

HITSP Immunization Document Component

HITSP/C78



Healthcare Information Technology Standards Panel

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Submitted by:

**Care Management and Health Records Domain Technical Committee
Population Perspective Technical Committee**



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1.0 INTRODUCTION

1.1 OVERVIEW

The HITSP Immunization Document Component defines the immunization data content to be exchanged between healthcare entities such as immunization information systems, Electronic Medical Record Systems, Personal Health Record Systems and other stakeholders. It is based upon the IHE Patient Care Coordination (PCC) Technical Framework Supplement 2008-2009, Immunization Content (IC), Trial Implementation Version 1.0.

1.2 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

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1.3 REFERENCE DOCUMENTS

A list of key reference documents and background material is provided in the table below. HITSP-maintained reference documents can be retrieved from the [HITSP Web Site](http://www.ihe.net).

Table 1-1 Reference Documents

Reference Document	Document Description
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents
TN901 – Clinical Documents	TN901 is a reference document that provides the overall context for use of the HITSP Care Management and Health Records constructs
TN903 – Data Architecture	TN903 is a reference document that provides the overall context for use of the HITSP Data Architecture constructs

1.4 CONFORMANCE

This section describes the conformance criteria, which are objective statements of requirements that can be used to determine if a specific behavior, function, interface, or code set has been implemented correctly.

1.4.1 CONFORMANCE CRITERIA

In order to claim conformance to this construct specification, an implementation must satisfy all the requirements and mandatory statements listed in this specification, the associated HITSP Interoperability Specification or Capability, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must also implement all of the required interfaces within the scope, subset or implementation option that is selected from the associated Interoperability Specification.

Claims of conformance may only be made for the overall HITSP Interoperability Specification or Capability with which this construct is associated.



1.4.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

A HITSP Interoperability Specification or Capability must be implemented in its entirety for an implementation to claim conformance to the specification. HITSP may define the permissibility for interface scoping, subsetting or implementation options by which the specification may be implemented in a limited manner. Such scoping, subsetting and options may extend to associated constructs, such as this construct. This construct must implement all requirements within the selected scope, subset or options as defined in the associated Interoperability Specification or Capability to claim conformance.



2.0 COMPONENT DEFINITION

2.1 CONTEXT OVERVIEW

To support “Immunization Feed”, HITSP is using the IHE Patient Care Coordination (PCC) Technical Framework Supplement 2008-2009, Immunization Content (IC), Trial Implementation Version 1.0.

As stated in IHE PCC-Technical Framework (TF):

The text for the PCC-TF specification begins here:

The Immunization Content Profile (IC) provides a standard document to exchange immunization data. It is intended to facilitate the exchange of immunization data among multiple systems belonging to a single or to multiple organizations. Data exchange with and among the installed base of U.S. Immunization Information System (IIS) base was a critical consideration in formulating this profile. However, its intention is to go beyond data exchange among IISs, and facilitate immunization data exchange on a healthcare information network that includes Electronic Medical Record (EMR) systems, Health Information Exchanges, other public health systems, Personal Health Record (PHR) systems, and other stakeholder systems. Thus, the profile specifies common data formats for exchanging immunization data only, or for exchanging immunization data along with medical summary data needed for the overall care of a patient related to immunizations.

To accomplish this, IC includes history of administered vaccines with such details as lot number, who administered the immunization, and so forth, and handles immunization as well as other information related to the patient's care. For example, it includes medical history, medications, allergies, vital signs, and so forth.

The text for the PCC-TF specification ends here.

The IHE PCC IC Integration Profile defines the Immunization Content Specification which is document based upon HL7 Version 3.0 Clinical Document Architecture (CDA).

2.1.1 COMPONENT DEPENDENCIES

Table 2-1 Component Dependencies

Standard/HITSP Component	Depends On (Name of standard/HITSP Component that it depends on)	Dependency Type (Pre-condition, Post-condition, General)	Purpose (Reason for this dependency)
HITSP/C78 - Immunization Document	HITSP/C83 - CDA Content Modules	General	Identifies Content Modules constrained by this Component to be applied within the exchange

2.2 RULES FOR IMPLEMENTING

2.2.1 DATA MAPPING

C78-[CT1-11] Implementations of this Component shall support the Immunization Content Modules as defined by IHE PCC Technical Framework Supplement 2008-2009, Immunization Content (IC), Trial Implementation Version 1.0. Table 2-2

The template identifier for this 2.16.840.1.113883.3.88.11.78.1

The HITSP template identifier is recommended to be used in exchanges, but is not required due to restrictions on major change. It is possible that the identifier could be required in future editions of this specification.



C78-[CT1-12] A CDA Document **SHOULD** declare conformance to this specification by including a <templateId> element with the root attribute set to the value 2.16.840.1.113883.3.88.11.78.1

C78-[CT1-13] The CDA document **SHALL** declare conformance to the IHE Immunization Content <templateId> 1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2

Additional HITSP constraints are specified in Table 2-2.

Table 2-2 Data Mapping - Immunization Content Modules

Constraint ID	Content Module	HITSP Optional Entry	HITSP Repeatable Entry	Specification Reference
C78-[CT1-1]	Person Information	R	N	See HITSP/C83 Section 2.2.2.1 Personal Information
C78-[CT1-2]	History of Immunizations	R	N	See HITSP/C83 Section 2.2.1.17 Immunizations Section Data Element Constraints: 13.02 Administered Date Optionality = R2, Repeat = N 13.08 Drug Manufacturer Optionality = R2, Repeat = N
C78-[CT1-3]	Problem List	R2	N	See HITSP/C83 Section 2.2.1.3 Problems List Section
C78-[CT1-4]	History of Past Illness	R2	N	See HITSP/C83 Section 2.2.1.4 History of Past Illness Section
C78-[CT1-5]	Allergies and Intolerances	R2	N	See HITSP/C83 Section 2.2.1.2 Allergies and Other Adverse Reactions Section
C78-[CT1-6]	Medications	R2	N	See HITSP/C83 Section 2.2.1.12 Medications Section
C78-[CT1-7]	Coded Results	R2	N	See HITSP/C83 Section 2.2.1.22 Diagnostic Results Section
C78-[CT1-8]	Coded Vital Signs	R2	N	See HITSP/C83 Section 2.2.1.19 Vital Signs Section
C78-[CT1-9]	Pregnancy History	R2	N	See IHE templateId 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4
C78-[CT1-10]	Advance Directives	R2	N	See HITSP/C83 Section 2.2.1.16 Advance Directives Section

Optionality Legend: "R" for Required, "O" for Optional, or "C" for Conditional

2.3 STANDARDS

2.3.1 REGULATORY GUIDANCE

Table 2-3 Regulatory Guidance

Regulation	Description
No applicable regulatory guidance	



2.3.2 SELECTED STANDARDS

Table 2-4 Selected Standards

Standard	Description
Health Level Seven (HL7) HL7 Version 3 Standard: Clinical Document Architecture (CDA), Release 2	The HL7 Clinical Document Architecture is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. Of particular focus for HITSP Interoperability Specifications are message formats for Laboratory Results and Continuity of Care (CCD) documents. Release 2 of the HL7 Clinical Document Architecture (CDA) is an extension to the original CDA document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. CDA R2 further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and Structures. For more information visit www.hl7.org
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Supplement 2008-2009, Immunization Content (IC), Trial Implementation Version 1.0	The IHE Patient Care Coordination Technical Framework (PCC TF) defines specific implementation (called Integration Profiles) of established standards to deal with integration issues the cross providers, patient problems or time. The Immunization Content (IC) Supplement enables sharing of a standard document to exchange immunization data. It is intended to facilitate the exchange of immunization data among multiple systems belonging to a single or to multiple organizations. For more information visit www.ihe.net

2.3.3 INFORMATIVE REFERENCE STANDARDS

Table 2-5 Informative Reference Standards

Standard	Description
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 4.0	The IHE Patient Care Coordination Technical Framework (PCC TF) defines specific implementations (called Integration Profiles) of established standards to deal with integration issues that cross providers, patient problems or time. The Cross-Enterprise Document Content Transactions (PCC-5) enables sharing of immunization information between immunization registries and clinical data consumers. In the registry, healthcare providers publish pointers to documents stored in distributed repositories. Other healthcare providers may search and retrieve these and other documents. For more information visit www.ihe.net



3.0 APPENDIX

3.1 TEMPLATE IDENTIFIERS

See the relevant HL7 Implementation Guides and IHE Profiles for a complete listing of all other template identifiers that are required for declaring conformance to HITSP defined templates.

- 2.16.840.1.113883.3.88.11.78.1 HITSP/C78 Immunization Document



4.0 DOCUMENT UPDATES

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

4.1 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).

5594

- Section 2.2.1 Data Mapping
 - Delete incorrect text related to discharge summary
 - Added text to require implementation support IHE PCC Technical Framework and HITSP constraints
 - Constrained Data Elements in History of Immunizations Content Module
 - Administered Date and Drug Manufacturer
- Section 2.3.3 Informative Reference Standards
 - Corrected Version for Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 4.0 in Table 2-5 Informative Reference Standards
- Global
 - Document Name change from Immunization and Response Component to Immunization Query and Response Component (this change was applied through-out the document for consistency with the HITSP suite of Interoperability Specifications)

4.2 DECEMBER 18, 2008

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

4.3 JUNE 30, 2009

The changes in this cycle address the following:

- Revised the document based on HITSP/TN903 Data Architecture
- Section 2.2 Rules for Implementing
 - Addition of Note on usage of HITSP Constraints
- Section 2.2.1 Data Mapping
 - Added Template Identifier to the Immunization Document
 - Added Constraint IDs to identify all HITSP Constraints
- 3.0 Appendix
 - Addition links to all C78 Immunization Data Element and HITSP Constraints
- Changes based upon Public Comments
 - 7071, 7078, 7114

Minor editorial changes were made to this construct. Removed boilerplate text for simplification. The term “actor” was replaced with “interface”.

4.4 JULY 8, 2009

Upon approval by the HITSP Panel on July 8, 2009, this document is now Released for Implementation.



4.5 JANUARY 18, 2010

Changes based upon Public Comments:

- 7123, 7130

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

Added reference to HITSP/TN903 – Data Architecture.

Section 2.1.1 was deleted because it is duplicate information.

Deleted text in Section 2.2 as it is duplicate text to constraint ID C78-[CT1-11]

Added constraints C78-[CT1-12] and C78-[CT1-13] to clarify conformance to HITSP and IHE document template OIDs

Modified Content Module Pregnancy History to point to IHE templateId 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4 Pregnancy History Section

Deleted Appendix Section 3.1 HITSP Constraints in this document as it is duplicate information already defined.

4.6 JANUARY 25, 2010

Upon approval by the HITSP Panel on January 25, 2010, this document is now Released for Implementation.

