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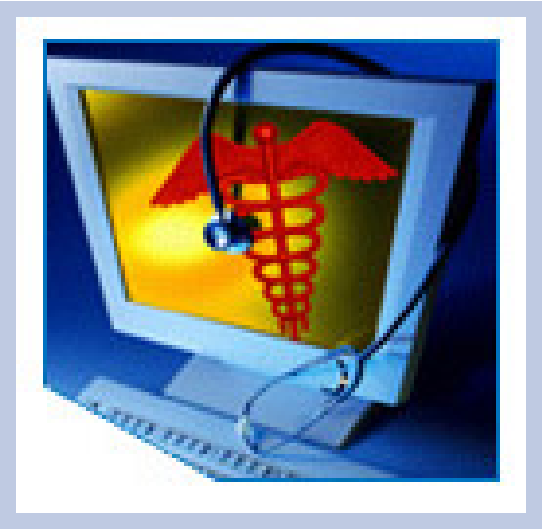
HITSP Technical Note for Clinical Documents

HITSP/TN901



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1.0 INTRODUCTION

As an introduction to the Healthcare Information Technology Standards Panel (HITSP) Technical Note for Clinical Documents, this section provides a high level overview of this Technical Note acknowledges the copyright protections that pertain, and provides a list of key reference documents and background material. If you are already familiar with this information, proceed to Section 2.0 Design Principles.

1.1 OVERVIEW

The HITSP Technical Note for Clinical Documents defines the implementation strategy and information architecture for the use of the HL7 Clinical Document Architecture (CDA) Release 2.0 in the development of HITSP constructs developed in response to the American Health Information Community (AHIC) Use Cases. It includes a design map of existing standards and specifications that will be used to meet the stated requirements of the Use Cases. As additional Use Cases are provided to HITSP, the Care Management and Health Records Domain Technical Committee will revise this document based on new requirements and consequent updates to the design and relationship of the constructs themselves.

1.2 COPYRIGHT PERMISSIONS

1.3 REFERENCE DOCUMENTS

This section provides a list of key reference documents and background material.

A list of key reference documents and background material is provided in the table below. These documents can be retrieved from www.hitsp.org.

Table 1.3-1 Reference Documents

Reference Document	Document Description
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Conventions List	Describes the conventions that are used to convey the full descriptions and usage of standards in the HITSP specifications
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents
HITSP Harmonization Framework	Describes the current framework within which the Interoperability Specifications are built
HITSP Interoperability Specification Overview	Provides background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. The document also provides a description of the HITSP process for healthcare standards harmonization and explains how to use the Interoperability Specifications and other related documents to inform your health IT product development or product refinement

2.0 DESIGN PRINCIPLES

2.1 MAXIMIZE REUSE

In developing the HITSP constructs, the Care Management and Health Records Domain Technical Committee considered a set of overarching concepts, derived from an analysis of the existing specifications. Clinical documents should be built upon an overarching framework that ensures:

- Representational consistency for interoperability across specifications; medications, problems, allergies, and other clinical information are reported using the same CDA structures (and entry patterns) across all HITSP CDA-based constructs
- Terminology consistency by the use of common vocabularies for describing the same concepts consistently across HITSP constructs

These design principles were arrived through an iterative process where concepts were identified and further refined during a review of the first two sets of HITSP Interoperability Specifications and constructs developed in 2006 and 2007, and applied to new Interoperability Specifications and constructs developed for the American Health Information Community (AHIC) Use Cases in 2008. Further refinement of the existing constructs will continue, and the principles applied to new constructs as new Use Cases are presented to HITSP. It is anticipated that future Interoperability Specifications and constructs will be able to easily re-use the harmonized HITSP CDA-based clinical document constructs.

2.2 CONTENT MODULES

HITSP introduces the concept of Content Modules to define a minimum set of data elements and requirements to provide consistent semantics and support across all exchange contexts for a given concept. A Content Module may be represented as a block of markup or a single element.

Two types of Content Modules are specified:

1. Entry Content Modules – a collection of data elements pertaining to a single instance of the specified concept. For example, the Allergy/Drug Sensitivity Entry Module describes all the data elements for one allergy
2. Section Content Modules – a collection of entries pertaining to a single specified concept. For example, the Allergies and Other Adverse Reactions Section can contain a list of allergies (multiple Entry Content Modules). Section Content Modules are typically selected from specifications created by Standard Development Organizations (SDOs), such as the HL7 Continuity of Care (CCD) and other Implementation Guides, and IHE Content Profiles such as XDS-MS

Content Modules may be composed of header or body elements, e.g., “patient identification and demographics” can be conveyed in the recordTarget element in the header while “vital signs” is a fully coded section within a structuredBody that includes entry-level content modules.

The HITSP/C83 CDA Content Modules specifies the universal HITSP definitions and declarations of semantics, syntax, structure, and vocabulary for Section and Entry Content Modules to ensure consistency across HITSP CDA based constructs.

Vocabulary and Value Sets are identified in HITSP/C83 CDA Content Modules for each content module with the details articulated in HITSP/C80 Clinical Document and Message Terminology. This Construct further defines the vocabularies and terminologies utilized by all HITSP specifications for clinical content, including both Clinical Documents and Messages.

This Technical Note does not address the transmission of HITSP CDA-based documents. The transmission is defined within HITSP Interoperability Specifications that enable the documents. See individual Interoperability Specification for details.

3.0 HITSP CDA-BASED CLINICAL CONSTRUCTS

This section provides a high level description of the HITSP constructs for clinical documents that are based upon HL7 CDA specifications.

The HITSP CDA-based constructs are the result of an assessment of the current practices for CDA Documents implemented within the scope of the harmonized American Health Information Community (AHIC) Use Cases. The HITSP CDA-based constructs are listed in the individual Interoperability Specifications.

It is important to note that CDA-based constructs may be further constrained in the context of the Interoperability Specification.

For example, when using Table 3-1 the reader is able to identify the use of HITSP/C37 Lab Report Document in three Interoperability Specifications. The HITSP/C37 construct defines the universal constraints that will apply to all Use Cases where HITSP/C37 is referenced. This use of HITSP/C37 is also listed in the construct list within each of the Interoperability Specifications.

If additional constraints are required to support the Personalized Healthcare AHIC Use Case, those constraints are stated in HITSP/IS08 Personalized Healthcare Interoperability Specification. The HITSP/C37 Lab Report Document construct, however, will have no information that HITSP/IS08 has chosen to further constrain it.

Table 3-1 HITSP CDA Constructs and Associated Interoperability Specifications

Construct	Interoperability Specification
HITSP/C28 - Emergency Care Summary Document Using IHE Emergency Department Encounter Summary (EDES)	HITSP/IS04 - Emergency Responder Electronic Health Record
HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	HITSP/IS03 - Consumer Empowerment and Access to Clinical Information via Networks HITSP/IS04 - Emergency Responder Electronic Health Record HITSP/IS05 - Consumer Empowerment and Access to Clinical Information via Media HITSP/IS07 - Medication Management HITSP/IS08 - Personalized Healthcare HITSP/IS09 – Consultations and Transfers of Care
HITSP/C37 - Lab Report Document	HITSP/IS01 - Electronic Health Records Laboratory Results Reporting HITSP/IS03 - Consumer Empowerment and Access to Clinical Information via Networks HITSP/IS05 - Consumer Empowerment and Access to Clinical Information via Media HITSP/IS08 - Personalized Healthcare HITSP/IS09 – Consultations and Transfers of Care

Construct	Interoperability Specification
HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	HITSP/IS06 – Quality
HITSP/C48 - Encounter Document Using IHE Medical Summary (XDS-MS)	HITSP/IS02 – Biosurveillance HITSP/IS04 - Emergency Responder Electronic Health Record HITSP/IS08 - Personalized Healthcare HITSP/IS09 – Consultations and Transfer of Care
HITSP/C74 - Remote Monitoring Observation	HITSP/IS77 - Remote Monitoring
HITSP/C75 - Drug Adverse Event Report	HITSP/IS11 - Public Health Case Reporting
HITSP/C76 - Case Report Pre-Populate	HITSP/IS11 - Public Health Case Reporting
HITSP/C78 - Immunization Content	HITSP/IS10 - Immunizations and Response Management
HITSP/C84 - Consult and History & Physical Note	HITSP/IS08 - Personalized Healthcare HITSP/IS09 – Consultations and Transfers of Care

The HITSP CDA-based constructs often specify constraints on Content Modules and Terminologies. The constructs in Table 3-2 are enabled by HITSP CDA-based constructs to provide such constraints.

Table 3-2 Content Module and Terminology Based Constructs

Construct	Interoperability Specification
HITSP/C35 - Lab Result Terminology	HITSP/IS01 - Electronic Health Records Laboratory Results Reporting HITSP/IS05 - Consumer Empowerment and Access to Clinical Information via Media
HITSP/C80 - Clinical Document and Message Terminology	HITSP/IS08 - Personalized Healthcare HITSP/IS09 - Consultations and Transfers of Care HITSP/IS10 - Immunizations and Response Management HITSP/IS11 - Public Health Case Reporting HITSP/IS77 - Remote Monitoring
HITSP/C83 - CDA Content Modules	HITSP/IS08 - Personalized Healthcare HITSP/IS09 - Consultations and Transfers of Care HITSP/IS10 - Immunizations and Response Management HITSP/IS11 - Public Health Case Reporting HITSP/IS77 - Remote Monitoring

Figure 3-1 HITSP Document Constructs illustrates the HITSP constructs discussed in this Technical Note. The HITSP constructs are shown in yellow and there are three different types related to the use of CDA:

1) Various HITSP Constructs that are based upon HL7 CDA/CCD clinical documents, such as HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD), HITSP/C48 Encounter Document Using IHE Medical Summary (XDS-MS), etc. These constructs are typically selected from implementation guides from SDOs such as HL7, IHE and other organizations

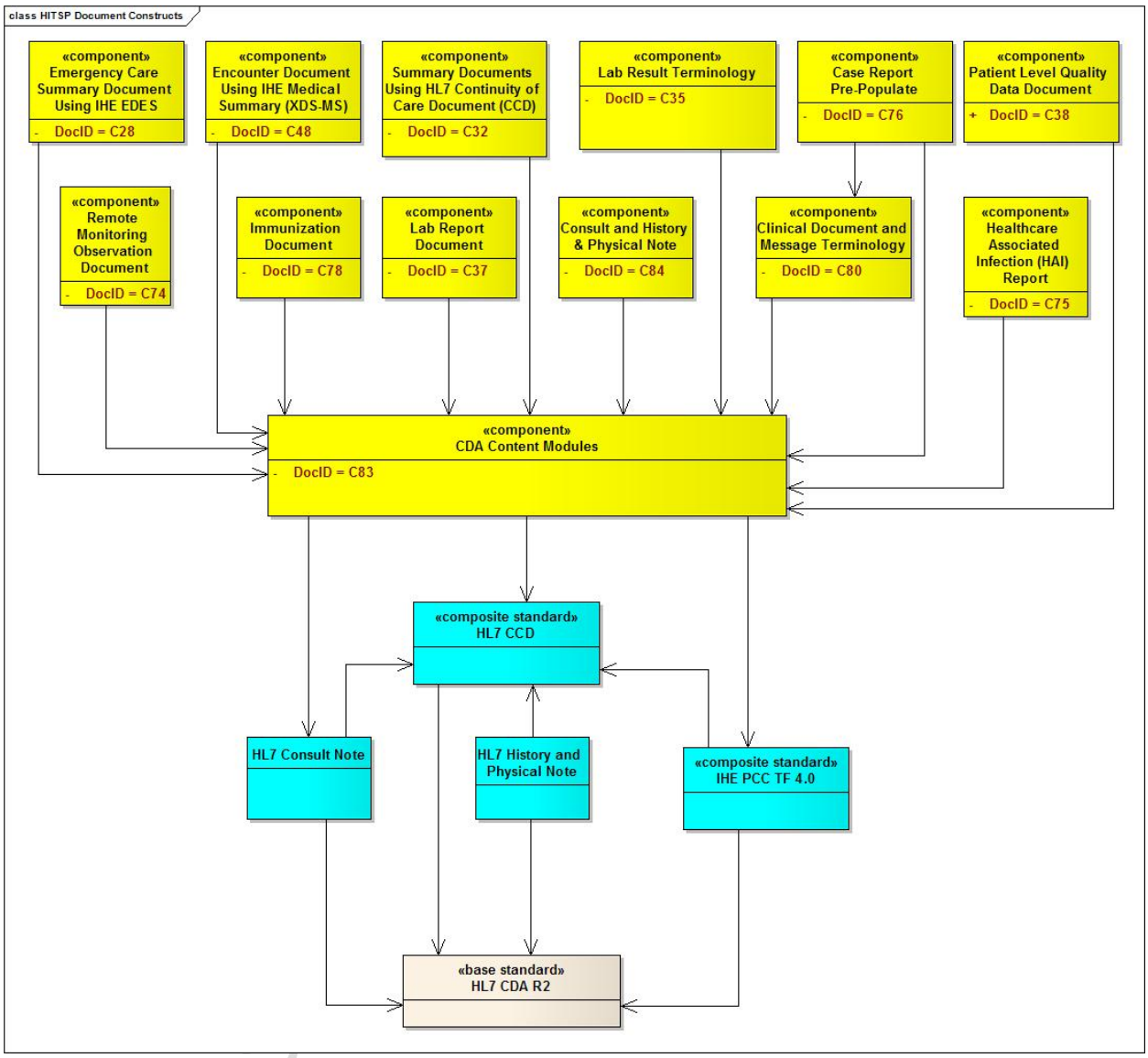
2) HITSP/C83 CDA Content Modules defines content modules. HITSP/C83 does NOT stand on its own and its use is always enabled by other HITSP constructs (such as those based upon HL7 CDA/CCD

documents). Those HITSP constructs that reference HITSP/C83 are shown in the Figure 3-1. The Content Modules in HITSP/C83 are based upon various SDO Implementation Guides that are shown in Figure 3-1, such as the HL7 CCD, IHE PCC Technical Framework, HL7 Consult Note, etc.

3) HITSP/C80 Clinical Document and Message Terminology defines the vocabularies and terminologies utilized by HITSP specifications for Clinical Documents and Messages. HITSP/C80 does not stand alone and its use is always enabled by other HITSP constructs, most notably HITSP/C83 CDA Content Modules

NOTE: In Figure 3-1, items in blue are implementation guides or composite standards and those in gray are base standards. TN901 only discusses documents related to Clinical Documents. Other HITSP Constructs (that are not discussed in this Technical Note) may also choose to reference HITSP/C83 CDA Content Modules and/or HITSP/C80 Clinical Document and Message Terminology.

Figure 3-1 HITSP Document Constructs



While there is no single framework for the construction of CDA documents, several organizations have developed implementation guides for clinical documents according to an overarching set of principles. The base standard selected for all HITSP clinical documents is the Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA) Release 2.0. Additional constraints to this standard have been applied from a number of sources (e.g., implementation guides), including:

- Health Level Seven (HL7) Version 3.0 Continuity of Care Document (CCD)
- IHE Content Profiles specified by the Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 4.0
- Health Level Seven (HL7) Implementation Guide for CDA Release 2.0: History and Physical (H&P) Notes
- Health Level Seven (HL7) Implementation Guide for CDA Release 2.0: Consultation Note

The Continuity of Care Document (CCD) describes one type of summary document useful for conveying information between Electronic Health Record (EHR) and Personal Health Record (PHR) applications. This implementation guide includes templates describing commonly used sections and entries for clinical statements that appear not only in documents defined by the CCD specification, but also for discharge summaries, referral summaries, emergency department encounter notes, physical examinations, and consultation notes.

Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 4.0 adds constraints to CDA and CCD-defined sections and entries to provide for more uniform exchange of clinical information. Several IHE Content Profiles selected for implementation in HITSP constructs (e.g., HITSP/C28 Emergency Care Summary Document Using IHE Emergency Department Encounter Summary (EDES), HITSP/C38 Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS), and HITSP/C48 Encounter Document Using IHE Medical Summary (XDS-MS)) come from this Technical Framework. The HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) construct originally defined by HITSP for use with the HITSP/IS03 Consumer Empowerment and Access to Clinical Information via Networks, and now used in five other HITSP Interoperability Specifications (HITSP/IS04 Emergency Responder Electronic Health Record, HITSP/IS05 Consumer Empowerment and Access to Clinical Information via Media, HITSP/IS07 Medication Management, HITSP/IS08 Personalized Healthcare, and HITSP/IS09 Consultations and Transfers of Care) has been restructured to adopt the same constraints for sections and entries used for HITSP/C28, HITSP/C38 and HITSP/C48. Those constructs in turn have adopted the same constraints for information contained therein as were present in the prior HITSP/C32 specification.

The HL7 History and Physical Note and Consultation Note Implementation Guides, developed by the CDA for Common Document Types project (CDA4CDT), and balloted through HL7 make use of existing templates for sections defined in both the Continuity of Care Document, and the IHE PCC Technical Framework.

3.1 GENERAL CONSTRAINTS APPLIED TO HITSP CDA-BASED DOCUMENTS

The formal constraints to be applied to HITSP CDA-based documents are defined in HITSP/C83 CDA Content Modules and, where appropriate, within the Interoperability Specifications. Following are a few examples of general rules that are applied:

- A clinical document may include other data elements not defined by HITSP in an instance of a Content Module. Receivers are not required to process these elements and if they do not understand them, they will ignore them. Thus, it is not an error to include more than is asked for, but it is an error to reject a Content Module because it contains more than is defined by the framework
- If a data element coded value may be derived from another data element coded value, the creator of a clinical document ensures the accuracy and consistency between the two data

elements. If the receiver detects an inconsistency, it does not correct the value without human intervention

- Templates in reference to a CDA Document declare a specific set of constraints on a document, section or clinical statement, and are assigned an Object Identifier (OID) to be uniquely identified over time. A clinical document that is created can then assert conformance to a template by the inclusion of the OID as the value for a templateID element in a document, section, or clinical statement. These may have multiple templateIDs provided there are no conflicting requirements as a result of aggregating the rules
- Template references may nest: A template may also require the presence of child templates in order to satisfy an exchange requirement. A document level template can require the presence of section level templates, which in turn may require entry templates to ensure a minimum level of information to be exchanged in a given context.
- Asserting conformance to this specification indicates that additional constraints such as:
    - Required modules are present and follow the associated constraints
    - Content Modules explicitly excluded from a clinical document specification are not present
    - Optional modules, when present, always follow the associated constraints if that module asserts conformance with HITSP, i.e., includes the associated templates
    - Additional CCD entry elements (the equivalent to Content Modules) may be present. The receiver of the document may choose to accept or exclude the additional content, but cannot reject the document solely based upon the presence of the additional content

3.2 CONCEPTS

3.2.1 CLINICAL DOCUMENT CONCEPTS

A Clinical Document is comprised of two parts; the header and the body.

3.2.1.1 Header

The header contains metadata about the document itself, including the type of document, the date it was created, and its identifier. It also describes participants in the event being documented, including the author, patient, and legal authenticator (signer). It also relates the document to the service being documented, the encounter in which the service was performed, and any prior documentation of that encounter or those services.

3.2.1.2 Body

A choice of body elements is available in CDA where the body may be an unstructured blob represented by the nonXMLBody or comprised of structured markup in the structuredBody element.

The body of a clinical document contains narrative (human readable) data found in sections of the document and machine readable data contained within section entries. The narrative content uses XML

markup to identify paragraphs, lists, tables, multimedia content, and other common structures for communication of narrative information.

The nonXMLBody is used when the content is an external file such as a TIFF image, MS RTF document, etc. There is little if any semantic interoperability as a result of using this type of body beyond the general context and minimum document management metadata conveyed in the required header elements.

The structuredBody is used when the body will be XML structured content, which is never referenced as an external file. This is the primary usage within the exchange context of the American Health Information Community (AHIC) Use Cases and the resulting Interoperability Specifications.

3.2.1.2.1 Sections

Clinical documents are organized into sections and subsections. The implementation guides that HITSP has selected for each type of clinical document constrain those documents with respect to the sections that must be present and others which may be present. Machine readable data associated with the narrative content is contained in entries, which are further described below.

3.2.1.2.2 Entries

Entries are used to contain information about the various clinical acts performed (medication administration or supply, procedures, encounters, problems, allergies, immunizations, diagnostic results, or other). The HITSP Interoperability Specifications and the implementation guides that HITSP has selected for use with Clinical Documents constrain the structure (see HITSP/C83 CDA Content Modules) and vocabulary (see HITSP/C80 Clinical Document and Message Terminology) that is used within these entries.

3.2.1.3 Constraining Clinical Documents using Templates

A general strategy for constraining clinical documents being used by HL7, IHE, and the CDA for Common Document Types workgroup is to create templates.

The text for the HL7 Version 3 Standard: Specification and Use of Reusable Constraint Templates, Release 2, p.12 begins here:

> A template is an expression of a set of constraints on the RIM or a RIM derived model that is used to apply additional constraints to a portion of an instance of data which is expressed in terms of some other Static Model. Templates are used to further define and refine these existing models to specify a narrower and more focused scope.
>
> A template is represented by:
>
> - a formal definition in one or more human readable languages or notations
> - [optionally] a formal definition as a static model

- [optionally] one or more implementation specific representations that can be used to validate instances in a particular context

The text for the HL7 Version 3 Standard: Specification and Use of Reusable Constraint Templates, Release 2, p.12 ends here.

A common implementation representation for templates uses the International Organization for Standardization (ISO) Schematron Standard to enforce the constraints.

3.2.2 VOCABULARY CONCEPTS

This section provides an introduction to the concepts used in describing vocabularies used in HITSP CDA-based documents. The HITSP construct that enables these concepts is HITSP/C80 Clinical Document and Message Terminology.

3.2.2.1 Vocabulary

A vocabulary (also known as a terminology) is a collection of concepts along with their relationships to each other. In some vocabularies, the relationships are hierarchical (such as ICD 9 Clinical Modifications), where some concepts are subtypes of other concepts, representing hyponymy[1]. In others, more complex relationships are recorded, such as in SNOMED CT®, where a single concept can be related to a number of other concepts through a variety of relationship types, and multiple hypernyms (or parent concepts) can be recorded. The term ontology is often used to describe these more complex vocabularies. Other vocabularies do not make these relationships explicit, and appear instead to be flat lists of codes, such as LOINC®. A final class of vocabularies deserves a special note. These vocabularies define a grammar through which legal vocabulary terms can be constructed. The Unified Code for Units of Measure (UCUM) is defined in this fashion. The list of vocabulary terms in UCUM is effectively infinite and therefore cannot be enumerated.

Examples of vocabularies include SNOMED CT®, LOINC®, UCUM, the Healthcare Provider Taxonomy, and the International Classification of Diseases (ICD). Vocabularies may have subsets, such as the SNOMED CT® defined non-human subset, or the VA/Kaiser Permanente subset of SNOMED CT®.

3.2.2.2 Concept

A concept is an atomic unit of a vocabulary. Each concept within a vocabulary has at least one unique identifier (known as the concept code or simply code) that identifies the concept within the context of a specific vocabulary. In addition to a code, a concept has at least one name, which is often displayed to represent the concept in user interfaces. Concepts can have more than one name, representing aliases or synonymous names for the concept, and these names may be in multiple languages. Typically, one of

[1] A hyponym is a word or phrase whose meaning is encompassed within another word. This is a fancy way to say "is a."

these names is the "preferred name" for the concept. Concepts may also have a definition, as is found in some cases in the LOINC® vocabulary, in the UMLS meta-thesaurus, or in the Healthcare Provider Taxonomy codes.

3.2.2.2.1 Identification of Vocabularies

Vocabularies should have at least one unique identifier. The vocabularies used by HITSP specifications are always uniquely identified by an OID, and these identifiers are registered in the HL7 OID Registry (see http://www.hl7.org/oid/index.cfm). For example, the OID for SNOMED CT® is 2.16.840.1.113883.6.96.

3.2.2.2.2 Versioning of Vocabularies

Vocabularies are maintained and updated periodically, producing new versions of the vocabulary. Standards development organizations use various methods to identify the different versions of their vocabularies. For example, the current release of LOINC® is version 2.24. Some organizations do not use a specific version, but rather have a release date (e.g., ICD-9-CM is released annually). To ensure consistent representation of vocabulary versions, the Care Management and Health Records Domain Technical Committee has established the following guidelines:

- When a vocabulary specification uses a numeric or decimal representation of the version number, the version identifier shall be that string, containing only numeric digits and decimal points, without any leading zeros for each subcomponent
- When a vocabulary specification uses the date of release to represent the version, the version identifier shall be the year, month and day of the release in ISO 8601 form, with no punctuation, represented as a string of 8 digits, in the form YYYYMMDD

3.2.2.2.3 Other Vocabulary Metadata

The HL7 Common Terminology Services specification notes other vocabulary metadata, including a local name, full name, description, copyright information, release format, release location, version order, effective dates, and supported languages. This metadata is relevant to terminology management, but is not necessary to be communicated to ensure interoperable exchange of terms from a value set.

3.2.2.3 Value Set

A vocabulary domain that has been constrained to a particular realm and coding system.

An Enumerated Value Set (also known as an Extensional Value Set) is one that is comprised of an explicit listing of the set of codes. Versioning occurs if values are added or deleted. SDOs typically have Static bindings to Enumerated Value Sets.

A Criteria-Based Value Set (also known as an Intentional Value Set) is one that is defined by a computable expression that can be resolved to an exact list of codes (e.g. “all SNOMED-CT concepts that are descendants of the -CT concept Diabetes Mellitus”). Versioning occurs if the criteria changes. SDOs typically have Dynamic bindings to Criteria-Based Value Sets.

3.2.2.3.1 Identification of Value Sets

Value Sets can also be identified using an OID. The Value Sets used by HITSP specifications are always uniquely identified by an OID, and these identifiers are registered in the HL7 OID Registry (see http://www.hl7.org/oid/index.cfm). For example, the OID for the HL7 defined ActNoImmunziationReason value set is 2.16.840.1.113883.11.19725, which comes from the HL7 defined Vocabulary ActReason, who's OID is 2.16.840.1.113883.5.8.

A vocabulary has by definition at least one Value Set, which is the set of all values in that vocabulary.

Within a HITSP Component, a message or document specification may limit the values for a coded field to one or more Value Sets.

3.2.2.4 Concept Domain

A Concept Domain is a high level, abstract grouping of like concepts. A Concept Domain represents the entire category of things possible to say about a particular subject, such as “all countries of the world” or “all orderable medications.”

A Concept Domain defines the scope of one or more Value Sets or vocabularies. The collection of Value Sets used to describe a medication is a Concept Domain.

3.2.2.5 Communicating Values Not in HITSP Value Sets

Occasionally it may be necessary to communicate a value that is not contained within a HITSP Value Set. The specific code may be unknown, or the concept may not exist in the Value Set.

3.2.2.5.1 Unknown and Missing Concepts in CDA and HL7 Version 3 Messages

Coded concepts communicated using the CDA and HL7 Version 3.0 messages are conveyed using the HL7 Concept Descriptor or a derived data type. The Concept Descriptor data type represents unknown and "other" using the nullFlavor attribute in the XML element, as shown below. The <originalText> may be included to indicate the concept that could not be coded.

Figure 3.2.2.5.1-1 Use of nullFlavor

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- an unknown value -->
<code nullFlavor='UNK'/>

<!-- a value not represented in the HITSP value set, without the "text to be coded" provided -->
<code nullFlavor='OTH'/>

<!-- a value not represented in the HITSP value set, with the "text to be coded" provided -->
<code nullFlavor='OTH'>
  <orginalText>Missing Concept</originalText>
</code>
```

3.2.2.5.2 Using Concepts from other Vocabularies in CDA and HL7 Version 3 messages

In some cases, an existing concept or a missing concept may be coded in another vocabulary. This information can be conveyed in a CDA Document or HL7 Version 3 message using the <translation> element of the concept descriptor data type, as shown below:

Figure 3.2.2.5.2-1 Use of <translation>

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->

<!-- Reporting other codes used for an existing concept -->
<code code='22298006' displayName='Myocardial Infartion'
     codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT' >
  <translation code='410' displayName='Acute Myocardial Infartion'
codeSystem='2.16.840.1.113883.6.103' codeSystemName='ICD-9-CM Diagnoses' />
  <orginalText>Missing Concept</originalText>
</code>

<!-- Reporting other codes used for missing concept -->
<code nullFlavor='OTH'>
  <translation code='' displayName='' codeSystem='' codeSystemName='' />
</code>
```

3.3 TABLE CONVENTIONS USED IN HITSP CDA CONSTRUCTS

The convention for the Content Module Requirement Tables used in HITSP constructs based upon HL7 CDA is shown in Table 3.3-1.

Table 3.3-1 Content Module Requirement Table Explanation

Content Module	HITSP Optional Entry	HITSP Repeatable Entry	Specification Reference
Identifies the name of the Content Module	Identifies the Optionality of the Content Module R, R2, O, C See below for description*	Identifies if the Content Module is Repeatable Y = Yes N = No	Specifies HITSP requirements and restriction on the Content Module, if needed Note: This often references Section and Entry Content Modules specified in HITSP/C83 – CDA Content Modules

- **R = Required** - Required Content Module that shall always be sent
- **R2 = Required if known** - If the sending application has data for the Content Module, it is required to populate the information
- **O = Optional** – Content Modules that are marked optional (O) may be sent at the choice of the sending application. Content Modules need not be sent, but when it is sent, the Content Module defines the meaning of the data elements within the Content Module and a receiver can always be assured of what data elements represents when it is present
- **C = Conditions** – The Content Module shall be supported if the conditions stated in the HITSP construct is met. It may be sent if the condition is not met

3.4 REFERENCE MATERIALS

The following reference materials were used in the analysis and development of this Technical Note and are recommended for further understanding of the HITSP CDA-based constructs:

Table 3.4-1 Reference Materials

Reference	Link
CDA Quick Start Guide (v1.5)	The CDA Quick Start Guide was created by Alschuler Associates, LLC. The guide helps implementers create a simple CDA document and then as they increase their knowledge of CDA, go on to create more complex versions using the resources cited in this *QSG* and their own experience. For more information visit www.alschulerassociates.com/library/documents/cda_qsg_v1.5.zip
Continuity of Care Document (CCD) Quick Start Guide	This CCD Quick Start Guide was created by the Healthcare Information and Management Systems Society Electronic Health Record Association (EHRA). This guide was developed to support CCD implementers. The scope is "just enough" to get started – it is *not* a standalone or complete guide or reference. For more information visit http://www.ehrva.org/ASP/CCD_QSG_20071112.asp
Document Schema Definition Language (DSDL) -- Part 3: Rule-based validation - Schematron ISO/IEC 19757-3:2006	ISO/IEC 19757-3:2006 specifies Schematron, a rules-based schema language for XML. It establishes requirements for Schematron schemas and specifies when an XML document matches the patterns specified by a Schematron schema http://webstore.ansi.org/RecordDetail.aspx?sku=ISO%2fIEC+19757-3%3a2006
Health Level Seven (HL7) Version 3 Standard: Specification and Use of Reusable Constraint Templates, Release 2	HL7 V3 provides a global framework for exchange of healthcare information as documents or messages by providing a framework for constructing instances of data according to agreed definitions in a standard fashion. Templates are used to provide this framework within the context of HL7 V3 and the Clinical Document Architecture. This document describes how templates are specified, registered and used. http://www.hl7.org
National Institute of Standards and Technology (NIST) Validator	NIST in collaboration with Alschuler Associates, LLC, Integrating the Healthcare Enterprise (IHE) and the CCHIT Health IT Collaboration Effort "LAIKA", is working on a series of testing tools for promoting the adoption of standards-based interoperability by vendors and users of healthcare information systems For more information visit xreg2.nist.gov/cda-validation/index.html
Schematron Home Page	This Schematron is owned by ISO. It allows you to develop and mix two kinds of schemas: Report elements allow you to diagnose which variant of a language you are dealing with Assert elements allow you to confirm that the document conforms to a particular schema. For more information visit www.schematron.com/

The quick start guides listed above provide a quick introduction the Clinical Document Architecture (CDA) and Continuity of Care Document (CCD) Specifications. These guides are intended to assist implementers quickly come up to speed on those implementation guides.

A variety of conformance-testing tools have been developed for the HITSP selected Implementation Guides. These conformance-testing tools rely upon Schematron, now an ISO Standard (ISO/IEC 19757-3:2006). The National Institute of Standards and Testing has developed a validator that applies the conformance rules to CDA instances and can report non-conforming documents.

4.0 ROADMAP AND GAPS

4.1 ROADMAP

Table 4.1-1 Components and Document Descriptions

Component	Document Description
2008	
HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	This Component has been updated to reflect new content structure and now references HITSP/C83 (and indirectly HITSP/C80) for content specifications
HITSP/C37 - Lab Report Document	This Component will be updated to reflect requirements to support genetic testing vocabularies when reporting genetic testing results
HITSP/C48 - Encounter Document Using IHE Medical Summary (XDS-MS)	This Component has been updated to reflect new content structures and now references HITSP/C83 (and indirectly HITSP/C80) for content specifications
HITSP/C70 - Immunization Query and Response	This Component has been created, and includes content that describes how to query and retrieve a patient's history of immunizations and references HITSP/C80
HITSP/C72 - Immunization Message	This Component has been created, and includes content that describes how to create a document describing the patient's history of immunizations and references HITSP/C80
HITSP/C74 - Remote Monitoring Observation Document	This Component has been created to describe how information will be communicated from remote patient motoring devices to EHR and PHR systems
HITSP/C75 - Healthcare Associated Infection (HAI) Report	This Component has been created to describe how information will be communicated to report information about healthcare associated infections to appropriate public health agencies
HITSP/C76 - Case Report Pre-Populate	This Component has been created to support the Data Mapping needed for Public Health Case Reports
HITSP/C78 - Immunization Document	This Component has been updated to reflect new content structures and now references HITSP/C83 (and indirectly HITSP/C80) for content specifications
HITSP/C80 - Clinical Document and Message Terminology	This Component has been created as a general specification describing HITSP defined and/or selected value sets that are used in clinical documents for various purposes
HITSP/C83 - CDA Content Modules	This Component has been created as a general specification describing sections and entries that can appear in clinical documents
2009	
HITSP/C35 - Lab Result Terminology	Existing constructs HITSP/C36 - Lab Result Message and HITSP/C37 will reference HITSP/C80 instead of HITSP/C35. The HITSP/C35 construct will be retained until the existing Interoperability Specifications (HITSP/IS01 - Electronic Health Records Laboratory Results Reporting, HITSP/IS02 - Biosurveillance, HITSP/IS05 - Medication Management) that rely upon it are updated to refer to new versions of HITSP/C36 and HITSP/C37 constructs that no longer do so. This allows existing implementations conforming to those Interoperability Specifications to remain consistent with HITSP constructs. Once all Interoperability Specifications no longer reference this component, it will be retired

HITSP/C28 - Emergency Care Summary Document Using IHE Emergency Department Encounter Summary (EDES)	This Component will be updated in 2009 to reflect the reorganization of HITSP Clinical Documents
HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)	This Component will be merged into HITSP/C48 in 2009 to reflect the reorganization of HITSP Clinical Documents. When HITSP/IS06 - Quality references the updated HITSP/C48 construct, this Component will be retired
HITSP/C80 - Clinical Document and Message Terminology	New material will be added to this Component to reflect additional value sets selected for documents updated in the 2009 cycle of development. Additional vocabularies relevant to HITSP messaging constructs will be incorporated
HITSP/C83 - CDA Content Modules	New material will be added to this Component to reflect additional sections and entries needed in existing (e.g., HITSP/C28 - Emergency Care Summary Document Using IHE Emergency Department Encounter Summary (EDES) and HITSP/C38) and new (e.g., Nursing Summary Component) constructs

4.2 GAPS/OVERLAPS

4.2.1 GAPS/OVERLAPS SPECIFIC TO CDA DOCUMENT CONSTRUCTS

This section describes gaps and overlaps in standards specific to Care Management and Health Records. Recommended resolutions were developed through a series of steps including the Technical Committee's initial recommendations, cross team validation of the gap, provisional recommendations and peer review by the team.

Table 4.2.1-1 Construct Standards Gaps/Overlaps

Construct	Identified Gaps/Overlaps	Recommended Resolution
Field/Ambulance Report	There are presently no implementation guides for the creation of clinical documents containing ambulance report information	Until such time as this implementation guide is available and approved for use, the Committee recommends the use of HITSP/C62 - Unstructured Document to convey case report information
Genomics Risk Assessment	There are presently no implementation guides for the creation of clinical documents containing a genetic risk assessment	Until such time as this implementation guide is available and approved for use, the committee recommends the use of HITSP/C62 - Unstructured Document to convey genetic risk assessment information
Genetic Laboratory Results	An implementation guide for structuring laboratory results is currently being developed by HL7 but is not ready today	Use the Genetic Testing Constraints found in HITSP/C80 - Clinical Document and Message Terminology with HITSP/C37 - Lab Report Document until such time as the completed implementation guide is available. These constraints are consistent with the current HL7 plans
Implanted Medical Device	The Medical Equipment Section does not include a template for Implanted Medical Devices	Members of the Care Management and Health Records Domain Technical Committee will consider adding a new section to HITSP/C83 – CDA Content Modules and vocabulary choice related to Implanted Medical Devices. IHE currently has a section defined

Construct	Identified Gaps/Overlaps	Recommended Resolution
Nursing Summary Component	There are presently no implementation guides for the creation of clinical documents containing nursing assessments and relevant summary information	Members of the Care Management and Health Records Domain Technical Committee have developed a proposal to be conveyed to relevant standards organizations to fill this gap. Until such time as this implementation guide is available and approved for use, the Committee recommends the use of HITSP/C62 - Unstructured Document to convey this information
Procedures	CCD allows for a number of vocabularies to be employed: SNOMED®, LOINC®, CPT4, ICD9 and ICD10. The wide variety of vocabularies, and the existence of additional procedures not currently addressed, complicates interoperability. This interoperability issue is recognized as a standards overlap	Until this overlap is addressed by the various stakeholder organizations, the coded procedure module is optional and not further constrained HITSP
Results Type	For Lab, LOINC has been chosen. However for other specialties there are other choices such as SNOMED-CT. This interoperability issue is recognized as a standards overlap	Members of the Care Management and Health Records Domain Technical Committee and the Foundations Committee should address harmonizing LOINC and SNOMED-CT
Standard Case Report Construct	There are presently no implementation guides for the creation of clinical documents containing case report information	Until such time as this implementation guide is available and approved for use, the committee recommends the use of HITSP/C62 - Unstructured Document to convey case report information. Members of the Care Management and Health Records Domain Technical Committee will be developing a proposal to be conveyed to relevant standards organizations to fill this gap

4.2.2 RESOLUTION PLAN

This section provides a plan for resolving the gaps/overlaps identified in Section 4.2.1.

Table 4.2.2-1 Resolution Plan

Date	Task to be Accomplished/Who is involved
September, 2008	Develop proposal for creation of nursing assessment implementation guide
September, 2008	Distribute nursing assessment proposal to relevant Standards Development Organizations (SDOs)
October, 2008	Review and coordinate responses on nursing assessment proposal from SDOs
TBD	Develop proposal for creation of case reporting implementation guide
TBD	Distribute case reporting proposal to relevant SDOs
TBD	Review and coordinate responses on case reporting proposal from SDOs

5.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

No additional information at this time.

6.0 DOCUMENT UPDATES

The following sections provide the details of updates made to this document.

6.1 DECEMBER 10, 2008

The changes in this construct address the following comments received during the Public Comment and Inspection Testing period (September 29 – October 24, 2008).

5338, 5341, 5348, 5351, 5358, 5362, 5364, 5367, 5368, 5416, 5417, 5419, 5420, 5421, 5424

The full text of the comments along with the Technical Committee's disposition can be reviewed on the HITSP Public Web Site.

6.1.1 GLOBAL

General editing for clarity and readability; the following changes were applies through-out the document for consistency with the HITSP suite of Interoperability Specifications

- Fixed various table numbering errors

6.1.2 SECTION 3.0 HITSP CDA-BASED CLINICAL CONSTRUCTS

- Update title to HITSP CDA-based Clinical Constructs
- Updated text in Section 3.0 to clarify the concepts of HITSP Clinical Documents and HI7 CDA-based specifications.
- Update title of Figure 3-1 to HITSP CDA Constructs and Associated Interoperability Specifications
- Updated Figure 3-1 with missing HITSP constructs
- Added text to describe Figure 3-1
- Added HITSP/C76 Case Report Pre-Populate Case Report Pre-Populate to Table 3-1 and Table 4.1
- Renamed Table 3-2 and provided introductory text to the table

6.1.3 SECTION 3.1 GENERAL CONSTRAINTS APPLIED TO HITSP CDA-BASED DOCUMENTS

Added new section to illustrate general rules used for HITSP CDA-based documents.

6.1.4 SECTION 3.2 TRANSMISSION OF HITSP CDA-BASED DOCUMENTS

Added new section to provide explanation about how HITSP CDA-based documents are registered and transferred.

6.1.5 SECTION 3.2.2 VOCABULARY CONCEPTS

Please note the section number has changed as a section was deleted during IRT review so it went from Section 3.3.2 to Section 3.2.2.

6.1.6 SECTION 3.3.2.6 COMMUNICATING VALUES NOT IN HITSP VALUE SETS

Deleted text in section and the complete Section 3.1.2.6.2 as it was describing HL7 V2 messages which were not in the scope of the Technical Note.

6.1.7 SECTION 3.4 TABLE CONVENTIONS USED IN HITSP CDA CONSTRUCTS

Added new Table 3.2-1 Content Module Requirement Table Explanation

6.1.8 SECTION 3.5 REFERENCE MATERIALS

Updated Health Level Seven (HL7) Version 3 Standard: Specification and Use of Reusable Constraint Templates, Release 1 to Health Level Seven (HL7) Version 3 Standard: Specification and Use of Reusable Constraint Templates, Release 2.

6.1.9 SECTION 4.2 STANDARDS GAP

- Added the vocabulary standard's overlap for Procedures
- Added the gap related to Implanted Medical Devices

6.2 DECEMBER 18, 2008

Upon approval by the HITSP Panel on December 18, 2008, this document is now Released for Implementation.