



HL7 CDA® R2 Implementation Guide:
NHSN Healthcare Associated Infection (HAI) Reports
Release 4, STU 2 –
US Realm
May 2022

HL7 STU Ballot
Volume 1 — Introductory Material

Sponsored by:
Structured Documents Work Group
National Healthcare Safety Network (NHSN)

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Structure of This Guide

Two volumes comprise the complete *HL7 CDA® R2 Implementation Guide: 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.

The HAI implementation guide also includes a third volume and a fourth volume that are stand-alone subsets for implementers. The third volume contains Single-Person (Numerator) and Summary (Denominator) Reports dealing with Antimicrobial Resistance (AR) and Antimicrobial Use (AU) data. The fourth volume contains the Summary (Denominator) Report dealing with Hemovigilance (HV) data. Both Volumes 3 and 4 contain most of the introductory material from Volume 1 as well as exact copies of the relevant (AU, AR, and HV) templates contained in Volume 2.

Additional information in Volume 1 of 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, 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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Acknowledgments

This implementation guide was produced and developed by Lantana Consulting Group in conjunction with the Division of Healthcare Quality Promotion in the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) at the Centers for Disease Control and Prevention (CDC). Its development and ultimate deployment is a result of the dedication of the team—led by Daniel A. Pollock, M.D., Surveillance Branch Chief, Division of Healthcare Quality Promotion, NCEZID, CDC—and their support of the development of interoperable data standards for the CDC's National Healthcare Safety Network (NHSN).

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.

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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 Laboratory-identified organism (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.

Release	Date	Notes
	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 implementation guide (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 (C-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

Release	Date	Notes
	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
	May 2015	First Normative ballot Created Volume 3, a stand-alone subset containing the Volume 1 introductory material and complete copies of all AU and AR reports. Updated three reports to update the template id representing the IG in which the template is published and from which the template will be implemented.
Normative Release 3	September 2015	(First ballot; DSTU 1) Added new Hemovigilance (HV) report Added templates to Dialysis Created Volume 4, a stand-alone subset containing the Volume 1 introductory material and complete copies of all HV report templates. Added new HTML format IG
	December 2015	Publication of DSTU 1
	September 2016	(Update to first ballot; DSTU 1.1) Added new template to Dialysis Added new template to HV Replaced pathogen codes Updated, added and removed codes
	October 2016	Publication of DSTU 1.1
	May 2017	(Second ballot; STU 2) Added new Ventilator Associated Event (VAE) Report Added new Healthcare Personnel Influenza Vaccination (HP-FLU) Summary report Added new Comment Section (for use in multiple reports) Updated Bloodstream Infection Report (BSI) with 3 new templates
	July 2017	Publication of STU 2
	May 2018	(Third ballot; STU 3) Added new Late Onset Sepsis/Meningitis (LOS) Event Report Added a Report No Events section to several report types Removed HAI Outpatient Procedure Component (OPC) Event Report Updated Bloodstream Infection Report (BSI) with 4 new templates Replaced pathogen codes Updated, added and removed codes Added a FHIR component for the new report (balloted separately)
	October 2018	Publication of STU 3.3

Release	Date	Notes
	May 2019	(Fourth ballot; STU 3) Added Outpatient Procedure Component Denominator for Same Day Outcome Measures Report Added Outpatient Procedure Component Denominator for Procedure Report Added Late Onset Sepsis/Meningitis Denominator (LOS/Men Denom) Report Added Outpatient Procedure Component Same Day Outcome Measures Event Report Added Outpatient Procedure Surgical Site Infection (SSI) Event Report Updated Antimicrobial Resistance Option (ARO) Summary Report Updated HAI Evidence of Infection (Dialysis) Report Updated Late Onset Sepsis/Meningitis Event (LOS) Report Updated, added and removed codes Added FHIR components for the new reports (balloted separately)
	December 2019	Publication of STU 3.4
	May 2020	(First ballot; Normative R3) Added Patient Admitted This Encounter Observation
	June 2020	Publication of Normative Release 3
Normative Release 4	January 2021	(First ballot: STU 1) Added COVID-19 Section Added NHSN COVID-19 Condition Observation Updated HAI Bloodstream Infection Report (BSI) Updated HAI Surgical Site Infection Report (SSI) Updated HAI Urinary Tract Infection Numerator Updated Ventilator Associated Event (VAE) Report Added value set Codes for Antimicrobial Resistance Option (ARO) Summary Data Updated value set Codes for Antimicrobial Resistance Option (ARO) Summary Data Moved most of the terminology from hai_voc_NRF.xml to Value Set Authority Center (VSAC): U.S. National Library of Medicine ¹
	June 2021	Publication of STU 4.1

¹ NIH, VSAC. <https://vsac.nlm.nih.gov/>

Release	Date	Notes
	May 2022	(Second ballot: STU 2) Added NHSN Social History Section Added Birth Sex Observation (C-CDA Companion Guide) Added Gender Identity Observation (C-CDA Companion Guide) Added Inpatient Rehabilitation (IRF) Unit in Facility Added Inpatient Psychiatric (IPF) Unit in Facility Removed Dialyzer Reused Observation Updated HAI Single-Person Report Generic Constraints (V2) Updated HAI AUR Antimicrobial Resistance Option (ARO) Report (V6) Updated HAI Bloodstream Infection Report (BSI) (V5) Updated HAI Central-Line Insertion Practice Numerator Report (V3) Updated HAI Evidence of Infection (Dialysis) Report (V7) Updated HAI Laboratory-Identified Organism (LIO) Report (V3) Updated HAI Procedure Denominator Report (V3) Updated HAI Surgical Site Infection Report (SSI) (V4) Updated HAI Urinary Tract Infection Numerator Report (UTI) (V3) Updated Late Onset Sepsis/Meningitis Denominator (LOS/Men Denom) Report (V2) Updated Late Onset Sepsis/Meningitis Event (LOS) Report (V3) Updated Outpatient Procedure Component Denominator for Procedure Report (V2) Updated Outpatient Procedure Component Same Day Outcome Measures Event Report (V2) Updated Outpatient Procedure Surgical Site Infection (SSI) Event Report (V2) Updated Ventilator Associated Event (VAE) Report (V3) Updated Prevention Process and Outcome Measures (POM) Summary Report (V4) Updated Risk Factors Section in an Evidence of Infection (Dialysis) Report (V3) Updated Summary Data Section (POM) (V3)

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1 INTRODUCTION

1.1 Purpose

The purpose of this implementation guide (IG) is to specify standards 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). This multi-volume 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 HAI reports to the NHSN (Volume 2). Volumes 1 and 2 comprise the normative content of this guide.

Two stand-alone subsets (Volume 3 and Volume 4) provide guidance on topic-specific implementations: Antimicrobial Resistance (AR) and Antimicrobial Use (AU) data (Volume 3), and Hemovigilance (HV) data (Volume 4). Volumes 3 and 4 are informative only.

As reports are modified and new report types are defined, CDC and Health Level Seven (HL7) will develop and publish additional constraints. These will be included in the normative IG (Volumes 1 and 2) and may be the topics of future stand-alone subsets.

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>. Provisions of the Public Health Service Act protect all data reported to NHSN from discovery through the Freedom of Information Act (FOIA).

1.2 Relationship to Another Standard

Starting in the May 2018 ballot cycle, HL7 developed a Fast Healthcare Interoperability Resources (FHIR) IG in parallel with the CDA IG. The FHIR IG includes all new forms as they are added to the HAI work, but does not yet include all forms added to the CDA IG before May 2018. In this CDA IG release, as there are no new forms and the changes to this CDA IG are to forms that are not yet part of the FHIR IG, there will not be a corresponding new FHIR IG release.

We anticipate several STU releases on the path to a Normative Release 1 of the *HL7 Implementation Guide for FHIR: Healthcare Associated Infection Reports*. The FHIR and CDA IGs will align at that point and a change to one standard will require the same change in the other.

1.3 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.

1.4 Organization of the Guide (Volumes 1 and 2)

This *HL7 CDA® R2 Implementation Guide: NHSN Healthcare Associated Infection (HAI) Reports* is organized into four volumes. The first two volumes contain the entire guide:

- Volume 1 contains primarily narrative text describing the HAI guide.
- Volume 2 contains normative CDA template definitions.
- Volume 3 provides guidance on Single-Person (Numerator) and Summary (Denominator) Reports dealing with Antimicrobial Resistance (AR) and Antimicrobial Use (AU) data. This volume contains an informative subset of the templates that are contained in Volume 2 and which are cited in Meaningful Use federal regulation. The purpose of the volume is as a convenience for implementers who are implementing that subset.
- Volume 4 provides guidance for the Hemovigilance (HV) Summary Report (Denominator). The templates provided in this guide are a subset of those in Volume 2. The purpose of the volume is as a convenience for implementers who are implementing that subset.

The sections below describe the organization of the first two volumes; similar sections in Volumes 3 and 4 describe the structure of those documents.

1.4.1 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 and HAI Reporting** contains project background and selected background material on the CDA Release 2 (CDA R2) base standard to aid the reader in conceptualizing the “templated CDA” approach to IG development.
- **Chapter 3—Design Considerations** describes 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** 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.
- **Chapter 5—References** lists documents and sources cited by this guide.

- **Appendices** include 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.

1.4.2 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** 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 they 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 IG.
- **Chapter 2—Section-Level Templates** 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** defines 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—Template IDs in This Guide** 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** lists all value set names and object identifiers (OIDs) used by HAI templates. Links are provided to external value set sources if appropriate.
- **Chapter 6—Code Systems in This Guide** 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** details all changes made in templates for this release. (A summary of changes in earlier releases is provided in Volume 1.)

1.4.3 Example Instance Identifiers

Much of the initial development of this guide was driven by a pilot project in July 2007. The pilot project used 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, whereas HL7 example identifiers begin with 2.16.840.1.113883.19.5. The pilot instance identifiers are used throughout this guide and are documented in the appendix on [Example Instance Identifiers \(Non-normative\)](#).

1.5 Contents of the Package

The following files comprise this package.

Table 1: Contents of the Package – Normative & Informative

Filename	Description	Normative	Informative
CDAR2_IG_HAIRPT_R4_D2_V1_Introductory_Material.docx	Vol 1: Introductory material for this implementation guide	Chapter 1 Chapter 4 Appendix A Appendix B	Chapter 2 Chapter 3 Chapter 5 Appendix C Appendix D Appendix E Appendix F
CDAR2_IG_HAIRPT_R4_D2_V2_Templates_and_Supporting.docx	Vol 2: Normative CDA templates for this implementation guide	Templates Appendices	Examples
CDAR2_IG_HAIRPT_R4_D2_V3_AU_AR_Appendix.docx	Vol 3: Introductory material and CDA templates for antimicrobial-related templates in this guide	Templates Appendices	Examples
CDAR2_IG_HAIRPT_R4_D2_V4_HV_Appendix.docx	Vol 4: Introductory material and CDA templates for hemovigilance-related templates in this guide	Templates Appendices	Examples

Table 2: GitHub Contents – Informative Only

Filename	Description
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
opc_proc-denom.xml	Outpatient procedure denominator
opc_sdom-num.xml	Outpatient procedure component same day outcome measures event
opc_ssi-num.xml	Outpatient procedure component surgical site infection (SSI) report
los-denom_location1.xml	Summary data - denominator for late onset sepsis/meningitis - first location of patient
los-denom_location2.xml	Summary data - denominator for late onset sepsis/meningitis - second location of patient
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
vae-num.xml	Ventilator Associated Event (VAE) numerator
los-num.xml	Late Onset Sepsis/Meningitis Event (LOS) Report numerator
pop_sum-denom.xml	Summary data – denominator (example for ICU/Other)
pop_sum-denom-NICU.xml	Summary data – denominator (example for Neonatal Intensive Care Unit [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-HV.xml	Summary data – denominator for hemovigilance reporting (HV)
pop-sum-denom-HP-FLU.xml	Summary data – denominator for influenza vaccination reporting (HP-FLU)
pop_sum-denom-OPC-SDOM.xml	Outpatient Procedure Component Denominator for Same Day Outcome Measures Report
Support files	
XML and Related files (Schematron, sample, html, stylesheet) are housed on the HL7 GitHub site: https://github.com/HL7/CDA-hai/tree/master/CDAR2_IG_HAIRPT_R4_D2_XML_and_Support_Files	
The latest CDA Schema is located on the HL7 GitHub site: https://github.com/HL7/cda-core-2.0/tree/master/schema/extensions	

2 CDA AND HAI REPORTING

2.1 CDA R2 Background

This IG uses the *HL7 Clinical Document Architecture, Release 2.0 (CDA R2)* as its base standard.² 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]. Clinical documents, according to CDA, have the following characteristics:

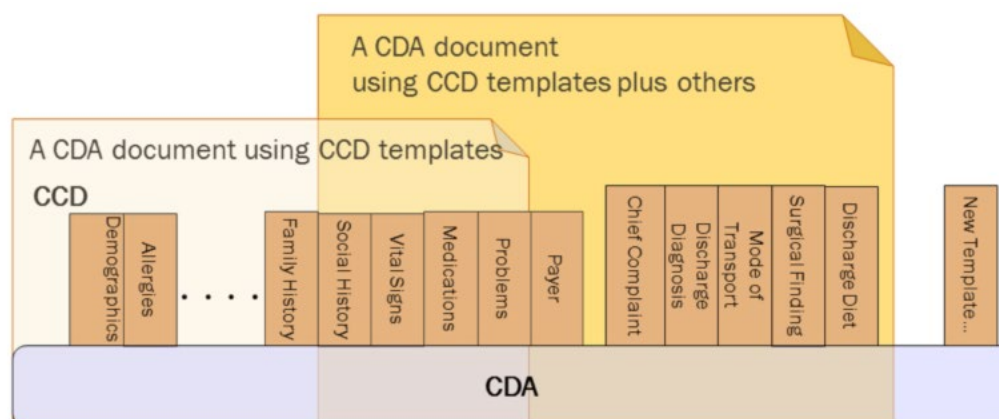
- Persistence
- Stewardship
- Potential for authentication
- Context
- Wholeness
- Human readability

CDA defines a header 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.

2.2 Templated CDA

CDA R2 can be constrained by mechanisms defined in the “Refinement and Localization”³ 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



² HL7 CDA R2. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

³ HL7 V3: Refinement, Constraint and Localization.

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

Many different kinds of templates may be created. Among them, the most common are:

- **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 IG (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 to assert conformance to a given template. On the receiving side, the recipient can not only test the instance for conformance against the CDA XML (Extensible Markup Language) schema but can also test the instance for conformance against asserted templates.

Template identifiers are critical to the validation methods chosen for submissions to the NHSN. NHSN may reject 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 type.

2.3 HAI Reporting Background

The CDA specification for HAI reporting was first released in 2008. It provided guidance on four reports: Blood Stream Infection (BSI) Report, Surgical Site Infection (SSI) Report, Procedure Report, and Intensive Care Unit (ICU)/Other Locations (not Neonatal Intensive Care Unit [NICU] or Specialty Care Area [SCA]) Report. Since 2008, this IG has been updated and expanded every year, going through the HL7 ballot comment and reconciliation process each time.

Subsequent releases added new report types and extended the population summary report to encompass additional data sets, including for the NHSN Antimicrobial Use and Resistance (AUR) Module, which contains two options for facilities, one focused on Antimicrobial Use (AU) reporting and the second focused on Antimicrobial Resistance (AR) reporting. Facilities participate in one or both options. For an overview of the changes in each release, see [Revision History](#) table and the Appendix [High-Level Changes from Previous Releases](#).

2.4 Current Release

This IG is the second STU release of the fourth normative release of the HAI reporting templates. It updates seventeen reports, updates one section, adds five templates, and removes one template.

This guide templates twenty-four HAI report types.

HAI Population Summary Reports:

1. Antimicrobial Resistance Option (ARO) Summary Report (V3)
2. Antimicrobial Use (AUP) Summary Report (V2)
3. Healthcare Personnel Influenza Vaccination (HP-FLU) Summary Report
4. Hemovigilance (HV) Summary Report (V2)
5. Intensive Care Unit (ICU) Summary Report (V3)
6. Neonatal Intensive Care Unit (NICU) Summary Report (V3)
7. Outpatient Procedure Component Denominator for Same Day Outcome Measures Report
8. Prevention Process and Outcome Measures (POM) Summary Report (V3)
9. Specialty Care Area (SCA) Summary Report (V3)
10. Vascular Access Type Report (VAT) Summary Report (V3)

HAI Single-Person Report Generic Constraints

11. Outpatient Procedure Component Denominator for Procedure Report
12. HAI AUR Antimicrobial Resistance Option (ARO) Report (V5)
13. HAI Bloodstream Infection Report (BSI) (V4)
14. HAI Central-Line Insertion Practice Numerator Report (V2)
15. HAI Evidence of Infection (Dialysis) Report (V6)
16. HAI Laboratory-Identified Organism (LIO) Report (V2)
17. HAI Procedure Denominator Report (V2)
18. HAI Surgical Site Infection Report (SSI) (V3)
19. HAI Urinary Tract Infection Numerator Report (UTI) (V2)
20. Late Onset Sepsis/Meningitis Denominator (LOS/Men Denom) Report
21. Late Onset Sepsis/Meningitis Event (LOS) Report (V2)
22. Outpatient Procedure Component Same Day Outcome Measures Event Report
23. Outpatient Procedure Surgical Site Infection (SSI) Event Report
24. Ventilator Associated Event (VAE) Report (V2)

Changes made in this release are summarized in the Appendix [High-Level Changes from Previous Releases](#). When new versions of templates appear for the first time in the IG, Volumes 2, 3, and 4 of this guide contain detailed sections in “Changes from Previous Version”.

2.5 Future Work

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

2.6 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. NHSN CDA related information may be found at <https://www.cdc.gov/nhsn/cdaportal/index.html>.

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. Volumes 3 and 4 contain both heuristics and subsets of the testable constraints.

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 measurable, 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 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 R2 normative standard.

Unless a `nullFlavor` is explicitly stated in a constraint in the IG, `nullFlavors` are not allowed.

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).

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 IG, 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 Reference Information Model (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*.

3.4 Summary Document ServiceEvent Codes

For all the summary reports, the documentationOf/serviceEvent/code element records the type of summary data reported. This corresponds to the NHSN form type. This pattern is similar to that used in C-CDA (all releases) (e.g., Operative Note).

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 (and Volumes 3 and 4) 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 Volumes 2, 3, and 4 of this IG 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 Volumes 2, 3, and 4 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 Volumes 2, 3, and 4 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 identifiers (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 IG reuses templates from the previous version. During the ballot phase or update phase, templates carry the designation “Published as part of <name of IG>” to indicate the template is unchanged from the previous version or “Draft as part of <name of IG>” to indicate a new or revised template.

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 IG (in the case of older templates, the `@extension` attribute will not be present). During a new ballot or update phase, “Published as part of <name of IG>” is appended to the main heading for the template to indicate that the template cannot be commented on in the ballot or update.

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 as part of <name of IG>” 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; this “Draft as part of <name of IG>” designation is updated to “Published as part of <name of IG>” in final publication versions.

A revised version of a template is explicitly linked to the prior version. When a new version appears for the first time in an IG, a detailed change log is automatically generated. All such changes for a given IG are shown in Volume 2 (and Volumes 3 and 4), 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

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).

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 $m \geq 1$ and $n \geq m$ 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 IG 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 2010*⁵ sections on Abstract Data Types and XML Data Types R1.

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.

Figure 19: 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: https://vsac.nlm.nih.gov			
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)
...			

⁵ HL7 Version 3 Interoperability Standards. [http://www.hl7.org/memonly/downloads/v3edition.cfm - V32010](http://www.hl7.org/memonly/downloads/v3edition.cfm-V32010)

4.2.8 Data Types

All data types used in a CDA document are described in the CDA R2 normative standard. 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 facility 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) notation⁶ in conformance statements and elsewhere to identify the XML elements and attributes 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.

⁶ W3C, *XML Path Language*. <http://www.w3.org/TR/xpath/>

Figure 20: 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 21: XPath Expression Example

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

4.3.2 XML Examples and Sample Documents

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 22: 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 and provides a non-normative set of Schematron schemas based on a 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_SDTC.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 Consulting Group’s CDA Validator.⁷ The CDA Validator is an online application that

⁷ Lantana Consulting Group, CDA Validator. <https://www.lantanagroup.com/validator/>

validates a CDA document's conformance to several standards and IGs; 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

- CDC, NHSN website. <http://www.cdc.gov/nhsn/>
- *HL7 Clinical Document Architecture, Release 2 (CDA R2), Normative Edition*. (May 2005). http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
- *HL7 Implementation Guide for CDA Release 2.0, Consolidated CDA Templates, R1.1 (US Realm)*. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258
- *HL7 Version 3 Interoperability Standards*, Normative Edition 2010. <http://www.hl7.org/memonly/downloads/v3edition.cfm - V32010>
- *HL7 Version 3 Publishing Facilitator's Guide*, Release 1. (2005). <http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm> (Login required)
- *HL7 Version 3 Standard: Refinement, Constraint and Localization to Version 3 Messages, Release 2* (9/9/2015). <http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm> (Login required)
- Lantana Consulting Group, CDA Validator. <http://www.lantanagroup.com/validator>
- LOINC®: Logical Observation Identifiers Names and Codes, Regenstrief Institute. Available at: <http://loinc.org>
- NIH, U.S. National Library of Medicine, Value Set Authority Center (VSAC). Available at: <https://vsac.nlm.nih.gov/>
- SNOMED CT®: SNOMED Clinical Terms SNOMED International Organization. Available at: <https://www.snomed.org/>
- W3C, *XML Path Language (XPath)* . <http://www.w3.org/TR/xpath/>

APPENDIX A — ACRONYMS AND ABBREVIATIONS

ACoS	American College of Surgeons
AMB	ambulatory (outpatient)
APRV	Airway Pressure Release Ventilation
AR	Antimicrobial Resistance
ARO	Antimicrobial Resistance Option
ASA	American Society of Anesthesiologists
AU	Antimicrobial Use
AUP	Antimicrobial Use, Pharmacy Option
AUR	Antimicrobial Use and Resistance
BPU	Blood Products Usage
BSI	Bloodstream Infection
C-CDA	Consolidated CDA
CDA	Clinical Document Architecture
CDAD	<i>C. difficile</i> -associated disease
CDC	Centers for Disease Control and Prevention
CDI	<i>C. difficile</i> infection
CHG	Chlorhexidine gluconate
CLIP	central-line insertion practice
CPT	Current Procedural Terminology
CRE	Carbapenem-resistant Enterobacteriaceae
DSTU	Draft Standard for Trial Use
ECLS	extracorporeal life support
EHR	electronic health record
EOID	Evidence of Infection, Dialysis
FHIR	Fast Healthcare Interoperability Resources
FOIA	Freedom of Information Act
HAI	Healthcare Associated Infection
HAR	Hemovigilance Adverse Reaction
HI	Hemovigilance Incident Report
HITSP	Healthcare Information Technology Standards Panel
HL7	Health Level Seven
HP-FLU	Healthcare Personnel Influenza Vaccination
HSLOC	NHSN Healthcare Facility Patient Care Location
HV	Hemovigilance
ICP	infection control professional
ICU	intensive care unit
ID	identifier
IDM	Information Data Model
IG	implementation guide
IHTSDO	International Health Terminology Standard Development Organisation
ISBT	International Society for Blood Transfusion
IV	intravenous
LIO	Laboratory-identified organism
LOINC	Logical Observation Identifiers Names and Codes
LOS	Late Onset Sepsis
LTAC	Long-term Acute Care
LTCF	long-term care facility
MDRO	Multi-drug-resistant organism

NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NHSN	National Healthcare Safety Network
NICU	Neonatal Intensive Care Unit
NUCC	National Uniform Claim Committee
OID	object identifier
ONC	oncology
OPC	Outpatient Procedure Component
PHIN VADS	Public Health Information Network Vocabulary Access and Distribution System
PICC/IV	peripherally inserted central catheter/intravenous
PNEU	pneumonia
POM	Process and Outcome Measure
R1, R2, etc.	Release 1, Release 2, etc.
RIM	Reference Information Model
SCA	Specialty Care Area
SDS	Synthetic Data Set
SME	subject matter expert
SNOMED CT	Systematized Nomenclature of Medicine, Clinical Terms
SSI	Surgical Site Infection
UCUM	Unified Code for Units of Measure
URL	Uniform Resource Locator
URN	Universal Resource Name
UTI	Urinary Tract Infection
V1, V2, etc.	Version 1, Version 2, etc.
VAD	Ventricular Assist Device
VAE	Ventilator Associated Event
VAT	Vascular Access Type
VSAC	Value Set Authority Center
XML	Extensible Markup Language

APPENDIX B — HIGH-LEVEL CHANGES FROM PREVIOUS RELEASES

This appendix summarizes the main changes to the standard since DSTU 3 (March 2009). This IG is the first STU for Normative Release 4.

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 IG.

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
- HAI 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

Normative Release 2

Three reports were revised:

- HAI AUR Antimicrobial Resistance Option (ARO) Report (V3)
- Antimicrobial Resistance Option (ARO) Summary Report (V2)
- Antimicrobial Use (AUP) Summary Report (V2)

One new template was added; this template is a refactoring of the generic Summary Data Observation that pulls out the AU/AR data into a separate template:

- Summary Data Observation (AU/AR)

Where necessary, templates above the new templates in the hierarchy have been versioned.

A third stand-alone volume was added. It consolidates copies of the antimicrobial use and resistance templates for single-person and summary reports; those templates also remain in Volume 2.

Normative Release 3, 1st DSTU

One report was added:

- Hemovigilance (HV) Summary Report

Two reports were revised:

- HAI Evidence of Infection (Dialysis) Report (V4)
- Vascular Access Type Report (VAT) Summary Report (V2)

Ten new templates were added:

- Summary Data Section (HV)
- Blood Product Usage Summary Observation
- Dialyzer Reused Observation
- Facility Transfuses Pathogen Reduced/Inactivated Blood Products Observation
- ISBT Product Code Summary Observation
- No Adverse Reactions Reported This Month Observation
- No Incidents Reported This Month Observation
- Summary Data Observation (HV)

- Summary Encounter (HV)
- Type of Antimicrobial Start Observation

Four templates were revised:

- Infection Indicator Organizer (V3)
- IV Antibiotic Start Clinical Statement (V2)
- Details Section in an Evidence of Infection (Dialysis) Report (V4)
- Risk Factors Section in an Evidence of Infection (Dialysis) Report (V2)

Thirty new value sets were added:

- NHSN Start or Continuation
- NHSN Summary Blood Product Usage
- NHSN Whole Blood Total
- NHSN Red Blood Cells/Whole Blood Derived/Not Irradiated or Leukocyte Reduced
- NHSN Red Blood Cells/Whole Blood Derived/Irradiated
- NHSN Red Blood Cells/Whole Blood Derived/Leukocyte Reduced
- NHSN Red Blood Cells/Whole Blood Derived/Irradiated and Leukocyte Reduced
- NHSN Red Blood Cells/Apheresis/Not Irradiated or Leukocyte Reduced
- NHSN Red Blood Cells/Apheresis/Irradiated
- NHSN Red Blood Cells/Apheresis/Leukocyte Reduced
- NHSN Red Blood Cells/Apheresis/Irradiated or Leukocyte Reduced
- NHSN Platelets/Whole Blood Derived/Not Irradiated or Leukocyte Reduced
- NHSN Platelets/Whole Blood Derived/Irradiated
- NHSN Platelets/Whole Blood Derived/Leukocyte Reduced
- NHSN Platelets/Whole Blood Derived/Irradiated and Leukocyte Reduced
- NHSN Platelets/Apheresis/Not Irradiated or Leukocyte Reduced
- NHSN Platelets/Apheresis/Irradiated
- NHSN Platelets/Apheresis/Leukocyte Reduced
- NHSN Platelets/Apheresis/Irradiated or Leukocyte Reduced
- NHSN Plasma/Whole Blood Derived/Total
- NHSN Plasma/Apheresis/Total
- NHSN Cryoprecipitate
- NHSN Platelets/Whole Blood Derived/Psoralein-Treated
- NHSN Platelets/Whole Blood Derived/Riboflavin-Treated
- NHSN Platelets/Apheresis/Psoralein-Treated

- NHSN Platelets/Apheresis/Riboflavin-Treated
- NHSN Plasma/Whole Blood Derived/Psoralein-Treated
- NHSN Plasma/Whole Blood Derived/Riboflavin-Treated
- NHSN Plasma/Apheresis/Psoralein-Treated
- NHSN Plasma/Apheresis/Riboflavin-Treated

One new code was added to the value set Codes for Vascular Access Type (Dialysis) Summary Data.

A fourth stand-alone volume was added. It consolidates copies of the hemovigilance templates summary report; those templates also remain in Volume 2.

Normative Release 3, Update to 1st DSTU

Three reports were revised:

- HAI Evidence of Infection (Dialysis) Report (V5)
- Hemovigilance (HV) Summary Report (V2)
- HAI AUR Antimicrobial Resistance Option (ARO) Report (V4)

Two new templates were added:

- Blood Sample Collected for Culture Observation
- Pathogen Reduced Apheresis Platelet Usage Summary Observation

Fourteen templates were revised:

- Antimicrobial Susceptibility Result Observation (V3)
- Antimicrobial Susceptibility Result Organizer (V3)
- Antimicrobial Susceptibility Tests Organizer (V3)
- Blood Product Usage Summary Observation (V2)
- Facility Transfuses Blood Products Treated with Pathogen Reduction Technology Observation (V2)
- Infection Indicator Organizer (V4)
- ISBT Product Code Summary Observation (V2)
- Isolate Susceptibility Tests Organizer (V3)
- IV Antibiotic Start Clinical Statement (V3)
- Specimen Collection Procedure (ARO) (V3)
- Summary Encounter (HV) (V2)
- Details Section in an Evidence of Infection (Dialysis) Report (V5)
- Findings Section in an ARO Report (V3)
- Summary Data Section (HV) (V2)

Twelve new value sets were added:

- NHSN Red Blood Cells/Whole Blood Derived/S-303-Treated
- NHSN Red Blood Cells/Whole Blood Derived/Riboflavin-Treated
- NHSN Red Blood Cells/Apheresis/S-303-Treated
- NHSN Red Blood Cells/Apheresis/Riboflavin-Treated
- NHSN Cryoprecipitate/Psoralein-Treated
- NHSN Cryoprecipitate/Riboflavin-Treated
- NHSN Platelets/Apheresis/Psoralein-Treated and In Plasma
- NHSN Platelets/Apheresis/Psoralein-Treated and In Platelet Additive Solution
- NHSN Platelets/Apheresis/Riboflavin-Treated and In Plasma
- NHSN Platelets/Apheresis/Riboflavin-Treated and In Platelet Additive Solution
- NHSNPathogenReducedApheresisPlateletUsage
- NHSNDrugSusceptibilityTestMethod

Six value sets were revised:

- NHSNHealthcareServiceLocationCode
- NHSNPathogenCode
- NHSNSpecimenTypeCode
- NHSNDrugSusceptibilityTestsCode
- NHSNCdiffTestMethod
- NHSNCriterionOfDiagnosisCode

Normative Release 3, 2nd STU

Two reports were added:

- Ventilator Associated Event (VAE) Report
- Healthcare Personnel Influenza Vaccination (HP-FLU) Summary Report

One report was revised:

- HAI Bloodstream Infection Report (BSI) (V2)

Twelve new templates were added:

- Summary Data Section (HP-FLU)
- Infection Details Section in a VAE Report
- Risk Factors Section in a VAE Report
- NHSN Comment Section
- Summary Encounter (HP-FLU)
- Vaccination Type Observation
- NHSN Comment

- Hemodialysis Catheter Present
- Extracorporeal Life Support Present
- Ventricular Assist Device (VAD) Present
- Mechanical Ventilation Initiation Act
- APRV or Related at Time of VAE Observation

One template was revised:

- Infection Risk Factors Section in a BSI Report (V2)

Two new value sets were added:

- NHSNHealthcarePersonnelType
- NHSNInfluenzaVaccinationSetting

Four value sets were revised:

- NHSNCriterionOfDiagnosis
- NHSNInfectionConditionCode
- NHSNInfectionTypeCode
- NHSNPopulationSummaryReportTypeCode

Normative Release 3, 3rd STU

One new report:

- Late Onset Sepsis/Meningitis Event (LOS) Report

Two removed (i.e., retired) reports:

- HAI Outpatient Procedure Component (OPC) Event Report
- HAI Outpatient Procedure Component (OPC) Summary Report

Six revised reports:

- Intensive Care Unit (ICU) Summary Report (V3)
- Neonatal Intensive Care Unit (NICU) Summary Report (V3)
- Prevention Process and Outcome Measures (POM) Summary Report (V3)
- Specialty Care Area (SCA) Summary Report (V3)
- Vascular Access Type Report (VAT) Summary Report (V3)
- HAI Bloodstream Infection Report (BSI) (V3)

Eleven new templates:

- Infection Details in Late Onset Sepsis Report
- Report No Events Section
- Risk Factors Section (LOS/Men)
- Epidermolysis Bullosa Observation

- Gestational Age Observation
- Group B Streptococcus in First 6 Days of Life Observation
- Inborn/Outborn Observation
- Known or Suspected Munchausen's by Proxy Observation
- Observed or Suspected Patient Injection into Vascular Line Observation
- Pus Present in Site and Matching Organism in Blood and Specimen Observation
- Report No Events Observation

Two revised templates:

- Infection Risk Factors Section in a BSI Report (V3)
- Summary Data Section (NICU) (V2)

Twelve removed (i.e., retired) templates:

- Infection First Reported Source Observation
- Procedure Category
- Prophylactic IV Antibiotic Timing Observation
- Same Day Outcome Measure Observation
- Same Day Outcome Measures Organizer
- Summary Data Observation (OPC)
- Summary Encounter (OPC)
- Surgical Site Infection Observation
- Findings Section in an OPC Report
- Other Event Details Section
- Summary Data Section (OPC)
- Surgical Site Infection Details Section in an OPC Report

Eight new value sets:

- NHSNInbornOutbornObservationCode
- NHSNLOS/MENEvent
- NHSNReportNoEventsICU
- NHSNReportNoEventsNICU
- NHSNReportNoEventsSCA
- NHSNReportNoEventsMDRO
- NHSNReportNoEventsDialysis
- NHSNVascularSpecimenCollectionSite

Seven revised value sets:

- NHSNCriterionofDiagnosis

- NHSNHealthcareServiceLocations
- NHSNInfectionCondition
- NHSNInfectionType
- NHSNPathogenCode
- NHSNPopulationSummaryReportType
- NHSNVascularAccessType

Normative Release 3, 4th STU

Five new reports:

- Outpatient Procedure Component Denominator for Same Day Outcome Measures Report
- Outpatient Procedure Component Denominator for Procedure Report
- Late Onset Sepsis/Meningitis Denominator (LOS/Men Denom) Report
- Outpatient Procedure Component Same Day Outcome Measures Event Report
- Outpatient Procedure Surgical Site Infection (SSI) Event Report

Three revised reports:

- Antimicrobial Resistance Option (ARO) Summary Report
- HAI Evidence of Infection (Dialysis) Report
- Late Onset Sepsis/Meningitis Event (LOS) Report

Twelve new templates:

- Encounters Section in a LOS/Men Denominator
- Findings Section in an OPC SSI Report
- Infection Details Section in an OPC SSI Report
- Infection Risk Factors Section in an OPC Denominator for Procedure
- Procedure Details Section in an OPC Denominator for Procedure
- Risk Factors Section in a LOS/Men Denominator
- Same Day Outcome Measures Event Details Section
- Infection-Type Observation in an OPC SSI Event
- Location Within Facility Encounter
- Procedure Details in an OPC Denominator for Procedure
- Procedure Details in an OPC SSI Event
- SSI Detection Method

Nine revised templates:

- Details Section in an Evidence of Infection (Dialysis) Report
- Summary Data Section (ARO)

- Infection Indicator Organizer
- IV Antibiotic Start Clinical Statement
- Positive Blood Culture Observation
- Pus, Redness, or Increased Swelling Observation
- Same Day Outcome Measure Observation
- Same Day Outcome Measures Organizer
- Summary Encounter (ARO)

Six new value sets:

- NHSNLOS/MENDischargeDisposition
- NHSNSSIDetectionMethod
- NHSNSSIDetectionMethodType
- NHSNOPCProcedureCategoryCode
- NHSNReportNoEventsAR
- NHSNReportNoEventsOPCSameDayOutcomeMeasures

Seven revised value sets:

- NHSNReportNoEventsNICU
- Codes for Neonatal Intensive Care Unit (NICU) Summary Data
- NHSNPopulationCategoryCode
- NHSNReportNoEventsICU
- NHSNReportNoEventsSCA
- NHSNReportNoEventsMDRO
- NHSNAntimicrobialAgentAURPCCode

Normative Release 3

One report was revised:

- HAI AUR Antimicrobial Resistance Option (ARO) Report

One new template was added:

- Patient Admitted This Encounter Observation

One new value set was added:

- NHSNPathogenCodeARO

One section-level template was revised:

- Findings Section in an ARO Report

Four entry-level templates were revised

- Antimicrobial Susceptibility Isolate Participant

- Isolate Susceptibility Tests Organizer
- Specimen Collection Encounter (ARO)
- Specimen Collection Procedure (ARO)

Normative Release 4, 1st STU

Four reports were revised:

- HAI Bloodstream Infection Report (BSI)
- HAI Surgical Site Infection Report (SSI)
- HAI Urinary Tract Infection Numerator Report (UTI)
- Ventilator Associated Event (VAE) Report

Two new templates were added:

- COVID-19 Section
- NHSN COVID-19 Condition Observation

One new value set was added:

- NHSN COVID19 Case Classification

One value set was updated:

- Codes for Antimicrobial Resistance Option (ARO) Summary Data

All terminology other than the ISBT codes were moved into VSAC

Normative Release 4, 2nd STU

Seventeen reports were revised:

- Updated HAI Single-Person Report Generic Constraints (V2)
- Updated HAI AUR Antimicrobial Resistance Option (ARO) Report (V6)
- Updated HAI Bloodstream Infection Report (BSI) (V5)
- Updated HAI Central-Line Insertion Practice Numerator Report (V3)
- Updated HAI Evidence of Infection (Dialysis) Report (V7)
- Updated HAI Laboratory-Identified Organism (LIO) Report (V3)
- Updated HAI Procedure Denominator Report (V3)
- Updated HAI Surgical Site Infection Report (SSI) (V4)
- Updated HAI Urinary Tract Infection Numerator Report (UTI) (V3)
- Updated Late Onset Sepsis/Meningitis Denominator (LOS/Men Denom) Report (V2)
- Updated Late Onset Sepsis/Meningitis Event (LOS) Report (V3)
- Updated Outpatient Procedure Component Denominator for Procedure Report (V2)

- Updated Outpatient Procedure Component Same Day Outcome Measures Event Report (V2)
- Updated Outpatient Procedure Surgical Site Infection (SSI) Event Report (V2)
- Updated Ventilator Associated Event (VAE) Report (V3)
- Updated Prevention Process and Outcome Measures (POM) Summary Report (V4)
- Updated Risk Factors Section in an Evidence of Infection (Dialysis) Report (V3)

One section was revised:

- Summary Data Section (POM) (V3)

Five new templates were added:

- NHSN Social History Section
- Birth Sex Observation (C-CDA Companion Guide)
- Gender Identity Observation (C-CDA Companion Guide)
- Inpatient Rehabilitation (IRF) Unit in Facility
- Inpatient Psychiatric (IPF) Unit in Facility

One template was removed:

- Removed Dialyzer Reused Observation

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

The templates in Volumes 2, 3, and 4 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 3: 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
		94721-8	COVID-19 Evaluation Note

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, R1.1 (US Realm)*.⁸

Table 4: 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, *Consolidated CDA*. 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 5: 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 6: 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 IGs 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 IGs 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.