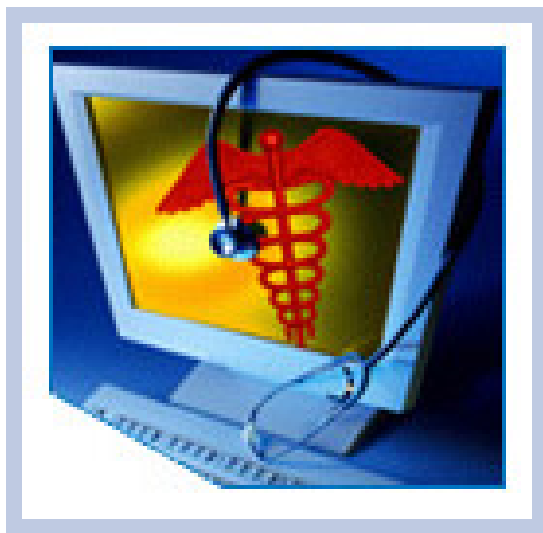


HITSP Immunizations and Response Management Use Case Requirements, Design and Standards Selection

HITSP/RDSS60



Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

**Population Perspective Technical Committee
(Formerly Population Health Technical Committee)**

With input from:

**Administrative and Financial Domain Technical Committee
Care Management and Health Records Domain Technical Committee
Security, Privacy and Infrastructure Domain Technical Committee (Formerly Security and Privacy Technical Committee)**



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1.0 INTRODUCTION

As an introduction to the HITSP Immunizations and Response Management Use Case Requirements, Design and Standards Selection, this section describes the purpose of the document, the intended audience for the technical content of the document, and how to use this document. It acknowledges the copyright protections that pertain, and provides a list of key reference documents and background material. If you are already familiar with this information, proceed to Section 2.0 Requirements Analysis.

1.1 PURPOSE

The Requirements, Design and Standards Selection document is used to define the requirements for the Use Case and the detailed HITSP Interoperability Specification design map of existing standards and specifications that will be used to meet the stated requirements. It is intended to describe the process by which the Use Case was analyzed, standards were selected and the design was developed.

1.2 AUDIENCE

The Requirements, Design and Standards Selection document is designed to be used by the HITSP Technical Committees or Work Groups to document their analysis and decisions, other analysts who need to understand and evaluate the requirements, design and selected standards, and by those intending to test the resulting Interoperability Specifications against the Use Case requirements. Understanding and using the relevant set of Interoperability Specifications is a key requirement for establishing interoperability compliance.

1.3 HOW TO USE THIS REQUIREMENTS, DESIGN AND STANDARDS SELECTION DOCUMENT

The Requirements, Design and Standards Selection document is divided into five main related sections. Each section provides background information for the Interoperability Specification. Section 1.0 provides a brief introduction to the document. Users of this document who are familiar with the content may choose to proceed to Section 2.0. In Section 2.0, the Requirements Analysis provides a general overview of the Use Case and the specific requirements of the Use Case including a mapping of the Use Case requirements to the extracted interoperability requirements, the data requirements of the Use Case, and an identification of the scenarios, business actors, their interactions, and data elements used in those interactions. The design for the Interoperability Specification is provided in Section 3.0. This includes the scope of the design, mapping of interoperability requirements to the specific technical requirements, actor interactions and groupings, detailed descriptions of data used by the Use Case actors, and a description of existing or new HITSP constructs that will be used by the Interoperability Specification. Section 4.0 describes the Standards Selection process, provides a table of the selected and candidate standards, a Gaps and Overlaps discussion and plan for resolution. Section 5.0 describes the next steps in the HITSP standards harmonization process and Section 6.0 provides relevant appendix material.



1.3.1 CONVENTIONS, ACRONYMS AND RESOURCES/REFERENCES

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

Table 1.3.1-1 Reference Documents

Reference Document	Document Description
HITSP Interoperability Specification Overview	Provides background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. The document also provides a description of the HITSP process for healthcare standards harmonization and explains how to use the Interoperability Specifications and other related documents to inform your health IT product development or product refinement.
HITSP Conventions List	Describes the conventions that are used to convey the full descriptions and usage of standards in the HITSP specifications
HITSP Acronyms List	Lists and defines the acronyms used in this document
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
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 glossary of terms used in all the Security and Privacy construct documents• 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>

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: <http://www.hhs.gov>
- IIS Data Code Book: <http://www.immregistries.org> prepared by The American Immunization Registry Association Data Definitions Working Group

1.4 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

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NOTE: HITSP will work with the appropriate standards organizations to obtain applicable copyright information for candidate standards.



2.0 REQUIREMENTS ANALYSIS

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

- Mapping from the Use Case Requirements to the Derived Interoperability Requirements – this table lists the requirements grouped by actor for each event and related action
- Data Element Requirements – this table further describes the data requirements for each specified interoperability requirement and the business actor that is responsible for the data
- Business Actors – this table defines the business actors that are included for the Interoperability Specification
- High-Level Unified Modeling Language (UML) Business Sequence 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 2007, American Health Information Community (AHIC) examined the exchange of information supporting the distribution and administration of medications, vaccinations, and other specific medical prophylaxis and treatment methods. AHIC then developed the Immunizations and Response Management Detailed Use Case, which focuses on the information needs of consumers, clinicians, registries, public health, and inventory managers carrying out routine care activities associated with immunizations. Portions of this Use Case recognize that 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 with needs for, and the administration of vaccines or drugs based on routine schedules, or by priorities dictated by emergency response. 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

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.

2.2.1 MAPPING OF USE CASE REQUIREMENTS TO INTEROPERABILITY REQUIREMENTS

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



Table 2.2.1-1 Mapping of Use Case Requirements to Interoperability Requirements

Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
Immunizations and Response Management	Clinician	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.	1. Need to support current practice for immunization schedules distribution – web locations – paper representation of schedule logic with migration to CDS capabilities 2. The IS needs to refer to this in an architecturally neutral way. In some states, it may be varied or perhaps regulated (funding, distribution, schedule) differences. (expression of schedule is in 7.4.1) 3. Need to keep track of the source/author of the schedule	5 Clinical Decision Support Content (immunization schedule knowledge) 11 Generic Alert to Identified Providers (Immunization Schedule)
				7.1.1.2 Action: Incorporate immunization schedules into the clinician's EHR.	1. Need to support current practice for immunization schedules distribution – web locations – paper representation of schedule logic with migration to CDS capabilities 2. The IS needs to refer to this in an architecturally neutral way. In some states, it may be varied or perhaps regulated (funding, distribution, schedule) differences. (expression of schedule is in 7.4.1) 3. Need to keep track of the source/author of the schedule	5 Clinical Decision Support Content (immunization schedule knowledge) 11 Generic Alert to Identified Providers (Immunization Schedule)



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
			7.1.2 Event: Identify individuals to receive vaccine or drug	7.1.2.1a Action: Identify individuals needing immunization or drug.	1. The registry may need to retrieve from multiple sources to compile the complete immunization history for a given patient 2. 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 3. The aggregated information must be provided to the clinician 4. The clinician can query the registry NOTE: today an immunization registry 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 registry would be a new functionality	1 Immunization Query and Response 5 Clinical Decision Support Content (Immunization Schedule Knowledge)



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				7.1.2.1b Alternative Action: Receive information about individuals needing prioritized intervention	1. Must support routine and non-routine situations 2. Need to support looking at characteristics of populations of high risk 3. Need to support adult immunization registries (e.g. emergency preparedness registry, chronic disease registry or EHR information sources) as input 4. Need to support different ways of representing the prioritization considerations 5. 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)	1 Immunization Query and Response 5 Clinical Decision Support Content (Prioritization, Immunization Schedule knowledge, Reminders) 11 Generic Alert to Identified Providers (Risk Notification) 12 Unstructured Document Component (Risk Notification)
			7.1.3 Event: Administer vaccine or drug	7.1.3.1 Action: Administer vaccine or drug to patient	No Interoperability Requirements NOTE: Edge system issue- this pertains to edge system requirements. Vaccine contraindication checks are typically described in the schedule. There may be 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 (see Section 3.1.1 Assumptions)	



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				7.1.3.2 Action: Record vaccine or drug administration information	1. Needs to capture the right elements and attributes – for this use the CDC core dataset that the immunization registry captures so that it is positioned to send it 2. Contraindication considerations	6 Vaccination 7 Medication administration (deferred) 5 Clinical Decision Support (Alerts – contraindications)
			7.1.4 Event: Report administration information to registries	7.1.4.1 Action: Report administration information to registries	1. T64 - Identify Communication Recipients Service (CRS) (May have multiple registries servicing an area, patient may be from another jurisdiction) 2. Transaction may be different – e.g. HL7 message, routine message, document- centric) 3. Transmission of dispensing of medication to a patient (Must support CRS Data Content) NOTE: Pharmacies may dispense immunization. This is a business actor NOTE: Just giving vaccine may not be the only impact on the stock pile	6 Vaccination 7 Medication Administration (CRS - for emergencies - deferred)
			7.1.5 Event: Monitor for adverse events	7.1.5.1 Event: Monitor for adverse events	See requirements for HITSP Public Health Case Reporting RDSS61 1. Need to support the type of adverse event reporting (VAERS) that exist 2. Must dovetail to other Adverse Drug Event Report Use Case (Public Health Case Reporting) 3. Adverse Drug Event Report may come from the registry or service provider	2 Adverse Event Report (FDA – MedWatch, Vaccine Reporting (VAERS)) 5 Clinical Decision Support Content (Active/Passive Surveillance for adverse event)



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				7.1.5.2 Action: Report adverse events	1. Before it becomes a formal adverse event, there needs to be a human intervention as these are investigated, tracked and assessed	2 Adverse Event Report (FDA – MedWatch, Vaccine Reporting (VAERS))
			7.1.6 Event: Receive vaccine recall information	7.1.6.1 Action: Receive vaccine recall information from registries	1. New communication requirement – distribution of recall information 2. T64 - Identify Communication Recipients (Service)– based on who may have received a bad lot (Review Bio 'Identify communication recipients')	4 Supply Chain Management (no apparent recall support for supply chain management (Vaccine Recall Notification) 11 Generic Alert to Identified Providers (Vaccine Recall Notification) 12 Unstructured Document Component (Vaccine Recall)
		Vaccine and Drug Inventory Reporting	7.4.1 Event: Report administration information to registries	7.4.1.1 Action: Report administration information to registries		6 Vaccination



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
	Registry	Vaccine and Drug Administration and Reporting	7.4.1 Event: Incorporate immunization schedules into registries	7.4.1.1 Action: Receive immunization schedules	<p>Mirror of clinician perspective requirements :</p> <ol style="list-style-type: none"> 1. Need to support current practice for immunization schedules distribution – web locations – paper representation of schedule logic with migration to CDS capabilities 2. The IS needs to refer to this in an architecturally neutral way. In some states, it may be varied or perhaps regulated (funding, distribution, schedule) differs. (see 7.4.1 above) 3. Need to keep track of the source/author of the schedule 4. Need to support the IIS as the source of information 5. Registry should be the source of the schedule in many cases – construct needs to support the registry as a source of information (NOTE: in some jurisdictions, providers resist getting schedule from registry and other sources) 6. Need support for decision support updates 7. Provider should be able to retrieve immunization schedule from source (e.g. CDC) 8. Provider should be able to modify the immunization schedule locally based upon the pattern of population that they see to better manage their workload 	<p>5 Clinical Decision Support Content (immunization schedule knowledge)</p> <p>11 Generic Alert to Identified Providers (Immunization Schedule)</p>



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				7.4.1.2 Action: Incorporate immunization schedules into the registry	However the schedule is retrieved, the schedule is loaded into the registry No interoperability requirement	6 Clinical Decision Support Content (immunization schedule knowledge) (see 7.4.1.1 above) 11 Generic Alert to Identified Providers (immunization schedule knowledge)



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
			7.4.2 Event: Provide vaccine or drug administration information	7.4.2.1 Action: Provide vaccine or drug administration information.	<ol style="list-style-type: none"> 1. Respond to request for information 2. Authorization check (Security& Privacy) 3. Consent 4. Provide the information via a portal, by responding to an interoperable query message, or by proactively sending notifications (HITSP/T29 candidate) 5. Need to 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 (NOTE: Supported by HITSP/TP13 and HITSP/C32 in part – see GAP and Scope) 6. Requirement that immunization registries pro-actively send notifications – Policy/implementation consideration, but we need supporting standards for this approach 7. Registries may or may not choose to receive data from PHRs or HIE connection 8. Source must be identified: <ul style="list-style-type: none"> • registry may not accept information until there is a validated source • individual recollection of information versus clinical system – Source of information must be indicated 	6 Vaccination 1 Immunization Query and Response 11 Generic Alert to Identified Providers (Alerts) 12 Unstructured Document Component (Alerts)



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Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
			7.4.3 Event: Retrieve vaccine or drug administration information	7.4.3.1 Action: Retrieve vaccine or drug administration information from external sources.	1. Immunization registry lives in HL7 world must be supported (VXU, VXR, VXQ) 2. Agreement verification – e.g. authorizations for registries to exchange information 3. Consent check 4. Workflow: Information may come in from pharmacy where there is no EHR system it would expect to use telecommunication standards for insurance – dispensing event – may be missing site of administration and other clinical elements. (see Section 4.2 GAPS) 5. Support for multiple communication options (Sources may include patient claim – payor source) (no EHR system); Senior Centers, Public Health workers doing vaccination campaign NOTE: When pharmacist is involved in immunization, most likely involved in adult immunization; pharmacist may be permitted to administer the vaccination (varies by state);	1 Immunization Query and Response
			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.	1. Support data from sources other than EHRs 2. Patient Matching (see HITSP/ TP22 /HITSP/TP 23)	1 Immunization Query and Response 6 Vaccination 9 Demographic Data



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				7.4.5	Recall information subsumed in other events/actions – no detailed events/actions provided	
	Consumer	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.	1. Need to access from PHR (HITSP/TP13) 2. A constrained/ consumer understandable view 3. HITSP/TP13 Interoperability for PHR communications Registry would need to publish a CDA – HITSP/C32 candidate – constrained subsets (see GAP for Immunization CDA Document) 4. Source of vaccination must be clearly identified NOTE: Where the data are imported into consumer PHR the trust is reduced	6 Vaccination 13 Consumer Vaccination View
			7.3.2 Event: Request immunization information	7.3.2.1 Action: Request available immunization information.	1. Need to access from PHR (HITSP/TP13) 2. A constrained/ consumer understandable view 3. HITSP/TP13 Interoperability for PHR communications. Registry would need to publish a CDA – HITSP/C32 candidate – constrained subsets. (see GAP for Immunization CDA Document) 4. Source of vaccination must be clearly identified NOTE: Where the data are imported into the PHR consumer trust is reduced	1 Immunization Query and Response 13 Consumer Vaccination View



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
			7.3.3 Event: Receive vaccine recall information	7.3.3.1 Action: Receive vaccine recall information from registries.	1. Need to access from PHR (HITSP/TP13) 2. A constrained/ consumer understandable view 3. HITSP/TP13 Interoperability for PHR communications. Registry would need to publish a CDA – HITSP/C32 candidate – constrained subsets. (see GAP for Immunization CDA Document) 4. Source of vaccination must be cleanly identified NOTE: Where the data are imported into the PHR the consumer trust is reduced. Need to support PHR or other means to retrieve immunization information 5. Workflow considerations for notifications without a description - Look to HITSP/T29 NAV – this implies a 2-stage process to address S&P 6. S&P considerations for potential mis-communications by mail, email, PHR 7. Identify Communication Recipients	1 Immunization Query and Response 4 Supply Chain Management Vaccine Recall (including consumer directed message) 11 Generic Alert to Identified Providers (Alerts – vaccine recall) 12 Unstructured Document Component (Alerts– vaccine recall) 13 Consumer Vaccination View
	Public Health	1Vaccine 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.	1. Need decision support with population data input – the population data may have multiple sources (e.g. clinical history, census) 2. Defer work on this item as inferred by the Use Case comment	1 Immunization Query and Response 5 Clinical Decision Support – (intervention priorities)



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				7.2.1.2 Action: Notify clinicians of individuals or population characteristics needing prioritized intervention.	1. Need decision support with population data input 2. May have new actors in an emergency situation (e.g. labs or employers, healthcare provider not traditionally involved in immunization administration, mobile service) 3. Registry reproduction and registry backup in case of emergency and synchronization of registries 4. Decision support feedback on public health event status 5. Implies some way of constructing the alert message and the variety of content the message may contain 6. Assumes 7.2.1.1 7. Communication of the alert message (HITSP/T31, HITSP/T33, HITSP/TP13) 8. Two types of messages/data requirements for individual-based vs population-based: Health Area Network (HAN) for population-based 9. Identification of communication recipients (based on CDS output) 10. Demographics – individually identified, clinical information – S&P consideration, Policy consideration	1 Immunization Query and Response 5 Clinical Decision Support (Prioritization -to determine who to notify, Public Health Event Status) 9 Demographic Data 11 Generic Alert to Identified Providers (Alerts – prioritization) 12 Unstructured Document Component (Alerts– prioritization)



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
		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.	1. Emergency/healthcare worker prioritization considerations for onsite response 2. Standards for travel vaccination for adult immunization considerations 3. Clinically verifiable source vs. consumer- entered data 4. Consumer consent 5. Support for consumer management of information from remote resource (non-PHR) 6. Need to provide to persons PHR is secondary to the providing to the person understandable view 7. HITSP/TP13 Interoperability for PHR communications. Registry would need to publish a CDA – HITSP/C32 – constrained subsets. (see GAP for Immunization CDA Document)	1 Immunization Query and Response 5 Clinical Decision Support Content (prioritization) 11 Generic Alert to Identified Providers (Alerts – prioritization) 12 Unstructured Document Component (Alerts– prioritization)



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
			8.2.2 Event: Monitor inventory status	8.2.2.1 Action: Receive and monitor inventory status information.	<p>1. 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</p> <p>2. Registry involvement must be specified further by the Use Case. NOTE: There is a mixed environment in the inventory management capabilities of Immunization Systems</p> <p>3. Use Case overall needs to better clarify the anticipated roles of stakeholders in the vaccine supply chain, monitoring processes, and distribution channels. In the diagram – inventory reporting column is to amorphous to determine who is in that 'role'</p> <p>NOTE: The normative information flow vs routine flow - both are changing models, and are in-flux</p> <p>NOTE: There is a lack of widespread implementation of clinician inventory systems that generate the inventory data</p>	<p>1 Immunization Query and Response</p> <p>3 Supply Chain Management Inventory management</p> <p>8 Aggregate Inventory of Available Vaccine</p>



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
			8.2.3 Event: Emergency Situations: Determine vaccine and drug inventory requirements	8.2.3.1 Action: Determine vaccine and drug inventory requirements	1. Transport construct 2. Need to support Risk plan 3. Need to support Risk/threat models (most jurisdictions have a preparedness plan – workflow, risk assessment) 4. Need to support Monitoring Transport/maintenance conditions : cold chain – handling, shipping conditions, storage conditions 5. Need to support the fact that in emergency situation, business actors may be different	3 Supply Chain Management Inventory management
				8.2.3.2 Action: Communicate inventory requirements to the inventory reporting perspective	1. Identify communication recipients; 2. Requirements communication vehicle 3. Privacy/security for delivery/inventory needs; Need to protect the message from someone viewing the message and identifying the vulnerabilities; Supply chain communication security	3 Supply Chain Management Inventory management
	Inventory Reporting	2 Vaccine and Drug Inventory Reporting	8.3.1 Event: Monitor inventory usage	8.3.1.1 Action: Monitor inventory usage	1. Query transport; similar to VFC vaccine reporting; in this case PH is playing the role of the inventory manager	3 Supply Chain Management Inventory management



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
			8.3.2 Event: Report available inventory information	8.3.2.1 Action: Report available inventory information	See 8.2.2.1	3 Supply Chain Management Inventory management
			8.3.3 Event: Determine need for additional resources	8.3.3.1 Action: Receive inventory requirements information	See 8.2.3.2	3 Supply Chain Management Inventory management
				8.3.3.2 Action: Determine need for additional inventory of vaccines or drugs	No interoperability requirement	3 Supply Chain Management Inventory management CDS – is a edge system issue
	Information Exchange	1 Vaccine and Drug Administration and Reporting 2 Vaccine and Drug Inventory		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	1. HITSP/TP13 and associated constructs does have the capacity to communicate immunizations within the document content; may be leveraged where HIE is immunization history source 2. Media (e.g. PHR source) 3. Reliable Interchange 4. May need new constructs for inventory communications 5. Existing Security Constructs	



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				9.2 Action: Data retrieval – including data lookup, retrieval and data location registries	1. HITSP/TP13 and associated constructs does have the capacity to communicate immunizations within the document content; may be leveraged where HIE is immunization history source 2. Media (e.g. PHR source) 3. Reliable Interchange 4. May need new constructs for inventory communications 5. Existing Security Constructs 6. Method for identifying where the patient's records are across multiple domains (HITSP/TP13- XCA) - need another method for identifying patient records in a non- document-centric environment	
				9.3 Action: Subject-data matching	1. HITSP/TP22 2. HITSP/T23 3. Need consideration for cross-domain patient identification/matching 4. Support current VXQ/VXR capabilities used by immunization registries	9 Demographic Data



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				9.4 Action: Data provisioning – including support for secondary uses; data provisioning and distribution of data transmission parameters	1. Vaccine inventory may be considered secondary use 2. 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 3. Edge System Requirement: Data quality: see MIROW 4. De-Duplication 5. Data provisioning for clinical decision support: Anonymize, Pseudonymize 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)	5 Clinical Decision Support (immunization schedule knowledge) 10 Terminology Services



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				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	1. Identify communication recipients: connection considerations – how is the HIE certain that the information is communicated to the right person. (see AHIC Patient-Provider Secure Messaging Use Case) 2. HITSP/TP13 Interoperability for PHR communications. Registry would need to publish a CDA – HITSP/C32 – constrained subsets. (see GAP for Immunization CDA Document)	
				9.6 Action: Emergency access – including capabilities to support appropriate individual and population emergency access needs	Not an interoperability consideration beyond what is defined in prior events/actions	

2.2.2 DATA AND INFORMATION REQUIREMENTS MATRIX

This section contains an extraction of data and information requirements with a listing of the actual data elements and information that meet the described data requirements.



Table 2.2.2-1 Data Element and Information Requirements

Requirement Number	Description
1 Immunization Query and Response	<p>Standard for Query/response (HL72 VXQ/VXR) – V2.5 and V3 is under development this year – goal to move toward these updated versions (2.5 may be completed by fall); CCD might be reasonable, but there is a GAP in immunization-specific work in CDA</p> <p>Query may not have a patient ID associated with it – may need to gather from other registries without patient-specific ID (e.g. NY to NJ for a NY address)</p> <p>Recognize that there is information about immunizations that do not involve the doctor/clinician (Medicare Part D); Flu vaccines</p> <p>Requirement to preserve the V2 messaging: Immunization registry lives in V2 HL7 world – must be supported; Subsequent changes we anticipate in the V2 messages must be supported and specified</p> <p>Need support for an aggregate result from query for Consumer view (which may be resolved by new SDO CDA for immunizations), and for supply chain management (deferred)</p> <p>See Tables 2.2.2-2 through 2.2.2-4 for detail</p> <p>From Use Case:</p> <p>Immunization history information describing all vaccinations received by an individual, including the dates administered, administering clinician, manufacturer and lot number, etc. The source of this information would need to be identified as coming from a clinically verifiable source, self-reported by a consumer, or provided from another non-clinically verifiable source</p> <p>Immunization status includes information describing the presence or absence of a specific immunization based upon published immunization schedules or other criteria. Status of the administration of drugs or other prophylaxis or treatment interventions may include similar types of information. – verify support from QED</p>
2 Adverse Event Report	<p>Overlap with Public Health Reporting; FDA – MedWatch, Vaccine Reporting (VAERS)) – Defer requirements specification to Public Health Case Reporting (PHCR) and leverage the resulting construct. NOTE: any deferrals and scoping in the development of the PHCR RDSS/IS will directly impact this requirement.</p>
3 Supply Chain Management Inventory Management	<p>Type of information part of drug /vaccine inventory requirements:</p> <p>Vaccine requirement/delivery instructions</p> <p>Query/Response</p> <p>Shipping/handling information data requirements</p> <p>Temp</p> <p>Storage conditions</p> <p>Breakage</p> <p>Humidity</p> <p>Air quality</p> <p>From Use Case:</p> <p>Inventory usage information includes detailed information identifying the quantity of vaccine utilized in a specific period of time, by location, by clinician, or by other geographic or non-geographic identifiers. Inventory usage information may also include manufacturer, lot number, expiration date, and other indicators relevant to the process of managing the pharmaceutical supply chain</p> <p>Data requirements are the same, but they need to be in aggregate</p> <p>See CRA Campaign detail – this list may need to be expanded in the supply chain context</p> <p>Inventory availability information includes detailed information identifying the quantity of vaccine or drugs available at a specific point in time, by location, or by other geographic or non-geographic identifiers. Information about on-hand inventory which has been committed or reserved for a specific use would also be included. Inventory availability information also includes manufacturer, lot number, expiration date, and other indicators relevant to the process of managing the pharmaceutical supply chain</p> <p>Scenario 2 Deferred (see scope): Need list of standards, healthcare-specific inventory standards, gaps, candidate transactions</p>



Requirement Number	Description
4 Supply Chain Management Vaccine Recall	<p>General:</p> <p>a constrained/ consumer understandable view - For consumer, this message may be the same message as the one that flows through the clinician or may need to be more consumer-friendly</p> <p>See VACMAN CDC for inventory management – not person-specific data</p> <p>May be able to repurpose the vaccine information, if not a gap may exist</p> <p>Data requirements for Notification and instructions to clinician - Present recall from FDA includes:</p> <p>Title (what is being recalled)</p> <p>Date of recall</p> <p>Lot #</p> <p>Expiration date</p> <p>Manufacturers</p> <p>Reason- text</p> <p>Action – text (interventions required for the recall)</p> <p>NOTE: Deferred to be further specified as part of Supply Chain Management in Scenario 2 (See Scope)</p>



Requirement Number	Description
5 Clinical Decision Support	<p>Data Input to CDS:</p> <p>CDC Core Dataset: Type of information captured when vaccinated (vaccination data)</p> <p>Contraindication data (reason not administered and reason scheduled modification – needs some standard associated with contraindication (are they calling for social or religious/refusal contraindication?) Contraindication documentation – non-medical reasons, content)</p> <p>Decision support data input (Need decision support with population data input)</p> <p>Decision support feedback on public health event status</p> <p>Logic for:</p> <p>Immunization Schedule Knowledge</p> <p>To support clinical decision support directions for Immunization schedule knowledge:</p> <p>The immunization schedule must be expressed in computable fashion</p> <p>The immunization schedule must be consumable by EHR</p> <p>Multiple sources of 'correct' immunization schedule; must be reconciled</p> <p>Timeliness of the EHR immunization schedule must be managed</p> <p>Need to support a third party source of immunization schedule knowledge (e.g. in many jurisdictions it is the Immunization Information System that serves as the local interpreter to the immunization schedule knowledge.)</p> <p>Advisory committee on Immunization practices + others – sources get their information from this group re-publishing ACIP is the authoritative source of the information</p> <p>Standards gap: Look at what is in the text versions to identify the data elements</p> <p>Immunization Reminders</p> <p>EHR can tell when an individual needs an immunization (See gaps)</p> <p>Criteria for immunization needs (immunization schedule)</p> <p>Schedule for alert content</p> <p>Immunization Prioritization</p> <p>ID of people over a certain age, environment – multiple sources of clinical history, census and other information sources</p> <p>EHR can tell when an individual needs an immunization (CDS)(See gaps)</p> <p>determine who to notify</p> <p>Note: 'Population Characteristics' is too vague a statement – could be any characteristic if it is beyond demographics – gap/requirements gap/policy element – scope to demographics for initial deliverable – to be expanded once requirements are fleshed out</p> <p>Criteria for prioritization (emergency and routine) Criteria to select patients:</p> <p>Age range</p> <p>Sex</p> <p>Race</p> <p>Deferred Criteria (pending further domain considerations):</p> <p>Risk</p> <p>Location of the exposure</p> <p>Date/time of exposure</p> <p>Type of exposure</p> <p>Occupation (e.g. first responders)</p> <p>Alerts</p> <p>Contraindications</p> <p>Active/Passive Surveillance for adverse event – defer to PHCR Use Case</p>



Requirement Number	Description
6 Vaccination	<p>A constrained/ consumer understandable view (see Requirement 13)</p> <p>Requirement to preserve the V2 messaging: Immunization registry lives in V2 hl7 world – must be supported; Subsequent changes we anticipate in the V2 messages must be supported and specified</p> <p>Emergency may be a superset of the routine (e.g. medication vs immunizations – most emergency systems may want immunization AND medication) – may require different types of information; Data Requirements are the same for the basic elements – may be different data requirements associated with a specific vaccines. Medication comes in a different message</p> <p>Use Case; is there a coordinated ‘single’ standard that can handle routine AND non-routine data elements (pending CRS/Supply Chain Management Deferred Efforts)</p> <p>Individual recollection of information versus clinical system – Source of information must be indicated</p> <p>There are differences with consumer-generated immunization content versus immunization registry maintained record identification of information source</p> <p>Potential GAP in NCPDP 5.1 as well for capture of immunization from pharmacy or other resolution to capture vaccinations from pharmacies</p> <p>From Use Case:</p> <p>Immunization history information describing all vaccinations received by an individual, including the dates administered, administering clinician, manufacturer and lot number, etc. The source of this information would need to be identified as coming from a clinically verifiable source, self-reported by a consumer, or provided from another non-clinically verifiable source. For certain vaccine programs, there may additional reporting requirements such as vaccine payment type, VCF eligibility status Administration of drugs or other prophylaxis or treatment intervention may include similar types of information</p> <p>From Use Case:</p> <p>Individual receiving the vaccination, the vaccine, manufacturer, lot number, expiration date, dosage amount, diluent: O, date/time and method of administration, the organization and clinician administering the vaccine. This may also include reasons that a vaccine could not be administered, such as the presence of a contraindication for the patient, documented immunity, or non-availability of the required vaccine</p> <p>(or refusal – TC addition e.g. for medical or philosophical reasons)</p> <p>NOTE: See data requirements table for details derived from the CDC Core Dataset</p>



Requirement Number	Description
7 Medication Administration	<p>Deferred: See Scope</p> <p>Review whether there a coordinated 'single' standard that can handle routine AND non-routine data elements</p> <p>Consider HITSP/C32</p> <p>transmission of dispensing of medication to a patient (Must support CRS Data Content)</p> <p>The administration of drugs needs to be able to track prophylactic and treatment interventions for readiness consideration</p> <p>From Use Case:</p> <p>Immunization history information describing all vaccinations received by an individual, including the dates administered, administering clinician, manufacturer and lot number, etc. The source of this information would need to be identified as coming from a clinically verifiable source, self-reported by a consumer, or provided from another non-clinically verifiable source. History of administration of drugs or other prophylaxis or treatment interventions may include similar types of information</p> <p>The administration of drugs needs to be able to track prophylactic and treatment interventions for readiness</p> <p>Medication administration standards need to be identified – need to support the reason for administration as prophylaxis</p> <p>Reason for drug administration- information does not go to registry unless given for prophylactic reason</p> <p>Data element for campaign for prophylactic drug use/context</p> <p>Data element for population that the campaign is directed toward</p> <p>Campaign ID</p> <p>Campaign name</p> <p>Campaign start/end date</p> <p>Campaign potential counter-measures</p> <p>See content for CDC file format for submitting data into CDC - summary level/aggregate data format (XML) NOTE- not at administration level</p> <p>NOTE: Imposing a data requirement on immunization registries that do not have at this time; Deferred</p>
8 Aggregate Inventory of Available Vaccine	<p>Pending Further Analysis on Scenario 2 for supply chain</p> <p>Data elements/attributes needed:</p> <p>Committed</p> <p>Doses remaining</p>
9 Demographic Data	See Tables 2.2.2-2 through 2.2.2-4 for detail
10 Terminology Services	Depends on other Use Cases; Leverage services for preparation of repurposed data
11 Generic Alert to Identified Providers	<p>See CDS Prioritization for trigger criteria</p> <p>Presentation Preserving</p> <p>NOTE: Sending system will deliver the message to the list via multiple mechanisms. Dotted arrow – non-specified from a system to a human being. Communications: HAN – may be a vehicle to use for this purpose; PHIN – technical communication standards (email, web, point to web) – state/region-based</p> <p>Requires support for:</p> <p>Population-based</p> <p>Clinician communication (e.g. Population-based alert to providers using email, out of band communications)</p> <p><i>Immunization Schedule</i></p> <p>Can be fulfilled through Generic Alert to providers initially. Future efforts may include Clinical Decision Support</p> <p><i>Alerts - Risk Notification</i></p> <p>(May be presented as a descriptive directive (e.g. patients over age 65)</p>



Requirement Number	Description
12 Unstructured Document Component	<p>See CDS Prioritization for trigger criteria</p> <p>Presentation Preserving</p> <p>Automation - NAV HITSP/T29 for sensitive communications</p> <p>Requires support for:</p> <p>Individual-Based</p> <p>Consumer/patient communication</p> <p>Clinician communication (e.g. patient listing alert to providers of patients needing vaccination)</p> <p>Enumerated case list is an option for structured content</p> <p>Information identifying individuals needing prioritized intervention includes the population characteristics of those individuals needing intervention, or may include information describing specific individuals needing intervention</p> <p>NOTE: Metadata may include - Title, clinic ID, date</p> <p>Alerts - Risk Notification</p> <p>Can be fulfilled through Unstructured Document Component initially. Future efforts may include Clinical Decision Support</p> <p>May be a list from census, immunization registry, or other non-descript source</p>
13 Consumer Vaccination View	<p>Content of the immunization documentation from the PHR may not be the same content as the immunization registry. Patients typically have all this detail. There may need to be more information given/reported – need to examine the consumer perspective and the immunization registry perspective (typically provide info to parent – sometimes limit the information to improve the clarity to the consumer - make consumer-friendly– e.g. remove duplicative doses)</p> <p>A constrained/ consumer understandable view</p> <p>See Tables 2.2.2-2 through 2.2.2-4 for detail</p>

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 systems and alignment with previously selected HITSP standards. Further analysis and review will be provided in the design of the IS.

Table 2.2.2-2 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
Data Type	Primitive data type that is collected with this data element (coded, numeric, text, date/time)
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 profession perspective in the RDSS. These may change pending Domain TC construct specification in the final IS delivered by HITSP



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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 2.2.2-3 Patient Data Elements

Data Element	Data Requirement (Query & Response, Vaccination, Demographic, Consumer Vaccination View)	Definition	Data Type	Data Requirement Standards	Required	Comments
PATIENT IDENTIFIERS						
Patient Name: First, Middle, Last	6, 9, 1, 13	The current, assumed legal name of the patient	XPN-48	HL7	R,R,R,R	(middle name is optional), Assure optimal linkages
Patient Alias Name: First, Middle, Last (former names for management of adoptions and name changes)	6, 9, 1, 13	This field contains names by which the patient has been known at some time	XPN-48	HL7	O,O,O,O	
Patient Address	6, 9, 1, 13	This field lists the mailing address of the patient	XAD-106	HL7	O,O,O,O	
Patient Phone Number	6, 9, 1, 13	The patient's personal phone numbers	XTN-40	HL7	O,O,O,O	Required for matching support
Patient Identifier	6, 9, 1, 13	may be populated with MRN, SSN, Medicaid Number, Local registry ID, or other identifiers collected			O,O,O,O	NOTE: Policy may restrict use of this attribute.
Patient Birth Date	6, 9, 1, 13	This is the date and time of an event	Timestamp	HL7 Timestamp	R,R,R,R	Assure optimal linkages
Patient Sex	6, 9, 1, 13	This is the Patient's Sex	Coded	HL7 2.5 Table 001 Administrative Sex M Male F Female U Undifferentiated	R,R,R,R	Assure optimal linkages



Data Element	Data Requirement (Query & Response, Vaccination, Demographic, Consumer Vaccination View)	Definition	Data Type	Data Requirement Standards	Required	Comments
Patient Race	6, 9, 1, 13	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: http://www.cdc.gov/od/hissb/docs/Race-EthnicityCodeSet.pdf	Coded	HL7 2.5 Table 005 Race	R2,R2,R2, R2	May be restricted by policy
Patient Ethnicity	6, 9, 1, 13	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	Coded	HL7 2.5 Table 125 Race	R2,R2,R2, R2	May be restricted by policy
Patient Primary Language	6, 9, 1, 13	This is the patient's primary language	Coded	HL7 2.5 Table 118 Ethnicity	O,O,O,O	
Patient Multiple Birth Indicator	6, 9, 1, 13	This field indicates whether the patient was part of a multiple birth	Coded	HL7 2.5 Table 136 - Yes/No indicator	R,R,R,R	Required for matching support
Patient Multiple Birth Order	6, 9, 1, 13	This is a number representing the patient's order of birth	Numeric	HL7	R,R,R,R	Required for matching support
Patient Birth Registration Number	6, 9, 1, 13	This is a number assigned to the patient by state for birth record purposes			O,O,O,O	
Patient Birth State/Country	6, 9, 1, 13	Shows state and country in which patient was born	Coded	FIPS	R2,R2,R2, R2	Covered in the immunization content file – for tracking, these are all covered; Not being used commonly for matching;
Patient Birthing Facility	6, 9, 1, 13	This is the facility where the patient was born			O,O,O,O	
Last Update Time/Date	6, 9, 1, 13				O,O,O,O	Required for matching



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Data Element	Data Requirement (Query & Response, Vaccination, Demographic, Consumer Vaccination View)	Definition	Data Type	Data Requirement Standards	Required	Comments
Last Update Facility	6, 9, 1, 13				0,0,0,0	Required for matching
PARENT IDENTIFIERS						
Mother's Name: First, Middle, Last	6, 9, 1, 13	The current, assumed legal name of the patient's mother			R2,R2,R2, R2	(Desirable, but not mandatory elements)
Mother's Maiden Name (not always available in an EHR-s)	6, 9, 1, 13	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			R2,R2,R2, R2	
Mother's SSN	6, 9, 1, 13	This is a number is assigned by the Social Security Administration			0,0,0,0	
Father's Name: First, Middle, Last	6, 9, 1, 13	The current, assumed legal name of the patient's father			0,0,0,0	
Father's SSN	6, 9, 1, 13	This is a number is assigned by the Social Security Administration			0,0,0,0	
ADDITIONAL PATIENT IDENTIFIER DATA ELEMENTS						
Insurance Plan	6, 9, 13	Financial class(es) assigned to the patient to identify sources of reimbursement Immunization registries may use this field to indicate several items: 1) eligibility for the Vaccines For Children (VFC) program; 2) eligibility for state or local reimbursement programs; and 3) type of insurance plan (e.g., Medicaid, HMO, self pay, etc.)	Coded	HL7 2.5 Table 0064 - Financial class	0,0,0	
Insurance Company	6, 9, 13	The organization providing health insurance to the patient at the time of the immunization event			0,0,0	
Next of Kin Relationship	6, 9, 13	This field defines the personal relationship of the next of kin	Coded	HL7 2.5 Table 0063 - Relationship	0,0,0	



Data Element	Data Requirement (Query & Response, Vaccination, Demographic, Consumer Vaccination View)	Definition	Data Type	Data Requirement Standards	Required	Comments
Next of Kin Address	6, 9, 13	This field lists the mailing address of the next of kin/associated party			0,0,0	
Next of Kin Telephone	6, 9, 13	The next of kin/associated party's personal phone numbers			0,0,0	
Next of Kin DOB	6, 9, 13	This field contains the next of kin/associated party's date of birth			0,0,0	

Table 2.2.2-4 Clinical Data Elements

Data Element	Data Requirement (Vaccination, Demographic, Query & Response)	Definition	Data Type	Data Requirement Standards	Required	Comments
IMMUNIZATION EVENT (Vaccination content only – not for matching or look-up)						
Immunization Event Identifier	6, 1, 13				R,R,R	
Vaccine Expiration Date	6, 1, 13	This is the date after which the vaccine/batch must not be use			0,0,0	
Vaccine Injection Site	6, 1, 13	This is the site on the patient where vaccine is administered	Coded	HL7 2.5 Table 0163 - Administrative site	0,0,0	
Vaccination Date	6, 1, 13	This is the date and time of an event			R,R,R	
Vaccine Lot Number	6, 1, 13	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,R,R	



Data Element	Data Requirement (Vaccination, Demographic, Query & Response)	Definition	Data Type	Data Requirement Standards	Required	Comments
Vaccine Administration Provider	6, 1, 13	This field is intended to contain the name and provider ID of the person physically administering the pharmaceutical			O,O,O	Communicate person administering the vaccine
Vaccine Administration Facility	6, 1, 13	Name and address of facility where medical substance was administered			O,O,O	Communicate Facility Name and/or Location
Vaccine Type	6, 1, 13	Code indicating which vaccine is being recorded		Use HL7-defined Table 0292 – Vaccines Administered (code=CVX) found in Appendix NOTE: Though CVX code is the standard for many, some registries use CPT codes. Other codes should be mapped to the interoperability standard code	R,R,R	



Data Element	Data Requirement (Vaccination, Demographic, Query & Response)	Definition	Data Type	Data Requirement Standards	Required	Comments
Vaccine Manufacturer	6, 1, 13	<p>This shows the manufacturer of the vaccine administered to the patient in the immunization event.</p> <p>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</p>		Use HL7-defined Table 0227 – Manufacturers of vaccines (code=MVX) found in Appendix 1	R,R,R	



Data Element	Data Requirement (Vaccination, Demographic, Query & Response)	Definition	Data Type	Data Requirement Standards	Required	Comments
Vaccine Dose Number	6, 1	This is the dose number of a vaccine, or a combination vaccine			O,O	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;
Historical Vaccination Flag Indicator	6, 1, 13	Indicates that an event represents either a current or a historical immunization		Use HL7 Table NIP001	R,R,R	NOTE: We use a more general notion of "Immunization source" which includes historical versus current. The CDC- maintained table has more choices.
VFC Eligibility	6, 1, 13	Indicates a class or category of payment method for immunization services provided. This is allowed to repeat.			R,R,R	
Reason for Non- Vaccination	6, 1, 13	To express concepts such as history of varicella disease indicator			O,O,O	
Patient Status in the Immunization Home	6, 1	Indication of the current status of the patient		Include active, inactive, MOGE, and other classifications Table 0441 HL7 User Defined table	O,O	



Data Element	Data Requirement (Vaccination, Demographic, Query & Response)	Definition	Data Type	Data Requirement Standards	Required	Comments
Immunization Information Source	6, 1	Indication of the source of the immunization information communicated (e.g. PHR, HIE, EMR)			0,0	
Amount Administered (dosage amount):	6, 1	This field records the amount of pharmaceutical administered			0,0	
Take Response Observation:	6, 1	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			0,0	
Read Date for Take Response	6, 1	Date the take response was read or observed	Timestamp		0,0	
ADDITIONAL VACCINATION DATA ELEMENTS						
Treatment Route	6, 1, 13	Route by which the vaccine is administered to the patient (only selected values listed)	Coded	HL7 2.5 Table 0162 - Route of administration	0,0,0	
Refusal Reason	6, 1, 13	This indicates the reason the patient or parent refused the vaccine	Coded	NIP002 - Substance refusal reason	0,0,0	



Data Element	Data Requirement (Vaccination, Demographic, Query & Response)	Definition	Data Type	Data Requirement Standards	Required	Comments
Action Code	6, 1	This indicates whether the message is related to a new event, modification of a previously submitted event	Coded	HL7 2.3 Table 0323	0,0	Used to differentiate from add or delete
Vaccine Dose Valid Flag	6, 1	Indicates that a dose administered is considered valid based on the immunization schedule active in the IIS		Y/N	0,0	
Immunization Recommendations	6, 1, 13	Indicates vaccines recommended for patient based on the patient's history and immunization schedule active in the IIS			0,0,0	This is to support clinical decision support

2.2.3 IDENTIFICATION OF BUSINESS ACTORS, AND SCENARIOS

This section describes the business actors that impact interoperability requirements for each scenario. A HITSP business actor should generally be an IT system that is directly engaged, and benefits from the real world information interchange defined within a business Use Case action. A business actor may also be a person or organization, however, only IT systems have associated technical actors (see Section 3.2 for technical actors). The table below identifies the significant Use Case business actors, their descriptions and the Use Case scenarios in which they are used.



Table 2.2.3-1 Business Actors

Business Actor	Description	Use Case Scenario
Distributor (Public and Private Sector Supply Chain, Inventory Managers)	Organizations managing the distribution of supplies. For the Immunizations and Response Management Use Case, those responsible for vaccines and associated supplies. 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
Clinical Information System (or HIS, EHR-S) (Healthcare Delivery Organizations, Ancillary Entities, Clinicians, Pharmacies) [Care Delivery Actor]	Information system supporting the clinical care and information management for organizations such as hospitals and physician practices that manage the delivery of care. They may also include institutional providers of healthcare such as ambulatory care and public health department immunization clinics providing quality data for measure	Vaccine and Drug Administration and Reporting Vaccine and Drug Inventory Reporting
Personal Health Record (PHR) Service Provider	The organization that supplies the Personal Health Record (PHR), a secure, real-time, point-of-care, person-centric information resource, for consumers	Vaccine and Drug Administration and Reporting
Information Exchange (RHIO/HIE)	An Information Exchange is a multi-stakeholder organization 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. (Optional)	Vaccine and Drug Administration and Reporting Vaccine and Drug Inventory Reporting
Public Health Agencies (local/state/federal) (Message Receiver/ Bio Data Receiver, Document Consumer)	Local, state, and federal government organizations and personnel that exist 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 BIS 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	Vaccine and Drug Administration and Reporting Vaccine and Drug Inventory Reporting



Business Actor	Description	Use Case Scenario
Emergency Operations Center (Biosurveillance System)	Local, state, and federal government organizations and personnel that exist 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	Vaccine and Drug Administration and Reporting Vaccine and Drug Inventory Reporting

2.2.4 HIGH-LEVEL UML BUSINESS SEQUENCE DIAGRAM

This section contains an explanation of the relationship between the business actors and data interactions between the primary actors and alternative actors for each Use Case scenario. The Unified Modeling Language (UML) diagrams that follow illustrate each scenario with a representation of a normal sequence of exchange between the primary actors.



Figure 2.2.4-1 Immunizations and Response Management (IRM) Business Sequence – Part 1

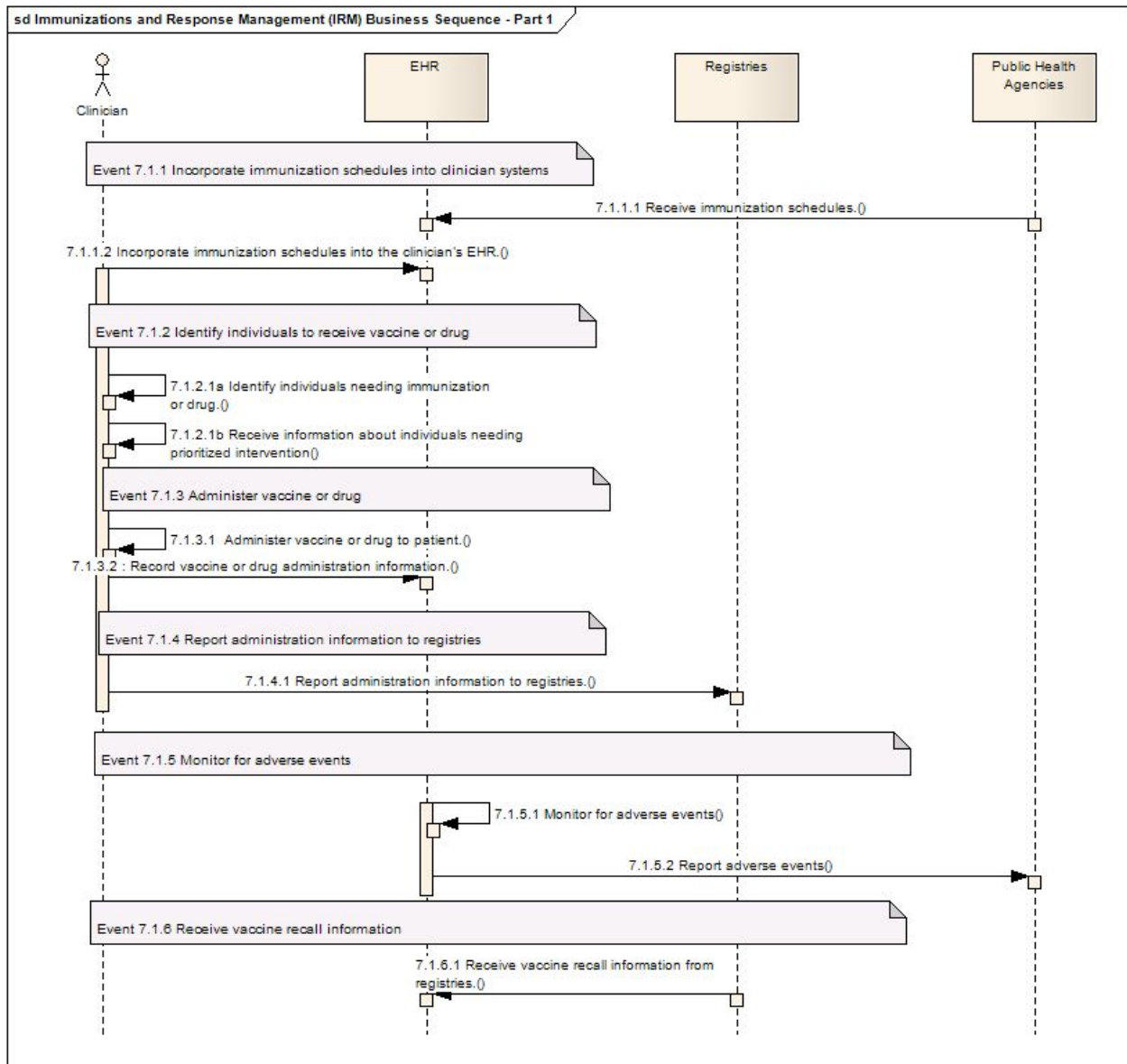


Figure 2.2.4-1 Immunizations and Response Management (IRM) Business Sequence – Part 2

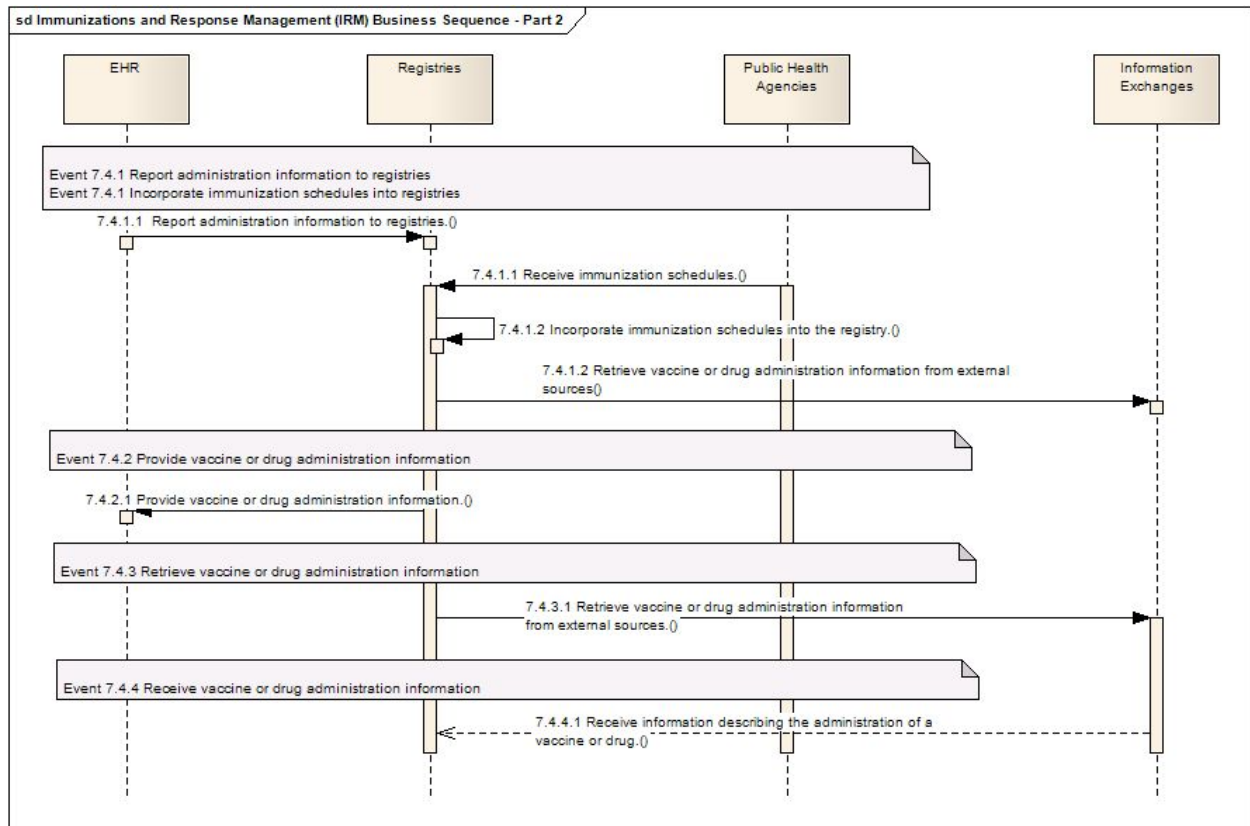


Figure 2.2.4-1 Immunizations and Response Management (IRM) Business Sequence – Part 3

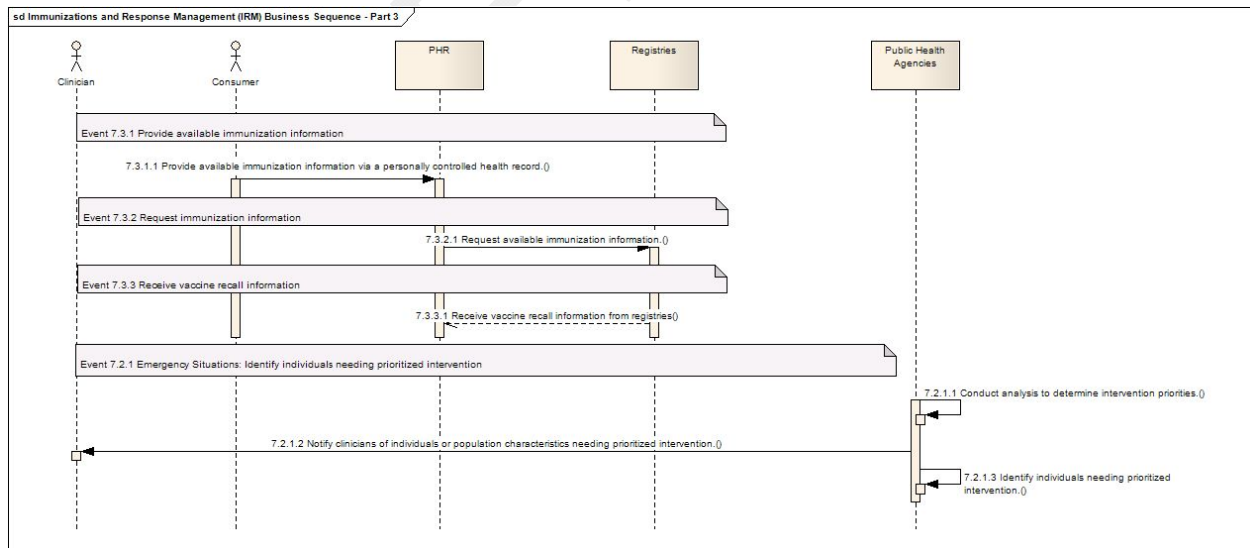
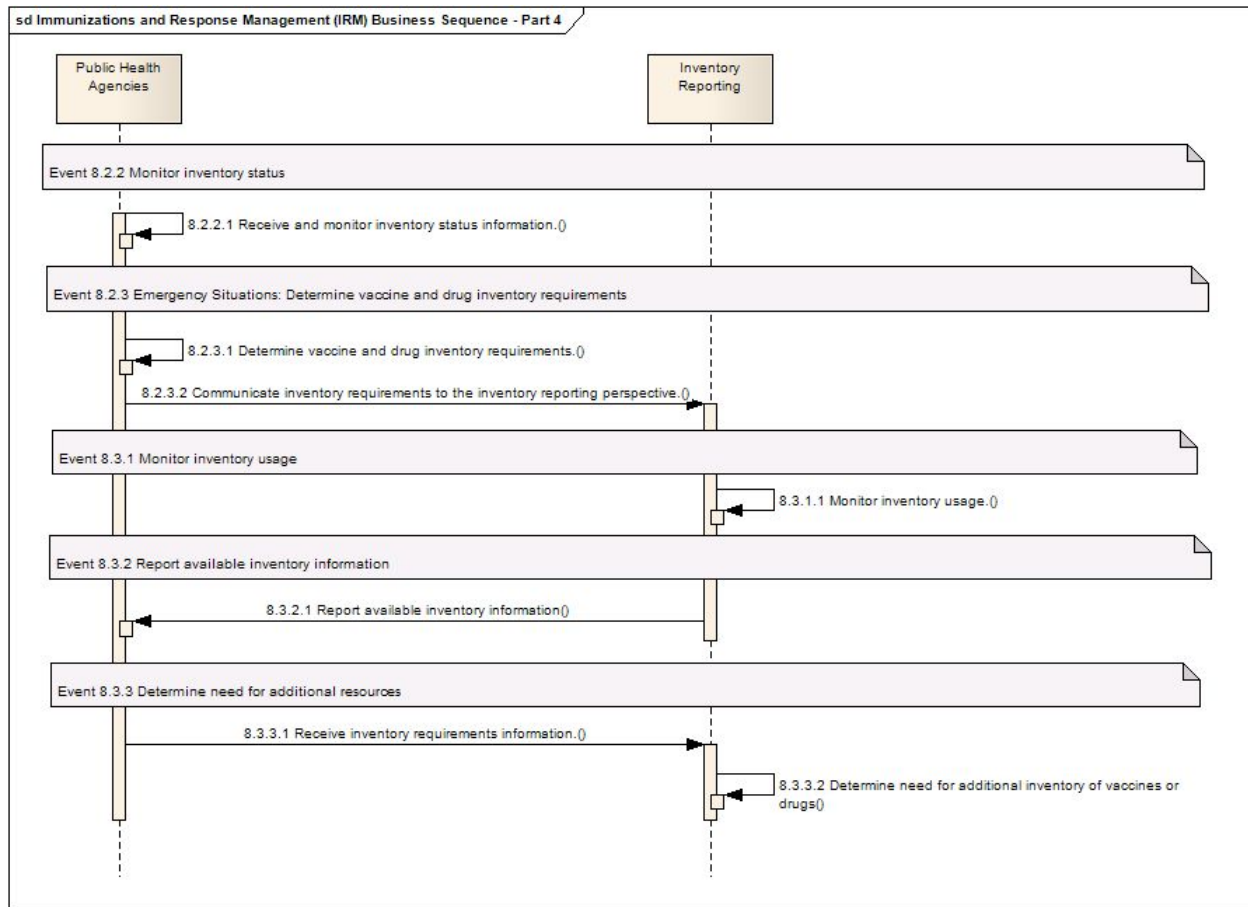


Figure 2.2.4-1 Immunizations and Response Management (IRM) Business Sequence – Part 4



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 events and actions of the design from the specified requirements. It also provides a detailed mapping of the specified requirements to the business and technical actors, and data elements. Groupings of specific actions and actors are illustrated to further describe the relevant interactions as 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 specification and 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 support methodologies are specified to support identification of communication recipients for alerts and notifications not containing 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 Population Health Perspective Committee to complete the analysis and Interoperability Specification development for the final Immunizations and Response Management Use Case.



The Population Perspective Technical Committee plans a multi-release approach, with each 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
- Establish Transaction Packages to 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
- Include Security and Privacy constraints for implementation of the Immunizations and Response Management Interoperability Specifications

Release 2:

This second release will address the following gaps identified by the HITSP Population Health 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 will specify Release 2:

NOTE: any deferrals and scoping in the development of the PHCR RDSS/IS will directly impact the ability to fulfill the Adverse Event Report requirement of this Use Case.

Table 3.1-1 Scenario 1 Scope

Activity	Topic	Scoped to:	Reason for Deferral	Requirement
Immunizations	Immunization Schedule Content	Year 2	Immature, standards in progress; Pending development of Clinical Decision Support construct	
	Update Information to Immunization Registry (vaccination)	Year 1 (see discussion)	NA	
	Immunization Query and Response	Year 1 (see discussion)	NA	



Activity	Topic	Scoped to:	Reason for Deferral	Requirement
	Consumer Vaccination View	Year 1 scoped to HITSP/C32 constraints; Year 2 add immunization-focused CDA support pending SDO progress	Interim, but not optimal solutions are available with HITSP/C32 already identified by HITSP for consumer-focused communications. HITSP/C32 is lacking sufficient detail which would be addressed through immunization-domain focused standard view. The Population Perspective TC expects to replace HITSP/C32 with SDO-generated immunization-focused standard with vocabulary constraints once available.	6 Vaccination 13 Consumer Vaccination View
	Vaccination Document	Year 2	Deferred pending HL7 work	6 Vaccination
Adverse Event Report (Overlap with Public Health Reporting)	FDA – MedWatch, Vaccine Reporting (VAERS)	Year 1 (see PHCR RDSS 61)	Scope dependent upon AHIC PHCR Use Case	
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	3 Supply Chain Management Inventory Management
	Vaccine Recall Joint with FDA/CDC – standards known			4 Supply Chain Management Vaccine Recall
Clinical Decision Support Content	Content (Immunization Schedules, Immunization Reminders, Immunization Prioritization)	Year 2	Pending further detail from CMHR DTC	5 Clinical Decision Support Content (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 Structured component efforts deferred	NA	
Unstructured Document Component	Content, Transport	Year 1 Structured component efforts deferred pending CDS	Pending CDS decision for Immunization prioritization	
Medication Administration	Support capture and management of CRA data	Deferred	Pending further Use Case specificity and workflow analysis	7 Medication Administration
Identify Communication Recipients	Support communication of non-PHI alerts and notifications	Year 1		



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Activity	Topic	Scoped to:	Reason for Deferral	Requirement
Terminology Services	Support translation to standard terminologies/vocabularies	Year 1		

Prioritization Notification:

Year 1 scope is limited to use of the Unstructured Document Component for patient identifiable communications and use of Generic Alert to identified providers with HITSP/T64 - Identify Communication Recipients (Service) for non-patient identifiable communications. 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 RDSS/IS will allow for migration options to enable current legacy installations Immunization Registry 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 pending Gap fulfillment under way with the SDO specification of HL7 Immunization CDA documents. Until such documents are specified, support for HITSP/TP13 - Manage Sharing of Documents will utilize HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) as constrained by this RDSS/IS. This will allow for implementation of Use Case requirements for PHR communications conformant with HITSP specifications for Consumer Empowerment related Use Cases. It is important, however, to recognize that HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) is insufficient to fully support the IRM Use Case requirements, and may further be misleading to the consumer in the absence of sufficient notification of these shortcomings. HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) can provide a quick view for the parent of the child's immunization history, but the information currently in HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) does not fully meet these needs. Once there is a standard Immunization CDA available to fulfill clinical, parental, and school views, the HITSP IRM Interoperability Specification will replace the HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) specification with the more tailored immunization CDA document(s) expressed as HITSP constructs.



Similarly, HITSP/TP21 - Query for Existing Data are intended for provisional acceptance. It is already recognized in the industry that the HL7 2.3.1 message used today needs to be updated. The targeted update is to the HL7 2.5.1 message. The industry would also like to move to web services. The Query/Response Transaction Package 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 from ONC as to alignment with CRA requirements and to better clarify 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 Finance Domain Technical Committee a plan to address the deferred scenario 2 RDSS/IS efforts:

1. Request further clarification of workflows and business actor responsibilities for scenario 2 from AHIC
2. TC Recruits and convenes the experts in this area
 - a. Call for participation will be sent to:
 - i. CDC countermeasure/Business inventory standards experts
 1. HC 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 CRA 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:
 - 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



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:</p> <p>Assumption: for scenario 1, assume that references to drugs is referring 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 VFC</p>	Vaccine and Drug Administration and Reporting
<p>General:</p> <p>adult immunization handling may be different throughout the Use Case (e.g., some immunization registries will not accept adult immunizations)</p>	<p>Vaccine and Drug Administration and Reporting</p> <p>Vaccine and Drug Inventory Reporting</p>
7.1.1.1 Schedule is received into clinician EHR system	Vaccine and Drug Administration and Reporting
<p>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</p> <p>CCHIT will at some point check for this</p>	Vaccine and Drug Administration and Reporting
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
7.1.2.1a Each immunization registry is presumed to have access to a complete immunization hx for the patient – clinician may be able to query the registry	Vaccine and Drug Administration and Reporting
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
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 of the schedule that the clinician chose to implement in the EHR)	Vaccine and Drug Administration and Reporting
7.1.4.1 The registry may or may not be the same for routine vs emergency reporting. – business actor	Vaccine and Drug Administration and Reporting
7.1.6.1 It looks like this is the text for the consumer perspective – assume the clinician is notified of the recall; - too much detail missing from the clinician perspective	Vaccine and Drug Administration and Reporting
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 supply chain data are captured by vaccination detail	Vaccine and Drug Administration and Reporting
7.3.1.1 Need to capture from PHR as well as through other means	Vaccine and Drug Administration and Reporting



Assumption	Use Case Scenario
7.3.1.1 PHR document source or consumer may be a portal service - not necessarily a PHR	Vaccine and Drug Administration and Reporting
7.3.3.1 IIS MAY ID individual consumers and registry notifies consumer, bypassing clinician. Policy issues; - communities may make a choice as to where this information flows	Vaccine and Drug Administration and Reporting
7.3.3.1 Communications of notifications to consumer may be by mail, email, PHR, or via clinician	Vaccine and Drug Administration and Reporting
7.4.1.1 Supply chain includes manufacturer of immunization	Vaccine and Drug Administration and Reporting
7.4.1.1 IIS is a source of this information	Vaccine and Drug Administration and Reporting
7.4.2.1 Policies permit school health records to be made available to registry	Vaccine and Drug Administration and Reporting
7.4.2.1, 9.4 Data quality considerations are scoped to edge server systems See standards for data quality checks – CDC/AIRA best practice in quality MIROW Need to verify that the data needed for those quality checks exists	Vaccine and Drug Administration and Reporting
7.4.3.1 Policy considerations – today is 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
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 NYC model)	Vaccine and Drug Inventory Reporting
8.2.2.1 The Use Case is setting PH up to determine the requirements for vaccine supply. Seems the sharing of provider inventory may be a business concern and intrusive	Vaccine and Drug Inventory Reporting
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
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
8.3.1.1 Policy appropriately defines the role of this group	Vaccine and Drug Inventory Reporting
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
9.6 Policy is in place that permits sharing : NOTE: Katrina example – lose ability to communicate basic PH situation – cross-state considerations for policy – legal barriers to transferring information across state lines Event was an emergency – 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

3.1.2 CONSTRAINTS

This section describes the constraints that limit the use of the Requirements and Design, or to which the design must conform in order to be used within the described context. 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 scenario. 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 Use Case scenario.

Table 3.1.2-1 Constraints

Constraint	Use Case Scenario
HITSP/T17 - Secure 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: Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS) Vaccination Medication Administration 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: Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS) Vaccination Medication Administration Unstructured Document Component	1 and 2
The policy of the implementation environment MAY require HITSP/C19 - Entity Identity Assertion	1 and 2
The policy of the implementation environment MAY require HITSP/C25 - Anonymize 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) be implemented for document information source initiating a HITSP Transaction with a payload of: Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS) Vaccination Medication Administration Unstructured Document Component	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 WILL require the HITSP/TP30 - Manage Consent Directives wherever access to IIHI is required	1 and 2



Constraint	Use Case Scenario
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

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
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
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 security and privacy	All
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 – Provide assertion HITSP/T16 Consistent Time – Maintain time HITSP/T17 Secure Communication Channel – Authenticate node HITSP/T15 Collect and Communicate Security Audit Trail – Record audit event in repository HITSP/TP30 Manage Consent Directive – Capture/Request consent directive HITSP/TP20 Access Control – Access control request	All
All pre-conditions from the lower level constructs are incorporated	All



Pre-condition	Use Case Scenario
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 Registry Check 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 use the data to assess VFC and programmatic compliance	1,2
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
<p>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)</p> <ul style="list-style-type: none"> New immunization schedule is announced and received 	1 Vaccine and Drug Administration and Reporting
<p>Use Case Scenario 1 Flow 2: Registries, including IISs, provide immunization information to clinicians, consumers, other registries and other organizations (from Use Case)</p> <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



Process Trigger	Use Case Scenario
<p>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)</p> <ul style="list-style-type: none"> • A vaccine has been administered (see item 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
<p>Use Case Scenario 1 Flow 4: Consumers provide available immunization information to clinicians (from Use Case)</p> <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
<p>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)</p> <ul style="list-style-type: none"> • Vaccination has been administered or attempted to be administered 	1 Vaccine and Drug Administration and Reporting
<p>Use Case Scenario 1 Flow 6: Public health gathers information to identify individuals needing prioritized intervention (from Use Case)</p> <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
<p>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)</p> <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
<p>Use Case Scenario 1 Flow 8: Registries provide information about vaccine recalls to clinicians and affected consumers (from Use Case)</p> <ul style="list-style-type: none"> • A vaccine is recalled 	1 Vaccine and Drug Administration and Reporting
<p>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)</p> <ul style="list-style-type: none"> • A vaccine is given 	2 Vaccine and Drug Inventory Reporting



Process Trigger	Use Case Scenario
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 will provide 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 planned constructs used to meet the business and technical requirements for this Use Case. Opportunities for reuse of existing HITSP constructs are outlined, along with a description of any necessary updates to existing constructs. Any variances in the security and privacy implementation are also described here.

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 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 (See TN900 for a discussion on the challenges with PKIs).

Immunization Feed Package

- Option 1 - Use just HL7 VXU from the message sender (clinician system) to the message receiver (immunization registry)
- Option 2 - If the HIE offers a PIX manager, the clinician system may first query the PIX manager and populate the patient identifier in the HL7 VXU message with the HIE domain identifier
- Option 3 – From the PHR, a document can be communicated as a shared document to a document repository or sent to the immunization registry using document reliable interchange (HITSP/T31) or via media (HITSP/T33). In the future, this document is expected to be optimized through ongoing HL7 efforts for Immunization. In the interim, the PHR could provisionally use HITSP/C32
- Option 4 – Once there is a fully specified CDA document for Immunizations conformant with the data requirements of this document, the document can be communicated as a shared document to a document repository or sent to the immunization registry using document reliable interchange



(HITSP/T31) or via media (HITSP/T33). The Immunization registry may retrieve the document from the document repository or from another jurisdiction document repository for cross-jurisdiction information sharing. As current immunization registries are not configured with these capabilities, this is a forward looking option

Immunization Query and Response Transaction Package

- Option 1 – Use the traditional HL7 VXQ to send a query from the message sender (clinician system) to the message receiver (immunization registry) and the HL7 VXR to send the result of the query from the message sender (immunization registry) to the message receiver (clinician system)
- Option 2 – If the HIE offers a PIX manager, the clinician system may first query the PIX manager and populate the patient identifier in the HL7 VXQ message with the HIE domain identifier and in the resulting VXR message. NOTE: policy would need to assert query result policies in PDQ as currently specified for VXR
- Option 3 - Use Query for existing data (HITSP/TP21) to request and receive immunization data; this may be preceded by a PIX/PDQ to 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 query/retrieve to gather immunization data. NOTE: The result of the HITSP/TP13 query may be a document generated dynamically or a persisted document (Unstructured document component containing summary or patient-specific immunization alert, HITSP/C32 in the interim or future HL7 construct)

Immunization Alert Functionality

For notification of immunization requirements, there are two types of communications:

- Option 1 – 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), the communication recipients are identified using the 'identify communication recipients' construct, and the generic alert is sent to those providers leveraging the 'Generic Alert to Identified Providers' construct. The communication itself may be conducted using email, health alert network, or other communication mechanisms left unspecified by this RDSS
- Option 2 – Where the alert is patient-specific in nature, the notification of document availability 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 component' which will contain the immunization notification alert and instructions for the clinician or patient

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 implement real world business actor information interchanges (see Section 2.2.3). The table below identifies the technical actors and gives 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
Audit Record Repository	This actor provides a repository for audit events.
Audit Record Source	The actor that, on behalf of another actor that performs an action requiring logging, creates and communicates an Audit Record to the Audit Record Repository
Clinical Data Consumer	A clinical data consumer makes use of clinical patient data
Consent Directive Requestor	Accesses consent directive located through a Consent Registry from Consent Repositories (lack of definition in current public comment version)
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
Consent Registry	Responsible for providing location information and sender notification regarding consent directives. The Consent Registry receives a Manage Consent Directive Metadata Request
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
Content Consumer	Responsible for viewing, import, or other processing of content created by a Content Creator Actor
Content Creator	Responsible for the creation of content and transmission to a Content Consumer
Directory Consumer	The Directory Consumer queries the Directory Service to obtain contact and communications information for healthcare related entities, their employees, and clinicians
Directory Service	The Directory Service actor is responsible for creating, maintaining, and providing contact and communications information for healthcare related entities, their employees, and clinicians
Document Consumer	The Document Consumer queries a Document Registry for documents meeting certain criteria, and retrieves selected documents from one or more Document Repository actors
Document Recipient	Document message recipient for point-to-point document communication (e.g., for measures, pre-release reports, etc)
Document Registry	The 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
Document Repository	The Document Repository is responsible for the persistent storage of documents and for their registration with the appropriate Document Registry. It assigns a URI to documents for subsequent retrieval by a Document Consumer.
Document Source	The Document Source is the producer and publisher of documents and information. It is responsible for sending documents to a Document Repository. It also supplies metadata to the Document Repository for subsequent registration of the documents with the Document Registry Actor. Also used for point-to-point document exchanges
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)
Immunizations Data Repository	Maintains patient immunization data



Technical Actor(s)	Actor Role
Medications Data Repository	A Medications Data Repository maintains patient medication data
Message Receiver	Supports message-based communications (e.g. for measures, pre-release reports, etc)
Message Sender	Supports message-based information source
Node	The originating or terminating point of information or signal flow in a telecommunications network. This actor is equivalent to the <i>Secure Node</i> in the IHE ATNA Transaction
Notification Receiver	Receives notifications of availability for documents in an XDS registry, and may optionally send acknowledgments of them
Notification Sender	Sends notifications of availability for documents in an XDS registry, and receives acknowledgments of these notifications
Patient Demographics Consumer	The Patient Demographics Consumer queries the Patient Demographics Supplier to obtain patient demographic data. It may receive matches for one or more patients that enable the selection of the desired patient. For Quality, used for identification of patient historical information for the patient level quality data. For Quality, used for identification of patient historical information for the patient level quality data
Patient Demographics Supplier	The Patient Demographics Supplier receives patient registration and update messages from other systems in the enterprise (e.g., ADT Patient Registration or Health Plan Membership Management systems), which may or may not represent different Patient ID Domains. It responds to queries for information
Patient Identifier Cross-Reference Consumer	The Patient Identifier Cross-Reference Consumer either queries for sets of cross-reference patient identifiers. It may also receive notifications about cross-reference changes. For Quality, used for identification of patient historical information for the patient level quality data
Patient Identity Source	Sends patient demographic information to the Patient Identifier Cross-Reference Manager. For Quality, used for identification of patient historical information for the patient level quality data
Person Identification Service	Manages identity resolution for persons in support of pseudonymization
PIX Manager	The Patient Identifier Cross-Reference Manager Actor is responsible for creating, maintaining and providing lists of identifiers that are aliases of one another across different Patient Identifier Domains
Portable Media Creator	The Portable Media Creator writes the selected information from a consumer's PHR to media following the directory structure outlined by XDM
Portable Media Importer	The Portable Media Importer processes all the contents written by a Portable Media Creator on the physical media. The Portable Media Importer must successfully process all documents
Pseudonymization Service	Supplier of alternative identification information that permits a patient to be referred to by a key that suppresses his/her actual identification information
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
Service Provider (SP)	The information resource, representing the information repositories and all capabilities that receive, process and fulfill authorized requests. The SP includes any local access decision and enforcement components that are part of the distributed capabilities
Service Provider Access Control Service (SP ACS)	Supports and implements the service-side access control capabilities. This is a service provider actor
Service User	The entity 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
Time Client	Establishes time synchronization with one or more Time Servers using the NTP protocol and either the NTP or SNTP algorithms. Maintains the local computer system clock synchronization with UTC based on synchronization with the Time Servers



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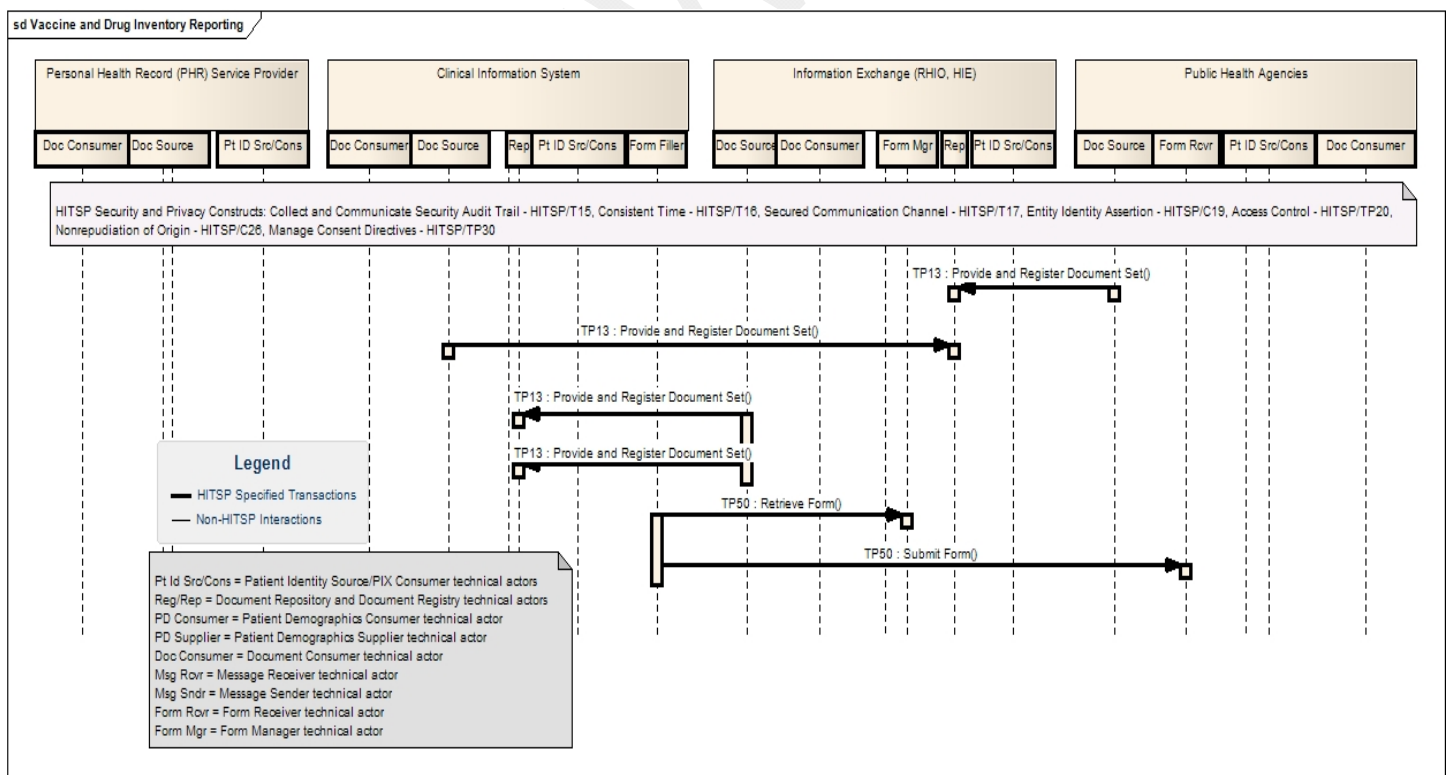
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Technical Actor(s)	Actor Role
Time Server	Provides NTP time services to Time Clients. It is either directly synchronized to a UTC master clock (e.g. satellite time signal) or is synchronized by being grouped with a Time Client to other Time Server(s)
User	The entity that takes on the actor role of initiator or claimant. This is an initiator actor
User Access Control Service (UACS)	The enterprise security service that supports and implements user-side access control capabilities. This is an initiator actor
Value Set Consumer	An actor who retrieves a specific new or updated Value Sets based on its OID
Value Set Repository	An actor whose role is to store the brand new or updated Value Sets

3.2.2 SEQUENCE DIAGRAM FOR PROCESS FLOW

This section incorporates the comprehensive business and technical requirements and a detailed analysis of the interactions and decisions undertaken for the primary actions in each Use Case scenario. The UML sequence diagrams used in this section incorporates 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 HITSP constructs). The detailed actor Transactions described in these diagrams show all common or independent actors, data, and the actual transactions from the HITSP constructs that are used for the Interoperability Specification.

Transactions that make use of existing HITSP constructs are shown explicitly, indicating opportunities for reuse.



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

The table below maps the individual business 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 to each business actor in the Interoperability Specification. For each implemented business actor, the table specifies:

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

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*
Personal Health Record (PHR) Service Provider	Patient Identity Source	C[101]	HITSP/T23	Patient Demographics Query	R
	PIX Consumer	C[101]	HITSP/TP22	PIX Identity Feed	R
				PIX Query	R
	Document Source	C[103] C[105]	HITSP/TP13	Provide & Register Document Set	R
	Document Consumer	C[103] C[106]	HITSP/TP13	Query Registry	R
				Retrieve Documents	R
	Content Creator	R	HITSP/C32	Creator-Registration Subset (see Section 3.2.3.1)	R
				Creator-Registration-Coded Subset (see Section 3.2.3.2)	R
				Creator-Medication and Immunization History Subset (see Section 3.2.3.3)	R
				Creator-Medication and Immunization History - Coded Subset (see Section 3.2.3.4)	R
		R	HITSP/TP30	Consent Document	R
		C[108]	HITSP/T24	Pseudonymization Request	R
		C[109]	HITSP/C25	Anonymize	R
	Content Consumer	R	HITSP/C32	Consumer-Document Display Subset (see Section 3.2.3.9)	R



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
				Consumer-Document Import Subset (see Section 3.2.3.10)	O
				Consumer-Registration Discrete Data Import Subset (see Section 3.2.3.11)	O
				Consumer-Medication and Immunization History Discrete Data Import Subset (see Section 3.2.3.12)	O
		R	HITSP/TP30	Consent Document	R
		O	HITSP/C62	Unstructured Document	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[110] C[105]	HITSP/T31	Provide & Register Document Set.b (online mode)	R
				Provide & Register Document Set (offline mode)	R
	Document Recipient	C[110] C[106]	HITSP/T31	Provide & Register Document Set.b (online mode)	R
				Provide & Register Document Set (offline mode)	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
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Service provider	C[103]	HITSP/C19	Convey 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
	User	R	HITSP/TP20	Access Control Request	O



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Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	User Access Control Service (UACS)	R	HITSP/TP20	Access Control Request	O
	Service Provider (SP)	C[102]	HITSP/TP20	Access Control Request	O
	Service Provider Access Control Service (SP ACS)	C[102]	HITSP/TP20	Access Control Request	O
Clinical Information System (or HIS, EHR-S) (Healthcare Delivery Organizations, Ancillary Entities, Clinicians, Pharmacies) [Care Delivery Actor]	Patient Identity Source	C[101]	HITSP/T23	Patient Demographics Query	R
	PIX Consumer	C[101]	HITSP/TP22	PIX Identity Feed	R
				PIX Query	R
	Message Sender	C[104]	HITSP/C72	Vaccination Message	R
		C[105]	HITSP/TP70	Vaccination Query Message	R
	Message Receiver	C[104]	HITSP/C72	Vaccination Message	R
		C[106]	HITSP/TP70	Vaccination Query 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)	[C201]
				Provide & Register Document Set (offline mode)	[C201]
	Document Recipient	C[103] C[106]	HITSP/T31	Provide & Register Document Set.b (online mode)	[C201]
				Provide & Register Document Set (offline mode)	[C201]
	Clinical Data Consumer	C[107]	HITSP/TP70	Query Immunizations	C[201]
		C[107]	HITSP/TP70	Vaccination Query Message (VXQ/VXR)	C[201]
	Content Creator	R	HITSP/C32	Creator-Registration Subset (see Section 3.2.3.1)	R
				Creator-Registration-Coded Subset (see Section 3.2.3.2)	R
				Creator-Medication and Immunization History Subset (see Section 3.2.3.3)	R
				Creator-Medication and Immunization History - Coded Subset (see Section 3.2.3.4)	R
		R	HITSP/TP30	Consent Document	R
		R	HITSP/C72	Vaccination Message	R
		R	HITSP/C62	Unstructured Document	O
		O	HITSP/C35	Lab Result Terminology	R
		O	HITSP/C36	Lab Result Message	R
		C[108]	HITSP/T24	Pseudonymization Request	R
		C[109]	HITSP/C25	Anonymize	R



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Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	Content Consumer	R	HITSP/C32	Consumer-Document Display Subset (see Section 3.2.3.9)	R
				Consumer-Document Import Subset (see Section 3.2.3.10)	O
				Consumer-Registration Discrete Data Import Subset (see Section 3.2.3.11)	O
				Consumer-Medication and Immunization History Discrete Data Import Subset (see Section 3.2.3.12)	O
		R	HITSP/TP30	Consent Document	R
		C[108]	HITSP/T24	Pseudonymization Request	R
		C[109]	HITSP/C25	Anonymize	R
		R	HITSP/C62	Unstructured Document	O
	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
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Service provider	C[103]	HITSP/C19	Convey 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
	User	R	HITSP/TP20	Access Control Request	O
	User Access Control Service (UACS)	R	HITSP/TP20	Access Control Request	O
	Service Provider (SP)	C[102]	HITSP/TP20	Access Control Request	O
	Service Provider Access Control Service (SP ACS)	C[102]	HITSP/TP20	Access Control Request	O
Information	Patient Identity Source	C[101]	HITSP/T23	Patient Demographics Query	R



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Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
Exchange (RHIO/HIE)	PIX Consumer	C[101]	HITSP/TP22	PIX Identity Feed	R
				PIX Query	R
	Message Sender	C[104] C[105]	HITSP/C72	Vaccination Message	R
			HITSP/TP70	Vaccination Query Message	
				Receive Acknowledgements	R
	Message Receiver	C[104] C[106]	HITSP/C72	Vaccination Message	R
			HITSP/TP70	Vaccination Query Message	
				Send Acknowledgements	R
	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
	Document Consumer	R	HITSP/TP13	Query Registry	R
				Retrieve Documents	R
	Content Creator	R	HITSP/C32	Creator-Registration Subset (See Section 3.2.3.1)	R
				Creator-Registration-Coded Subset (see Section 3.2.3.2)	R
				Creator-Medication and Immunization History Subset (see Section 3.2.3.3)	R
				Creator-Medication and Immunization History - Coded Subset (see Section 3.2.3.4)	R
		R	HITSP/TP30	Consent Document	R
		R	HITSP/C62	Unstructured Document	O
	Content Consumer	R	HITSP/C32	Consumer-Document Display Subset (see Section 3.2.3.9)	R
				Consumer-Document Import Subset (see Section 3.2.3.10)	O
				Consumer-Registration Discrete Data Import Subset (see Section 3.2.3.11)	O
				Consumer-Medication and Immunization History Discrete Data Import Subset (see Section 3.2.3.12)	O
				Consumer-Conditions and Allergy Discrete Data Import Subset (see Section 3.2.3.13)	O
				Consumer-Laboratory Discrete Data Import Subset (see Section 3.2.3.14)	O
		R	HITSP/TP30	Consent Document	R
		R	HITSP/C62	Unstructured Document	O
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R



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Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	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
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Service Provider	C[103]	HITSP/C19	Convey 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
	User	R	HITSP/TP20	Access Control Request	O
	User Access Control Service (UACS)	R	HITSP/TP20	Access Control Request	O
	Service Provider (SP)	C[102]	HITSP/TP20	Access Control Request	O
	Service Provider Access Control Service (SP ACS)	C[102]	HITSP/TP20	Access Control Request	O
Public Health Agencies (local/state/federal) (Message Receiver/ Bio Data Receiver, Document Consumer)	Patient Identity Source	C[101]	HITSP/T23	Patient Demographics Query	R
	PIX Consumer	C[101]	HITSP/TP22	PIX Identity Feed	R
				PIX Query	R
	Message Sender	C[104] C[105]	HITSP/C72	Vaccination Message	R
			HITSP/TP70	Vaccination Query Message	R
				Receive Acknowledgements	R
	Message Receiver	C[104] C[106]	HITSP/C72	Vaccination Message	R
			HITSP/TP70	Vaccination Query Message	R
				Send Acknowledgements	R
	Document Source	R	HITSP/TP13	Provide & Register Document Set	R
	Document Consumer	R	HITSP/TP13	Query Registry	R
				Retrieve Documents	R



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Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	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)	[C201]
				Provide & Register Document Set (offline mode)	[C201]
	Document Recipient	C[103] C[106]	HITSP/T31	Provide & Register Document Set.b (online mode)	[C201]
				Provide & Register Document Set (offline mode)	[C201]
	Clinical Data Consumer	C[107]	HITSP/TP70	Query Immunizations	C[201]
		C[107]	HITSP/TP70	Vaccination Query Message (VXQ/VXR)	C[201]
	Content Creator	R	HITSP/C32	Creator-Registration Subset (see Section 3.2.3.1)	R
				Creator-Registration-Coded Subset (see Section 3.2.3.2)	R
				Creator-Medication and Immunization History Subset (see Section 3.2.3.3)	R
				Creator-Medication and Immunization History - Coded Subset (see Section 3.2.3.4)	R
		C[108]	HITSP/T24	Pseudonymization Request	R
		C[109]	HITSP/C25	Anonymize	R
		R	HITSP/C62	Unstructured Document	O
		R	HITSP/TP30	Consent Document	R
		R	HITSP/C62	Unstructured Document	O
	Content Consumer	C[112]	HITSP/C32	Consumer-Document Display Subset (see Section 3.2.3.9)	R
				Consumer-Document Import Subset (see Section 3.2.3.10)	R
				Consumer-Registration Discrete Data Import Subset (see Section 3.2.3.11)	R
				Consumer-Medication and Immunization History Discrete Data Import Subset (see Section 3.2.3.12)	R
		R	HITSP/C35	Lab Result Terminology	R
		R	HITSP/C36	Lab Result Message	R
		R	HITSP/TP30	Consent Document	R
		R	HITSP/C72	Vaccination Message	R
		R	HITSP/C62	Unstructured Document	O
	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



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Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Service Provider	C[103]	HITSP/C19	Convey 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
	User	R	HITSP/TP20	Access Control Request	O
	User Access Control Service (UACS)	R	HITSP/TP20	Access Control Request	O
	Service Provider (SP)	C[102]	HITSP/TP20	Access Control Request	O
	Service Provider Access Control Service (SP ACS)	C[102]	HITSP/TP20	Access Control Request	O
Distributor (Public and Private Sector Supply Chain, Inventory Managers)	Deferred				

***NOTE:** Optionality = “R” for Required, or “O” for Optional, or “C” for Conditional. Conditional footnotes are further described below.

Actor Optionality Conditions

- C[101] - Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer where shared patient identity management interoperability is to be supported
- C[102] – Required if Access Control Request Transaction is not supported
- C[103] – Required when a Document Repository and/or a Document Registry is supported
- C[104] – Required for message-based vaccination query/response (VXQ/VXR) or submissions (VXU)
- C[105] – Business Actor shall support at least one of these technical actors to communicate outbound content
- C[106] – Business Actor shall support at least one of these technical actors to receive or retrieve inbound content



- C[107] – One or both of these are required for vaccination query/response
- C[108] – Required where pseudonymization is required by the jurisdiction or information sharing agreements or selected by PHR
- C[109] – Required where anonymization is required by the jurisdiction or information sharing agreements or selected by PH
- C[110] – Required for Document Reliable Interchange support
- C[111] – Required for Portable Media support
- C[112] – Required where PHR-generated vaccinations are supported for HITSP/C32

Transaction/Content (T/C) Optionality Conditions

- C[201] – The Actor shall support at least one of these transactions

3.2.3.1 HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) “Creator-Registration Subset”

This subset impacts the content of the HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) document produced by a Content Creator technical actor. It requires the Content Creator to have the ability to create the content of the following content modules, with variants as specified in the HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) Construct:

Table 3.2.3.1-1 Creator Registration Subset Content Modules

Content Modules
Person Information
Language Spoken
Support
Healthcare Provider
Insurance Provider
Pregnancy
Information Source
Comments
Advance Directives

Note: HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) Required Modules that are not listed above shall contain “unknown”.

The type of payer and type of payer entries contain the concepts but without the HITSP/C32 specified code set.



3.2.3.2 HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) “Creator-Registration-Coded Subset”

This subset is identical to the Creator-Registration Subset but requires the creation of type of payer and type of payer entries with the HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) specified code set.

3.2.3.3 HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) “Creator-Medication and Immunization History Subset”

This subset impacts the content of the HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) document produced by a Content Creator technical actor. It requires the Content Creator to have the ability to create the content of the following content module, with variants as specified in the HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) construct:

Table 3.2.3.3-1 Creator Medication and Immunization History Subset Content Modules

Content Modules
Person Information
Healthcare Provider
Medications – Prescription and Non-Prescription
Information Source
Comments

Note: HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) Required Modules that are not listed above shall contain “unknown”.

The medication entry may contain the concepts but without an associated code.

3.2.3.4 HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) “Creator-Medication and Immunization History-Coded Subset”

This subset is identical to the Creator-Medication Subset but requires the creation of medication entries with the HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) specified code sets.

3.2.4 DATA DETAIL

This section details the data elements and related Transactions that were extracted from the selected standards and describes any corresponding HITSP imposed constraints (e.g., required or optional).



Table 3.2.4-1 Data Element Constraints

Data Element	Transaction	Constraint	Constraint Type (Pre-condition, post-condition, general)	Purpose (Reason for this constraint)
Patient Multiple Birth Order	Vaccination	Where this data element is not known or not applicable, element shall be populated with 'NA'	General	Support for required value where the value is not applicable or not known
	Demographic Data	Where this data element is not known or not applicable, element shall be populated with 'NA'	General	Support for required value where the value is not applicable or not known
	Query & Response	Where this data element is not known or not applicable, element shall be populated with 'NA'	General	Support for required value where the value is not applicable or not known
	HITSP/TP22	Where this data element is not known or not applicable, element shall be populated with 'NA'	General	Support for required value where the value is not applicable or not known
	HITSP/T23	Where this data element is not known or not applicable, element shall be populated with 'NA'	General	Support for required value where the value is not applicable or not known
	Generic Alert to identified providers	This construct cannot be a targeted communication as this would entail risks of disclosure of PHI	General	Support PHI Protection
HITSP/C32	HITSP/TP13, HITSP/T31, HITSP/T33	Need to provide notification to consumer regarding limitations of HITSP/C32 in representation of immunization history	Pre-condition	Avoid misleading the consumer in interpreting HITSP/C32-based immunization data

3.2.5 NEW HITSP CONSTRUCTS

This section describes the new HITSP constructs (including Interoperability Specifications, Transaction Packages, Transactions and Components) that are expected to be used for the Use Case. A current list of all existing HITSP constructs that are being used can be found in Section 3.2.6.

The table below provides a description of the new HITSP constructs that will be created for this Use Case.



Table 3.2.5-1 New HITSP Constructs

New Construct	Construct Description	Technical Actors	Interoperability or Data Requirement
HITSP/T64 - Identify Communication Recipients (Service)	This infrastructure construct will allow for the identification of communication recipients for the delivery of alerts, and bi-directional communications from public health services	Directory Service Directory Consumer	11 Generic Alert to identified providers 6 Vaccination Supply Chain/Recall (deferred)
HITSP/TP70 - Immunization Query and Response Transaction Package	<p>Immunization Query Package: This Transaction Package will address multiple transaction combinations that may be optionally be used for immunization query and response. This will involve optional use of HITSP/TP21 or VXQ/VXR or</p> <p>PIX/PDQ Query+VXQ/VXR: (NOTE: VXQ returns only if single ID as a matter of policy: in most IIS implementations, by policy it will only return a single match; Would need to assert the same policy on PDQ) or QBP or</p> <p>PIX/PDQ+QBP</p> <p>HITSP/TP13 query/retrieve</p> <p>HITSP/TP13 query/generate dynamic document OR Persistent document (HITSP/C32 or future HL7 construct)</p> <p>NOTE: HITSP/TP21 is intended for provisional acceptance. See Scope statement.</p> <p>NOTE: HITSP/C32: is intended for interim use only pending GAP resolution.</p>	<p>Message Sender Message Receiver Clinical Data Consumer Data Repository, Patient Identity Source, PIX Manager, Patient Identity Consumer, Patient Demographics Consumer, Patient Demographics Supplier, Document Source, Document Consumer, Document Registry, Document Repository</p>	1 Immunization Query and Response



New Construct	Construct Description	Technical Actors	Interoperability or Data Requirement
HITSP/TP71 - Immunization Feed Transaction Package	<p>This Transaction Package will address multiple transaction combinations that may be optionally be used to communicate the vaccination data. This will involve optional use of PIX/PDQ Transactions to pre-identify the patient identifiers interoperable within the domain. It also addresses variations of direct message feeds, or document sharing feeds/imports using HITSP/C32 (until other IIS CDA document is defined by HL7);</p> <p>(HITSP/TP22, HITSP/T23 and Vaccination)</p> <p>HITSP/TP13 Provide and Register - to HIE; IIS Retrieve/Document consumer with import option;</p> <p>HITSP/TP13 Provide and Register - IIS Retrieve; Document consumer optional</p>	<p>Message Sender</p> <p>Message Receiver</p> <p>Patient Identity Source, PIX Manager, Patient Identity Consumer, Patient Demographics Consumer, Patient Demographics Supplier, Document Source, Document Consumer, Document Registry, Document Repository</p>	6 Vaccination
HITSP/C72 - Vaccination Component (part of Immunization Feed TP)	Vaccination message using HL7 VXU;	<p>Content creator</p> <p>Content consumer</p>	6 Vaccination
HITSP/C62 - Unstructured Document Component	<p>Document that contains simple text such as a note to the patient or a note from the patient. This document could include an unstructured, presentation preserved format, such as PDF (only utilizing the presentation preserving capability within the construct)</p> <p>Scanned document with metadata; for this Use Case, can be used for the vaccination camp form summary and for Alerts</p> <p>Requires support for:</p> <p>Individual-Based</p> <p>Consumer communication</p> <p>Clinician communication</p> <p>Patient communication</p> <p>(previously referenced as 'Scanned Document')</p>	<p>Content creator</p> <p>Content consumer</p>	<p>The construct has the following data requirement:</p> <p>Metadata for the payload/image is required</p> <p>6 Vaccination</p> <p>11 Generic Alert to identified providers</p> <p>7 Prioritization Notification</p> <p>12 Unstructured Document Component</p> <p>13 Consumer Vaccination View</p>



New Construct	Construct Description	Technical Actors	Interoperability or Data Requirement
HITSP/C65 - Generic Alert to Identified Providers	Communication of non-individual identifiable Health information data to: Population-based Consumer communication Clinician communication Recommendation Patient communication – Generic (aligned with ER-HER population based	Content creator Content consumer	7 Prioritization Notification 11 Generic Alert to identified providers NOTE: This cannot be a targeted communication as this would be PHI NOTE: Coupled with T64 - Identify Communication Recipients (Service) for this Design
HITSP/T66 - Terminology Service	Infrastructure service, not content	Value set consumer Value set repository	10 Terminology Services May or not be deferred depending upon tier 2

3.2.6 MODIFICATIONS TO EXISTING HITSP CONSTRUCTS

The table below provides a description of the existing HITSP constructs that will be used for this Use Case. It also specifies whether the construct will require modification based on the new sets of requirements that are being satisfied by the construct.

Table 3.2.6-1 Existing HITSP Constructs

HITSP Construct	Construct Description	Technical Actors	Interoperability or Data Requirement Number	Modification Required
HITSP/TP21	Query for Existing Data	Clinical Data Consumer Data Repository: Vital Signs Problems and Allergies Medications Immunizations Diagnostic Data Professional Services	7.1.2.1a 7.3.2.1 7.3.3.1 7.4.2.1 8.3.2.1	May need to extend the HITSP/TP21: QED if data requirements are supported
HITSP/TP13	Manage Sharing of Documents	Document Source, Document Consumer, Document Registry, Document Repository	7.1.2.1a 7.4.3.1 9.1 9.2	None anticipated
HITSP/C32	HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component	Content Creator Content Consumer	7.1.2.1a 7.4.3.1 9.1 9.2	Pending Domain TC document harmonization



HITSP Construct	Construct Description	Technical Actors	Interoperability or Data Requirement Number	Modification Required
HITSP/C48	HITSP Encounter Documents Using IHE Medical Summary (XDS-MS) Component	Content Creator Content Consumer	7.1.2.1a 7.4.3.1 9.1 9.2	Pending Domain TC document harmonization
HITSP/C25	Anonymize	Content Creator Content Consumer	9.4	Update to assess new content considerations for Immunization
HITSP/T24	Pseudonymize	Patient Identity Source, Pseudonymization Service, PIX Manager	9.4	None anticipated
HITSP/T23	Patient Demographics Query	Patient Demographics Consumer, Patient Demographics Supplier	7.4.4.1	Add support for immunization specific demographics
HITSP/T29	Notification of Document Availability	Notification Sender, Notification Receiver	7.3.3.1 7.4.2.1	None anticipated
HITSP/TP22	Patient ID Cross-Referencing	Patient Identity Source, PIX Manager, Patient Identity Consumer	7.4.4.1	Add support for immunization specific demographics
HITSP/T16	Consistent Time	Time Server, Time Client	9.1, 9.2	None anticipated
HITSP/T17	Secured Communication Channel	Node	9.1, 9.2	None anticipated
HITSP/C26	Nonrepudiation of Origin	Content Creator Content Consumer	9.1, 9.2	None anticipated
HITSP/C19	Entity Identity Assertion	Entity, Identity Provider, Authentication Provider	9.1, 9.2	None anticipated
HITSP/T15	Collect and Communicate Security Audit Trail	Audit Record Source, Audit Record Repository	9.1, 9.2	None anticipated
HITSP/TP30	Manage Consent Directives	Consent Originator Consent Registry Consent Repository Consent Directive Requestor	9.1, 9.2	None anticipated



HITSP Construct	Construct Description	Technical Actors	Interoperability or Data Requirement Number	Modification Required
HITSP/TP20	Access Control	Service User Identity provider Service provider User User Access Control Service (UACS) Service Provider (SP) Service Provider Access Control Service (SP ACS)	9.1, 9.2	None anticipated
HITSP/T31	Document Reliable Interchange	Document Source, Document Recipient	7.3.1.1, 9.1, 9.2	None anticipated; IS level constraint - Specify Form receipt to support digital receipt Use Case requirements
HITSP/T33	HITSP Transfer of Documents on Media Transaction	Portable Media Creator, Portable Media Importer	7.3.1.1, 9.1, 9.2	None anticipated

3.2.7 DOCUMENT MAP

The document map summarizes the suite of constructs that are the detailed map to existing standards and specifications used to satisfy the requirements imposed by the Immunizations and Response Management Use Case. The most effective way to see the construct breakdown is to begin with the document indicated at the top of the diagram.



Figure 3.2.7-1 Requirements, Design and Standards Selection Document Map

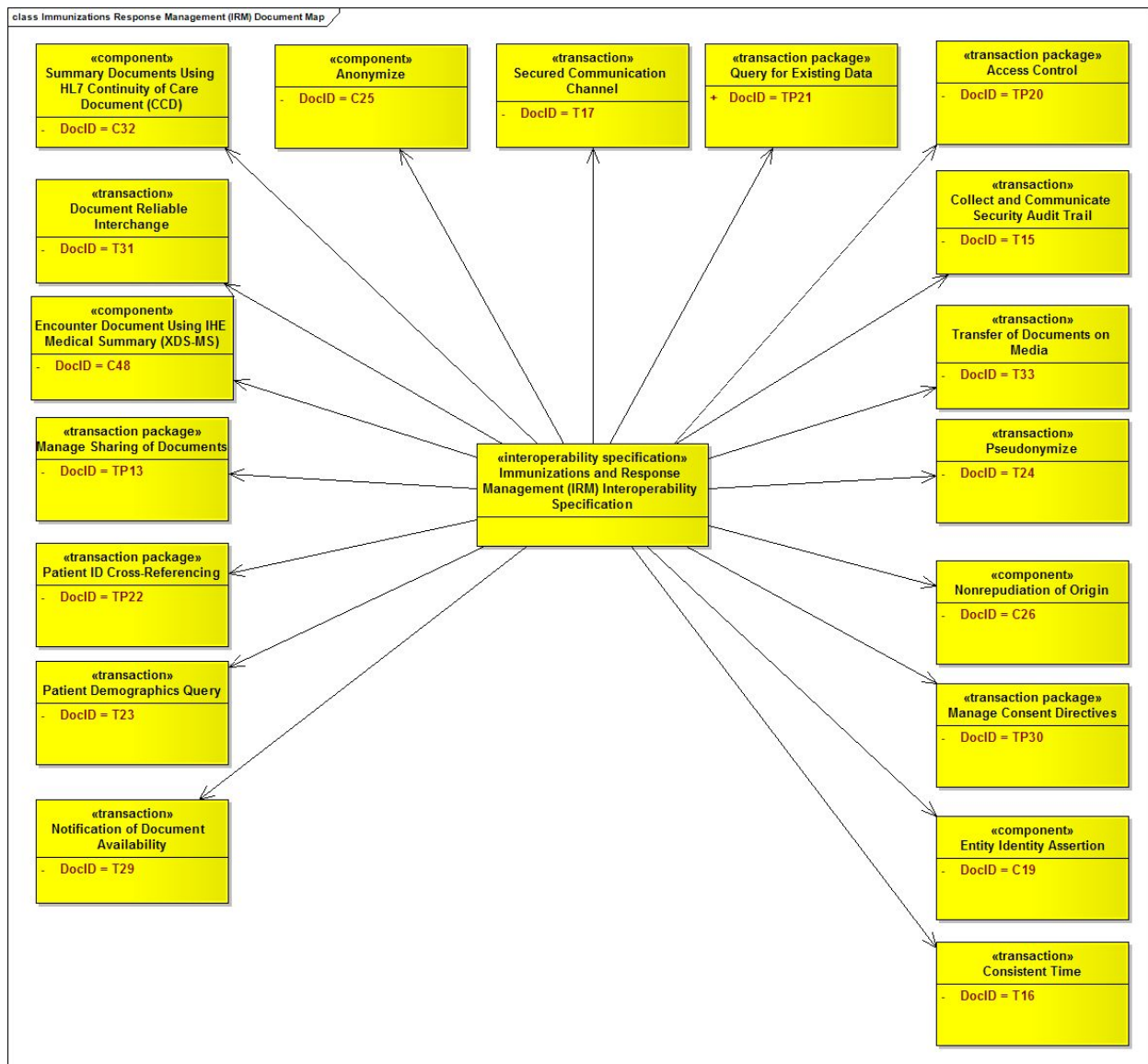
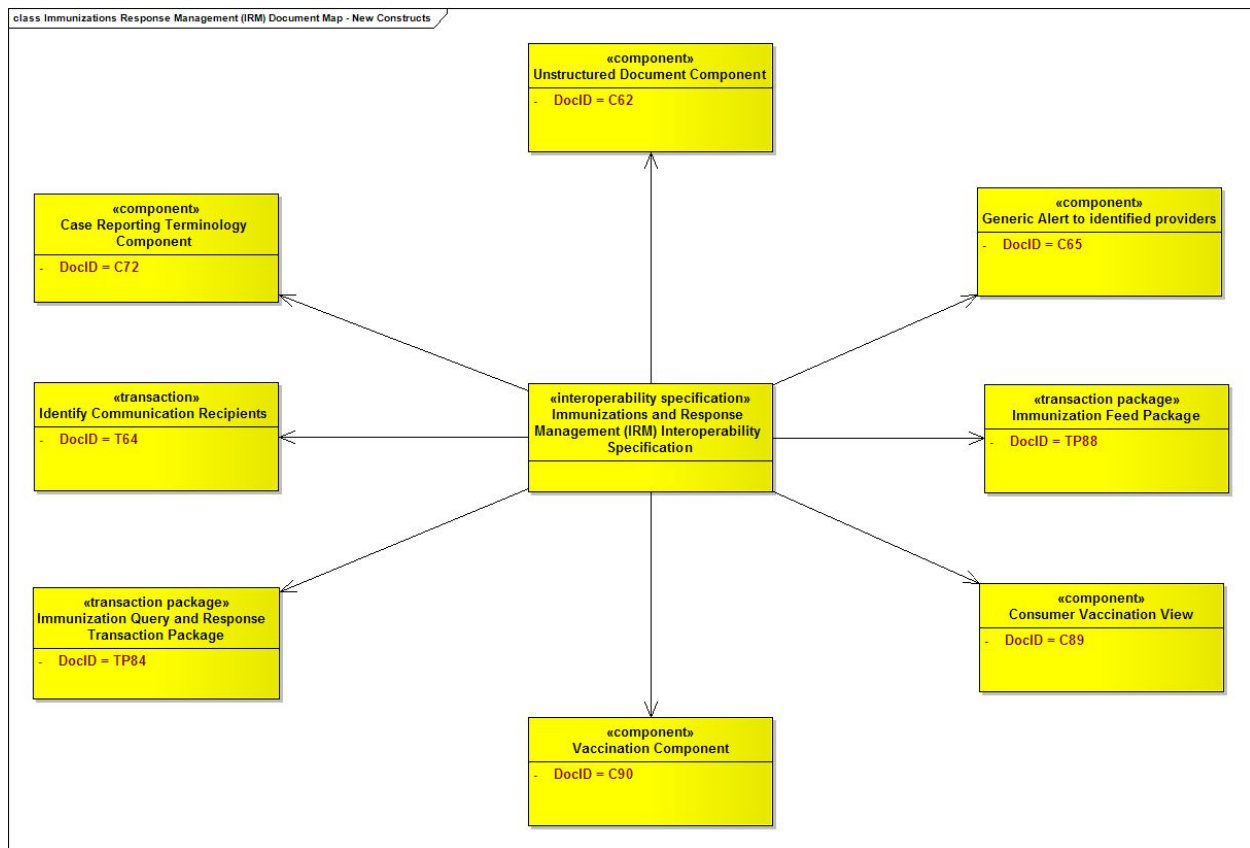


Figure 3.2.7-2 Requirements, Design and Standards Selection Document Map - New Constructs



4.0 CANDIDATE STANDARDS

This section presents the candidate standards that may support the major Use Case events described in the requirements analysis. During Interoperability Specification development, standards selection will be based on the following process:

- **Evaluation:** The Technical Committee evaluates the standards using the Tier 2 Readiness Criteria. Standards considered for use may include provisional or to be named standards
- **Selection:** Based on the Tier 2 evaluations, named standards are selected and listed in Table 4.1.2-1. 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. During the actual construction of Interoperability Specifications, the Technical Committee may need to refine this listing based on detailed analysis
- **Gap and Overlap Analysis and Recommendations:** The Technical Committee also identifies, and analyzes gaps and overlaps within the standards industry as they related to the specific Use Case. The TC will provide a description of the gaps, including missing or incomplete standards, provide a description of all overlaps, or competition among standards for the relevant Use Cases, and recommendations for resolving these gaps and overlaps

Thus the following section lists a summary of the standards that will be further refined during the Interoperability Specification development phase.

4.1 LIST OF SELECTED AND CANDIDATE STANDARDS

This section presents the selected, and candidate standards that may support the Use Case events described in the requirements analysis. As used by HITSP, the term “standard” refers, but is not limited to Specifications, Implementation Guides, Code Sets, Terminologies, and Integration Profiles. A standard should be produced through a well-defined approach that supports a business process and

1. has been agreed upon by a group of experts
2. has been publicly vetted
3. provides rules, guidelines, or characteristics
4. helps to ensure that materials, products, processes, and services are fit for their intended purpose
5. is available in an accessible format
6. is subject to an ongoing review and revision process

Candidate standards are then evaluated using the HITSP Tier 2 Readiness Criteria. Final selection does not occur until the Interoperability Specifications are completed. Thus there may be additions or deletions to this list.



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

- Regulatory and guidance standards are legal or other authoritative declarations that HITSP must abide by. These may also be guidelines and recommendations that HITSP has adopted to aid in the selection of standards (see Section 4.1.1)
- Selected candidate standards are those candidate standards that are selected within the context of the specific Use Case requirements, and are evaluated for inclusion as part of the Interoperability Specification (see Section 4.1.2)

4.1.1 REGULATORY AND GUIDANCE STANDARDS

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 the Interoperability Specification.

Table 4.1.1-1 Regulatory and Guidance Standards

Standard	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.

4.1.2 SELECTED AND CANDIDATE STANDARDS

The section provides a mapping of candidate standards that may be required to implement the requirements of the Interoperability Specification to the Use Case action codes which are supported.

Section 3.2 provides a description and listing of the new and existing constructs that are used by this Requirements, Design, and Standards Selection specification. Section 3.2.6 describes existing constructs that are expected to be used in this specification without changes (reused), or modified to include additional requirements (repurposed). Selected standards that are used by existing constructs are provided in the published construct specifications available from www.hitsp.org, and are not duplicated in this document. The following table only lists candidate standards that may be selected to meet Use Case requirements for new or repurposed constructs used in this specification. A detailed description of each standard is also provided in the appendix.

Table 4.1.2-1 Selected and Candidate Standards Linked to Requirements

SDO and Standard Name	Event/Action Code	Category	Remarks/ Minor Gaps
Health Level Seven (HL7) Version 2.3.1+ Unsolicited Vaccination Update (VXU) NOTE: This standard is being updated by CDC	7.1.3.2 7.1.4.1	HITSP/C72 Vaccination Component (part of Immunization Feed TP)	



SDO and Standard Name	Event/Action Code	Category	Remarks/ Minor Gaps
Health Level Seven (HL7) Version 2.3.1+ Query for Vaccination Record (VXQ), Response to Vaccination Query Returning Multiple PID Matches (VXX), and Vaccination Record Response (VRR)	7.1.4.1, 9.3	HITSP/TP70 - Immunization Query and Response Transaction Package	Deprecated – 2.4 or 2.5 replaced QRD/QRF structure overlaps V3 that is not existing yet; Review use of VXQ message and how patient matching is being done in this message
Health Level Seven (HL7) Version 2.3.1+ Pharmacy/Treatment Administration Message (RAS)	7.1.4.1 7.4.3.1	HITSP/C72 - Vaccination Component (part of Immunization Feed TP)	Currently scoped out of RDSS (see scoping statement) Overlaps with HL7 vaccine possibly VXU
National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide	7.1.4.1 7.4.3.1	HITSP/C72 - Vaccination Component (part of Immunization Feed TP)	NOTE: Medication administration Currently scoped out of RDSS (see scoping statement)
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) 2008-2009 Supplement: Public Comment - Pediatric Demographics Option	7.2.1.2 7.4.4.1 9.3	HITSP/ TP22 - Patient ID Cross-Referencing and HITSP/ T23 - Patient Demographics Query	Profile released for comment
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) 2008-2009 Trial Implementation Supplement Sharing Value Sets (SVS)	9.4	HITSP/T66 - Terminology Service	Profile released for public comment
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) – Care Management (CM), Technical Framework Supplement, Volume I, Revision 3.0, 2007-2008, Immunization Content Profile (IC)	8.2.2.1	HITSP/TP71 - Immunization Feed Transaction Package	Profile released for public comment

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 endorsement 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 Immunizations and Response Management Use Case event. Recommended resolutions were developed through a series of steps including the committee's initial recommendations, cross team validation of the gap, provisional recommendations and peer review by the team.



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

Table 4.2-1 Use Case Events and Associated Gaps

Event Code	Event Description	Identified Gaps	Recommended Resolution
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 CDS 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 CDS 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	in progress through HL7 SOA – Decision Support efforts – Query and response to the algorithm; this is not the PH emergency response effort – this is the SOA; dependent upon the gap resolution above for immunization schedules Proprietary solutions may be leveraged in the interim Look at what is in the text versions to identify the data element requirements
7.1.1.1	Action: Receive immunization schedules	No content standards other than paper formats in use	
7.1.1.1	Action: Receive immunization schedules	Most EHR systems today do not have a thorough immunization schedule	
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 CDS work on standardized service/algorithm
7.1.2.1a	Action: Identify individuals needing immunization or drug	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
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 CDS work on standardized service/algorithm



Event Code	Event Description	Identified Gaps	Recommended Resolution
7.1.2.1b, 7.2.1.1, 7.2.1.2, 7.2.1.1	<p>Alternative Action: Receive information about individuals needing prioritized intervention</p> <p>Action: Conduct analysis to determine intervention priorities</p> <p>Action: Notify clinicians of individuals or population characteristics needing prioritized intervention</p> <p>Action: Identify individuals needing prioritized intervention</p>	<p>There are no standards for prioritization</p> <p>Gap/policy element</p>	<p>This is a CDS effort – we may approach this in deferred HITSP CDS effort scoped to demographics for initial deliverable; This may be expanded once requirements are fleshed out</p> <p>The requirements beyond demographics need to be defined to fit within HITSP CDS</p>
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
7.1.6.1	Action: Receive vaccine recall information from registries	Standards gap – today this is done by human communications	<p>Continue human communication until an appropriate message can be developed</p> <p>Leverage Unstructured Document Component approach defined by HITSP construct where appropriate</p> <p>Refer to and appropriate SDO to define standards. Monitor and contribute to effort</p>
7.2.1.1	Action: Identify individuals needing prioritized intervention	no standard for the consumer-friendly decision	<p>May be influenced by policy decisions</p> <p>Refer to and appropriate SDO to define standards. Monitor and contribute to effort</p>
7.3.1.1, 7.3.2.1	<p>Action: Provide available immunization information via a personally controlled health record</p> <p>Action: Request available immunization information</p>	HITSP/C32 and constrained subsets are insufficient to represent vaccination administration events and immunization summaries. An immunization-focused CDA document or documents supporting these is needed	<p>Interim solution, specify HITSP/C32 constraints.</p> <p>Monitor and contribute to current HL7 and IHE efforts to specify and constrain these documents to assure that the Use Case needs may also be fulfilled by these ongoing standardization efforts</p>
7.4.1.1	Action: 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
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
		Policy gap in standard requirements for consumer-facing communications of immunization data	
7.4.2.1, 9.4	<p>Action: Provide vaccine or drug administration information.</p> <p>Data provisioning – including support for secondary uses; data provisioning and distribution of data transmission parameters</p>	<p>Gap in Data Quality routine checking/automation</p> <p>Gap is in Clinical Decision Support – transmission of rules for record checking</p>	<p>Need standards for the transmission of the immunization rules the data quality rules.</p> <p>Refer to SDOs for consideration as to whether this can be combined as a common standard</p>



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Event Code	Event Description	Identified Gaps	Recommended Resolution
7.1.2.1a 7.1.2.1b 7.4.2.1 7.4.3.1 7.4.4.1 7.3.2.1 7.2.1.1 7.2.1.2 8.2.2.1 8.3.1.1	Action: Identify individuals needing immunization or drug Alternative Action: Receive information about individuals needing prioritized intervention Action: Provide vaccine or drug administration information. Action: Retrieve vaccine or drug administration information from external sources Action: Receive information describing the administration of a vaccine or drug Action: Request available immunization information Action: Conduct analysis to determine intervention priorities Action: Notify clinicians of individuals or population characteristics needing prioritized intervention Action: Receive and monitor inventory status information 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
7.3.1.1, 7.3.2.1	Action: Provide available immunization information via a personally controlled health record Action: Request available immunization information	Immunization CDA document is not currently available from HL7	Work with ongoing HL7 SDO effort to assure that the resulting immunization specific document supports the Use Case requirements Initially leverage the HITSP/C32, until a more specific HL7 CDA Immunization standard is available
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
7.1.6.1 , 7.3.3.1	Action: Receive vaccine recall information from registries 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. The overlap is only relative to the specific Use Case event. Overlaps refer to instances where some of the requirements are met by multiple standards. The overlap is only relative to the specific Immunizations and Response Management. Recommended resolutions were developed through a series of steps including the committee's initial recommendations, cross team validation of the overlap, provisional recommendations and peer review by the team.



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

Table 4.3-1 Standard Overlaps

Event Code	Event Description	Standard Overlap	Recommended Resolution
7.1.2.1a 7.1.2.1b 7.4.2.1 7.4.3.1 7.4.4.1 7.3.2.1 7.2.1.1 7.2.1.2 8.2.2.1 8.3.1.1	<p>Action: Identify individuals needing immunization or drug</p> <p>Alternative Action: Receive information about individuals needing prioritized intervention</p> <p>Action: Provide vaccine or drug administration information</p> <p>Action: Retrieve vaccine or drug administration information from external sources</p> <p>Action: Receive information describing the administration of a vaccine or drug</p> <p>Action: Request available immunization information</p> <p>Action: Conduct analysis to determine intervention priorities</p> <p>Action: Notify clinicians of individuals or population characteristics needing prioritized intervention</p> <p>Action: Receive and monitor inventory status information</p> <p>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 that is not existing yet</p>	<p>Support what exists today (VXQ/VXR) and allow for the new pilot testing to migrate toward Support for V3 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>
7.4.4.1	<p>Action: Receive information describing the administration of a vaccine or drug</p>	<p>With or without PIX – send demographics and substance in one message rather than in a 2-step manner</p> <p>Both processes are doing the same thing in a one-step process versus a two step process;</p>	<p>We want something that allows for this in one step</p>



Event Code	Event Description	Standard Overlap	Recommended Resolution
7.1.1.1 7.1.1.2 7.1.2.1a 7.1.2.1b 7.1.3.2 7.1.5.1 7.4.1.1 7.4.1.2 7.2.1.1 9.4	Action: Receive immunization schedules Action: Incorporate immunization schedules into the clinician's EHR Action: Identify individuals needing immunization or drug Alternative Action: Receive information about individuals needing prioritized intervention Action: Record vaccine or drug administration information Event: Monitor for adverse events Action: Receive immunization schedules Action: Incorporate immunization schedules into the registry Action: Conduct analysis to determine intervention priorities Action: Identify individuals needing prioritized intervention Data provisioning – including support for secondary uses; data provisioning and distribution of data transmission parameters	There are multiple standards for expression of clinical knowledge: Arden, GELLO, OWL, Common Logic, HL7 SOA SIG, W3C Web Services	Tier-2 Selection process; Work with SDOs to align and harmonize the standardization efforts in this area
7.1.3.2 7.1.4.1 7.4.1.1 7.4.2.1 7.4.4.1 7.3.1.1	Action: Record vaccine or drug administration information Action: Report administration information to registries Action: Report administration information to registries Action: Provide vaccine or drug administration information Action: Receive information describing the administration of a vaccine or drug Action: Provide available immunization information via a personally controlled health record Vaccination	V2 messages from today, V3 messages for immunization pending Messaging versus Document potential for immunization	Describe migration path and timeframe through professional societies and SDOs Describe migration path and timeframe through professional societies and SDOs. It may not be just a migration path – it may be a duality situation



5.0 NEXT STEPS

The first step in the HITSP harmonization process is requirements analysis and design. Upon completion of the Requirements, Design and Standards Selection for the Immunizations and Response Management Use Case, the following steps will occur:

- This document will be submitted to the HITSP Panel and interested Public for comment
- After the comment period, the Technical Committee or Work Group will disposition the comments, maintaining a written log of all dispositions assigned to the TC/WG
- Persuasive comments will be used to inform the construction of the Interoperability Specification (IS)
- Non-persuasive comments or comments that are not applicable to the construction of the IS will be deferred with reason/explanation (e.g., need additional information or further analysis during construction)
- In parallel to the steps described above, the Technical Committee/Work Group will begin the construction of the Interoperability Specifications



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 standards that are referenced by this Requirements, Design, and Standards Selection Specification:

Table 6.1-1 Description of Standards

SDO and Standard Name	Description
Health Level Seven (HL7) Version 2.3.1+ Unsolicited Vaccination Update (VXU) NOTE: This standard is being updated by CDC	The HL7 Version 2.3.1+ Messaging Standards are application protocols for electronic data exchange in healthcare. Current 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 this HITSP Interoperability Specifications is the section on Vaccine Trigger events and message types described in Chapter 4. Immunization registries that maintain vaccination records need to be able to transmit patient-specific records of vaccines administered to other registries to provide access to the record at the time healthcare is given and to allow tracking of progress in reaching age-appropriate immunization coverage. The applicable activity is the unsolicited update to an immunization registry (VXU). For more information, visit www.hl7.org .
Health Level Seven (HL7) Version 2.3.1+ Query for Vaccination Record (VXQ), Response to Vaccination Query Returning Multiple PID Matches (VXX), and Vaccination Record Response (VRR)	The HL7 Version 2.3.1+ Messaging Standards are application protocols for electronic data exchange in healthcare. Current 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 this HITSP Interoperability Specifications is the section on Vaccine Trigger events and message types described in Chapter 4. Immunization registries that maintain vaccination records need to be able to transmit patient-specific records of vaccines administered to other registries to provide access to the record at the time healthcare is given and to allow tracking of progress in reaching age-appropriate immunization coverage. The following activities are applicable: (1) a query from one system for a patient's vaccination record that is held in another system (VXQ), (2) a response to a query containing multiple patient matches to the query (VXX), (3) a response to a query containing the vaccination record (VXR). For more information, visit www.hl7.org .



SDO and Standard Name	Description
Health Level Seven (HL7) Version 2.3.1+ Pharmacy/Treatment Administration Message (RAS)	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 (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 this HITSP Interoperability Specifications is the message format described in Chapters 4. In the most common cases, the Pharmacy/Treatment Administration Message would be sent from an administering application to a pharmacy or treatment application (or to an ordering application or another clinical application), which could use the data to generate medication administration reports. For more information, visit www.hl7.org .
National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide	Provides prescription claim transactions between Providers and Adjudicators, and between Adjudicators (aka Payer-to-Payer). The Telecommunication Standard Implementation Guide supports the following processes: <ol style="list-style-type: none"> 1. Eligibility Verification 2. Claim 3. Service 4. Information Reporting 5. Prior Authorization 6. Predetermination of Benefits. For more information, visit www.ncdpd.org .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) 2008-2009 Supplement: Public Comment - Pediatric Demographics Option	Pediatrics Demographics Option is a supplement to PIX and PDQ containing additional fields for searching and matching for large pediatric databases, especially immunization information systems. For more information, visit www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) 2008-2009 Trial Implementation Supplement Sharing Value Sets (SVS)	The Sharing Value Sets (SVS) profile provides a means through which healthcare systems that produce 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, shared nomenclature managed in a centralized fashion. Such shared nomenclatures are essential to semantic interoperability, for example as lists of orderable or billable procedures, types of healthcare facilities, or classifications of healthcare providers. This profile describes a mechanism of retrieving a Resolved Value Set from a Value Set Repository by a Value Set Consumer. A single Value Set Repository can be accessed by many Value Set Consumers, establishing a domain for consistent and uniform nomenclature. It supports automated loading of Value Sets in the Value Set Consumers, reducing the burden of manual configuration, and allowing a single application design to operate in a variety of different domains (e.g. international). For more information visit www.ihe.net .
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) – Care Management (CM), Technical Framework Supplement, Volume I, Revision 3.0, 2007-2008, Immunization Content Profile (IC)	The Immunization Content Profile defines standard immunization data content for Immunization Information Systems (IISs), other public health systems, electronic medical records (EMR) systems, Health Information Exchanges, and others wishing to exchange immunization data electronically in a standard format. For more information visit www.ihe.net .



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7.0 CHANGE HISTORY

The following sections provide the history of changes made to this document.

No change at this time. This is the first published version.

