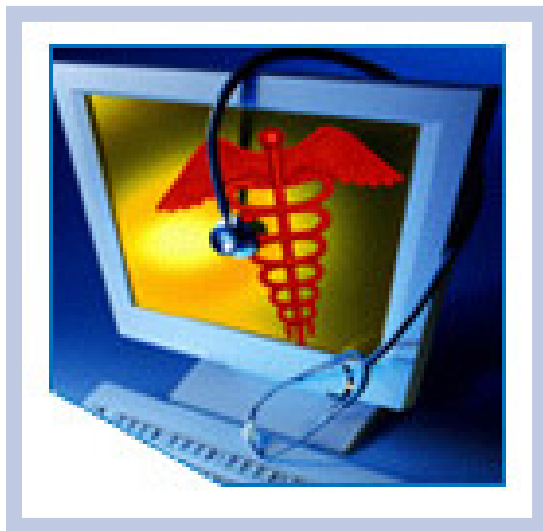


HITSP Immunizations and Response Management Interoperability Specification

HITSP/IS10



Submitted to:
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1.0 INTRODUCTION

As an introduction to the Healthcare Information Technology Standards Panel (HITSP) Immunizations and Response Management Interoperability Specification, this section provides a high level overview of the information sharing scenario enabled by following this specification, provides a document map of the construct relationships for the Interoperability Specification, acknowledges the copyright protections that pertain, and provides a list of key reference documents and background material.

1.1 INTEROPERABILITY SPECIFICATION OVERVIEW

This section provides a high level definition of this Interoperability Specification and background information about the underlying Use Case that it is based upon.

The HITSP Immunizations and Response Management Interoperability Specification is created to be architecture neutral. It is intended to support current interoperability approaches installed between Electronic Health Records (EHRs) and Immunization Information Systems while allowing for a migration toward emerging interoperability implementations and document sharing environments where Personal Health Records (PHRs) are able to be included in the information flow. The Interoperability Specification also allows for basic electronic information exchanges to enable requirement communications and alerting mechanisms and to lay the foundation for future clinical support capabilities. These requirements and alerts are largely unstructured at this time pending further standardization efforts.

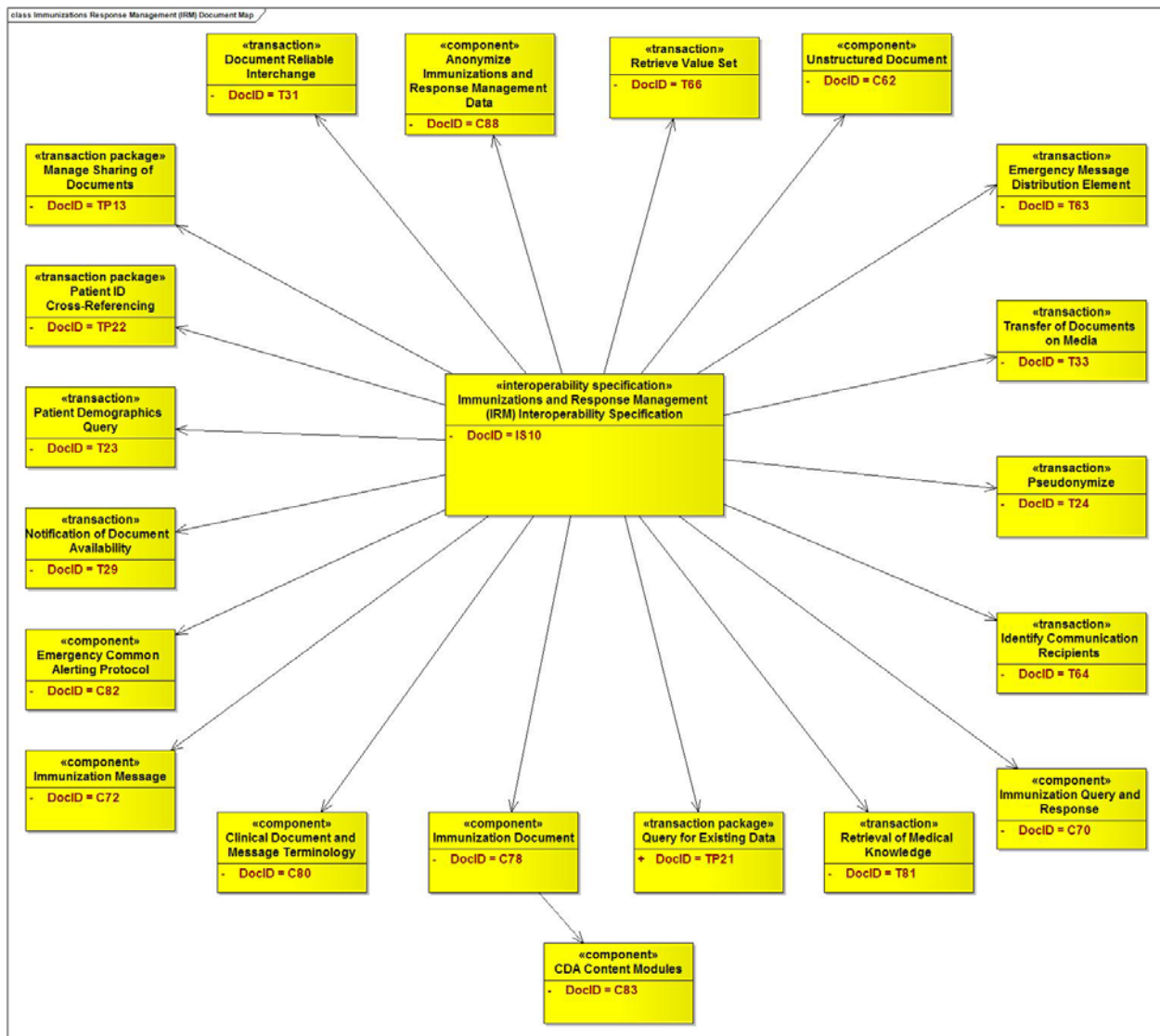
NOTE: All of the Immunizations and Response Management Use Case requirements have not been resolved at this time. The reader is referred to this specification, Section [3.1 Scope of Design](#) for scoping details.

1.2 INTEROPERABILITY SPECIFICATION DOCUMENT MAP

Each HITSP Interoperability Specification (IS) is comprised of a suite of constructs that, taken as a whole, define how to integrate and constrain existing standards and specifications to satisfy the requirements imposed by a given Use Case. The IS groups specific actions and actors to describe the relevant context(s) for the use of HITSP constructs that further identify and constrain standards where necessary. In addition to ISs, there are three other types of HITSP constructs called Transaction Packages (TP), Transactions (T), and Components (C). The document map in Figure 1.2-1 depicts how this IS integrates and constrains HITSP constructs to support the information exchange, within the defined context of the Use Case. Implementers should read the documents that describe the constructs depicted in the diagram for their details and specific uses. Note that the baseline Security and Privacy constructs are not shown in the diagram, however, they are described in Table 1.2.1-1.



Figure 1.2-1 Interoperability Specification Document Map



1.2.1 LIST OF CONSTRUCTS

The following table lists and describes the HITSP constructs that are used by the Interoperability Specification. All references to HITSP specifications are to the current, and Panel approved 'Released for Implementation' versions of the specifications retrieved from www.hitsp.org.

Where HITSP has adopted HL7 V3.0 CDA/CCD for conveying information between Electronic Health Record (EHR) and Personal Health Record (PHR) applications and in other healthcare scenarios, it has consolidated common constraints applied against the Content Modules in HITSP/C83 CDA Content Modules. Likewise, HITSP/C80 Clinical Document and Message Terminology maintains commonly applied terminology constraints. Readers should refer to HITSP/TN901 Technical Note for Clinical Documents to better understand how HITSP/C83 and HITSP/C80 are used by other constructs that are



based upon HL7 V3.0 CDA/CCD (e.g., HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD), HITSP/C48 Encounter Document Using IHE Medical Summary (XDS-MS) and HITSP/C84 Consult and History & Physical Note).

Table 1.2.1-1 List of Constructs

Construct	Description
HITSP/C19 - Entity Identity Assertion	The Entity Identity Assertion Component provides the mechanisms to ensure that an entity is the person or application that claims the identity provided. An example of this Component is the validation and assertion of a consumer logging on to a Personal Health Record (PHR) system
HITSP/C26 - Nonrepudiation of Origin	The Nonrepudiation of Origin Component provides the mechanisms to support Nonrepudiation of Origin, which refers to both the proof of the integrity and origin of documents in a high-assurance manner, which can be verified by any party. This Component does not provide Nonrepudiation of Receipt
HITSP/C62 - Unstructured Document	The Unstructured Document Component is provided for the capture and storage of patient identifiable, unstructured document content, such as text, PDF, and images rendered in PDF. It is based on the Cross-Enterprise Sharing of Scanned Documents (XDS-SD) profile from the Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF)
HITSP/C70 - Immunization Query and Response	The Immunization Query and Response Component is used for a message based exchange of immunization information. It specifies the use of HL7 Version 2.3.1 Query for Vaccination Record (VXQ), to send a query from the message sender (clinician system, schools, IIS) to the message receiver (immunization registry)
HITSP/C72 - Immunization Message	The Immunization Message Component provides the capability to communicate an update to a patient's vaccination record. It is based upon the Centers for Disease Control and Prevention Implementation Guide for Immunizations Data Transaction using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol Implementation Guide Version 2.2 June 2006
HITSP/C78 - Immunization Document	The Immunization Document Component defines the immunization data content to be exchanged between healthcare entities such as immunization information systems, electronic medical records systems, personal healthcare 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
HITSP/C80 - Clinical Document and Message Terminology	The Clinical Document and Message Terminology Component defines the vocabularies and terminologies utilized by HITSP specifications for Clinical Documents and Messages used to support the interoperable transmission of information
HITSP/C82 - Emergency Common Alerting Protocol	The Emergency Common Alerting Protocol Component selects the OASIS Common Alerting Protocol (CAP) v1.1 standard, and is used as a multicast notification message sent to an identified channel. The intended recipients are populations such as "all emergency departments in XXX county", "within a geographic area", etc
HITSP/C83 - CDA Content Modules	The CDA Content Modules Component defines the content modules for document based HITSP constructs utilizing clinical information. These Content Modules are based on IHE PCC Technical Framework Volume II, Release 4. These technical frameworks contain specifications for document sections that are consistent with all implementation guides for clinical documents currently selected for HITSP constructs



Construct	Description
HITSP/C88 - Anonymize Immunizations and Response Management Data	The Anonymize Immunizations and Response Management Data Component provides the ability to anonymize patient identifiable information for Immunization and Response Management. It provides specific instruction for anonymizing data that was created as part of routine clinical care delivery in preparation for repurposing the data. Anonymization, according to the International Organization for Standardization (ISO), is the process that removes the association between the identifying data set and the data subject
HITSP/T15 - Collect and Communicate Security Audit Trail	The Collect and Communicate Security Audit Trail Transaction is a means to provide assurance that security policies are being followed or enforced and that risks are being mitigated. This document describes the mechanisms to define and identify security relevant events and the data to be collected and communicated as determined by policy, regulation or risk analysis. It also provides the mechanism to determine the record format to support analytical reports that are needed
HITSP/T16 - Consistent Time	The Consistent Time Transaction provides a mechanism to ensure that all of the entities that are communicating within the network have synchronized system clocks
HITSP/T17 - Secured Communication Channel	The Secured Communication Channel Transaction provides the mechanisms to ensure the authenticity, integrity, and confidentiality of transmissions, and the mutual trust between communicating parties. Its objectives include providing: Mutual node authentication to assure each node of the others' identity; Transmission integrity to guard against improper information modification or destruction while in transit; and Transmission confidentiality to ensure that information in transit is not disclosed to unauthorized individuals, entities, or processes
HITSP/T23 - Patient Demographics Query	The Patient Demographics Query Transaction is intended to provide a 'list patients and their demographics' query/patient(s) and their demographics identified' response message pair (QBP^Q22, RSP^K22) for use wherever such needs exist. This Transaction document extracts the Health Level Seven (HL7) version 2.5 Query and Response data mapping. The underlying basis for this extraction can be found in the Integrating the Healthcare Enterprise IT Infrastructure Technical Framework, Patient Demographics Query integration profile
HITSP/T24- Pseudonymize	The Pseudonymize Transaction is to describe a framework for including Pseudonymization Services where the use of "dummy" or pseudo references to specific patients or providers is required. Pseudo-identifiers are intended to allow accessibility to clinical information, while safeguarding any information that may compromise the privacy of the individual patient or provider. Using pseudo-identifiers can assist in compliance with HIPAA regulations regarding suppression of patient identification information
HITSP/T29 - Notification of Document Availability	The Notification of Document Availability Transaction is based on the Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement - Notification of Document Availability (NAV). The Notification of Document Availability Transaction defines a mechanism for a healthcare stakeholder (e.g. provider, public health, etc) to notify providers or the patient about information that is available for retrieval pertaining to an identified patient. This Transaction defines the format, content, encoding and transmission of notification messages and acknowledgements between IHE NAV Actors and a known recipient (either a person or system) that participate in the same XDS Affinity Domain



Construct	Description
HITSP/T31 - Document Reliable Interchange	The Document Reliable Interchange Transaction provides a standards-based mechanism for conveying a set of medical documents in a point-to-point network-based communication. This Transaction uses the IHE Cross-Enterprise Document Reliable Interchange (XDR) Integration Profile, a companion to the IHE Cross-Enterprise Document Sharing (XDS) Integration Profile. Cross-Enterprise Document Reliable Interchange (XDR) uses the XDS defined metadata formats in a simpler environment in which the communicating parties have agreed to a point-to-point interchange rather than communicating via document sharing
HITSP/T33 - Transfer of Documents on Media	The Transfer of Documents on Media Transaction describes both the type of media (CD-ROM, USB Memory, and e-Mail) that may be used to write the documents and provides a directory structure that must be followed in order for the contents to be successfully accessed and processed by systems. An example might be to transport data from one healthcare provider to another healthcare provider, or a healthcare consumer may wish to move the contents of a Personal Health Record (PHR) using physical media or e-mail. This Transaction uses the IHE Cross-Enterprise Document Media Interchange Integration Profile developed by Integrating the Healthcare Enterprise (IHE), a companion to the IHE Cross-Enterprise Document Sharing (XDS) Integration Profile
HITSP/T63 - Emergency Message Distribution Element	The Emergency Message Distribution Element Transaction selects the Emergency Data Exchange Language (EDXL) Distribution Element (DE) v1.0 standard, and is a multicast notification message sent to an identified population (it is assumed this is not to the general public, but to specifically identified populations, such as emergency departments)
HITSP/T64 - Identify Communication Recipients	The Identify Communication Recipients Transaction is intended to serve the purpose of identification of communication recipients and the subsequent purpose of delivery of alerts and bi-directional communications (e.g., public health agencies notifying a specific group of service providers about an event.) The method and criteria by which individuals are added to a directory is a policy decision, which is out of scope for this construct. It uses the Integrating the Healthcare Enterprise (IHE) Personnel White Pages profile which provides access to basic directory information for identifying one or more recipients
HITSP/T66 - Retrieve Value Set	The Retrieve Value Set Transaction is used to transform human or computer vocabularies. For example, it can be used to convert the initial capture of a human-readable concept into a computer vocabulary captured in a document or message that will be communicated. It may also be used in the reverse, to take computer vocabulary and convert to human-readable form
HITSP/T81 - Retrieval of Medical Knowledge	The Retrieval of Medical Knowledge Transaction enables the request and receipt of additional knowledge about a medical concept based on specific context parameters. This Transaction does not prescribe the knowledge content of the message returned but provides the specifications for the query for and receipt of additional knowledge. It uses the Health Level 7 (HL7) Context-Aware Information Retrieval (Infobutton) Specification: URL Implementation Guide as the base standard for implementation
HITSP/TP13 - Manage Sharing of Documents	The Manage Sharing of Documents Transaction Package supports the sharing of patient records in the form of source attested objects called documents. A healthcare document is a composite of structured and coded health information, both narrative and tabular, that describes acts, observations and services for the purpose of exchange. No assumption is made by this construct in terms of the format and structure of the content of documents shared



Construct	Description
HITSP/TP20 - Access Control	The Access Control Transaction Package provides the mechanism for security authorizations which control the enforcement of security policies including: role-based access control; entity based access control; context based access control; and the execution of consent directives. An example of this is a functional role that has the permission to perform an act (e.g., consumer updating a Personal Health Record (PHR). In an emergency, this construct must support the capability to alter access privileges to the appropriate level (failsafe/emergency access), which may include override of non-emergency consents
HITSP/TP21 - Query for Existing Data	The Query for Existing Data Transaction Package is based on the IHE Query for Existing Data Integration Profile (QED) which supports dynamic queries for clinical data, including vital signs, problems, medications, immunizations, diagnostic results, procedures and visit history. A wide variety of systems often needs access to dynamic clinical information stored and maintained in an EMR system or other clinical data repository. The construct makes the information widely available to other systems within and across enterprises to support provision of better clinical care
HITSP/TP22 - Patient ID Cross-Referencing	The Patient ID Cross-Referencing Transaction Package is used for identifying and cross-referencing different attributes for the same patient. It contains a query for cross-reference and patient identity feed transactions. These transactions are used to identify patients from a list of potentials, and/or to communicate patient demographic data
HITSP/TP30 - Manage Consent Directives	The Manage Consent Directives Transaction Package describes the messages needed to capture, manage, and communicate rights granted or withheld by a consumer to one or more identified entities in a defined role to access, collect, use or disclose Individually Identifiable Health Information (IIHI), and also supports the delegation of the patient's right to consent. The transactions described in this construct are intended to be carried out by HITSP/TP13 - Manage Sharing of Documents

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1.4 REFERENCE DOCUMENTS

This section provides a list of key reference documents and background material. If you are already familiar with this information, proceed to Section 2.

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 1.4-1 Reference Documents

Construct	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 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 system development or refinement
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
Immunizations & Response Management, Detailed Use Case, March 21, 2008	AHIC Use Case that is the basis of this Interoperability Specification



Construct	Description
TN900 - Security and Privacy Technical Note	<p>Developed as a reference document to provide the overall context for use of the HITSP Security and Privacy constructs. It includes the following:</p> <ul style="list-style-type: none"> • The scope, reference policy background, and Security and Privacy principles used in the development of the constructs • A detailed description and schematics of the conceptual relationship between the Security and Privacy constructs • A mapping of existing standards and constructs to be used in meeting the stated requirements of the AHIC Use Cases • A list of identified gaps and the recommended approaches to resolving those gaps • A roadmap for how the Security and Privacy constructs will evolve and eventually align with other HITSP Interoperability Specifications • A conceptual framework for Security and Privacy management, including reference information on privacy policies, risk assessment, and risk management • A description of the application of the Security and Privacy constructs to the HITSP Interoperability Specifications for the three initial AHIC Use Cases – Biosurveillance, Electronic Health Records - Laboratory Results Reporting, and Consumer Empowerment <p>HITSP will periodically update this Technical Note as required by the introduction of new contexts for use.</p>
TN901 - Technical Note for Clinical Documents	<p>Developed as a reference document to provide the overall context for use of the HITSP Care Management and Health Records constructs. It includes the following:</p> <ul style="list-style-type: none"> • The scope, background, and principles for use in the development of the CMHR constructs • A detailed description and schematics of the relationship between CMHR constructs • A conceptual framework for the construction of clinical documents • An overview of Clinical Document concepts • An overview of Vocabulary concepts

Specific to the Immunizations and Response Management Use Case, the following are referenced for source data requirements:

Standards:

- Vaccine Management System (VACMAN)
- Strategic National Stockpile Systems and Vendor Management Inventory Systems
- American Immunization Registry Association (AIRA) Modeling of Immunization Registry Operations Workgroup (MIROW) Management of Moved or Gone Elsewhere (MOGE) Status and Other Patient Designations in Immunization Information Systems, December, 2005
- American Immunization Registry Association (AIRA) Modeling of Immunization Registry Operations Workgroup (MIROW) Vaccination level deduplication in Immunization Information Systems, December, 2006



- American Immunization Registry Association (AIRA) Modeling of Immunization Registry Operations Workgroup (MIROW). Data quality assurance in Immunization Information Systems: Incoming Data, February 2008

Documents:

- Immunization Information Systems NVAC Progress Report, February 2007: www.hhs.gov
- IIS Data Code Book: www.immregistries.org prepared by The American Immunization Registry Association Data Definitions Working Group



2.0 REQUIREMENTS

This section provides a high level description of the Immunizations and Response Management Use Case, as well as the specific information exchange and data requirements that are extracted from the Use Case. It includes the following information:

- Mapping from the Use Case actions and events, to the derived information exchange and data requirements – this table lists the requirements grouped by actor for each event and related action
- Data requirements – this table further describes the data requirements for each specified information exchange requirement
- Information exchange requirements – this table further describes the information exchange requirements for each applicable Use Case action
- Business Actors – this table defines the business actors that are included for the Interoperability Specification, and maps them to the applicable scenario, information exchange, and data requirements
- High Level Diagrams – these diagrams are used to describe the interaction between the business actors, and the data involved in each scenario that is documented

2.1 USE CASE SYNOPSIS

This section provides a synopsis of the Immunizations and Response Management Use Case, including any applicable scenarios that are part of the Use Case.

In July 2007, AHIC approved a recommendation to develop a Use Case which addresses the exchange of information supporting the distribution and administration of medications, vaccinations, and other specific medical prophylaxis and treatment methods. The Immunizations and Response Management Use Case focuses on the information needs of consumers, clinicians, registries, public health and inventory managers carrying out routine care activities associated with immunizations. The Use Case recognizes during non-routine or emergency situations, as well as those necessary to support public health outcomes, could be accomplished using the same infrastructure. This Use Case, however, does not address all capabilities required for public health response planning or response management in emergency situations.

AHIC prioritized needs related to this Use Case include:

- Automated integration of EHRs with related registries, such as immunization registries, registries of emergency response volunteers, registries of individuals given other prevention and treatment interventions, and registries supporting long-term follow-up will support case management activities
- The ability to exchange information such as the need to administer resources, the availability of resources and their actual administration (including isolation and quarantine) in coordinating response activities, and managing available medical resources during a public health emergency



- The integration of supply chain information from public and private sectors to provide data to support informed decision making as well as support response and treatment activities

2.2 USE CASE REQUIREMENTS

This section describes the Use Case requirements and outlines all the given scenarios at a high level.

The Immunizations and Response Management Use Case focuses on: 1) access to information about individuals who need to receive specific vaccines, drugs, or other interventions; 2) the ability to report, track, and manage administration of vaccines, drugs, isolation, and quarantine; 3) the ability to identify and electronically exchange information describing the treatment or prophylaxis status of populations; 4) the ability to exchange specific resource and supply chain data from public and private sectors. The draft detailed Use Case describes these activities within the context of two scenarios:

Vaccine and Drug Administration and Reporting: This scenario describes the process of identifying individuals and populations requiring and the administration of vaccines or drugs based on routine schedules, or as dictated by emergency response priorities. Additionally, this scenario describes the exchange of data necessary to support countermeasure and response administration of prophylaxis and treatment modalities, and the supply of data between appropriate registries and other sources of data to support clinical care and public health follow-up activities.

Vaccine and Drug Inventory Reporting: This scenario describes how information regarding the need for, and availability of, vaccines and/or drugs is collected and exchanged to support coordinated delivery of care

NOTE: Vaccine and Drug Inventory Reporting is deferred in this IS

Associations between the scenarios in this Use Case and the AHIC Public Health Case Reporting Use Case are also described.

This Use Case assumes the developing presence of electronic systems such as Electronic Health Records (EHRs), Personal Health Records (PHRs), and other local or Web-based solutions supporting consumers and clinicians, while recognizing the issues and obstacles associated with these assumptions. This approach helps promote the development of longer-term efforts.

NOTE: All of the Immunizations and Response Management Use Case requirements have not been resolved at this time. The reader is referred to Section [3.1 Scope of Design](#) for scoping details.

NOTE: While the Use Case does not specifically cite processing a query and response solely for the sake of getting the data without the goal of identifying whether or not a vaccination is needed (e.g. for school registration), this functionality is addressed by this IS.



2.2.1 MAPPING OF USE CASE ACTIONS TO INFORMATION EXCHANGE REQUIREMENTS

This section contains an extraction of business actors, required interactions and conditions/scenarios from the Use Case into a matrix/table.

Section 6.3 contains the perspectives, scenarios, and events from the Use Case. This section maps these events and actions to extracted Information Exchange Requirements (IER), and Data Requirements (DR) that are described in Section 2.2.2. An Information Exchange Requirements (IER) describes a requirement for information exchange between HITSP Business Actors. Data Requirements (DR) define requirements for part, or all, of the data exchanged by one or more IERs. The DR's are defined as a set of information attributes with specific details for each attribute. IER's and DR's form the basis for the construct requirements of the Interoperability Specification that are described in Section 3.

2.2.2 DATA AND INFORMATION EXCHANGE REQUIREMENTS

This section contains an extraction of data and information requirements (Table 2.2.2-1) and information exchange requirements (Table 2.2.2-2).

Table 2.2.2-1 provides the data requirement numbers, requirement descriptions, and a listing of the actual data elements and information that meet the data requirements. These requirements are referenced from the Data Requirements column of the Use Case Mapping Table 6.3-1 provided in Section 6.3.

Table 2.2.2-1 Data Element and Information Requirements (DR)

Data Requirement Number (DR)	Description
DR8	Unstructured Data: Document that contains simple text such as a note to the patient, about a patient, or a note from the patient (e.g. camp form immunization summary, patient-specific immunization alert, patient listing alert to providers of patients needing vaccination). This document could include an unstructured, presentation preserved format, such as PDF. Metadata may include but is not limited to:
	<ul style="list-style-type: none">TitleClinic IDDate
DR11	Immunization response data: Immunization details returned in response to immunization inquiry including (but not limited to):



Data Requirement Number (DR)	Description	
	<ul style="list-style-type: none"> • Patient Name: First, Middle, Last • Patient Alias Name: First, Middle, Last • Patient Address • Patient Phone Number • Patient Identifier • Patient Birth Date • Patient Sex • Patient Race • Patient Ethnicity • Patient Primary Language • Patient Multiple Birth Indicator • Patient Multiple Birth Order • Patient Birth Registration Number • Patient Birth State/Country • Patient Birthing Facility • Mother's Name: First, Middle, Last • Mother's Maiden Name • Mother's SSN • Father's Name: First, Middle, Last • Father's SSN • Insurance Plan • Insurance Company • Immunization Services Funding Eligibility • Next of Kin Relationship • Next of Kin Address • Next of Kin Telephone • Next of Kin DOB • Last Update Time/Date 	<ul style="list-style-type: none"> • Last Update Facility • Immunization Event Identifier • Vaccine Expiration Date • Vaccine Injection Site • Vaccination Date • Vaccine Lot Number • Vaccine Administration Provider • Vaccine Administration Facility • Vaccine Type • Vaccine Manufacturer • Vaccine Dose Number • Reason for Non-Vaccination • Patient Status in the Immunization Home • Transaction Information Source • Immunization Information Source • Amount Administered (dosage amount): • Smallpox Take Response Observation • Read Date for Take Response • Treatment Route • Refusal Reason • Action Code • Vaccine Dose Valid Flag • Immunization Recommendations • Vaccine Information Sheet (VIS) date • Vaccine Information Sheet (VIS) version • Vaccine Recall Effective Date • Vaccine Lot # Recall Code
DR12	Adverse Event Report: A report of a Vaccine Adverse Event. See requirements for HITSP/IS11 - Public Health Case Reporting for Adverse Event Report (FDA – MedWatch, Vaccine Adverse Events Reporting System (VAERS))	
DR13	Drug/Vaccine Inventory Data: detail-level content supporting the inventory management functions of vaccine supply. NOTE: Scenario 2 deferred (see Section 3.1 Scope of Design) Data requirements include (but are not limited to):	
	<ul style="list-style-type: none"> • quantity of vaccine • location • clinician • geographic identifiers 	<ul style="list-style-type: none"> • non-geographic identifiers • manufacturer • lot number • expiration date
DR14	Drug/Vaccine Inventory Usage Data: Aggregate content supporting the inventory usage functions of vaccine supply. NOTE: Scenario 2 deferred (see Section 3.1 Scope of Design) Data requirements include (but are not limited to):	



Data Requirement Number (DR)	Description	
	<ul style="list-style-type: none"> • quantity of vaccine utilized in a specific period of time • location • clinician • geographic identifiers 	<ul style="list-style-type: none"> • non-geographic identifiers • manufacturer • lot number • expiration date
DR15	Drug/Vaccine Inventory Availability Data: Aggregated content supporting the inventory availability functions of vaccine supply. NOTE: Scenario 2 deferred (see Section 3.1 Scope of Design) Data requirements include (but are not limited to):	
	<ul style="list-style-type: none"> • quantity of vaccine available in a specific period of time • location • clinician • geographic identifiers 	<ul style="list-style-type: none"> • non-geographic identifiers • manufacturer • lot number • expiration date
DR16	Supply Chain Management Vaccine Recall: Content that supports the vaccine recall functions of the vaccine supply chain. NOTE: Scenario 2 deferred (see Section 3.1 Scope of Design) Data requirements include (but are not limited to):	
	<ul style="list-style-type: none"> • Title (what is being recalled) • Date of recall • Lot # • Expiration date • Manufacturers • Reason- text 	<ul style="list-style-type: none"> • Action – text (interventions required for the recall) NOTE: Deferred to be further specified as part of Supply Chain Management in Scenario 2 (see Section 3.1 Scope of Design) NOTE: This information could come from adverse event monitoring (a 'research' function) or a Clinical Decision Support actor such as Surveillance
DR17	Decision Support Data: Employed to evaluate a given clinical situation to suggest a course of action, or to set up criteria to trigger one or more actions when a clinical event meets those criteria. NOTE: Component Specification deferred due to standards gaps (see scope and gaps) Data requirements include (but are not limited to):	



Data Requirement Number (DR)	Description	
	<p>In general, the data may include, but is not limited to:</p> <ul style="list-style-type: none"> • Medication reconciliation • Clinical protocols • Administrative protocols (e.g: Insurance) • Diagnosis • Laboratory results 	<p>For this Interoperability Specification, data may also include, but is not limited to:</p> <ul style="list-style-type: none"> • Decision support data input <ul style="list-style-type: none"> ○ Age range ○ Sex ○ Race ○ Risk ○ Location of the exposure ○ Date/time of exposure ○ Type of exposure ○ Occupation (e.g. first responders) ○ Clinical history • Patient Birth Date • Decision support feedback (pending further analysis) • Logic <ul style="list-style-type: none"> ○ Contraindications ○ Policy ○ Trigger Criteria ○ Other pending further analysis
DR18	<p>Vaccination Data: The immunization data content to be exchanged between healthcare entities such as immunization information systems; electronic medical records systems, personal healthcare record systems and other stakeholders. Data requirements include (but are not limited to):</p>	



Data Requirement Number (DR)	Description	
	<ul style="list-style-type: none">• Patient Name: First, Middle, Last• Patient Alias Name: First, Middle, Last• Patient Address• Patient Phone Number• Patient Identifier• Patient Birth Date• Patient Sex• Patient Race• Patient Ethnicity• Patient Primary Language• Patient Multiple Birth Indicator• Patient Multiple Birth Order• Patient Birth Registration Number• Patient Birth State/Country• Patient Birthing Facility• Mother's Name: First, Middle, Last• Mother's Maiden Name• Mother's SSN• Father's Name: First, Middle, Last• Father's SSN• Insurance Plan• Insurance Company• Immunization Services Funding Eligibility• Next of Kin Relationship• Next of Kin Address• Next of Kin Telephone• Next of Kin DOB Last Update Time/Date	<ul style="list-style-type: none">• Last Update Facility• Immunization Event Identifier• Vaccine Expiration Date• Vaccine Injection Site• Vaccination Date• Vaccine Lot Number• Vaccine Administration Provider• Vaccine Administration Facility• Vaccine Type• Vaccine Manufacturer• Vaccine Dose Number• Reason for Non-Vaccination• Patient Status in the Immunization Home• Transaction Information Source• Immunization Information Source• Amount Administered (dosage amount)• Smallpox Take Response Observation• Read Date for Take Response• Treatment Route• Refusal Reason• Action Code• Vaccine Dose Valid Flag• Immunization Recommendations• Vaccine Information Sheet (VIS) date• Vaccine Information Sheet (VIS) version• Vaccine Recall Effective Date• Vaccine Lot # Recall Code
DR19	<p>Medication Administration data: The Medication Administration data content to be exchanged between healthcare entities such as immunization information systems and electronic medical records systems, in support of Countermeasure and Response Administration.</p> <p>NOTE: Imposing a data requirement on immunization registries that they do not have at this time (deferred see Section 3.1 Scope of Design)</p>	
	<ul style="list-style-type: none">• vaccinations received by an individual• dates administered• administering clinician• manufacturer and lot number• source of this information (clinically verifiable source, self-reported by a consumer, or provided from another non-clinically verifiable source)• reason for drug administration- information does not go to registry unless given for prophylactic reason	<ul style="list-style-type: none">• campaign for prophylactic drug use/context• population that the campaign is directed toward• campaign ID• campaign name• campaign start/end date• campaign potential counter-measures <p>See content for CDC file format for submitting data into CDC – summary level/aggregate data format (XML) NOTE: not at administration level</p>



Data Requirement Number (DR)	Description		
DR20	<p>Aggregate Inventory of Available Vaccine: The Aggregate Inventory of Available Vaccine data content to be exchanged between healthcare entities inventory systems such as Immunization Information Systems and Electronic Medical Records Systems, in support of Vaccine Supply monitoring and management.</p> <p>NOTE: Scenario 2 deferred (see Section 3.1 Scope of Design)</p> <p>Data requirements (pending further analysis on Scenario 2 for supply chain) include (but are not limited to):</p> <table border="1" data-bbox="380 457 1409 653"> <tr> <td data-bbox="380 457 906 653"> <ul style="list-style-type: none"> • quantity of vaccine available <ul style="list-style-type: none"> ◦ doses committed ◦ doses remaining • location • clinician </td><td data-bbox="906 457 1409 653"> <ul style="list-style-type: none"> • geographic identifiers • non-geographic identifiers • manufacturer • lot number • expiration date </td></tr> </table>	<ul style="list-style-type: none"> • quantity of vaccine available <ul style="list-style-type: none"> ◦ doses committed ◦ doses remaining • location • clinician 	<ul style="list-style-type: none"> • geographic identifiers • non-geographic identifiers • manufacturer • lot number • expiration date
<ul style="list-style-type: none"> • quantity of vaccine available <ul style="list-style-type: none"> ◦ doses committed ◦ doses remaining • location • clinician 	<ul style="list-style-type: none"> • geographic identifiers • non-geographic identifiers • manufacturer • lot number • expiration date 		
DR21	Terminology Data: Used to transform human or computer vocabularies. Data attributes may be specified based upon implementation		
DR22	<p>Generic Alert Data – Immunizations: A non-patient identifiable alert (message or presentation preserving document) sent to an identified set of recipients. This may be used to communicate immunization schedules, prioritization notices, and alerts.</p> <p>NOTE: See Clinical Decision Support Prioritization for trigger criteria</p> <p>Data requirements include (but are not limited to):</p> <table border="1" data-bbox="380 894 1409 1129"> <tr> <td data-bbox="380 894 906 1129"> <ul style="list-style-type: none"> • Target population • Alert delivery timeframe • A descriptive directive • Alert title/subject • Date/time of alert • Alert type </td><td data-bbox="906 894 1409 1129"> <ul style="list-style-type: none"> • Severity • Source/Author • Alert identifier • Alert status • Acknowledge requirements </td></tr> </table>	<ul style="list-style-type: none"> • Target population • Alert delivery timeframe • A descriptive directive • Alert title/subject • Date/time of alert • Alert type 	<ul style="list-style-type: none"> • Severity • Source/Author • Alert identifier • Alert status • Acknowledge requirements
<ul style="list-style-type: none"> • Target population • Alert delivery timeframe • A descriptive directive • Alert title/subject • Date/time of alert • Alert type 	<ul style="list-style-type: none"> • Severity • Source/Author • Alert identifier • Alert status • Acknowledge requirements 		
DR23	Consumer Vaccination View: This is a consumer friendly view of a person's immunization history/record.		



Data Requirement Number (DR)	Description	
	<ul style="list-style-type: none"> • Patient Name: First, Middle, Last • Patient Alias Name: First, Middle, Last • Patient Address • Patient Phone Number • Patient Identifier • Patient Birth Date • Patient Sex • Patient Race • Patient Ethnicity • Patient Primary Language • Patient Multiple Birth Indicator • Patient Multiple Birth Order • Patient Birth Registration Number • Patient Birth State/Country • Patient Birthing Facility • Mother's Name: First, Middle, Last • Mother's Maiden Name • Mother's SSN • Father's Name: First, Middle, Last • Father's SSN • Insurance Plan • Insurance Company • Immunization Services Funding Eligibility • Next of Kin Relationship • Next of Kin Address • Next of Kin Telephone • Next of Kin DOB • Last Update Time/Date 	<ul style="list-style-type: none"> • Last Update Facility • Immunization Event Identifier • Vaccine Expiration Date • Vaccine Injection Site • Vaccination Date • Vaccine Lot Number • Vaccine Administration Provider • Vaccine Administration Facility • Vaccine Type • Vaccine Manufacturer • Vaccine Dose Number • Reason for Non-Vaccination • Patient Status in the Immunization Home • Transaction Information Source • Immunization Information Source • Amount Administered (dosage amount): • Smallpox Take Response Observation • Read Date for Take Response • Treatment Route • Refusal Reason • Action Code • Vaccine Dose Valid Flag • Immunization Recommendations • Vaccine Information Sheet (VIS) date • Vaccine Information Sheet (VIS) version • Vaccine Recall Effective Date • Vaccine Lot # Recall Code
DR58	Demographic Data – Vaccination: The demographic data content to be exchanged to appropriately associate the patient vaccination or vaccination inquiry data with vaccination data maintained in another system. Data requirements include (but are not limited to):	



Data Requirement Number (DR)	Description	
	<ul style="list-style-type: none">• Patient Name: First, Middle, Last• Patient Alias Name: First, Middle, Last• Patient Address• Patient Phone Number• Patient Identifier• Patient Birth Date• Patient Sex• Patient Race• Patient Ethnicity• Patient Primary Language• Patient Multiple Birth Indicator• Patient Multiple Birth Order• Patient Birth Registration Number• Patient Birth State/Country• Patient Birthing Facility	<ul style="list-style-type: none">• Mother's Name: First, Middle, Last• Mother's Maiden Name• Mother's SSN• Father's Name: First, Middle, Last• Father's SSN• Insurance Plan• Insurance Company• Immunization Services Funding Eligibility• Next of Kin Relationship• Next of Kin Address• Next of Kin Telephone• Next of Kin DOB• Last Update Time/Date• Last Update Facility
DR76	Immunization query data: data attributes sent for request of immunization data including (but not limited to):	
	<ul style="list-style-type: none">• Patient Name: First, Middle, Last• Patient Alias Name: First, Middle, Last• Patient Address• Patient Phone Number• Patient Identifier• Patient Birth Date• Patient Sex• Patient Race• Patient Ethnicity• Patient Primary Language• Patient Multiple Birth Indicator• Patient Multiple Birth Order• Patient Birth Registration Number• Patient Birth State/Country• Patient Birthing Facility	<ul style="list-style-type: none">• Mother's Name: First, Middle, Last• Mother's Maiden Name• Mother's SSN• Father's Name: First, Middle, Last• Father's SSN• Insurance Plan• Insurance Company• Immunization Services Funding Eligibility• Next of Kin Relationship• Next of Kin Address• Next of Kin Telephone• Next of Kin DOB• Last Update Time/Date• Last Update Facility
DR77	Drug/Vaccine query data: Content for an inquiry of available vaccine (subject to further analysis of scenario 2). Data requirements include (but are not limited to):	
	<ul style="list-style-type: none">• vaccine name• location• clinician• geographic identifiers	<ul style="list-style-type: none">• non-geographic identifiers• manufacturer• lot number• expiration date
DR78	Drug/vaccine response data: Content for an inquiry response for available vaccine (subject to further analysis of scenario 2). Data requirements include (but are not limited to):	



Data Requirement Number (DR)	Description	
	<ul style="list-style-type: none"> quantity of vaccine location clinician geographic identifiers 	<ul style="list-style-type: none"> non-geographic identifiers manufacturer lot number expiration date
DR79	Drug/Vaccine Inventory Requirements: Content for communication of inventory needs/requirements. NOTE: Scenario 2 deferred (see Section 3.1 Scope of Design) Data requirements include (but are not limited to):	
	<ul style="list-style-type: none"> Vaccine requirement/delivery instructions Shipping/handling information data requirements Temperature Storage conditions Breakage 	<ul style="list-style-type: none"> Humidity Air quality See Countermeasure and Response Administration Campaign for additional detail

Table 2.2.2-2 below contains an extraction of the Information Exchange Requirements from the Use Case. Information Exchange Requirements map to the Information Exchange Requirements column in the Use Case Mapping Table 6.3-1 provided in Section 6.3.

Table 2.2.2-2 Information Exchange Requirements (IER)

Information Exchange Requirement Number (IER)	Description
IER01	Provide authorization and consent: Support for consent directives and security authorizations which control the enforcement of security policies including: <ul style="list-style-type: none"> Role-based access control; entity based access control; context based access control The execution of consent directives Agreement verification – e.g. authorizations for registries to exchange information May have new actors in an emergency situation (e.g. labs or employers, healthcare provider not traditionally involved in immunization administration, mobile service)
IER02	Send data over secured communication channel: A session oriented, synchronous, point-to-point communication channel establishing a secure path through which data can be transmitted, including communications with providers, schools, and emergency support providers)
IER03	Create audit log entry: Provides assurance that security policies are being followed or enforced and that risks are being mitigated
IER04	Synchronize system time: Ensures that all of the entities that are communicating within the network have synchronized system clocks
IER05	Verify entity identity: Entities are asserted to assure that the entity is the person or application that claims the identity.
IER06	Provide proof of document integrity and origin: Support Nonrepudiation of Origin, which refers to both the proof of the integrity and origin of documents in a high-assurance manner which can be verified by any party
IER10	Identify patient: Support for identifying, cross referencing, and query of patients. NOTE: Method for identifying where the patient's records across multiple domains provided. For cross community access, need another method for identifying patient records in a non-document-centric environment



Information Exchange Requirement Number (IER)	Description
IER13	Send/receive notification of document availability: Defines a mechanism to notify providers or the patient that there is patient-related information available for retrieval supporting the pro-active sending of notifications from public health agencies
IER18	Send/receive clinical document: Supports the sharing of patient records in the form of source attested objects called documents, using physical media and email to transport clinical document information from a source to a destination, or communicate a clinical document to a recipient through direct communication conveying a set of medical documents in a point-to-point network-based communication
IER26	Identify communication recipients: Allow for the identification of communication recipients for the delivery of alerts, and bi-directional communications from public health services (e.g. identify communication details for those who may have received a bad lot of vaccine, based upon clinical decision support output, providers in a particular geographic area at risk)
IER27	Send non-patient notification message or alert: Supports the communication of text-based, non-patient specific notifications supporting pro-active notifications from public health (e.g. notification of a population at risk in need of vaccination)
IER 40	Query for existing Existing dataData: Supports dynamic queries for clinical data, including vital signs, problems, medications, immunizations, diagnostic results, procedures and visit history
IER42	Request/receive medical concept knowledge: Supports the query and receipt of ancillary medical knowledge
IER54	Query/response for clinical message data: Supports transactions to enable query for immunization data and response from the queried system with the immunization details
IER55	Anonymize patient identifiable data: Supports the process that removes the association between the identifying data set and the data subject. For this specification, this specifically supports data provisioning for clinical decision support NOTE: Secondary use has not been specified by the Use Case:: How much vaccine is needed for the community is a secondary use, but there are no triggering criteria specified by the Use Case (e.g. condition to need more vaccine)
IER56	Pseudonymize patient identifying information: Supports Pseudonymization, which is a particular type of anonymization that both removes the association with a data subject and adds an association between a particular set of characteristics relating to the data subject and one or more pseudonyms. For this specification, this specifically supports data provisioning for clinical decision support. NOTE: Secondary use has not been specified by the Use Case:: How much vaccine is needed for the community is a secondary use, but there are no triggering criteria specified by the Use Case (e.g. condition to need more vaccine)
IER67	Send/receive clinical message: Send/receive clinical content using traditional HL7 messaging
IER78	Send/receive Vaccine Inventory Requirements: Supports the communication of Vaccine Inventory Requirements Data (Deferred pending further analysis of scenario 2)
IER79	Query/response for inventory usage data: Supports the query and receipt of Vaccine Inventory Usage Data (Deferred pending further analysis of scenario 2)
IER80	Send/receive Vaccine Inventory Data: Supports the communication of Vaccine Inventory Data (Deferred pending further analysis of scenario 2)

2.2.3 IDENTIFICATION OF BUSINESS ACTORS, MAPPED TO REQUIREMENTS

A Business Actor is an abstraction instantiated as an IT system application used by a Stakeholder in the exchange of data necessary to complete Use Case action(s); a Business Actor is not a Stakeholder. A



HITSP Stakeholder is a person, organization or “personified system” that performs actions in a Use Case. Only Business Actors as an IT system application are directly engaged, and benefit from the real world information exchange defined within a business Use Case action. Only Business Actors are associated with Technical Actors, which support the data exchanges of the Business Actors (see Section 3.2 Technical Actors). The table below identifies the significant Use Case Business Actors, their descriptions, the Stakeholders they support, the Use Case scenarios, and the information exchange or data requirements for which they are used. Refer to the Use Case for a more detailed description of the listed stakeholders.



Table 2.2.3-1 Business Actors

Business Actor	Description	Supported Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
Electronic Health Record (EHR) System	The Electronic Health Record (EHR) System is a secure, real-time, point-of-care, patient-centric information resource for clinicians	EHR System Suppliers, Healthcare Entities, Providers, (including healthcare delivery organizations, ancillary entities, clinicians pharmacy-based care delivery and immunization clinics), On-site care providers, and Schools	Vaccine and Drug Administration and Reporting Vaccine and Drug Inventory Reporting	IER26 Identify communication recipients IER27 Send non-patient notification message or alert IER42 Request/receive medical concept knowledge IER54 Query/response for clinical message data IER67 Send/receive clinical message IER40 Query for existing data IER18 Send/receive clinical document IER10 Identify patient IER13 Send/receive notification of document availability IER1 Provide authorization and consent IER05 Verify Entity Identity IER01 Provide Authorization and Consent IER3 Create audit log entry IER6 Provide proof of document integrity and origin IER4 Synchronize system time	DR11 Immunization response data DR76 Immunization query data DR16 Supply chain management vaccine recall (no apparent recall support for supply chain management (Vaccine recall notification) DR17 Decision support data (immunization schedule knowledge) DR18 Vaccination data DR19 Medication administration data (deferred) DR58 Demographic data – vaccination DR22 Generic alert data – immunizations (immunization schedule) DR8 Unstructured data DR8 Unstructured data (risk notification) DR23 Consumer Vaccination View



Business Actor	Description	Supported Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
Health Information Exchange (HIE)	A Health Information Exchange (HIE) is a multi-stakeholder system that enables the exchange and use of health information, in a secure manner, for the purpose of promoting the improvement of health quality, safety and efficiency	Geographic Health Information Exchange/Regional Health Information Organization, Point-to-Point Exchanges	Vaccine and Drug Administration and Reporting Vaccine and Drug Inventory Reporting	<p>IER26 Identify communication recipients</p> <p>IER27 Send non-patient notification message or alert</p> <p>IER42 Request/receive medical concept knowledge</p> <p>IER54 Query/response for clinical message data</p> <p>IER67 Send/receive clinical message</p> <p>IER40 Query for existing data</p> <p>IER18 Send/receive clinical document</p> <p>IER10 Identify patient</p> <p>IER13 Send/receive notification of document availability</p> <p>IER1 Provide authorization and consent</p> <p>IER05 Verify Entity Identity</p> <p>IER01 Provide Authorization and Consent</p> <p>IER55 Anonymize patient identifiable data</p> <p>IER56 Pseudonymize patient identifying information</p> <p>IER3 Create audit log entry</p> <p>IER6 Provide proof of document integrity and origin</p> <p>IER4 Synchronize system time</p>	<p>DR11 Immunization response data</p> <p>DR76 Immunization query data</p> <p>DR17 Decision support data (immunization schedule knowledge)</p> <p>DR18 Vaccination data</p> <p>DR58 Demographic data – vaccination</p> <p>DR21 Terminology data</p> <p>DR22 Generic alert data – immunizations (immunization schedule)</p> <p>DR8 Unstructured data</p> <p>DR8 Unstructured data (Alerts)</p>



Business Actor	Description	Supported Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
Immunization Information System (IIS)	IIS is used by local, state, and federal government organizations to identify populations at high risk for vaccine-preventable diseases and to target interventions and resources efficiently. Staff of stakeholder agencies interact with the IIS to verify and validate system indications of public health threats, and to assert acknowledgements that may be required by system processes. This includes, for instance, emergency preparedness registry, chronic disease registry	Government Agencies, Healthcare Payors, Knowledge Providers, Public and Private Immunology, Vaccine Response, and Adverse Event Experts, Registries, Public Health Agencies/Organizations (federal/state/local/territorial/tribal)	Vaccine and Drug Administration and Reporting Vaccine and Drug Inventory Reporting	IER54 Query/response for clinical message data IER67 Send/receive clinical message IER40 Query for existing data IER18 Send/receive clinical document IER10 Identify patient IER13 Send/receive notification of document availability IER27 Send non-patient notification message or alert IER1 Provide authorization and consent IER5 Verify entity identity IER55 Anonymize patient identifiable data IER56 Pseudonymize patient identifying information	DR11 Immunization response data DR76 Immunization query data DR17 Decision support data (immunization schedule knowledge) DR18 Vaccination data DR58 Demographic data – vaccination DR22 Generic alert data – immunizations (Alerts – prioritization) DR8 Unstructured data DR8 Unstructured data (Alerts–prioritization)



Business Actor	Description	Supported Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
Personal Health Record (PHR) Systems	A healthcare record system used to create, review, annotate and maintain records by the patient or the caregiver for a patient. The PHR may include any aspect(s) of the health condition, medications, medical problems, allergies, vaccination history, visit history or communications with healthcare providers	Consumers, Patients, Personal Health Record (PHR) System Suppliers	Vaccine and Drug Administration and Reporting	IER26 Identify communication recipients IER42 Request/receive medical concept knowledge IER18 Send/receive clinical document IER10 Identify patient IER13 Send/receive notification of document availability	DR16 Supply chain management vaccine recall (including consumer directed message) DR18 Vaccination data DR58 Demographic data – vaccination DR22 Generic alert data – immunizations (Vaccine recall notification) DR8 Unstructured data DR8 Unstructured data (Vaccine recall notification) DR23 Consumer Vaccination View



Business Actor	Description	Supported Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
Public Health Information System	An automated and integrated system used to document and address information of interest to public health. Local, state, and federal government organizations and personnel use these systems to help protect and improve the health of their respective constituents. A critical effort under this charge is collecting health information to monitor for the existence of emerging health threats appearing in the population and manage these threats once manifested. Staff of these agencies interacts with the public health information system to verify and validate system indications of public health threats, and to assert acknowledgements that may be required by system processes	Government Agencies, Knowledge Providers, Public and Private Immunology, Vaccine Response, and Adverse Event Experts, Registries, Response Management Organizations, Public Health Agencies/Organizations (federal/state/local/territorial/tribal)	Vaccine and Drug Administration and Reporting Vaccine and Drug Inventory Reporting	IER80 Send/receive vaccine inventory data IER78 Send/receive vaccine inventory requirements IER79 Query/response for inventory usage data	DR13 Drug/Vaccine Inventory Data DR14 Drug/vaccine inventory usage data DR15 Drug/vaccine inventory availability data DR16 Supply chain management vaccine recall DR79 Drug/Vaccine Inventory Requirement (Deferred)



Business Actor	Description	Supported Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
Supply Chain Management System	A system used by organizations managing the distribution of supplies and the oversight of materials, information, and finances as they move in a process from supplier to manufacturer to wholesaler to retailer to consumer. For example, used to track vaccines and associated supplies	Public and Private Sector Supply Chain, Inventory Managers NOTE: Varying and changing business models impact the stakeholder that serves as this business actor in any given implementation (e.g. contracted distributor, manufacturer, public health authority, Registry etc)	Vaccine and Drug Administration and Reporting Vaccine and Drug Inventory Reporting	IER80 Send/receive vaccine inventory data IER78 Send/receive vaccine inventory requirements IER79 Query/response for inventory usage data	DR13 Drug/vaccine Inventory Data DR14 Drug/vaccine inventory usage data DR15 Drug/vaccine inventory availability data DR16 Supply chain management vaccine recall DR79 Drug/vaccine Inventory Requirement

2.2.4 HIGH-LEVEL DIAGRAMS

This section contains diagrams that describe the relationships and data interactions between the primary and alternative business actors and stakeholders for each Use Case scenario.

High Level Sequence diagrams are provided in Section 6.4 that illustrate each Use Case scenario with a representation of a normal sequence of exchange between the primary actors. The interactions are supported by the various constructs which will be introduced in Section 3 of this Interoperability Specification.

The figures below are Component Data Flow diagrams that illustrate the data flow and information exchanges between the primary HITSP Business Actors. The information exchange and data requirement numbers from tables in Section 2.2.2 are annotated on the diagrams to show how the requirements relate to the primary actors. The in-scope requirements are supported by constructs which will be introduced in Section 3 of this Interoperability Specification. Figure 2.2.4-1 is a legend for reading the Component Data Flow diagrams.



Figure 2.2.4-1 Legend for Component Diagrams

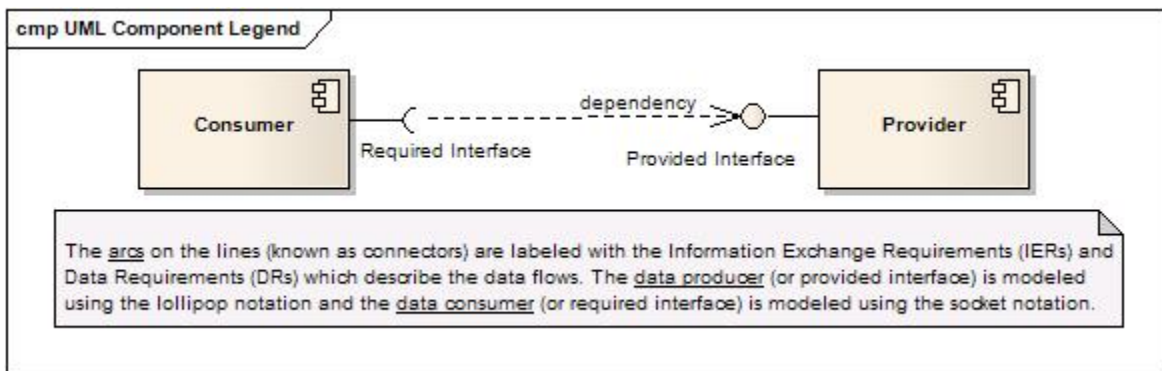
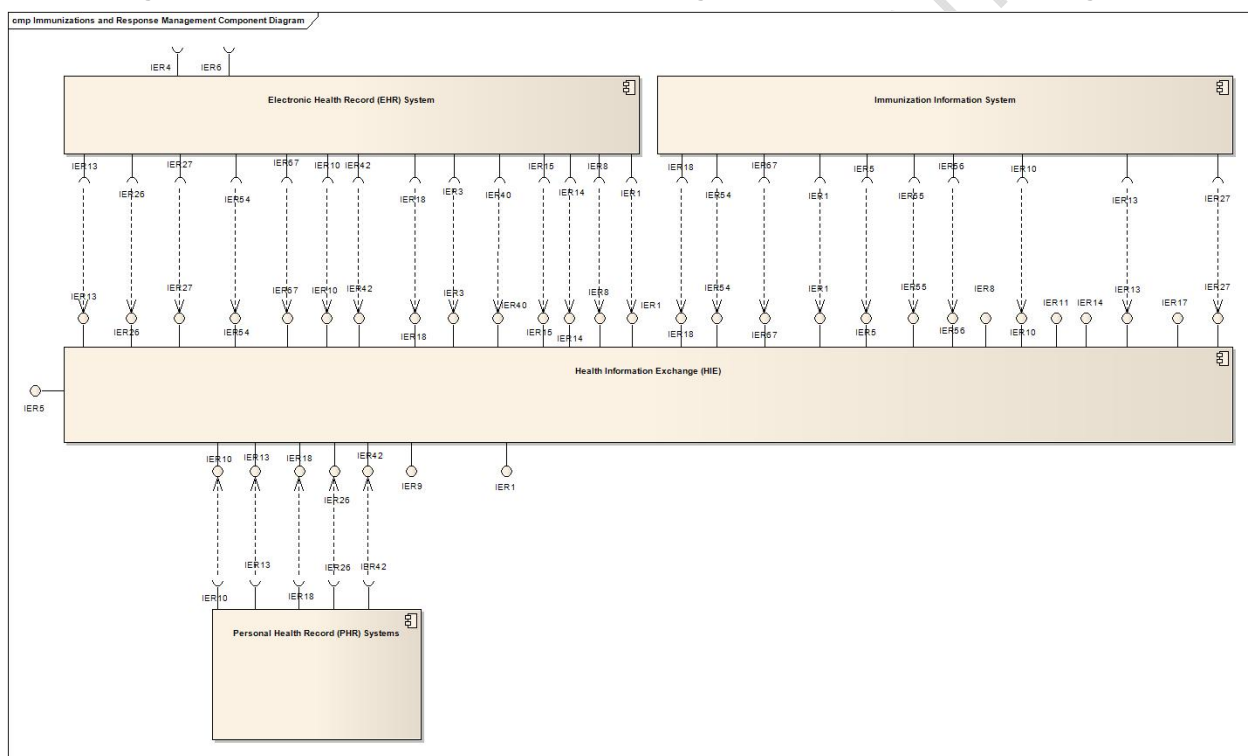


Figure 2.2.4-2 Immunizations and Response Management Component Data Flow Diagram



3.0 DESIGN

The design for the Interoperability Specification is the result of the requirements analysis and iterative standards selection process. This section describes the design based on the specified Business Actors and their information exchange and data requirements. It provides a detailed mapping of the specified requirements to HITSP constructs and their technical actors. Groupings of specific technical actors, which support Business Actors, are specified to further describe the relevant interactions from existing or new HITSP constructs required for interoperability.

3.1 SCOPE OF DESIGN

This section describes the scope of the design as it relates to the requirements for this Use Case that were identified in Section 2.2 above. The scope identifies the assumptions that provide the boundaries for the specification and the constraints that limit the use of the specification. In addition, any pre-conditions, post-conditions and triggers that underlie the interactions between the various actors, data and transactions are provided.

The focus of the initial design is to enable electronic communication of immunization data among clinicians, with patients, and with other immunization registries as identified in Scenario 1. All specification for Scenario 2 has been deferred pending further analysis of the workflow, business actor responsibilities, and available standards suitable to fulfill the needs identified through this effort.

The design leverages existing HITSP constructs and communication methodologies. Additional communication methodologies are specified to support identification of communication recipients for alerts and notifications not containing Protected Health Information (PHI).

Use Case actions requiring clinical decision support capabilities are deferred pending the development of HITSP constructs supporting the expression and communication of associated logic. This includes support for:

- Immunization Schedules
- Immunization Reminders
- Immunization Prioritizations
- Contraindication Alerts
- Active/Passive Surveillance for Adverse events

The following schedule indicates the proposed multi-release implementation plan for the HITSP Population Perspective Technical Committee (TC) to complete the analysis and Interoperability Specification development for the final Immunizations and Response Management Use Case.

The HITSP Population Perspective TC plans a multi-release approach, with each new release adding to the value and capabilities of the proposed constructs.



Release 1:

- Establish Transaction Packages, Transactions, and Components to complete the Use Case requirements related to the communication of vaccination information between patients, providers, and immunization registries, including registry-to-registry communications
- Enable optionality of architectures supporting traditional legacy message-based communications, addition of support for patient identification services (HITSP/TP22 Patient ID Cross-Referencing, HITSP/T23 Patient Demographics Query) and the addition of support for document-centric sharing and point-to-point communications. This optionality will allow existing systems a migration path to adopt patient identity services and document sharing approaches without disrupting operational environments
- Adoption of HL7 V2.3.1 messaging with the expectation that this will be updated in accordance with future HL7 implementation guides
- Include Security and Privacy constraints for implementation of the Immunizations and Response Management Interoperability Specifications

NOTE: Scenario 2: Vaccine and Drug Inventory Reporting is deferred for Release 1

Release 2:

This second release will address the following gaps identified by the HITSP Population Perspective Technical Committee:

- Lack of specification and standard business workflows for supply chain and distribution management of vaccines
- Incorporation of the vaccine recall processes in the supply chain management
- Availability of constructs supporting Clinical Decision Support

The following table identifies constructs that the Population Perspective Technical Committee anticipates:

NOTE: Any deferrals and scoping in the development of the Immunizations and Response Management Interoperability Specification will directly impact the ability to fulfill the immunization requirements of this Use Case.

Table 3.1-1 Scenario 1 Scope

Activity	Topic	Scoped to:	Reason for Deferral	Requirement
Immunizations	Immunization Schedule Content: using scanned, presentation preserving content	Year 1	Future releases will adopt structured content pending SDO development	DR22 Generic alert data – Immunizations IER27 Send non-patient notification message or alert IER42 Request/receive medical concept knowledge



Activity	Topic	Scoped to:	Reason for Deferral	Requirement
	Update Information to Immunization Information System (vaccination)	Year 1	NA	DR58 Demographic data - vaccination DR18 Vaccination data IER10 Identify patient IER67 Send/receive clinical message IER18 Send/receive clinical document
	Immunization Query and Response	Year 1	NA	DR58 Demographic data - vaccination DR11 Immunization response data DR76 Immunization query data IER10 Identify patient IER54 Query/response for clinical message data IER40 Query for existing data
	Consumer Vaccination View	Year 1: Future release to address 'yellow-card' view	Immunization focused standard with vocabulary constraints once available; Pending SDO activity for 'yellow-card' structured document	DR58 Demographic data - vaccination DR18 Vaccination data DR23 Consumer Vaccination View IER67 Send/receive clinical message IER18 Send/receive clinical document
	Vaccination Document	Year 1		DR58 Demographic data - vaccination DR18 Vaccination data
Adverse Event Report (Overlap with Public Health Reporting)	FDA – MedWatch, Vaccine Adverse Events Reporting System (VAERS)	Year 2	Scope dependent upon AHIC Public Health Case Reporting Use Case	DR12 Adverse Event Report
Supply Chain Management	Inventory management – May be X12 or OASIS	Year 2	Needs domain expert evaluation of workflow, business actor responsibilities, and supply chain standards availability	DR13 Drug/vaccine inventory data DR14 Drug/vaccine inventory usage data DR15 Drug/vaccine inventory availability data DR77 Drug/vaccine query data DR78 Drug/vaccine response data DR79 Drug/vaccine inventory requirements



Activity	Topic	Scoped to:	Reason for Deferral	Requirement
	Vaccine Recall Joint with FDA/CDC – standards known			DR16 Supply chain management vaccine recall
Clinical Decision Support Content	Content (Immunization Schedules, Immunization Reminders, Immunization Prioritization)	Year 2	Pending further Clinical Decision Support development efforts from HITSP Care Management and Health Records Domain Technical Committee	DR17 Decision support data (Immunization Schedule knowledge, Reminders, Prioritization, Alerts – contraindications, Active/Passive Surveillance for adverse event)
Generic Alert to Identified Providers	Content (alert, prioritizations) Non-patient-identifiable	Year 1: Text, Presentation Preserving; Structured component efforts deferred	NA	DR22 Generic alert data – Immunizations
Unstructured Document	Content, Transport	Year 1: Structured component efforts deferred pending Clinical Decision Support	Pending Clinical Decision Support decision for Immunization prioritization	DR8 Unstructured data IER13 Send/receive notification of document availability IER18 Send/receive clinical document
Medication Administration	Support capture and management of Countermeasure and Response Administration data	Deferred	Pending further Use Case specificity and workflow analysis	DR19 Medication Administration data
Identify Communication Recipients	Support communication of non-PHI alerts and notifications	Year 1		IER26 Identify communication recipients
Terminology Services	Support translation to standard terminologies/vocabularies	Year 1		DR21 Terminology data
Clinical Document & Message Terminology	Common HITSP terminology for CDA Documents and Messages	Year 1		DR18 Vaccination data DR23 Consumer Vaccination View DR11 Immunization response data DR76 Immunization query data DR58 Demographic data - vaccination



Activity	Topic	Scoped to:	Reason for Deferral	Requirement
Security Functions	Common security functions	Year 1		IER1 Provide authorization and consent IER5 Verify entity identity IER2 Send data over secured communication channel IER55 Anonymize patient identifiable data IER56 Pseudonymize patient identifying information IER3 Create audit log entry IER6 Provide proof of document integrity and origin IER4 Synchronize system time

Prioritization Notification:

Year 1 scope is limited to use of the HITSP/C62 Unstructured Document Component for patient identifiable communications with HITSP/T29 Notification of Document Availability or for generic notifications, the use of HITSP/C82 Emergency Common Alerting Protocol communicates using HITSP T/63 Emergency Message Distribution Element. In both cases, the provider contact details may be identified using the HITSP/T64 Identify Communication Recipients. Further refinement of the prioritization and notification capabilities may be provided in subsequent releases of the Interoperability Specification pending SDO generation of supporting content constructs and HITSP development of Clinical Decision Support constructs. Initial context for prioritization assessments will be limited to demographic information. Extended support may be added for other risk factors pending further domain analysis such as:

- Risk
- Location of the exposure
- Date/time of exposure
- Type of exposure
- Occupation (e.g., first responders)

Immunization Communications and Query/Response Support:

It is important to preserve the optionality of HITSP Interoperability Specifications for immunization communications, and query/response functionality in order to allow the industry to identify a best approach moving forward in an area where there are multiple approaches emerging. This HITSP Immunizations and Response Management Interoperability Specification will allow for migration options to enable current legacy installations of Immunization Information System implementations to proceed while allowing for incremental support for emerging HITSP-specified implementations of patient identification services (as specified by HITSP/TP22 Patient ID Cross-Referencing and HITSP/T23 Patient



Demographics Query) and the adoption of Immunization CDA documents. This will allow for implementation of Use Case requirements for PHR communications conformant with HITSP specifications for Consumer Perspective related Use Cases and will allow document sharing approaches for provider to provider communications. It will also allow for migration toward CDA immunization document support for Immunization Information Systems.

Similarly, HITSP/TP21 Query for Existing Data is specified as an implementation option to allow for migration options for Immunization Information System implementations. HL7 V2.3.1 messages used today are specified by this Interoperability Specification with the intent to update this specification once the industry completes the replacement of the implementation guide. The HITSP/C70 Immunization Query and Response Component will allow for optionality of these multiple approaches to provide for a path forward from current installations toward the adoption of new approaches specified by HITSP.

Scenario 2 Scope

Scenario 2 is deferred pending further analysis.

Clarification is needed as to alignment with Countermeasure and Response Administration requirements and to better understand expected workflows and business actor responsibilities that are implied by the Use Case. Use Case information flows do not accurately reflect how the current information and product flow happens today and this deviation must be better reconciled.

The Population Perspective Technical Committee has identified jointly with the Administrative and Financial Domain Technical Committee a plan to address the deferred Scenario 2 efforts:

1. Request further clarification of workflows and business actor responsibilities for Scenario 2 from
2. Technical Committee recruits experts in this area:
 - a. Call for Participation will be sent to:
 - i. CDC countermeasure/business inventory standards experts
 1. Healthcare distribution management association
 2. ANSI – X12
 3. HL7 Inventory messages (chapter 8, chapter 17 – materials management, lot numbers;)
 4. International hospital federation – GS1
 5. Inventory with HCPC code
 6. Healthcare financial management association
 - ii. CDC identified experts currently supporting Countermeasure and Response Administration and vaccine inventory management/distribution efforts
 - iii. Vendors currently engaged in vaccine inventory management
 - iv. Drug manufacturers for vaccines
 - v. CDC countermeasure – standards for inventory tracking for immunizations
 - vi. Establish liaison to the effort VTrckS process
 - b. Planning Meeting



- c. Report out to Panel from planning meeting
- d. Convene a meeting of the experts
- e. Report out on more detailed roadmap/plan

NOTES for consideration during pending detailed analysis:

- Need Security/Privacy for supply chain communication (e.g. Need to protect the message from someone viewing the message and identifying the vulnerabilities)

NOTES for consideration during pending detailed analysis (8.2.2.1):

- Registry involvement must be specified further by the Use Case.
- There is a mixed environment in the inventory management capabilities of Immunization Information Systems
- Use Case overall needs to better clarify the anticipated roles of stakeholders in the vaccine supply chain, monitoring processes, and distribution channels. In the Use Case Diagram – inventory reporting column is too amorphous to determine who is in that 'role'
- The normative information flow vs routine flow – both are changing models, and are in-flux
- There is a lack of widespread implementation of clinician inventory systems that generate the inventory data
- Support variation in workflow for routine and emergency activities: flow is somewhat different when national stockpile is involved vs routine immunizations; some differences among states with how vaccine is acquired (e.g. pandemic). Different flows as to the distributor – how the supply gets to the distributor may differ

NOTES for consideration during pending detailed analysis (8.2.3.1)

- Need to support Risk plan
- Need to support Risk/threat models (most jurisdictions have a preparedness plan – workflow, risk assessment)
- Need to support Monitoring Transport/maintenance conditions: cold chain – handling, shipping conditions, storage conditions
- Need to support the fact that in emergency situations, business actors may be different

NOTES for consideration during pending detailed analysis (8.2.3.1)

- Similar to VFC Vaccine Adverse Events Reporting System; in this case PH is playing the role of the inventory manager

3.1.1 ASSUMPTIONS

This section provides an overview of the assumptions, including the circumstances, actors, policies and/or technologies that need to be in place for the design to be completed as specified. Assumptions are different from constraints which are specifically used to narrow the definition, or indicate limitations of the specified interactions.



Table 3.1.1-1 Assumptions

Assumption	Use Case Scenario
<p>General: Scenario 1 assumes that references to drugs refers to a vaccine, and excludes prophylactic drugs (e.g., Cipro, anti-viral drugs)</p> <p>Data Quality Considerations: Policy – edge system to execute the data quality; many of the quality checking processes are conducted at the edge system and often involve manual processes</p> <p>The term ‘gather’ may be a push or pull of information</p> <p>Payment type (from the Use Case) is the same information reflected by the Vaccines for Children Program (VFC)</p>	Vaccine and Drug Administration and Reporting
General: Public Health business actor or stakeholder has a number of related components, including IIS. Most IIS are under state (or regional) Public Health Jurisdiction. In addition, Public Health has national, state and regional components	
General: Registries may or may not choose to receive data from PHRs or HIE connection	Vaccine and Drug Administration and Reporting
General: Adult immunization handling may be different throughout the Use Case (e.g., some immunization registries will not accept adult immunizations)	Vaccine and Drug Administration and Reporting Vaccine and Drug Inventory Reporting
1. 7.1.1.1 Schedule is received into clinician EHR system	Vaccine and Drug Administration and Reporting
2. 7.1.1.1 EHR systems are capable of entering a current and accurate immunization schedule and for that schedule to be expressed as a functionality element of the EHR. Update to EHR is updated in a non-standard fashion CCHIT will at some point check for this	Vaccine and Drug Administration and Reporting
3. 7.1.1.1 The Immunization Information Systems may be the source of the schedule and may serve as the local interpreter to the immunization schedule knowledge	Vaccine and Drug Administration and Reporting
4. 7.1.2.1a Each Immunization Information System is presumed to have access to a complete immunization history for the patient. Clinician may be able to query the registry	Vaccine and Drug Administration and Reporting
5. 7.1.2.1a From the clinician perspective, the assumption is that they are pointing to a complete immunization resource	Vaccine and Drug Administration and Reporting
6. 7.1.3.2 Assumption is that modifications to the schedule may be done locally to optimize the clinician workflow and patient population. (Need clarification on modification of schedule – is this of a standard schedule or the schedule that the clinician chose to implement in the EHR?)	Vaccine and Drug Administration and Reporting
7. 7.1.4.1 The registry may or may not be the same business actor for routine vs. emergency reporting	Vaccine and Drug Administration and Reporting
8. 7.1.6.1 It looks like this is the Use Case text for this action is copied from the consumer perspective in error – assume it is the clinician that is notified of the recall	Vaccine and Drug Administration and Reporting
9. 7.1.6.1, 7.3.3.1, 8.2.2.1, 8.2.3.1, 8.2.3.2, 8.3.1.1, 8.3.2.1, 8.3.3.1, 8.3.3.2 The source supply chain data are captured as part of the vaccination data	Vaccine and Drug Administration and Reporting
10. 7.3.1.1 Need to capture from PHR as well as through other means	Vaccine and Drug Administration and Reporting
11. 7.3.1.1 PHR document source or consumer may be a portal service – not necessarily a PHR	Vaccine and Drug Administration and Reporting
12. Content of the immunization documentation from the PHR may not be the same content as the Immunization Information System. Patients typically have all this detail. There may need to be more information given/reported. The consumer vaccination view limits the information provided to improve the clarity to the consumer so as to make the content consumer-friendly– e.g. remove duplicative doses)	Vaccine and Drug Administration and Reporting



Assumption	Use Case Scenario
13. 7.3.3.1 The Immunization Information System may identify and contact individual consumers directly, bypassing the clinician. This approach entails consideration and specification of Policy. A given community or health information exchange may make a choice as to where this information flows	Vaccine and Drug Administration and Reporting
14. 7.3.3.1 Communications of notifications to consumer may be by mail, email, PHR, or via clinician	Vaccine and Drug Administration and Reporting
15. 7.4.1.1 Supply chain includes manufacturer of immunization	Vaccine and Drug Administration and Reporting
16. 7.4.1.1 Immunization Information System is a source of this information	Vaccine and Drug Administration and Reporting
17. 7.4.2.1 Policies permit school health records to be made available to registry	Vaccine and Drug Administration and Reporting
18. Document sharing can support sources of vaccine or drug administration information from schools, or other entities as well as providers (e.g. camps, daycare), or from other immunization registries/jurisdictions	Vaccine and Drug Administration and Reporting
19. 7.4.2.1, 9.4 Data quality considerations are scoped to edge server systems NOTE: See standards to verify data quality checks that exist – CDC/AIRA best practice in quality MIROW	Vaccine and Drug Administration and Reporting
20. 7.4.3.1 Policy considerations today are typically a bulk/batch exchange rather than a dynamic request/on-demand. There is a desire to establish a real-time request	Vaccine and Drug Administration and Reporting
21. 8.2.2.1, 8.3.1.1, 8.3.2.1 Flow should reflect that the source of the inventory status is the clinician; With business change it would be difficult to identify non-clinician systems as the source as this model is in-flux (NOTE: Consider New York City model)	Vaccine and Drug Inventory Reporting
22. 8.2.2.1 The Use Case is setting Public Health up to determine the requirements for vaccine supply. It seems that the sharing of provider inventory may be a business concern and intrusive	Vaccine and Drug Inventory Reporting
23. 8.2.3 Vaccination for the emergency responder/healthcare workers immunization management in an emergency is part of the requirement	Vaccine and Drug Inventory Reporting
24. 8.2.3.2, 8.3.1.1 The purpose is to re-distribute or order vaccine The effective manner may be to move the patients rather than the inventory. Those involved in inventory management are authorized to order and capable of ordering/distributing vaccine – Policy consideration, particularly cross-jurisdiction	Vaccine and Drug Inventory Reporting
25. 8.3.1.1 Policy appropriately defines the role of this group	Vaccine and Drug Inventory Reporting
26. 9.2 Policy allows Inter-jurisdiction communications for immunization information sharing and inventory management functions	Vaccine and Drug Administration and Reporting Vaccine and Drug Inventory Reporting
27. 9.6 Policy is in place that permits sharing NOTE: For example during Katrina there was a loss of the ability to communicate basic PH cross-state considerations for policies and legal barriers to transferring information across state lines Emergency Event: access to immunization information during re-location was for normal medical care. If it were a PH event, it may have fallen under a PH exclusion	Vaccine and Drug Administration and Reporting Vaccine and Drug Inventory Reporting
28. Duplicating immunization reconciliation is an edge system responsibility and out of scope of the Use Case	Vaccine and Drug Administration and Reporting
29. Patient query is only supporting query for specified patient(s)	Vaccine and Drug Administration and Reporting
30. 7.1.1.1 The Interoperability Specification needs to refer to this in an architecturally neutral way. In some states, it may be varied or perhaps have egulated (funding, distribution, schedule) differences. The expression of schedule is in 7.4.1	Vaccine and Drug Administration and Reporting



Assumption	Use Case Scenario
31. 7.1.1.1 Need to support current practice for immunization schedules distribution – web locations – paper representation of schedule logic with migration to Clinical Decision Support capabilities. The IIS may be the broker of the immunization schedules	Vaccine and Drug Administration and Reporting
32. 7.1.1.1 Provider should be able to retrieve immunization schedule from source (e.g. CDC)	Vaccine and Drug Administration and Reporting
33. 7.1.1.1 Provider should be able to modify the immunization schedule locally based upon the pattern of population that is seen in order to better manage their workload	Vaccine and Drug Administration and Reporting
34. 7.1.2.1a Health Information Exchange (HIE) or query to other immunization registries may be needed to assemble the ‘complete’ set of information. This is not implying that the information be compiled into a single location, only that a given location can provide the compiled set to the inquirer	Vaccine and Drug Administration and Reporting
35. 7.1.2.1a Today an Immunization Information System has a constrained mode of operation to collect and provide that complete information in a single location – a registry function such as a Record Locator Service (RLS) of an Immunization Information System may be a new functionality	Vaccine and Drug Administration and Reporting
36. 7.1.2.1b Must support routine and non-routine situations	Vaccine and Drug Administration and Reporting
37. 7.1.2.1b Need to describe interoperability list of standards that result in a standard query to multiple data providing sources (e.g. registries, Healthcare Information Systems (HISs), Master Patient Index (MPIs), non-healthcare sources)	Vaccine and Drug Administration and Reporting
38. 7.1.3.1 Edge system issue- this pertains to edge system requirements. Vaccine contraindication checks are typically described in the schedule. There may be a rule logic within the EHR. This step is not the interoperability, but relies on the earlier step of immunization schedule logic, and applying that logic locally	Vaccine and Drug Administration and Reporting
39. 7.1.3.2 Need to capture the right elements and attributes (for this use the CDC core dataset that the Immunization Information System captures) so that it is positioned to send it	Vaccine and Drug Administration and Reporting
40. 7.1.4.1 Transaction may be different – e.g. HL7 message, routine message, document-centric)	Vaccine and Drug Administration and Reporting
41. 7.1.4.1 Pharmacies may dispense immunization	Vaccine and Drug Administration and Reporting
42. 7.1.4.1 Where secondary use of the vaccination is used for inventory management, it should be recognized that just giving the vaccine may not be the only impact on the inventory	Vaccine and Drug Administration and Reporting
43. 7.1.5.1 Adverse Drug Event Report may come from the registry or service provider	Vaccine and Drug Administration and Reporting
44. 7.1.5.2 Before it becomes a formal adverse event, there needs to be a human intervention as these are investigated, tracked and assessed	Vaccine and Drug Administration and Reporting
45. 7.1.6.1 This information could come from adverse event monitoring (a ‘research’ function) or a Clinical Decision Support actor such as Surveillance	Vaccine and Drug Administration and Reporting
46. 7.4.1.1 Need to support current practice for immunization schedules distribution – web locations – paper representation of schedule logic with migration to Clinical Decision Support capabilities	Vaccine and Drug Administration and Reporting
47. 7.4.1.1 Mirror of clinician perspective requirements	Vaccine and Drug Administration and Reporting
48. 7.4.1.1 The HITSP Interoperability Specification needs to refer to this in an architecturally neutral way. In some states, it may be varied or perhaps regulated (funding, distribution, schedule) differently. (see 7.4.1)	Vaccine and Drug Administration and Reporting
49. 7.4.1.1 Need to support current practice for immunization schedules distribution – web locations – paper representation of schedule logic with migration to Clinical Decision Support capabilities. The IIS may be the broker of the immunization schedules	Vaccine and Drug Administration and Reporting
50. 7.4.1.2 However the schedule is retrieved, the schedule is loaded into the registry	Vaccine and Drug Administration and Reporting



Assumption	Use Case Scenario
51. 7.4.3.1 Information may come in from pharmacy where there is no EHR system. It is expected that telecommunication standards for insurance (dispensing event – may be missing site of administration) and other clinical elements would be used. (see Section 4.2 GAPS)	Vaccine and Drug Administration and Reporting
52. 7.4.3.1 Support for multiple communication options: Sources may include patient claim – payor source, no EHR system, Senior Centers and Public Health workers doing vaccination campaign	Vaccine and Drug Administration and Reporting
53. 7.4.3.1 When pharmacist is involved in immunization, most likely involved in adult immunization; pharmacist may be permitted to administer the vaccination (varies by state)	Vaccine and Drug Administration and Reporting
54. 7.3.1.1, 7.3.2.1 HITSP Consumer Perspective TC is continuing work on how to express bi-directional trust into/out of PHRs NOTE: Recognize that work is ongoing and whatever exchange is done to/from, needs to conform to the Consumer Perspective requirements	Vaccine and Drug Administration and Reporting
55. 7.3.1.1, 7.3.2.1 Need to access from PHR using HITSP/TP13-Manage Sharing of Documents or media	Vaccine and Drug Administration and Reporting
56. 7.2.1.1, 7.3.1.1, 7.3.2.1 A constrained/consumer understandable view is needed	Vaccine and Drug Administration and Reporting
57. 7.2.1.1, 7.3.1.1, 7.3.2.1 For HITSP/TP13-Manage Sharing of Documents interoperability requirements for PHR communications, that a Registry would need to publish a CDA	Vaccine and Drug Administration and Reporting
58. 7.3.3.1 A constrained/consumer understandable view is needed	Vaccine and Drug Administration and Reporting
59. 7.3.3.1 HITSP/TP13-Manage Sharing of Documents interoperability requirements for PHR communications a Registry would need to publish a CDA	Vaccine and Drug Administration and Reporting
60. 7.3.3.1 There are significant Security and Privacy considerations for potential miscommunications by mail, email, PHR NOTE: Recommend use of Notification of Document Availability for any active alerting	Vaccine and Drug Administration and Reporting
61. 7.2.1.1 Need decision support with population data input – the population data may have multiple sources (e.g. clinical history, census)	Vaccine and Drug Administration and Reporting
62. 7.2.1.1 Defer work on this item as inferred by the Use Case comment which indicates 'This action and flow 5 has been included to provide context for subsequent activities. It is not a focus area for this Use Case.'	Vaccine and Drug Administration and Reporting
63. 7.2.1.2 Need decision support feedback on public health event status	Vaccine and Drug Administration and Reporting
64. 7.2.1.2 Two types of messages/data requirements for individual-based versus population-based: Health Alert Network (HAN) for population-based	Vaccine and Drug Administration and Reporting
65. 7.2.1.2 Demographics – individually identified, clinical information – There are Security and Privacy considerations, as well as Policy considerations	Vaccine and Drug Administration and Reporting
66. 7.2.1.2 Registry reproduction and registry backup in case of emergency and synchronization of registries is needed	Vaccine and Drug Administration and Reporting
67. 7.2.1.2 Implies some way of constructing the alert message and the variety of content the message may contain	Vaccine and Drug Administration and Reporting
68. 7.2.1.2 Assumes 7.2.1.1	Vaccine and Drug Administration and Reporting
69. 7.2.1.2 Need decision support with population data input (retrieved in 7.2.1.1)	Vaccine and Drug Administration and Reporting
70. 7.2.1.2 May have new actors in an emergency situation (e.g. labs or employers, healthcare provider not traditionally involved in immunization administration, and mobile service)	Vaccine and Drug Administration and Reporting



Assumption	Use Case Scenario
71. 7.2.1.1 Need support for consumer management of information from remote resource (non-PHR)	Vaccine and Drug Administration and Reporting
72. 7.2.1.1 The need to provide to a person's PHR is secondary to the need to provide prioritization information to the person in an understandable format	Vaccine and Drug Administration and Reporting
73. 9.4 Vaccine inventory may be considered secondary use	Vaccine and Drug Inventory Reporting
74. 9.4 Further Use Case analysis and specification needed to define the workflow: Something is needed before the inventory summary would take place, or before the data are sent to the inventory manager	Vaccine and Drug Inventory Reporting
75. 9.4 Edge System Requirement: Data quality: see Modeling of Immunization Registry Operations Workgroup (MIROW)	Vaccine and Drug Administration and Reporting
76. 9.4 Duplication removal is needed	Vaccine and Drug Administration and Reporting

3.1.2 CONSTRAINTS

This section describes the constraints that limit the context in which the Interoperability Specification may be used. A constraint describes a rule that limits the use of the actors, actions or data within the given context, or to which the interactions must conform to be used within the described context. It is a description of the limits and scope of the interactions and can describe actions or events that are not part of the initial definition for the context.

Table 3.1.2-1 Constraints

Constraint	Use Case Scenario
HITSP/T17 - Secured Communication Channel SHALL be implemented for each system grouping of actors	1 and 2
The policy of the implementation environment MAY require HITSP/C26 - Nonrepudiation of Origin for one or more information sources initiating a HITSP Transaction with a payload of: <ul style="list-style-type: none"> Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Adverse Events Reporting System (VAERS) Vaccination Medication Administration Generic Alert Unstructured Document Component 	1 and 2
HITSP/T15 - Collect and Communicate Security Audit Trail SHALL be implemented for each information source initiating a HITSP Transaction with a payload of: <ul style="list-style-type: none"> Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Adverse Events Reporting System (VAERS) Vaccination Medication Administration Vaccination Query/Response Unstructured Document Component 	1 and 2
The policy of the implementation environment MAY require HITSP/C19 - Entity Identity Assertion	1 and 2



Constraint	Use Case Scenario
The policy of the implementation environment MAY require HITSP/C88 – Anonymize Immunizations and Response Management for analytical data uses	1 and 2
The policy of the implementation environment MAY require HITSP/T24 - Pseudonymize for analytical data uses	1 and 2
The policy of the implementation environment MAY require HITSP/TP13 - Manage Sharing of Documents (including “Document Integrity” options) be implemented for document information source initiating a HITSP Transaction with a payload of: <ul style="list-style-type: none"> Immunization Query/Response Vaccination Medication Administration Unstructured Document 	1 and 2
The policy of the implementation environment MAY require HITSP/TP13 - Manage Sharing of Documents support for XCA options which may be required for sharing immunizations across jurisdictions or HIEs	1 and 2
The policy of the implementation environment MAY require the HITSP/TP20 - Access Control	1 and 2
The policy of the implementation environment MUST require the HITSP/TP30 - Manage Consent Directives wherever access to IIHI is required	1 and 2
HITSP/TP13 Manage Sharing of Document SHALL be constrained where used for analytical purposes: Support to return multiple documents for stored Query; Metadata constraints: XDSDocumentEntry.eventCodeList may need to support eventCodeList to optimize analytical query capabilities for Immunization analysis. XDSDocumentEntry.confidentialityCode, XDSDocumentEntry.patientID and XDSSubmissionSet.patientID, and XDSDocumentEntry.sourcePatientID and XDSSubmissionSet.sourcePatientID may need to be constrained to support pseudo-identifiers for Immunization analytical purposes	1 and 2
Implementations SHALL leverage the pediatric demographic options for HITSP/T23 Patient Demographics Query and HITSP/TP22 Patient ID Cross-Referencing	1 and 2

3.1.3 PRE-CONDITIONS

This section describes the necessary conditions that must be in place prior to the start of each scenario. The pre-conditions are used to convey any conditions that must be true at the outset of a scenario. It describes the context that must be established before the scenario is executed. They are not however the triggers that initiate a Use Case. Where one or more pre-conditions are not met, the behavior of the Use Case should be considered uncertain.

Table 3.1.3-1 Pre-conditions

Pre-condition	Use Case Scenario
Support the technical measures to ensure Security and Privacy of consumer/patient health information	All
Authentication service to authenticate requestors and/or data submissions from various locations	All
Security and Privacy policies, procedures and practices are commonly implemented to support acceptable levels of consumer/patient privacy and security	All



Pre-condition	Use Case Scenario
Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect	All
Support the following HITSP Security and Privacy constructs: HITSP/C19 - Entity Identity Assertion HITSP/T16 - Consistent Time – Maintain time HITSP/T17 - Secured Communication Channel – Authenticate node HITSP/T15 - Collect and Communicate Security Audit Trail – Record audit event in repository HITSP/TP30 - Manage Consent Directives – Capture/Request consent directive HITSP/TP20 - Access Control – Access control request	All
Pre-certification process for data to verify that the data sources format constructs and processes correctly	1
EHR certification including capabilities to generate a well-formed message from the information source; this is not in lieu of data pre-certification	1
Policies exist authorizing registries to exchange information	1
HITSP/T16 - Consistent Time SHALL be implemented for each system grouping of actors	1 and 2
Need further clarification for scenario 2 to identify specific scenario pre-conditions	2
All pre-conditions from the lower level constructs are incorporated	All
When needed, the patient is uniquely registered with the Patient Identity Cross-Referencing service	All
Patient Identities (name, demographics etc.) are known and are consistent with policies	All

3.1.4 POST-CONDITIONS

This section provides an overview of the conditions or results that must occur at the end of each scenario in order for the scenario to be deemed successfully completed. This includes any required outputs from the scenario, or specific actor states.

Table 3.1.4-1 Post-conditions

Post-condition	Use Case Scenario
Immunization Information System checks the data in some fashion so that it conforms with the data quality standards identified by MIROW	1
Use of immunization data for population assessment of practices and clinical treatment	1
Jurisdictions may use the data to assess VFC and programmatic compliance	1 and 2
Vaccination data are used to inform the supply chain system	1
Clinical data and vaccinations are available for accurate billing purposes	1
Need further clarification for scenario 2 to identify specific scenario pre-conditions	2



3.1.5 PROCESS TRIGGERS

This section describes the triggers, including actors and/or processes, which are necessary to start any scenarios, actions or events. It can be an automatic or manual process or result that in turn starts off another scenario, action or event. A trigger is not the same as a pre-condition that describes a context that needs to be in place at the start of the event.

Table 3.1.5-1 Process Triggers

Process Trigger	Use Case Scenario
Use Case Scenario 1 Flow 1: Immunization knowledge providers distribute immunization schedules for incorporation into IIS, other registries, EHR systems and possibly health information exchange (from Use Case) New immunization schedule is announced and received	1 Vaccine and Drug Administration and Reporting
Use Case Scenario 1 Flow 2: Registries, including IISs, provide immunization information to clinicians, consumers, other registries and other organizations (from Use Case) <ul style="list-style-type: none"> New immunization schedule is received and disseminated to users There has been some notification concerning the present immunization information There is a request from a provider, school, or practitioner concerning anything about immunizations 	1 Vaccine and Drug Administration and Reporting
Use Case Scenario 1 Flow 3: Registries, including IISs, gather vaccine or drug administration information from clinicians, consumers, other registries and other organizations (from Use Case) <ul style="list-style-type: none"> A vaccine has been administered (see Scenario 1 Flow 5 as well) Consumer or provider needs/wants to send information to registry (e.g. new patient, an encounter, PHR) Registries have negotiated an exchange of immunization information, and there is new data since the last exchange (for periodic exchange agreements) A vaccine has been administered to a patient from another IIS Registry jurisdiction 	1 Vaccine and Drug Administration and Reporting
Use Case Scenario 1 Flow 4: Consumers provide available immunization information to clinicians (from Use Case) <ul style="list-style-type: none"> Consumer presents to an office visit Consumer decides to share PHR vaccination information 	1 Vaccine and Drug Administration and Reporting
Use Case Scenario 1 Flow 5: Following administration of (or inability to administer) a vaccine or drug the clinician provides appropriate clinical documentation to registries, consumers and others (from Use Case) <ul style="list-style-type: none"> Vaccination has been administered or attempted to be administered 	1 Vaccine and Drug Administration and Reporting
Use Case Scenario 1 Flow 6: Public health gathers information to identify individuals needing prioritized intervention (from Use Case) <ul style="list-style-type: none"> Routine public health surveillance and monitoring A public health wellness campaign is identified A public health threat occurs or is suspected 	1 Vaccine and Drug Administration and Reporting



Process Trigger	Use Case Scenario
Use Case Scenario 1 Flow 7: Public Health provides information to clinicians about populations or individuals having special needs for immunization or other intervention (from Use Case) <ul style="list-style-type: none"> • Routine public health surveillance and monitoring • A public health wellness campaign is identified • A public health threat occurs or is suspected 	1 Vaccine and Drug Administration and Reporting
Use Case Scenario 1 Flow 8: Registries provide information about vaccine recalls to clinicians and affected consumers (from Use Case) <ul style="list-style-type: none"> • A vaccine is recalled 	1 Vaccine and Drug Administration and Reporting
Use Case Scenario 2 Flow 5: Following administration of (or inability to administer) a vaccine or drug the clinician provides appropriate clinical documentation to registries, consumers and other system. This same information is communicated to the Inventory Reporting perspective. In addition, information about expired doses, lost doses, etc. would be communicated to Inventory Reporting (from Use Case) <ul style="list-style-type: none"> • A vaccine is given 	2 Vaccine and Drug Inventory Reporting
Use Case Scenario 2 Flow 9: Inventory Reporting communicates inventory availability and usage information to public health (from Use Case) <ul style="list-style-type: none"> • Inventory change needs to be communicated 	2 Vaccine and Drug Inventory Reporting
Use Case Scenario 2 Flow 10: Public Health communicates vaccine and drug inventory needs (from Use Case) <ul style="list-style-type: none"> • Public Health identifies vaccine and drug inventory needs 	2 Vaccine and Drug Inventory Reporting

3.2 DETAILED DESIGN

This section provides a detailed description of the technical design, along with an analysis of the main interactions and decisions between all actors, actions and data in support of the specific requirements for each scenario of the Use Case. In addition, this section provides the data element details and an overview of the HITSP constructs used to meet the business and technical requirements for this Use Case. Any variances in the Security and Privacy implementation are also described here.

Note that with respect to Security and Privacy, local implementation policy as determined by risk assessment, including assessment of jurisdictional and regulatory requirements, will determine which assurance level of nonrepudiation of origin is needed. For instance, in document-based transmissions, a low level is offered by the basic use of HITSP/TP13 Manage Sharing of Documents construct. A medium level of assurance is offered by the use of the HITSP/TP13 construct option called "Document Integrity". A high level of assurance is offered by the use of the HITSP/C26 Nonrepudiation of Origin construct which requires the existence of a Public Key Infrastructure (PKI) (See TN900 for a discussion on the challenges with PKI's).

The ability to convey the patient's authorization for sharing information is managed differently by individual states and needs to be addressed as a policy issue. The IS allows for this process to be asserted by policy leveraging HITSP/TP30 Manage Consent Directives for primary information use and for information repurposing.



Examples:

- "Opt out" functionality can be supported by HITSP/TP30 Manage Consent Directives
- A policy to prevent redistribution of data can be enforced by HITSP/TP20 Access Control and HITSP/TP30 Manage Consent Directives, but utilizing BPPC. Facilities will need to determine through policy if a consumer choice or regulatory requirement would prohibit or restrict distribution of EHR data

For analytical information repurposing, policy which could be asserted by HITSP/TP30 Manage Consent Directives may also call for anonymization (HITSP/C88 - Anonymize Immunizations and Response Management Data) or pseudonymization (HITSP/T24 Pseudonymize).

HITSP/TP30 could be used to communicate obligations to be performed by applications. Pseudonymization and Anonymization are not performed in the underlying security infrastructure.

Access to patient information should be in the context of appropriate use as directed by policy (policy managed by HITSP/TP30, and access managed by HITSP/TP20 Access Control). Refer to TN900 for a discussion on separation of functionality and policy.

Underlying principles

There are multiple implementation options provided in this design which are intended to enable current co-existence with operational systems, and enable evolution toward newer standards. The following principles apply:

- Options – a particular option is negotiated and established in a particular implementation
- Parties need to negotiate and agree on formats that are communicated
- Responsibility – the Immunization Information System (IIS) defines the required receipt format. The format may be dictated by state or local law
- The Continuity of Care Document (CCD) is an established standard for the exchange of information among clinical systems such as EMRs
- Where there is difference in format from the sending and receiving side, the HIE or other stakeholder could provide transformation services to minimize any need for the IIS or the EHR system to support multiple formats

NOTE: The adoption of CCD does not imply that HL7 V3 messaging is adopted in full

Communicate Vaccinations

Multiple options are specified for communication of immunization information in order to enable current operational systems migration toward shared patient identification services as defined by HITSP/TP22 Patient ID Cross-Referencing and HITSP/T23 Patient Demographics Query. A CDA vaccination (HITSP/C78 Immunization Content) is also specified to support PHR interoperability and as an option for providers and the Immunization Information System to engage in document sharing of immunizations.



- Option 1 - Use just HL7 VXU (HITSP/C72) from the message sender (clinician system or Immunization Information System) to the message receiver (Immunization Information System)
- Option 2 - If the HIE offers a HITSP/TP22 PIX manager, the clinician system shall first query the PIX manager using a PIX (HITSP/TP22) or PDQ (HITSP/T23) query transaction and populate the patient identifier in the HL7 VXU (HITSP/C72) message with the HIE domain identifier
- Option 3 – From the PHR, a HITSP/C78 Immunization Document can be communicated as a shared document to a document repository or sent to the Immunization Information System using document reliable interchange (HITSP/T31) or via media/email (HITSP/T33)
- Option 4 –The HITSP/C78 document can be communicated as a shared document to a document repository (HITSP/TP13) or sent to another provider o using document reliable interchange (HITSP/T31) or via media/email (HITSP/T33)
- Option 5 – An Immunization Information System may optionally support a document repository and receive vaccination data using document reliable interchange (HITSP/T31) or via media/email (HITSP/T33). The Immunization Information System may retrieve an Immunization Document (HITSP/C78) from the document repository or from another jurisdiction document repository for cross-jurisdiction information sharing leveraging query and retrieve transactions and the Cross Community Access option in HITSP/TP13. As current immunization registries are not configured with these capabilities, this is a forward looking option
- Option 6 – An Immunization Information System may optionally send an unsolicited notification using HITSP/C72 to a clinical information system to indicate that one of their patients has received an immunization from another clinician (e.g. Airport, school, another clinician)

Immunization Query and Response

Multiple options are specified for Immunization Query and Response in order to enable current operational systems migration toward shared patient identification services as defined by HITSP/TP22 and HITSP/T23 and to enable migration toward HITSP/TP21:

- Option 1 – Use the traditional HL7 VXQ to send a query from the message sender (clinician system) to the message receiver (Immunization Information System) and the HL7 VXR to send the result of the query from the message sender (Immunization Information System) to the message receiver (clinician system) (HITSP/C70)
- Option 2 – If the HIE offers a PIX manager (HITSP/TP22), the clinician system shall first query the PIX manager (using HITSP/TP22 or HITSP T23) and populate the patient identifier in the HL7 VXQ message with the HIE domain identifier and in the resulting VXR message (HITSP/C70). NOTE: policy would need to assert query result policies in PDQ as currently specified for VXR
- Option 3 - Use HITSP/TP21 Query for Existing Data to request and receive immunization data; If the HIE offers a PIX manager, the clinician system shall first query the PIX manager and populate the patient identifier in the HITSP/TP21 query
- Option 4 – Where there are immunization documents available in the HIE Document repository, use HITSP/TP13 Manage Sharing of Documents query/retrieve to gather the most up-to-date immunization data available. which may be published as HITSP/C62 Unstructured Document



Component containing summary or patient-specific immunization alert, HITSP/C78 Immunization Document)

Immunization Alert Functionality

Until there is structured content defined for alerts by the SDOs, all alerts are expected to be text or presentation preserving (e.g. scanned documents).

For notification of immunization requirements, there are multiple options for communication:

- Option 1 - Non-patient specific push – Where the alert is generic and not specific to a particular patient (e.g. immunizations required for a particular population such as those over the age of 65) and the communication requires presentation preserving properties, the communication recipients are identified using the Identify Communication Recipients (HITSP/T64) construct, and the generic alert is sent to those providers leveraging the Emergency Message Distribution Element (HITSP/T63) with the Emergency Common Alerting Protocol (HITSP/C82). The communication itself may be conducted using email, Health Alert Network (HAN), or FAX as specified by the implementation. Communication recipients may be identified using the Identify Communication Recipients (HITSP/T64) construct
- Option 2 - Where the alert is generic and not specific to a particular patient (e.g. immunizations required for a particular population such as those over the age of 65) and the communication is text-based, the communication recipients are identified using the Identify Communication Recipients (HITSP/T64) construct, and the generic alert is sent to those providers using the Emergency Message Distribution Element (HITSP/T63) with the Emergency Common Alerting Protocol (HITSP/C82).
- Option 3 – Where the alert is patient-specific in nature, the notification of document availability (HITSP/T29) is sent to the alert recipient (may be patient or provider). The person receiving the alert may then retrieve the patient-specific alert as an Unstructured Document (HITSP/C62) which will contain the immunization notification alert and instructions for the clinician or patient.
- Option 4 – Context specific information may be requested by the EHR or PHR using Retrieval of Medical Knowledge (HITSP/T81) as part of the user interface or pre-fetching options. This approach may be used to address the request of immunization data for assessment if a vaccine is needed. This option leverages a retrieval model and can not be leveraged for a distribution only approach.

3.2.1 TECHNICAL ACTOR ROLE DESCRIPTIONS

This section identifies the Technical Actors used within the Interoperability Specification. Note that a Technical Actor represents an internal software component or IT system, which supports a specific aspect of a real world business information interchange (e.g., set of message exchanges). Technical Actors implement system data exchange transactions, which support real world Business Actor information interchanges (see Section 2.2.3 for Business Actor definitions). Table 3.2.1-1 below identifies the Technical Actors and provides a description of the Technical Actor roles involved in the Interoperability Specification.



Table 3.2.1-1 Technical Actor Role Descriptions

Technical Actor(s)	Actor Role	Construct
Access Control Service (ACS)	The enterprise security service that supports and implements user-side and service side access control capabilities. This service would be utilized by the Service User, and/or Service Provider	HITSP/TP20
Alert Message Receiver	This actor receives notifications and emergency data from the Message Transmitter	HITSP/T63
Alert Message Transmitter	The holder of emergency data that is communicating that data to the message receiver	HITSP/T63
Audit Record Repository	Provides a repository for audit events	HITSP/T15
Audit Record Source	Creates and communicates an Audit Record to the Audit Record Repository on behalf of another actor that performs an action requiring logging	HITSP/T15
Clinical Data Consumer	A clinical data consumer makes use of clinical patient data	HITSP/TP21
Clinical Data Source	Maintains patient information about vital signs, problem and allergies, results from diagnostic tests (e.g., Lab, Imaging, or other test results), medications, immunizations or historical or planned visits and procedures	HITSP/TP21
Consent Directive Requestor	Accesses consent directive located through a Consent Registry from Consent Repositories (lack of definition in current public comment version)	HITSP/TP30
Consent Originator	Captures consent directives and may publish the consent directive as a document. It is responsible for sending Manage Consent Directive Requests to a Consent Repository. It also supplies Metadata to the Consent Repository for subsequent registration of the Consent within a Consent Registry	HITSP/TP30
Consent Registry	Responsible for providing location information and sender notification regarding consent directives. The Consent Registry receives a Manage Consent Directive Metadata Request	HITSP/TP30
Consent Repository	Responsible for both the persistent storage of consent directives as well as for their registration with the appropriate Consent Registry. It assigns a Uniform Resource Identifier (URI) and Metadata such as confidentiality codes to the consent directive for subsequent retrieval by an authorized consumer, e.g., for association with published personal health information or for evaluation at a policy decision point	HITSP/TP30
Content Consumer	Responsible for viewing, import, or other processing of content created by a Content Creator Actor	HITSP/C62 HITSP/C72 HITSP/C78 HITSP/C88 HITSP/C26
Content Creator	Responsible for the creation of content and transmission to a Content Consumer	HITSP/C62 HITSP/C72 HITSP/C78 HITSP/C88 HITSP/C26
DNS Server	This actor has authoritative location information	HITSP/T64
Document Consumer	Queries a Document Registry for documents meeting certain criteria, and retrieves selected documents from one or more Document Repository actors	HITSP/TP13



Technical Actor(s)	Actor Role	Construct
Document Recipient	Receives a set of documents sent by another actor. Typically this document set will be made available to the intended recipient who will choose to either view it or integrate it into a health record	HITSP/T31
Document Registry	Maintains metadata about each registered document in a document entry. This includes a link to the Document in the Repository where it is stored. The Document Registry responds to queries from Document Consumer actors about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration	HITSP/TP13
Document Repository	Responsible for both the persistent storage of these documents as well as for their registration with the appropriate Document Registry. It assigns a Uniform Resource Identifier (URI) to documents for subsequent retrieval by a Document Consumer	HITSP/TP13
Document Source	Producer and publisher of documents. It is responsible for sending documents to a Document Repository Actor. It also supplies metadata to the Document Repository Actor for subsequent registration of the documents with the Document Registry Actor	HITSP/TP13
Identity Provider	Receives the credentials and identifier from the Entity (principal). It may perform authentication at that point or may require additional authentication from another source (the Service Provider)	HITSP/C19
Initiating Gateway	Supports all outgoing inter-community communications	HITSP/TP13
Knowledge Requestor	System that formulates and sends a contextual request for ancillary information about a medical concept. Takes the parameters and sends to the resource available	HITSP/T81
Knowledge Resource	The system that holds the information requested and responds to the request from the Knowledge Requestor	HITSP/T81
Message Receiver	Supports message-based communications (e.g. for measures, pre-release reports, etc.)	HITSP/C70 HITSP/C72
Message Sender	Supports message-based information source	HITSP/C70 HITSP/C72
Node	The originating or terminating point of information or signal flow in a telecommunications network. This actor is equivalent to the Secure Node in the IHE-ITI-TF ATNA Transaction	HITSP/T17
Notification Receiver	Receives notifications of availability for documents in an XDS registry, and may optionally send acknowledgments of them	HITSP/T29
Notification Sender	Sends notifications of availability for documents in an XDS registry, and receives acknowledgements of these notifications	HITSP/T29
Patient Demographics Consumer	Queries the Patient Demographics Supplier for a list of patient demographic information, if any, and receives a list of corresponding patient demographic information from the Patient Demographics Supplier	HITSP/T23
Patient Demographics Supplier	Receives the query for a list of corresponding patient demographics from the Patient Demographics Consumer, sends a list of corresponding patient demographic information to the Patient Demographics Consumer, maintains one or more Patient Information Sources of patient demographics data	HITSP/T23



Technical Actor(s)	Actor Role	Construct
Patient Identifier Cross-Reference (PIX) Consumer	Queries the Patient Identifier Cross-Reference Manager for a list of corresponding patient identifiers, if any and receives a list of corresponding patient identifiers from the Patient Identifier Cross-Reference Manager	HITSP/TP22
Patient Identifier Cross-Reference (PIX) Manager	Receives the query for a list of corresponding patient identifiers from the Patient Identifier Cross-Reference Consumer. Sends a list of corresponding patient identifiers to the Patient Identifier Cross-Reference Consumer. Receives patient demographic information from the Patient Identity Source	HITSP/TP22 HITSP/T24
Patient Identity Source	Sends patient demographic information when requested, assigns a unique identifier to each instance of a patient, and maintains a collection of identity traits	HITSP/TP22 HITSP/T24
Person Identification Service	System that maintains a cross-domain person and/or patient index including all known identifiers (real and pseudo) for each person and/or patient, within all domains with which it communicates	HITSP/T24
Person Identity Consumer	System that wishes to know alternate identifiers (real and pseudo) for person and/or patients within its domain or pseudo-identifiers for person and/or patients outside its domain (for patients, this is Patient Identity Consumer)	HITSP/T24
Personnel White Pages Consumer	This actor has a use for information that can be found in the Personnel White Pages Directory	HITSP/T64
Personnel White Pages Directory	This actor has authoritative Personnel White Pages information on the human workforce members of the enterprise	HITSP/T64
Portable Media Creator	The Portable Media Creator writes the selected information to media (CD-ROM, USB-Memory, e-Mail) following the directory structure outlined by XDM	HITSP/T33
Portable Media Importer	The Portable Media Importer reads the selected information from media (CD-ROM, USB-Memory, e-Mail) following the directory structure outlined by XDM	HITSP/T33
Pseudonymization Service	Supplier of alternative identification information that permits a patient to be referred to by a key that suppresses the actual identification information. It is a module or service that can be invoked by Patient Identifier Cross-Reference (PIX) Manager to return pseudo-identifier upon request	HITSP/T24
Responding Gateway	Supports all incoming inter-community communications	HITSP/TP13
Service Provider	Represents the system providing a service to all entities that need an assertion or authentication. The service (or assertion) provider is the trusted third party issuer of the trustable identity assertion	HITSP/C19 HITSP/TP20
Service User	Represents any individual entity (such as a clinician or an EHR/PHR system) that needs to make a service request of a Service Provider. The Entity may also be known as a principal and/or entity, which represents an end user, an application, a machine, or any other type of entity that may act as a requestor in a transaction. A principal is typically represented in a transaction with a digital identity and the principal may have multiple valid digital identities to use with different transaction	HITSP/TP20 HITSP/C19
Time Client	Establishes time synchronization with one or more Time Servers using either the Network Time Protocol (NTP) or Simple Network Time Protocol (SNTP) algorithms. Maintains the local computer system clock synchronization with Coordinated Universal Time (UTC) based on synchronization with the Time Servers	HITSP/T16



Technical Actor(s)	Actor Role	Construct
Time Server	Provides Network Time Protocol (NTP) time services to Time Clients. It is either directly synchronized to a Coordinated Universal Time (UTC) master clock (e.g. satellite time signal) or is synchronized by being grouped with a Time Client to other Time Server(s)	HITSP/T16
Value Set Consumer	An actor that receives a specific, new, or updated terminology based on its OID, and possibly its version if the latter is available	HITSP/T66
Value Set Repository	An actor that has the role of providing the Resolved Value Sets	HITSP/T66

3.2.2 CONSTRUCT REQUIREMENTS

This section incorporates the comprehensive business and technical requirements and a detailed specification of the actions and decisions undertaken for the primary actions in each Use Case scenario.

Table 6.5-1 (see Section 6.0) provides a mapping of the HITSP constructs that will be used in the design of the Interoperability Specification, and the data and information exchange requirements that are being satisfied by the construct. The requirements are limited to those that are deemed within scope for this interoperability specification, which are described in Section 3.1. Further details about the required technical actors, transactions, and content are also provided in the sections below.

The UML sequence diagrams used in this section incorporate the detailed data requirements for the selected standards (defined in Section 2.2.2), with the Technical Actors, and their specific and detailed Transactions and content (encapsulated in the HITSP constructs listed above). The detailed actor Transactions described in these diagrams show all common or independent technical actors, data, and the specific transactions from the HITSP constructs that are used for the Interoperability Specification.

Figure 3.2.2-1 below depicts the options supported to communicate vaccinations. Multiple options are specified for communication of immunization information in order to enable current operational systems migration toward shared patient identification services as defined by HITSP/TP22 and HITSP/T23. A CDA vaccination (HITSP/C78) is also specified to support PHR interoperability and as an option for providers and Immunization Information System to engage in document sharing of immunizations.

- Option 1 - Use just HL7 VXU (HITSP/C72) from the message sender (clinician system or Immunization Information System) to the message receiver (Immunization Information System)
- Option 2 - If the HIE offers a HITSP/TP22 PIX manager, the clinician system shall first query the PIX manager using a PIX (HITSP/TP22) or PDQ (HITSP/T23) query transaction and populate the patient identifier in the HL7 VXU (HITSP/C72) message with the HIE domain identifier
- Option 3 – From the PHR, a HITSP/C78 Immunization Document can be communicated as a shared document to a document repository or sent to the Immunization Information System using document reliable interchange (HITSP/T31) or via media/email (HITSP/T33).
- Option 4 –The HITSP/C78 document can be communicated as a shared document to a document repository (HITSP/TP13) or sent to another provider o using document reliable interchange (HITSP/T31) or via media/email (HITSP/T33)



- Option 5 – An Immunization Information System may optionally support a document repository and receive vaccination data using document reliable interchange (HITSP/T31) or via media/email (HITSP/T33). The Immunization Information System may retrieve an Immunization document (HITSP/C78) from the document repository or from another jurisdiction document repository for cross-jurisdiction information sharing leveraging query and retrieve transactions and the Cross Community Access option in HITSP/TP13. As current immunization registries are not configured with these capabilities, this is a forward looking option
- Option 6 – An Immunization Information System may optionally send an unsolicited notification using HITSP/C72 to a clinical information system to indicate that one of their patients has received an immunization from another clinician (e.g. Airport, school, another clinician)

Figure 3.2.2-1 Communicate Vaccinations

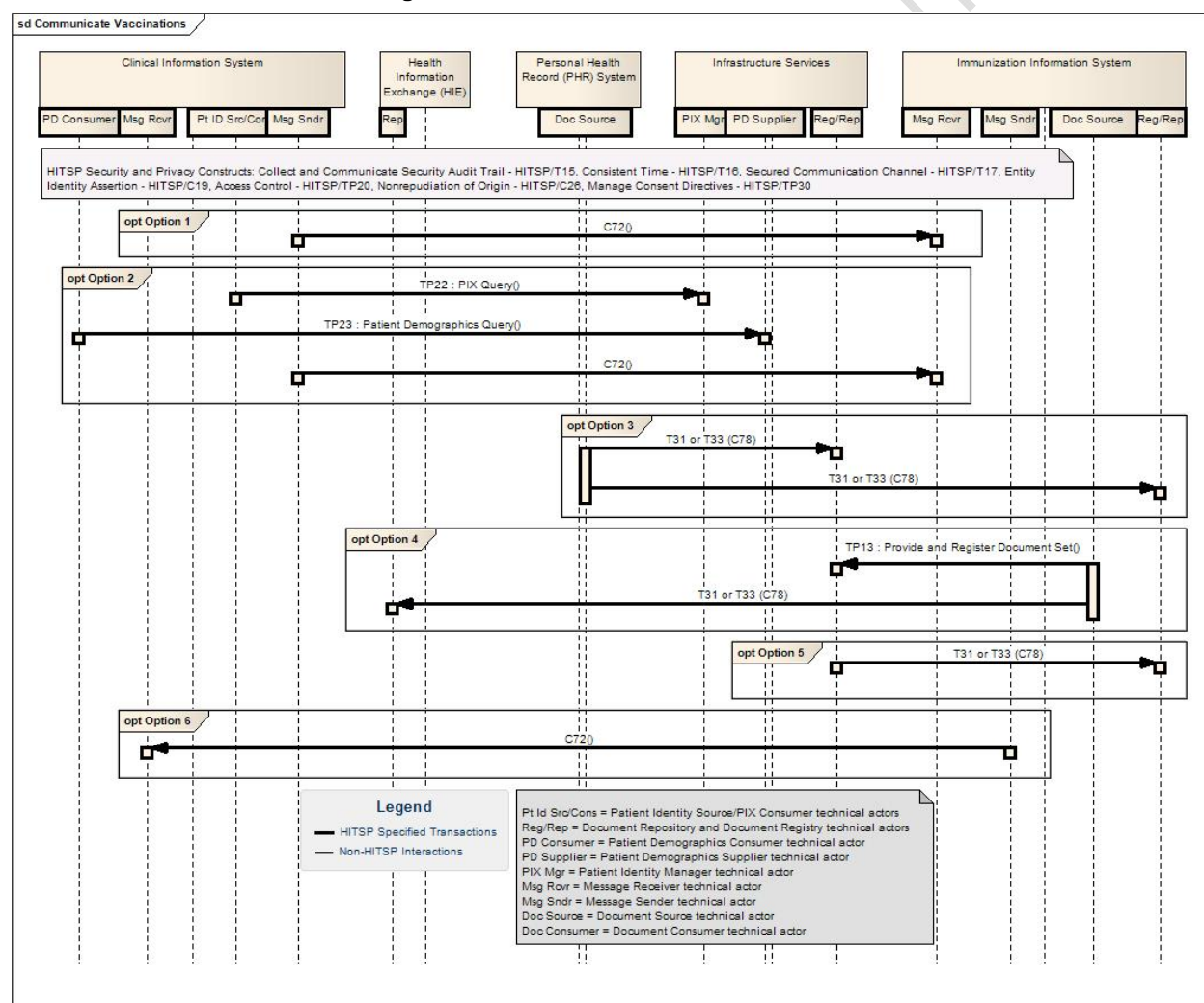


Figure 3.2.2-2 below depicts the options supported to communicate Immunization Query and Response.



Multiple options are specified for Immunization Query and Response in order to enable current operational systems migration toward shared patient identification services as defined by HITSP/TP22 and HITSP/T23 and to enable migration toward HITSP/TP21:

- Option 1 – Use the traditional HL7 VXQ to send a query from the message sender (clinician system) to the message receiver (Immunization Information System) and the HL7 VXR to send the result of the query from the message sender (Immunization Information System) to the message receiver (clinician system) (HITSP/C70)
- Option 2 – If the HIE offers a PIX manager (HITSP/TP22), the clinician system shall first query the PIX manager (using HITSP/TP22 or HITSP T23) and populate the patient identifier in the HL7 VXQ message with the HIE domain identifier and in the resulting VXR message (HITSP/C70). NOTE: policy would need to assert query result policies in PDQ as currently specified for VXR
- Option 3 - Use HITSP/TP21 Query for Existing Data to request and receive immunization data; If the HIE offers a PIX manager, the clinician system shall first query the PIX manager and populate the patient identifier in the HITSP/TP21 query
- Option 4 – Where there are immunization documents available in the HIE Document repository, use HITSP/TP13 Manage Sharing of Documents query/retrieve to gather the most up-to-date immunization data available. which may be published as HITSP/C62 Unstructured Document Component containing summary or patient-specific immunization alert, HITSP/C78 Immunization Document)

Immunization Alert Functionality

Until there is structured content defined for alerts by the SDOs, all alerts are expected to be text or presentation preserving (e.g. scanned documents).



Figure 3.2.2-2 Immunization Query and Response

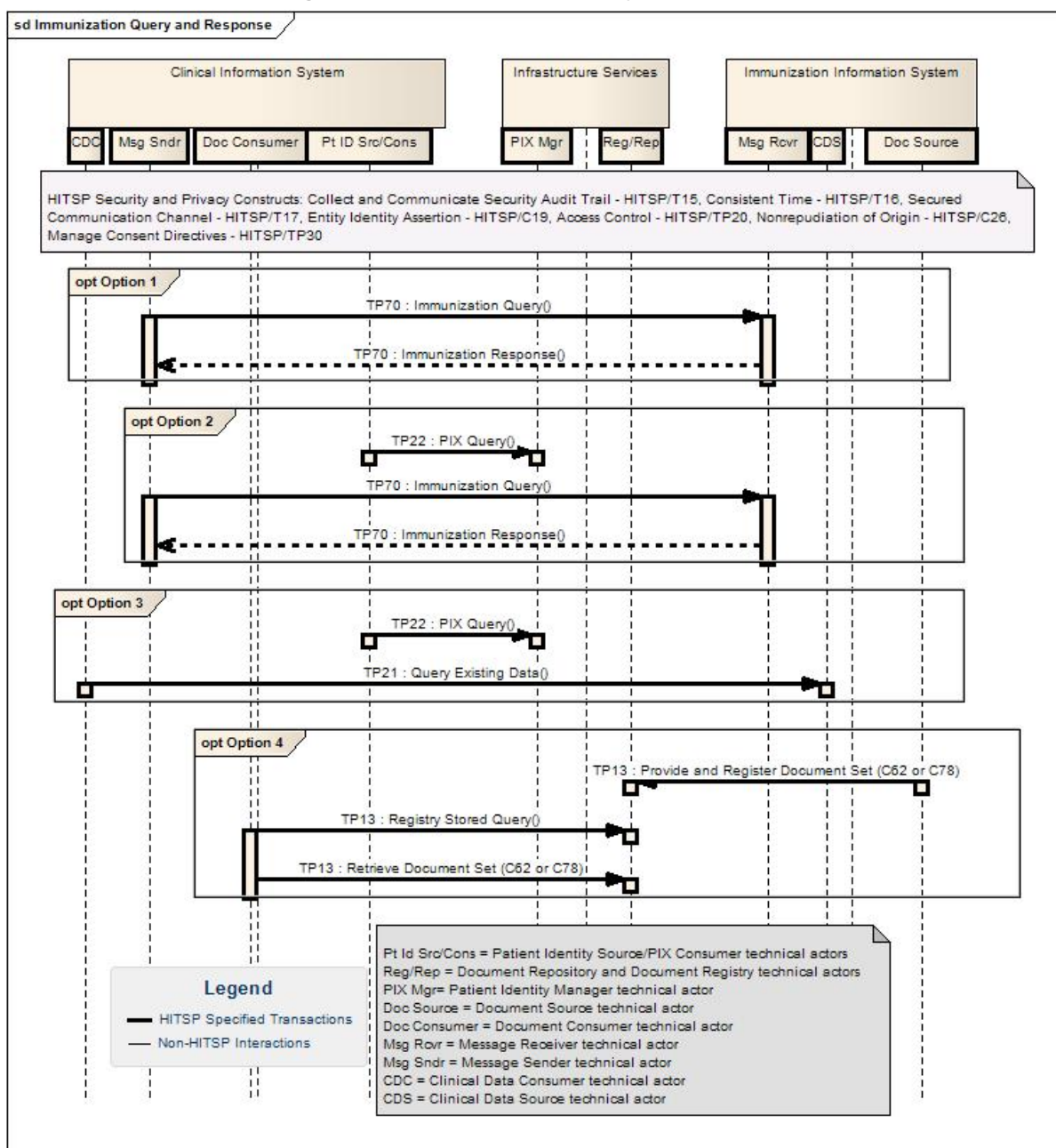


Figure 3.2.2-2 below depicts the options supported to communicate notification of immunization related alerts;

- Option 1 – Non-patient specific push – Where the alert is generic and not specific to a particular patient (e.g. immunizations required for a particular population such as those over the age of 65) and the communication requires presentation preserving properties, the communication recipients are identified using the Identify Communication Recipients (HITSP/T64) construct, and the generic alert is

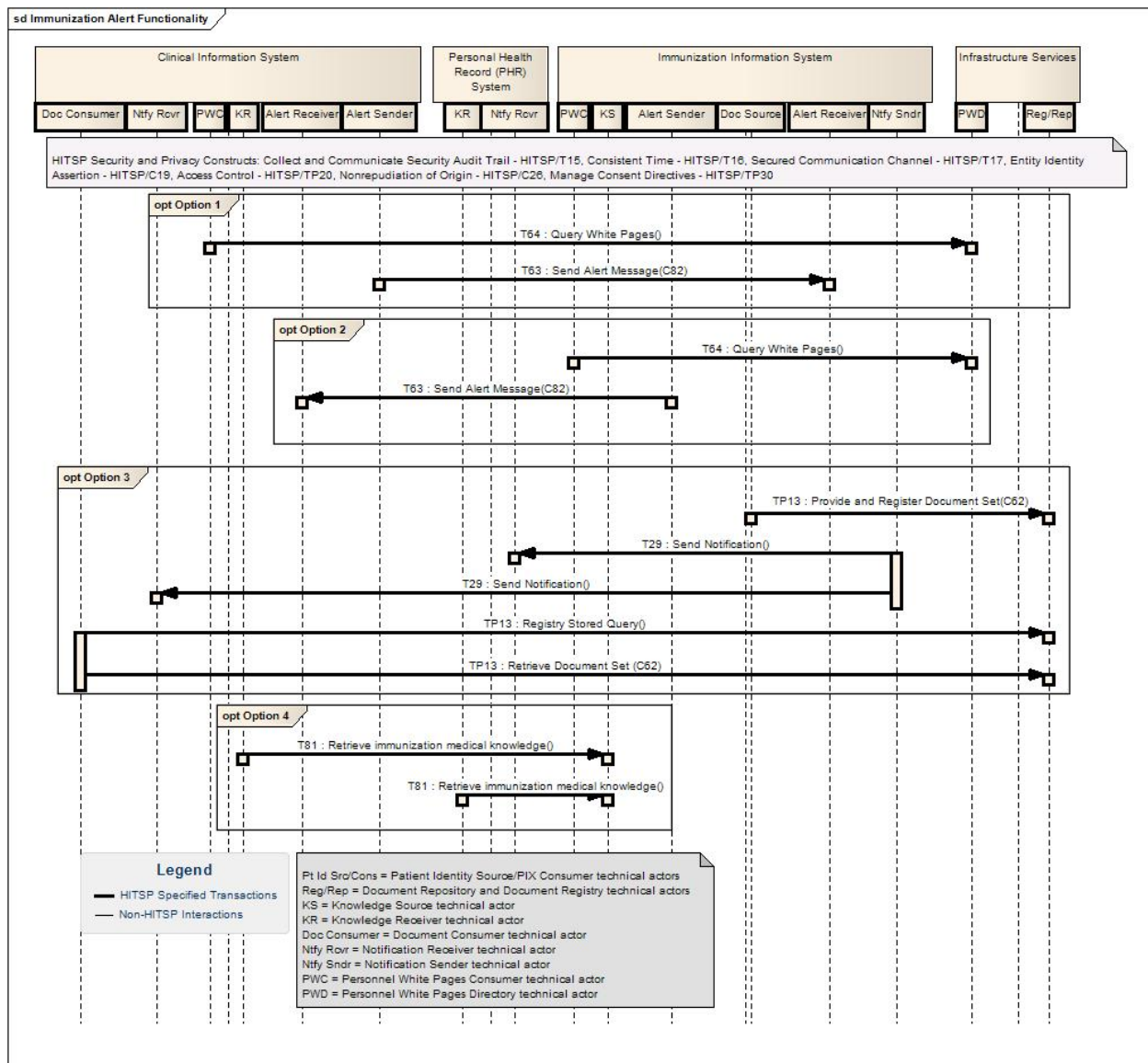


sent to those providers leveraging the Emergency Message Distribution Element (HITSP/T63) with the Emergency Common Alerting Protocol (HITSP/C82). The communication itself may be conducted using email, Health Alert Network (HAN), or FAX as specified by the implementation. Communication recipients may be identified using the Identify Communication Recipients (HITSP/T64) construct

- Option 2 – Where the alert is generic and not specific to a particular patient (e.g. immunizations required for a particular population such as those over the age of 65) and the communication is text-based, the communication recipients are identified using the Identify Communication Recipients (HITSP/T64) construct, and the generic alert is sent to those providers using the Emergency Message Distribution Element (HITSP/T63) with the Emergency Common Alerting Protocol (HITSP/C82).
- Option 3 – Where the alert is patient-specific in nature, the notification of document availability (HITSP/T29) is sent to the alert recipient (may be patient or provider). The person receiving the alert may then retrieve the patient-specific alert as an Unstructured Document (HITSP/C62) which will contain the immunization notification alert and instructions for the clinician or patient.
- Option 4 – Context specific information may be requested by the EHR or PHR using Retrieval of Medical Knowledge (HITSP/T81) as part of the user interface or pre-fetching options. This approach may be used to address the request of immunization data for assessment if a vaccine is needed. This option leverages a retrieval model and can not be leveraged for a distribution only approach.



Figure 3.2.2-3 Vaccine and Drug Inventory Reporting



3.2.3 MAPPING OF BUSINESS ACTORS TO TECHNICAL ACTORS AND CONSTRUCTS WITH OPTIONALITY

The table below maps the individual business actors to the technical actors defined in the Interoperability Specification and depicted in the above detailed UML sequence diagram. Table 3.2.3-1 below specifies the requirements associated with each business actor in the Interoperability Specification. For each implemented business actor, the table specifies the following:

1. All Required or Conditionally Required technical actors listed for the business actor shall be supported as specified in the associated construct
2. Optional technical actors listed for the business actor may be supported as specified in the associated construct



3. All Required or Conditionally Required transactions and content subsets listed for each implemented technical actor assigned to the business actor shall be supported as specified in the associated construct
4. Optional transactions and content subsets listed for each implemented technical actor assigned to the business actor may be supported as specified in the associated construct

This table also includes the corresponding technical actors associated with the relevant Security and Privacy constructs that are used for this Interoperability Specification. Section 1.2 provides a summary description of all the referenced HITSP constructs. Note that this table only shows the business and technical actors that are implemented by the specification. Business actors that are out of scope, or gaps are not included in this section, however, they are discussed in Section 3.1 if they are out of scope, or in Section 4.2 if they are found to be gaps where there are no standards.

Table 3.2.3-1 Business-Technical Actor Mapping to Transaction and/or Content

Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality ¹
Personal Health Record (PHR) Systems	Patient Demographic Consumer	C ^[101]	HITSP/T23	Patient Demographics Query	R
	Patient Identity Source	C ^[101]	HITSP/TP22	PIX Identity Feed	R
	PIX Consumer	C ^[101]	HITSP/TP22	PIX Query	R
	Document Source	C ^[103]	HITSP/TP13	Provide & Register Document Set	R
		C ^[105]	HITSP/C19	Convey Assertion	O
	Document Consumer	C ^[103]	HITSP/TP13	Query Registry	R
		C ^[106]		Retrieve Documents	R
			HITSP/C19	Convey Assertion	O
	Content Creator	R	HITSP/C78	Immunization Content	R
		R	HITSP/TP30	Consent Document	R
		C ^[108]	HITSP/T24	Pseudonymization Request	R
		C ^[109]	HITSP/C88	Anonymize for IRM	R
		O	HITSP/C26	Nonrepudiation	R
		R	HITSP/C80	Clinical Document and Message Terminology	R
		R	HITSP/C83	CDA Content Modules	R
		R	HITSP/C78	Immunization Content	R
	Content Consumer	R	HITSP/TP30	Consent Document	R
		O	HITSP/C62	Unstructured Document	O
		O	HITSP/C26	Nonrepudiation	R
		O	HITSP/C82	Non Patient Notification Message	R

¹ Optionality = "R" for Required, "O" for Optional, or "C" for Conditional



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality ¹
		R	HITSP/C80	Clinical Document and Message Terminology	R
		R	HITSP/C83	CDA Content Modules	R
	Portable Media Creator	C ^[105] C ^[111]	HITSP/T33	Distribute Document Set on Media	R
	Portable Media Importer	C ^[106] C ^[111]	HITSP/T33	Distribute Document Set on Media	R
	Document Source	C ^[110] C ^[105]	HITSP/T31	Provide & Register Document Set.b (online mode)	R
			HITSP/C19	Convey Assertion	O
	Document Recipient	C ^[110] C ^[106]	HITSP/T31	Provide & Register Document Set.b (online mode)	R
			HITSP/C19	Convey Assertion	O
	Personnel White Pages Consumer	O	HITSP/T64	Find Personnel White Pages	O
				Query Personnel White Pages	R
	Notification Receiver	O	HITSP/T29	Receive Notification	R
	Notification Sender	O	HITSP/T29	Send Notification	R
	Value Set Consumer	O	HITSP/T66	Retrieve Value Set	R
	Knowledge Requestor	O	HITSP/T81	Retrieve Topic Medical Knowledge	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Identity Provider	C ^[113]	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Consent Originator	O	HITSP/TP30	Provide and Register Document Set	R
	Consent Registry	O	HITSP/TP30	Register Document Set	R
				Stored Query	R
	Consent Repository	O	HITSP/TP30	Provide and Register Document Set	R
				Register Document Set	R
	Consent Directive Requestor	R	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	Service User	R	HITSP/TP20	Access Control Request	O



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality ¹
	Access Control Service	R	HITSP/TP20	Access Control Request	O
	Service Provider	C ^[102]	HITSP/TP20	Access Control Request	O
Electronic Health Record (EHR) System	Patient Demographic Consumer	C ^[101]	HITSP/T23	Patient Demographics Query	R
	Patient Identity Source	C ^[101]	HITSP/TP22	PIX Identity Feed	R
	PIX Consumer	C ^[101]	HITSP/TP22	PIX Query	R
	Message Sender	C ^[104] C ^[105]	HITSP/C72	Vaccination Message	R
			HITSP/C70	Vaccination Query Message	R
				Vaccination Response Message	O
	Message Receiver	C ^[104] C ^[106]	HITSP/C72	Vaccination Message	R
			HITSP/C70	Vaccination Query Message	O
				Vaccination Response Message	R
	Portable Media Creator	C ^[105] C ^[111]	HITSP/T33	Distribute Document Set on Media	R
	Portable Media Importer	C ^[106] C ^[111]	HITSP/T33	Distribute Document Set on Media	R
	Document Source	C ^[103] C ^[105]	HITSP/T31	Provide & Register Document Set.b (online mode)	R
			HITSP/C19	Convey Assertion	O
	Document Recipient	C ^[103] C ^[106]	HITSP/T31	Provide & Register Document Set.b (online mode)	R
			HITSP/C19	Convey Assertion	O
	Document Consumer	C ^[103] C ^[106]	HITSP/TP13	Query Registry	R
				Retrieve Documents	R
			HITSP/C19	Convey Assertion	O
	Document Repository	O	HITSP/TP13	Retrieve Documents	R
				Provide & Register Document Set.b (online mode)	C ^[201]
				Provide & Register Document Set (offline mode)	C ^[201]
			HITSP/C19	Convey Assertion	O
	Clinical Data Consumer	C ^[107]	HITSP/TP21	Query Existing Data	C ^[201]
			HITSP/C19	Convey Assertion	O



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality ¹
	Clinical Data Source	C ^[107]	HITSP/TP21	Query Existing Data	C ^[201]
			HITSP/C19	Convey Assertion	O
	Content Creator	R	HITSP/C78	Immunization Content	R
		R	HITSP/TP30	Consent Document	R
		R	HITSP/C72	Vaccination Message	R
		C ^[107]	HITSP/C70	Vaccination Query Message (VXQ/VXR) (Query)	R
				Vaccination Query Message (VXQ/VXR) (Response)	O
		R	HITSP/C62	Unstructured Document	O
		C ^[108]	HITSP/T24	Pseudonymization Request	R
		C ^[109]	HITSP/C88	Anonymize for IRM	R
		O	HITSP/C26	Nonrepudiation	R
		R	HITSP/C80	Clinical Document and Message Terminology	R
		R	HITSP/C83	CDA Content Modules	R
	Content Consumer	R	HITSP/C78	Immunization Content	R
		O	HITSP/C72	Vaccination Message	R
		C ^[107]	HITSP/C70	Vaccination Query Message (VXQ/VXR) (Query)	O
				Vaccination Query Message (VXQ/VXR) (Response)	R
		R	HITSP/TP30	Consent Document	R
		C ^[108]	HITSP/T24	Pseudonymization Request	R
		C ^[109]	HITSP/C88	Anonymize for IRM	R
		R	HITSP/C62	Unstructured Document	O
		O	HITSP/C26	Nonrepudiation	R
		O	HITSP/C82	Non Patient Notification Message	R
		R	HITSP/C80	Clinical Document and Message Terminology	R
		R	HITSP/C83	CDA Content Modules	R
	Personnel White Pages Consumer	O	HITSP/T64	Find Personnel White Pages	O
				Query Personnel White Pages	R
	Notification Receiver	O	HITSP/T29	Receive Notification	R
	Notification Sender	O	HITSP/T29	Send Notification	R
	Value Set Consumer	O	HITSP/T66	Retrieve Value Set (request)	R
	Knowledge Requestor	O	HITSP/T81	Retrieve Topic Medical Knowledge	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality ¹
	Node	R	HITSP/T17	Secured Communication Channel	R
	Identity provider	C ^[113]	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Consent Originator	O	HITSP/TP30	Provide and Register Document Set	R
	Consent Registry	O	HITSP/TP30	Register Document Set	R
				Stored Query	R
	Consent Repository	O	HITSP/TP30	Provide and Register Document Set	R
				Register Document Set	R
	Consent Directive Requestor	R	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	Service User	R	HITSP/TP20	Access Control Request	O
Access Control Service	R	HITSP/TP20	Access Control Request	O	
Service Provider	C ^[102]	HITSP/TP20	Access Control Request	O	
Health Information Exchange (HIE)	Patient Demographic Supplier	C ^[101]	HITSP/T23	Patient Demographics Query	R
	PIX Manager	C ^[101]	HITSP/TP22	PIX Identity Feed	R
				PIX Query	R
	Message Sender	C ^[104] C ^[105]	HITSP/C72 HITSP/C70	Vaccination Message	R
				Vaccination Query Message	C ^[201]
				Vaccination Response Message	C ^[201]
	Message Receiver	C ^[104] C ^[106]	HITSP/C72 HITSP/C70	Vaccination Message	R
				Vaccination Query Message	C ^[201]
				Vaccination Response Message	C ^[201]
	Person Identification Service	C ^[108]	HITSP/T24	Person Identity Feed	R
				Person Identity Cross-Reference Query	R
				PIX Update Notification	R
				Pseudonymization Request	R
	Document Source	R	HITSP/TP13	Provide & Register Document Set	R
			HITSP/C19	Convey Assertion	O
	Document Registry	R	HITSP/TP13	Provide & Register Document Set	R
				Query Registry	R
			HITSP/C19	Convey Assertion	O
	Document Repository	O	HITSP/TP13	Retrieve Documents	R
				Provide & Register Document Set.b (online mode)	C ^[201]
				Provide & Register Document Set (offline mode)	C ^[201]



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality ¹
	Personnel White Pages Directory	O	HITSP/C19	Convey Assertion	O
			HITSP/T64	Find Personnel White Pages	O
				Query Personnel White Pages	R
	Notification Sender	O	HITSP/T29	Send Notification	R
	Document Recipient	O	HITSP/T31	Receive Document	R
			HITSP/C19	Convey Assertion	O
	Message Transmitter	O	HITSP/T63	Send Alert Message	R
			HITSP/C82	Non Patient Notification Message	C ^[201]
			HITSP/C19	Convey Assertion	O
	Value Set Repository	O	HITSP/T66	Retrieve Value Set (response)	R
	Pseudonymization Service	O	HITSP/T24	Pseudonymize	R
	Knowledge Resource	O	HITSP/T81	Retrieve Topic Medical Knowledge	R
	Message Receiver	O	HITSP/T63	Send Alert Message	C ^[201]
			HITSP/C82	Non Patient Notification Message	C ^[201]
			HITSP/C19	Convey Assertion	O
	Document Consumer	R	HITSP/TP13	Query Registry	R
				Retrieve Documents	R
			HITSP/C19	Convey Assertion	O
	Content Creator	R	HITSP/C78	Immunization Content	R
		O	HITSP/C72	Vaccination Message	R
		O	HITSP/C70	Vaccination Query Message (VXQ/VXR) (Query)	O
				Vaccination Query Message (VXQ/VXR) (Response)	R
		R	HITSP/TP30	Consent Document	R
		R	HITSP/C62	Unstructured Document	O
		O	HITSP/C26	Nonrepudiation	R
		O	HITSP/C82	Non Patient Notification Message	R
		R	HITSP/C80	Clinical Document and Message Terminology	R
		R	HITSP/C83	CDA Content Modules	R
	Content Consumer	R	HITSP/C78	Immunization Content	R
		O	HITSP/C72	Vaccination Message	R
		O	HITSP/C70	Vaccination Query Message (VXQ/VXR) (Query)	O
				Vaccination Query Message (VXQ/VXR) (Response)	R
		R	HITSP/TP30	Consent Document	R
		R	HITSP/C62	Unstructured Document	O
		O	HITSP/C26	Nonrepudiation	R



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality ¹
		O	HITSP/C82	Non Patient Notification Message	R
		R	HITSP/C80	Clinical Document and Message Terminology	R
		R	HITSP/C83	CDA Content Modules	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Identity Provider	C ^[113]	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Consent Originator	O	HITSP/TP30	Provide and Register Document Set	R
	Consent Registry	O	HITSP/TP30	Register Document Set	R
				Stored Query	R
	Consent Repository	O	HITSP/TP30	Provide and Register Document Set	R
				Register Document Set	R
	Consent Directive Requestor	R	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	Service User	R	HITSP/TP20	Access Control Request	O
	Access Control Service	R	HITSP/TP20	Access Control Request	O
	Service Provider	C ^[102]	HITSP/TP20	Access Control Request	O
Immunization Information System (IIS)	Patient Demographic Consumer	O	HITSP/T23	Patient Demographics Query	R
	Patient Identity Source	O	HITSP/TP22	PIX Identity Feed	R
	PIX Consumer	O	HITSP/TP22	PIX Query	R
	Message Sender	C ^[104] C ^[105]	HITSP/C72	Vaccination Message	R
			HITSP/C70	Vaccination Query Message	O
				Vaccination Response Message	R
	Message Receiver	C ^[104] C ^[106]	HITSP/C72	Vaccination Message	R
			HITSP/C70	Vaccination Query Message	R
				Vaccination Response Message	O
	Personnel White Pages Directory	O	HITSP/T64	Query Personnel White Pages	R
	Personnel White Pages Consumer	O	HITSP/T64	Find Personnel White Pages	O
				Query Personnel White Pages	R



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality ¹
	Notification Sender	O	HITSP/T29	Send Notification	R
	Notification Receiver	O	HITSP/T29	Send Notification	R
	Document Recipient	O	HITSP/T31	Receive Document	R
			HITSP/C19	Convey Assertion	O
	Message Transmitter	O	HITSP/T63	Send Alert Message	R
			HITSP/C82	Non Patient Notification Message	C ^[201]
			HITSP/C19	Convey Assertion	O
	Value Set Repository	O	HITSP/T66	Retrieve Value Set (response)	R
	Pseudonymization Service	O	HTISP/T24	Pseudonymize	R
	Knowledge Resource	O	HTISP/T81	Retrieve Topic Medical Knowledge	R
	Message Receiver	O	HITSP/T63	Send Alert Message	C ^[201]
			HITSP/C82	Non Patient Notification Message	C ^[201]
			HITSP/C19	Convey Assertion	O
	Document Source	C ^[103] C ^[105]	HITSP/TP13	Provide & Register Document Set	R
			HITSP/C19	Convey Assertion	O
	Document Repository	O	HITSP/TP13	Retrieve Documents	R
				Provide & Register Document Set.b (online mode)	C ^[201]
				Provide & Register Document Set (offline mode)	C ^[201]
	Document Consumer	C ^[103] C ^[105]	HITSP/TP13	Query Registry	R
				Retrieve Documents	R
			HITSP/C19	Convey Assertion	O
	Portable Media Creator	C ^[105] C ^[111]	HITSP/T33	Distribute Document Set on Media	R
	Portable Media Importer	C ^[106] C ^[111]	HITSP/T33	Distribute Document Set on Media	R
	Document Source	C ^[103] C ^[105]	HITSP/T31	Provide & Register Document Set.b (online mode)	R
			HITSP/C19	Convey Assertion	O
	Document Recipient	C ^[103] C ^[106]	HITSP/T31	Provide & Register Document Set.b (online mode)	C ^[201]
			HITSP/C19	Convey Assertion	O
	Clinical Data Consumer	C ^[107]	HITSP/TP21	Query Existing Data	C ^[201]



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality ¹
	Clinical Data Source	C ^[107]	HITSP/C19	Convey Assertion	O
			HITSP/TP21	Query Existing Data	C ^[201]
			HITSP/C19	Convey Assertion	O
	Content Creator	R	HITSP/C78	Immunization Content	R
		O	HITSP/C72	Vaccination Message	R
		C ^[107]	HITSP/C70	Vaccination Query Message (VXQ/VXR) (Query)	O
				Vaccination Query Message (VXQ/VXR) (Response)	R
		C ^[108]	HITSP/T24	Pseudonymization Request	R
		C ^[109]	HITSP/C88	Anonymize for IRM	R
		R	HITSP/C62	Unstructured Document	O
		R	HITSP/TP30	Consent Document	R
		R	HITSP/C62	Unstructured Document	O
		O	HITSP/C26	Nonrepudiation	R
		O	HITSP/C82	Non Patient Notification Message	R
		R	HITSP/C80	Clinical Document and Message Terminology	R
		R	HITSP/C83	CDA Content Modules	R
	Content Consumer	C ^[112]	HITSP/C78	Immunization Content	R
		O	HITSP/C72	Vaccination Message	R
		C ^[107]	HITSP/C70	Vaccination Query Message (VXQ/VXR) (Query)	R
				Vaccination Query Message (VXQ/VXR) (Response)	O
		R	HITSP/TP30	Consent Document	R
		R	HITSP/C72	Vaccination Message	R
		R	HITSP/C62	Unstructured Document	O
		O	HITSP/C26	Nonrepudiation	R
		O	HITSP/C82	Non Patient Notification Message	R
		R	HITSP/C80	Clinical Document and Message Terminology	R
		R	HITSP/C83	CDA Content Modules	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Identity Provider	C ^[113]	HITSP/C19	Provide Assertion	R
				Verify Assertion	O



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality ¹
	Consent Originator	O	HITSP/TP30	Provide and Register Document Set	R
	Consent Registry	O	HITSP/TP30	Register Document Set	R
				Stored Query	R
	Consent Repository	O	HITSP/TP30	Provide and Register Document Set	R
				Register Document Set	R
	Consent Directive Requestor	R	HITSP/TP30	Stored Query	R
				Retrieve Document Set	R
	Service User	R	HITSP/TP20	Access Control Request	O
	Access Control Service	R	HITSP/TP20	Access Control Request	O
	Service Provider	C ^[102]	HITSP/TP20	Access Control Request	O

Implementation Conditions/Constraints

The following table describes the implementation conditions or constraints placed on the technical actors, transactions, or content. The constraint codes listed below correspond to the codes placed in the Actor and Transaction/Content optionality column in Table 3.2.3-1 above. For example, the Patient Demographics Consumer Technical Actor has an optionality code of C^{[105] [106]} which represents a conditionally required Actor with the constraint codes of 105 and 106 described in the table below.

Table 3.2.3-2 Implementation Conditions/Constraints

Constraint Code	Constraint Description
IS10-101	Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer where shared patient identity management interoperability is to be supported
IS10-102	Required if Access Control Request Transaction is not supported
IS10-103	Required when a Document Repository and/or a Document Registry is supported
IS10-104	Required for message-based vaccination query/response (VXQ/VXR) or submissions (VXU)
IS10-105	Business Actor shall support at least one of these technical actors to communicate outbound content
IS10-106	Business Actor shall support at least one of these technical actors to receive or retrieve inbound content
IS10-107	One or both of these are required for vaccination query/response
IS10-108	Required where pseudonymization is required by the jurisdiction or information sharing agreements or selected by PHR
IS10-109	Required where anonymization is required by the jurisdiction or information sharing agreements or selected by PH
IS10-110	Required for Document Reliable Interchange support
IS10-111	Required for Portable Media support
IS10-112	Required where PHR-generated vaccinations are supported for HITSP/C78 - Patient Health Plan Authorization Request and Response



Constraint Code	Constraint Description
IS10-113	There must be at least one in a group of business actors
IS10-201	The Actor shall support at least one of these transactions

3.2.4 CONSTRUCT DEPENDENCIES

The following table shows a list of constructs with their existing dependencies. Dependencies usually exist when there are some additional pre-requisites for a specific construct. To support a dependent construct, a technical actor must implement all the required actions in the pre-requisite construct, or be grouped together with another construct as specified in the table below:

Table 3.2.4-1 Construct Dependencies

Construct	Depends On (Name of construct that it depends on)	Dependency Type (Pre-condition, Post-condition, General)	Purpose (Reason for this dependency)
T63 - Emergency Message Distribution Element	HITSP/T64 - Identify Communication Recipients	Pre-condition	Retrieve communication parameters
C82 - Emergency Common Alerting Protocol	HITSP/T64 - Identify Communication Recipients	Pre-condition	Retrieve communication parameters
C82 - Emergency Common Alerting Protocol	HITSP/T29 - Notification of Document Availability	Pre-condition where the intent is for the recipient to retrieve the unstructured document from a document sharing resource	Communicate notification of document availability and location
C82 - Emergency Common Alerting Protocol	HITSP/TP13 – Managing Sharing of Documents or HITSP/T31 - Document Reliable Interchange or HITSP/T33 - Transfer of Documents on Media	Pre-condition	Transport mechanism for notification

3.2.5 ADDITIONAL CONSTRAINTS ON REQUIRED CONSTRUCTS

This section describes the constraints that further limit the constructs that are used by this Interoperability Specification.

Table 3.2.5-1 Additional Constraints on Required Constructs

Data Element	Construct	Constraint	Constraint Type (Pre-condition, Post-condition, General)	Purpose (Reason for this constraint)
Patient Name	HITSP/C72 - Immunization Message	Where there is not a PIX manager, then patient name is required	General	



Data Element	Construct	Constraint	Constraint Type (Pre-condition, Post-condition, General)	Purpose (Reason for this constraint)
All Pediatric Demographic Option (PDO) constrained data elements for PIX Feed	HITSP/TP22 - Patient ID Cross-Referencing	Data elements shall be constrained in accordance with the Pediatric Demographic Options constraints	Pre-condition	Support pediatric demographics for children's immunizations
All Pediatric Demographic Option (PDO) constrained data elements for Patient Demographic Query and Response	HITSP/T23 - Patient Demographics Query	Data elements shall be constrained in accordance with the Pediatric Demographic Options constraints	Pre-condition	Support pediatric demographics queries for children's immunizations



4.0 STANDARDS SELECTION

This section presents the standards required to support each major Use Case event. Standards selection is based on the following process:

- **Evaluation:** The Technical Committee evaluates the standards using the Tier 2 Readiness Criteria.
- **Selection:** Based on the Tier 2 evaluations, named standards are selected and listed in the table of selected standards below. It is important to understand that the standards selected here are within the context of the specific Use Case requirements and do not necessarily reflect selection in other contexts
- **Gap and Overlap Analysis and Recommendations:** The Technical Committee also identifies and analyzes gaps and overlaps within the standards industry as they relate to the specific Use Case. The Technical Committee provides a description of the gaps, including missing or incomplete standards, a description of all overlaps, or competition among standards for the relevant Use Cases, and recommendations for resolving these gaps and overlaps

It is HITSP's policy to incorporate only standards that have been approved according to the formal policy of the standards organization, as defined by HITSP, which publishes the standard. HITSP interprets approval to include Draft Standards for Trial Use. The objective is to incorporate only standards that are managed within a formal life cycle process as defined by the standards organization. In some cases, where we believe a standard that is not yet approved may best meet the requirements of an Interoperability Specification, HITSP may provide a roadmap of its future intent conditional on future actions by either or both the standards organization and the HITSP Technical Committee. Thus there are four classes of HITSP-committed standards.

- **Approved for Use** – standards included for unconditional use within a HITSP construct
- **Interim** – standards included for use now within a HITSP construct but for a defined time period or conditional on future actions, e.g., "Intended for Use" standard is available
- **Provisional** - standards that are not yet but are expected to be approved by the standards organization at the time the Interoperability Specification is released by HITSP. A "Provisional" standard becomes an "Approved for Use" standard only if:
 - It is approved by the Standards Organization by the time that the Interoperability Specification is released by HITSP and
 - It is substantially the same as it was when it was provisionally used and
 - It requires no further action by the Technical Committee
- **Intended for Use** – proposed standards that are roadmapped for future use pending actions by the Technical Committee and/or the standards organization. Therefore a standard is defined as "Intended for Use" if it will not be approved by the standard organization at the time that the HITSP construct is released, but is sufficiently defined to enable detailed evaluation of how well it will meet technical and information exchange requirements.



HITSP may continue to use “Provisional” or “Interim” standards as they existed when incorporated into the HITSP construct if the expected conditions are not satisfied until such time as HITSP can replace it with a more suitable standard. In this circumstance, the standards organization would have no responsibility to maintain or correct this artifact. If a standard “Intended for Use” is not developed and approved in terms of time frame or content as expected by the Technical Committee at the time of its initial selection, it may be replaced. All standards used by HITSP must meet the HITSP selection criteria. The use of “Interim” and “Intended for Use” standards will be weighed against the alternative of simply declaring a gap for HITSP and the standards organizations to resolve.

4.1 STANDARDS

It is important to understand that the standards selected here are within the context of the specific Use Case requirements and do not necessarily reflect selection in other contexts. In addition, adherence to the selected standards alone is not sufficient to ensure interoperability. In order to ensure interoperability for the Use Case, and to claim conformance to the specification, an implementation must satisfy all the requirements and mandatory statements listed in the HITSP Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must also be constrained as specified in Table 3.1.2-1, and implement all of the required technical actors from Table 3.2.3-1, within the scope and implementation subset that is selected.

The standards used by this Interoperability Specification fall into the following categories:

- Regulatory guidance is a legal or other authoritative declaration that HITSP must abide by in standards selection (see Section 4.1.1)
- Selected standards are necessary for interoperability. These are standards that are used to meet information exchange requirements of associated constructs. For example, they are used to realize direct information exchange, to provide the transport mechanism, to specify the content, or to address security (see Section 4.1.2)
- Informative reference standards provide additional background information or guidance, and are not required for interoperability. These standards are not required to implement the Interoperability Specification (see Section 4.1.3)

4.1.1 REGULATORY GUIDANCE

The following table provides a list of legal or other authoritative guidelines that HITSP must abide by, or has agreed to use as guidance in the selection of standards. Note that only the referenced sections of the regulations are relevant to this Interoperability Specification.

Table 4.1.1-1 Regulatory Guidance

Regulation	Description
For Regulatory and Guidance Standards relating to the Security and Privacy of Health Information, please see HITSP/TN900 Security and Privacy Technical Note	The HITSP/TN900 document is a reference document that provides the overall context for use of the HITSP Security and Privacy constructs. It also includes a set of overarching principles and concepts, derived from an analysis of major federal and common state laws and regulations.



Regulation	Description
Centers for Disease Control and Prevention Implementation Guide for Immunizations Data Transaction using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol. Implementation Guide Version 2.2 June 2006	This Guide is intended for use by immunization registries that want to participate in a strictly-defined record exchange agreement that limits the amount of optionality normally expected when using the HL7 standard. The Guide describes the most frequently used segments in their entirety, while giving a minimum description of segments containing only a few useful fields for registries. The Guide fully describes the fields within the segments used frequently by immunization registries, while the others are omitted in this document. With this limited scope, this <i>Guide</i> can in no way serve as a substitute for a thorough study of the entire set of HL7 specifications for electronic data interchange in health care environments. For more information visit www.cdc.gov .
Family Educational Rights and Privacy Act (FERPA) The Department of Education Student Rule	FERPA is a Federal law that applies to educational agencies and institutions that receive funding under a program administered by the U. S. Department of Education. The statute is found at 20 U.S.C. § 1232g and the Department's regulations are found at 34 CFR Part 99.
National Vaccine Advisory Committee: Immunization Information Systems NVAC Progress Report, February 2007	National Vaccine Advisory Committee (NVAC) undertook an Initiative on Immunization Registries by forming a workgroup made up of NVAC members and others. The workgroup was charged with identifying barriers to developing and implementing immunization registries, and defining milestones for the development and implementation of a comprehensive plan for the implementation of universal state-based and community-based immunization registries. For more information visit www.hhs.gov .
Health Insurance Portability and Accountability Act (HIPAA) Code of Federal Regulations (CFR) Title 45, Part 164, Section 502(d) (CFR§164.502(d))	This is a specific reference to 45 CFR 164.502(d) which specifies the general rules for uses and disclosures of de-identified protected health information.
Health Insurance Portability and Accountability Act (HIPAA) -- Administrative Simplification	A listing of national standards plus rules adopted by federal regulation for electronically communicating specified administrative and financial healthcare transactions, and protecting the security and privacy of healthcare information, as applied to the three types of defined covered entities: health plans, healthcare clearinghouses, and healthcare providers who conduct any of the specified healthcare transactions. See the Code of Federal Regulations, Title 45, Parts 160, et. seq. for more information.

4.1.2 SELECTED STANDARDS

The following table provides a list of standards that are used to meet information exchange requirements of the Interoperability Specification, and the HITSP constructs that use each standard. A detailed description of each standard is also provided in the Appendix.

Note that the standards selected for this Interoperability Specification are approved for use as defined in Section 4.0 above.

Table 4.1.2-1 Selected Standards Linked to HITSP Constructs

Standard	HITSP Construct	Remarks/ Minor Gaps
Accredited Standards Committee (ASC) X12 Standards Release 004010	HITSP/C80 - Clinical Document and Message Terminology	
American Medical Association (AMA) Current Procedural Terminology (CPT®) Fourth Edition (CPT-4); CPT Evaluation and Management Codes	HITSP/C80 - Clinical Document and Message Terminology	



Standard	HITSP Construct	Remarks/ Minor Gaps
ASTM International Standard Guide for Electronic Authentication of Health Care Information: # E1762-95 (2003)	HITSP/C26 - Nonrepudiation of Origin	
CDC Race and Ethnicity Code Sets	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C78
Center for Disease Control and Prevention Implementation Guide for Immunizations Data Transaction using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol. Implementation Guide Version 2.2 June 2006	HITSP/C70 - Immunization Query and Response HITSP/C72 - Immunization Message HITSP/C80 - Clinical Document and Message Terminology	
Digital Imaging and Communications in Medicine (DICOM) Part 3.12: Media Formats and Physical Media for Media Interchange	HITSP/T33 - Transfer of Documents on Media	
European Telecommunications Standards Institute (ETSI) Technical Specification TS 101 903: XML Advanced Electronic Signatures (XadES)	HITSP/C26 - Nonrepudiation of Origin	
Federal Information Processing Standards (FIPS) Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5-2, May, 1987	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C78
Food and Drug Administration (FDA) - Unique Ingredient Identifier (UNII)	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C78 where optional medication detail is provided
Food and Drug Administration (FDA) - National Drug Code (NDC)	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C78 where optional medication detail is provided
Health Care Provider Taxonomy	HITSP/C80 - Clinical Document and Message Terminology	
Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 2.0	HITSP/C78 - Immunization Document HITSP/C83 - CDA Content Modules	
Health Level Seven (HL7) Common Terminology Services (CTS) Release 1	HITSP/T66 - Retrieve Value Set	
Health Level Seven (HL7) Implementation Guide for CDA Release 2: History and Physical (H&P) Notes	HITSP/C83 - CDA Content Modules	
Health Level Seven (HL7) Implementation Guide for CDA Release 2: Consultation Note	HITSP/C83 - CDA Content Modules	
Health Level Seven (HL7) Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), April 01, 2007	HITSP/C83 - CDA Content Modules	
Health Level Seven (HL7) Standard Code Set CVX - Vaccines Administered	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C78



Standard	HITSP Construct	Remarks/ Minor Gaps
Health Level Seven (HL7) Standard Code Set MVX - Manufacturers of Vaccines	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C78
Health Level Seven (HL7) V3 RBAC, R1-2008, HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1, February 2008	HITSP/TP20 - Access Control	
Health Level Seven (HL7) Version 2.3.1	HITSP/C70 - Immunization Query and Response	
Health Level Seven (HL7) Version 2.3.1 Chapter 2 – Control, Chapter 3 – Patient Administration	HITSP/TP22 - Patient ID Cross-Referencing	
Health Level Seven (HL7) Version 2.5, Chapter 2 – Control, Chapter 3 – Patient Administration, Chapter 5 – Query	HITSP/TP22 - Patient ID Cross-Referencing	
Health Level Seven (HL7) Version 2.5, Chapter 2 – Control, Chapter 3 – Patient Administration, Chapter 5 - Query	HITSP/T23 - Patient Demographics Query	
Health Level Seven (HL7) Version 2.5.1	HITSP/C80 - Clinical Document and Message Terminology	
Health Level Seven (HL7) Version 3.0 - Vocabularies and Value Sets	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C78
Health Level Seven (HL7) Version 3.0 Context-Aware Information Retrieval Specification: URL Implementation Guide	HITSP/T81 - Retrieval of Medical Knowledge	
Health Level Seven (HL7) Version 3.0 Infrastructure Management - Query Infrastructure, Release 2 DSTU Ballot 1 - September 2008	HITSP/TP21 - Query for Existing Data	
Health Level Seven (HL7) Version 3.0 Privacy Consent related specifications RCMR_RM010001 - Data Consent	HITSP/TP30 - Manage Consent Directives	
Health Level Seven (HL7) Version 3.0 Standard: Transport Specification - Web Services Profile, Release 2 Committee Ballot 1 - May 2008	HITSP/TP21 - Query for Existing Data	
HUGO Gene Nomenclature Committee at the European Bioinformatics Institute - Gene Names	HITSP/C80 - Clinical Document and Message Terminology	
Human Genome Variation Society (HGVS) - Description of Sequence Variants – February, 20, 2008	HITSP/C80 - Clinical Document and Message Terminology	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise User Assertion (XUA)	HITSP/C19 - Entity Identity Assertion	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement Volume 3 – Document Digital Signature (DSG) Content Profile	HITSP/C26 - Nonrepudiation of Origin	



Standard	HITSP Construct	Remarks/ Minor Gaps
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) – Revision 5.0 or later, Cross Enterprise Sharing of Scanned Documents (XDS-SD) Integration Profile	HITSP/C62 - Unstructured Document	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Audit Trail and Node Authentication (ATNA) Integration Profile	HITSP/T15 - Collect and Communicate Security Audit Trail	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Audit Trail and Node Authentication (ATNA) Integration Profile, Section 9.1 Authentication	HITSP/T17 - Secured Communication Channel	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Consistent Time (CT) Integration Profile	HITSP/T16 - Consistent Time	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Patient Demographics Query (PDQ) Integration Profile	HITSP/T23 - Patient Demographics Query	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework Supplement 2008 - 2009, Pediatric Demographics, Draft for Trial Implementation (August 22, 2008)	HITSP/T23 - Patient Demographics Query	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0	HITSP/T24 - Pseudonymize	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement 2007 – 2008, Notification of Document Availability Integration Profile, Draft for Trial Implementation, October 10, 2008	HITSP/T29 - Notification of Document Availability	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) 2007-2008 Trial Implementation Supplement Cross-enterprise Document Reliable Interchange (XDR) Release 3	HITSP/T31 - Document Reliable Interchange	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF), Revision 4, Personnel White Pages profile	HITSP/T64 - Identify Communication Recipients	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Section 10 Cross-Enterprise Document Sharing (XDS.a)	HITSP/TP13 - Manage Sharing of Documents HITSP/TP30 - Manage Consent Directives	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 - Registry Stored Query Transaction for XDS Profile Supplement [ITI-18]	HITSP/TP13 - Manage Sharing of Documents HITSP/TP30 - Manage Consent Directives	



Standard	HITSP Construct	Remarks/ Minor Gaps
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 XCA Supplement	HITSP/TP13 - Manage Sharing of Documents HITSP/TP30 - Manage Consent Directives	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise Document Sharing-B (XDS.b)	HITSP/TP13 - Manage Sharing of Documents HITSP/TP30 - Manage Consent Directives	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2007 - 2008 Basic Patient Privacy Consents (BPPC) – Trial Implementation	HITSP/TP30 - Manage Consent Directives	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Patient Identifier Cross-Referencing Integration Profile (PIX)	HITSP/TP22 - Patient ID Cross-Referencing	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Cross-Enterprise Document Media Interchange (XDM) Integration Profile	HITSP/T33 - Transfer of Documents on Media	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2008-2009 Sharing Value Sets (SVS)	HITSP/T66 - Retrieve Value Set	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework Supplement 2008 - 2009, Pediatric Demographics, Draft for Trial Implementation (August 22, 2008)	HITSP/TP22 - Patient ID Cross-Referencing	
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Supplement 2008-2009, Immunization Content (IC), Trial Implementation Version 1.0	HITSP/C78 - Immunization Document	
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Supplement 2008 – 2009, Draft for Trial Implementation, August 22, 2008	HITSP/TP21 - Query for Existing Data	
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Revision 4.0	HITSP/C83 - CDA Content Modules	
International Classification of Functioning, Disability and Health (ICF)	HITSP/C80 - Clinical Document and Message Terminology	
International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C78
International Organization for Standardization (ISO) Health Informatics -- Pseudonymisation, Unpublished Technical Specification # 25237	HITSP/C88 - Anonymize Immunizations and Response Management Data HITSP/T24 - Pseudonymize	
International Organization for Standardization (ISO) Health informatics - 9660 Level 1	HITSP/T33 - Transfer of Documents on Media	



Standard	HITSP Construct	Remarks/ Minor Gaps
International Organization for Standardization (ISO) PDF/A ISO 19005-1b. Document management - Electronic document file format for long-term preservation - Part 1: Use of PDF (PDF/A)	HITSP/C62 - Unstructured Document	
International Organization for Standards – ISO 3166-1	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C78
Internet Engineering Task Force (IETF) Network Time Protocol (Version 3) Specification, Implementation and Analysis, "Request for Comment" (RFC) #1305, March, 1992	HITSP/T16 - Consistent Time	
Internet Engineering Task Force (IETF) Simple Network Time Protocol (SNTP) Version 4, "Request for Comment" (RFC) #2030, October, 1996	HITSP/T16 - Consistent Time	
Internet Engineering Task Force (IETF) Tags for Identifying Languages, "Request for Comment" (RFC) # 4646, September, 2006	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C78
Logical Observation Identifiers Names and Codes (LOINC®)	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C78
National Cancer Institute (NCI) Thesaurus: Route of Administration	HITSP/C80 – Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C78 where optional medication detail is provided
National Center for Biotechnology Information (NCBI) - Genetic Reference Sequences	HITSP/C80 - Clinical Document and Message Terminology	
National Center for Biotechnology Information (NCBI) - Single Nucleotide Polymorphisms	HITSP/C80 - Clinical Document and Message Terminology	
National Library of Medicine (NLM) Unified Medical Language System (UMLS) RxNorm	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C78 where optional medication detail is provided
National Uniform Billing Committee (NUBC) Uniform Bill Version 2007 (UB-04) Current UB Data Specification Manual Field 22, Patient Discharge Status, Codes	HITSP/C80 - Clinical Document and Message Terminology	
Organization for the Advancement of Structured Information Standards (OASIS) Common Alerting Protocol (CAP) V1.1, October 2005	HITSP/C82 - Emergency Common Alerting Protocol	
Organization for the Advancement of Structured Information Standards (OASIS) Emergency Data Exchange Language (EDXL) Distribution Element (DE) Version 1.0	HITSP/T63 - Emergency Message Distribution Element	
Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) Core v2.0 OASIS Standard; ITU-T X.1141	HITSP/TP20 - Access Control	



Standard	HITSP Construct	Remarks/ Minor Gaps
Organization for the Advancement of Structured Information Standards (OASIS) WS-Trust Version 1.3, March 2007	HITSP/TP20 - Access Control	
Organization for the Advancement of Structured Information Standards (OASIS) eXtensible Access Control Markup Language (XACML), ITU-T Recommendation X.1142, February 2005	HITSP/TP20 - Access Control	
Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.1	HITSP/TP21 - Query for Existing Data	
Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.2	HITSP/TP21 - Query for Existing Data	
Unified Code for Units of Measure (UCUM)	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C78
United States Postal Service (USPS) – Postal Codes	HITSP/C80 - Clinical Document and Message Terminology	
USB Removable Device Type 2.0 (USB Implementers Forum)	HITSP/T33 - Transfer of Documents on Media	
VHA National Drug File Reference Terminology (NDF-RT) Formulary	HITSP/C80 - Clinical Document and Message Terminology	Vocabularies are enabled via HITSP/C78 where optional medication detail is provided

4.1.3 INFORMATIVE REFERENCE STANDARDS

The following table lists standards that provide additional background information or guidance; however, they are not required for the implementation of the Interoperability Specification.

Table 4.1.3-1 Informative Reference Standards

Standard	Reason for Use
American National Standards Institute (ANSI) International Committee for Information Technology Standards (INCITS), #359-2004	This standard describes RBAC features that have achieved acceptance in the commercial marketplace. It includes a reference model and functional specifications for the RBAC features defined in the reference model. It is intended for (1) software engineers and product development managers who design products incorporating access control features; and (2) managers and procurement officials who seek to acquire computer security products with features that provide access control capabilities in accordance with commonly known and understood terminology and functional. For more information visit www.ansi.org .



Standard	Reason for Use
ASTM International Standard Guide for Privilege Management Infrastructure (PMI) Guidelines: #E2595-07	<p>Defines interoperable mechanisms to manage privileges in a distributed environment. This standard is oriented towards support of a distributed or service-oriented architecture (SOA) where security services are themselves distributed and applications are consumers of distributed services. This standard incorporates privilege management mechanisms alluded to in a number of existing standards (e.g., E1986, E2084). The privilege mechanisms in this standard support policy-based access control (including role, entity and contextual-based access control) including the application of policy constraints, patient requested restrictions and delegation. Finally, the standard supports hierarchical, enterprise-wide privilege management.</p> <p>The mechanisms defined in this standard may be used to support a privilege management infrastructure (PMI) using existing public key infrastructure (PKI) technology. This standard does not specifically support mechanisms based on secret-key cryptography. Mechanisms involving privilege credentials are specified in International Organization for Standardization (ISO) 9594-8:2000 (attribute certificates), and Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) (attribute assertions); however, this standard does not mandate or assume the use of such standards.</p> <p>Many current systems require only local privilege management functionality (on a single computer system). Such systems frequently use proprietary mechanisms. This standard does not address this type of functionality; rather, it addresses an environment where privileges and capabilities (authorizations) must be managed between computer systems across the enterprise, and with business partners. For more information visit www.astm.org.</p>
ASTM International Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems: # E2147-01	E2147-01 "is for the development and implementation of security audit/disclosure logs for health information. It specifies how to design an access audit log to record all access to patient identifiable information maintained in computer systems and includes principles for developing policies, procedures, and functions of health information logs to document all disclosure of health information to external users for use in manual and computer systems. The process of information disclosure and auditing should conform, where relevant, with the Privacy Act of 1974 (1)." For more information visit www.astm.org .
Digital Imaging and Communications in Medicine (DICOM) Attribute Level Confidentiality Supplement: # 55	Adds a mechanism for selective protection of individual attributes within arbitrary DICOM service-object pair (SOP) instances. It may be used to achieve protection of identifying information, e.g., a reversible anonymization or pseudonymization of DICOM SOP instances while continuing to use unmodified lower level message and protocol services for network transfer, storage, and media exchange of composite image information objects. For more information visit medical.nema.org .
Food and Drug Administration (FDA) - Unique Ingredient Identifier (UNII)	Provides codes developed by FDA to uniquely identify all ingredients used in marketed medications in the United States. Each UNII is assigned based on molecular structure, manufacturing process, or other characteristics. UNII is part of the Federal Medication Terminologies. For more information visit www.fda.gov/oc/dataacouncil/SRS.htm
Food and Drug Administration (FDA) - National Drug Code (NDC)	Provides drug codes for prescription medicine and insulin products. NDC is managed by the FDA and is part of the Federal Medication Terminologies. For more information visit www.fda.gov/cder/ndc/database/default.htm
Health Level Seven (HL7) Consent related vocabulary including Confidentiality Codes	HL7 concept domains, including ConfidentialityCodes, ActInformationCategoryCode, ActInformationAccessType, ActInformationAccessContextCode, AuthorizedParticipationFunctionCode, ActPolicyType, ActConsentType, and ActMaskableCode For more information visit www.hl7.org .



Standard	Reason for Use
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Volume 2 Transactions, Appendix M Using Patient Demographics Query in a Multi-Domain Environment	Appendix M - Using Patient Data Query (PDQ) in a Multi-Domain Environment, provides an architectural discussion of how Query Parameter Definition, QPD-8 is processed.
International Organization for Standardization (ISO) Health informatics -- Information technology -- Open Systems Interconnection -- Systems Management: Security alarm reporting function, Technical Specification #10164-- Part 7: Security Alarm Reporting Function, 1992	Establishes user requirements for the service definition needed to support the security alarm reporting function, defines the service provided by the security alarm reporting function, specifies the protocol that is necessary in order to provide the service, defines the relationship between the service and management notifications, defines relationships with other systems management functions, specifies conformance requirements. The security alarm reporting function is a systems management function which may be used by an application process in a centralized or decentralized management environment to exchange information for the purpose of systems management. For more information visit www.iso.org .
International Organization for Standardization (ISO) Health informatics -- Directory services for security, communications and identification of professionals and patients, Technical Specification #21091	Defines minimal specifications for directory services for health care using the X.500 framework. This Technical Specification provides the common directory information and services needed to support the secure exchange of health care information over public networks. It addresses the health directory from a community perspective in anticipation of supporting inter-enterprise, inter-jurisdiction and international health care communications. ISO/TS 21091:2005 also supports directory services aiming to support identification of health professionals and organizations and the patients/consumers. The latter services include aspects sometimes referred to as master patient indices. The health care directory will only support standard LDAP Client searches. Specific implementation guidance, search criteria and support are out of scope of this document. For more information visit www.iso.org .
International Organization for Standardization (ISO) Health informatics -- Information technology -- Text and office systems - Office Document Architecture (ODA) and interchange format, Technical Report on ISO 8613 implementation testing, Technical Specification # ISO/IEC CD 10183 -- Part 3: Testing procedure	Specifies a general framework for the provision of access control. The purpose of access control is to counter the threat of unauthorized operations involving a computer or communication system. For more information visit www.iso.org .
International Organization for Standardization (ISO) Health informatics -- Privilege management and access control (PMAC), Technical Specification #22600 -- Part 1: Overview and policy management, July 2006	Supports the needs of healthcare information sharing across unaffiliated providers of healthcare, healthcare organizations, health insurance companies, their patients, staff members and trading partners. It is also intended to support inquiries from both individuals and application systems. For more information visit www.iso.org .



Standard	Reason for Use
International Organization for Standardization (ISO) Health informatics – Functional and Structural Roles (ISO SF Roles), Technical Specification #21298 , Draft May, 2007	<p>This document contains a specification for encoding information related to roles for health professionals and consumers. At least four areas have been identified where a model for encoding role information is needed.</p> <p>Privilege management and access control: role-based access control is not possible without an effective means of recording role information for healthcare actors.</p> <p>Directory services: structural roles are usefully recorded within directories of health care providers (see for example, ISO TS 21091 Health Informatics – Directory services for security, communications, and identification of professionals and patients).</p> <p>Audit trails: functional roles are usefully recorded within audit trails for health information applications.</p> <p>Public key infrastructure (PKI): The three part ISO standard 17090 Health Informatics – Public Key Infrastructure (PKI) allows for the encoding of healthcare roles in certificate extensions, but no structured vocabulary for such roles is specified. This technical specification identifies such a coded vocabulary.</p> <p>For more information visit www.iso.org.</p>
Internet Engineering Task Force (IETF) Tags for the Identification of Languages, "Request for Comment" (RFC) #3066, January, 2001	Describes a language tag for use in cases where it is desired to indicate the language used in an information object, how to register values for use in this language tag, and a construct for matching such language tags. For more information visit www.ietf.org .
Internet Engineering Task Force (IETF) The application/pdf Media Type (RFC 3778)	PDF, the 'Portable Document Format', is a general document representation language that has been in use for document exchange on the Internet since 1993. This document provides an overview of the PDF format, explains the mechanisms for digital signatures and encryption within PDF files, and updates the media type registration of 'application/pdf'. For more information visit www.ietf.org .
Internet Engineering Task Force (IETF), HTTP HyperText Transfer Protocol HTTP/1.1 (RFC 2616)	The Hypertext Transfer Protocol (HTTP) is an application-level protocol for distributed, collaborative, hypermedia information systems. It is a generic, stateless, protocol, which can be used for many tasks beyond its use for hypertext, such as name servers and distributed object management systems, through extension of its request methods, error codes and headers [47]. A feature of HTTP is the typing and negotiation of data representation, allowing systems to be built independently of the data being transferred. For more information visit www.ietf.org .
Internet Engineering Task Force (IETF), MIME Multipurpose Internet Message Extensions (RFC 2045 to RFC 2049)	The first and second documents in this set define MIME header fields and the initial set of MIME media types. The third document describes extensions to RFC 822 formats to allow for character sets other than US-ASCII. The fourth document describes what portions of MIME must be supported by a conformant MIME implementation. It also describes various pitfalls of contemporary messaging systems as well as the canonical encoding model MIME is based on. For more information visit www.ietf.org .
Internet Engineering Task Force (IETF), SMTP Simple Mail Transfer Protocol (RFC 2821)	The objective of the Simple Mail Transfer Protocol (SMTP) is to transfer mail reliably and efficiently. SMTP is independent of the particular transmission subsystem and requires only a reliable ordered data stream channel. While this document specifically discusses transport over TCP, other transports are possible. For more information visit www.ietf.org .
Internet Engineering Task Force (IETF), The MIME Multipart/Related Content-type (RFC 2387)	The Multipart/Related content-type provides a common mechanism for representing objects that are aggregates of related MIME body parts. This document defines the Multipart/Related content-type and provides examples of its use. For more information visit www.ietf.org .
National Cancer Institute (NCI) Thesaurus	The NCI Thesaurus is a reference terminology and biomedical ontology used in a growing number of NCI and other systems. It covers vocabulary for clinical care, translational and basic research, and public information and administrative activities. The NCI Thesaurus provides definitions, synonyms, and other information on nearly 10,000 cancers and related diseases, 8,000 single agents and combination therapies, and a wide range of other topics related to cancer and biomedical research. It is part of the Federal Medication Terminologies. For more information visit www.cancer.gov .



Standard	Reason for Use
National Library of Medicine (NLM) Unified Medical Language System (UMLS) RxNorm	Provides standard names for (1) clinical drugs and (2) drug dose forms as administered to a patient. Also provides links from clinical drugs, both branded and generic, to their active ingredients, drug components (active ingredient + strength), and related brand names. Food and Drug Administration (FDA) National Drug Codes (NDCs) for specific drug products and many of the drug vocabularies commonly used in pharmacy management and drug interaction software are additionally linked to RxNorm. RxNorm is a part of the Federal Medication Terminologies. For more information visit www.nlm.nih.gov
Organization for the Advancement of Structured Information Standards (OASIS) Web Services Security SOAP Message Security Version 1.0	Describes enhancements to SOAP messaging to provide message integrity and confidentiality. The specified mechanisms can be used to accommodate a wide variety of security models and encryption technologies. This specification also provides a general-purpose mechanism for associating security tokens with message content. No specific type of security token is required, the specification is designed to be extensible (i.e., support multiple security token formats. Additionally, this specification describes how to encode binary security tokens, a framework for XML-based tokens, and how to include opaque encrypted keys. It also includes extensibility mechanisms that can be used to further describe the characteristics of the tokens that are included with a message. For more information visit www.oasis-open.org .
Organization for the Advancement of Structured Information Standards (OASIS) - ebRIM OASIS – ebXML Registry Information Model v2.1	The Registry Information Model provides a blueprint or high-level schema for the ebXML Registry. Its primary value is for implementers of ebXML Registries. It provides these implementers with information on the type of metadata that is stored in the Registry as well as the relationships among metadata Classes. The Registry information model: a) Defines what types of objects are stored in the Registry; b) Defines how stored objects are organized in the Registry. For more information visit www.oasis-open.org .
Organization for the Advancement of Structured Information Standards (OASIS) - ebMS OASIS/ebXML Messaging Services Specifications v2.1	Defines a Message Service protocol for reliable Business-to-Business data interchange. ebMS v2.1 adds quality of service features on top of transfer protocols such as HTTP and SMTP. Key qualities of service features include guaranteed delivery and nonrepudiation of receipt. ebMS v2.1 can reliably transfer any data type including XML, X12, EDIFACT, or binary data between two parties over the Internet. For more information visit www.oasis-open.org .
Organization for the Advancement of Structured Information Standards (OASIS) - ebRS OASIS – ebXML Registry Services Specifications v2.1	The ebXML Registry provides a set of services that enable sharing of information between interested parties for the purpose of enabling business process integration between such parties based on the ebXML specifications. The shared information is maintained as objects in a repository and managed by the ebXML Registry Services defined in this document. For more information visit www.oasis-open.org .
Organization for the Advancement of Structured Information Standards (OASIS) – ebXML Registry Information Model (3.0)	The Registry Information Model provides a blueprint or high-level schema for the ebXML Registry. Its primary value is for implementers of ebXML Registries. It provides these implementers with information on the type of metadata that is stored in the Registry as well as the relationships among metadata Classes. The Registry information model: a) Defines what types of objects are stored in the Registry; b) Defines how stored objects are organized in the Registry. For more information visit www.oasis-open.org .
Organization for the Advancement of Structured Information Standards (OASIS) – ebXML Registry Services Specification (3.0)	The ebXML Registry provides a set of services that enable sharing of information between interested parties for the purpose of enabling business process integration between such parties based on the ebXML specifications. The shared information is maintained as objects in a repository and managed by the ebXML Registry Services defined in this document. For more information visit www.oasis-open.org .
World Wide Web Consortium (W3C) Web Services Description Language (WSDL) v1.1	WSDL is an XML-based language that provides a model for describing Web services. It is also an XML-based service description on how to communicate using web services. The WSDL defines services as collections of network endpoints, or ports. WSDL specification provides an XML format for documents for this purpose. For more information visit www.w3.org .
VHA National Drug File Reference Terminology (NDF-RT) Formulary	Provides standard names for (1) mechanism of action, (2) Physiologic Effect and (3) Structural Class. NDF-RT is part of the Federal Medication Terminologies. For more information visit www.cancer.gov/cancertopics/terminologyresources/page5



4.2 GAPS WHERE THERE ARE NO STANDARDS

This section describes gaps in standards. Gaps occur in the following two cases, where HITSP has:

- Identified requirements derived from the context that have no standards that meet all tiers of HITSP criteria to merit selection for that context
- Identified a single standard that encompasses and singly fulfills a set of tightly-coupled standards from the given context, yet is lacking in fulfilling one or more of the tightly-coupled requirements

The gap is only relative to the specific Use Case requirement. Recommended resolutions were developed through a series of steps including the Technical Committee's initial recommendations, cross Technical Committee validation of the gap, provisional recommendations and peer review by the Technical Committee.

The table below identifies the Use Case requirements and known associated gaps, along with the recommended resolutions.

Table 4.2-1 Use Case Requirements and Associated Standards Gaps

Requirement Number	Summary Description	Identified Gaps	Recommended Resolution
DR17	Decision Support Data (immunization schedule)	7.1.1.2 Action: Incorporate immunization schedules into the clinician's EHR: for incorporation in a computable fashion gap for content – this is an active issue around the country	There is HL7 Clinical Decision Support work in this area for immunization schedules The Advisory Committee on Immunization Practice (ACIP) is providing the content in a standard as a standard table distributed in a text format every year based upon CDC recommendations. As currently done, proprietary implementations of these specifications may be leveraged for system automation. Once the Clinical Decision Support specifications are defined, specify a method to express the schedules
		7.1.1.1 Action: Receive immunization schedules : - Currently no standards for automated updates – gap - No content standards other than paper formats in use - Most EHR systems today do not have a thorough immunization schedule	In progress through HL7 SOA, HSP and Clinical Decision Support "; this is not the PH this is not the PH emergency response effort – this is the SOA; dependent upon the gap resolution above for immunization schedules; NOTE: Further details are pending HITSP Clinical Decision Support specifications. Proprietary solutions may be leveraged in the interim Look at what is in the text versions to identify the data element requirements
DR17	Decision Support Data (Immunization reminders)	7.1.2.1a : Action: Identify individuals needing immunization or drug: - No approved standard for identifying individuals needing immunization or drug	Monitor and contribute to HL7 Clinical Decision Support work on standardized service/algorithm



Requirement Number	Summary Description	Identified Gaps	Recommended Resolution
		Web Services approach for Entity identification services	Monitor and contribute to work under way with ISO TS21091, which is adding SOA in collaboration with HSSP work in updating the TS to IS
DR17	Decision Support Data (Prioritization)	7.1.2.1b Alternative Action: Receive information about individuals needing prioritized intervention: Typically adults that may not be in immunization registries – they may be in an emergency preparedness registry, chronic disease registry, or from the EHR	Monitor and contribute to HL7 Clinical Decision Support work on standardized service/algorithm
		7.1.2.1b, Alternative Action: Receive information about individuals needing prioritized intervention, 7.2.1.1 Action: Conduct analysis to determine intervention priorities, 7.2.1.2 Action: Notify clinicians of individuals or population characteristics needing prioritized intervention Action: Identify individuals needing prioritized intervention: There are no standards for prioritization Gap/policy element	This is a Clinical Decision Support effort – we may approach this in deferred HITSP Clinical Decision Support effort scoped to demographics for initial deliverable; This may be expanded once requirements are fleshed out The requirements beyond demographics need to be defined to fit within HITSP Clinical Decision Support
DR19	Medication Administration data	7.1.3.2 Action: Record vaccine or drug administration information: Gap in standards to fulfill Counter-measure Response Administration (CRA) requirements implied by the Use Case which may be population based	Refer to and appropriate SDO to define standards. Monitor and contribute to effort
DR17	Decision Support Data (Alert - Recall)	7.1.6.1 Action: Receive vaccine recall information from registries : Standards gap – today this is done by human communications	Continue human communication until an appropriate message can be developed Leverage Unstructured Document Component approach defined by HITSP construct where appropriate Refer to and appropriate SDO to define standards. Monitor and contribute to effort
DR17	Decision Support Data (Prioritization)	7.2.1.1 Action: Identify individuals needing prioritized intervention : no standard for the consumer-friendly decision	May be influenced by policy decisions Refer to and appropriate SDO to define standards. Monitor and contribute to effort
DR19	Medication Administration data	7.4.1.1Action: Report administration information to registries Standards gap to transmit in a computable way– Standards gap	Refer to and appropriate SDO to define standards. Monitor and contribute to effort
DR18 DR19	Vaccination Data Medication Administration	7.4.2.1 Action: Provide vaccine or drug administration information Policy Gap: School health records may not be able to be made available to registry	Refer to appropriate policy group; Implications with various federal law; HISPC referral



Requirement Number	Summary Description	Identified Gaps	Recommended Resolution
DR23	Consumer Vaccination View	Policy gap in standard requirements for consumer-facing communications of immunization data	
DR18 DR19	Vaccination Data Medication Administration	7.4.2.1: Action: Provide vaccine or drug administration information. 9.4: Data provisioning – including support for secondary uses; data provisioning and distribution of data transmission parameters Gap in Data Quality routine checking/automation Gap is in Clinical Decision Support – transmission of rules for record checking	Need standards for the transmission of the immunization rules the data quality rules. Refer to SDOs for consideration as to whether this can be combined as a common standard
DR11 DR76	Immunization response data Immunization query data	7.1.2.1a Action: Identify individuals needing immunization or drug 7.1.2.1b Alternative Action: Receive information about individuals needing prioritized intervention 7.4.2.1 Action: Provide vaccine or drug administration information. 7.4.3.1 Action: Retrieve vaccine or drug administration information from external sources 7.4.4.1 Action: Receive information describing the administration of a vaccine or drug 7.3.2.1 Action: Request available immunization information 7.2.1.1 Action: Conduct analysis to determine intervention priorities 7.2.1.2 Action: Notify clinicians of individuals or population characteristics needing prioritized intervention 8.2.2.1 Action: Receive and monitor inventory status information 8.3.1.1 Action: Monitor inventory usage VXQ/VXR – There is a deprecation of these and an update in progress from CDC to the implementation guide	We intend to leverage this new work and will provisionally select these updated approaches in the HITSP IRM IS Align Query/Response construct with the emerging implementation guide and updated HL7 messages and provisionally select these newer standards. It is possible that the IS will be published prior to the completion of the underlying update in which case we will generate an update once the work is complete and updated in the associated HITSP constructs
DR18 DR19	Vaccination Data Medication Administration	7.4.3.1 Action: Retrieve vaccine or drug administration information from external sources NCPDP – does not conform to the Vaccination data details	Either pharmacies conform to HL7 standard or update NCPDP standard to conform to immunization data requirements
DR16	Supply Chain Management Vaccine Recall/Vaccine Recall (including consumer directed message)	7.1.6.1 Action: Receive vaccine recall information from registries 7.3.3.1 Action: Receive vaccine recall information from registries GAP: Possible if the vaccine recall information does not contain enough info to update the supply chain	Work with SDOs to update the standards to conform to the data requirements



4.3 STANDARD OVERLAPS

This section describes the instances where there are overlaps among standards for the Use Case requirements. The overlap is only relative to the specific Use Case requirement. Overlaps refer to instances wherein some of the requirements are met by multiple standards. Recommended resolutions were developed through a series of steps including the Technical Committee's initial recommendations, cross Technical Committee validation of the overlap, provisional recommendations and peer review by the Technical Committees.

The table below presents the identified overlaps and the respective resolution plans.

Table 4.3-1 Use Case Requirements and Associated Standard Overlaps

Requirement Number	Summary Description	Standard Overlap	Recommended Resolution
DR11 Immunization response data DR76 Immunization query data	Immunization Query and Response	<p>7.1.2.1a Action: Identify individuals needing immunization or drug</p> <p>7.1.2.1b Alternative Action: Receive information about individuals needing prioritized intervention</p> <p>7.4.2.1 Action: Provide vaccine or drug administration information</p> <p>7.4.3.1 Action: Retrieve vaccine or drug administration information from external sources</p> <p>7.4.4.1 Action: Receive information describing the administration of a vaccine or drug</p> <p>7.3.2.1 Action: Request available immunization information</p> <p>7.2.1.1 Action: Conduct analysis to determine intervention priorities</p> <p>7.2.1.2 Action: Notify clinicians of individuals or population characteristics needing prioritized intervention</p> <p>8.2.2.1 Action: Receive and monitor inventory status information</p> <p>8.3.1.1 Action: Monitor inventory usage</p> <p>HITSP/TP21 (this leverages Care Record and Care Record Query DSTU's, from the HL7 Care Provision Domain) HL7 V2.4+ overlaps VXQ/VXR V2.3 and earlier</p> <p>VXQ/VXR is Deprecated – 2.4 or 2.5 and replaced QRD/QRF structure. This also overlaps V3 which exists as a DSTU</p>	<p>Support what exists today (VXQ/VXR) and allow for the new pilot testing to migrate toward Support for V3 and IHE components, including XDS, that might be used in lieu of VXQ and VXR and possibly web services through provisional standards selection</p> <p>Work with HL7 to resolve concerns that deprecation of VXQ/VXR may impact functionality requirements for immunization registries</p>
DR18	Vaccination Data	<p>7.4.4.1 Action: Receive information describing the administration of a vaccine or drug</p> <p>We will continue to support 2.3.1 messages with optionality to include PIX/PDQ where supported.</p>	We want something that allows for this in one step



Requirement Number	Summary Description	Standard Overlap	Recommended Resolution
DR17	Decision Support Data	<p>7.1.1.1 Action: Receive immunization schedules</p> <p>7.1.1.2 Action: Incorporate immunization schedules into the clinician's EHR</p> <p>7.1.2.1a Action: Identify individuals needing immunization or drug</p> <p>7.1.2.1b Alternative Action: Receive information about individuals needing prioritized intervention</p> <p>7.1.3.2 Action: Record vaccine or drug administration information</p> <p>7.1.5.1 Action: Receive immunization schedules</p> <p>7.4.1.1 Action: Incorporate immunization schedules into the registry</p> <p>7.4.1.2 Action: Conduct analysis to determine intervention priorities</p> <p>7.2.1.1 Action: Identify individuals needing prioritized intervention</p> <p>9.4 Data provisioning – including support for secondary uses; data provisioning and distribution of data transmission parameters</p> <p>There are multiple standards for expression of clinical knowledge: Arden, GELLO, OWL, Common Logic, HL7 SOA SIG, W3C Web Services</p>	Tier-2 Selection process; Work with SDOs to align and harmonize the standardization efforts in this area
IER54 Query/response for clinical message data DR18	Immunization Query and Response Vaccination Data	<p>7.1.3.2 Action: Record vaccine or drug administration information</p> <p>7.1.4.1 Action: Report administration information to registries</p> <p>7.4.1.1 Action: Report administration information to registries</p> <p>7.4.2.1 Action: Provide vaccine or drug administration information</p> <p>7.4.4.1 Action: Receive information describing the administration of a vaccine or drug</p> <p>7.3.1.1 Action: Provide available immunization information via a personally controlled health record</p> <p>Vaccination</p> <p>V2 messages from today, V3 which exists as a DSTU</p>	Specify optionality to allow for a dual approach of V2.3.1 and TP21 capabilities with TP22 (PIX) and TP23 (PDQ) specified as optional for Immunization Information Systems, but required where available for EHR systems



5.0 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.

5.1 CONFORMANCE CRITERIA

In order to claim conformance to the specification, an implementation must satisfy all the requirements and mandatory statements listed in the HITSP Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must be constrained as specified in Table 3.1.2-1, and implement all of the required actors from Table 3.2.3-1, within the scope, subset or implementation option that is selected from Section 5.2 below.

Claims of conformance to this specification must be made using the following language:
This product conforms to HITSP's Immunizations and Response Management Interoperability Specification, available at www.hitsp.org.

5.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

A HITSP Interoperability Specification can be implemented for individual business actors defined in the Interoperability Specification. An implementation claiming conformance to a specific business actor from the Interoperability Specification shall support all of the requirements associated to that business actor as described in Table 3.2.3-1.

This means that **for each implemented business actor**:

1. All Required or Conditionally Required technical actors listed for the business actor shall be supported as specified in the associated construct
2. Optional technical actors listed for the business actor may be supported as specified in the associated construct
3. All Required or Conditionally Required transactions and content subsets listed for each implemented technical actor assigned to the business actor shall be supported as specified in the associated construct
4. Optional transactions and content subsets listed for each implemented technical actor assigned to the business actor may be supported as specified in the associated construct

Implementers of this Interoperability Specification who follow the principles listed above are being provided a level of implementation flexibility, while maintaining interoperability.



5.3 TEST METHODS

HITSP relies on the conformance test methods, test tools and other test-related material produced by, or under the auspices, of standards developers, profiling organizations and implementation guide producers as part of its collaborative implementation testing effort. Efforts to produce conformance test methods, tools, etc. may be internal to the organization, or provided by an external organization.

A Health Information Technology (HIT) Implementation Testing website has been developed in collaboration with HITSP, the National Institute of Standards and Technology (NIST), the Certification Commission for Healthcare Information Technology (CCHIT), and the Office of the National Coordinator (ONC) to advance conformance and interoperability testing capabilities. This website provides HIT implementers with the necessary resources to support and test their implementation of standards-based health systems. For more information, visit NIST at www.nist.gov.



6.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

6.1 DESCRIPTION OF STANDARDS

The following table contains descriptions of the selected standards from Section 4.1.2 above:

Table 6.1-1 Description of Standards

Standard	Description
Accredited Standards Committee (ASC) X12 Standards Release 004010	Release (version) 004010 of the Accredited Standards Committee (ASC) X12 standards including the X12.5 Interchange Control, X12.6 Application Control Structure, 270 Eligibility, Coverage or Benefit Inquiry, 271 Eligibility, Coverage or Benefit Information and other control standards for the uniform electronic interchange of business transactions. Published by the Data Interchange Standards Association (DISA). For more information visit www.x12.org .
American Medical Association (AMA) Current Procedural Terminology (CPT®) Fourth Edition (CPT-4); CPT Evaluation and Management Codes	A uniform coding system used primarily to identify medical services and procedures furnished by physicians and other healthcare professionals. For more information visit www.ama-assn.org .
ASTM International Standard Guide for Electronic Authentication of Health Care Information: # E1762-95(2003)	Defines a document structure for use by electronic signature mechanisms, describes the characteristics of an electronic signature process. Defines minimum requirements for different electronic signature mechanisms, defines signature attributes for use with electronic signature mechanisms, describes acceptable electronic signature mechanisms and technologies, defines minimum requirements for user identification, access control, and other security requirements for electronic signatures, and outlines technical details for all electronic signature mechanisms in sufficient detail to allow interoperability between systems supporting the same signature mechanism. For more information visit www.astm.org .
CDC Race and Ethnicity Code Sets	The U.S. Centers for Disease Control and Prevention (CDC) has prepared a code set for use in coding race and ethnicity data. This code set is based on current federal standards for classifying data on race and ethnicity, specifically the minimum race and ethnicity categories defined by the U.S. Office of Management and Budget (OMB) and a more detailed set of race and ethnicity categories maintained by the U.S. Bureau of the Census (BC). The main purpose of the code set is to facilitate use of federal standards for classifying data on race and ethnicity when these data are exchanged, stored, retrieved, or analyzed in electronic form. At the same time, the code set can be applied to paper-based record systems to the extent that these systems are used to collect, maintain, and report data on race and ethnicity in accordance with current federal standards. For more information visit www.cdc.gov .
Centers for Disease Control and Prevention Implementation Guide for Immunizations Data Transaction using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol. Implementation Guide Version 2.2 June 2006	This Guide is intended for use by immunization registries that want to participate in a strictly-defined record exchange agreement that limits the amount of optionality normally expected when using the HL7 standard. The Guide describes the most frequently used segments in their entirety, while giving a minimum description of segments containing only a few useful fields for registries. The Guide fully describes the fields within the segments used frequently by immunization registries, while the others are omitted in this document. With this limited scope, this <i>Guide</i> can in no way serve as a substitute for a thorough study of the entire set of HL7 specifications for electronic data interchange in health care environments. For more information visit www.cdc.gov/vaccines/programs/iis/stds/downloads/hl7guide.pdf .



Standard	Description
Digital Imaging and Communications in Medicine (DICOM) Part 3.12: Media Formats and Physical Media for Media Interchange	This DICOM Standard describes the services and the data necessary for the interchange of information between digital imaging computer systems found in health care settings. PS 3.12 of the DICOM Standard articulates the structure between the Media Storage Model and specific media. Media physical characteristics are also covered. For more information visit medical.nema.org .
European Telecommunications Standards Institute (ETSI) Technical Specification TS 101 903: XML Advanced Electronic Signatures (XadES)	Extends the IETF/W3CXML-Signature Syntax and Processing specification [XMLDSIG] into the domain of non-repudiation by defining XML formats for advanced electronic signatures that remain valid over long periods and are compliant with the European Directive. This includes evidence as to its validity even if the signer or verifying party later attempts to deny (repudiates) the validity of the signature. An advanced electronic signature aligned with this document can, in consequence, be used for arbitration in case of a dispute between the signer and verifier, which may occur at some later time, even years later. For more information visit www.etsi.org .
Federal Information Processing Standards (FIPS) Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5-2, May, 1987	A set of two-digit numeric codes and a set of two-letter alphabetic codes for representing the 50 states, the District of Columbia and the outlying areas of the United States, and associated areas. The standard covers all land areas under the sovereignty of the United States, the freely associated states of Federated States of Micronesia and Marshall Islands, and the trust territory of Palau. For more information visit www.itl.nist.gov . NOTE: ASC X12 transactions and ASC X12N Implementation Guides do not allow use of this standard; instead they require use of the U.S. Postal Service's National Zip Code and Post Office Directory -- which provides similar alphabetic code values.
Food and Drug Administration (FDA) - Unique Ingredient Identifier (UNII)	Provides codes developed by FDA to uniquely identify all ingredients used in marketed medications in the United States. Each UNII is assigned based on molecular structure, manufacturing process, or other characteristics. UNII is part of the Federal Medication Terminologies. For more information visit www.fda.gov/oc/datacouncil/SRS.htm .
Food and Drug Administration (FDA) - National Drug Code (NDC)	Provides drug codes for prescription medicine and insulin products. NDC is managed by the FDA and is part of the Federal Medication Terminologies. For more information visit www.fda.gov/cder/ndc/database/default.htm .
Health Care Provider Taxonomy	The Health Care Provider Taxonomy code set is a collection of unique alphanumeric codes, ten characters in length. The Health Care Provider Taxonomy code set includes specialty categories for individuals, groups of individuals, and non-individuals. The National Uniform Claims Committee maintains this code set. The complete code set is available from the Washington Publishing Company at www.wpc-edi.com .
Health Level 7 (HL7) version 3.0 Context-Aware Information Retrieval Specification: URL Implementation Guide	Informative implementation guide for URL-based implementations of the context-aware information retrieval ("Infobutton") The goal of this infobutton implementation guide is to recommend a URL-based implementation of the context-aware information retrieval ("infobutton") domain. The intent is to provide a simple way to implement infobuttons that is compatible with the current state of the market in this area. Most infobutton implementations to date, especially on the side of on-line information resources, rely on URL-based APIs.



Standard	Description
Health Level Seven (HL7) Clinical Document Architecture (CDA) Release 2.0	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 .
Health Level Seven (HL7) Common Terminology Services (CTS) Release 1	<p>The HL7 Common Terminology Services (HL7 CTS) defines an Application Programming Interface (API) that can be used when accessing terminological content. The CTS specification was developed as an alternative to a common data structure. Instead of specifying what an external terminology must look like, HL7 has chosen to identify the common functional characteristics that an external terminology must be able to provide. As an example, an HL7 compliant terminology service will need to be able to determine whether a given concept code is valid within the particular resource. Instead of describing a table keyed by the resource identifier and concept code, the CTS specification describes an Application Programming Interface (API) call that takes a resource identifier and concept code as input and returns a true/false value. Each terminology developer is free to implement this API call in whatever way is most appropriate for them.</p> <p>It describes a set of API calls that represent the core functionality that will be needed by basic HL7 Version 3 applications.</p>
Health Level Seven (HL7) Implementation Guide for CDA Release 2: History and Physical (H&P) Notes	The HL7 Implementation Guide for CDA Release 2: History and Physical (H&P) Notes defines additional constraints on the CDA Header and Body used in a History and Physical document in the U.S. realm, and provides examples of conforming fragments in the body of the document and an example of a conforming XML instance.
Health Level Seven (HL7) Implementation Guide for CDA Release 2: Consultation Note	The HL7 Implementation Guide for CDA Release 2: Consultation Note defines additional constraints on the CDA Header and Body used in a Consultation document in the U.S. realm, and provides examples of conforming fragments in the body of the document and an example of a conforming XML instance.
Health Level Seven (HL7) Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), April 01, 2007	The Continuity of Care Document implementation guide describes constraints on the HL7 Clinical Document Architecture, Release 2 (CDA) specification in accordance with requirements set forward in ASTM E2369-05 Standard Specification for Continuity of Care Record (CCR). The resulting specification, known as the Continuity of Care Document (CCD), is developed as a collaborative effort between ASTM and HL7. It is intended as an alternate implementation to the one specified in ASTM ADJE2369 for those institutions or organizations committed to implementation of the HL7 Clinical Document Architecture. For more information visit www.hl7.org .
Health Level Seven (HL7) V3 RBAC, R1-2008, HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1, February 2008	The Healthcare Permission Catalog provides the necessary content for creating interoperable roles facilitating inter-organizational communications and information sharing among healthcare organizations and their business partners. For more information visit www.hl7.org .



Standard	Description
Health Level Seven (HL7) Version 2.3.1	The HL7 Version 2.3.1 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets/code tables are contained in the standard. For more information visit www.hl7.org .
Health Level Seven (HL7) Version 2.3.1 Chapter 2 – Control, Chapter 3 – Patient Administration	The HL7 Version 2.3.1 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets/code tables are contained in the standard. For more information visit www.hl7.org .
Health Level Seven (HL7) Version 2.5, Chapter 2 – Control, Chapter 3 – Patient Administration, Chapter 5 – Query	The HL7 Version 2.5 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets/code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. For more information visit www.hl7.org .
Health Level Seven (HL7) Version 2.5, Chapter 2 – Control, Chapter 3 – Patient Administration, Chapter 5 – Query	The HL7 Version 2.5 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets/code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. For more information visit www.hl7.org .
Health Level Seven (HL7) Version 2.5.1	The HL7 Version 2.5.1 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets/code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 4, 5, and 7 including patient demographic (ADT), and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ) and Acknowledgements. They are also used in HL7 order messages. For more information visit www.hl7.org .
Health Level Seven (HL7) Version 3.0	The HL7 Version 3.0 Messaging Standard is an application protocol for electronic data exchange in healthcare. Version 3.0 is based on a Reference Information Model (RIM); which is used to instantiate various message formats. Value sets/code tables are contained in the standard. For more information visit www.hl7.org .
Health Level Seven (HL7) Version 3.0 - Vocabularies and Value Sets	The HL7 Version 3.0 Messaging Standard is an application protocol for electronic data exchange in healthcare. Version 3.0 is based on a Reference Information Model (RIM); which is used to instantiate various message formats. Value sets/code tables are contained in the standard. For more information visit www.hl7.org .
Health Level Seven (HL7) Version 3.0 Infrastructure Management - Query Infrastructure, Release 2 DSTU Ballot 1 - September 2008	Query Infrastructure domain specifies the formation of information queries and the responses to these queries to meet the needs of healthcare applications using the HL7 version 3 messaging standard. For more information visit www.hl7.org .
Health Level Seven (HL7) Version 3.0 Privacy Consent related specifications RCMR_RM010001 - Data Consent	The Data Consent RMIM captures the data and associations needed to (1) record or report a consumer's consent or dissent to authorize the access, collection, use, or disclosure of personally identifiable information; (2) convey a provider's request or intent to override a patient's recorded consent or dissent; (3) convey a type of consent directive associated with a privacy policy; or (4) to record or report a consumer's consent directive, which is to be applied to future access, collection, use or disclosure of personally identifiable information. For more information visit www.hl7.org .



Standard	Description
Health Level Seven (HL7) Standard Code Set CVX - Vaccines Administered	The CDC's National Center of Immunization and Respiratory Diseases (NCIRD) maintains the HL7 external code set CVX. The implementation of the HL7 standard for immunization data exchange is described in Chapter 4 of the HL7 standard. The codes in HL7 Version 2.3 table 0292, represented the initial content of the external CVX code set. Since vaccines have to be added to this table more quickly than new versions of HL7 are released, this document represents the most up-to-date version of the CVX code set. Items have been added. Others have been added for planning purposes, pending FDA approval. For more information visit www.cdc.gov/vaccines/programs/iis/stds/cvx.htm .
Health Level Seven (HL7) Standard Code Set MVX - Manufacturers of Vaccines	The CDC's National Center for Immunization and Respiratory Diseases (NCIRD) maintains the HL7 external code set MVX. The implementation of the HL7 standard for immunization data exchange is described in Chapter 4 of the HL7 standard. The codes in HL7 Version 2.3 table 0227 represent the initial content of the external MVX code set. This document represents the most up-to-date version of the MVX code set. For more information visit www.cdc.gov/vaccines/programs/iis/stds/mvx.htm .
Health Level Seven (HL7) Version 3.0 Standard: Transport Specification - Web Services Profile, Release 2 Committee Ballot 1 - May 2008	The Web Services Profile for HL7 promotes the use of Web Services to exchange HL7 messages and to ease interoperability between implementations. The profile focuses on basic Web services protocols and technologies like SOAP (Simple Object Access Protocol) and WSDL (Web Services Description Language), which lay the groundwork for more complex interactions based on higher-level Web services specifications. For more information visit www.hl7.org .
HUGO Gene Nomenclature Committee at the European Bioinformatics Institute - Gene Names	For each known human gene, HUGO approves a gene name and symbol (short-form abbreviation). All approved symbols are stored in the HGNC database. Each symbol is unique and HUGO ensures that each gene is only given one approved gene symbol. In preference each symbol maintains parallel construction in different members of a gene family and can also be used in other species, especially the mouse. For more information visit www.genenames.org .
Human Genome Variation Society (HGVS) - Description of Sequence Variants – February, 20, 2008	Discussions regarding the uniform and unequivocal description of sequence variants in DNA and protein sequences (mutations, polymorphisms) were initiated by two papers published in 1993; Beaudet AL & Tsui LC and Beutler E. Current rules (den Dunnen, JT and Antonarakis, SE [2000]) however do not extensively cover all types of variants and the more complex changes. These pages list, based on the last publication, the existing nomenclature recommendations as well as the most recent suggestions. The article den Dunnen JT and Antonarakis SE (2000). Hum.Mutat. 15:7-12 provide more detail explanation. For more information visit www.hgvs.org/mutnomen/recs.html#intro .
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 .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise User Assertion (XUA)	The Cross-Enterprise User Assertion Profile (XUA) provides a means to communicate claims about the user identity of an authenticated principal (user, application, system...) in transactions that cross enterprise boundaries. To provide accountability in these cross enterprise transactions there is a need to identify the requesting user in a way that the receiver can make access decisions and proper audit entries. The XUA Profile supports enterprises that have chosen to have their own user directory with their own unique method of authenticating the entities, and others that may have chosen to use a third party to perform the authentication. For more information visit www.ihe.net .



Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITF) Supplement Volume 3 – Document Digital Signature (DSG) Content Profile	Specifies the use of digital signatures for documents that are shared between organizations. The latest version of the IHE Technical Framework is available at www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) –Revision 5.0 or later, Cross Enterprise Sharing of Scanned Documents (XDS-SD) Integration Profile	This profile defines how to store healthcare metadata in clinical documents, including patient identifiers, demographics, encounter, order or service information, represented within a structured HL7 CDA R2 header, with a PDF or plaintext formatted document containing clinical information. For more information visit www.ihe.net to retrieve Volume 1, and Volume 2 of the framework.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Audit Trail and Node Authentication (ATNA) Integration Profile	Audit Trail and Node Authentication (ATNA) establishes the characteristics of a Basic Secure Node. It describes the security environment (user identification, authentication, authorization, access control, etc.) assumed for the node so that security reviewers may decide whether this matches their environments. It defines basic auditing requirements for the node. It defines basic security requirements for the communications of the node using TLS or equivalent functionality. It establishes the characteristics of the communication of audit messages between the Basic Secure Nodes and Audit Repository nodes that collect audit information. This integration profile has been designed so that specific domain frameworks may extend it through an option defined in the domain specific technical framework. Extensions are used to define additional audit event reporting requirements, especially actor specific requirements. The latest version of the IHE Technical Framework is available at www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Consistent Time (CT) Integration Profile	The Consistent Time Integration Profile (CT) provides a means to ensure that the system clocks and time stamps of the many computers in a network are well synchronized. This profile specifies synchronization with a median error less than 1 second. This is sufficient for most purposes. The current version of the ITI-TF Final Text, specifies the IHE CT Integration Profile, and other transactions defined and implemented as of October 10, 2008. The latest version of the IHE Technical Framework is available at www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Audit Trail and Node Authentication (ATNA) Integration Profile, Section 9.1 Authentication	Audit Trail and Node Authentication (ATNA) establishes the characteristics of a Basic Secure Node. It describes the security environment (user identification, authentication, authorization, access control, etc.) assumed for the node so that security reviewers may decide whether this matches their environments. It defines basic auditing requirements for the node. It defines basic security requirements for the communications of the node using TLS or equivalent functionality. It establishes the characteristics of the communication of audit messages between the Basic Secure Nodes and Audit Repository nodes that collect audit information. This integration profile has been designed so that specific domain frameworks may extend it through an option defined in the domain specific technical framework. Extensions are used to define additional audit event reporting requirements, especially actor specific requirements. The latest version of the IHE Technical Framework is available at www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Patient Demographics Query (PDQ) Integration Profile	Provides ways for multiple distributed applications to query a central patient information server for a list of patients, based on user-defined search criteria, and retrieve a patient's demographic (and, optionally, visit or visit-related) information directly into the application. For more information visit www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2008 - 2009, Pediatric Demographics, Draft for Trial Implementation (August 22, 2008)	The experience of immunization registries and other public health population databases has shown that matching and linking patient records from different sources for the same individual person in environments with large proportions of pediatric records requires additional demographic data. Pediatric Demographics makes use of the following six additional demographic fields to aid record matching in databases with many pediatric records. The latest version of the IHE Technical Framework is available at www.ihe.net .



Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 4.0 for Final Text, specifies the IHE transactions defined and implemented as of August 22, 2007. For more information visit www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement 2007 – 2008, Notification of Document Availability Integration Profile, Draft for Trial Implementation, October 10, 2008	The Notification of Document Availability Profile (NAV) introduces a mechanism allowing notifications to be sent point-to-point to systems within a Cross-Enterprise Document Sharing affinity domain (See IHE IT Infrastructure XDS Integration Profile), eliminating the need for manual steps or polling mechanisms for a Document Consumer to be aware that documents that may be of interest have been registered with an XDS Document Registry Actor. For further information, visit www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) 2007-2008 Trial Implementation Supplement Cross-enterprise Document Reliable Interchange (XDR) Release 3	This Supplement to the IHE IT Infrastructure Technical Framework provides a generic, standards based mechanism for conveying a set of medical documents in a point-to-point networked based communication. The current version of the XDR is specified in the XDR Trial Implementation Supplement to the ITI-TF, rev. 5.0, which is consistent with IHE XDS.b Supplement in term of document entry metadata. For more information visit www.ihe.net/technical_framework . NOTE: off-line mode transaction expected to be updated once standards are available for Web Services Off-line.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 5.0 or later, Cross-Enterprise Document Media Interchange (XDM) Integration Profile	Provides document interchange using a common file and directory structure over several standard media types. This permits the patient to use physical media to carry medical documents. This also permits the use of person-to-person email to convey medical documents. XDM supports the transfer of data about multiple patients within one data exchange. For more information visit www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework, Revision 4.0 or later, Personnel White Pages profile	The Personnel White Pages (PWP) Profile provides access to basic directory information on human workforce members to other workforce members within the enterprise. This information has broad use among many clinical and non-clinical applications across the healthcare enterprise. This Personnel White Pages Profile specifies a method of finding directory information on the User Identities (user@realm) supplied by the Enterprise User Authentication (EUA) Integration Profile. For more information, visit www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2008-2009 Sharing Value Sets (SVS)	The Sharing Value Sets (SVS) profile provides a means through which healthcare systems producing clinical or administrative data, such as diagnostic imaging equipment, laboratory reporting systems, primary care physician office EMR systems, or national healthcare record systems, can receive a common, uniform nomenclature managed centrally. Shared nomenclatures are essential to achieving semantic interoperability.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Section 10 Cross-Enterprise Document Sharing (XDS.a)	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. Section 10, Cross-Enterprise Document Sharing facilitates the registration, distribution and access across health enterprises of patient electronic health records. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 4.0 for Final Text, specifies the IHE transactions defined and implemented as of August 22, 2007. For more information visit www.ihe.net .



Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 - Registry Stored Query Transaction for XDS Profile Supplement [ITI-18]	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The Registry Stored Query Transaction Trial Implementation Supplement specifies an IHE transaction that provides optimization and implementation simplification. For more information visit www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 XCA Supplement	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The trial implementation version of the XCA Supplement to the ITI-TF, rev. 4.0 Final Text, specifies the IHE transactions that support access between communities in a manner compatible with the XDS Integration profile. For more information visit www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise Document Sharing-B (XDS.b)	The Cross-Enterprise Document Sharing-B Profile (XDS.b) supplement provides a new implementation choice for the Cross-Enterprise Document Sharing (XDS) Integration Profile based on use of the Web Services and ebXML Reg/Rep standards that is consistent with current developments and best practices in the industry. For more information visit www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Patient Identifier Cross-Referencing Integration Profile (PIX)	<p>The Patient Identifier Cross-referencing Integration Profile (PIX) is targeted at healthcare enterprises of a broad range of sizes (hospital, a clinic, a physician office, etc.). It supports the cross-referencing of patient identifiers from multiple Patient Identifier Domains via the following interactions: 1) The transmission of patient identity information from an identity source to the Patient Identifier Cross-reference Manager. 2) The ability to access the list(s) of cross-referenced patient identifiers either via a query/ response or via update notification.</p> <p>By specifying the above transactions among specific actors, this integration profile does not define any specific enterprise policies or cross-referencing algorithms. By encapsulating these behaviors in a single actor, this integration profile provides the necessary interoperability while maintaining the flexibility to be used with any cross-referencing policy and algorithm as deemed adequate by the enterprise. For more information visit www.ihe.net.</p>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2008 - 2009, Pediatric Demographics, Draft for Trial Implementation (August 22, 2008)	The experience of immunization registries and other public health population databases has shown that matching and linking patient records from different sources for the same individual person in environments with large proportions of pediatric records requires additional demographic data. Pediatric Demographics makes use of the following six additional demographic fields to aid record matching in databases with many pediatric records. The latest version of the IHE Technical Framework is available at www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2007 - 2008 Basic Patient Privacy Consents (BPPC) – Trial Implementation	The Basic Patient Privacy Consents (BPPC) profile provides a mechanism to record the patient privacy consent(s), a method to mark documents published to XDS with the patient privacy consent that was used to authorize the publication, and a method for XDS Consumers to use to enforce the privacy consent appropriate to the use. This profile complements XDS by describing a mechanism whereby an XDS Affinity Domain can develop and implement multiple privacy policies, and describes how that mechanism can be integrated with the access control mechanisms supported by the XDS Actors (e.g. systems). There are two key parts of the profile: 1) It provides a document content specification for capturing a patient acknowledgement of a privacy consent policy or policies. 2) It describes the method by which XD* Actors can enforce the privacy policies determined by the document confidentialityCode related to the patient privacy consents. For more information visit www.ihe.net .



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 .
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Supplement 2008 – 2009, Draft for Trial Implementation, August 22, 2008	The Query for Existing Data Profile (QED) supports dynamic queries for clinical data, including vital signs, problems, medications, immunizations, diagnostic results, procedures and visit history. This profile makes the information widely available to other systems within and across enterprises to support provision of better clinical care. The QED profile leverages the existing content modeling defined previously in other IHE document profiles and the HL7 CCD implementation guide to deliver information that is semantically equivalent as a web service using the IHE ITI web services and HL7 web services guidelines. For more information visit www.ihe.net .
International Classification of Functioning, Disability and Health (ICF)	The International Classification of Functioning, Disability and Health, known more commonly as ICF, is a classification of health and health-related domains. These domains are classified from body, individual and societal perspectives by means of two lists: a list of body functions and structure, and a list of domains of activity and participation. Since an individual's functioning and disability occurs in a context, the ICF also includes a list of environmental factors. See www.who.int/classifications/icf/en/ .
International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	SNOMED CT consists of a technical design, core content architecture, and Core content. SNOMED CT Core content includes the technical specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content also includes a concepts table, description table, relationships table, history table, ICD-9-CM mapping, and Technical Reference Guide. Additionally, SNOMED CT provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms unique to particular organizations or localities. For more information visit www.ihtsdo.com .
International Organization for Standardization (ISO) – ISO 3166-1	The International Standard for country codes. The purpose of ISO 3166 is to establish codes for the representation of names of countries, territories or areas of geographical interest, and their subdivisions. For more information visit www.iso.org .
Internet Engineering Task Force (IETF) Tags for Identifying Languages, "Request for Comment" (RFC) # 4646, September, 2006	This document describes the structure, content, construction, and semantics of language tags for use in cases where it is desirable to indicate the language used in an information object. It also describes how to register values for use in language tags and the creation of user-defined extensions for private interchange. This document, in combination with RFC 4647, replaces RFC 3066, which replaced RFC 1766. For more information visit www.ietf.org/rfc/rfc4646.txt .
International Organization for Standardization (ISO) Health Informatics -- Pseudonymisation, Unpublished Technical Specification # 25237	Health Informatics – Pseudonymisation. Approved as a Technical Specification March, 2007. For more information visit www.iso.org .
International Organization for Standardization (ISO) Health Informatics - 9660 Level 1	Defines a common logical format for files and directories so discs written to ISO 9660 specifications can be read by a wide array of computer operating systems. For more information visit www.iso.org .
International Organization for Standardization (ISO) PDF/A ISO 19005-1b. Document management - Electronic document file format for long-term preservation - Part 1: Use of PDF (PDF/A)	Specifies how to use the Portable Document Format (PDF) 1.4 for long-term preservation of electronic documents. It is applicable to documents containing combinations of character, raster and vector data. For more information visit www.iso.org .



Standard	Description
Internet Engineering Task Force (IETF) Network Time Protocol (Version 3) Specification, Implementation and Analysis, "Request for Comment" (RFC) #1305, March, 1992	Describes the Network Time Protocol (NTP): the mechanisms to synchronize time and coordinate time distribution in a large, diverse internet operating at rates from mundane to lightwave. For more information visit www.ietf.org .
Internet Engineering Task Force (IETF) Simple Network Time Protocol (SNTP) Version 4, "Request for Comment" (RFC) #2030, October, 1996	Describes the Simple Network Time Protocol (SNTP) Version 4, which is an adaptation of the Network Time Protocol (NTP). SNTP can be used when the ultimate performance of the full NTP implementation is not needed or justified. When operating with current and previous NTP and SNTP versions, SNTP Version 4 involves no changes to the NTP specification or known implementations, but is rather a clarification of certain design features of NTP. For more information visit www.ietf.org .
Internet Society – Tags for Identifying Languages - 2005	This document describes the structure, content, construction, and semantics of language tags for use in cases where it is desirable to indicate the language used in an information object. It also describes how to register values for use in language tags and the creation of user-defined extensions for private interchange. This document, in combination with RFC 4647, replaces RFC 3066, which replaced RFC 1766. For more information visit www.ietf.org/rfc/rfc4646.txt .
Logical Observation Identifiers Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. For more information visit www.loinc.org .
National Center for Biotechnology Information (NCBI) - Genetic Reference Sequences	Established in 1988 as a national resource for molecular biology information, NCBI creates public databases, conducts research in computational biology, develops software tools for analyzing genome data, and disseminates biomedical information - all for the better understanding of molecular processes affecting human health and disease. The Entrez Nucleotide database is a collection of sequences from several sources, including GenBank, RefSeq, and PDB. The number of bases in these databases continues to grow at an exponential rate. For more information visit www.ncbi.nlm.nih.gov .
National Center for Biotechnology Information (NCBI) - Single Nucleotide Polymorphisms	Established in 1988 as a national resource for molecular biology information, NCBI creates public databases, conducts research in computational biology, develops software tools for analyzing genome data, and disseminates biomedical information - all for the better understanding of molecular processes affecting human health and disease. A key aspect of research in genetics is associating sequence variations with heritable phenotypes. The most common variations are single nucleotide polymorphisms (SNPs), which occur approximately once every 100 to 300 bases. For more information visit www.ncbi.nlm.nih.gov .
National Uniform Billing Committee (NUBC) Uniform Bill Version 2007 (UB-04) Current UB Data Specification Manual Field 22, Patient Discharge Status, Codes	A code set identifying status of patient discharge on an institutional claim (e.g., inpatient, outpatient, hospice, home care). For more information visit www.nubc.org .
Organization for the Advancement of Structured Information Standards (OASIS) Common Alerting Protocol (CAP) V1.1, October 2005	This is a simple but general format for exchanging all-hazard emergency alerts and public warnings over all kinds of networks. CAP allows a consistent warning message to be disseminated simultaneously over many different warning systems, thus increasing warning effectiveness while simplifying the warning task. CAP also facilitates the detection of emerging patterns in local warnings of various kinds, such as might indicate an undetected hazard or hostile act. And CAP provides a template for effective warning messages based on best practices identified in academic research and real-world experience.



Standard	Description
Organization for the Advancement of Structured Information Standards (OASIS) Emergency Data Exchange Language (EDXL) Distribution Element (DE) Version 1.0	This is a standard message distribution framework for data sharing among emergency information systems using the XML-based Emergency Data Exchange Language (EDXL). This format may be used over any data transmission system, including but not limited to the SOAP HTTP binding. It is a routing element intended to route payloads of any kind, including other OASIS emergency message standards such as CAP, HAVE and Resource Messaging, but also any of the HITSP constructs, NIEM IEPDS, etc. It is designed to be provisioned by core services to route based on geography, incident type, agency type, or level of government. It can also be provisioned with access control and other security data. For more information visit docs.oasis-open.org .
Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) Core v2.0 OASIS Standard; ITU-T X.1141	SAML, developed by the Security Services Technical Committee of OASIS, is an XML-based framework for communicating user authentication, entitlement, and attribute information. As its name suggests, SAML allows business entities to make assertions regarding the identity, attributes, and entitlements of a subject (an entity that is often a human user) to other entities, such as a partner company or another enterprise application. For more information visit www.oasis-open.org .
Organization for the Advancement of Structured Information Standards (OASIS) WS-Trust Version 1.3, March 2007	Defines extensions that build on [WS-Security] to provide a framework for requesting and issuing security tokens, and to broker trust relationships. Defines Security Token Service (STS) model for security tokens including requesting, issuing, renewing, canceling and validating. For more information visit www.oasis-open.org .
Organization for the Advancement of Structured Information Standards (OASIS) eXtensible Access Control Markup Language (XACML), ITU-T Recommendation X.1142, February 2005	The Organization for the Advancement of Structured Information Standards (OASIS) standards group developed the eXtensible Access Control Markup Language (XACML) as a language to express and evaluate access decisions. The XACML technical specification includes a profile for RBAC using XACML that complies with the ANSI RBAC standard. The HL7 RBAC Permission Catalog provides a standard vocabulary that can be used for cross-enterprise access control. For more information visit www.oasis-open.org .
Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.1	SOAP is a protocol specification for invoking methods on servers, services, components and objects. SOAP codifies the existing practice of using XML and HTTP as a method invocation mechanism. The SOAP specification mandates a small number of HTTP headers that facilitate firewall/proxy filtering plus an XML vocabulary that is used for representing method parameters, return values, and exceptions." {DevelopMentor} SOAP consists of three parts: an envelope that defines a framework for describing what is in a message and how to process it, a set of encoding rules for expressing instances of application-defined data types, and a convention for representing remote procedure calls and responses. For more information visit www.oasis-open.org .
Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.2	SOAP is a protocol specification for invoking methods on servers, services, components and objects. SOAP codifies the existing practice of using XML and HTTP as a method invocation mechanism. The SOAP specification mandates a small number of HTTP headers that facilitate firewall/proxy filtering plus an XML vocabulary that is used for representing method parameters, return values, and exceptions." {DevelopMentor} SOAP consists of three parts: an envelope that defines a framework for describing what is in a message and how to process it, a set of encoding rules for expressing instances of application-defined data types, and a convention for representing remote procedure calls and responses. For more information visit www.oasis-open.org .
Unified Code for Units of Measure (UCUM)	A code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans. For more information visit aurora.regenstrief.org .



Standard	Description
United States Postal Service (USPS) – Postal Codes	List of United States postal codes (known in various countries as a post code, postcode, or ZIP code) appended to a postal address for the purpose of sorting mail. For more information visit www.usps.com .
USB Removable Device Type 2.0 (USB Implementers Forum)	The USB-IF was formed to provide a support organization and forum for the advancement and adoption of Universal Serial Bus technology. The Forum facilitates the development of high-quality compatible USB peripherals (devices), and promotes the benefits of USB and the quality of products that have passed compliance testing. For more information visit www.usb.org .
VHA National Drug File Reference Terminology (NDF-RT) Formulary	Provides standard names for (1) mechanism of action, (2) Physiologic Effect and (3) Structural Class. NDF-RT is part of the Federal Medication Terminologies. For more information visit www.cancer.gov/cancertopics/terminologyresources/page5 .



6.2 VACCINATION AND PATIENT DEMOGRAPHIC DATA ELEMENTS

Vaccination and Patient Demographic Data Elements

In fulfillment of data and information requirements for query & response, vaccinations, demographics, and Consumer Vaccination View (Data Requirements 1, 6, 9, and 13), the following data dictionary was generated by the HITSP Population Perspective Technical Committee (formerly the HITSP Population Health Technical Committee) based upon analysis of industry data requirements provided by the IIS Data Code Book and the Immunization Information Systems NVAC Progress Report. Standards shown in the tables below were provided as part of the data requirements to ensure interoperability with industry Immunization Information Systems and alignment with previously selected HITSP standards. Further analysis and review will be provided in the design of the IS.

Table 6.2-1 Data Elements Cross Reference

DATA ELEMENTS CROSS REFERENCE	
Column	Definition
Vaccination Data Element	Data element name/identifier
Data Requirement	Indicates the data requirement supported by the attribute
Definition	Data element description as listed by USHIK for the selected standard for the data element
Usage	Indicates which Data Requirement Number is constrained by the data variable: V : Requirement # 6 – Vaccination, D : Requirement # 9 – Demographic, Q : Requirement # 1 – Query & Response (Query Only) R : Requirement # 1 – Query & Response (Response Only) CV: Requirement # 13 – Consumer View, CDS: Requirement # 5 – Clinical Decision Support
Data Requirement Standards	Standards previously selected by HITSP or currently in use by the immunization community. NOTE: This is for information purposes provided as an example as to the professional perspective in the RDSS. These may change pending HITSP Domain TC construct specification in the final IS delivered by HITSP
Required	Indicates optionality of the attribute: (R=Required, O=Optional, RE=Required if known); Codes refer to the data requirements listed in the 'Data Requirement' column in the order listed in the respective row
Comments	Pertinent comments and usage

Table 6.2-2 Patient Data Elements

Data Element	Usage	Definition	Data Requirement Standards	Required by Client (Source, Consumer) Actor Optionality	Required by Service (Manager, Supplier) Actor Optionality	Comments
PATIENT IDENTIFIERS						



Data Element	Usage	Definition	Data Requirement Standards	Required by Client (Source, Consumer) Actor Optionality	Required by Service (Manager, Supplier) Actor Optionality	Comments
Patient Name: First, Middle, Last	V D QR CV	The current, assumed legal name of the patient	HL7	R:V R:D R:QR R:CV	R:V R:D R:QR R:CV	Assure optimal linkages, (middle name is optional)
Patient Alias Name: First, Middle, Last (former names for management of adoptions and name changes)	V D QR CV	This field contains names by which the patient has been known at some time	HL7	O:V O:D O:QR O:CV	O:V O:D O:QR O:CV	
Patient Address	V D QR CV	This field lists the mailing address of the patient	HL7	O:V RE:D O:QR O:CV	O:V R:D R:QR O:CV	Used for matching – the receiver must be able to receive the data in the message
Patient Phone Number	V D QR CV	The patient's personal phone numbers	HL7	RE:V O:D O:QR O:CV	R:V R:D O:QR O:CV	Used for matching – the receiver must be able to receive the data in the message
Patient Identifier	V D QR CV	May be populated with MRN, SSN, Medicaid Number, Local registry ID, or other identifiers collected		R:V R:D O:QR O:CV	R:V R:D R:QR O:CV	NOTE: Policy may restrict use of this attribute
Patient Birth Date	V D QR CV CDS	This is the date and time of an event	HL7 Timestamp	O:V RE:D O:QR R:CV R:CDS	O:V R:D R:QR R:CV R:CDS	Assure optimal linkages
Patient Sex	V D QR CV CDS	This is the Patient's Sex	Shall be coded as specified in HITSP/C80 Section 2.2.1.1...2.1.1 V2 Administrative Gender Vocabulary M Male F Female U Undifferentiated	O:V RE:D O:QR R:CV R:CDS	O:V R:D R:QR R:CV R:CDS	Assure optimal linkages NOTE: Data requirements updated for HITSP harmonization



Data Element	Usage	Definition	Data Requirement Standards	Required by Client (Source, Consumer) Actor Optionality	Required by Service (Manager, Supplier) Actor Optionality	Comments
Patient Race	V D QR CV	These values are consistent with the OMB Notice of revised categories for collection of race and ethnicity data-the combined format. The complete set is available at: www.cdc.gov	Shall be coded as specified in HITSP/C80 Section 2.2.1.1..2.7 RACE CDC Race and Ethnicity Code Set	O:V RE:D O:QR O:CV	O:V RE:D O:QR O:CV	May be restricted by policy NOTE: Data requirements updated for HITSP harmonization
Patient Ethnicity	V D QR CV	A segment of a larger society whose members have a common origin and share a common culture. This field further defines patient ancestry. This is allowed to repeat	Shall be coded as specified in HITSP/C80 Section 2.2.1.1.2.2 Ethnicity CDC Race and Ethnicity Code Set	O:V RE:D O:QR O:CV	O:V RE:D O:QR O:CV	May be restricted by policy NOTE: Data requirements updated for HITSP harmonization
Patient Primary Language	V D QR CV	This is the patient's primary language	Shall be coded as specified in HITSP/C80 Section 2.2.1.1.2.9 Language The value set is defined by Internet RFC 4646 (replacing RFC 3066)	O:V O:D O:QR O:CV	O:V O:D O:QR O:CV	NOTE: Data requirements updated for HITSP harmonization
Patient Multiple Birth Indicator	V D QR CV	This field indicates whether the patient was part of a multiple birth	HL7 2.5 Table CV6 – Yes/No indicator	O:V RE:D O:QR O:CV	O:V R:D O (RE in response):QR O:CV	Used for matching – the receiver must be able to receive the data in the message
Patient Multiple Birth Order	V D QR CV	This is a number representing the patient's order of birth	HL7, CHI: Where this data element is not known or not applicable, element shall be populated with an appropriate 'null' value" from the HL7 V#3 table called 'Null Flavor'	O:V RE:D O:QR O:CV	O:V R:D O (RE in response):QR O:CV	Used for matching – the receiver must be able to receive the data in the message This data element is used only in the case that Patient Multiple Birth Indicator ='Yes'



Data Element	Usage	Definition	Data Requirement Standards	Required by Client (Source, Consumer) Actor Optionality	Required by Service (Manager, Supplier) Actor Optionality	Comments
Patient Birth Registration Number	V D QR CV	This is a number assigned to the patient by state for birth record purposes		O:V O:D O:QR O:CV	O:V O:D O:QR O:CV	Used for matching – the receiver must be able to receive the data in the message
Patient Birth State/Country	V D QR CV	This shows state and country in which patient was born	FIPS	O:V RE:D RE:QR O:CV	O:V RE:D RE:QR O:CV	Covered in the immunization content file – for tracking, these are all covered; Not being used commonly for matching
Patient Birthing Facility	V D QR CV	This is the facility where the patient was born		O:V O:D O:QR O:CV	O:V O:D O:QR O:CV	
Last Update Time/Date	V D QR CV	This field contains the last update date and time for the patient's/person's identifying and demographic data, as defined in the PID segment. Receiving systems will use this field to determine how to apply the transaction to their systems. If the receiving system (such as an enterprise master patient index) already has a record for the person with a later last update date/time, then the EMPI could decide not to apply the patient's/person's demographic and identifying data from this transaction		O:V RE:D O:QR O:CV	O:V R:D O (RE in response):QR O:CV	Used for matching – the receiver must be able to receive the data in the message NOTE: This is not supported in HL7 V2.3.1 messages



Data Element	Usage	Definition	Data Requirement Standards	Required by Client (Source, Consumer) Actor Optionality	Required by Service (Manager, Supplier) Actor Optionality	Comments
Last Update Facility	V D QR CV	This field identifies the facility of the last update to a patient's/person's identifying and demographic data, as defined in the PID segment. Receiving systems or users will use this field to determine how to apply the transaction to their systems. If the receiving system (such as a hospital's patient management system) already has a record for the patient/person, then it may decide to only update its data if the source is a "trusted" source. A hospital might consider other hospitals trusted sources, but not "trust" updates from non-acute care facilities		O:V RE:D O:QR O:CV	O:V R:D O (RE in response):QR O:CV	Used for matching – the receiver must be able to receive the data in the message NOTE: This is not supported in HL7 V2.3.1 messages
PARENT IDENTIFIERS						
Mother's Name: First, Middle, Last	V D QR CV	The current, assumed legal name of the patient's mother		O:V O:D O:QR O:CV	O:V O:D O:QR O:CV	(Desirable, but not mandatory elements)
Mother's Maiden Name (not always available in an EHR-s)	V D QR CV	This field contains the family name under which the mother was born (i.e., before marriage). It is used to distinguish between patients with the same last name		O:V RE:D O:QR O:CV	O:V R:D R:QR O:CV	Used for matching – the receiver must be able to receive the data in the message
Mother's SSN	V D QR CV	This is a number that is assigned by the Social Security Administration		O:V O:D O:QR O:CV	O:V O:D O:QR O:CV	
Father's Name: First, Middle, Last	V D QR CV	The current, assumed legal name of the patient's father		O:V O:D O:QR O:CV	O:V O:D O:QR O:CV	



Data Element	Usage	Definition	Data Requirement Standards	Required by Client (Source, Consumer) Actor Optionality	Required by Service (Manager, Supplier) Actor Optionality	Comments
Father's SSN	V D QR CV	This is a number that is assigned by the Social Security Administration		O:V O:D O:QR O:CV	O:V O:D O:QR O:CV	
ADDITIONAL PATIENT IDENTIFIER DATA ELEMENTS						
Insurance Plan	V D QR CV	Type of insurance plan (e.g., Medicaid, HMO, self pay, etc.)		O:V O:D O:QR O:CV	O:V O:D O:QR O:CV	
Insurance Company	V D QR CV	The organization providing health insurance to the patient at the time of the immunization event		O:V O:D O:QR O:CV	O:V O:D O:QR O:CV	
Immunization Services Funding Eligibility	V D QR CV	Indicates a class or category of payment method for immunization services provided. This is allowed to repeat	2.3.1 Immunization Implementation Guide Table 0064 – Financial class	R:V O:D R:QR O:CV	R:V O:D R:QR O:CV	This data element relates to a person, but it is important to understand that this is eligibility at a particular point of time relevant to the administration of a particular immunization. NOTE: This is intended to indicate eligibility for VFC Eligibility, but may be extended to express eligibility for other services
Next of Kin Relationship	V D QR CV	This field defines the personal relationship of the next of kin	Shall be coded as specified in HITSP/C80 Section 2.2.1.1.2.5 Family Relationship	O:V O:D O:QR O:CV	O:V O:D O:QR O:CV	NOTE: Data requirements updated for HITSP harmonization
Next of Kin Address	V D QR CV	This field lists the mailing address of the next of kin/associated party		O:V O:D O:QR O:CV	O:V O:D O:QR O:CV	



Data Element	Usage	Definition	Data Requirement Standards	Required by Client (Source, Consumer) Actor Optionality	Required by Service (Manager, Supplier) Actor Optionality	Comments
Next of Kin Telephone	V D QR CV	The next of kin/associated party's personal phone numbers		O:V O:D O:QR O:CV	O:V O:D O:QR O:CV	
Next of Kin DOB	V D QR CV	This field contains the next of kin/associated party's date of birth		O:V O:D O:QR O:CV	O:V O:D O:QR O:CV	

NOTE: in the table below, the Demographic Query does not contain any clinical elements. The Query Response data elements required are listed below.

Table 6.2-3 Clinical Data Elements

Data Element	Usage	Definition	Data Requirement Standards	Required NOTE: for QR response only	Comments
IMMUNIZATION EVENT (Vaccination content only – not for matching or look-up)					
Immunization Event Identifier	V QR CV	Value assigned by sending system to uniquely identify the immunization transaction being transmitted		R:V R:QR O:CV	
Vaccine Expiration Date	V QR CV	This is the date after which the vaccine/batch must not be use		O:V O:QR O:CV	
Vaccine Injection Site	V QR CV	This is the site on the patient where vaccine is administered	HL7 2.5 Table 0163 – Administrative site	O:V O:QR O:CV	
Vaccination Date	V QR CV	This is the date and time of an event		R:V R:QR R:CV	
Vaccine Lot Number	V QR CV	This is the lot number of the administered vaccine(s), as shown on the vaccine vial, syringe, or box. This is allowed to repeat		R:V R:QR O:CV	
Vaccine Administration Provider	V QR CV	This field is intended to contain the name and provider ID of the person physically administering the pharmaceutical		O:V O:QR O:CV	Communicate person administering the vaccine



Data Element	Usage	Definition	Data Requirement Standards	Required NOTE: for QR response only	Comments
Vaccine Administration Facility	V QR CV	Name and address of facility where medical substance was administered		O:V O:QR O:CV	Communicate Facility Name and/or Location
Vaccine Type	V QR CV	Code indicating which vaccine is being recorded	Use HL7-defined Table 0292 – Vaccines Administered (code=CVX) found in Appendix NOTE: Other codes, such as CPT code, are used by some Immunization Information Systems (IIS). If using a different code, for interoperability these other codes should be able to be mapped to CVX.	R:V R:QR R:CV	
Vaccine Manufacturer	V QR CV	This shows the manufacturer of the vaccine administered to the patient in the immunization event. Developed by CDC, this code set assigned a two letter (later three) code to manufacturers existing at the time. For purposes of consistency in maintaining accurate historical immunization records, the codes have remained intact (or additions made) while the manufacturer names have been updated (e.g. due to mergers of acquisitions) to show the current names. Inactive codes and pointers to current codes are indicated in brackets [] following the manufacturer name. Notes in italics indicate predecessor organization	Use HL7-defined Table 0227 – Manufacturers of vaccines (code=MVX) found in Appendix 1	R:V R:QR O:CV	



Data Element	Usage	Definition	Data Requirement Standards	Required NOTE: for QR response only	Comments
Vaccine Dose Number	V QR CV	This is the dose number of a vaccine, or a combination vaccine. For HITSP, the valid dose number of a vaccine series		O:V O:QR O:CV	This is a decision support field that may not be included in the exchanged content, and may be subject to further standardization refinement. NOTE: With a fully operating system, this variable is not needed. However, in the real world, and particularly during the initial startup phase, many systems will be gathering partial histories; therefore, to evaluate histories properly, dosage; This is typically derived; NOTE: The registry will need to validate the accuracy of this number
Reason for Non-Vaccination	V QR CV	To express concepts such as history of varicella disease indicator		RE:V O:QR O:CV	
Patient Status in the Immunization Home	V QR CV	Indication of the current status of the patient	Include active, inactive, Moved or Gone Elsewhere (MOGE), and other classifications Table 0441 HL7 User Defined table	O:V O:QR O:CV	This is a decision support field that may not be included in the exchanged content, and may be subject to further standardization refinement
Transaction Information Source	V QR CV	Indication of the source of the immunization information communicated (e.g. PHR, IIS, EMR) Indication of the system type communicating the immunization information (e.g. PHR, IIS, EMR)		O:V O:QR O:CV	This data element is based upon the Use Case needed to determine if this is patient-generated, provider-generated, or IIS
Immunization Information Source	V QR CV	Indicates that an event represents either a current or a historical immunization	Use CDC HL7 2.3.1 Implementation Guide Table NIP001	R:V R:QR O:CV	NOTE: Typically communicated via RXA-9 This is a Historical Vaccination Flag/ Indicator from the NVAC



Data Element	Usage	Definition	Data Requirement Standards	Required NOTE: for QR response only	Comments
Amount Administered (dosage amount):	V QR CV	This field records the amount of pharmaceutical administered		O:V O:QR O:CV	
Smallpox Take Response Observation	V QR CV	For specific vaccines such as smallpox: vaccine specific Optional except if referring to specific vaccines for which smallpox is the only current example Y/N/Equivocal /Unknown/loss-to-follow-up	NIP table 011	O:V O:QR O:CV	
Read Date for Take Response	V QR CV	Date the take response was read or observed		O:V O:QR O:CV	
ADDITIONAL VACCINATION DATA ELEMENTS					
Treatment	V QR CV	Route by which the vaccine is administered to the patient (only selected values listed)	HL7 V2.5 Table 0162 – Route of administration	O:V O:QR O:CV	
Refusal Reason	V QR CV	This indicates the reason the patient or parent refused the vaccine	NIP002 – Substance refusal reason	O:V O:QR O:CV	
Action Code	V QR CV	This indicates whether the message is related to a new event, modification of a previously submitted event	HL7 V2.3 Table 0323	O:V O:QR O:CV	Used to differentiate from add or delete
Vaccine Dose Valid Flag	V QR CV	Indicates that a dose administered is considered valid based on the immunization schedule active in the IIS	Y/N	O:V O:QR R:CV	This is a decision support field that may not be included in the exchanged content, and may be subject to further standardization refinement
Immunization Recommendations	V QR CV	Indicates vaccines recommended for patient based on the patient's history and immunization schedule active in the IIS		O:V O:QR R:CV	This is a decision support field that may not be included in the exchanged content, and may be subject to further standardization refinement
Vaccine Information Sheet (VIS) date	V R CV	Date VIS was given to patient	HL7 Timestamp	O:V O:R O:CV	
Vaccine Information Sheet (VIS) version	V R CV	Version of VIS given to patient		O:V O:R O:CV	



Data Element	Usage	Definition	Data Requirement Standards	Required NOTE: for QR response only	Comments
Vaccine Recall Effective Date	V R CV	Effective date that the vaccine provided to the patient was recalled by the manufacturer or public health agency	HL7 Timestamp	O:V O:R O:CV	
Vaccine Lot # Recall Code	V R CV			O:V O:R O:CV	

6.3 USE CASE TO INFORMATION EXCHANGE AND DATA REQUIREMENTS

This section contains an extraction of business actors, required interactions and conditions/scenarios from the Use Case into a matrix/table.

Table 6.3-1 Mapping of Use Case Actions to Information Exchange Requirements

Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
Immunizations and Response Management: Clinician – Scenario 1 Vaccine and Drug Administration and Reporting			
7.1.1 Event: Incorporate immunization schedules into clinician systems	7.1.1.1 Action: Receive immunization schedules	IER26 Identify communication recipients	
		IER27 Send non-patient notification message or alert	DR22 Generic alert data - Immunizations (immunization schedule)
		IER42 Request/receive medical concept knowledge	DR22 Generic alert data - Immunizations (immunization schedule) DR17 Decision support data (immunization schedule knowledge)
	7.1.1.2 Action: Incorporate immunization schedules into the clinician's EHR	No Information Exchange Requirements	DR17 Decision support data (immunization schedule knowledge) DR22 Generic alert data - Immunizations (immunization schedule)
Immunizations and Response Management: Clinician - Scenario 1 Vaccine and Drug Administration and Reporting			
7.1.2 Event: Identify individuals to receive vaccine or drug	7.1.2.1a Action: Identify individuals needing immunization or drug	IER54 Query/response for clinical message data	DR58 Demographic data - vaccination DR11 Immunization response data DR76 Immunization query data
		IER67 Send/receive clinical message	DR58 Demographic data - vaccination DR18 Vaccination data



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
		IER40 Query for existing data	DR58 Demographic data - vaccination DR11 Immunization response data DR76 Immunization query data
		IER18 Send/receive clinical document	DR18 Vaccination data DR8 Unstructured data DR8 Unstructured data
		IER10 Identify patient	DR58 Demographic data - vaccination
		IER42 Request/receive medical concept knowledge	DR17 Decision support data content (immunization schedule knowledge)
	7.1.2.1b Alternative Action: Receive information about individuals needing prioritized intervention	IER26 Identify communication recipients	
		IER27 Send non-patient notification message or alert	DR22 Generic alert data – immunizations (risk notification) DR22 Generic alert data – immunizations (risk notification)
		IER42 Request/receive medical concept knowledge	DR17 Decision support data (prioritization, immunization schedule knowledge, reminders)
		IER54 Query/response for clinical message data	DR58 Demographic data - vaccination DR11 Immunization response data DR76 Immunization query data
		IER67 Send/receive clinical message	DR58 Demographic data - vaccination DR18 Vaccination data
		IER40 Query for existing data	DR58 Demographic data - vaccination DR11 Immunization response data DR76 Immunization query data
		IER18 Send/receive clinical document	DR18 Vaccination data DR8 Unstructured data DR8 Unstructured data



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
		IER10 Identify patient	DR58 Demographic data – vaccination
		IER13 Send/receive notification of document availability	DR8 Unstructured data DR8 Unstructured data (risk notification)
Immunizations and Response Management: Clinician – Scenario 1 Vaccine and Drug Administration and Reporting			
7.1.3 Event: Administer vaccine or drug	7.1.3.1 Action: Administer vaccine or drug to patient	No Interoperability Requirements	
	7.1.3.2 Action: Record vaccine or drug administration information	No Interoperability Requirements	DR18 Vaccination data DR19 Medication administration data (deferred)
		IER42 Request/receive medical concept knowledge	DR17 Decision support data (Alerts – contraindications)
7.1.4 Event: Report administration information to registries	7.1.4.1 Action: Report administration information to registries	IER26 Identify communication recipients	
		IER67 Send/receive clinical message	DR18 Vaccination data DR19 Medication administration data (CRS – for emergencies – deferred)
		IER54 Query/response for clinical message data	DR58 Demographic data - vaccination DR11 Immunization response data DR76 Immunization query data
		IER67 Send/receive clinical message	DR58 Demographic data - vaccination DR18 Vaccination data
		IER18 Send/receive clinical document	DR18 Vaccination data DR19 Medication administration data (CRS – for emergencies – deferred)
		IER10 Identify patient	DR58 Demographic data – vaccination



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
7.1.5 Event: Monitor for adverse events	7.1.5.1 Event: Monitor for adverse events	NOTE: See requirements for HITSP/IS11 Public Health Case Reporting	DR12 Adverse Event Report NOTE: See requirements for HITSP/ IS11 Public Health Case Reporting for Adverse Event Report (FDA – MedWatch, Vaccine Adverse Events Reporting System (VAERS)) DR17 Decision support data (Active/Passive Surveillance for adverse event)
	7.1.5.2 Action: Report adverse events	NOTE: See requirements for HITSP/IS11 Public Health Case Reporting	DR12 Adverse Event Report NOTE: See requirements for HITSP/IS11 Public Health Case Reporting for Adverse Event Report (FDA – MedWatch, Vaccine Adverse Events Reporting System (VAERS))
7.1.6 Event: Receive vaccine recall information	7.1.6.1 Action: Receive vaccine recall information from registries	IER26 Identify communication recipients	
		IER27 Send non-patient notification message or alert	DR22 Generic alert data – immunizations (Vaccine recall notification) DR16 Supply chain management vaccine recall
		IER42 Request/receive medical concept knowledge	DR17 Decision support data (Vaccine recall notification)
		IER13 Send/receive notification of document availability	DR8 Unstructured data Unstructured data (Vaccine Recall) DR16 Supply chain management vaccine recall
		IER18 Send/receive clinical document	DR8 Unstructured data
Immunizations and Response Management: Clinician - Scenario 2 Vaccine and Drug Inventory Reporting			
7.4.1 Event: Report administration information to registries	7.4.1.1 Action: Report administration information to registries	IER67 Send/receive clinical message	DR18 Vaccination data
		IER18 Send/receive clinical document	DR18 Vaccination data
		IER10 Identify patient	DR58 Demographic data – vaccination
Immunizations and Response Management: Registry - Scenario 1 Vaccine and Drug Administration and Reporting			
7.4.1 Event: Incorporate immunization schedules into	7.4.1.1 Action: Receive immunization schedules	IER26 Identify communication recipients	
		IER27 Send non-patient notification message or alert	DR22 Generic alert data – immunizations (immunization schedule)



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
registries		IER42 Request/receive medical concept knowledge	DR17 Decision support data (immunization schedule knowledge)
	7.4.1.2 Action: Incorporate immunization schedules into the registry	No interoperability requirement	DR17 Decision support data (immunization schedule knowledge) (see 7.4.1.1 above)
7.4.2 Event: Provide vaccine or drug administration information	7.4.2.1 Action: Provide vaccine or drug administration information	IER67 Send/receive clinical message	DR18 Vaccination data
		IER54 Query/response for clinical message data	DR58 Demographic data - vaccination DR11 Immunization response data DR76 Immunization query data
		IER67 Send/receive clinical message	DR58 Demographic data - vaccination DR18 Vaccination data
		IER18 Send/receive clinical document	DR18 Vaccination data
		IER10 Identify patient	DR58 Demographic data - vaccination
		IER1 Provide authorization and consent	
		IER5 Verify entity identity	
		IER2 Send data over secured communication channel	
7.4.3 Event: Retrieve vaccine or drug administration information	7.4.3.1 Action: Retrieve vaccine or drug administration information from external sources	IER54 Query/response for clinical message data	DR58 Demographic data - vaccination DR11 Immunization response data DR76 Immunization query data
		IER67 Send/receive clinical message	DR58 Demographic data - vaccination DR18 Vaccination data
		IER40 Query for existing data	DR11 Immunization response data DR58 Demographic data - vaccination DR76 Immunization query data
		IER18 Send/receive clinical document	DR18 Vaccination data
		IER10 Identify patient	DR58 Demographic data - vaccination
		IER1 Provide authorization and consent	
		IER5 Verify entity identity	



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
		IER2 Send data over secured communication channel	
7.4.4 Event: Receive vaccine or drug administration information	7.4.4.1 Action: Receive information describing the administration of a vaccine or drug	IER54 Query/response for clinical message data	DR58 Demographic data - vaccination DR11 Immunization response data DR76 Immunization query data
		IER67 Send/receive clinical message	DR58 Demographic data - vaccination DR18 Vaccination data
		IER40 Query for existing data	DR11 Immunization response data DR58 Demographic data – vaccination DR76 Immunization query data
		IER18 Send/receive clinical document	DR18 Vaccination data
		IER10 Identify patient	DR58 Demographic data – vaccination
		IER1 Provide authorization and consent	
		IER5 Verify entity identity	
		IER2 Send data over secured communication channel	
7.4.5		NOTE: Recall information subsumed in other events/actions – no detailed events/actions provided by the Use Case	
Immunizations and Response Management: Consumer - Scenario 1 Vaccine and Drug Administration and Reporting			
7.3.1 Event: Provide available immunization information	7.3.1.1 Action: Provide available immunization information via a personally controlled health record	IER18 Send/receive clinical document	DR23 Consumer vaccination view DR18 Vaccination data
		IER10 Identify patient	DR58 Demographic data – vaccination
7.3.2 Event: Request immunization information	7.3.2.1 Action: Request available immunization information	IER18 Send/receive clinical document	DR23 Consumer vaccination view DR18 Vaccination data
		IER10 Identify patient	DR58 Demographic data – vaccination
7.3.3 Event: Receive	7.3.3.1 Action: Receive vaccine recall	IER26 Identify communication recipients	



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
vaccine recall information	information from registries	IER27 Send non-patient notification message or alert	DR22 Generic alert data – immunizations (Vaccine recall notification) DR16 Supply chain management vaccine recall
		IER42 Request/receive medical concept knowledge	DR17 Decision support data (Vaccine recall notification)
		IER18 Send/receive clinical document	DR8 Unstructured data
		IER13 Send/receive notification of document availability	DR8 Unstructured data (Alerts–vaccine recall) DR23 Consumer vaccination view DR16 Supply chain management vaccine recall
Immunizations and Response Management: Public Health - Scenario 1 Vaccine and Drug Administration and Reporting			
7.2.1 Event: Emergency Situations: Identify individuals needing prioritized intervention	7.2.1.1 Action: Conduct analysis to determine intervention priorities	IER54 Query/response for clinical message data	DR58 Demographic data - vaccination DR11 Immunization response data DR76 Immunization query data
		IER67 Send/receive clinical message	DR58 Demographic data - vaccination DR18 Vaccination data
		IER40 Query for existing data	DR11 Immunization response data DR58 Demographic data – vaccination DR76 Immunization query data
		IER18 Send/receive clinical document	DR18 Vaccination data
		IER10 Identify patient	DR58 Demographic data – vaccination
		IER42 Request/receive medical concept knowledge	DR17 Decision support data - intervention priorities
		IER1 Provide authorization and consent	
		IER55 Anonymize patient identifiable data	
	IER56 Pseudonymize patient identifying information		
	7.2.1.2 Action: Notify clinicians of individuals or population characteristics needing prioritized	IER26 Identify communication recipients	
IER27 Send non-patient notification message or alert		DR22 Generic alert data – immunizations (Alerts – prioritization)	



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	intervention	IER42 Request/receive medical concept knowledge	DR17 Decision support data Prioritization –to determine who to notify, Public Health Event Status
		IER18 Send/receive clinical document	DR8 Unstructured data (Alerts–prioritization)
		IER10 Identify patient	DR58 Demographic data –vaccination
		IER13 Send/receive notification of document availability	DR8 Unstructured data (Alerts–prioritization)
Immunizations and Response Management: Public Health - Scenario 2 Vaccine and Drug Inventory Reporting			
7.2.1 Event: Emergency Situations: Identify individuals needing prioritized intervention	7.2.1.1 Action: Identify individuals needing prioritized intervention	IER54 Query/response for clinical message data	DR58 Demographic data - vaccination DR11 Immunization response data DR76 Immunization query data
		IER67 Send/receive clinical message	DR58 Demographic data - vaccination DR18 Vaccination data
		IER40 Query for existing data	DR11 Immunization response data DR58 Demographic data – vaccination DR76 Immunization query data
		IER18 Send/receive clinical document	DR18 Vaccination data
		IER10 Identify patient	DR58 Demographic data – vaccination
		IER42 Request/receive medical concept knowledge	DR17 Decision support data (intervention priorities)
		IER1 Provide authorization and consent	
		IER55 Anonymize patient identifiable data	
		IER56 Pseudonymize patient identifying information	
	7.2.1.2 Action: Notify clinicians of individuals or population characteristics needing prioritized intervention	IER26 Identify communication recipients	
		IER27 Send non-patient notification message or alert	DR22 Generic alert data – immunizations (Alerts – prioritization)
		IER42 Request/receive medical concept knowledge	DR17 Decision support data (Alerts– prioritization) (Prioritization –to determine who to notify, Public Health Event Status)



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
		IER18 Send/receive clinical document	DR8 Unstructured data (Alerts–prioritization)
		IER10 Identify patient	DR58 Demographic data – vaccination
		IER13 Send/receive notification of document availability	DR8 Unstructured data (Alerts–prioritization)
8.2.2 Event: Monitor inventory status	8.2.2.1 Action: Receive and monitor inventory status information	IER54 Query/response for clinical message data	DR58 Demographic data - vaccination DR11 Immunization response data DR76 Immunization query data
		IER67 Send/receive clinical message	DR58 Demographic data - vaccination DR18 Vaccination data
		IER40 Query for existing data	DR11 Immunization response data DR58 Demographic data – vaccination DR76 Immunization query data
		IER18 Send/receive clinical document	DR18 Vaccination data
		IER10 Identify patient	DR58 Demographic data – vaccination
		IER80 Send/receive vaccine inventory data	DR13 Drug/vaccine inventory data DR14 Drug/vaccine inventory usage data DR15 Drug/vaccine inventory availability data DR20 Aggregate inventory of available vaccine
8.2.3 Event: Emergency Situations: Determine vaccine and drug inventory requirements	8.2.3.1 Action: Determine vaccine and drug inventory requirements	IER80 Send/receive vaccine inventory data	DR13 Drug/vaccine inventory data DR14 Drug/vaccine inventory usage data DR15 Drug/vaccine inventory availability data
	8.2.3.2 Action: Communicate inventory requirements to the inventory reporting perspective	IER26 Identify communication recipients	DR13 Drug/vaccine inventory data DR14 Drug/vaccine inventory usage data DR15 Drug/vaccine inventory availability data
		IER78 Send/receive vaccine inventory requirements	DR79 Drug/vaccine inventory requirements



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
Immunizations and Response Management: Inventory Reporting 2 Vaccine and Drug Inventory Reporting			
8.3.1 Event: Monitor inventory usage	8.3.1.1 Action: Monitor inventory usage	IER79 Query/response for inventory usage data	DR77 Drug/Vaccine query data DR78 Drug/vaccine response data
8.3.2 Event: Report available inventory information	8.3.2.1 Action: Report available inventory information	NOTE: See 8.2.2.1	
8.3.3 Event: Determine need for additional resources	8.3.3.1 Action: Receive inventory requirements information	NOTE: See 8.2.3.2	
	8.3.3.2 Action: Determine need for additional inventory of vaccines or drugs	No interoperability requirement NOTE: Inventory Decision Support – is a edge system issue	
Immunizations and Response Management: Information Exchange - Scenario 1 Vaccine and Drug Administration and Reporting 2 Vaccine and Drug Inventory Reporting			
	9.1 Action: Data delivery – including secure data delivery, data receipt including confirmation of delivery to EHRs, personally controlled health records, other systems and networks	IER26 Identify communication recipients	
		IER27 Send non-patient notification message or alert	DR22 Generic alert data – immunizations (immunization schedule)
		IER42 Request/receive medical concept knowledge	DR17 Decision support data (immunization schedule)
		IER54 Query/response for clinical message data	DR58 Demographic data - vaccination DR11 Immunization response data DR76 Immunization query data
		IER67 Send/receive clinical message	DR58 Demographic data - vaccination DR18 Vaccination data
		IER40 Query for existing data	DR11 Immunization response data DR58 Demographic data – vaccination DR76 Immunization query data
		IER18 Send/receive clinical document	DR18 Vaccination data DR8 Unstructured data
		IER10 Identify patient	DR58 Demographic data – vaccination



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
		IER13 Send/receive notification of document availability	DR8 Unstructured data (Alerts)
		IER80 Send/receive vaccine inventory data	DR13 Drug/vaccine inventory data DR14 Drug/vaccine inventory usage data DR15 Drug/vaccine inventory availability data DR20 Aggregate inventory of available vaccine
		IER78 Send/receive vaccine inventory requirements	DR79 Drug/vaccine inventory requirements
		IER78 Query/response for inventory usage data	DR77 Drug/Vaccine query data DR78 Drug/vaccine response data
		IER1 Provide authorization and consent	
		IER5 Verify entity identity	
		IER2 Send data over secured communication channel	
		IER3 Create audit log entry	
		IER6 Provide proof of document integrity and origin	
		IER4 Synchronize system time	
	9.2 Action: Data retrieval – including data lookup, retrieval and data location registries	IER54 Query/response for clinical message data	DR58 Demographic data - vaccination DR11 Immunization response data DR76 Immunization query data
		IER67 Send/receive clinical message	DR58 Demographic data - vaccination DR18 Vaccination data
		IER40 Query for existing data	DR11 Immunization response data DR58 Demographic data – vaccination DR76 Immunization query data
		IER18 Send/receive clinical document	DR18 Vaccination data



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
		IER80 Send/receive vaccine inventory data	DR13 Drug/vaccine inventory data DR14 Drug/vaccine inventory usage data DR15 Drug/vaccine inventory availability data DR20 Aggregate inventory of available vaccine
		IER78 Send/receive vaccine inventory requirements	DR79 Drug/vaccine inventory requirements
		IER79 Query/response for inventory usage data	DR77 Drug/Vaccine query data DR78 Drug/vaccine response data
		IER1 Provide authorization and consent	
		IER5 Verify entity identity	
		IER1 Provide authorization and consent	
		IER2 Send data over secured communication channel	
		IER3 Create audit log entry	
		IER6 Provide proof of document integrity and origin	
		IER4 Synchronize system time	
	9.3 Action: Subject-data matching	IER10 Identify patient	DR58 Demographic data – vaccination
	9.4 Action: Data provisioning – including support for secondary uses; data provisioning and distribution of data transmission parameters	IER55 Anonymize patient identifiable data	
		IER56 Pseudonymize patient identifying information	
			DR21 Terminology data
	9.5 Action: Support for personally controlled health records – including managing consumer-identified locations to store their personally controlled health information; support consumer requests for information as well as routing of information to the consumer's preferred personally controlled health record		DR17 Decision support data (immunization schedule knowledge)
		IER26 Identify communication recipients	
		IER42 Request/receive medical concept knowledge	DR17 Decision support data (Alerts)
		IER18 Send/receive clinical document	DR18 Vaccination data DR8 Unstructured data
		IER10 Identify patient	DR58 Demographic data – vaccination
		IER13 Send/receive notification of document availability	DR8 Unstructured data (Alerts)



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	9.6 Action: Emergency access – including capabilities to support appropriate individual and population emergency access needs	NOTE: Not an interoperability consideration beyond what is defined in prior events/actions	

6.4 USE CASE SEQUENCE DIAGRAMS

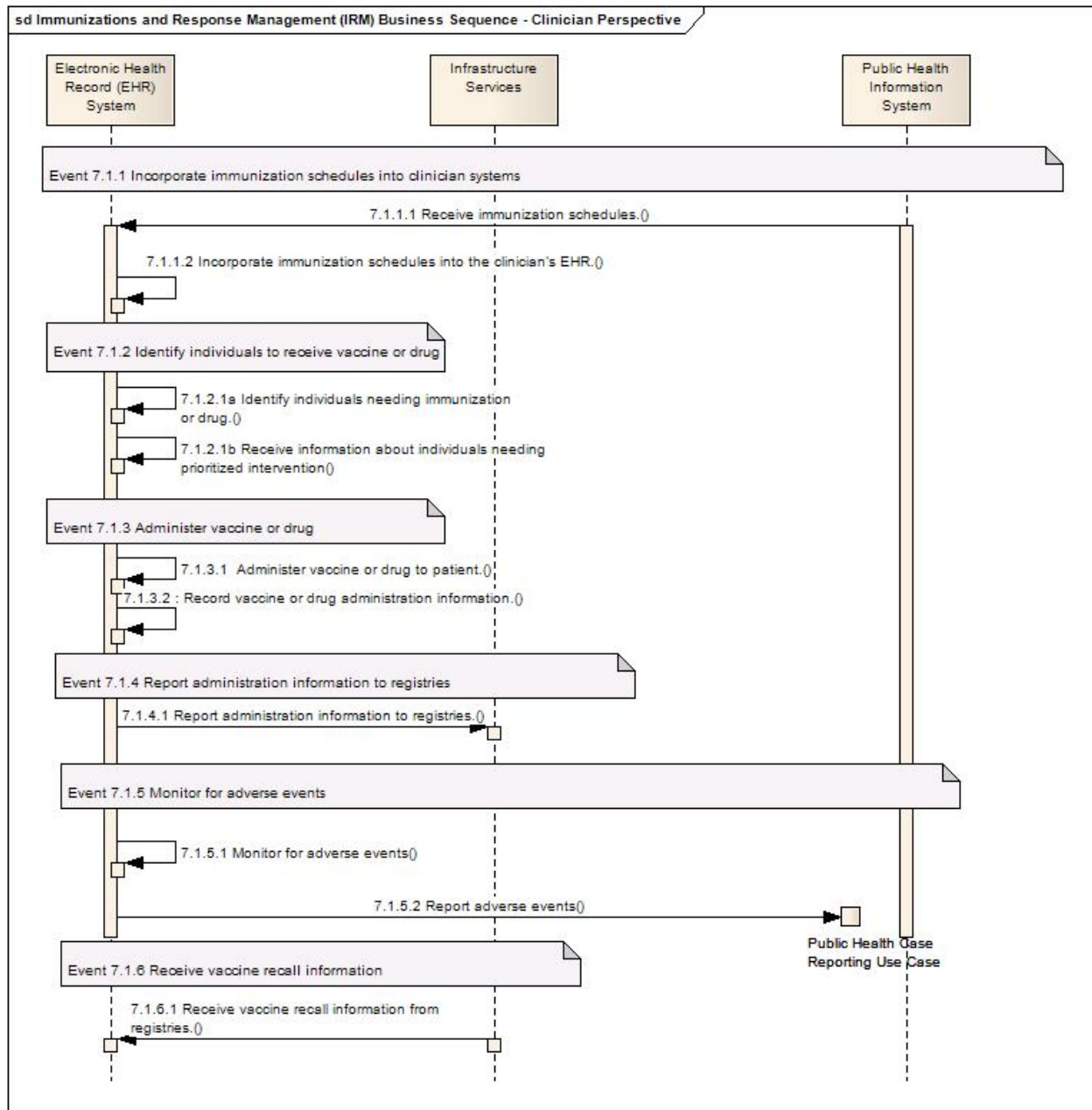
The Use Case sequence diagrams illustrate each Use Case scenario with a representation of a normal sequence of exchange between the primary actors. The event codes from the Use Case are annotated on the diagrams to show how the interactions relate to the Use Case. The interactions are supported by the various constructs which are introduced in Section 3.0 of this Interoperability Specification.

The high level sequence diagrams illustrate each Use Case scenario with a representation of a normal sequence of exchange between the primary actors. The event codes from the Use Case are annotated on the diagrams to show how the interactions relate to the Use Case. The interactions are supported by the various constructs which will be introduced in Section 3 of this Interoperability Specification.

The following diagram depicts the events and actions associated with the clinician perspective from the Immunizations and response management Scenario 2: Vaccine and Drug Administration and Reporting. The clinician in this exchange may represent clinicians performing administration and treatment routine care settings and non-routine settings including, but not limited to physician offices, hospitals, clinics, field medical stations, pharmacies, incident locations. It is assumed in this diagram that the clinician is supported in the interactions with registries and other business actors through the EHR.



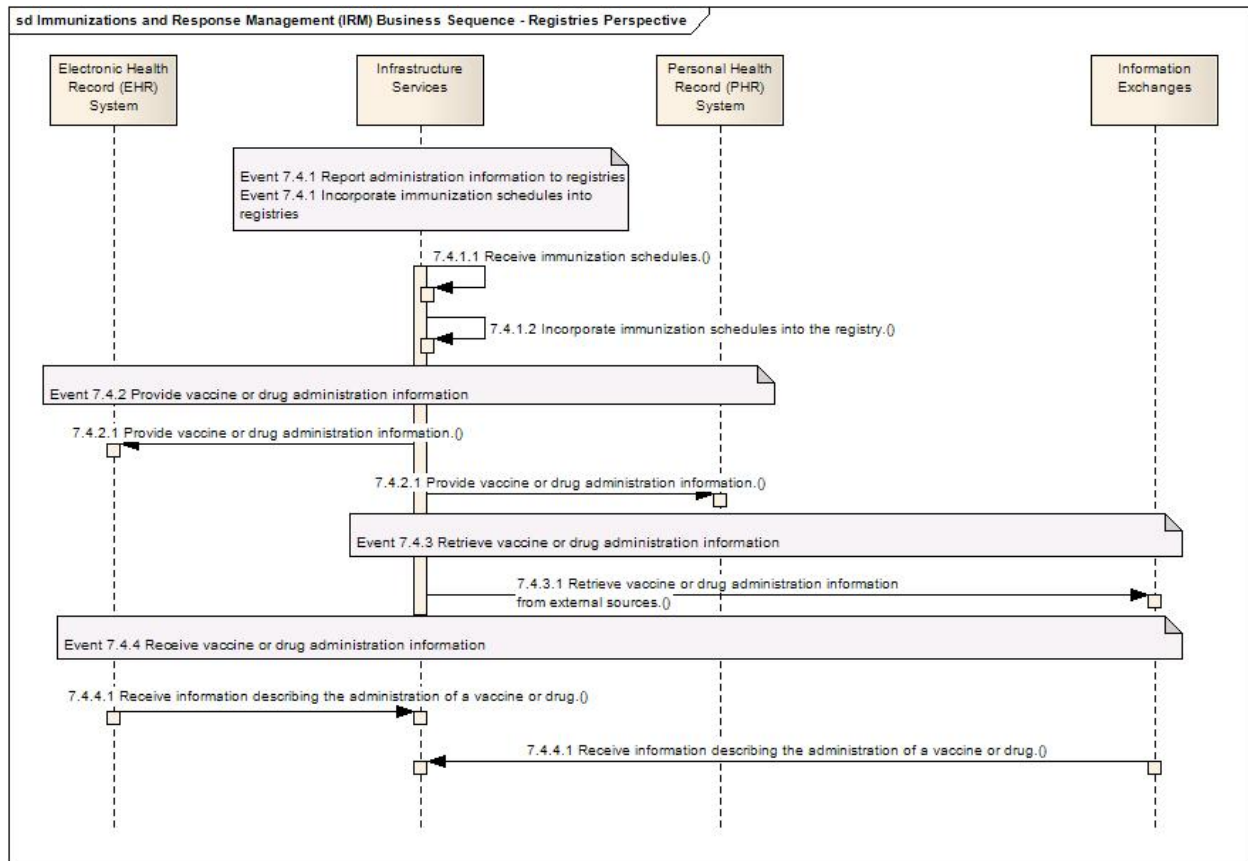
Figure 6.4-1 Immunizations and Response Management (IRM) Business Sequence – Part 1 – Clinician Perspective: Immunizations and Response Management Scenario 2: Vaccine and Drug Administration and Reporting



The following diagram depicts the events and actions associated with the registries perspective from the Immunizations and Response Management Scenario 2: Vaccine and Drug Administration and Reporting. It is assumed in this diagram that the public health and registry personnel are supported in the interactions with other business actors through the registries.



Figure 6.4-2 Immunizations and Response Management (IRM) Business Sequence – Part 2 – Registries Perspective: Immunizations and response management Scenario 2: Vaccine and Drug Administration and Reporting



The following diagram depicts the events and actions associated with the consumer perspective from the Immunizations and response management Scenario 2: Vaccine and Drug Administration and Reporting. It is assumed in this diagram that the consumer is supported in the interactions with other business actors either through the PHR or through interactions with their clinicians, who are supported through the EHR.



Figure 6.4-3 Immunizations and Response Management (IRM) Business Sequence – Part 3– Consumer Perspective: Immunizations and response management Scenario 2: Vaccine and Drug Administration and Reporting

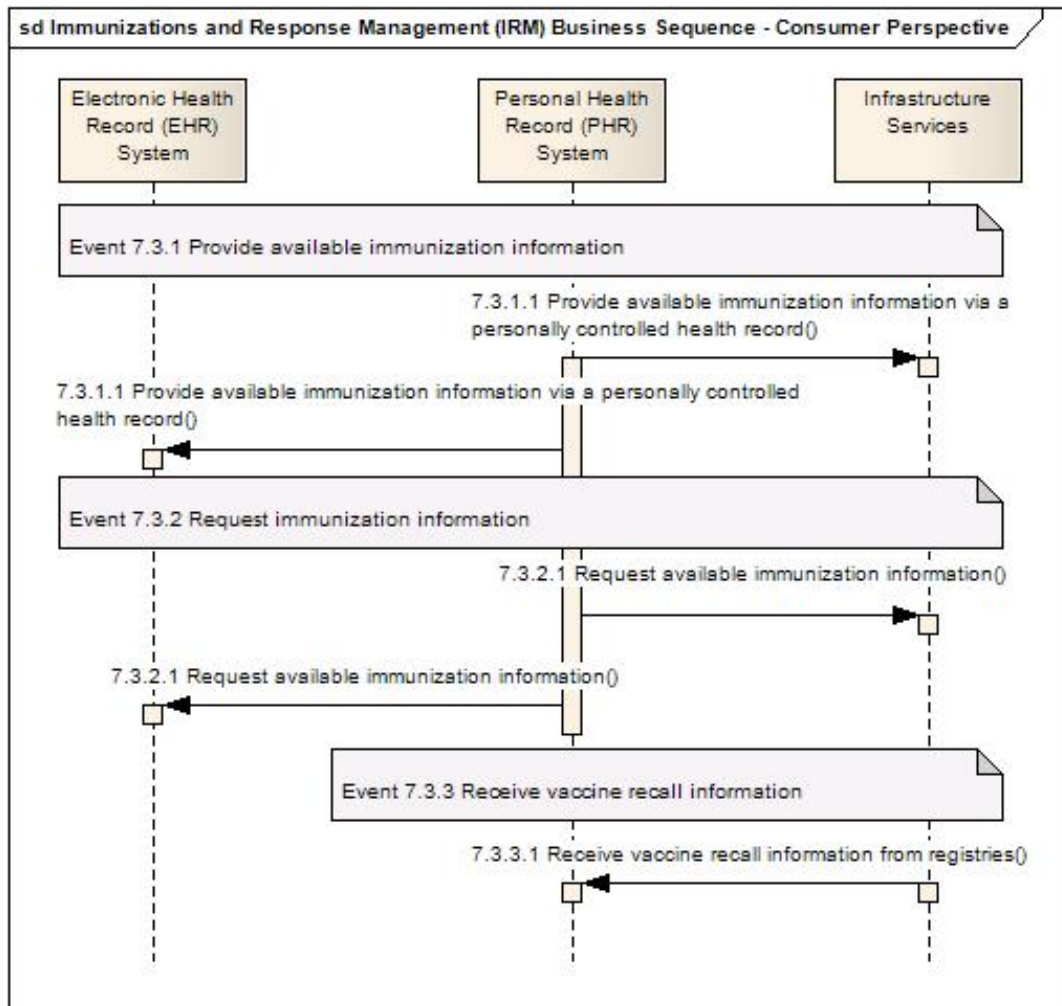
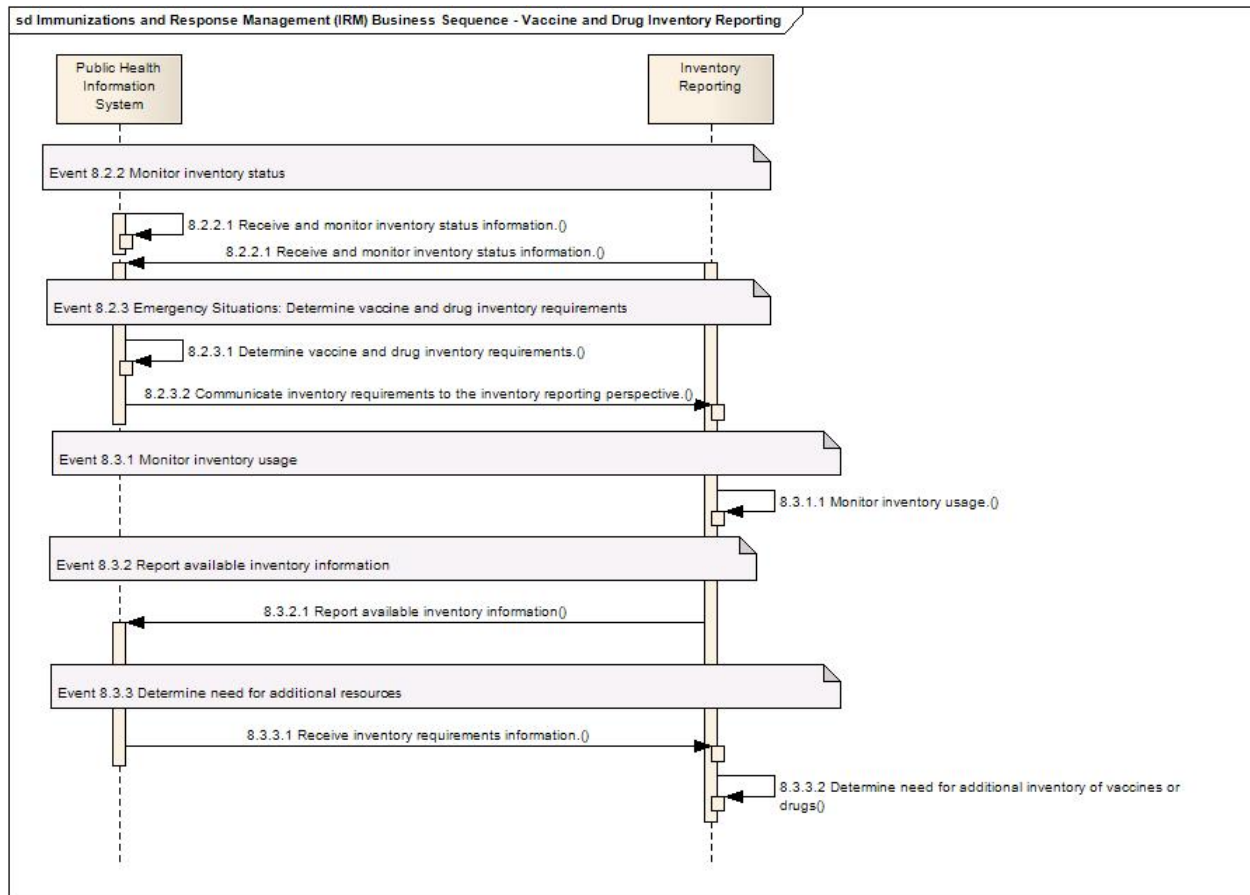


Figure 6.4-4 Immunizations and Response Management (IRM) Business Sequence – Part 4



6.5 MAPPING OF CONSTRUCTS TO INFORMATION EXCHANGE AND DATA REQUIREMENTS

Table 6.5-1 below provides a mapping of the HITSP constructs that will be used in the design of the Interoperability Specification, and the data and information exchange requirements that are being satisfied by the construct. These requirements are limited to those that are deemed within scope for this interoperability specification, which are described in Section 3.1.

Table 6.5-1 Mapping of Requirements to HITSP Constructs

Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
HITSP/C19 - Entity Identity Assertion	IER5 Verify entity identity	
HITSP/C26 - Nonrepudiation of Origin	IER6 Provide proof of document integrity and origin	
HITSP/C62 - Unstructured Document		DR8 Unstructured data DR8 Unstructured data data



Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
HITSP/C70 - Immunization Query and Response	IER54 Query/response for clinical message data	DR11 Immunization response data DR76 Immunization query data
HITSP/C72 - Immunization Message	IER67 Send/receive clinical message	DR18 Vaccination data
HITSP/C78 - Immunization Document		DR18 Vaccination data DR23 Consumer vaccination view
HITSP/C80 – Document and Message Terminology		DR11 Immunization response data DR76 Immunization query data DR18 Vaccination data DR58 Demographic data – vaccination DR23 Consumer vaccination view
HITSP/C83 – CDA Content Modules		DR18 Vaccination data DR58 Demographic data – vaccination DR23 Consumer vaccination view
HITSP/C88 - Anonymize Immunizations and Response Management Data	IER55 Anonymize patient identifiable data	
HITSP/T63 - Emergency Message Distribution Element	IER27 Send non-patient notification message or alert	DR22 Generic alert data - Immunizations
HITSP/64 - Identify Communication Recipients	IER26 Identify communication recipients	DR22 Generic alert data - Immunizations DR8 Unstructured data (Alerts) DR18 Vaccination data DR16 Supply chain management vaccine recall (deferred)
HITSP/C82 - Emergency Common Alerting Protocol	IER27 Send non-patient notification message or alert	DR22 Generic alert data – Immunizations
HITSP/T15 - Collect and Communicate Security Audit Trail	IER3 Create audit log entry	
HITSP/T16 - Consistent Time	IER4 Synchronize system time	
HITSP/T17 - Secured Communication Channel	IER2 Send data over secured communication channel	
HITSP/T23 - Patient Demographics Query	IER10 Identify patient	DR58 Demographic data - vaccination
HITSP/T24 - Pseudonymize	IER56 Pseudonymize patient identifying information	
HITSP/T29 - Notification of Document Availability	IER13 Send/receive notification of document availability	DR8 Unstructured data
HITSP/T31 - Document Reliable Interchange	IER18 Send/receive clinical document	
HITSP/T33 - Transfer of Documents on Media	IER18 Send/receive clinical document	
HITSP/T66 - Retrieve Value Set Terminology Service		DR21 Terminology data
HITSP/T81 - Retrieval of Medical Knowledge	IER42 Request/receive medical concept knowledge	



Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
HITSP/TP13 - Manage Sharing of Documents	IER18 Send/receive clinical document	
HITSP/TP20 - Access Control	IER1 Provide authorization and consent	
HITSP/TP21 - Query for Existing Data	IER40 Query for existing data	
HITSP/TP22 - Patient ID Cross-Referencing	IER10 Identify patient	DR58 Demographic data – vaccination
HITSP/TP30 - Manage Consent Directives	IER1 Provide authorization and consent	



7.0 DOCUMENT UPDATES

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

7.1 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).

5154, 5391, 5453, 5529, 5530, 5659, 5660, 5661, 5662, 5672, 5673, 5674, 5675, 5676, 5677, 5678, 5679, 6641

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

Changes also reflect the following:

- Renamed Business actors and adopted cross-IS harmonized descriptions, adjusting diagrams to align with the renaming
- Adjusted all Data Requirements and IERs to use cross-IS harmonized concepts and descriptions
- Moved the Detailed Data Requirements table to the appendix as an informative reference and propagated the data elements to the Data Requirements table
- Modified descriptions of constructs in Table 1.2.1-1
- Added HITSP/C80 Clinical Document and Message Terminology, HITSP/C83 CDA Content Modules
- Updated the technical actor role descriptions in Table 3.2.1-1
- Updated the Table 2.2.3-1 Business Actor to include IER03 and IER04
- Updated Table 3.2.3-1 to correct references to HITSP/TP20 Access Control and HITSP/C19 Entity Identity Assertion
- Updated HITSP/TP21 Query for Existing Data Technical Actors and references to reflect updated HITSP/TP21

Minor editorial changes were made to this construct.

7.2 DECEMBER 18, 2008

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

