



**HL7 Implementation Guide for CDA® Release 2—Level 3:
NHSN Healthcare Associated Infection (HAI) Reports
Release 2, DSTU Release 2.1—US Realm**

Volume 1—Introductory Material

December 2014

Update to 2nd HL7 Draft Standard for Trial Use (DSTU)

Sponsored by:
Structured Documents Work Group
National Healthcare Safety Network

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Following this 24 month evaluation period, this draft standard, revised as necessary, will be submitted to a normative ballot in preparation for approval by ANSI as an American National Standard. Implementations of this draft standard shall be viable throughout the normative ballot process and for up to six months after publication of the relevant normative standard.

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Structure of This Guide

Two volumes comprise this *HL7 Implementation Guide for CDA® Release 2: NHSN Healthcare Associated Infection (HAI) Reports*. Volume 1 provides narrative introductory and background material pertinent to this implementation guide, including information on how to understand and use the templates in Volume 2. Volume 2 contains the normative Clinical Document Architecture (CDA) templates for this guide along with lists of all templates, code systems, value sets, and, when appropriate, changes from the previous version.

Additional information in Volume 1 for the HAI implementation guide includes a summary of changes from all previous versions, document and section codes used in HAI reports, a list of Consolidated CDA (C-CDA) templates referenced by HAI templates, information and examples of non-normative identifiers, and an explanation of vocabulary heuristics for code systems and value sets used by HAI templates.

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The best standards are those driven by business requirements. A strong set of Healthcare Associated Infection (HAI) surveillance application vendors monitor, evaluate, and test each release of this guide.

Past contributors: The vendors who participated in the 2007-2008 pilot activities of Bloodstream Infection Reports and Surgical Site Infection deserve special thanks and acknowledgment: MedMined™ services from Cardinal Health, EpiQuest, ICPA, Premier, TheraDoc, and Vecna Technologies. Throughout the development of this guide, Marla Albitz provided essential translation of NHSN business and technical requirements so that Kate Hamilton, Bob Dolin, Rick Geimer, and Susan Hardy could turn those requirements into a CDA-compliant specification. Liora Alschuler provided oversight and review. Additional contributors to the DSTU releases have been Jonathan Edwards, Maggie Dudeck, Dawn Sievert, Teresa Horan, Mary Andrus, Melinda Neuhauser, Ruby Phelps, Mindy Durrance, Alicia Shugart, Tygh Walker, Chris Cole, Cindy Gross, and Scott Fridkin (data specifications); Wenkai Li, Pavla Frazier, Gaye Dolin, Margaret Marshburn, Rob Hausam, Sundak Ganesan, and Denny Cordy (vocabulary); Kelly Peterson (database administration); Venu Sarraff (data importation); and Brett Marquard and Lauren Wood (project management and technical editing). We also thank Ted Klein, Cecil Lynch, and Daniel Vreeman for timely issuance of identifiers and codes.

This specification is a set of constraints on existing work, and the extent to which it can accommodate the expressive requirements of HAI reporting over time is a function of the richness of the model on which it is built, the Health Level Seven (HL7) Reference Information Model (RIM) and the RIM document standard, and the Clinical Document Architecture Release 2 (CDA R2). We thank all those who have worked for over a decade to produce these fundamental specifications; we especially thank structured documents co-chairs Bob Dolin, Keith Boone, Calvin Beebe, and Brett Marquard for their support of this project.

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Revision History

Release	Date	Notes
DSTU 1	February 28, 2008	First release of the DSTU
DSTU 2	August 6, 2008	Updated four reports, added one report
	December 4, 2008	Updated five reports, added eight reports
	February 27, 2009	Integrated January 2009 ballot resolutions
DSTU 3	March 30, 2009	Added two reports
	June 25, 2009	Integrated May 2009 ballot resolutions Replaced fine-grained NHSN codeSystems with a single NHSN vocabulary Replaced temporary NHSN code values with final NHSN code values
DSTU 4	August 7, 2009	Added one report, updated Population Summary Reports to include a new form. Converted to Templates Database constraints format.
	October 30, 2009	Integrated September 2009 ballot resolutions.
DSTU 4.1	January 14, 2010	Updated UTI Urinary Catheter Observation. Added History of Object Presence Observation.
DSTU 5	April 7, 2010	Added Hemovigilance Incident Report (HI). In the Population Summary Reports, added a code in the header to distinguish types of summary report; added values to support summary reporting for hemovigilance incidents and blood-product usage; converted some value sets to lists of single-value bindings. Modified data reported in the CLIP, Procedure, and LIO Reports as requested by NHSN.
	June 28, 2010	Incorporated May 2010 ballot resolutions.
DSTU 6	August 27, 2010	Added Hemovigilance Adverse Reaction Report (HAR). In the Population Summary Reports, added values to support antimicrobial usage and resistance data (AUP). Adapted several clinical statements to support nullFlavor or text.
	January 20, 2011	Incorporated September 2010 ballot resolutions
DSTU 7	August 5, 2011	Added Dialysis Event Numerator Report. In Population Summary Reports, added values for dialysis reporting. Removed the MDRO/CDAD Report and the clinical statements uniquely identified with it Replaced the MDRO Observation with an MDRO/CDI Observation. Updated the Findings Section in infection-type reports to require the new MDRO/CDI Observation, and in Generic Infection Report also to require a Significant Pathogens Observation. Updated the LIO Report to require a Significant Pathogens Observation.
	January 15, 2012	Updated vocabulary and value sets per CDC/NHSN requirements. Updated the top-level templateId. Removed the Generic Infection Report (not used). Updated the templateId for Findings Section in a LIO Report and Findings Section in infection-type reports, plus the templateIds of those reports. Updated Dialysis Event Numerator Report, renamed as Evidence of

		Infection (Dialysis) Report. Converted some value sets from STATIC to DYNAMIC bindings.
DSTU 8	July 2012	No new reports in this release. Minor revisions to several templates. Updated the top-level templateId. Recast the population summary body templates and created a separate section for them, in response to user ease-of-use wishes (no modeling change). Refactored the distribution of header constraints between header templates, to remove exceptions that have accumulated over time (no modeling change). Edited constraints to contain only one XML node per constraint (no modeling change).
DSTU 9	September 2012	This release added no new reports. Four numerator reports and four denominator reports were removed from this release of the HAI IG. These reports may be reintroduced in future. Reasons for removal include (1) not yet implemented, and/or (2) undergoing substantial change. Minor revisions to several templates. Added several new templates. Updated the top-level templateId.
Normative Release 1	January 2013	(First ballot) Restructure of IG to align with "state of the art" HL7 IGs for easier navigation. HAI templates now based on Consolidated CDA templates Summary reports moved into separate templates Narrative constraints converted to computable constraints. Added Antimicrobial Resistance Option (ARO) Summary Report and HAI AUR Antimicrobial Resistance Option (ARO) Report
	March 2013	(Second ballot) Remodeled Antimicrobial Resistance Option (ARO) Summary Report
	June 2013	Publication of Normative Release 1
Normative Release 2	September 2013	(First ballot; DSTU 1) Added no new reports. Added templates to SSI, Procedure, and Dialysis Added codes to ICU Summary, NICU Summary, SCA Summary, and Dialysis Reports
	January 2014	(Update to first ballot; DSTU 1.1) No normative / substantive changes Split guide into two volumes Added and/or deprecated values in some value sets
	February 2014	Publication of DSTU 1.1
	May 2014	(Second ballot) Added two new reports
	June 2014	Publication of DSTU 2
	December 2014	(Update to second ballot; DSTU 2.1) Included new system of identifying templates by oid or urn Updated seven reports

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1 INTRODUCTION

1.1 Purpose

This two-volume implementation guide (IG) contains an overview of Clinical Document Architecture (CDA) markup standards, design, and use (Volume 1) and a library of CDA templates for electronic submission of Healthcare Associated Infection (HAI) Reports to the National Healthcare Safety Network (NHSN) of the Centers for Disease Control and Prevention (CDC) (Volume 2).

These two volumes comprise a Draft Standard for Trial Use (DSTU). They define the overall approach and method of electronic submission and also develop constraints defining specific HAI report types. As reports are modified and new report types are defined, CDC and Health Level Seven (HL7) will develop and publish additional constraints.

Throughout this process, CDC remains the authority on NHSN data collection protocols. When healthcare enterprises choose to participate in NHSN, they must report to CDC occurrences such as specific reportable procedures, even those without complications, and events such as a bloodstream infection, either confirmed by a positive blood culture or supported by a patient's clinical symptoms. This specification opens the channel for data submission by all applications compliant with the data coding requirements defined here.

Note that participation in the NHSN requires enrollment and filing of reporting plans, which are not defined by this specification. For an overview of NHSN and full information on NHSN participation requirements, see: <http://www.cdc.gov/nhsn/>

Note that provisions of the Public Health Service Act protect all data reported to NHSN from discovery through the Freedom Of Information Act.

1.2 Audience

The audience for this work is all developers of software systems who want to enable their systems for reporting HAI data to the NHSN.

1.3 Organization of the Guide

This *HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection (HAI) Reports* is organized into two volumes. Volume 1 contains primarily narrative text describing the HAI guide, whereas Volume 2 contains normative CDA template definitions.

1.3.1 Volume 1 Introductory Material

This document, Volume 1, provides an overview of Clinical Document Architecture (CDA), recent changes to the standard, and information on how to understand and use the CDA templates provided in Volume 2.

- **Chapter 1**—Introduction
- **Chapter 2**—CDA R2 Background. This section contains selected background material on the CDA Release 2 (CDA R2) base standard to aid the reader in conceptualizing the “templated CDA” approach to implementation guide development.
- **Chapter 3**—Design Considerations. This section includes design considerations and overarching principles that have been developed and applied across the CDA templates in this guide. Material in this section can be thought of as “heuristics”, as opposed to the formal and testable constraints found in Volume 2 of this guide.
- **Chapter 4**—Using This Implementation Guide. This section describes the rules and formalisms used to constrain the CDA R2 standard. It describes the formal representation of CDA templates, the mechanism by which templates are bound to vocabulary, and additional information necessary to understand and correctly implement the normative content found in Volume 2 of this guide.
- **Appendices.** The Appendices include a list of acronyms and abbreviations, a high-level change log for this and all previous releases, a list of codes used by HAI reports, a list of Consolidated CDA (C-CDA) templates to which HAI templates conform, example instance identifiers, and vocabulary heuristics for code systems and value sets.

1.3.2 Volume 2 CDA Templates and Supporting Material

Volume 2 includes CDA templates and prescribes their use for a set of specific document types. The main chapters are:

- **Chapter 1**—Document-Level Templates. This chapter defines the report requirements for all HAI CDA documents.

The Healthcare Associated Infection Report requirements apply to any HAI CDA document. They apply to constraints on the CDA header and sections, and include the requirement that the body be represented by a `structuredBody` element.

The header requirements for population summary reports and for single-person reports differ significantly. HAI defines a generic header template for each of these two sets of requirements. Report-specific templates give additional requirements for each report type in this implementation guide.

- **Chapter 2**—Section-Level Templates. This chapter defines the generic constraints that apply to all sections along with specific requirements for each section used by the HAI reports in this guide.
- **Chapter 3**—Entry-Level Templates. This chapter defines entry-level templates, called clinical statements. Machine processable data are sent in the entry

templates. The entry templates are referenced by one or more section templates. Entry-level templates are always contained in section-level templates, and section-level templates are always contained in a document. Requirements for all entries (including organizers) used by the reports in this guide are in alphabetical order.

- **Chapter 4**—TemplateIds in This Guide. This chapter lists the template identifiers used by this guide for HAI reporting to NHSN. These template identifiers are assigned at the document, section, and entry level. Tables list NHSN templates by type and name and by containment. (Consolidated CDA (C-CDA) templates to which the NHSN templates conform are listed in Volume 1).
- **Chapter 5**—Value Sets in This Guide. This chapter lists all value set names and OIDs used by HAI templates. Links are provided to external value set sources if appropriate. Additionally, the `hai_voc.xls` spreadsheet is provided as a resource for value-set information.
- **Chapter 6**—Code Systems in This Guide. This chapter lists all code system names and OIDs used by HAI templates, both for value sets and single-value bindings.
- **Chapter 7**—Changes From Previous Version (when appropriate). This chapter details all changes made in templates for this release. (A summary of changes in earlier releases is provided in Volume 1).

1.3.3 Example Instance Identifiers

Much of the initial development of this guide was driven by a pilot project in July 2007. The pilot project used object identifiers (OIDs) assigned to a fictional facility and vendor to illustrate the numbering schemes for which facilities and vendors are responsible.

Except for the example patient identifiers, the example code in this document and the accompanying sample files use these pilot OIDs. Example patient identifiers use the HL7 example OID. In practice, the identifiers will be assigned by facilities and software applications submitting reports to NHSN.

These pilot instance identifiers begin with 2.16.840.1.113883.3.117.1.1.5; HL7 example identifiers begin with 2.16.840.1.113883.19.5. They are used throughout this guide and are documented in the appendix on [Example Instance Identifiers \(Non-normative\)](#).

1.4 Contents of the Package

The following files comprise this package.

Table 1: Contents of the Package

Documents	
CDAR2_IG_HAIRPT_R2_D2_1_2014DEC_V1_Introductory_Material.docx	Vol 1: Introductory material for this implementation guide
CDAR2_IG_HAIRPT_R2_D2_1_2014DEC_V2_Templates_and_Supporting.docx	Vol 2: Normative CDA templates for this implementation guide
hai_voc.xls	Vocabulary spreadsheet
Sample files	
bsi-num.xml	Bloodstream infection (BSI) numerator
ssi-num.xml	Surgical site infection (SSI) numerator
uti-num.xml	Urinary tract infection (UTI) numerator
proc-denom.xml	Procedure denominator
clip-num.xml	Central-line insertion practice (CLIP) numerator
lio-num.xml	Laboratory-identified organism (LIO) numerator
eoid-num.xml	Dialysis numerator
aro-num.xml	Antimicrobial Resistance Option (ARO) numerator
opc-num.xml	Outpatient Procedure Component (OPC) Event numerator
pop_sum-denom.xml	Summary data – denominator (example for ICU/Other)
pop_sum-denom-NICU.xml	Summary data – denominator (example for NICU)
pop_sum-denom-POM-FACWIDEOUT.xml	Summary data – denominator for prevention process and outcome measures monthly monitoring (POM) for facility-wide out-patient data
pop_sum-denom-POM-FACWIDEIN.xml	Summary data – denominator for prevention process and outcome measures monthly monitoring (POM) for facility-wide in-patient data
pop_sum-denom-AUP.xml	Summary data – denominator for antimicrobial usage
pop-sum-denom-SCA.xml	Summary data – denominator for specialty care area
pop-sum-denom-VAT.xml	Summary data – denominator for chronic hemodialysis patients
pop-sum-denom-ARO.xml	Summary data - denominator for antimicrobial resistance option (ARO)
pop-sum-denom-OPC.xml	Summary data - denominator for outpatient procedure component (OPC)
Transforms and associated files	
hai-display.xsl	Stylesheet for display of HAI instances
nhsnlogo_small.gif	Graphic logo for hai-display.xsl

2 CDA R2 BACKGROUND

CDA R2 is “... a document markup standard that specifies the structure and semantics of ‘clinical documents’ for the purpose of exchange” [CDA R2, Section 1.1]¹. Clinical documents, according to CDA, have the following characteristics:

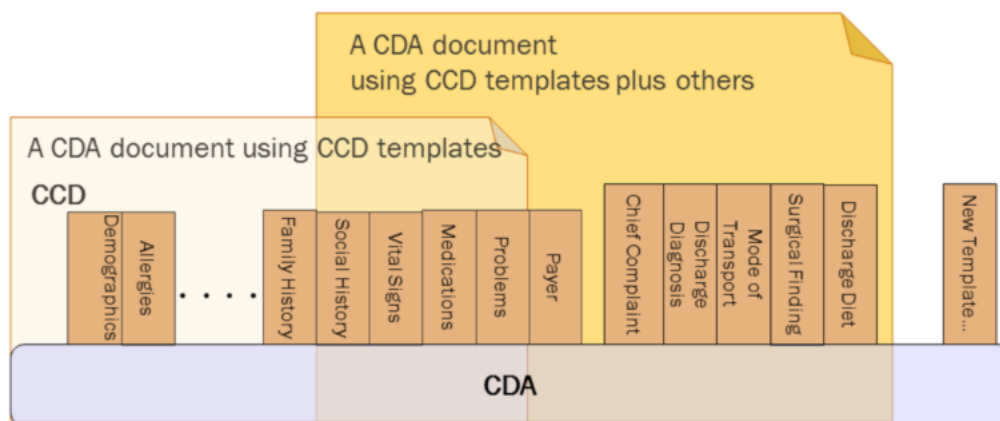
- Persistence
- Stewardship
- Potential for authentication
- Context
- Wholeness
- Human readability

CDA defines a header that for classification and management and a document body that carries the clinical record. While the header metadata are prescriptive and designed for consistency across all instances, the body is highly generic, leaving the designation of semantic requirements to implementation.

2.1 Templated CDA

CDA R2 can be constrained by mechanisms defined in the “Refinement and Localization”² section of the *HL7 Version 3 Interoperability Standards*. The mechanism most commonly used to constrain CDA is referred to as “templated CDA”. In this approach, a library is created containing modular CDA templates such that the templates can be reused across any number of CDA document types, as shown in the following figure.

Figure 1: Templated CDA



There are many different kinds of templates that might be created. Among them, the most common are:

¹ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

² <http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm>

- **Document-level templates:** These templates constrain fields in the CDA header, and define containment relationships to CDA sections. For example, a History-and-Physical document-level template might require that the patient's name be present, and that the document contain a Physical Exam section.
- **Section-level templates:** These templates constrain fields in the CDA section, and define containment relationships to CDA entries. For example, a Physical-exam section-level template might require that the section/code be fixed to a particular LOINC code, and that the section contain a Systolic Blood Pressure observation.
- **Entry-level templates:** These templates constrain the CDA clinical statement model in accordance with real world observations and acts. For example, a Systolic-blood-pressure entry-level template defines how the CDA Observation class is constrained (how to populate observation/code, how to populate observation/value, etc.) to represent the notion of a systolic blood pressure.

A CDA implementation guide (such as this one) includes reference to those templates that are applicable. On the implementation side, a CDA instance populates the template identifier (`templateId`) field where it wants to assert conformance to a given template. On the receiving side, the recipient can then not only test the instance for conformance against the CDA XML schema, but also test the instance for conformance against asserted templates.

Template identifiers are critical to the validation methods chosen at this time for submissions to the NHSN. NHSN may reject as nonconformant instances that do not conform to the template identifier constraints defined here.

Please reference the NHSN webpage (<http://www.cdc.gov/nhsn/>) to identify which HAI release NHSN currently supports for a given report.

2.2 Background

In the development of this specification, we compared the baseline requirements for HAI reporting against CDA R2 to determine initially whether CDA—designed for clinical reports that become part of a patient chart—was suitable for HAI reporting or whether significant modifications would be required. That analysis showed that the only anomaly between the two was the requirement for a single-record target (patient), which is appropriate for reports focused on individual patients such as the Bloodstream Infection (BSI) Report, and not appropriate for population summary reports that summarize data for many patients over a period of time. This implementation guide addresses this issue in population summary reports through use of a null flavor for the record target and a participant defined as a “group”.

After the initial evaluation, we analyzed and mapped four HAI report types to the CDA header and body, noting similarities and differences between the report types. From this analysis, we developed the first in a set of “straw man” instances illustrating the proposed approach. These initial samples were reviewed informally by the Structured Documents Working Group (SDWG), which is the sponsor of this guide within HL7; the stakeholders in HAI exchange; the NHSN, which is the overall sponsor of the activity; and the software vendors whose systems will use the specification for NHSN reporting.

Design considerations included consistency with published CDA IGs and with the RMIMs of related domain committees, specifically those for laboratory reporting, while retaining fidelity with the data structures of the NHSN database.

An implementation pilot that ran in late July 2007 tested a preliminary design for the BSI and Intensive Care Unit (ICU) Summary (now part of Population Summary) forms. Later releases incorporated findings from that pilot.

In response to comments received on the first ballot for Draft Standard for Trial Use (DSTU), a rigorous evaluation ensured use of standard codes in every instance where their use was fully expressive and supported by NHSN. The criteria for this evaluation are described in the Appendix on [Vocabulary Heuristics for Codes and Value Sets \(Non-normative\)](#). We incorporated changes through the reconciliation process from the second ballot for DSTU held in December 2007 and January 2008.

A second development cycle updated the constraints on several reports and added a new Multi-drug-resistant Organism (MDRO) Infection report. These updates were reviewed informally by the SDWG and balloted in September 2008. We incorporated changes through the reconciliation process, and published Release 2 of the DSTU in March 2009.

Subsequent releases have added new report types and extended the population summary report to encompass additional data sets. For an overview of the changes in each release before this current release, see the appendix on [High-Level Changes from Previous Releases](#).

2.3 Current Release

This implementation guide is an update to the second DSTU release of the second normative release of the HAI reporting templates. It makes changes to the following reports:

- HAI AUR Antimicrobial Resistance Option (ARO) Report
- HAI Central-Line Insertion Practice Numerator Report
- HAI Evidence of Infection (Dialysis) Report
- HAI Laboratory-Identified Organism (LIO) Report
- Prevention Process and Outcome Measures (POM) Summary Report

Changes made in [this release](#) are summarized in the Appendix on [High-Level Changes from Previous Releases](#). Volume 2 of this guide contains a detailed section on “Changes from Previous Version”.

2.4 Future Work

Future work on HAI reporting will continue to expand the set of forms covered by the specification.

2.5 Change Notification Process

CDC maintains an e-mail list of contacts at organizations interested in or responsible for implementations of CDA for HAI reporting to NHSN. To be added to the list, send a request with your contact information to nhsncda@cdc.gov. CDC uses the list for e-mail notifications of changes, including new data requirements. Changes may apply to this IG and to other documents such as business rules that are needed to implement and support CDA for HAI reporting to NHSN. In addition, the CDA tab at the NHSN members' website (<http://www.cdc.gov/nhsn/CDA/index.html>) contains additional information about reporting to NHSN via CDA.

3 DESIGN CONSIDERATIONS

Design considerations describe overarching principles that have been developed and applied across the CDA templates in this guide. Material in this section can be thought of as “heuristics”, as opposed to the formal and testable constraints found in Volume 2 of this guide.

3.1 *Rendering Header Information for Human Presentation*

Metadata carried in the header may already be available for rendering from electronic health records (EHRs) or other sources external to the document; therefore, there is no strict requirement to render directly from the document. An example of this would be a doctor using an EHR that already contains the patient’s name, date of birth, current address, and phone number. When a CDA document is rendered within that EHR, those pieces of information may not need to be displayed since they are already known and displayed within the EHR’s user interface.

Good practice recommends that the following be present whenever the document is viewed:

- Document title and document dates
- Service and encounter types, and date ranges as appropriate
- Names of all persons along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Names of selected organizations along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Date of birth for `recordTarget(s)`

3.2 *Unknown and No Known Information*

Information technology solutions store and manage data, but sometimes data are not available. An item may be unknown, not relevant, or not computable or measureable, such as where a patient arrives at an Emergency Department unconscious and with no identification.

In many cases, the CDA standard will stipulate that a piece of information is required (e.g., via a **SHALL** conformance verb). However, in most of these cases, the standard provides an “out”, allowing the sender to indicate that the information isn’t known.

Here, we provide guidance on representing unknown information. Further details can be found in the HL7 V3 Data Types, Release One specification that accompanies the CDA R2 normative standard.

A “@nullFlavor” attribute may be used to indicate that information is unknown. Allowable values for populating the attribute give more details about the reason the information is unknown, as shown in the following example.

Figure 2: nullFlavor Example

```
<!-- CDA requires the consumable element, however NHSN does not
collect further information about the antifungal -->
<consumable>
  <manufacturedProduct>
    <templateId root="2.16.840.1.113883.10.20.22.4.37"/>
    <manufacturedMaterial>
      <code nullFlavor="NI"/>
    </manufacturedMaterial>
  </manufacturedProduct>
</consumable>
```

Use null flavors for unknown, required, or optional attributes, where allowed per the NHSN protocol:

NI	No information. This is the most general and default null flavor.
NA	Not applicable. Known to have no proper value (e.g., last menstrual period for a male).
UNK	Unknown. A proper value is applicable, but is not known.
ASKU	Asked, but not known. Information was sought, but not found (e.g., the patient was asked but did not know).
NAV	Temporarily unavailable. The information is not available, but is expected to be available later.
NASK	Not asked. The patient was not asked.
MSK	There is information on this item available but it has not been provided by the sender due to security, privacy, or other reasons. There may be an alternate mechanism for gaining access to this information.
OTH	The actual value is not an element in the value domain of a variable. (e.g., concept not provided by required code system).

The list above contains those null flavors that are commonly used in clinical documents. For the full list and descriptions, see the `nullFlavor` vocabulary domain in the CDA normative edition.³

Any **SHALL**, **SHOULD** and **MAY** conformance statement may use `nullFlavor`, unless the `nullFlavor` is explicitly disallowed (e.g., through another conformance statement).

Figure 3: Attribute Required—nullFlavor not allowed

1. **SHALL** contain exactly one [1..1] `code` (CONF:15407).
 - a. This `code` **SHALL** contain exactly one [1..1] `@code="11450-4" Problem List` (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:15408).
- or
2. **SHALL** contain exactly one [1..1] `effectiveTime/@value` (CONF:5256).

³ HL7 Clinical Document Architecture (CDA Release 2) <http://www.hl7.org/implement/standards/cda.cfm>

Figure 4: Allowed nullFlavors When Element is Required—with XML examples

```
1. SHALL contain at least one [1..*] id
2. SHALL contain exactly one [1..1] code
3. SHALL contain exactly one [1..1] effectiveTime

<entry>
  <observation classCode="OBS" moodCode="EVN">
    <id nullFlavor="NI"/>
    <code nullFlavor="OTH">
      <originalText>New Grading system</originalText>
    </code>
    <statusCode code="completed"/>
    <effectiveTime nullFlavor="UNK"/>
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
    </value>
  </observation>
</entry>
```

If a sender wants to state that a piece of information is unknown, the following principles apply:

1. If the sender doesn't know an attribute of an act, that attribute can be null.

Figure 5: Unknown Medication Example

```
<entry>
  <text>patient was given a medication but I do not know what it was</text>
  <substanceAdministration moodCode="EVN" classCode="SBADM">
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code nullFlavor="NI"/>
        </manufacturedLabeledDrug>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
```

2. If the sender doesn't know if an act occurred, the nullFlavor is on the act (detail could include specific allergy, drug, etc.).

Figure 6: Unknown Medication Use of Anticoagulant Drug Example

```
<entry>
  <substanceAdministration moodCode="EVN" classCode="SBADM" nullFlavor="NI">
    <text>I do not know whether or not patient received an anticoagulant
      drug</text>
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code code="81839001" displayName="anticoagulant drug"
            codeSystem="2.16.840.1.113883.6.96"
            codeSystemName="SNOMED CT"/>
        </manufacturedLabeledDrug>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
```

3. If the sender wants to state 'no known', a negationInd can be used on the corresponding act (substanceAdministration, Procedure, etc.)

Figure 7: No Known Medications Example

```
<entry>
  <substanceAdministration moodCode="EVN" classCode="SBADM" negationInd="true">
    <text>No known medications</text>
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code code="410942007" displayName="drug or medication"
            codeSystem="2.16.840.1.113883.6.96"
            codeSystemName="SNOMED CT"/>
        </manufacturedLabeledDrug>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
```

These next examples illustrate additional nuances of representing unknown information in coded fields.

Figure 8: Value Known—code for value not known

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    ...
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
    </value>
  </observation>
</entry>
```

Figure 9: Value Completely Unknown

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    ...
    <value xsi:type="CD" nullFlavor="UNK"/>
  </observation>
</entry>
```

Figure 10: Value Known—code in required code system not known but code from another code system is known

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    ...
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
      <translation code="129742005" displayName="spiculated lesion"
        codeSystem="2.16.840.1.113883.6.96"
        codeSystemName="SNOMED CT"/>
    </value>
  </observation>
</entry>
```

3.3 Negating Clinical Statements

Usually, clinical statements in a CDA document assert positive statements. A procedure element represents a procedure that took place and an observation represents an observation about a patient condition or a lab result. In this implementation guide, when `negationInd` is set to true, it is understood that it negates the act as described by the act's descriptive properties (including `act.code`, `procedure.effectiveTime`, `observation.value`, etc.) and any of the act's components, rather than at the level of a specific value in the act. The inert properties such as `act.id`, `act.moodCode`, and `act.confidentialityCode` are not negated and always have the same meaning. In other words, when an act is negated, it indicates that the event as specified did not occur. For example, if the clinical statement is asserting that a wrong procedure has been performed on a certain date and its `negationInd` is set to true, the whole clinical statement is negated, including any attributes such as the assertion and the `effectiveTime`. This clinical statement indicates that we are not asserting that this event occurred on this date—there is no assertion that a wrong procedure was performed on this date. For further details and examples, see the definition of `Act.negationInd` in the HL7 RIM, Version 2.07 (the version of the HL7 RIM from which CDA, Release 2 is derived) and the discussion of *Negation Indicators in RIM Classes in Core Principles and Properties of V3 Models*.

4 USING THIS IMPLEMENTATION GUIDE

This chapter describes the rules and formalisms used to constrain the CDA R2 standard. It describes the formal representation of CDA templates, the mechanism by which templates are bound to vocabulary, and additional information necessary to understand and correctly implement the normative content found in Volume 2 of this guide.

4.1 Levels of Constraint

The CDA standard describes conformance requirements in terms of three general levels corresponding to three different, incremental types of conformance statements:

- Level 1 requirements impose constraints upon the CDA Header. The body of a Level 1 document may be XML or an alternate allowed format. If XML, it must be CDA-conformant markup.
- Level 2 requirements specify constraints at the section level of a CDA XML document: most critically, the section code and the cardinality of the sections themselves, whether optional or required.
- Level 3 requirements specify constraints at the entry level within a section. A specification is considered “Level 3” if it requires any entry-level templates.

Note that these levels are rough indications of what a recipient can expect in terms of machine-processable coding and content reuse. They do not reflect the level or type of clinical content, and many additional levels of reusability could be defined.

The section libraries for each document type list the required and optional sections.

4.2 Conformance Conventions Used in This Guide

4.2.1 Templates and Conformance Statements

Conformance statements within Volume 2 of this implementation guide are presented as constraints from Trifolia Workbench, a template repository. An algorithm converts constraints recorded in Trifolia to a printable presentation. Each constraint is uniquely identified by an identifier at or near the end of the constraint (e.g., CONF:86-7345). The digits in the conformance number before the hyphen identify which IG the template belongs to and the number after the hyphen is unique to the owning IG. Together, these two numbers uniquely identify each constraint. These identifiers are persistent but not sequential. Conformance numbers in this guide associated with a conformance statement that is carried forward from a previous version of this guide will carry the same conformance number from the previous version. This is true even if slightly edited. If a conformance statement is entirely new, it will have a new conformance number.

Bracketed information following each template title indicates the template type (section, observation, act, procedure, etc.), the identifier oid or identifier urn, and whether the template is [open or closed](#). The identifier oid is the templateId/@root

value; all templateIds have an @root value. Newer and/or versioned templates also have an @extension value, which is a date identifying the version of this template; such templates are identified by urn and the HL7 version (urn:hl7ii). The urn identifier includes both the @root and @extension value for the templateId (for example, identifier urn:hl7ii:2.16.840.1.113883.10.20.5.5.41:2014-06-09).

Each section and entry template in Volume 2 of this guide includes a context table. The "Contained By" column indicates which templates use this template, and if the template is optional or required in the containing template. The "Contains" column indicates any templates that the template uses.

Figure 11: Context Tables

XXX: Allergy Problem Act (V2) Contexts

Contained By:	Contains:
Allergies Section (entries optional) (V2) (optional)	Allergy - Intolerance Observation (V2)
Allergies Section (entries required) (V2) (required)	Author Participation

Each template also includes a constraint overview table to summarize the constraints in the template.

Figure 12: Constraints Overview Table Example

XPath	Card.	Verb	Data Type	CONF#	Fixed Value
observation[identifier: oid:2.16.840.1.113883.10.20.22.4.31]					
@classCode	1..1	SHALL		XXXX	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		XXXX	2.16.840.1.113883.5.1001 (ActMood) = EVN
code	1..1	SHALL		XXXX	
@code	1..1	SHALL		XXXX	2.16.840.1.113883.6.96 (SNOMED CT) = 445518008
value	1..1	SHALL	PQ	XXXX	
@unit	1..1	SHALL	CS	XXXX	2.16.840.1.113883.11.20.9.21 (AgePQ_UCUM)
templateId	1..1	SHALL		XXXX	
@root	1..1	SHALL		XXXX	2.16.840.1.113883.10.20.22.4.31
statusCode	1..1	SHALL		XXXX	
@code	1..1	SHALL		XXXX	2.16.840.1.113883.5.14 (ActStatus) = completed

The following figure shows a typical template's set of constraints presented in Volume 2 of this guide. The next chapters describe specific aspects of conformance statements—open vs. closed statements, conformance verbs, cardinality, vocabulary conformance, containment relationships, and null flavors. The expression “such that it” means, you (**SHALL/SHOULD/MAY**) have one of those things that look like that, but you can also have another one of those things that look different. The example below states that you must

have `templateId` with a root of 2.16.840.1.113883.10.20.22.4.31 but you can also have other template IDs.

Figure 13: Constraints Format Example

Age Observation

```
[observation: identifier oid:2.16.840.1.113883.10.20.22.4.31 (open)]
```

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:XXXX).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF: XXXX).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:XXXX) such that it
 - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.31" (CONF: XXXX).
4. **SHALL** contain exactly one [1..1] **code** (CONF:7615).
 - a. This code **SHALL** contain exactly one [1..1] **@code**="445518008" Age At Onset (CodeSystem: SNOMED CT 2.16.840.1.113883.6.96 **STATIC**) (CONF: XXXX).
5. **SHALL** contain exactly one [1..1] **statusCode** (CONF: XXXX).
 - a. This **statusCode** **SHALL** contain exactly one [1..1] **@code**="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF: XXXX).
6. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="PQ" (CONF:XXXX).
 - a. This value **SHALL** contain exactly one [1..1] **@unit**, which **SHALL** be selected from ValueSet [AgePQ UCUM](#) 2.16.840.1.113883.11.20.9.21 **DYNAMIC** (CONF: XXXX).

4.2.2 Template Versioning

A new version of an existing implementation guide reuses templates from the previous version. During the ballot phase or update phase, templates carry the designation “Published” to indicate the template is unchanged from the previous version or “Draft” to indicate a new or revised template. Substantial revisions to previously published templates are always indicated by “(Vn)” in all cases: ballot-phase, update-phase, and published guides.

If there are no substantive changes to a template that has been successfully published, the template will carry the same `templateId/@root` (identifier oid) and `templateId/@extension` as in the previous implementation guide (in the case of older templates, the `@extension` attribute will not be present). During a new ballot or update phase, “Published” is appended to the main heading for the template to indicate that the template cannot be commented on in the ballot or update. The “Published” designation is removed on final publication versions.

A revised version of a previously published template keeps the same `templateId/@root` as the previous version, but it is assigned a new

templateId/@extension. The notation “(Vn)” (V2, V3, etc.) is also added to the template name. Versions are not necessarily forward or backward compatible. A versioning may be due to substantive changes in the template and/or the fact that a contained template has changed. The “(Vn)” designation is persistent; it appears with that template when it is used in subsequent guides. During a new ballot or update phase, “Draft” is appended to the main heading for the template to indicate that it may be voted on in the ballot or commented on in the update; the “Draft” designation is removed on final publication versions.

A revised version of a template is explicitly linked to the prior version, enabling the automatic generation of the detailed change log found in Volume 2, Section 6 “Changes From Previous Version”.

The following figure shows an example of a versioned template: HAI AUR Antimicrobial Resistance Option (ARO) Report (oid:2.16.840.1.113883.10.20.5.31) has versioned to HAI AUR Antimicrobial Resistance Option (ARO) Report (V2) (urn:hl7ii:2.16.840.1.113883.10.20.5.31:2014-06-09).

Figure 14: Versioned Template Change Log Example

Change	Old	New
Name	HAI AUR Antimicrobial Resistance Option (ARO) Report	HAI AUR Antimicrobial Resistance Option (ARO) Report (V2)
Oid	oid:2.16.840.1.113883.10.20.5.31	urn:hl7ii:2.16.840.1.113883.10.20.5.31:2014-06-09
CONF #: 1129-30474 Added		SHALL contain exactly one [1..1] @extension="2014-06-09" (CONF:1129-30474).
CONF #: 1129-21153 Modified	SHALL contain exactly one [1..1] Findings Section in an ARO Report (identifier: oid:2.16.840.1.113883.10.20.5.5.32)	SHALL contain exactly one [1..1] Findings Section in an ARO Report (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.5.32:2014-06-09)

4.2.3 Open and Closed Templates

HAI templates are, with one exception, closed templates. This means that the template constraints specify everything that is allowed. In open templates, by contrast, all of the features of the CDA R2 base specification are allowed except as constrained by the templates.

The exception to closed templates in HAI reports is that the `structuredBody` is open: it may contain sections not specified in this guide. The content of such unspecified sections is not processed by NHSN.

4.2.4 Conformance Verbs (Keywords)

The keywords **SHALL**, **SHOULD**, **MAY**, **NEED NOT**, **SHOULD NOT**, and **SHALL NOT** in this document are to be interpreted as described in the HL7 Version 3 Publishing Facilitator's Guide.⁴

- **SHALL**: an absolute requirement
- **SHALL NOT**: an absolute prohibition against inclusion
- **SHOULD/SHOULD NOT**: best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course
- **MAY/NEED NOT**: truly optional; can be included or omitted as the author decides with no implications

The keyword "**SHALL**" allows the use of `nullFlavor` unless the requirement is on an attribute or the use of `nullFlavor` is explicitly precluded.

4.2.5 Cardinality

The cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within a document instance. The cardinality indicators are interpreted with the following format "m..n" where m represents the least and n the most:

- 0..1 zero or one
- 1..1 exactly one
- 1..* at least one
- 0..* zero or more
- 1..n at least one and not more than n

When a constraint has subordinate clauses, the scope of the cardinality of the parent constraint must be clear. In the next figure, the constraint says exactly one participant is to be present. The subordinate constraint specifies some additional characteristics of that participant.

Figure 15: Constraints Format—only one allowed

<p>1. SHALL contain exactly one [1..1] participant (CONF:2777). a. This participant SHALL contain exactly one [1..1] @typeCode="LOC" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230).</p>

In the next figure, the constraint says only one participant "like this" is to be present. Other participant elements are not precluded by this constraint.

⁴ HL7, Version 3 Publishing Facilitator's Guide. <http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm>

Figure 16: Constraints Format—only one like this allowed

- | |
|--|
| <ol style="list-style-type: none">1. SHALL contain exactly one [1..1] participant (CONF:2777) such that it<ol style="list-style-type: none">a. SHALL contain exactly one [1..1] @typeCode="LOC" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230). |
|--|

4.2.6 Optional and Required with Cardinality

The terms *optional* and *required* describe the *lower* bound of cardinality as follows:

Optional means that the number of allowable occurrences of an element may be 0; the cardinality will be expressed as [0..1] or [0..*] or similar. In these cases, the element may not be present in the instance.

Required means that the number of allowable occurrences of an element must be at least 1; the cardinality will be expressed as [m..n] where m >=1 and n >=1 for example [1..1] or [1..*]. In these cases, the element must be present in the instance. If an element is required, but is not known (and would otherwise be omitted if it were optional), it must be represented by a null flavor. See [“Unknown and No Known Information”](#).

4.2.7 Vocabulary Conformance

The templates in this document use terms from several code systems. These vocabularies are defined in various supporting specifications and may be maintained by other bodies, as is the case for the LOINC and SNOMED CT vocabularies.

Note that value-set identifiers (e.g., ValueSet 2.16.840.1.113883.1.11.78 Observation Interpretation (HL7) **DYNAMIC**) do not appear in CDA submissions; they tie the conformance requirements of an implementation guide to the appropriate code system for validation.

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. Value-set constraints can be **STATIC**, meaning that they are bound to a specified version of a value set, or **DYNAMIC**, meaning that they are bound to the most current version of the value set. A simplified constraint, used when the binding is to a single code, includes the meaning of the code, as follows.

Figure 17: Binding to a Single Code

- | |
|---|
| <ol style="list-style-type: none">2. SHALL contain exactly one [1..1] code (CONF:15403).<ol style="list-style-type: none">a) This code SHALL contain exactly one [1..1] @code="11450-4" Problem List (CONF:15408).b) This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF: 31141). |
|---|

The notation conveys the actual code (11450-4), the code's `displayName` (Problem List), the `OID` of the `codeSystem` from which the code is drawn (2.16.840.1.113883.6.1), and the `codeSystemName` (LOINC).

HL7 Data Types Release 1 requires the `codeSystem` attribute unless the underlying data type is “Coded Simple” or “CS”, in which case it is prohibited. The `displayName` and the `codeSystemName` are optional, but recommended, in all cases.

The above example would be properly expressed as follows.

Figure 18: XML Expression of a Single-code Binding

```
<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"/>

<!-- or -->

<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
      displayName="Problem List"
      codeSystemName="LOINC"/>
```

A full discussion of the representation of vocabulary is outside the scope of this document; for more information, see the HL7 V3 Normative Edition 2010⁵ sections on Abstract Data Types and XML Data Types R1.

There is a discrepancy in the implementation of translation code versus the original code between HL7 Data Types R1 and the convention agreed upon for this specification. The R1 data type requires the original code in the root. This implementation guide specifies the standard code in the root, whether it is original or a translation. This discrepancy is resolved in HL7 Data Types R2.

Figure 19: Translation Code Example

```
<code code='206525008'
      displayName='neonatal necrotizing enterocolitis'
      codeSystem='2.16.840.1.113883.6.96'
      codeSystemName='SNOMED CT'>
  <translation code='NEC-1'
    displayName='necrotizing enterocolitis'
    codeSystem='2.16.840.1.113883.19'/>
</code>
```

Value set tables are presented below the first template that uses that value set; links are provided in subsequent templates that use the same value set. The value set tables include the value set identifier, a description, a link (where appropriate), and a list of codes in the value set. Ellipses in the last row of value-set members shown indicate that the list is an excerpt and the complete source must be accessed to see all members. Where the table is an excerpt and no link is provided, the full set of values are contained in the `hai_voc.xls` spreadsheet included with this package.

⁵ HL7 Version 3 Interoperability Standards, Normative Edition 2010.
<http://www.hl7.org/memonly/downloads/v3edition.cfm> - V32010

Figure 20: Example Value Set Table

Value Set: Referral Types 2.16.840.1.113883.11.20.9.56 A value set of SNOMED CT codes descending from "3457005" patient referral (procedure). Value Set Source: http://vtsl.vetmed.vt.edu/			
Code	Code System	Code System OID	Print Name
44383000	SNOMED CT	2.16.840.1.113883.6.96	Patient referral for consultation
391034007	SNOMED CT	2.16.840.1.113883.6.96	Refer for falls assessment (procedure)
86395003	SNOMED CT	2.16.840.1.113883.6.96	patient referral for family planning (procedure)
306106002	SNOMED CT	2.16.840.1.113883.6.96	referral to intensive care service (procedure)
306140002	SNOMED CT	2.16.840.1.113883.6.96	referral to clinical oncology service (procedure)
396150002	SNOMED CT	2.16.840.1.113883.6.96	Referral for substance abuse (procedure)
...			

4.2.8 Data Types

All data types used in a CDA document are described in the CDA R2 normative edition⁶. All attributes of a data type are allowed unless explicitly prohibited by this specification.

4.2.9 Succession Management

CDA-conformant HAI instances use the elements defined in the CDA header (`documentId`, `setId`, `version` number, and `relatedDocument/typeCode`) to manage replacements and updates of the documents. As with all CDA documents, the `ClinicalDocument/id` uniquely identifies a document instance (an electronic file). Incremented version numbers identify subsequent versions of the document.

NHSN assigns each participating vendor a root OID. The vendor system generates the `ClinicalDocument/setId`. The vendor is responsible for extending its OID as necessary to support the several unique numbering schemes it must generate; these include document identifiers and facility-generated procedure identifiers.

4.3 XML Conventions Used in This Guide

4.3.1 XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this document uses XML Path Language (XPath) notation⁷ in conformance statements and elsewhere to identify the Extensible Markup Language (XML) elements and attributes

⁶ HL7 Clinical Document Architecture (CDA Release 2). <http://www.hl7.org/implement/standards/cda.cfm>

⁷ <http://www.w3.org/TR/xpath/>

within the CDA document instance to which various constraints are applied. The implicit context of these expressions is the root of the document. This notation provides a mechanism that will be familiar to developers for identifying parts of an XML document.

XPath statements appear in this document in a `monospace font`.

XPath syntax selects nodes from an XML document using a path containing the context of the node(s). The path is constructed from node names and attribute names (prefixed by a '@') and catenated with a '/' symbol.

Figure 21: XML Document Example

```
<author>
  <assignedAuthor>
    ...
    <code codeSystem='2.16.840.1.113883.6.96'
          codeSystemName='SNOMED CT'
          code='17561000'
          displayName='Cardiologist' />
    ...
  </assignedAuthor>
</author>
```

In the above example, the `code` attribute of the `code` could be selected with the XPath expression in the next figure.

Figure 22: XPath Expression Example

```
author/assignedAuthor/code/@code
```

4.3.2 XML Examples and Sample Documents

Extensible Mark-up Language (XML) examples appear in figures in this document in this `monospace font`. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (...) as shown in the example below.

Figure 23: ClinicalDocument Example

```
<ClinicalDocument xmlns="urn:h17-org:v3">
  ...
</ClinicalDocument>
```

Within the narrative, XML element (`code`, `assignedAuthor`, etc.) and attribute (`SNOMED CT`, `17561000`, etc.) names also appear in this `monospace font`.

This package includes sample documents as listed in the [Contents of the Package](#) table.

4.4 Supporting Tools

4.4.1 Validation

This guide expresses CDA R2 constraints in a technology-neutral formalism. The release when published also provides a non-normative set of Schematron schemas based on the technology-neutral formalism, which can test template conformance.

Schematron is “a language for making assertions about patterns found in XML documents.” The schemas provided for CDA and for this package support two-stage validation. First, the CDA schema CDA.xsd validates the basic structural and semantic requirements of any CDA instance. Second, the IG-specific Schematron schema validates the specific requirements of this package.

Validation services are provided through the NHSN import mechanism and by Lantana Group’s CDA Validator (<https://www.lantanagroup.com/validator/>). The CDA Validator is an online application that validates a CDA document’s conformance to several standards and implementation guides; it includes the Schematron files described above.

4.4.2 Generation of Narrative Block

Clinical documents generated by clinicians for a patient chart can assume an almost infinite set of semantic structures. For this reason, CDA relies on a narrative block (section/text) to convey the comprehensive clinical report, i.e., all the information that a human reader would consider the definitive, legal content of the record. (Human readability and rendering requirements are described in CDA R2, Section 1.2.3. See [References](#).)

In contrast, the structure and semantics of HAI reports to the NHSN are tightly constrained for unambiguous insertion into the NHSN database. Few elements allow unstructured, uncoded narrative. The definitive, human-readable, legal contents of a report can be derived entirely from the CDA titles and coded entries. Therefore, for the convenience of implementers, this project created a transform that derives the narrative block from the CDA entries. Use of this transform is not required; implementers can use local methods to create the CDA narrative block.

4.4.3 Display Transforms

The content required for correct interpretation by a human reader of a compliant instance must be displayable using any CDA stylesheet. Thus, instances conforming to this IG can be viewed using CDA.xsl or any other stylesheet.

In addition, this project has a customized stylesheet that conforms more closely to the display format typical of such records.

5 REFERENCES

- "The Clinical Document Architecture Quick Start Guide (CDA Quick Start Guide)", Alschuler Associates, LLC (became Lantana Consulting Group on January 1, 2011). Available at: <https://www.lantanagroup.com/resources/free-tools/>.
- CDA Validator, <http://www.lantanagroup.com/validator>.
- 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 to HL7 members at: http://www.hl7.org/documentcenter/private/standards/cda/r2/cda_r2_normativewebedition.zip.
- 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>.
- Extensible Markup Language, www.w3.org/XML.
- HL7 Governance and Operations Manual, http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf.
- *HL7 Implementation Guide for CDA Release 2.0, Consolidated CDA Templates, (US Realm)*. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258
- HL7 Version 3 Publishing Facilitator's Guide, available to HL7 members at: <http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm>.
- **LOINC®**: Logical Observation Identifiers Names and Codes, Regenstrief Institute. Available at: <http://loinc.org>
- NHSN members' website, <http://www.cdc.gov/nhsn/>.
- **SNOMED CT®**: SNOMED Clinical Terms SNOMED International Organization. Available at: <http://www.ihtsdo.org/snomed-ct>.

APPENDIX A — ACRONYMS AND ABBREVIATIONS

ACoS	American College of Surgeons
AUP	Antimicrobial Use, Pharmacy Option (AUP) Summary Report
BSI	Bloodstream Infection
C-CDA	Consolidated CDA
CDA	Clinical Document Architecture
CDAD	C. difficile-associated disease
CDA R2	CDA Release 2
CDI	C. difficile
CDC	Centers for Disease Control and Prevention
CHI	Consolidated Health Informatics
CLIP	central-line insertion practice
CPT	Current Procedural Terminology
DSTU	Draft Standard for Trial Use
EHR	electronic health record
EOID	Evidence of Infection (Dialysis) Report
GIN	Generic Incident Notification
HAI	Healthcare Associated Infection
HITSP	Healthcare Information Technology Standards Panel
HL7	Health Level Seven
ICP	infection control professional
ICU	intensive care unit
ID	identifier
IG	implementation guide
LIO	Laboratory-identified organism
MDRO	Multi-drug-resistant organism
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NHSN	National Healthcare Safety Network
NICU	Neonatal Intensive Care Unit
OID	object identifier
OPC	Outpatient Procedure Component
PHCR	Public Health Case Reports
PHIN VADS	Public Health Information Network Vocabulary Access and Distribution System
PICC/IV	peripherally inserted central catheter/intravenous
POM	Prevention Process and Outcome Measures Monthly Monitoring
RIM	Reference Information Model
RMIM	Refined Message Information Model
SCA	Specialty Care Area
SDWG	Structured Documents Working Group
SSI	Surgical Site Infection
TA-GVHD	Transfusion associated graft vs. host disease
TSC	Technical Steering Committee
URL	Uniform Resource Locator
URN	Universal Resource Name
UTI	Urinary Tract Infection

VAT	Denominator for Maintenance Hemodialysis Patients Stratified by
	Vascular Access Type Report
XML	Extensible Markup Language

APPENDIX B — HIGH-LEVEL CHANGES FROM PREVIOUS RELEASES

Before this release of HAI reports, there were nine DSTU releases and one Normative Release. This appendix summarizes the main changes in DSTU releases 3 through 9, Normative Release 1, and the first DSTU ballot for Normative Release 2. This IG is an update to that first DSTU ballot and contains no normative changes.

DSTU Release 3

Release 3 updated the value set in the population summary report to include the Specialty Care Area (SCA) and Neonatal Intensive Care Unit (NICU) Monthly forms.

To accommodate the recording of sub-groups in the NICU Monthly form, the Summary Encounter now allows a `participant` element specifying the characteristic of the subgroup (e.g., birth weight under 750g).

A single NHSN code system replaced the finer-grained NHSN code systems.

Final values replaced temporary values in the NHSN code system.

Final values were assigned to two temporary value-set OIDs.

An influenza immunization report no longer records the in-facility location and type.

DSTU Release 4

Release 4 introduced the Laboratory-identified Organisms (LIO) report and updated the population summary report to include the Prevention Process and Outcome Measures Monthly Monitoring (POM) form.

To accommodate the grouping of information in the POM monthly form, the Summary Data Observation may now contain subordinate observations.

In population summary reports, in-facility location and code are now recorded as a participant in the Summary Encounter. Previously, this information was recorded in the header.

A population summary report that does not report in-facility identifier and type now records them with nullFlavors.

In several observations, the values for `@classCode`, `@moodCode`, and `statusCode/@code` were made explicit, making the representation of these templates consistent with the approach elsewhere in this guide.

The guide now uses the Templates Database constraints format.

Resolutions from the September 2009 ballot have been incorporated.

In future releases, an appendix referenced by this summary section will document detailed changes to constraints.

DSTU Release 4.1

Release 4.1 made minor updates to the Urinary Tract Infection (UTI) Report. The Urinary Catheter Observation now conditionally requires a (new) History of Object Presence Observation.

DSTU Release 5

Release 5 included a new report type, the Hemovigilance Incident (HI) Report, and extended the population summary report to support reporting hemovigilance incident summary data and blood-product usage data.

In the Population Summary Report template, a code in the header of the report now identifies the data content of the report.

In the Population Summary Report template, the representation of terms was converted from a value set to tables of single-value bindings.

The NHSN Healthcare Service Location value set changed from **STATIC** to **DYNAMIC**.

Release 5 also implemented NHSN changes to data requirements in the Central-line Insertion Practices (CLIP), Procedure, and LIO Reports.

DSTU Release 6

Release 6 included a new report type, Hemovigilance Adverse Reaction (HAR) Report, extended the population summary report to support reporting antimicrobial usage and resistance data (AUP) and C.difficile days in a POM report, and made minor changes within existing templates.

Finally, beginning with this release, hai_voc.xls is a new, reader-friendly resource for value-set information, substituting for the Word tables previously provided at the end of this implementation guide.

DSTU Release 7

Release 7 included a new report type, Evidence of Infection (Dialysis) Report (EOID), and updates to the tables of values for the Population Summary Reports template to support summary reporting for maintenance (also known as chronic) hemodialysis patients.

The guide no longer includes the MDRO/CDAD Report or the clinical statements uniquely associated with it. The MDRO Observation, used in the Findings Section, is updated to also report C. difficile infections. The guide no longer includes the Generic Infection Report.

Several value set bindings changed from **STATIC** to **DYNAMIC**.

DSTU Release 8

There were no new reports in this release.

A small number of templates were updated to reflect changes in data collected by the CDC.

The population summary reports were recast for ease of use. This did not change the modeling.

The header templates were refactored for ease of use. This did not change the modeling.

Constraints were edited to record only one element per constraint. This did not change the modeling.

DSTU Release 9

This release added no new reports.

Four numerator reports and four denominator reports that have not yet been implemented or are undergoing substantial change were removed from this release of the HAI IG. These reports may be reintroduced in future.

The numerator reports that were removed are:

- HAI Hemovigilance Adverse Reaction Report (HAR)
- HAI Hemovigilance Incident Report
- HIA Immunization Numerator Report
- HAI Pneumonia Infection Numerator Report (PNEU)

The denominator reports that were removed are:

- Hemovigilance Incidents (HI) Summary Report
- Blood Products Usage (BPU) Summary Report
- Immunization Summary Reports

The top-level `templateId` was updated. Several templates were new and several had minor revisions.

Normative Release 1

In addition to the report and template changes described below, the format of the guide itself was restructured to align with the current HL7 state-of-the-art guides. The restructuring simplifies navigation and produces a guide that is more familiar to implementers, reviewers, analysts, and any other consumers.

Two new report(s) were added and none were removed:

- Antimicrobial Resistance Option (ARO) Summary Report
- HAI AUR Antimicrobial Resistance Option (ARO) Report

Although they are not new to the IG, the following reports now have separate templates and `templateIds` rather than being described purely in narrative:

- Antimicrobial Use (AUP) Summary Report
- Intensive Care Unit (ICU) Summary Report
- Neonatal Intensive Care Unit (NICU) Summary Report
- Prevention Process and Outcome Measures (POM) Summary Report
- Specialty Care Area (SCA) Summary Report
- Vascular Access Type Report (VAT) Summary Report

No templates were removed in this release.

Where possible, the HAI templates now conform to Consolidated CDA (C-CDA) templates, which is a requirement of Meaningful Use 2. C-CDA templates represent a significant effort by industry stakeholders; they are the best available standard to require for certification and to meet policy objectives for interoperability.

Summary reports were moved from purely narrative descriptions into report-specific templates.

Most narrative constraints were converted to computable constraints.

Normative Release 2, 1st DSTU

No reports were added or removed. Four new entry-level templates were added

- Infection Present at the Time of Surgery Observation
- SSI Detected Using Toolkit Observation
- Revision Associated with Prior Infection Observation
- Loss of Vascular Access Observation

No new value sets were added, but some codes were added or removed:

- A code for “Number of APRV days” (1834-1) from codeSystem cdcNHSN (2.16.840.1.113883.6.277), was added to the Intensive Care Unit (ICU) Summary Report and the Neonatal Intensive Care Unit (NICU) Summary Report.
- A code “Number of central line days” (1833-3) from codeSystem cdcNHSN (2.16.840.1.113883.6.277) was deprecated from the Neonatal Intensive Care Unit (NICU) Summary Data table.
- A code “Number of central line days including umbilical catheter” (1854-9) from codeSystem cdcNHSN (2.16.840.1.113883.6.277) was added to the Neonatal Intensive Care Unit (NICU) Summary Data table.
- A code for “Urinary Tract Infection” (68566005) from codeSystem SNOMED CT (2.16.840.1.113883.6.96), was added to the Infection Type Value Set for the Criterion of Diagnosis Observation.

Normative Release 2, Update to 1st DSTU

There were no normative changes in this update.

The guide was divided into two volumes. Volume 1 contains an overview of Clinical Document Architecture (CDA) markup standards, design, and use. Volume 2 contains the library of CDA templates for electronic submission of HAI Reports to NHSN-CDC.

Three codes were added to and two codes were deprecated from the Criterion of Diagnosis value set.

Normative Release 2, 2nd DSTU

Two new reports, each containing new templates, were added:

- HAI Outpatient Procedure Component (OPC) Event Report, 2.16.840.1.113883.10.20.5.47
 - Findings Section in an OPC Report, 2.16.840.1.113883.10.20.5.5.55
 - Other Event Details Section, 2.16.840.1.113883.10.20.5.5.54
 - Prophylactic IV Antibiotic Timing Observation, 2.16.840.1.113883.10.20.5.6.209
 - Same Day Outcome Measures Organizer, 2.16.840.1.113883.10.20.5.6.212
 - Same Day Outcome Measure Observation, 2.16.840.1.113883.10.20.5.6.208
 - Surgical Site Infection Details Section in an OPC Report, 2.16.840.1.113883.10.20.5.5.53
 - Infection First Reported Source Observation, 2.16.840.1.113883.10.20.5.6.207
 - Procedure Details in an OPC Report, 2.16.840.1.113883.10.20.5.6.211
 - Surgical Site Infection Observation, 2.16.840.1.113883.10.20.5.6.210
- HAI Outpatient Procedure Component (OPC) Summary Report, 2.16.840.1.113883.10.20.5.48
 - Summary Data Section (OPC), 2.16.840.1.113883.10.20.5.5.56
 - Summary Encounter (OPC), 2.16.840.1.113883.10.20.5.6.213
 - Summary Data Observation (OPC), 2.16.840.1.113883.10.20.5.6.214
 - Procedure Category, 2.16.840.1.113883.10.20.5.6.215

Normative Release 2, Update to 2nd DSTU

No reports were added or removed. Five reports were revised:

- HAI AUR Antimicrobial Resistance Option (ARO) Report
- HAI Central-Line Insertion Practice Numerator Report
- HAI Evidence of Infection (Dialysis) Report
- HAI Laboratory-Identified Organism (LIO) Report
- Prevention Process and Outcome Measures (POM) Summary Report

Eleven new templates were added:

- Antimicrobial Coated Catheter Used Observation
- Bacterial Isolate Tested for Carbapenemase Observation
- Blood Collection Location
- Carbapenemase Test Observation
- Carbapenemase Test Organizer
- Carbapenemase Type Identified Observation
- Contraindication Type Observation
- Last Physical Overnight Location
- Other Facility Discharge Encounter
- Positive Test for Carbapenemase Observation
- Primary C. Difficile Testing Method This Quarter

Three new value sets were added:

- NHSNArDrugSuscTestsCode (2.16.840.1.114222.4.11.7230)
- NullValues_UNK_OTH (2.16.840.1.113883.10.20.5.9.1)
- NullValues_UNK_NA (2.16.840.1.113883.10.20.5.9.2)
- NHSNLastLocationEncounterTypeCode (2.16.840.1.113883.10.20.5.9.2)

One new code was added for use in the Summary Encounter in the Intensive Care Unit (ICU) Summary Report and the Specialty Care Area (SCA) Summary Report:

- New Episodes of Mechanical Ventilation

APPENDIX C — DOCUMENT AND SECTION CODES (NON-NORMATIVE)

The templates in Volume 2 use LOINC codes to identify the document type and section types. The document and section templates specify which code to use. This appendix is provided as a convenient summary for the implementer.

Table 2: Document and Section Codes

codeSystem	Name	code	Meaning
2.16.840.1.113883.6.1	LOINC	51897-7	Healthcare Associated Infection Report
		51898-5	Risk Factors Section
		51899-3	Details Section
		18769-0	Findings Section
		51900-9	Summary Data Section
		46240-8	History of Encounters
		99999-9	Infection Details Section

APPENDIX D — CONSOLIDATED CDA (C-CDA) TEMPLATES REFERENCED IN THIS GUIDE

A few NHSN templates conform to templates in the C-CDA guide: *HL7 Implementation Guide for CDA Release 2.0, Consolidated CDA Templates, (US Realm)*⁸.

Table 3: C-CDA Template OIDs

Template Title	Template OID
Deceased Observation	2.16.840.1.113883.10.20.22.4.79
Encounter Activities	2.16.840.1.113883.10.20.22.4.49
Indication	2.16.840.1.113883.10.20.22.4.19
Medication Activity	2.16.840.1.113883.10.20.22.4.16
Problem Observation	2.16.840.1.113883.10.20.22.4.4
Procedure Activity Act	2.16.840.1.113883.10.20.22.4.12
Procedure Activity Observation	2.16.840.1.113883.10.20.22.4.13
Procedure Activity Procedure	2.16.840.1.113883.10.20.22.4.14
Result Observation	2.16.840.1.113883.10.20.22.4.2
Result Organizer	2.16.840.1.113883.10.20.22.4.1
Vital Sign Observation	2.16.840.1.113883.10.20.22.4.27

⁸ *HL7 Implementation Guide for CDA Release 2.0, Consolidated CDA Templates, (US Realm)*.
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258

APPENDIX E — EXAMPLE INSTANCE IDENTIFIERS (NON-NORMATIVE)

As discussed in [Background](#) and [Example Instance Identifiers](#), much of the development of this guide was driven by a pilot project in July 2007. The pilot project assigned example OIDs to a fictional facility and vendor to illustrate the numbering schemes for which facilities and vendors are responsible. In practice, these identifiers will be assigned by facilities and software applications within those facilities participating in the NHSN.

All example OIDs in this IG and in the accompanying sample files begin with 2.16.840.1.113883.3.117.1.1.5. and are documented below for reference.

Each OID-owner such as a facility or vendor controls the structure of the OIDs it assigns under its root, and is responsible for ensuring that each identifier it issues is globally unique. A vendor must, for example, ensure that there is no duplication amongst the `setIds` issued by its various software installations. The example instance identifiers in this guide use the following plan for assigning instance identifiers:

Table 4: Structure of Example OIDs

Usage	OID
a healthcare facility OID	2.16.840.1.113883.3.117.1.1.5.1.1
its patient IDs	2.16.840.1.113883.3.117.1.1.5.1.1.1
its personnel IDs	2.16.840.1.113883.3.117.1.1.5.1.1.2
a vendor OID	2.16.840.1.113883.3.117.1.1.5.2.1
its first software installation	2.16.840.1.113883.3.117.1.1.5.2.1.1
its <code>setIds</code>	2.16.840.1.113883.3.117.1.1.5.2.1.1.1
its document IDs	2.16.840.1.113883.3.117.1.1.5.2.1.1.2
its encounter IDs	2.16.840.1.113883.3.117.1.1.5.2.1.1.3
its procedure IDs	2.16.840.1.113883.3.117.1.1.5.2.1.1.4
its event / incident IDs	2.16.840.1.113883.3.117.1.1.5.2.1.1.5
etc.	

Conformant to that structure, the following example instance identifiers may be used in this guide and in the sample files.

Table 5: Values of Example Instance Identifiers Used in This Guide

Facility IDs and Facility-assigned OIDs		
Usage	OID	extension
a location in a facility	2.16.840.1.113883.3.117.1.1.5.1.1	9W
a patient ID	2.16.840.1.113883.3.117.1.1.5.1.1.1	123456
facility personnel:		
author ID	2.16.840.1.113883.3.117.1.1.5.1.1.2	anAuthorID
legal authenticator ID	2.16.840.1.113883.3.117.1.1.5.1.1.2	aLegalAuthenticatorID
performer (nurse)	2.16.840.1.113883.3.117.1.1.5.1.1.2	24242424
Vendor-software-assigned OIDs		
Usage	OID	extension
software ID	2.16.840.1.113883.3.117.1.1.5.2.1.1	aSoftwareID
setId	2.16.840.1.113883.3.117.1.1.5.2.1.1.1	31
document ID	2.16.840.1.113883.3.117.1.1.5.2.1.1.2	20202201 93
encounter ID	2.16.840.1.113883.3.117.1.1.5.2.1.1.3	31
procedure ID	2.16.840.1.113883.3.117.1.1.5.2.1.1.4	92
event / incident ID	2.16.840.1.113883.3.117.1.1.5.2.1.1.5	21987654321 11987654321

APPENDIX F — VOCABULARY HEURISTICS FOR CODES AND VALUE SETS (NON-NORMATIVE)

The CDC has identified questions and allowable responses for HAI form fields. In many cases these questions and responses have been mapped to local CDC/NHSN codes, and it is the CDC's intention to identify corresponding standard codes. Within the CDC, different groups have done vocabulary mapping work (e.g., with HL7 V2 messages), often with different results, and efforts are underway to not only reconcile internal CDC vocabulary usage, but also reconcile CDC vocabulary usage with the Healthcare Information Standards Technology Panel (HITSP) recommendations.

Vocabularies recommended in this guide are primarily standard vocabularies recommended for use in particular domains. In many cases these vocabularies are further constrained into value sets for use within this guide or were previously constrained into value sets by the CDC.

The incremental strategy for vocabulary reconciliation for codes, code systems, and value sets in this document is as follows.

Code and codeSystem Selection

- Where there is conflicting precedent within the CDC, CDC will advise on the preferred CDC code system.
- Where there is a preferred code system within the CDC that is consistent with HITSP recommendations, existing CDC-cited code systems are used.
- Where there is a preferred code system within the CDC that is not consistent with HITSP recommendations, divergence from HITSP is flagged, and reconciliation between CDC and HITSP is planned (but outside the scope of this document).
- Where there is no established precedent within the CDC, available HITSP recommendations will be followed.
- Where there is no established precedent within the CDC and no HITSP recommendations, precedent in prior CDA Implementation Guides will be followed.
- Where there is no established precedent within the CDC, no HITSP recommendations, and no prior CDA IG precedent:
 - An attempt will be made to map CDC/NHSN local codes to standard codes (e.g., SNOMED, HL7 V3 vocabularies).
 - Where there is no corresponding standard code, the CDC/NHSN local code will be cited. (Submitting local CDC/NHSN codes to SNOMED is outside the scope of this document.)
- If post-coordination of SNOMED terms and codes would be required to capture the CDC/NHSN concept, the local CDC/NHSN code will be used.

Value Set Assignment and Maintenance

- Where there is conflicting precedent within the CDC, CDC will advise on the preferred CDC value set.
- Where there is a preferred CDC value set that is consistent with HITSP recommendations, existing CDC value sets are used.
- Where there is a preferred CDC value set that is not consistent with HITSP recommendations, divergence from HITSP is flagged, and reconciliation between CDC and HITSP is planned (but outside the scope of this document).
- Where there is no established precedent within the CDC, available HITSP recommendations will be followed.
- Where there is no established precedent within the CDC and no HITSP recommendations, then precedent in prior CDA Implementation Guides will be followed.
- Where there is no established precedent within the CDC, no HITSP recommendations, and no prior CDA IG precedent, new value sets will be created, each having a value set OID assigned by the CDC.