is the 3rd in a series
10. **MAY** contain zero or one [0..1] **`routeCode`**, which **MAY** be selected from ValueSet `2.16.840.1.113883.3.88.12.3221.8.7` *`Medication Route FDA`* **STATIC** 1 (CONF:7514)
11. **MAY** contain zero or one [0..1] **`approachSiteCode`**, which **MAY** be selected from ValueSet `2.16.840.1.113883.3.88.12.3221.8.9` *`Body Site`* **STATIC** 2 (CONF:7515)
12. **SHOULD** contain zero or one [0..1] **`doseQuantity`** (CONF:7516)
    - Pre-coordinated consumable: If the consumable code is a precoordinated unit dose (e.g. metoprolol 25mg tablet) then doseQuantity is a unitless number that indicates the number of products given per administration (e.g. 2, meaning 2 x metoprolol 25mg tablet) Not pre-coordinated consumable: If the consumable code is not pre-coordinated (e.g. is simply metoprolol), then doseQuantity must represent a physical quantity with @unit, e.g. 25 and mg, specifying the amount of product given per administration
13. **MAY** contain zero or one [0..1] **`rateQuantity`** (CONF:7517)
14. **MAY** contain zero or one [0..1] **`maxDoseQuantity`** (CONF:7518)
15. **MAY** contain zero or one [0..1] **`administrationUnitCode`**, which **MAY** be selected from ValueSet `2.16.840.1.113883.3.88.12.3221.8.11` *`Medication Product Form`* **STATIC** 1 (CONF:7519)
16. Contains exactly one [1..1] **`consumable`**, where its type is *Consumable*
17. **MAY** contain zero or one [0..1] **`performer`** (CONF:7522)
18. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:7541)
    a. Contains **`@typeCode="`**`SUBJ"` *SUBJ*
    b. Contains exactly one [1..1] *Instructions* (templateId: `2.16.840.1.113883.10.20.22.4.20`)
19. **MAY** contain at least one [1..*] **`entryRelationship`** (CONF:7545)
    a. Contains **`@typeCode="`**`REFR"` *REFR*
    b. Contains exactly one [1..1] *Medication Supply Order* (templateId: `2.16.840.1.113883.10.20.22.4.17`)
20. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:7548)
    a. Contains **`@typeCode="`**`CAUS"` *CAUS*
    b. Contains exactly one [1..1] *Reaction Observation* (templateId: `2.16.840.1.113883.10.20.22.4.9`)

21. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:7538)
    a. Contains **`@typeCode="RSON"`** *RSON*
    b. Contains exactly one [1..1] *Indication* (templateId: `2.16.840.1.113883.10.20.22.4.19`)
22. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:7554)
    a. Contains **`@typeCode="REFR"`** *REFR*
    b. Contains exactly one [1..1] *Medication Dispense* (templateId: `2.16.840.1.113883.10.20.22.4.18`)
23. **MAY** contain zero or more [0..*] **`precondition`** (CONF:7546)
    a. Contains exactly one [1..1] *Precondition For Substance Administration* (templateId: `2.16.840.1.113883.10.20.22.4.25`)
24. **MAY** contain zero or more [0..*] **`participant`** (CONF:7523)
    a. Contains exactly one [1..1] *Drug Vehicle* (templateId: `2.16.840.1.113883.10.20.22.4.24`)
25. **SHALL** contain exactly one [1..1] **`consumable`** (CONF:7520)
    a. Contains exactly one [1..1] *Medication Information* (templateId: `2.16.840.1.113883.10.20.22.4.23`)
26. **SHALL** contain at least one [1..*] **`entryRelationship`** (CONF:7538)
    a. Contains **`@typeCode="RSON"`** *RSON*
    b. Contains exactly one [1..1] *Consol Indication* (templateId: `2.16.840.1.113883.10.20.22.4.19`)
27. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:7541)
    a. Contains **`@typeCode="SUBJ"`** *SUBJ*
    b. Contains exactly one [1..1] *Consol Instructions* (templateId: `2.16.840.1.113883.10.20.22.4.20`)
28. **SHALL** contain exactly one [1..1] **`author`**
29. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="RSON"`** *RSON*
    b. Contains exactly one [1..1] *Consol Comment* (templateId: `2.16.840.1.113883.10.20.22.4.64`)

    - This is to document why the patient stopped using the drug

30. Medication Activity **SHOULD** include doseQuantity OR rateQuantity

    - `[OCL]: self.doseQuantity->size() = 1 xor self.rateQuantity->size() = 1`

31. text, if present, **SHOULD** contain zero or one [0..1] reference/@value (CONF:7502)

    - ```
      [OCL]: not self.text.oclIsUndefined() implies not
       self.text.reference.value.oclIsUndefined()
      ```

32. reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:7503)
33. **SHALL** contain exactly one [1..1] effectiveTime such that it **SHALL** contain exactly one [1..1] @xsi:type = "IVL_TS" (CONF:7508, CONF:9104)

    - ```
      [OCL]: self.effectiveTime->exists(ef : datatypes::SXCM_TS |
       ef.oclIsTypeOf(datatypes::IVL_TS))
      ```

34. effectiveTime with @xsi:type="IVL_TS" **SHALL** contain exactly one [1..1] low
35. effectiveTime with @xsi:type="IVL_TS" **SHALL** contain exactly one [1..1] high
36. **SHOULD** contain zero or one [0..1] effectiveTime such that it **SHALL** contain exactly one [1..1] @xsi:type = "PIVL_TS" or "EIVL_TS" (CONF:7513, CONF:9105)

    - ```
      [OCL]: self.effectiveTime->exists(ef : datatypes::SXCM_TS
       | ef.oclIsTypeOf(datatypes::PIVL_TS) xor
       ef.oclIsTypeOf(datatypes::EIVL_TS))
      ```

37. effectiveTime with @xsi:type = "PIVL_TS" or "EIVL_TS" **SHALL** contain exactly one [1..1] @operator="A" and (CONF:9106)
      ```

38. doseQuantity, if present, **SHOULD** contain zero or one [0..1] @unit, which **SHALL** be selected from ValueSet UCUM Units of Measure (case sensitive) 2.16.840.1.113883.1.11.12839 DYNAMIC (CONF:7526)

- ```
  [OCL]: not self.doseQuantity.oclIsUndefined() implies not
   self.doseQuantity.unit.oclIsUndefined()
  ```

39. participant with target entry Drug Vehicle **SHALL** contain exactly one [1..1] @typeCode="CSM" (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90) (CONF:7524)

- ```
  [OCL]: self.participant->select(par : cda::Participant2 |
   par.participantRole.oclIsKindOf(consol::DrugVehicle))->forAll(p :
   cda::Participant2 | p.typeCode=vocab::ParticipationType::CSM)
  ```

40. entryRelationship with target entry Instructions **SHALL** contain exactly one [1..1] @inversionInd="true" True (CONF:7542)

- ```
  [OCL]: self.entryRelationship->select(er : cda::EntryRelationship
   | er.act.oclIsKindOf(consol::Instructions))->forAll(ent :
   cda::EntryRelationship | ent.inversionInd=true)
  ```

41. Precondition for Substance Administration **SHALL** contain exactly one [1..1] @typeCode="PRCN" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:7550)

- ```
  [OCL]: self.precondition->select(par : cda::Precondition |
   par.oclIsKindOf(consol::PreconditionForSubstanceAdministration))-
  >forAll(p : cda::Precondition |
   p.typeCode=vocab::ActRelationshipType::PRCN)
  ```

MTM Medication Activity 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

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

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*