CDAR2\_IG\_HAIRPT\_R3\_D2\_2017JULY\_

Vol4\_HV\_Appendix



**HL7 CDA® R2 Implementation Guide:**

**NHSN Healthcare Associated Infection (HAI) Reports**

**Release 3, STU 2—US Realm**

**Volume 4 – Appendix:**

**Hemovigilance (HV)**

**Subset For Implementers**

July 2017

**Release 3, 2nd HL7 Standard for Trial Use (STU)**

**Sponsored by:   
Structured Documents Work Group**

**National Healthcare Safety Network**

Copyright © 2017 Health Level Seven International ® ALL RIGHTS RESERVED. The reproduction of this material in any form is strictly forbidden without the written permission of the publisher. HL7 and Health Level Seven are registered trademarks of Health Level Seven International. Reg. U.S. Pat & TM Off**.**

Use of this material is governed by HL7's [**IP Compliance Policy**](http://www.hl7.org/legal/ippolicy.cfm?ref=nav).

|  |  |  |  |
| --- | --- | --- | --- |
| Co-Chair: | Calvin Beebe Mayo Clinic [cbeebe@mayo.edu](mailto:cbeebe@mayo.edu) | Co-Chair: | Austin Kreisler Leidos Consultant to CDC/NHSN [duz1@cdc.gov](mailto:duz1@cdc.gov) |
| Co-Chair: | Brett Marquard River Rock Associates [brett@riverrockassociates.com](mailto:brett@riverrockassociates.com) | Co-Chair: | Gaye Dolin M.S.N., R.N. Intelligent Medical Objects [gdolin@imo-online.com](mailto:gdolin@imo-online.com) |
| Co-Chair: | Rick Geimer Lantana Consulting Group [rick.geimer@lantanagroup.com](mailto:rick.geimer@lantanagroup.com) | Co-Chair: | John Roberts Tennessee Department of Health [john.a.roberts@tn.gov](mailto:john.a.roberts@tn.gov) |
| Co-Chair: | Rob Savage MS  Rob Savage Consulting [rob.savage50@gmail.com](mailto:rob.savage50@gmail.com) | Co-Chair: | Joginder Madra  Madra Consulting Inc. [hl7@madraconsulting.com](mailto:hl7@madraconsulting.com) |
| Co-Chair: | Erin Holt MPH  Tennessee Department of Health [erin.holt@tn.gov](mailto:erin.holt@tn.gov) | Co-Chair: | Ben Flessner [b.d.flessner@gmail.com](mailto:b.d.flessner@gmail.com) |
| Primary Editor: | Sarah Gaunt Lantana Consulting Group [sarah.gaunt@lantanagroup.com](mailto:sarah.gaunt@lantanagroup.com) | Co-Editor: | Mindy Durrance  Leidos Consultant to CDC/NHSN [mdq1@cdc.gov](mailto:mdq1@cdc.gov) |
| Co-Editor: | Daniel Pollock, M.D. CDC [DPollock@cdc.gov](mailto:DPollock@cdc.gov) | Co-Editor: | Kathryn Haass  Northrop Grumman Consultant to CDC/NHSN  [myoc0@cdc.gov](mailto:myoc0@cdc.gov) |
| Co-Editor: | Barry Rhodes CDC  [mbr1@cdc.gov](mailto:mbr1@cdc.gov) | Co-Editor: | Misha Baker  CDC  [mxwt1@cdc.gov](mailto:mxwt1@cdc.gov) |
| Co-Editor: | Amy Webb Lantana Consulting Group  [amy.webb@lantanagroup.com](mailto:amy.webb@lantanagroup.com) | Co-Editor: | James Davis  Leidos Consultant to CDC/NHSN  [mync0@cdc.gov](mailto:mync0@cdc.gov) |
| Co-Editor: | George Koromia Lantana Consulting Group [george.koromia@lantanagroup.com](mailto:george.koromia@lantanagroup.com) | Co-Editor: | Beau Bannerman  Lantana Consulting Group [beau.bannerman@lantanagroup.com](mailto:beau.bannerman@lantanagroup.com) |
| Co-Editor: | Lauren Wood Lantana Consulting Group [lauren.wood@lantanagroup.com](mailto:lauren.wood@lantanagroup.com) | Co-Editor: | Eric Parapini Lantana Consulting Group [eric.parapini@lantanagroup.com](mailto:eric.parapini@lantanagroup.com) |
| Co-Editor: | Zabrina Gonzaga Lantana Consulting Group [zabrina.gonzaga@lantanagroup.com](mailto:zabrina.gonzaga@lantanagroup.com) | Technical Editor: | Diana Wright Lantana Consulting Group [diana.wright@lantanagroup.com](mailto:diana.wright@lantanagroup.com) |

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.

This material contains content from SNOMED CT® (<http://www.ihtsdo.org/snomed-ct/>). SNOMED CT is a registered trademark of the International Health Terminology Standard Development Organisation (IHTSDO).

This material contains content from LOINC® ([http://loinc.org](http://loinc.org/)). The LOINC table, LOINC codes, and LOINC panels and forms file are copyright © 1995-2017, Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC) Committee and available at no cost under the license at <http://loinc.org/terms-of-use>.

Contents

1 Introduction 9

1.1 Purpose 9

1.2 Audience 9

1.3 Organization of the Appendix 9

1.3.1 Introductory Material 9

1.3.2 CDA Templates and Supporting Material 9

1.3.3 Example Instance Identifiers 10

2 CDA R2 Background 11

2.1 Templated CDA 11

2.2 Change Notification Process 12

3 Design Considerations 13

3.1 Rendering Header Information for Human Presentation 13

3.2 Unknown and No Known Information 13

3.3 Negating Clinical Statements 17

3.4 Summary Document ServiceEvent Codes 17

4 Using This Implementation Guide 19

4.1 Levels of Constraint 19

4.2 Conformance Conventions Used in This Guide 19

4.2.1 Templates and Conformance Statements 19

4.2.2 Template Versioning 21

4.2.3 Open and Closed Templates 22

4.2.4 Conformance Verbs (Keywords) 22

4.2.5 Cardinality 23

4.2.6 Optional and Required with Cardinality 23

4.2.7 Vocabulary Conformance 24

4.2.8 Data Types 25

4.2.9 Succession Management 25

4.3 XML Conventions Used in This Guide 26

4.3.1 XPath Notation 26

4.3.2 XML Examples and Sample Documents 26

4.4 Supporting Tools 27

4.4.1 Validation 27

4.4.2 Generation of Narrative Block 27

4.4.3 Display Transforms 27

5 Document-Level Templates 28

5.1 Healthcare Associated Infection Report 28

5.1.1 HAI Population Summary Report Generic Constraints 34

5.1.2 Hemovigilance (HV) Summary Report (V2) 40

6 Section-Level Templates 43

6.1 HAI Section Generic Constraints 43

6.1.1 Summary Data Section (HV) (V2) 44

7 Entry-Level Templates 48

7.1 Blood Product Usage Summary Observation (V2) 48

7.2 Facility Transfuses Blood Products Treated with Pathogen Reduction Technology Observation (V2) 53

7.3 ISBT Product Code Summary Observation (V2) 56

7.4 No Hemovigilance Adverse Reactions Reported This Month Observation 62

7.5 No Hemovigilance Incidents Reported This Month Observation 65

7.6 Pathogen Reduced Apheresis Platelet Usage Summary Observation 68

7.7 Summary Data Observation (HV) 73

7.8 Summary Encounter (HV) (V2) 75

8 Template Ids in This Guide 83

9 Value Sets In This Guide 85

10 Code Systems in This Guide 86

11 Changes from Previous Version 87

12 References 88

Appendix A — Acronyms and Abbreviations 89

Appendix B — Example Instance Identifiers (Non-normative) 92

Appendix C — Vocabulary Heuristics for Codes and Value Sets (Non-normative) 94

Code and codeSystem Selection 94

Value Set Assignment and Maintenance 94

Figures

Figure 1: Templated CDA 11

Figure 2: nullFlavor Example 14

Figure 3: Attribute Required—nullFlavor not allowed 14

Figure 4: Allowed nullFlavors When Element is Required—with XML examples 15

Figure 5: Unknown Medication Example 15

Figure 6: Unknown Medication Use of Anticoagulant Drug Example 16

Figure 7: No Known Medications Example 16

Figure 8: Value Known—code for value not known 16

Figure 9: Value Completely Unknown 17

Figure 10: Value Known—code in required code system not known but code from another code system is known 17

Figure 11: Context Tables 20

Figure 12: Constraints Overview Table Example 20

Figure 13: Constraints Format Example 21

Figure 14: Versioned Template Change Log Example 22

Figure 15: Constraints Format—only one allowed 23

Figure 16: Constraints Format—only one like this allowed 23

Figure 17: Binding to a Single Code 24

Figure 18: XML Expression of a Single-code Binding 24

Figure 19: Example Value Set Table 25

Figure 20: XML Document Example 26

Figure 21: XPath Expression Example 26

Figure 22: ClinicalDocument Example 27

Figure 23: Summary Data Section (HV) (V2) Example 47

Figure 24: Blood Product Usage Summary Observation (V2) Example 52

Figure 25: Facility Transfuses Blood Products Treated with Pathogen Reduction Technology Observation (V2) Example 55

Figure 26: ISBT Product Code Summary Observation Example 61

Figure 27: No Hemovigilance Adverse Reactions Reported This Month Observation Example 64

Figure 28: No Hemovigilance Incidents Reported This Month Observation 67

Figure 29: Pathogen Reduced Apheresis Platelet Usage Summary Example 73

Figure 30: Summary Data Observation (HV) Example 75

Figure 31: Summary Encounter (HV) (V2) Example 81

Tables

Table 1: Healthcare Associated Infection Report Constraints Overview 29

Table 2: HAI Population Summary Report Generic Constraints Constraints Overview 36

Table 3: NHSNPopulationSummaryReportTypeCode 40

Table 4: Hemovigilance (HV) Summary Report (V2) Contexts 40

Table 5: Hemovigilance (HV) Summary Report (V2) Constraints Overview 41

Table 6: HAI Section Generic Constraints Constraints Overview 43

Table 7: Summary Data Section (HV) (V2) Contexts 44

Table 8: Summary Data Section (HV) (V2) Constraints Overview 45

Table 9: Blood Product Usage Summary Observation (V2) Contexts 48

Table 10: Blood Product Usage Summary Observation (V2) Constraints Overview 49

Table 11: NHSN Summary Blood Product Usage 51

Table 12: Facility Transfuses Blood Products Treated with Pathogen Reduction Technology Observation (V2) Contexts 53

Table 13: Facility Transfuses Blood Products Treated with Pathogen Reduction Technology Observation (V2) Constraints Overview 54

Table 14: ISBT Product Code Summary Observation (V2) Contexts 56

Table 15: ISBT Product Code Summary Observation (V2) Constraints Overview 56

Table 16: NHSN Plasma/Apheresis/Psoralen-Treated 61

Table 17: No Hemovigilance Adverse Reactions Reported This Month Observation Contexts 62

Table 18: No Hemovigilance Adverse Reactions Reported This Month Observation Constraints Overview 63

Table 19: No Hemovigilance Incidents Reported This Month Observation Contexts 65

Table 20: No Hemovigilance Incidents Reported This Month Observation Constraints Overview 66

Table 21: Pathogen Reduced Apheresis Platelet Usage Summary Observation Contexts 68

Table 22: Pathogen Reduced Apheresis Platelet Usage Summary Observation Constraints Overview 69

Table 23: NHSN Pathogen Reduced Apheresis Platelet Usage 71

Table 24: Summary Data Observation (HV) Contexts 73

Table 25: Summary Data Observation (HV) Constraints Overview 74

Table 26: Codes for Hemovigilance (HV) Summary Data 75

Table 27: Summary Encounter (HV) (V2) Contexts 75

Table 28: Summary Encounter (HV) (V2) Constraints Overview 77

Table 29: Template List 83

Table 30: Template Containments 84

Table 31: Value Sets 85

Table 32: Code Systems 86

Table 33: Structure of Example OIDs 92

Table 34: Values of Example Instance Identifiers Used in This Guide 93

# Introduction

Purpose

This appendix is a stand-alone document containing the CDA implementation guidance for the Summary (Denominator) Report dealing with Hemovigilance (HV) data. This report is the Hemovigilance (HV) Summary Report (Denominator).

The templates contained in this appendix document are exact copies of the HV templates contained in *HL7 Implementation Guide for CDA® Release 2: NHSN Healthcare Associated Infection (HAI) Reports Release 3, STU 2—US Realm, Volume 2 - Templates and Supporting Material.*

This appendix also contains much of the material presented in the *HL7 Implementation Guide for CDA® Release 2: NHSN Healthcare Associated Infection (HAI) Reports Release 3, DSTU 2—US Realm, Volume 1 - Introductory Material.*

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.

Organization of the Appendix

Introductory Material

These chapters provide an overview of Clinical Document Architecture (CDA), recent changes to the standard, and information on how to understand and use the CDA templates provided.

* **Chapter 1—Introduction**
* **Chapter 2—CDA R2 Background** contains selected background material on the CDA Release 2 (CDA R2) base standard to aid the reader in conceptualizing the “templated CDA” approach to implementation guide development.
* **Chapter 3—Design Considerations** describes design considerations and overarching principles that have been developed and applied across the CDA templates in this guide. Material in this section can be thought of as “heuristics”, as opposed to the formal and testable constraints found in chapters 5 through 7 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 chapters 5 through 7 of this guide.

CDA Templates and Supporting Material

* **Chapter 5—Document-Level Templates** defines the report requirements for HAI CDA documents.

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

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

* **Chapter 6—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 7—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 8—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.
* **Chapter 9—Value Sets in This Guide** lists all value set names and OIDs used by HAI templates in this guide. Links are provided to external value set sources if appropriate. Additionally, the hai\_voc.xls spreadsheet is provided as a resource for value-set information.
* **Chapter 10—Code Systems in This Guide** lists all code system names and OIDs used by HAI templates in this guide, both for value sets and single-value bindings.
* **Chapter 11—Changes From Previous Version** details all changes made in templates for this release.
* **Chapter 12—References** lists documents and sources cited by this guide.
* **Appendices** include a list of acronyms and abbreviations, example instance identifiers, and vocabulary heuristics for code systems and value sets.

Example Instance Identifiers

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

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

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

# CDA R2 Background

This implementation guide uses the *HL7 Clinical Document Architecture, Release 2.0 (CDA R2)* as its base standard.[[1]](#footnote-1) 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 that for classification and management and a document body that carries the clinical record. While the header metadata are prescriptive and designed for consistency across all instances, the body is highly generic, leaving the designation of semantic requirements to implementation.

Templated CDA

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

Figure 1: Templated CDA



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

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

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

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 guide 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>.

# 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 chapters 5 through 7 of this guide.

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)

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 it has not been provided by the sender due to security, privacy, or other reasons. There may be an alternate mechanism for gaining access to this information.

OTH The actual value is not an element in the value domain of a variable. (e.g., concept not provided by required code system).

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

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 laboratory result. In this implementation guide, when negationInd is set to true, it is understood that it negates the act as described by the act’s descriptive properties (including act.code, procedure.effectiveTime, observation.value, etc.) and any of the act’s components, rather than at the level of a specific value in the act. The inert properties such as act.id, act.moodCode, and act.confidentialityCode are not negated and always have the same meaning. In other words, when an act is negated, it indicates that the event as specified did not occur. For example, if the clinical statement is asserting that a wrong procedure has been performed on a certain date and its negationInd is set to true, the whole clinical statement is negated, including any attributes such as the assertion and the effectiveTime. This clinical statement indicates that we are not asserting that this event occurred on this date—there is no assertion that a wrong procedure was performed on this date. For further details and examples, see the definition of Act.negationInd in the HL7 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*.

## 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).

# 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 chapters 5 through 7 of this guide.

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.

Conformance Conventions Used in This Guide

Templates and Conformance Statements

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

Bracketed information following each template title indicates the template type (section, observation, act, procedure, etc.), the identifier oid or identifier urn, and whether the template is [open or closed](#IG_S_Open_and_Closed_Templates). 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 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)  Allergies Section (entries required) (V2) (required) | Allergy - Intolerance Observation (V2)  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 this guide. The next chapters describe specific aspects of conformance statements—open vs. closed statements, conformance verbs, cardinality, vocabulary conformance, containment relationships, and null flavors. The expression “such that it” means, you (SHALL/SHOULD/MAY) have one of those things that look like that, but you can also have another one of those things that look different. The example below states that you must have templateId with a root of 2.16.840.1.113883.10.20.22.4.31 but you can also have other template IDs.

Figure 13: Constraints Format Example

***Age Observation***

[observation: identifier oid:2.16.840.1.113883.10.20.22.4.31(open)]

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:XXXX).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF: XXXX).
3. SHALL contain exactly one [1..1] templateId (CONF:XXXX) such that it
   1. 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).
   1. 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).
   1. 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).
   1. 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).

Template Versioning

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

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

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

A revised version of a template is explicitly linked to the prior version. When a new version appears for the first time in an IG, a detailed change log is automatically generated, a detailed change log is automatically generated. All such changes for a given IG are shown in Chapter 12 “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) |

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.

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.[[3]](#footnote-3)

* 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.

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 participantSHALL 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.

Figure 16: Constraints Format—only one like this allowed

1. SHALL contain exactly one [1..1] **participant** (CONF:2777) such that it

a. SHALL contain exactly one [1..1] **@typeCode**="LOC" (CodeSystem:

2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230).

Optional and Required with Cardinality

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

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

*Required* means that the number of allowable occurrences of an element must be at least 1; the cardinality will be expressed as [m..n] where m >=1 and n >=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”](#IG_S_Unknown_and_No_Known_Information).

Vocabulary Conformance

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

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

Value-set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (shall, should, may, etc.) and an indication of dynamic vs. static binding. Value-set constraints can be static, meaning that they are bound to a specified version of a value set, or dynamic, meaning that they are bound to the most current version of the value set. A simplified constraint, used when the binding is to a single code, includes the meaning of the code, as follows.

Figure 17: Binding to a Single Code

2. SHALL contain exactly one [1..1] code (CONF:15403).

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[[4]](#footnote-4) 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. Where the table is an excerpt and no link is provided, the full set of values are contained in the hai\_voc.xls spreadsheet included with this package.

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) |
| ... |  |  |  |

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.

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.

XML Conventions Used in This Guide

XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this document uses XML Path Language (XPath) notation[[5]](#footnote-5) in conformance statements and elsewhere to identify the Extensible Markup Language (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.

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

XML Examples and Sample Documents

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

Figure 22: ClinicalDocument Example

<ClinicalDocument xmls="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.

Supporting Tools

Validation

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

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

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

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](#IG_S_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.

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.

# Document-Level Templates

Healthcare Associated Infection Report

[ClinicalDocument: identifier urn:oid:2.16.840.1.113883.10.20.5.4.25 (open)]

Published as part of NHSN Healthcare Associated Infection (HAI) Reports Release 1 - US Realm

This template records constraints on all NHSN Healthcare Associated Infection Reports (generic constraints). Further constraints are found in the specialization templates for single-patient and population summary reports, and in the templates for specific report types.

Annotations before some constraints provide additional information for the implementer.

Elements required by CDA that are not further constrained in this guide are not presented as HAI-specific constraints.

Note: The section on “Template Ids in this Guide” includes a containment table showing all the entries within each report type.

Table 1: Healthcare Associated Infection Report Constraints Overview

| XPath | Card. | Verb | Data Type | CONF# | Value |
| --- | --- | --- | --- | --- | --- |
| ClinicalDocument (identifier: urn:oid:2.16.840.1.113883.10.20.5.4.25) | | | | | |
| realmCode | 1..1 | SHALL |  | [86-18431](#C_86-18431) |  |
| @code | 1..1 | SHALL | CD | [86-18432](#C_86-18432) | US |
| typeId | 1..1 | SHALL |  | [86-18463](#C_86-18463) |  |
| @root | 1..1 | SHALL |  | [86-18464](#C_86-18464) | 2.16.840.1.113883.1.3 |
| @extension | 1..1 | SHALL |  | [86-18465](#C_86-18465) | POCD\_HD000040 |
| templateId | 1..1 | SHALL |  | [86-18460](#C_86-18460) |  |
| @root | 1..1 | SHALL |  | [86-18461](#C_86-18461) | 2.16.840.1.113883.10.20.5.4.25 |
| @extension | 0..0 | SHALL NOT |  | [86-18462](#C_86-18462) |  |
| id | 1..1 | SHALL |  | [86-18466](#C_86-18466) |  |
| @root | 0..1 | MAY |  | [86-18467](#C_86-18467) |  |
| @extension | 0..1 | MAY |  | [86-18468](#C_86-18468) |  |
| code | 1..1 | SHALL |  | [86-18433](#C_86-18433) |  |
| @code | 1..1 | SHALL |  | [86-18434](#C_86-18434) | 51897-7 |
| @codeSystem | 1..1 | SHALL |  | [86-27413](#C_86-27413) | urn:oid:2.16.840.1.113883.6.1 (LOINC) |
| title | 1..1 | SHALL |  | [86-18435](#C_86-18435) |  |
| effectiveTime | 1..1 | SHALL |  | [86-18436](#C_86-18436) |  |
| confidentialityCode | 1..1 | SHALL |  | [86-18437](#C_86-18437) |  |
| @code | 1..1 | SHALL | CD | [86-18438](#C_86-18438) | urn:oid:2.16.840.1.113883.5.25 (HL7Confidentiality) = N |
| languageCode | 1..1 | SHALL |  | [86-18439](#C_86-18439) |  |
| @code | 1..1 | SHALL |  | [86-18440](#C_86-18440) | en-US |
| setId | 1..1 | SHALL |  | [86-18441](#C_86-18441) |  |
| versionNumber | 1..1 | SHALL |  | [86-18442](#C_86-18442) |  |
| recordTarget | 1..\* | SHALL |  | [86-18472](#C_86-18472) |  |
| author | 1..\* | SHALL |  | [86-18473](#C_86-18473) |  |
| custodian | 1..1 | SHALL |  | [86-18443](#C_86-18443) |  |
| assignedCustodian | 1..1 | SHALL |  | [86-18444](#C_86-18444) |  |
| representedCustodianOrganization | 1..1 | SHALL |  | [86-18445](#C_86-18445) |  |
| id | 1..1 | SHALL |  | [86-18446](#C_86-18446) |  |
| @root | 1..1 | SHALL |  | [86-18447](#C_86-18447) | 2.16.840.1.114222.4.3.2.11 |
| legalAuthenticator | 0..1 | SHOULD |  | [86-18474](#C_86-18474) |  |
| relatedDocument | 0..\* | MAY |  | [86-18469](#C_86-18469) |  |
| @typeCode | 1..1 | SHALL |  | [86-18470](#C_86-18470) | urn:oid:2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RPLC |
| parentDocument | 1..1 | SHALL |  | [86-28401](#C_86-28401) |  |
| id | 1..\* | SHALL |  | [86-28402](#C_86-28402) |  |
| component | 1..1 | SHALL |  | [86-18448](#C_86-18448) |  |
| structuredBody | 1..1 | SHALL |  | [86-18449](#C_86-18449) |  |
| component | 1..\* | SHALL |  | [86-18475](#C_86-18475) |  |

1. SHALL contain exactly one [1..1] realmCode (CONF:86-18431).
   1. This realmCode SHALL contain exactly one [1..1] @code="US" (CONF:86-18432).
2. SHALL contain exactly one [1..1] typeId (CONF:86-18463).
   1. This typeId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.1.3" (CONF:86-18464).
   2. This typeId SHALL contain exactly one [1..1] @extension="POCD\_HD000040" (CONF:86-18465).
3. SHALL contain exactly one [1..1] templateId (CONF:86-18460) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.5.4.25" (CONF:86-18461).
   2. SHALL NOT contain [0..0] @extension (CONF:86-18462).

CDA requires a ClinicalDocument/id element representing a unique identifier for the document. The id may be represented by either @root or @root plus @extension, so long as the resulting id is globally unique.

CDA provides id, setId, versionNumber, and relatedDocument elements to support succession management (document versioning).

The id element identifies the CDA document instance (the electronic file). It is independent of the setId and versionNumber elements.

1. SHALL contain exactly one [1..1] id (CONF:86-18466).
   1. This id MAY contain zero or one [0..1] @root (CONF:86-18467).
   2. This id MAY contain zero or one [0..1] @extension (CONF:86-18468).
2. SHALL contain exactly one [1..1] code (CONF:86-18433).
   1. This code SHALL contain exactly one [1..1] @code="51897-7" Healthcare Associated Infection Report (CONF:86-18434).
   2. This code SHALL contain exactly one [1..1] @codeSystem (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:86-27413).

The preferred title content for each report type is given with the constraints for each report type.

1. SHALL contain exactly one [1..1] title (CONF:86-18435).
2. SHALL contain exactly one [1..1] effectiveTime (CONF:86-18436).

CDA requires a confidentiality code that indicates the sensitivity of the document. All HAI submissions carry the same value of "normal". Note that this designation does not affect local policy on safeguarding confidentiality of patient-identifiable personal health information.

1. SHALL contain exactly one [1..1] confidentialityCode (CONF:86-18437).
   1. This confidentialityCode SHALL contain exactly one [1..1] @code="N" Normal (CodeSystem: HL7Confidentiality urn:oid:2.16.840.1.113883.5.25 STATIC) (CONF:86-18438).
2. SHALL contain exactly one [1..1] languageCode (CONF:86-18439).
   1. This languageCode SHALL contain exactly one [1..1] @code="en-US" (CONF:86-18440).
3. SHALL contain exactly one [1..1] setId (CONF:86-18441).
4. SHALL contain exactly one [1..1] versionNumber (CONF:86-18442).

CDA requires a recordTarget element that must contain a patientRole element. This is represented differently in single-person and population summary reports. See the templates for generic single-person and population summary reports for details of how to represent the patient or group subject.

1. SHALL contain at least one [1..\*] recordTarget (CONF:86-18472).

In a single-person report, the author may be software or may be a person in the role of infection control professional (ICP). In a population summary report, the author will be the software forming the message. The effect of the CDA Release 2.0 requirements is:

An author element shall be present. The author element shall contain a time element that represents the time of authoring of the information, and an assignedAuthor element that represents the author of the information. The assignedAuthor element shall contain an id element. (from CDA R2)

When the report author is vendor software, it can record the software installation id, an email address, and the vendor name.

1. SHALL contain at least one [1..\*] author (CONF:86-18473).

CDA requires that the document custodian be recorded. The NHSN is the custodian of NHSN HAI Reports.

1. SHALL contain exactly one [1..1] custodian (CONF:86-18443).
   1. This custodian SHALL contain exactly one [1..1] assignedCustodian (CONF:86-18444).
      1. This assignedCustodian SHALL contain exactly one [1..1] representedCustodianOrganization (CONF:86-18445).
         1. This representedCustodianOrganization SHALL contain exactly one [1..1] id (CONF:86-18446).
            1. This id SHALL contain exactly one [1..1] @root="2.16.840.1.114222.4.3.2.11" (CONF:86-18447).

CDA requires that a legalAuthenticator element be present if the document has been legally authenticated. Local policy may delegate the function of legal authentication to a device or system that generates the CDA document.  In these cases, the legal authenticator must still be a person accepting responsibility for the document content, not the device or system. The effect of the CDA Release 2.0 requirements is:

The legalAuthenticator element shall contain a time element that represents the time of authentication of the document, a signatureCode element where the value of @code is S, and an assignedEntity element that represents the authenticator of the document. The assignedEntity element shall contain an id element. (from CDA R2)

HAI Reports are not signed reports and do not require a legalAuthenticator.

1. SHOULD contain zero or one [0..1] legalAuthenticator (CONF:86-18474).
2. MAY contain zero or more [0..\*] relatedDocument (CONF:86-18469).
   1. The relatedDocument, if present, SHALL contain exactly one [1..1] @typeCode="RPLC" replace (CodeSystem: HL7ActRelationshipType urn:oid:2.16.840.1.113883.5.1002 STATIC) (CONF:86-18470).
   2. The relatedDocument, if present, SHALL contain exactly one [1..1] parentDocument (CONF:86-28401).
      1. This parentDocument SHALL contain at least one [1..\*] id (CONF:86-28402).
         1. The value of id SHALL be populated with the ClinicalDocument/id of the document being replaced (CONF:86-28403).
   3. If versionNumber/@value is greater than 1, a relatedDocument element SHALL be present (CONF:86-18471).
3. SHALL contain exactly one [1..1] component (CONF:86-18448).
   1. This component SHALL contain exactly one [1..1] structuredBody (CONF:86-18449).
      1. This structuredBody SHALL contain at least one [1..\*] component (CONF:86-18475).
      2. The structuredBody element SHALL contain a component element for each section required by the particular report type. Additional sections may be present but their content will not be processed by NHSN (CONF:86-18450).

HAI Population Summary Report Generic Constraints

[ClinicalDocument: identifier urn:oid:2.16.840.1.113883.10.20.5.4.28 (open)]

Published as part of NHSN Healthcare Associated Infection (HAI) Reports Release 1 - US Realm

A Population Summary Report records summary data for a group, such as the patients in a particular ward, during a specified period. This report type differs in several ways from the HAI single-person reports.

These report types are used to record many different data sets. The basic structure of the body templates for this report type are:

   •  A Summary Data Section:

      o  A Summary Encounter records the location to which the data pertain.

      o  Various Summary Data Observations record data as code-value pairs.

A population-summary report must conform to the Healthcare Associated Infection Report above. In addition:

   •  The patient identifier (required by CDA) is recorded with a nullFlavor.

   •  A participant element records that the subject of the report is a group.

   •  A second participant element records the reporting facility.  (The in-facility unit identifier and type to which the data pertain are recorded in the Summary Encounter Section of the document body.)

   •  In the documentationOf/serviceEvent element,

      o  The effectiveTime element records the first and last days of the period reported.

      o  The code element records the type of summary data reported. This corresponds to the NHSN form type.

The data set being reported is identified by a code in the CDA header; for example, the cdcNHSN concept “1887-9” identifies the data set “Summary data reporting Antimicrobial Usage”. The codes for these data sets are listed in value set NHSNPopulationSummaryReportTypeCode (2.16.840.1.114222.4.11.3595).

Note that a few data sets are stratified. For example, the NICU (Neonatal Intensive Care Unit) data set is stratified by birthweight; the Antimicrobial Usage data set is stratified by antimicrobial and by route of administration. The stratifying factor is recorded as a CDA element in the Summary Encounter or Summary Data Observation. For example, in an Antimicrobial Use report, the antimicrobial information is represented as a participant. The requirements for each data set are provided in the relevant Summary Data Observation.

Most of the concepts reported are defined for the NHSN protocol and are not expected to see widespread external use: the codes for these concepts come from the NHSN code system.

Key encounter data:

   •  Facility identifier is required. This represents the reporting facility; the location to which the data pertain, such as a unit, is recorded with the data in the Summary Encounter.

   •  A code identifying the data set is required.

   •  The period reported is required.

Note: The section on “Template Ids in this Guide” includes a containment table showing all the entries within each report type.

Table 2: HAI Population Summary Report Generic Constraints Constraints Overview

| XPath | Card. | Verb | Data Type | CONF# | Value |
| --- | --- | --- | --- | --- | --- |
| ClinicalDocument (identifier: urn:oid:2.16.840.1.113883.10.20.5.4.28) | | | | | |
| templateId | 1..1 | SHALL |  | [86-22431](#C_86-22431) |  |
| @root | 1..1 | SHALL |  | [86-22432](#C_86-22432) | 2.16.840.1.113883.10.20.5.4.28 |
| recordTarget | 1..1 | SHALL |  | [86-22433](#C_86-22433) |  |
| patientRole | 1..1 | SHALL |  | [86-22434](#C_86-22434) |  |
| id | 1..1 | SHALL |  | [86-22435](#C_86-22435) |  |
| @nullFlavor | 1..1 | SHALL |  | [86-22436](#C_86-22436) | NA |
| participant | 1..1 | SHALL |  | [86-22437](#C_86-22437) |  |
| @typeCode | 1..1 | SHALL |  | [86-22438](#C_86-22438) | urn:oid:2.16.840.1.113883.5.90 (HL7ParticipationType) = SBJ |
| @contextControlCode | 1..1 | SHALL | CS | [86-22439](#C_86-22439) | urn:oid:2.16.840.1.113883.5.1057 (HL7ContextControl) = OP |
| associatedEntity | 1..1 | SHALL |  | [86-22440](#C_86-22440) |  |
| @classCode | 1..1 | SHALL |  | [86-22441](#C_86-22441) | urn:oid:2.16.840.1.113883.5.41 (HL7EntityClass) = PRS |
| code | 1..1 | SHALL |  | [86-22442](#C_86-22442) |  |
| @code | 1..1 | SHALL |  | [86-22443](#C_86-22443) | urn:oid:2.16.840.1.113883.6.96 (SNOMED CT) = 389109008 |
| participant | 1..1 | SHALL |  | [86-22444](#C_86-22444) |  |
| @typeCode | 1..1 | SHALL |  | [86-22445](#C_86-22445) | urn:oid:2.16.840.1.113883.5.90 (HL7ParticipationType) = LOC |
| @contextControlCode | 1..1 | SHALL | CS | [86-22446](#C_86-22446) | urn:oid:2.16.840.1.113883.5.1057 (HL7ContextControl) = OP |
| associatedEntity | 1..1 | SHALL |  | [86-22447](#C_86-22447) |  |
| @classCode | 1..1 | SHALL |  | [86-22448](#C_86-22448) | urn:oid:2.16.840.1.113883.5.110 (HL7RoleClass) = SDLOC |
| id | 1..1 | SHALL |  | [86-22449](#C_86-22449) |  |
| @root | 1..1 | SHALL |  | [86-22450](#C_86-22450) |  |
| documentationOf | 1..1 | SHALL |  | [86-22451](#C_86-22451) |  |
| serviceEvent | 1..1 | SHALL |  | [86-22452](#C_86-22452) |  |
| @classCode | 1..1 | SHALL |  | [86-22453](#C_86-22453) | urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = CASE |
| code | 1..1 | SHALL |  | [86-22454](#C_86-22454) | urn:oid:2.16.840.1.114222.4.11.3595 (NHSNPopulationSummaryReportTypeCode) |
| effectiveTime | 1..1 | SHALL |  | [86-22456](#C_86-22456) |  |
| low | 1..1 | SHALL |  | [86-22457](#C_86-22457) |  |
| high | 1..1 | SHALL |  | [86-22458](#C_86-22458) |  |

1. Conforms to [Healthcare Associated Infection Report](#D_Healthcare_Associated_Infection_Repor) template (identifier: urn:oid:2.16.840.1.113883.10.20.5.4.25).
2. SHALL contain exactly one [1..1] templateId (CONF:86-22431) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.5.4.28" (CONF:86-22432).
3. SHALL contain exactly one [1..1] recordTarget (CONF:86-22433).
   1. This recordTarget SHALL contain exactly one [1..1] patientRole (CONF:86-22434).
      1. This patientRole SHALL contain exactly one [1..1] id (CONF:86-22435).
         1. This id SHALL contain exactly one [1..1] @nullFlavor="NA" not applicable (CONF:86-22436).
4. SHALL contain exactly one [1..1] participant (CONF:86-22437) such that it
   1. SHALL contain exactly one [1..1] @typeCode="SBJ" Subject (CodeSystem: HL7ParticipationType urn:oid:2.16.840.1.113883.5.90 STATIC) (CONF:86-22438).
   2. SHALL contain exactly one [1..1] @contextControlCode="OP" (CodeSystem: HL7ContextControl urn:oid:2.16.840.1.113883.5.1057 STATIC) (CONF:86-22439).
   3. SHALL contain exactly one [1..1] associatedEntity (CONF:86-22440).
      1. This associatedEntity SHALL contain exactly one [1..1] @classCode="PRS" Person (CodeSystem: HL7EntityClass urn:oid:2.16.840.1.113883.5.41 STATIC) (CONF:86-22441).
      2. This associatedEntity SHALL contain exactly one [1..1] code (CONF:86-22442).
         1. This code SHALL contain exactly one [1..1] @code="389109008" Group (CodeSystem: SNOMED CT urn:oid:2.16.840.1.113883.6.96 STATIC) (CONF:86-22443).
5. SHALL contain exactly one [1..1] participant (CONF:86-22444) such that it
   1. SHALL contain exactly one [1..1] @typeCode="LOC" Location (CodeSystem: HL7ParticipationType urn:oid:2.16.840.1.113883.5.90 STATIC) (CONF:86-22445).
   2. SHALL contain exactly one [1..1] @contextControlCode="OP" (CodeSystem: HL7ContextControl urn:oid:2.16.840.1.113883.5.1057 STATIC) (CONF:86-22446).
   3. SHALL contain exactly one [1..1] associatedEntity (CONF:86-22447).
      1. This associatedEntity SHALL contain exactly one [1..1] @classCode="SDLOC" Service delivery location (CodeSystem: HL7RoleClass urn:oid:2.16.840.1.113883.5.110 STATIC) (CONF:86-22448).
      2. This associatedEntity SHALL contain exactly one [1..1] id (CONF:86-22449).

The value of @root must be the NHSN assigned Facility OID.

* + - 1. This id SHALL contain exactly one [1..1] @root (CONF:86-22450).

1. SHALL contain exactly one [1..1] documentationOf (CONF:86-22451).
   1. This documentationOf SHALL contain exactly one [1..1] serviceEvent (CONF:86-22452).
      1. This serviceEvent SHALL contain exactly one [1..1] @classCode="CASE" (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 STATIC) (CONF:86-22453).
      2. This serviceEvent SHALL contain exactly one [1..1] code, which SHALL be selected from ValueSet [NHSNPopulationSummaryReportTypeCode](#NHSNPopulationSummaryReportTypeCode) urn:oid:2.16.840.1.114222.4.11.3595 STATIC (CONF:86-22454).
      3. This serviceEvent SHALL contain exactly one [1..1] effectiveTime (CONF:86-22456).
         1. This effectiveTime SHALL contain exactly one [1..1] low (CONF:86-22457).
         2. This effectiveTime SHALL contain exactly one [1..1] high (CONF:86-22458).
2. The author SHALL represent the software forming the message (CONF:86-22459).

Table 3: NHSNPopulationSummaryReportTypeCode

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: NHSNPopulationSummaryReportTypeCode urn:oid:2.16.840.1.114222.4.11.3595  A full listing of codes can be found in the hai\_voc.xls file provided with this package. | | | |
| Code | Code System | Code System OID | Print Name |
| 1879-6 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Summary data reporting catheter and ventilator use in a ICU/Other |
| 1880-4 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Summary data reporting catheter and ventilator use in a SCA |
| 1881-2 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Summary data reporting catheter and ventilator use in a NICU |
| 1884-6 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Summary data reporting Active Surveillance Testing |
| 2316-8 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Summary data reporting vascular access types for chronic hemodialysis patients |
| 1887-9 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Summary data reporting Antimicrobial Usage |
| 2410-9 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Summary data reporting antimicrobial resistance patterns at a facility |
| 1657-6 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Summary data reporting Outpatient procedure component events at a facility |
| 2543-7 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Hemovigilance Module - Monthly Reporting Denominator |
| 86558-4 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Summary data reporting healthcare personnel influenza vaccinations |

Hemovigilance (HV) Summary Report (V2)

[ClinicalDocument: identifier urn:hl7ii:2.16.840.1.113883.10.20.5.49:2016-08-01 (closed)]

Published as part of NHSN Healthcare Associated Infection (HAI) Reports Release 3, DSTU 1.1 - US Realm

Table 4: Hemovigilance (HV) Summary Report (V2) Contexts

| Contained By: | Contains: |
| --- | --- |
|  | [Summary Data Section (HV) (V2)](#S_Summary_Data_Section_HV_V2) |

Note: The section on “Template Ids in this Guide” includes a containment table showing all the entries within each report type.

The required title for the CDA document is the “Hemovigilance Module - Monthly Reporting Denominator”.

The HV Summary Report records monthly summary data for a facility.

Table 5: Hemovigilance (HV) Summary Report (V2) Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.49:2016-08-01) | | | | | |
| templateId | 1..1 | SHALL |  | [3247-30738](#C_3247-30738) |  |
| @root | 1..1 | SHALL |  | [3247-30608](#C_3247-30608) | 2.16.840.1.113883.10.20.5.7.3.1.1 |
| templateId | 1..1 | SHALL |  | [3247-30606](#C_3247-30606) |  |
| @root | 1..1 | SHALL |  | [3247-30611](#C_3247-30611) | 2.16.840.1.113883.10.20.5.49 |
| @extension | 1..1 | SHALL |  | [3247-30612](#C_3247-30612) | 2016-08-01 |
| title | 1..1 | SHALL |  | [3247-30613](#C_3247-30613) | Hemovigilance Module - Monthly Reporting Denominator |
| documentationOf | 1..1 | SHALL |  | [3247-30600](#C_3247-30600) |  |
| serviceEvent | 1..1 | SHALL |  | [3247-30739](#C_3247-30739) |  |
| code | 1..1 | SHALL |  | [3247-30740](#C_3247-30740) |  |
| @code | 1..1 | SHALL |  | [3247-30609](#C_3247-30609) | 2543-7 |
| @codeSystem | 1..1 | SHALL |  | [3247-30610](#C_3247-30610) | urn:oid:2.16.840.1.113883.6.277 (cdcNHSN) = 2.16.840.1.113883.6.277 |
| component | 1..1 | SHALL |  | [3247-30741](#C_3247-30741) |  |
| structuredBody | 1..1 | SHALL |  | [3247-30604](#C_3247-30604) |  |
| component | 1..1 | SHALL |  | [3247-30605](#C_3247-30605) |  |
| section | 1..1 | SHALL |  | [3247-30607](#C_3247-30607) | [Summary Data Section (HV) (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.5.57:2016-08-01](#S_Summary_Data_Section_HV_V2) |

1. Conforms to [HAI Population Summary Report Generic Constraints](#D_HAI_Population_Summary_Report_Generic) template (identifier: urn:oid:2.16.840.1.113883.10.20.5.4.28).

This template id represents the IG in which this template is published.

1. SHALL contain exactly one [1..1] templateId (CONF:3247-30738) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.5.7.3.1.1" (CONF:3247-30608).
2. SHALL contain exactly one [1..1] templateId (CONF:3247-30606) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.5.49" (CONF:3247-30611).
   2. SHALL contain exactly one [1..1] @extension="2016-08-01" (CONF:3247-30612).
3. SHALL contain exactly one [1..1] title="Hemovigilance Module - Monthly Reporting Denominator" (CONF:3247-30613).
4. SHALL contain exactly one [1..1] documentationOf (CONF:3247-30600).
   1. This documentationOf SHALL contain exactly one [1..1] serviceEvent (CONF:3247-30739).
      1. This serviceEvent SHALL contain exactly one [1..1] code (CONF:3247-30740).
         1. This code SHALL contain exactly one [1..1] @code="2543-7" Hemovigilance Module - Monthly Reporting Denominator (CONF:3247-30609).
         2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.277" (CodeSystem: cdcNHSN urn:oid:2.16.840.1.113883.6.277) (CONF:3247-30610).
5. SHALL contain exactly one [1..1] component (CONF:3247-30741).
   1. This component SHALL contain exactly one [1..1] structuredBody (CONF:3247-30604).
      1. This structuredBody SHALL contain exactly one [1..1] component (CONF:3247-30605).
         1. This component SHALL contain exactly one [1..1] [Summary Data Section (HV) (V2)](#S_Summary_Data_Section_HV_V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.5.57:2016-08-01) (CONF:3247-30607).

# Section-Level Templates

HAI Section Generic Constraints

[section: identifier urn:oid:2.16.840.1.113883.10.20.5.4.26 (closed)]

Published as part of NHSN Healthcare Associated Infection (HAI) Reports Release 1 - US Realm

This template records the constraints that apply to all sections specified in the NHSN HAI Implementation Guide.

Table 6: HAI Section Generic Constraints Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| section (identifier: urn:oid:2.16.840.1.113883.10.20.5.4.26) | | | | | |
| templateId | 1..1 | SHALL |  | [86-21958](#C_86-21958) |  |
| @root | 1..1 | SHALL |  | [86-21959](#C_86-21959) | 2.16.840.1.113883.10.20.5.4.26 |
| code | 1..1 | SHALL |  | [86-21953](#C_86-21953) |  |
| @code | 1..1 | SHALL |  | [86-21954](#C_86-21954) | urn:oid:2.16.840.1.113883.6.1 (LOINC) |
| title | 1..1 | SHALL |  | [86-21955](#C_86-21955) |  |
| text | 1..1 | SHALL |  | [86-21956](#C_86-21956) |  |
| entry | 1..\* | SHALL |  | [86-21957](#C_86-21957) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:86-21958) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.5.4.26" (CONF:86-21959).
2. SHALL contain exactly one [1..1] code (CONF:86-21953).
   1. This code SHALL contain exactly one [1..1] @code (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1 STATIC) (CONF:86-21954).
3. SHALL contain exactly one [1..1] title (CONF:86-21955).
4. SHALL contain exactly one [1..1] text (CONF:86-21956).
5. SHALL contain at least one [1..\*] entry (CONF:86-21957).

Summary Data Section (HV) (V2)

[section: identifier urn:hl7ii:2.16.840.1.113883.10.20.5.5.57:2016-08-01 (closed)]

Published as part of NHSN Healthcare Associated Infection (HAI) Reports Release 3, DSTU 1.1 - US Realm

Table 7: Summary Data Section (HV) (V2) Contexts

| Contained By: | Contains: |
| --- | --- |
| [Hemovigilance (HV) Summary Report (V2)](#D_Hemovigilance_HV_Summary_Report_V2) (required) | [No Hemovigilance Adverse Reactions Reported This Month Observation](#E_No_Hemovigilance_Adverse_Reactions_Re)  [No Hemovigilance Incidents Reported This Month Observation](#E_No_Hemovigilance_Incidents_Reported_T)  [Summary Encounter (HV) (V2)](#E_Summary_Encounter_HV_V2) |

The Summary Data Section is used in a population summary report. The specific counts to be reported in the Summary Data Section vary by report topic, but the section itself conveys the same kind of information wherever used; therefore, the section is represented by the same LOINC section code whatever the data reported.

The Summary Data Section (HV) extends its generic equivalent, but is specific to the HAI Hemovigilance (HV) Summary Report.

Table 8: Summary Data Section (HV) (V2) Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| section (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.5.57:2016-08-01) | | | | | |
| templateId | 1..1 | SHALL |  | [3247-30615](#C_3247-30615) |  |
| @root | 1..1 | SHALL |  | [3247-30619](#C_3247-30619) | 2.16.840.1.113883.10.20.5.5.57 |
| @extension | 1..1 | SHALL |  | [3247-30620](#C_3247-30620) | 2016-08-01 |
| code | 1..1 | SHALL |  | [3247-30616](#C_3247-30616) |  |
| @code | 1..1 | SHALL |  | [3247-30621](#C_3247-30621) | 51900-9 |
| @codeSystem | 1..1 | SHALL |  | [3247-30622](#C_3247-30622) | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| entry | 1..1 | SHALL |  | [3247-30614](#C_3247-30614) |  |
| observation | 1..1 | SHALL |  | [3247-30685](#C_3247-30685) | [No Hemovigilance Adverse Reactions Reported This Month Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.232:2015-10-01](#E_No_Hemovigilance_Adverse_Reactions_Re) |
| entry | 1..\* | SHALL |  | [3247-30617](#C_3247-30617) |  |
| observation | 1..1 | SHALL |  | [3247-30686](#C_3247-30686) | [No Hemovigilance Incidents Reported This Month Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.233:2015-10-01](#E_No_Hemovigilance_Incidents_Reported_T) |
| entry | 1..\* | SHALL |  | [3247-30736](#C_3247-30736) |  |
| encounter | 1..1 | SHALL |  | [3247-30737](#C_3247-30737) | [Summary Encounter (HV) (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.234:2016-08-01](#E_Summary_Encounter_HV_V2) |

1. Conforms to [HAI Section Generic Constraints](#S_HAI_Section_Generic_Constraints) template (identifier: urn:oid:2.16.840.1.113883.10.20.5.4.26).
2. SHALL contain exactly one [1..1] templateId (CONF:3247-30615) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.5.5.57" (CONF:3247-30619).
   2. SHALL contain exactly one [1..1] @extension="2016-08-01" (CONF:3247-30620).
3. SHALL contain exactly one [1..1] code (CONF:3247-30616).
   1. This code SHALL contain exactly one [1..1] @code="51900-9" Summary Data Section (CONF:3247-30621).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:3247-30622).
4. SHALL contain exactly one [1..1] entry (CONF:3247-30614) such that it
   1. SHALL contain exactly one [1..1] [No Hemovigilance Adverse Reactions Reported This Month Observation](#E_No_Hemovigilance_Adverse_Reactions_Re) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.232:2015-10-01) (CONF:3247-30685).
5. SHALL contain at least one [1..\*] entry (CONF:3247-30617) such that it
   1. SHALL contain exactly one [1..1] [No Hemovigilance Incidents Reported This Month Observation](#E_No_Hemovigilance_Incidents_Reported_T) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.233:2015-10-01) (CONF:3247-30686).
6. SHALL contain at least one [1..\*] entry (CONF:3247-30736) such that it
   1. SHALL contain exactly one [1..1] [Summary Encounter (HV) (V2)](#E_Summary_Encounter_HV_V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.234:2016-08-01) (CONF:3247-30737).

Figure 23: Summary Data Section (HV) (V2) Example

<section>

<!-- [HAI R1] HAI Section Generic Constraints -->

<templateId root="2.16.840.1.113883.10.20.5.4.26" />

<!-- [HAI R3D1.1] Summary Data Section (HV) (V2) -->

<templateId root="2.16.840.1.113883.10.20.5.5.57"

extension="2016-08-01" />

<code codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC" code="51900-9"

displayName="Summary Data Section" />

<title>Summary Data</title>

<text>...</text>

<entry typeCode="DRIV">

<!-- No Adverse Reactions Reported This Month Observation -->

<observation classCode="OBS" moodCode="EVN"

negationInd="false">

<!-- [HAI R3D1] No Adverse Reactions Reported This Month Observation -->

<templateId root="2.16.840.1.113883.10.20.5.6.232"

extension="2015-10-01"

/>

...

</observation>

</entry>

<entry typeCode="DRIV">

<!-- No Incidents Reported This Month Observation -->

<observation classCode="OBS" moodCode="EVN"

negationInd="true">

<!-- [HAI R3D1] No Incidents Reported This Month Observation -->

<templateId root="2.16.840.1.113883.10.20.5.6.233"

extension="2015-10-01"

/>

...

</observation>

</entry>

<entry typeCode="DRIV">

<encounter classCode="ENC" moodCode="EVN">

<!-- [HAI R3D1.1] Summary Encounter (HV) (V2)-->

<templateId root="2.16.840.1.113883.10.20.5.6.234"

extension="2016-08-01" />

...

</encounter>

</entry>

</section>

# Entry-Level Templates

Blood Product Usage Summary Observation (V2)

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.5.6.237:2016-08-01 (closed)]

Published as part of NHSN Healthcare Associated Infection (HAI) Reports Release 3, DSTU 1.1 - US Realm

Table 9: Blood Product Usage Summary Observation (V2) Contexts

| Contained By: | Contains: |
| --- | --- |
| [Summary Encounter (HV) (V2)](#E_Summary_Encounter_HV_V2) (required) | [ISBT Product Code Summary Observation (V2)](#E_ISBT_Product_Code_Summary_Observation) |

This template represents the number of units transfused, aliquots transfused, or total discards for each type of blood product.

If the value = 0 or type of product is one of the following, there **SHALL NOT** be a contained observation:

    Red Blood Cells/Whole Blood Derived/Total (3401-7, 3402-5, 3470-2)

    Red Blood Cells/Apheresis/Total (3409-0, 3410-8, 3477-7)

    Platelets/Whole Blood Derived/Total (3417-3, 3484-3)

    Platelets/Apheresis/Total (3421-5, 3422-3, 3490-0)

    Red Blood Cells/Whole Blood Derived/S-303 and Riboflavin Treated/Total (3544-4, 3545-1, 3546-9)

    Red Blood Cells/Apheresis/S-303 and Riboflavin Treated/Total (3553-5, 3554-3, 3555-0)

    Platelets/Whole Blood Derived/Psoralen and Riboflavin Treated/Total (3502-2, 3504-8)

    Platelets/Apheresis/Psoralen and Riboflavin Treated/Total (3511-3, 3512-1, 3513-9)

    Plasma/Whole Blood Derived/Psoralen and Riboflavin Treated/Total (3520-4, 3521-2, 3522-0)

    Plasma/Apheresis/Psoralen and Riboflavin Treated/Total (3529-5, 3530-3, 3531-1)

    Cryoprecipitate/Psoralen and Riboflavin Treated/Total (3562-6, 3563-4)

If the value is > 0 and the type of product is not one of those listed above, then each specific subcategory product that is > 0 **SHALL** be listed in a separate contained ISBT Product Code Summary Observation.

Table 10: Blood Product Usage Summary Observation (V2) Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.237:2016-08-01) | | | | | |
| @classCode | 1..1 | SHALL |  | [3247-30705](#C_3247-30705) | urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
| @moodCode | 1..1 | SHALL |  | [3247-30706](#C_3247-30706) | urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN |
| templateId | 1..1 | SHALL |  | [3247-30701](#C_3247-30701) |  |
| @root | 1..1 | SHALL |  | [3247-30707](#C_3247-30707) | 2.16.840.1.113883.10.20.5.6.237 |
| @extension | 1..1 | SHALL |  | [3247-30714](#C_3247-30714) | 2016-08-01 |
| code | 1..1 | SHALL |  | [3247-30702](#C_3247-30702) |  |
| @code | 1..1 | SHALL |  | [3247-30715](#C_3247-30715) | urn:oid:2.16.840.1.114222.4.11.7353 (NHSN Summary Blood Product Usage) |
| statusCode | 1..1 | SHALL |  | [3247-30703](#C_3247-30703) |  |
| @code | 1..1 | SHALL |  | [3247-30713](#C_3247-30713) | urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed |
| value | 1..1 | SHALL | INT | [3247-30704](#C_3247-30704) |  |
| entryRelationship | 0..\* | SHOULD |  | [3247-30728](#C_3247-30728) |  |
| observation | 1..1 | SHALL |  | [3247-30729](#C_3247-30729) | [ISBT Product Code Summary Observation (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.238:2016-08-01](#E_ISBT_Product_Code_Summary_Observation) |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:3247-30705).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:3247-30706).
3. SHALL contain exactly one [1..1] templateId (CONF:3247-30701) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.5.6.237" (CONF:3247-30707).
   2. SHALL contain exactly one [1..1] @extension="2016-08-01" (CONF:3247-30714).
4. SHALL contain exactly one [1..1] code (CONF:3247-30702).
   1. This code SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet [NHSN Summary Blood Product Usage](#NHSN_Summary_Blood_Product_Usage) urn:oid:2.16.840.1.114222.4.11.7353 DYNAMIC (CONF:3247-30715).
5. SHALL contain exactly one [1..1] statusCode (CONF:3247-30703).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:3247-30713).
6. SHALL contain exactly one [1..1] value with @xsi:type="INT" (CONF:3247-30704).
7. SHOULD contain zero or more [0..\*] entryRelationship (CONF:3247-30728).
   1. The entryRelationship, if present, SHALL contain exactly one [1..1] [ISBT Product Code Summary Observation (V2)](#E_ISBT_Product_Code_Summary_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.238:2016-08-01) (CONF:3247-30729).
8. If the value = 0 or type of product is one of the following, there SHALL NOT be a contained observation:  
       Red Blood Cells/Whole Blood Derived/Total (3401-7, 3402-5, 3470-2)  
       Red Blood Cells/Apheresis/Total (3409-0, 3410-8, 3477-7)  
       Platelets/Whole Blood Derived/Total (3417-3, 3484-3)  
       Platelets/Apheresis/Total (3421-5, 3422-3, 3490-0)  
       Red Blood Cells/Whole Blood Derived/S-303 and Riboflavin Treated/Total (3544-4, 3545-1, 3546-9)  
       Red Blood Cells/Apheresis/S-303 and Riboflavin Treated/Total (3553-5, 3554-3, 3555-0)  
       Platelets/Whole Blood Derived/Psoralen and Riboflavin Treated/Total (3502-2, 3504-8)  
       Platelets/Apheresis/Psoralen and Riboflavin Treated/Total (3511-3, 3512-1, 3513-9)  
       Plasma/Whole Blood Derived/Psoralen and Riboflavin Treated/Total (3520-4, 3521-2, 3522-0)  
       Plasma/Apheresis/Psoralen and Riboflavin Treated/Total (3529-5, 3530-3, 3531-1)  
       Cryoprecipitate/Psoralen and Riboflavin Treated/Total (3562-6, 3563-4)  
   If the value is > 0 and the type of product is not one of those listed above, then each specific subcategory product that is > 0 SHALL be listed in a separate contained ISBT Product Code Summary Observation (CONF:3247-30764).

Table 11: NHSN Summary Blood Product Usage

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: NHSN Summary Blood Product Usage urn:oid:2.16.840.1.114222.4.11.7353  These codes specify the usage for each group of blood product by the type, collection method, and modification or pathogen-reduction methodology.  A full listing of codes can be found in the hai\_voc.xls file provided with this package. | | | |
| Code | Code System | Code System OID | Print Name |
| 3467-8 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Total number of units transfused - Whole blood |
| 3468-6 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Total number of aliquots transfused - Whole blood |
| 3469-4 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Total number of Discards - Whole blood |
| 3401-7 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Total number of units transfused - Red Blood Cells/Whole Blood Derived |
| 3402-5 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Total number of aliquots transfused - Red Blood Cells/Whole Blood Derived |
| 3470-2 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Total number Discards - Red Blood Cells/Whole Blood Derived |
| 3471-0 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Number of units transfused - Red Blood Cells/Whole Blood Derived/Not irradiated or leukocyte reduced |
| 3472-8 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Number of aliquots transfused - Red Blood Cells/Whole Blood Derived/Not irradiated or leukocyte reduced |
| 3473-6 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Number of Discards - Red Blood Cells/Whole Blood Derived/Not irradiated or leukocyte reduced |
| 3403-3 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Number of units transfused - Red Blood Cells/Whole Blood Derived/Irradiated |
| ... | | | |

Figure 24: Blood Product Usage Summary Observation (V2) Example

<observation classCode="OBS" moodCode="EVN">

<!-- [HAI R3D1.1] Blood Product Usage Summary Observation (V2) -->

<templateId root="2.16.840.1.113883.10.20.5.6.237" extension="2016-08-01" />

<code codeSystem="2.16.840.1.113883.6.277"

codeSystemName="cdcNHSN"

code="3467-8"

displayName="Total number of units transfused - Whole blood" />

<statusCode code="completed" />

<value xsi:type="INT" value="100" />

<!--

If the value = 0 or type of product is one of the following,

there SHALL NOT be a contained observation:

Red Blood Cells/Whole Blood Derived/Total (3401-7, 3402-5, 3470-2)

Red Blood Cells/Apheresis/Total (3409-0, 3410-8, 3477-7)

Platelets/Whole Blood Derived/Total (3417-3, 3484-3)

Platelets/Apheresis/Total (3421-5, 3422-3, 3490-0)

Red Blood Cells/Whole Blood Derived/S-303 and Riboflavin Treated/Total (3544-4, 3545-1, 3546-9)

Red Blood Cells/Apheresis/S-303 and Riboflavin Treated/Total (3553-5, 3554-3, 3555-0)

Platelets/Whole Blood Derived/Psoralen and Riboflavin Treated/Total (3502-2, 3504-8)

Platelets/Apheresis/Psoralen and Riboflavin Treated/Total (3511-3, 3512-1, 3513-9)

Plasma/Whole Blood Derived/Psoralen and Riboflavin Treated/Total (3520-4, 3521-2, 3522-0)

Plasma/Apheresis/Psoralen and Riboflavin Treated/Total (3529-5, 3530-3, 3531-1)

Cryoprecipitate/Psoralen and Riboflavin Treated/Total (3562-6, 3563-4)

If the value is > 0 and the type of product is not one of those listed above,

then each specific subcategory product that is > 0 SHALL be listed in a

separate contained ISBT Product Code Summary Observation.

-->

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<!-- ISBT Product Code Summary Observation (V2) -->

<templateId root="2.16.840.1.113883.10.20.5.6.238" extension="2016-08-01" />

..

</observation>

</entryRelationship>

...

</observation>

Facility Transfuses Blood Products Treated with Pathogen Reduction Technology Observation (V2)

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.5.6.236:2016-08-01 (closed)]

Published as part of NHSN Healthcare Associated Infection (HAI) Reports Release 3, DSTU 1.1 - US Realm

Table 12: Facility Transfuses Blood Products Treated with Pathogen Reduction Technology Observation (V2) Contexts

| Contained By: | Contains: |
| --- | --- |
| [Summary Encounter (HV) (V2)](#E_Summary_Encounter_HV_V2) (required) |  |

This clinical statement represents whether or not the facility transfuses blood products treated with pathogen reduction technology.

If the facility does transfuse blood products treated with pathogen reduction technology, set the value of @negationInd to false. If the facility does not transfuse blood products treated with pathogen reduction technology, set the value of @negationInd to true.

Table 13: Facility Transfuses Blood Products Treated with Pathogen Reduction Technology Observation (V2) Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.236:2016-08-01) | | | | | |
| @classCode | 1..1 | SHALL |  | [3247-30698](#C_3247-30698) | urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
| @moodCode | 1..1 | SHALL |  | [3247-30699](#C_3247-30699) | urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN |
| @negationInd | 1..1 | SHALL |  | [3247-30700](#C_3247-30700) |  |
| templateId | 1..1 | SHALL |  | [3247-30690](#C_3247-30690) |  |
| @root | 1..1 | SHALL |  | [3247-30696](#C_3247-30696) | 2.16.840.1.113883.10.20.5.6.236 |
| @extension | 1..1 | SHALL |  | [3247-30697](#C_3247-30697) | 2016-08-01 |
| code | 1..1 | SHALL |  | [3247-30687](#C_3247-30687) |  |
| @code | 1..1 | SHALL | CS | [3247-30691](#C_3247-30691) | ASSERTION |
| @codeSystem | 1..1 | SHALL |  | [3247-30692](#C_3247-30692) | urn:oid:2.16.840.1.113883.5.4 (HL7ActCode) = 2.16.840.1.113883.5.4 |
| statusCode | 1..1 | SHALL |  | [3247-30688](#C_3247-30688) |  |
| @code | 1..1 | SHALL |  | [3247-30693](#C_3247-30693) | urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed |
| value | 1..1 | SHALL | CD | [3247-30689](#C_3247-30689) |  |
| @code | 1..1 | SHALL |  | [3247-30694](#C_3247-30694) | 3542-8 |
| @codeSystem | 1..1 | SHALL |  | [3247-30695](#C_3247-30695) | urn:oid:2.16.840.1.113883.6.277 (cdcNHSN) = 2.16.840.1.113883.6.277 |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 STATIC) (CONF:3247-30698).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001 STATIC) (CONF:3247-30699).

If the facility does transfuse blood products treated with pathogen reduction technology, set the value of @negationInd to false. If the facility does not transfuse blood products treated with pathogen reduction technology, set the value of @negationInd to true.

1. SHALL contain exactly one [1..1] @negationInd (CONF:3247-30700).
2. SHALL contain exactly one [1..1] templateId (CONF:3247-30690) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.5.6.236" (CONF:3247-30696).
   2. SHALL contain exactly one [1..1] @extension="2016-08-01" (CONF:3247-30697).
3. SHALL contain exactly one [1..1] code (CONF:3247-30687).
   1. This code SHALL contain exactly one [1..1] @code="ASSERTION" Assertion (CONF:3247-30691).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.5.4" (CodeSystem: HL7ActCode urn:oid:2.16.840.1.113883.5.4) (CONF:3247-30692).
4. SHALL contain exactly one [1..1] statusCode (CONF:3247-30688).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14 STATIC) (CONF:3247-30693).
5. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:3247-30689).
   1. This value SHALL contain exactly one [1..1] @code="3542-8" Facility transfuses blood products treated with pathogen reduction technology (CONF:3247-30694).
   2. This value SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.277" (CodeSystem: cdcNHSN urn:oid:2.16.840.1.113883.6.277) (CONF:3247-30695).

Figure 25: Facility Transfuses Blood Products Treated with Pathogen Reduction Technology Observation (V2) Example

<!-- Facility Transfuses Blood Products Treated with Pathogen Reduction Technology Observation -->

<!-- If the facility does transfuse blood products treated with pathogen reduction technology,

set the value of @negationInd to false.

If the facility does not transfuse blood products treated with pathogen reduction technology,

set the value of @negationInd to true. -->

<!-- The facility does transfuse blood products treated with pathogen reduction technology

so negationInd='false' -->

<observation classCode="OBS" moodCode="EVN" negationInd="false">

<!-- [HAI R3D1.1] Facility Transfuses Blood Products Treated with

Pathogen Reduction Technology Observation -->

<templateId root="2.16.840.1.113883.10.20.5.6.236" extension="2016-08-01" />

<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />

<statusCode code="completed" />

<value xsi:type="CD"

codeSystem="2.16.840.1.113883.6.277"

codeSystemName="cdcNHSN"

code="3542-8"

displayName="Facility transfuses blood products treated with pathogen reduction technology" />

</observation>

ISBT Product Code Summary Observation (V2)

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.5.6.238:2016-08-01 (closed)]

Published as part of NHSN Healthcare Associated Infection (HAI) Reports Release 3, DSTU 1.1 - US Realm

Table 14: ISBT Product Code Summary Observation (V2) Contexts

| Contained By: | Contains: |
| --- | --- |
| [Blood Product Usage Summary Observation (V2)](#E_Blood_Product_Usage_Summary_Observati) (optional)  [Pathogen Reduced Apheresis Platelet Usage Summary Observation](#E_Pathogen_Reduced_Apheresis_Platelet_U) (optional) |  |

This observation represents the number of units transfused, aliquots transfused, or total discards for each group of blood product split out by type, collection method, and modification or pathogen-reduction methodology, broken down by ISBT (International Society for Blood Transfusion) Product Code.

Table 15: ISBT Product Code Summary Observation (V2) Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.238:2016-08-01) | | | | | |
| @classCode | 1..1 | SHALL |  | [3247-30724](#C_3247-30724) | urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
| @moodCode | 1..1 | SHALL |  | [3247-30725](#C_3247-30725) | urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN |
| templateId | 1..1 | SHALL |  | [3247-30716](#C_3247-30716) |  |
| @root | 1..1 | SHALL |  | [3247-30719](#C_3247-30719) | 2.16.840.1.113883.10.20.5.6.238 |
| @extension | 1..1 | SHALL |  | [3247-30720](#C_3247-30720) | 2016-08-01 |
| code | 1..1 | SHALL |  | [3247-30717](#C_3247-30717) |  |
| statusCode | 1..1 | SHALL |  | [3247-30718](#C_3247-30718) |  |
| @code | 1..1 | SHALL |  | [3247-30722](#C_3247-30722) | urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed |
| value | 1..1 | SHALL | INT | [3247-30723](#C_3247-30723) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:3247-30724).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:3247-30725).
3. SHALL contain exactly one [1..1] templateId (CONF:3247-30716) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.5.6.238" (CONF:3247-30719).
   2. SHALL contain exactly one [1..1] @extension="2016-08-01" (CONF:3247-30720).

**The value sets bound to the code element are detailed in the hai\_voc.xlsx file provided with this package.**

1. SHALL contain exactly one [1..1] code (CONF:3247-30717).
   1. If the product specified in the containing Blood Product Usage Summary Observation is Whole Blood (3467-8, 3468-6, 3469-4), then valueSet NHSN Whole Blood Total (urn:oid:2.16.840.1.114222.4.11.7292) SHALL be used (CONF:3247-30726).
   2. If the product specified in the containing Blood Product Usage Summary Observation is Red Blood Cells/Whole Blood Derived/Not irradiated or Leukocyte Reduced (3471-0, 3472-8, 3473-6), then valueSet NHSN Red Blood Cells/Whole Blood Derived/Not Irradiated or Leukocyte Reduced (urn:oid:2.16.840.1.114222.4.11.7294) SHALL be used (CONF:3247-30727).
   3. If the product specified in the containing Blood Product Usage Summary Observation is Red Blood Cells/Whole Blood Derived/Irradiated (3403-3, 3404-1, 3474-4), then valueSet NHSN Red Blood Cells/Whole Blood Derived/Irradiated (urn:oid:2.16.840.1.114222.4.11.7295) SHALL be used (CONF:3247-30765).
   4. If the product specified in the containing Blood Product Usage Summary Observation is Red Blood Cells/Whole Blood Derived/Irradiated and Leukocyte Reduced (3407-4, 3408-2, 3476-9), then valueSet NHSN Red Blood Cells/Whole Blood Derived/Irradiated and Leukocyte Reduced (urn:oid:2.16.840.1.114222.4.11.7297) SHALL be used (CONF:3247-30766).
   5. If the product specified in the containing Blood Product Usage Summary Observation is Red Blood Cells/Apheresis/Not Irradiated or Leukocyte Reduced (3478-5, 3479-3, 3480-1), then valueSet NHSN Red Blood Cells/Apheresis/Not Irradiated or Leukocyte Reduced (urn:oid:2.16.840.1.114222.4.11.7299) SHALL be used (CONF:3247-30768).
   6. If the product specified in the containing Blood Product Usage Summary Observation is Red Blood Cells/Apheresis/Irradiated (3411-6, 3412-4, 3481-9), then valueSet NHSN Red Blood Cells/Apheresis/Irradiated (urn:oid:2.16.840.1.114222.4.11.7300) SHALL be used (CONF:3247-30742).
   7. If the product specified in the containing Blood Product Usage Summary Observation is Red Blood Cells/Apheresis/Leukocyte Reduced (3413-2, 3414-0, 3482-7), then valueSet NHSN Red Blood Cells/Apheresis/Leukocyte Reduced (urn:oid:2.16.840.1.114222.4.11.7301) SHALL be used (CONF:3247-30743).
   8. If the product specified in the containing Blood Product Usage Summary Observation is Plasma/Apheresis/Riboflavin-Treated (3535-2, 3536-0, 3537-8), then valueSet NHSN Plasma/Apheresis/Riboflavin-Treated (urn:oid:2.16.840.1.114222.4.11.7327) SHALL be used (CONF:3247-30744).
   9. If the product specified in the containing Blood Product Usage Summary Observation is Plasma/Apheresis/Psoralen-Treated (3532-9, 3533-7, 3534-5), then valueSet NHSN Plasma/Apheresis/Psoralen-Treated (urn:oid:2.16.840.1.114222.4.11.7326) SHALL be used (CONF:3247-30745).
   10. If the product specified in the containing Blood Product Usage Summary Observation is Plasma/Whole Blood Derived/Riboflavin-Treated (3526-1, 3527-9, 3528-7), then valueSet NHSN Plasma/Whole Blood Derived/Riboflavin-Treated (urn:oid:2.16.840.1.114222.4.11.7324) SHALL be used (CONF:3247-30746).
   11. If the product specified in the containing Blood Product Usage Summary Observation is Plasma/Whole Blood Derived/Psoralen-Treated (3523-8, 3524-6, 3525-3), then valueSet NHSN Plasma/Whole Blood Derived/Psoralen-Treated (urn:oid:2.16.840.1.114222.4.11.7323) SHALL be used (CONF:3247-30747).
   12. If the product specified in the containing Blood Product Usage Summary Observation is Platelets/Apheresis/Riboflavin-Treated (3517-0, 3518-8, 3519-6 ), then valueSet NHSN Platelets/Apheresis/Riboflavin-Treated (urn:oid:2.16.840.1.114222.4.11.7321) SHALL be used (CONF:3247-30748).
   13. If the product specified in the containing Blood Product Usage Summary Observation is Platelets/Apheresis/Psoralen-Treated (3514-7, 3515-4, 3516-2), then valueSet NHSN Platelets/Apheresis/Psoralen-Treated (urn:oid:2.16.840.1.114222.4.11.7320) SHALL be used (CONF:3247-30749).
   14. If the product specified in the containing Blood Product Usage Summary Observation is Platelets/Whole Blood Derived/Riboflavin-Treated (3517-0, 3518-8), then valueSet NHSN Platelets/Whole Blood Derived/Riboflavin-Treated (urn:oid:2.16.840.1.114222.4.11.7318) SHALL be used (CONF:3247-30750).
   15. If the product specified in the containing Blood Product Usage Summary Observation is Platelets/Whole Blood Derived/Psoralen-Treated (3505-5, 3507-1), then valueSet NHSN Platelets/Whole Blood Derived/Psoralen-Treated (urn:oid:2.16.840.1.114222.4.11.7317) SHALL be used (CONF:3247-30751).
   16. If the product specified in the containing Blood Product Usage Summary Observation is Cryoprecipitate (3562-6, 3563-4), then valueSet NHSN Cryoprecipitate (urn:oid:2.16.840.1.114222.4.11.7315) SHALL be used (CONF:3247-30752).
   17. If the product specified in the containing Blood Product Usage Summary Observation is Plasma/Apheresis/Total (3529-5, 3530-3, 3531-1), then valueSet NHSN Plasma/Apheresis/Total (urn:oid:2.16.840.1.114222.4.11.7314) SHALL be used (CONF:3247-30753).
   18. If the product specified in the containing Blood Product Usage Summary Observation is Plasma/Whole Blood Derived/Total (3520-4, 3521-2, 3522-0), then valueSet NHSN Plasma/Whole Blood Derived/Total (urn:oid:2.16.840.1.114222.4.11.7313) SHALL be used (CONF:3247-30754).
   19. If the product specified in the containing Blood Product Usage Summary Observation is Platelets/Apheresis/Irradiated or Leukocyte Reduced (3427-2, 3428-0, 3496-7), then valueSet NHSN Platelets/Apheresis/Irradiated or Leukocyte Reduced (urn:oid:2.16.840.1.114222.4.11.7312) SHALL be used (CONF:3247-30755).
   20. If the product specified in the containing Blood Product Usage Summary Observation is Platelets/Apheresis/Leukocyte Reduced (3425-6, 3426-4, 3495-9), then valueSet NHSN Platelets/Apheresis/Leukocyte Reduced (urn:oid:2.16.840.1.114222.4.11.7311) SHALL be used (CONF:3247-30756).
   21. If the product specified in the containing Blood Product Usage Summary Observation is Platelets/Apheresis/Irradiated (3423-1, 3424-9, 3494-2), then valueSet NHSN Platelets/Apheresis/Irradiated (urn:oid:2.16.840.1.114222.4.11.7310) SHALL be used (CONF:3247-30757).
   22. If the product specified in the containing Blood Product Usage Summary Observation is Platelets/Apheresis/Not Irradiated or Leukocyte Reduced (3491-8, 3492-6, 3493-4), then valueSet NHSN Platelets/Apheresis/Not Irradiated or Leukocyte Reduced (urn:oid:2.16.840.1.114222.4.11.7309) SHALL be used (CONF:3247-30758).
   23. If the product specified in the containing Blood Product Usage Summary Observation is Platelets/Whole Blood Derived/Irradiated and Leukocyte Reduced (3420-7, 3489-2), then valueSet NHSN Platelets/Whole Blood Derived/Irradiated and Leukocyte Reduced (urn:oid:2.16.840.1.114222.4.11.7307) SHALL be used (CONF:3247-30759).
   24. If the product specified in the containing Blood Product Usage Summary Observation is Platelets/Whole Blood Derived/Leukocyte Reduced (3419-9, 3488-4), then valueSet NHSN Platelets/Whole Blood Derived/Leukocyte Reduced (urn:oid:2.16.840.1.114222.4.11.7306) SHALL be used (CONF:3247-30760).
   25. If the product specified in the containing Blood Product Usage Summary Observation is Platelets/Whole Blood Derived/Irradiated (3418-1, 3487-6), then valueSet NHSN Platelets/Whole Blood Derived/Irradiated (urn:oid:2.16.840.1.114222.4.11.7305) SHALL be used (CONF:3247-30761).
   26. If the product specified in the containing Blood Product Usage Summary Observation is Platelets/Whole Blood Derived/Not Irradiated or Leukocyte Reduced (3485-0, 3486-8), then valueSet NHSN Platelets/Whole Blood Derived/Not Irradiated or Leukocyte Reduced (urn:oid:2.16.840.1.114222.4.11.7304) SHALL be used (CONF:3247-30762).
   27. If the product specified in the containing Blood Product Usage Summary Observation is Red Blood Cells/Apheresis/Irradiated or Leukocyte Reduced (3415-7, 3416-5, 3483-5), then valueSet NHSN Red Blood Cells/Apheresis/Irradiated or Leukocyte Reduced (urn:oid:2.16.840.1.114222.4.11.7302) SHALL be used (CONF:3247-30763).
   28. If the product specified in the containing Blood Product Usage Summary Observation is Red Blood Cells/Whole Blood Derived/Leukocyte Reduced (3405-8, 3406-6, 3475-1), then valueSet NHSN Red Blood Cells/Whole Blood Derived/Leukocyte Reduced (urn:oid:2.16.840.1.114222.4.11.7296) SHALL be used (CONF:3247-30767).
   29. If the product specified in the containing Blood Product Usage Summary Observation is Red Blood Cells/Whole Blood Derived/S-303-Treated (3547-7, 3548-5, 3549-3), then valueSet NHSN Red Blood Cells/Whole Blood Derived/S-303-Treated (urn:oid:2.16.840.1.114222.4.11.7498) SHALL be used (CONF:3247-30769).
   30. If the product specified in the containing Blood Product Usage Summary Observation is Red Blood Cells/Whole Blood Derived/Riboflavin-Treated (3550-1, 3551-9, 3552-7), then valueSet NHSN Red Blood Cells/Whole Blood Derived/Riboflavin-Treated (urn:oid:2.16.840.1.114222.4.11.7499) SHALL be used (CONF:3247-30770).
   31. If the product specified in the containing Blood Product Usage Summary Observation is Red Blood Cells/Apheresis/S-303-Treated (3556-8, 3557-6, 3558-4), then valueSet NHSN Red Blood Cells/Apheresis/S-303-Treated (urn:oid:2.16.840.1.114222.4.11.7500) SHALL be used (CONF:3247-30771).
   32. If the product specified in the containing Blood Product Usage Summary Observation is Red Blood Cells/Apheresis/Riboflavin-Treated (3559-2, 3560-0, 3561-8), then valueSet NHSN Red Blood Cells/Apheresis/Riboflavin-Treated (urn:oid:2.16.840.1.114222.4.11.7501) SHALL be used (CONF:3247-30772).
   33. If the product specified in the containing Blood Product Usage Summary Observation is Cryoprecipitate/Psoralen-Treated (3564-2, 3565-9), then valueSet NHSN Cryoprecipitate/Psoralen-Treated (urn:oid:2.16.840.1.114222.4.11.7502) SHALL be used (CONF:3247-30773).
   34. If the product specified in the containing Blood Product Usage Summary Observation is Cryoprecipitate/Psoralen-Treated (3566-7, 3567-5), then valueSet NHSN Cryoprecipitate/Psoralen-Treated (urn:oid:2.16.840.1.114222.4.11.7502) SHALL be used (CONF:3247-30774).
   35. If the product specified in the containing Blood Product Usage Summary Observation is Platelets/Apheresis/Psoralen-Treated and In Plasma (3568-3, 3569-1, 3570-9), then valueSet NHSN Platelets/Apheresis/Psoralen-Treated and In Plasma (urn:oid:2.16.840.1.114222.4.11.7504) SHALL be used (CONF:3247-30775).
   36. If the product specified in the containing Blood Product Usage Summary Observation is Platelets/Apheresis/Psoralen-Treated and In Platelet Additive Solution (3571-7, 3572-5, 3573-3), then valueSet NHSN Platelets/Apheresis/Psoralen-Treated (urn:oid:2.16.840.1.114222.4.11.7320) SHALL be used (CONF:3247-30776).
   37. If the product specified in the containing Blood Product Usage Summary Observation is Platelets/Apheresis/Riboflavin-Treated and In Plasma (3574-1, 3575-8, 3576-6), then valueSet NHSN Platelets/Apheresis/Riboflavin-Treated and In Plasma (urn:oid:2.16.840.1.114222.4.11.7506) SHALL be used (CONF:3247-30777).
   38. If the product specified in the containing Blood Product Usage Summary Observation is Platelets/Apheresis/Riboflavin-Treated and In Platelet Additive Solution (3577-4, 3578-2, 3579-0), then valueSet NHSN Platelets/Apheresis/Riboflavin-Treated and In Platelet Additive Solution (urn:oid:2.16.840.1.114222.4.11.7507) SHALL be used (CONF:3247-30778).
2. SHALL contain exactly one [1..1] statusCode (CONF:3247-30718).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:3247-30722).
3. SHALL contain exactly one [1..1] value with @xsi:type="INT" (CONF:3247-30723).

Table 16: NHSN Plasma/Apheresis/Psoralen-Treated

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: NHSN Plasma/Apheresis/Psoralen-Treated urn:oid:2.16.840.1.114222.4.11.7326  NHSN Protocol specifies which ISBT Blood Product codes to use for each blood product type.  The ISBT blood product codes for NHSN Plasma/Apheresis/Psoralen-Treated reporting, at the time of publication, are contained in this table.  A full listing of codes can be found in the hai\_voc.xls file provided with this package. | | | |
| Code | Code System | Code System OID | Print Name |
| E4984 | ISBT-128 | urn:oid:2.16.840.1.113883.6.18 | Apheresis FRESH FROZEN PLASMA|CPD-50/XX/<-30C|Psoralen-treated |
| E5732 | ISBT-128 | urn:oid:2.16.840.1.113883.6.18 | Apheresis FRESH FROZEN PLASMA|CPD-50/XX/<-25 C|1st container|Psoralen-treated |
| E5733 | ISBT-128 | urn:oid:2.16.840.1.113883.6.18 | Apheresis FRESH FROZEN PLASMA|CPD-50/XX/<-25 C|2nd container|Psoralen-treated |
| ... | | | |

Figure 26: ISBT Product Code Summary Observation Example

<observation classCode="OBS" moodCode="EVN">

<!-- ISBT Product Code Summary Observation -->

<templateId root="2.16.840.1.113883.10.20.5.6.238"

extension="2015-10-01" />

<code codeSystem="2.16.840.1.113883.6.18"

codeSystemName="ISBT-128" code="E0009"

displayName="WHOLE BLOOD|CPD/450mL/refg" />

<statusCode code="completed" />

<value xsi:type="INT" value="2" />

</observation>

No Hemovigilance Adverse Reactions Reported This Month Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.5.6.232:2015-10-01 (closed)]

Published as part of NHSN Healthcare Associated Infection (HAI) Reports Release 3, DSTU 1 - US Realm

Table 17: No Hemovigilance Adverse Reactions Reported This Month Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Summary Data Section (HV) (V2)](#S_Summary_Data_Section_HV_V2) (required) |  |

This clinical statement represents whether or not there were no hemovigilance adverse reactions reported this month.

If there were no hemovigilance adverse reactions reported this month, set the value of @negationInd to false, otherwise, set the value of @negationInd to true.

On the form from which this template is modeled, this datum is reported as a check box stating that there were no hemovigilance adverse reactions reported this month. Thus, this template reports a "negative" finding. To report that this check box was not checked is to say that it is not the case that no hemovigilance adverse reactions were reported this month, which is subtly different from stating that there were hemovigilance adverse reactions reported this month. Because we are reporting a "negative" finding, negating the statement necessitates some seemingly counter-intuitive logic as follows:

* No hemovigilance adverse reactions reported this month = ASSERTION + negationInd="false" (the assertion that there were no HV adverse reactions is not negated)
* Otherwise = ASSERTION + negationInd="true" (the assertion that there were no HV adverse reactions is negated).

Table 18: No Hemovigilance Adverse Reactions Reported This Month Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.232:2015-10-01) | | | | | |
| @classCode | 1..1 | SHALL |  | [1202-30632](#C_1202-30632) | urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
| @moodCode | 1..1 | SHALL |  | [1202-30633](#C_1202-30633) | urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN |
| @negationInd | 1..1 | SHALL |  | [1202-30634](#C_1202-30634) |  |
| templateId | 1..1 | SHALL |  | [1202-30627](#C_1202-30627) |  |
| @root | 1..1 | SHALL |  | [1202-30635](#C_1202-30635) | 2.16.840.1.113883.10.20.5.6.232 |
| @extension | 1..1 | SHALL |  | [1202-30636](#C_1202-30636) | 2015-10-01 |
| code | 1..1 | SHALL |  | [1202-30624](#C_1202-30624) |  |
| @code | 1..1 | SHALL | CS | [1202-30628](#C_1202-30628) | ASSERTION |
| @codeSystem | 1..1 | SHALL |  | [1202-30629](#C_1202-30629) | urn:oid:2.16.840.1.113883.5.4 (HL7ActCode) = 2.16.840.1.113883.5.4 |
| statusCode | 1..1 | SHALL |  | [1202-30625](#C_1202-30625) |  |
| @code | 1..1 | SHALL |  | [1202-30630](#C_1202-30630) | urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed |
| value | 1..1 | SHALL | CD | [1202-30626](#C_1202-30626) |  |
| @code | 1..1 | SHALL |  | [1202-30631](#C_1202-30631) | 3540-2 |
| @codeSystem | 1..1 | SHALL |  | [1202-30651](#C_1202-30651) | urn:oid:2.16.840.1.113883.6.277 (cdcNHSN) = 2.16.840.1.113883.6.277 |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 STATIC) (CONF:1202-30632).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001 STATIC) (CONF:1202-30633).

If there were no hemovigilance adverse reactions reported this month, set the value of @negationInd to false. If there were hemovigilance adverse reactions reported this month, set the value of @negationInd to true.

1. SHALL contain exactly one [1..1] @negationInd (CONF:1202-30634).
2. SHALL contain exactly one [1..1] templateId (CONF:1202-30627) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.5.6.232" (CONF:1202-30635).
   2. SHALL contain exactly one [1..1] @extension="2015-10-01" (CONF:1202-30636).
3. SHALL contain exactly one [1..1] code (CONF:1202-30624).
   1. This code SHALL contain exactly one [1..1] @code="ASSERTION" Assertion (CONF:1202-30628).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.5.4" (CodeSystem: HL7ActCode urn:oid:2.16.840.1.113883.5.4) (CONF:1202-30629).
4. SHALL contain exactly one [1..1] statusCode (CONF:1202-30625).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14 STATIC) (CONF:1202-30630).
5. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:1202-30626).
   1. This value SHALL contain exactly one [1..1] @code="3540-2" No hemovigilance adverse reactions reported this month (CONF:1202-30631).
   2. This value SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.277" (CodeSystem: cdcNHSN urn:oid:2.16.840.1.113883.6.277) (CONF:1202-30651).

Figure 27: No Hemovigilance Adverse Reactions Reported This Month Observation Example

<!-- If there were no hemovigilance adverse reactions reported this month,

set the value of @negationInd to false.

If there were hemovigilance adverse reactions reported this month,

set the value of @negationInd to true. -->

<!-- There were no hemovigilance adverse reactions reported this month so negationInd='false' -->

<observation classCode="OBS" moodCode="EVN" negationInd="false">

<!-- No Hemovigilance Adverse Reactions Reported This Month Observation templateId -->

<templateId root="2.16.840.1.113883.10.20.5.6.232"

extension="2015-10-01" />

<code code="ASSERTION"

codeSystem="2.16.840.1.113883.5.4" />

<statusCode code="completed"/>

<value xsi:type="CD"

codeSystem="2.16.840.1.113883.6.277"

codeSystemName="cdcNHSN"

code="3540-2"

displayName="No hemovigilance adverse reactions reported this month" />

</observation>

No Hemovigilance Incidents Reported This Month Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.5.6.233:2015-10-01 (closed)]

Published as part of NHSN Healthcare Associated Infection (HAI) Reports Release 3, DSTU 1 - US Realm

Table 19: No Hemovigilance Incidents Reported This Month Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Summary Data Section (HV) (V2)](#S_Summary_Data_Section_HV_V2) (required) |  |

This clinical statement represents whether or not there were no hemovigilance incidents reported this month.

If there were no hemovigilance incidents reported this month, set the value of @negationInd to false, otherwise, set the value of @negationInd to true.

On the form from which this template is modeled, this datum is reported as a check box stating that there were no incidents reported this month. Thus, this template reports a "negative" finding. To report that this check box was not checked is to say that it is not the case that no hemovigilance incidents were reported this month, which is subtly different from stating that there were hemovigilance incidents reported this month. Because we are reporting a "negative" finding, negating the statement necessitates some seemingly counter-intuitive logic as follows:

* No hemovigilance incidents reported this month = ASSERTION + negationInd="false" (the assertion that there were no HV incidents is not negated)
* Otherwise = ASSERTION + negationInd="true" (the assertion that there were no HV incidents is negated).

Table 20: No Hemovigilance Incidents Reported This Month Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.233:2015-10-01) | | | | | |
| @classCode | 1..1 | SHALL |  | [1202-30647](#C_1202-30647) | urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
| @moodCode | 1..1 | SHALL |  | [1202-30648](#C_1202-30648) | urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN |
| @negationInd | 1..1 | SHALL |  | [1202-30649](#C_1202-30649) |  |
| templateId | 1..1 | SHALL |  | [1202-30640](#C_1202-30640) |  |
| @root | 1..1 | SHALL |  | [1202-30645](#C_1202-30645) | 2.16.840.1.113883.10.20.5.6.233 |
| @extension | 1..1 | SHALL |  | [1202-30646](#C_1202-30646) | 2015-10-01 |
| code | 1..1 | SHALL |  | [1202-30637](#C_1202-30637) |  |
| @code | 1..1 | SHALL | CS | [1202-30641](#C_1202-30641) | ASSERTION |
| @codeSystem | 1..1 | SHALL |  | [1202-30642](#C_1202-30642) | urn:oid:2.16.840.1.113883.5.4 (HL7ActCode) = 2.16.840.1.113883.5.4 |
| statusCode | 1..1 | SHALL |  | [1202-30638](#C_1202-30638) |  |
| @code | 1..1 | SHALL |  | [1202-30643](#C_1202-30643) | urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed |
| value | 1..1 | SHALL | CD | [1202-30639](#C_1202-30639) |  |
| @code | 1..1 | SHALL |  | [1202-30644](#C_1202-30644) | 3541-0 |
| @codeSystem | 1..1 | SHALL |  | [1202-30650](#C_1202-30650) | urn:oid:2.16.840.1.113883.6.277 (cdcNHSN) = 2.16.840.1.113883.6.277 |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 STATIC) (CONF:1202-30647).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001 STATIC) (CONF:1202-30648).

If there were no hemovigilance incidents reported this month, set the value of @negationInd to false. If there were hemovigilance incidents reported this month, set the value of @negationInd to true.

1. SHALL contain exactly one [1..1] @negationInd (CONF:1202-30649).
2. SHALL contain exactly one [1..1] templateId (CONF:1202-30640) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.5.6.233" (CONF:1202-30645).
   2. SHALL contain exactly one [1..1] @extension="2015-10-01" (CONF:1202-30646).
3. SHALL contain exactly one [1..1] code (CONF:1202-30637).
   1. This code SHALL contain exactly one [1..1] @code="ASSERTION" Assertion (CONF:1202-30641).
   2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.5.4" (CodeSystem: HL7ActCode urn:oid:2.16.840.1.113883.5.4) (CONF:1202-30642).
4. SHALL contain exactly one [1..1] statusCode (CONF:1202-30638).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14 STATIC) (CONF:1202-30643).
5. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:1202-30639).
   1. This value SHALL contain exactly one [1..1] @code="3541-0" No hemovigilance incidents reported this month (CONF:1202-30644).
   2. This value SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.277" (CodeSystem: cdcNHSN urn:oid:2.16.840.1.113883.6.277) (CONF:1202-30650).

Figure 28: No Hemovigilance Incidents Reported This Month Observation

<!-- No Hemovigilance Incidents Reported This Month Observation -->

<!-- If there were no hemovigilance incidents reported this month,

set the value of @negationInd to false.

If there were hemovigilance incidents reported this month,

set the value of @negationInd to true. -->

<!-- There were hemovigilance incidents reported this month so negationInd='true' -->

<observation classCode="OBS" moodCode="EVN" negationInd="true">

<!-- No Hemovigilance Incidents Reported This Month Observation -->

<templateId root="2.16.840.1.113883.10.20.5.6.233"

extension="2015-10-01" />

<code code="ASSERTION"

codeSystem="2.16.840.1.113883.5.4" />

<statusCode code="completed"/>

<value xsi:type="CD"

codeSystem="2.16.840.1.113883.6.277"

codeSystemName="cdcNHSN" code="3541-0"

displayName="No hemovigilance incidents reported this month" />

</observation>

Pathogen Reduced Apheresis Platelet Usage Summary Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.5.6.240:2016-08-01 (closed)]

Published as part of NHSN Healthcare Associated Infection (HAI) Reports Release 3, DSTU 1.1 - US Realm

Table 21: Pathogen Reduced Apheresis Platelet Usage Summary Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [Summary Encounter (HV) (V2)](#E_Summary_Encounter_HV_V2) (optional) | [ISBT Product Code Summary Observation (V2)](#E_ISBT_Product_Code_Summary_Observation) |

This template represents the number of units transfused, aliquots transfused, or total discards for pathogen reduced apheresis platelets.

If the value = 0, there **SHALL NOT** be a contained observation. If the value is > 0 then each specific subcategory product that is > 0 **SHALL** be listed in a separate contained ISBT Product Code Summary Observation.

Table 22: Pathogen Reduced Apheresis Platelet Usage Summary Observation Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.240:2016-08-01) | | | | | |
| @classCode | 1..1 | SHALL |  | [3247-30789](#C_3247-30789) | urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
| @moodCode | 1..1 | SHALL |  | [3247-30790](#C_3247-30790) | urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN |
| templateId | 1..1 | SHALL |  | [3247-30780](#C_3247-30780) |  |
| @root | 1..1 | SHALL |  | [3247-30784](#C_3247-30784) | 2.16.840.1.113883.10.20.5.6.240 |
| @extension | 1..1 | SHALL |  | [3247-30785](#C_3247-30785) | 2016-08-01 |
| code | 1..1 | SHALL |  | [3247-30781](#C_3247-30781) |  |
| @code | 1..1 | SHALL |  | [3247-30786](#C_3247-30786) | urn:oid:2.16.840.1.113883.10.20.5.9.5 (NHSN Pathogen Reduced Apheresis Platelet Usage) |
| statusCode | 1..1 | SHALL |  | [3247-30782](#C_3247-30782) |  |
| @code | 1..1 | SHALL |  | [3247-30787](#C_3247-30787) | urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed |
| value | 1..1 | SHALL | INT | [3247-30788](#C_3247-30788) |  |
| entryRelationship | 0..\* | SHOULD |  | [3247-30779](#C_3247-30779) |  |
| observation | 1..1 | SHALL |  | [3247-30783](#C_3247-30783) | [ISBT Product Code Summary Observation (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.238:2016-08-01](#E_ISBT_Product_Code_Summary_Observation) |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:3247-30789).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:3247-30790).
3. SHALL contain exactly one [1..1] templateId (CONF:3247-30780) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.5.6.240" (CONF:3247-30784).
   2. SHALL contain exactly one [1..1] @extension="2016-08-01" (CONF:3247-30785).
4. SHALL contain exactly one [1..1] code (CONF:3247-30781).
   1. This code SHALL contain exactly one [1..1] @code, which SHALL be selected from ValueSet [NHSN Pathogen Reduced Apheresis Platelet Usage](#NHSN_Pathogen_Reduced_Apheresis_Platele) urn:oid:2.16.840.1.113883.10.20.5.9.5 DYNAMIC (CONF:3247-30786).
5. SHALL contain exactly one [1..1] statusCode (CONF:3247-30782).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:3247-30787).
6. SHALL contain exactly one [1..1] value with @xsi:type="INT" (CONF:3247-30788).
7. SHOULD contain zero or more [0..\*] entryRelationship (CONF:3247-30779).
   1. The entryRelationship, if present, SHALL contain exactly one [1..1] [ISBT Product Code Summary Observation (V2)](#E_ISBT_Product_Code_Summary_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.238:2016-08-01) (CONF:3247-30783).
8. If the value = 0 there SHALL NOT be a contained observation. If the value is > 0 then each specific subcategory product that is > 0 SHALL be listed in a separate contained ISBT Product Code Summary Observation (CONF:3247-30791).

Table 23: NHSN Pathogen Reduced Apheresis Platelet Usage

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: NHSN Pathogen Reduced Apheresis Platelet Usage urn:oid:2.16.840.1.113883.10.20.5.9.5 | | | |
| Code | Code System | Code System OID | Print Name |
| 3568-3 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Number of units transfused - Platelets/Apheresis/Psoralen-Treated and in Plasma |
| 3569-1 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Number of aliquots transfused - Platelets/Apheresis/Psoralen-Treated and in Plasma |
| 3570-9 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Number of Discards -Platelets - Platelets/Apheresis/Psoralen-Treated and in Plasma |
| 3571-7 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Number of units transfused - Platelets/Apheresis/Psoralen-Treated and in Platelet Additive Solution |
| 3572-5 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Number of aliquots transfused - Platelets/Apheresis/Psoralen-Treated and in Platelet Additive Solution |
| 3573-3 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Number of Discards - Platelets/Apheresis/Psoralen-Treated and in Platelet Additive Solution |
| 3574-1 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Number of units transfused - Platelets/Apheresis/Riboflavin-Treated and in Plasma |
| 3575-8 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Number of aliquots transfused - Platelets/Apheresis/Riboflavin-Treated and in Plasma |
| 3576-6 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Number of Discards - Platelets/Apheresis/Riboflavin-Treated and in Plasma |
| 3577-4 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Number of units transfused - Platelets/Apheresis/Riboflavin-Treated and in Platelet Additive Solution |
| ... | | | |

Figure 29: Pathogen Reduced Apheresis Platelet Usage Summary Example

<observation classCode="OBS" moodCode="EVN">

<!-- [HAI R3D1.1] Pathogen Reduced Apheresis Platelet Usage Summary Observation -->

<templateId root="2.16.840.1.113883.10.20.5.6.240" extension="2016-08-01" />

<code codeSystem="2.16.840.1.113883.6.277"

codeSystemName="cdcNHSN"

code="3571-7"

displayName="Number of units transfused - Platelets/Apheresis/Psoralen-Treated and in Platelet Additive Solution" />

<statusCode code="completed" />

<value xsi:type="INT" value="75" />

<!--

If the value = 0, there SHALL NOT be a contained observation.

If the value is > 0 then each specific subcategory product that is > 0

SHALL be listed in a separate contained ISBT Product Code Summary Observation.

-->

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<!-- ISBT Product Code Summary Observation (V2) -->

<templateId root="2.16.840.1.113883.10.20.5.6.238" extension="2016-08-01" />

...

</observation>

</entryRelationship>

...

</observation>

Summary Data Observation (HV)

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.5.6.235:2015-10-01 (closed)]

Published as part of NHSN Healthcare Associated Infection (HAI) Reports Release 3, DSTU 1 - US Realm

Table 24: Summary Data Observation (HV) Contexts

| Contained By: | Contains: |
| --- | --- |
| [Summary Encounter (HV) (V2)](#E_Summary_Encounter_HV_V2) (required) |  |

This template specializes the Summary Data Observation for an HAI Hemovigilance (HV) Summary Report.

The documentationOf/serviceEvent/code in the header identifies the intended content of the report. NHSN protocol specifies which data to report for each type of content. The data required by NHSN for each type of content, at time of publication, are shown in the tables below.

The table of codes for a particular report indicate what data are required at time of publication for the NHSN protocol. Accordingly, the Summary Encounter will contain the same number of Summary Data Observations as codes in the table.

Most Summary Data Observations are a simple code-value pair. The code element identifies the datum being reported, and the value element records a number of days, patients, episodes, or events.

Table 25: Summary Data Observation (HV) Constraints Overview

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| XPath | Card. | Verb | Data Type | CONF# | Value |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.235:2015-10-01) | | | | | |
| @classCode | 1..1 | SHALL |  | [1202-30675](#C_1202-30675) | urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
| @moodCode | 1..1 | SHALL |  | [1202-30676](#C_1202-30676) | urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN |
| templateId | 1..1 | SHALL |  | [1202-30671](#C_1202-30671) |  |
| @root | 1..1 | SHALL |  | [1202-30677](#C_1202-30677) | 2.16.840.1.113883.10.20.5.6.235 |
| @extension | 1..1 | SHALL |  | [1202-30684](#C_1202-30684) | 2015-10-01 |
| code | 1..1 | SHALL |  | [1202-30672](#C_1202-30672) | urn:oid:2.16.840.1.113883.10.20.5.9.11 (Codes for Hemovigilance (HV) Summary Data) |
| statusCode | 1..1 | SHALL |  | [1202-30673](#C_1202-30673) |  |
| @code | 1..1 | SHALL |  | [1202-30683](#C_1202-30683) | urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed |
| value | 1..1 | SHALL | INT | [1202-30674](#C_1202-30674) |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:1202-30675).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:1202-30676).
3. SHALL contain exactly one [1..1] templateId (CONF:1202-30671) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.5.6.235" (CONF:1202-30677).
   2. SHALL contain exactly one [1..1] @extension="2015-10-01" (CONF:1202-30684).
4. SHALL contain exactly one [1..1] code, which SHOULD be selected from ValueSet [Codes for Hemovigilance (HV) Summary Data](#Codes_for_Hemovigilance_HV_Summary_Data) urn:oid:2.16.840.1.113883.10.20.5.9.11 DYNAMIC (CONF:1202-30672).
5. SHALL contain exactly one [1..1] statusCode (CONF:1202-30673).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:1202-30683).
6. SHALL contain exactly one [1..1] value with @xsi:type="INT" (CONF:1202-30674).

Table 26: Codes for Hemovigilance (HV) Summary Data

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: Codes for Hemovigilance (HV) Summary Data urn:oid:2.16.840.1.113883.10.20.5.9.11  NHSN protocol specifies which data to report for each type of content. The data required by NHSN for IV Summary, at the time of publication, is contained in this table.   A full listing of codes can be found in the hai\_voc.xls file provided with this package. | | | |
| Code | Code System | Code System OID | Print Name |
| 3436-3 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Number of Patient samples collected for type and screen or crossmatch |
| 3538-6 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Total crossmatch procedures |
| 3539-4 | cdcNHSN | urn:oid:2.16.840.1.113883.6.277 | Total patients transfused |

Figure 30: Summary Data Observation (HV) Example

<observation classCode="OBS" moodCode="EVN">

<!-- Summary Data Observation (HV) -->

<templateId root="2.16.840.1.113883.10.20.5.6.235"

extension="2015-10-01" />

<code codeSystem="2.16.840.1.113883.6.277"

codeSystemName="cdcNHSN"

code="3539-4"

displayName="Total patients transfused" />

<statusCode code="completed" />

<value xsi:type="INT" value="74" />

</observation>

Summary Encounter (HV) (V2)

[encounter: identifier urn:hl7ii:2.16.840.1.113883.10.20.5.6.234:2016-08-01 (closed)]

Published as part of NHSN Healthcare Associated Infection (HAI) Reports Release 3, DSTU 1.1 - US Realm

Table 27: Summary Encounter (HV) (V2) Contexts

| Contained By: | Contains: |
| --- | --- |
| [Summary Data Section (HV) (V2)](#S_Summary_Data_Section_HV_V2) (required) | [Blood Product Usage Summary Observation (V2)](#E_Blood_Product_Usage_Summary_Observati)  [Facility Transfuses Blood Products Treated with Pathogen Reduction Technology Observation (V2)](#E_Facility_Transfuses_Blood_Products_Tr)  [Pathogen Reduced Apheresis Platelet Usage Summary Observation](#E_Pathogen_Reduced_Apheresis_Platelet_U)  [Summary Data Observation (HV)](#E_Summary_Data_Observation_HV) |

A Summary Encounter records a set of summary data, usually for a population such as the patients in a ward in a specified period. The NHSN protocol defines which data to record for each type of summary report.

For a Hemovigilance Summary Report, each datum is recorded as a Summary Data Observation (HV).  The data requirements at time of publication are shown in a table under the Summary Data Observation (HV) template, above.

The Summary Encounter (HV) includes a Blood Product Usage Summary Observation for each type of blood product being reported and, conditionally (if the facility transfused pathogen reduced apheresis platelets), a Pathogen Reduced Apheresis Platelet Usage Summary Observation for each type of pathogen reduced apheresis platelet being reported.

A participant element records the location to which the data pertains. The location id has the form <id root=”…” extension=”…”/> with an extension of 'FACWIDEIN' representing the whole facility.

Table 28: Summary Encounter (HV) (V2) Constraints Overview

| XPath | Card. | Verb | Data Type | CONF# | Value |
| --- | --- | --- | --- | --- | --- |
| encounter (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.234:2016-08-01) | | | | | |
| @classCode | 1..1 | SHALL |  | [3247-30669](#C_3247-30669) | urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = ENC |
| @moodCode | 1..1 | SHALL |  | [3247-30670](#C_3247-30670) | urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN |
| templateId | 1..1 | SHALL |  | [3247-30653](#C_3247-30653) |  |
| @root | 1..1 | SHALL |  | [3247-30660](#C_3247-30660) | 2.16.840.1.113883.10.20.5.6.234 |
| @extension | 1..1 | SHALL |  | [3247-30661](#C_3247-30661) | 2016-08-01 |
| participant | 1..1 | SHALL |  | [3247-30654](#C_3247-30654) |  |
| @typeCode | 1..1 | SHALL |  | [3247-30668](#C_3247-30668) | urn:oid:2.16.840.1.113883.5.90 (HL7ParticipationType) = LOC |
| participantRole | 1..1 | SHALL |  | [3247-30655](#C_3247-30655) |  |
| @classCode | 1..1 | SHALL |  | [3247-30667](#C_3247-30667) | urn:oid:2.16.840.1.113883.5.41 (HL7EntityClass) = SDLOC |
| id | 1..1 | SHALL |  | [3247-30656](#C_3247-30656) |  |
| @root | 1..1 | SHALL |  | [3247-30662](#C_3247-30662) |  |
| @extension | 1..1 | SHALL |  | [3247-30663](#C_3247-30663) | FACWIDEIN |
| code | 1..1 | SHALL |  | [3247-30657](#C_3247-30657) | urn:oid:2.16.840.1.113883.6.259 (HL7 HealthcareServiceLocation) |
| @code | 1..1 | SHALL |  | [3247-30664](#C_3247-30664) | 1250-0 |
| @codeSystem | 1..1 | SHALL |  | [3247-30665](#C_3247-30665) | 2.16.840.1.113883.6.259 |
| @displayName | 1..1 | SHOULD |  | [3247-30666](#C_3247-30666) | Facility Wide Inpatient |
| entryRelationship | 1..\* | SHALL |  | [3247-30652](#C_3247-30652) |  |
| @typeCode | 1..1 | SHALL |  | [3247-30659](#C_3247-30659) | urn:oid:2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP |
| observation | 1..1 | SHALL |  | [3247-30658](#C_3247-30658) | [Facility Transfuses Blood Products Treated with Pathogen Reduction Technology Observation (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.236:2016-08-01](#E_Facility_Transfuses_Blood_Products_Tr) |
| entryRelationship | 1..\* | SHALL |  | [3247-30733](#C_3247-30733) |  |
| @typeCode | 1..1 | SHALL |  | [3247-30734](#C_3247-30734) | COMP |
| observation | 1..1 | SHALL |  | [3247-30735](#C_3247-30735) | [Blood Product Usage Summary Observation (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.237:2016-08-01](#E_Blood_Product_Usage_Summary_Observati) |
| entryRelationship | 0..\* | MAY |  | [3247-30792](#C_3247-30792) |  |
| observation | 1..1 | SHALL |  | [3247-30793](#C_3247-30793) | [Pathogen Reduced Apheresis Platelet Usage Summary Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.240:2016-08-01](#E_Pathogen_Reduced_Apheresis_Platelet_U) |
| entryRelationship | 1..\* | SHALL |  | [3247-30730](#C_3247-30730) |  |
| @typeCode | 1..1 | SHALL |  | [3247-30731](#C_3247-30731) | COMP |
| observation | 1..1 | SHALL |  | [3247-30732](#C_3247-30732) | [Summary Data Observation (HV) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.235:2015-10-01](#E_Summary_Data_Observation_HV) |

1. SHALL contain exactly one [1..1] @classCode="ENC" Encounter (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 STATIC) (CONF:3247-30669).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001 STATIC) (CONF:3247-30670).
3. SHALL contain exactly one [1..1] templateId (CONF:3247-30653) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.5.6.234" (CONF:3247-30660).
   2. SHALL contain exactly one [1..1] @extension="2016-08-01" (CONF:3247-30661).
4. SHALL contain exactly one [1..1] participant (CONF:3247-30654) such that it
   1. SHALL contain exactly one [1..1] @typeCode="LOC" Location (CodeSystem: HL7ParticipationType urn:oid:2.16.840.1.113883.5.90 STATIC) (CONF:3247-30668).
   2. SHALL contain exactly one [1..1] participantRole (CONF:3247-30655).
      1. This participantRole SHALL contain exactly one [1..1] @classCode="SDLOC" Service Delivery Location (CodeSystem: HL7EntityClass urn:oid:2.16.840.1.113883.5.41 STATIC) (CONF:3247-30667).
      2. This participantRole SHALL contain exactly one [1..1] id (CONF:3247-30656).

The value of @root must be the NHSN assigned Facility OID.

* + - 1. This id SHALL contain exactly one [1..1] @root (CONF:3247-30662).

The value of @extension must be a value registered with NHSN.

* + - 1. This id SHALL contain exactly one [1..1] @extension="FACWIDEIN" (CONF:3247-30663).
    1. This participantRole SHALL contain exactly one [1..1] code (CodeSystem: HL7 HealthcareServiceLocation urn:oid:2.16.840.1.113883.6.259 DYNAMIC) (CONF:3247-30657).
       1. This code SHALL contain exactly one [1..1] @code="1250-0" (CONF:3247-30664).
       2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.259" (CONF:3247-30665).
       3. This code SHOULD contain exactly one [1..1] @displayName="Facility Wide Inpatient" (CONF:3247-30666).

1. SHALL contain at least one [1..\*] entryRelationship (CONF:3247-30652) such that it
   1. SHALL contain exactly one [1..1] @typeCode="COMP" Has component (CodeSystem: HL7ActRelationshipType urn:oid:2.16.840.1.113883.5.1002 STATIC) (CONF:3247-30659).
   2. SHALL contain exactly one [1..1] [Facility Transfuses Blood Products Treated with Pathogen Reduction Technology Observation (V2)](#E_Facility_Transfuses_Blood_Products_Tr) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.236:2016-08-01) (CONF:3247-30658).

There **SHALL** be exactly 123 Blood Product Usage Summary Observation entryRelationships (one for each value in the value set NHSN Summary Blood Product Usage (urn:oid:2.16.840.1.114222.4.11.7353))

1. SHALL contain at least one [1..\*] entryRelationship (CONF:3247-30733) such that it
   1. SHALL contain exactly one [1..1] @typeCode="COMP" Has component (CONF:3247-30734).
   2. SHALL contain exactly one [1..1] [Blood Product Usage Summary Observation (V2)](#E_Blood_Product_Usage_Summary_Observati) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.237:2016-08-01) (CONF:3247-30735).

If the facility transfused pathogen reduced apheresis platelets (i.e. the apheresis platelet total for any of codes 3514-7, 3515-4, 3516-2, 3517-0, 3518-8, or 3519-6 is > 0) then there **SHALL** be exactly 12 Pathogen Reduced Apheresis Platelet Usage Summary Observation entryRelationships (one for each value in the value set NHSN Pathogen Reduced Apheresis Platelet Usage (urn:oid:2.16.840.1.113883.10.20.5.9.5))

1. MAY contain zero or more [0..\*] entryRelationship (CONF:3247-30792) such that it
   1. SHALL contain exactly one [1..1] [Pathogen Reduced Apheresis Platelet Usage Summary Observation](#E_Pathogen_Reduced_Apheresis_Platelet_U) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.240:2016-08-01) (CONF:3247-30793).
2. SHALL contain at least one [1..\*] entryRelationship (CONF:3247-30730) such that it
   1. SHALL contain exactly one [1..1] @typeCode="COMP" Has component (CONF:3247-30731).
   2. SHALL contain exactly one [1..1] [Summary Data Observation (HV)](#E_Summary_Data_Observation_HV) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.5.6.235:2015-10-01) (CONF:3247-30732).

Figure 31: Summary Encounter (HV) (V2) Example

<encounter classCode="ENC" moodCode="EVN">

<!-- Summary Encounter (HV) (V2) -->

<templateId root="2.16.840.1.113883.10.20.5.6.234" extension="2016-08-01" />

<!-- the location ID and type -->

<participant typeCode="LOC">

<participantRole classCode="SDLOC">

<id root="2.16.840.1.113883.3.117.1.1.5.1.1" extension="FACWIDEIN" />

<code codeSystem="2.16.840.1.113883.6.259" codeSystemName="HL7 HealthCareServiceLocation" code="1250-0" displayName="FACWIDEIN" />

</participantRole>

</participant>

<!-- Blood product summaries

There SHALL be exactly 102 Blood Product Usage Summary Observation

entryRelationships (one for each value in the value set NHSN Summary

Blood Product Usage (urn:oid:2.16.840.1.114222.4.11.7353))

-->

<!-- Total number of units transfused - Whole blood -->

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<!-- [HAI] Blood Product Usage Summary Observation -->

<templateId root="2.16.840.1.113883.10.20.5.6.237" extension="2015-10-01" />

...

</observation>

</entryRelationship>

<!-- Total number of aliquots transfused - Whole blood -->

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<!-- [HAI] Blood Product Usage Summary Observation -->

<templateId root="2.16.840.1.113883.10.20.5.6.237" extension="2015-10-01" />

...

</observation>

</entryRelationship>

<!-- Total number of Discards - Whole blood -->

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<!-- [HAI] Blood Product Usage Summary Observation -->

<templateId root="2.16.840.1.113883.10.20.5.6.237" extension="2015-10-01" />

...

</observation>

</entryRelationship>

...

<entryRelationship typeCode="COMP">

<!-- Facility Transfuses Blood Products Treated with Pathogen Reduction Technology Observation -->

<observation classCode="OBS" moodCode="EVN" negationInd="false">

<!-- [HAI R3D1.1] Facility Transfuses Blood Products Treated with

Pathogen Reduction Technology Observation -->

<templateId root="2.16.840.1.113883.10.20.5.6.236" extension="2016-08-01" />

...

</observation>

</entryRelationship>

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<!-- Summary Data Observation (HV) -->

<templateId root="2.16.840.1.113883.10.20.5.6.235" extension="2015-10-01" />

...

</observation>

</entryRelationship>

...

</encounter>

# Template Ids in This Guide

Table 29: Template List

| Template Title | Template Type | templateId |
| --- | --- | --- |
| [HAI Population Summary Report Generic Constraints](#D_HAI_Population_Summary_Report_Generic) | document | urn:oid:2.16.840.1.113883.10.20.5.4.28 |
| [Healthcare Associated Infection Report](#D_Healthcare_Associated_Infection_Repor) | document | urn:oid:2.16.840.1.113883.10.20.5.4.25 |
| [Hemovigilance (HV) Summary Report (V2)](#D_Hemovigilance_HV_Summary_Report_V2) | document | urn:hl7ii:2.16.840.1.113883.10.20.5.49:2016-08-01 |
| [HAI Section Generic Constraints](#S_HAI_Section_Generic_Constraints) | section | urn:oid:2.16.840.1.113883.10.20.5.4.26 |
| [Summary Data Section (HV) (V2)](#S_Summary_Data_Section_HV_V2) | section | urn:hl7ii:2.16.840.1.113883.10.20.5.5.57:2016-08-01 |
| [Blood Product Usage Summary Observation (V2)](#E_Blood_Product_Usage_Summary_Observati) | entry | urn:hl7ii:2.16.840.1.113883.10.20.5.6.237:2016-08-01 |
| [Facility Transfuses Blood Products Treated with Pathogen Reduction Technology Observation (V2)](#E_Facility_Transfuses_Blood_Products_Tr) | entry | urn:hl7ii:2.16.840.1.113883.10.20.5.6.236:2016-08-01 |
| [ISBT Product Code Summary Observation (V2)](#E_ISBT_Product_Code_Summary_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.5.6.238:2016-08-01 |
| [No Hemovigilance Adverse Reactions Reported This Month Observation](#E_No_Hemovigilance_Adverse_Reactions_Re) | entry | urn:hl7ii:2.16.840.1.113883.10.20.5.6.232:2015-10-01 |
| [No Hemovigilance Incidents Reported This Month Observation](#E_No_Hemovigilance_Incidents_Reported_T) | entry | urn:hl7ii:2.16.840.1.113883.10.20.5.6.233:2015-10-01 |
| [Pathogen Reduced Apheresis Platelet Usage Summary Observation](#E_Pathogen_Reduced_Apheresis_Platelet_U) | entry | urn:hl7ii:2.16.840.1.113883.10.20.5.6.240:2016-08-01 |
| [Summary Data Observation (HV)](#E_Summary_Data_Observation_HV) | entry | urn:hl7ii:2.16.840.1.113883.10.20.5.6.235:2015-10-01 |
| [Summary Encounter (HV) (V2)](#E_Summary_Encounter_HV_V2) | entry | urn:hl7ii:2.16.840.1.113883.10.20.5.6.234:2016-08-01 |

Table 30: Template Containments

| Template Title | Template Type | templateId |
| --- | --- | --- |
| [HAI Population Summary Report Generic Constraints](#D_HAI_Population_Summary_Report_Generic) | document | urn:oid:2.16.840.1.113883.10.20.5.4.28 |
| [Healthcare Associated Infection Report](#D_Healthcare_Associated_Infection_Repor) | document | urn:oid:2.16.840.1.113883.10.20.5.4.25 |
| [Hemovigilance (HV) Summary Report (V2)](#D_Hemovigilance_HV_Summary_Report_V2) | document | urn:hl7ii:2.16.840.1.113883.10.20.5.49:2016-08-01 |
| [Summary Data Section (HV) (V2)](#S_Summary_Data_Section_HV_V2) | section | urn:hl7ii:2.16.840.1.113883.10.20.5.5.57:2016-08-01 |
| [No Hemovigilance Adverse Reactions Reported This Month Observation](#E_No_Hemovigilance_Adverse_Reactions_Re) | entry | urn:hl7ii:2.16.840.1.113883.10.20.5.6.232:2015-10-01 |
| [No Hemovigilance Incidents Reported This Month Observation](#E_No_Hemovigilance_Incidents_Reported_T) | entry | urn:hl7ii:2.16.840.1.113883.10.20.5.6.233:2015-10-01 |
| [Summary Encounter (HV) (V2)](#E_Summary_Encounter_HV_V2) | entry | urn:hl7ii:2.16.840.1.113883.10.20.5.6.234:2016-08-01 |
| [Blood Product Usage Summary Observation (V2)](#E_Blood_Product_Usage_Summary_Observati) | entry | urn:hl7ii:2.16.840.1.113883.10.20.5.6.237:2016-08-01 |
| [ISBT Product Code Summary Observation (V2)](#E_ISBT_Product_Code_Summary_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.5.6.238:2016-08-01 |
| [Facility Transfuses Blood Products Treated with Pathogen Reduction Technology Observation (V2)](#E_Facility_Transfuses_Blood_Products_Tr) | entry | urn:hl7ii:2.16.840.1.113883.10.20.5.6.236:2016-08-01 |
| [Pathogen Reduced Apheresis Platelet Usage Summary Observation](#E_Pathogen_Reduced_Apheresis_Platelet_U) | entry | urn:hl7ii:2.16.840.1.113883.10.20.5.6.240:2016-08-01 |
| [ISBT Product Code Summary Observation (V2)](#E_ISBT_Product_Code_Summary_Observation) | entry | urn:hl7ii:2.16.840.1.113883.10.20.5.6.238:2016-08-01 |
| [Summary Data Observation (HV)](#E_Summary_Data_Observation_HV) | entry | urn:hl7ii:2.16.840.1.113883.10.20.5.6.235:2015-10-01 |
| [HAI Section Generic Constraints](#S_HAI_Section_Generic_Constraints) | section | urn:oid:2.16.840.1.113883.10.20.5.4.26 |

# Value Sets In This Guide

Table 31: Value Sets

| Name | OID | URL |
| --- | --- | --- |
| [Codes for Hemovigilance (HV) Summary Data](#Codes_for_Hemovigilance_HV_Summary_Data) | urn:oid:2.16.840.1.113883.10.20.5.9.11 | N/A |
| [NHSN Pathogen Reduced Apheresis Platelet Usage](#NHSN_Pathogen_Reduced_Apheresis_Platele) | urn:oid:2.16.840.1.113883.10.20.5.9.5 | N/A |
| [NHSN Plasma/Apheresis/Psoralen-Treated](#NHSN_PlasmaApheresisPsoralenTreated) | urn:oid:2.16.840.1.114222.4.11.7326 | N/A |
| [NHSN Summary Blood Product Usage](#NHSN_Summary_Blood_Product_Usage) | urn:oid:2.16.840.1.114222.4.11.7353 | N/A |
| [NHSNPopulationSummaryReportTypeCode](#NHSNPopulationSummaryReportTypeCode) | urn:oid:2.16.840.1.114222.4.11.3595 | N/A |

# Code Systems in This Guide

Table 32: Code Systems

| Name | OID |
| --- | --- |
| cdcNHSN | urn:oid:2.16.840.1.113883.6.277 |
| Healthcare Provider Taxonomy (HIPAA) | urn:oid:2.16.840.1.113883.6.101 |
| HL7 HealthcareServiceLocation | urn:oid:2.16.840.1.113883.6.259 |
| HL7ActClass | urn:oid:2.16.840.1.113883.5.6 |
| HL7ActCode | urn:oid:2.16.840.1.113883.5.4 |
| HL7ActMood | urn:oid:2.16.840.1.113883.5.1001 |
| HL7ActRelationshipType | urn:oid:2.16.840.1.113883.5.1002 |
| HL7ActStatus | urn:oid:2.16.840.1.113883.5.14 |
| HL7AdministrativeGender | urn:oid:2.16.840.1.113883.5.1 |
| HL7Confidentiality | urn:oid:2.16.840.1.113883.5.25 |
| HL7ContextControl | urn:oid:2.16.840.1.113883.5.1057 |
| HL7EntityClass | urn:oid:2.16.840.1.113883.5.41 |
| HL7NullFlavor | urn:oid:2.16.840.1.113883.5.1008 |
| HL7ObservationInterpretation | urn:oid:2.16.840.1.113883.5.83 |
| HL7ParticipationType | urn:oid:2.16.840.1.113883.5.90 |
| HL7RoleClass | urn:oid:2.16.840.1.113883.5.110 |
| ISBT-128 | urn:oid:2.16.840.1.113883.6.18 |
| LOINC | urn:oid:2.16.840.1.113883.6.1 |
| Race & Ethnicity - CDC | urn:oid:2.16.840.1.113883.6.238 |
| RxNorm | urn:oid:2.16.840.1.113883.6.88 |
| SNOMED CT | urn:oid:2.16.840.1.113883.6.96 |

# Changes from Previous Version

# References

* CDA Validator, [http://www.lantanagroup.com/validator.](http://www.lantanagroup.com/validator)
* Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A, (Editors). *HL7 Clinical Document Architecture, Release 2.0*. ANSI-approved HL7 Standard; May 2005. Ann Arbor, Mich.: Health Level Seven, Inc. Available to HL7 members at:  
  <http://www.hl7.org/documentcenter/private/standards/cda/r2/cda_r2_normativewebedition.zip>.
* Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A., HL7 Clinical Document Architecture, Release 2. *J Am Med Inform Assoc.* 2006;13:30­39. Available at: <http://www.jamia.org/cgi/reprint/13/1/30>.
* Extensible Markup Language, [www.w3.org/XML](http://www.w3.org/XML).
* HL7 Governance and Operations Manual, <http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf>.
* *HL7 Implementation Guide for CDA Release 2.0, Consolidated CDA Templates, (US Realm).* <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258>
* HL7 Version 3 Publishing Facilitator’s Guide, available to HL7 members at: <http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm>.
* [LOINC®](http://www.regenstrief.org/loinc): Logical Observation Identifiers Names and Codes, Regenstrief Institute. Available at: <http://loinc.org>
* NHSN members’ website, <http://www.cdc.gov/nhsn/>.
* [SNOMED CT](http://www.snomed.org/snomedct/index.html)®: SNOMED Clinical Terms SNOMED International Organization. Available at: <http://www.ihtsdo.org/snomed-ct>.

1. Acronyms and Abbreviations

ACoS American College of Surgeons

AR Antimicrobial Resistance

ARO Antimicrobial Resistance Option

ASA American Society of Anesthesiologists

APRV Airway Pressure Release Ventilation

AU Antimicrobial Use

AUP Antimicrobial Use, Pharmacy Option (AUP) Summary Report

AUR Antimicrobial Use and Resistance Module

BPU Blood Products Usage

BSI Bloodstream Infection

C-CDA Consolidated CDA

CDA R2 CDA Release 2

CDA Clinical Document Architecture

CDAD C. difficile-associated disease

CDC Centers for Disease Control and Prevention

CDI *C. difficile* infection

CHI Consolidated Health Informatics

CLIP central-line insertion practice

CPT Current Procedural Terminology

DSTU Draft Standard for Trial Use

EHR electronic health record

EOID Evidence of Infection (Dialysis) Report

FOIA Freedom of Information Act

GIN Generic Incident Notification

HAI Healthcare Associated Infection

HAR Hemovigilance Adverse Reaction

HI Hemovigilance Incident Report

HITSP Healthcare Information Technology Standards Panel

HL7 Health Level Seven

HP FLU Influenza Vaccination Summary

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

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

OPC Outpatient Procedure Component

PHCR Public Health Case Reports

PHIN VADS Public Health Information Network Vocabulary Access and Distribution System

PICC/IV peripherally inserted central catheter/intravenous

PNEU Pneumonia Infection Numerator Report

POM Prevention Process and Outcome Measures Monthly Monitoring

RIM Reference Information Model

RMIM Refined Message Information Model

SCA Specialty Care Area

SDWG Structured Documents Working Group

SNOMED-CT Systematized Nomenclature of Medicine--Clinical Terms

SSI Surgical Site Infection

TA-GVHD Transfusion associated graft vs. host disease

TSC Technical Steering Committee

URL Uniform Resource Locator

URN Universal Resource Name

UTI Urinary Tract Infection

VAE Ventilator Associated Event

VAD Ventricular Assist Device

VAT Vascular Access Type

XML Extensible Markup Language

1. Example Instance Identifiers (Non-normative)

As discussed in [Example Instance Identifiers](#IG_S_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 33: 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 setIds | 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 34: 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 |

1. Vocabulary Heuristics for Codes and Value Sets (Non-normative)

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

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

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

Code and codeSystem Selection

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

Value Set Assignment and Maintenance

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

1. HL7 CDA R2. <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7> [↑](#footnote-ref-1)
2. *HL7 V3: Refinement, Constraint and Localization.* <http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm> [↑](#footnote-ref-2)
3. *HL7 Version 3 Publishing Facilitator's Guide.* <http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm> [↑](#footnote-ref-3)
4. *HL7 Version 3 Interoperability Standards*. [http://www.hl7.org/memonly/downloads/v3edition.cfm - V32010](http://www.hl7.org/memonly/downloads/v3edition.cfm#V32010) [↑](#footnote-ref-4)
5. W3C, *XML Path Language.* <http://www.w3.org/TR/xpath/> [↑](#footnote-ref-5)