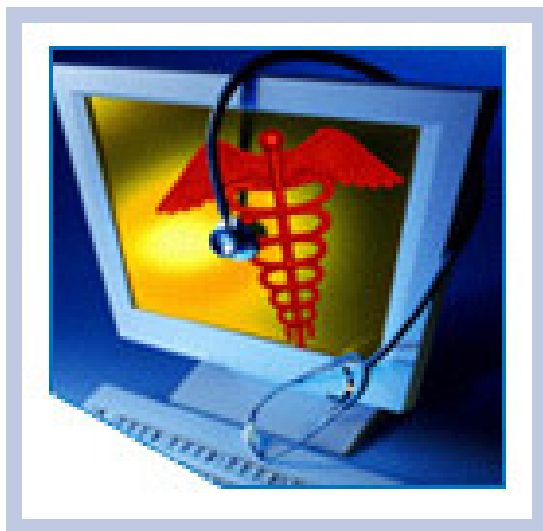


HITSP Public Health Case Reporting Use Case Requirements, Design and Standards Selection

HITSP/RDSS61



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)**



DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
1.0	Review Copy	Population Perspective 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)	June 27, 2008



TABLE OF CONTENTS

1.0	INTRODUCTION	6
1.1	Purpose	6
1.2	Audience	6
1.3	How to Use this Requirements, Design and Standards Selection Document.....	6
1.3.1	Conventions, Acronyms and Resources/References.....	7
1.4	Copyright Permissions.....	8
2.0	REQUIREMENTS ANALYSIS	9
2.1	Use Case Synopsis	9
2.2	Use Case Requirements	11
2.2.1	Mapping of Use Case Requirements to Interoperability Requirements	12
2.2.2	Data and information Requirements Matrix.....	27
2.2.3	Identification of Business Actors, and Scenarios	67
2.2.4	High-Level UML Business Sequence Diagram	68
3.0	DESIGN.....	72
3.1	Scope of Design	72
3.1.1	Assumptions	75
3.1.2	Constraints	77
3.1.3	Pre-conditions.....	77
3.1.4	Post-conditions	78
3.1.5	Process Triggers	79
3.2	Detailed Design	80
3.2.1	Technical Actor Role Descriptions	81
3.2.2	Sequence Diagram for Process Flow	84
3.2.3	Mapping of Business Actors to Technical Actors and Constructs with optionality	84
3.2.4	Data Detail.....	92
3.2.5	New HITSP Constructs.....	93
3.2.6	Modifications to Existing HITSP Constructs	94
3.2.7	Document Map	98
4.0	CANDIDATE STANDARDS.....	99
4.1	List of Selected AND Candidate Standards	99
4.1.1	Regulatory and Guidance Standards	100
4.1.2	Selected and Candidate Standards.....	100
4.2	Gaps Where There Are No Standards	105
4.3	Standard Overlaps.....	109



5.0	NEXT STEPS	112
6.0	APPENDIX	113
6.1	Description of Standards	113
6.2	Harmonization efforts for Public Health Case Reporting.....	118
6.3	USHIK Data Element Definitions for Identified Common Data Elements	119
7.0	CHANGE HISTORY	161



FIGURES AND TABLES

Figure 2.2.4-1 Public Health Case Reporting (PHCR) Business Sequence – Part 1	69
Figure 2.2.4-1 Public Health Case Reporting (PHCR) Business Sequence – Part 2	70
Figure 2.2.4-1 Public Health Case Reporting (PHCR) Business Sequence – Part 3	71
Figure 3.2.2-1 Detailed Sequence Diagram for Scenario 1	84
Figure 3.2.7-1 Requirements, Design and Standards Selection Document Map	98
Table 1.3.1-1 Reference Documents	7
Table 2.2.1-1 Mapping of Use Case Requirements to Interoperability Requirements	12
Table 2.2.2-1 Data Element and Information Requirements	28
Table 2.2.2-2 Data Elements Cross Reference for High-level cross-cutting tables	32
Table 2.2.2-3 Facility Data Elements	33
Table 2.2.2-4 Report Data Elements	34
Table 2.2.2-5 Patient Data Elements	36
Table 2.2.2-6 Clinical Data Elements	39
Table 2.2.3-1 Business Actors	67
Table 3.1-1 Scope for Releases 1 and 2	74
Table 3.1.1-1 Assumptions	75
Table 3.1.2-1 Constraints	77
Table 3.1.3-1 Pre-conditions	78
Table 3.1.4-1 Post-conditions	78
Table 3.1.5-1 Process Triggers	79
Table 3.2.1-1 Technical Actor Role Descriptions	81
Table 3.2.3-1 Business-Technical Actor Mapping to Transaction and/or Content	85
Table 3.2.4-1 Data Element Constraints	92
Table 3.2.5-1 New HITSP Constructs	93
Table 3.2.6-1 Existing HITSP Constructs	94
Table 4.1.1-1 Regulatory and Guidance Standards	100
Table 4.1.2-1 Selected and Candidate Standards Linked to Requirements	101
Table 4.2-1 Use Case Events and Associated Gaps	106
Table 4.3-1 Standard Overlaps	109
Table 6.1-1 Description of Standards	113



1.0 INTRODUCTION

As an introduction to the HITSP Public Health Case Reporting 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 acknowledges the copyright protections that pertain, and provides a list of key reference documents and background material.

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
Public Health Case Reporting 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>



1.4 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

© 2008 ANSI. This material may be copied without permission from ANSI only if and to the extent that the text is not altered in any fashion and ANSI's copyright is clearly noted.

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 Public Health Case Reporting 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 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 Public Health Case Reporting Use Case, including any applicable scenarios that are part of the Use Case.

In January 2007, AHIC approved a recommendation to develop a Use Case addressing population health relating to aspects of Public Health Case (PH Case) reporting and Adverse Event (AE) reporting. For the purposes of this Use Case, PH Case reporting may include the reporting of communicable/infectious and non-infectious diseases/conditions. AE reporting may include the reporting of AEs associated with post-market vaccines and medications. For both PH Case reporting and AE reporting, this Use Case focuses on using data in EHRs and augmenting EHR data in order to assist those individuals or entities performing provider roles in reporting to public health, manufacturers, etc.

This Use Case also discusses the incorporation of reporting criteria into EHRs which may assist in the possible identification and reporting of PH Cases and AEs. Reporting criteria which are incorporated and utilized by EHRs may include: general and specific reporting considerations, as well as the identification of data and events that may trigger a report, additional questions that may need to be asked of reporters, and the identification of specific data that may need to be reported. There are various stakeholders and methods used in determining reporting criteria. Specifics regarding PH Case reporting criteria are discussed further in 7.1.1.2., 7.2.1.1, and 7.2.1.2. Specifics regarding AE reporting criteria are discussed further in 7.1.1.3 and 7.2.1.3. Reporting criteria may differ for different types of PH Cases and AEs, but there are common technologies and information exchanges as well as data which will be helpful in supporting the wide range of activities.

Following the reporting of possible PH Cases, investigation and information sharing may occur by public health personnel in clinical care settings or public health agencies. There may be similar processes which



support AE investigation and follow-up, but due to the presence of different information flows and stakeholders, AE investigations and recalls are not addressed in the scope of this Use Case. Leveraging electronic clinical information to address population health data needs can also support providers in their decision making. Specifically, providers may benefit from having access to population health data (sometimes called bi-directional communication in reference to data flowing back from public health to clinical care personnel) to support decision support. As expressed in Section 10.0, Data Set Considerations and Appendix B, capabilities for data flowing back to clinical care personnel from public health may include communications which are: case-specific or patient-specific, generalized to clinically relevant public health functions, or broad enough to be publicly available.

Providers and Public Health will benefit from having the ability to electronically exchange PH Case and AE information among various systems:

- Providers and Public Health will benefit from having the ability to electronically integrate reporting criteria into EHRs and/or other systems;
- Providers and Public Health will benefit from having the ability to use trigger data and events and reporting specifications to help identify possible PH Cases or AEs. In different circumstances trigger events or data may be based on the presence of clinical data in the EHR, Laboratory Information System (LIS), or potentially other sources of information. The utilization of trigger data and events and standardized electronic questions and forms will assist in pre-populating reporting data where possible and making multi-organizational data more comparable;
- Providers will still need to exercise clinical judgment, however; there may be instances where the capabilities described above may support the automated reporting of specific information or reports from providers to those performing public health functions; and
- Providers will benefit from population-level information being integrated with decision support in EHRs

One of the goals of AHIC is to establish a pathway, based on common data and technical standards that facilitates and incorporates interoperable reporting criteria including trigger data and events and reporting specifications into EHRs and/or other tools. This approach can support the reporting of AEs, as well as support the reporting, investigation, and information sharing associated with PH Cases. This Use Case was developed to support the various stakeholders who are active in the development and implementation of EHRs and those facilitating health information exchange activities, including those engaged in activities related to standards, interoperability, harmonization, architecture, policy development, and certification.



2.2 USE CASE REQUIREMENTS

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

This Public Health Case Reporting Use Case focuses on the exchange of information between providers' EHRs, public health organizations, manufacturers, laboratories, and describes the following scenarios:

Reporting from EHRs

Reporting criteria such as case criteria, including trigger data and events are identified and incorporated into providers' EHRs for the reporting of possible PH Cases or, where available AEs. Information within EHRs and the ability to augment EHR information may assist providers in reporting possible PH Cases and AEs. The queuing of standardized report forms for completion by clinical support personnel and the pre-population of available EHR data will help to minimize provider burden. Specifics regarding criteria and reporting specifications are further addressed in the events and actions in sections 7.0 and 8.0.

Public Health Case Investigation and Information Sharing

In evaluating the need for further actions, those performing public health functions may request and receive various types of appropriate authorized information when performing their investigations. The information exchanges and analysis conducted during investigations will assist public health in case status, refining reporting criteria, performing contact tracing to determine who else may have been exposed, assessing impact, determining management and response plans, and communicating appropriate public health information.

There are specific associations between the scenarios in this Use Case and the scenarios in the 2008 Immunizations and Response Management Detailed Use Case.

This Use Case assumes the developing presence of electronic systems such as EHRs, LISs and other local or web-based solutions supporting providers, laboratories, and public health. This Use Case also notes the variations in requirements for reporting across local, state, tribal, and territorial boundaries as well as voluntary versus mandatory requirements. Whereas mandated requirements for PH Case reporting at the federal level do not exist, the federal government accepts and currently receives information which has been voluntarily reported. In some cases, disease prevention and control programs may provide funding that requires compliance with reporting requirements and in some cases, public health emergencies require more intense management of cases.

For reporting of AEs, both mandatory, as designated by the statutes and regulations of the Food and Drug Administration (FDA), and voluntary reporting exists. While acknowledging the issues and obstacles associated with this environment, this Use Case recognizes current efforts to standardize reporting requirements as well as reporting criteria, including those being focused on by Council of State and



Territorial Epidemiologists (CSTE), Centers for Disease Control and Prevention (CDC), FDA, and others to advance these and other initiatives, which promote improved population health.

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
Public Health Case Reporting	Provider	Reporting from EHRs	7.1.1 Event: Receive and incorporate trigger data and reporting specifications	7.1.1.1 Action: Receive and incorporate reporting criteria for both PH Cases and AEs. Reporting criteria include: trigger data and reporting specifications	Trigger data may not apply to AE Requires a HC provider or someone in the care process to make judgment that an AE occurred NOTE: For AE if it meets regulatory definition for AE, then there must an investigation. For PH the decision to investigate may be more subjective. Medical judgment may need attestation from the clinician; post-marketing situations may have certain tracking/PH response or severity-based decisions (e.g. syphilis – VDRL – lab generates a report to PH – in a 72yr old man – clinician may look at this and determine other potential reasons for a false positive – and rules out a case). May need clinician validation/human judgment to kick off a next step. There may be a cascade of trigger events – there may be limited knowledge as to how to respond to a trigger event. Same would apply well to patient safety	1. CDS Reporting/trigger criteria for PH, Reporting/trigger criteria for AE
				7.1.1.2 Action: Incorporate PH trigger data and reporting specifications	Capture report data Communicate trigger events Electronic form transmission – HITSP/TP50 - CDC	1. CDS Reporting/trigger criteria for PH Terminology service



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				7.1.1.3 Action: Incorporate AE trigger data and reporting specifications	1. Capture report data 2. Communicate trigger events 3. Electronic form transmission – (HITSP/TP50) 4. Must be expressed in computable fashion 5. Must be consumable by EHR 6. Multiple sources of 'correct' immunization schedule; must be reconciled 7. Timeliness of the EHR immunization schedule must be managed 8. Need to support a third party source of immunization schedule knowledge (e.g. in many jurisdiction it is the Immunization Information System that serves as the local interpreter to the immunization schedule knowledge) 9. Our 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. (expression of schedule is in 7.4.1)	1. CDS Reporting/trigger criteria for AE 2. Terminology service
			7.1.2 Event: Monitor EHR data and identify possible PH Cases or AEs	7.1.2.1 Action: Monitor EHR data for information matching inclusion/exclusion factors	1. Human review is required always for medication and devices; AE – automated process is prone to numerous false positives; 2. Handling between PH/AE may be different	1. CDS Reporting/trigger criteria for PH Reporting/trigger criteria for AE
				7.1.2.2 Action: Identify, view, evaluate, and triage possible PH Cases and AEs	1. Report Form 2. AE – automated process is prone to numerous false positives; NOTE: Human review is required always for medication and devices (see 7.1.3); 3. Reporting workflow: ID, review, report NOTE: Handling between PH/AE may be different	1. CDS Reporting/trigger criteria for PH Reporting/trigger criteria for AE
			7.1.3 Event: View possible reports	7.1.3.1 Action: Select possible PH Cases or AEs	1. Human review is required always for medication and devices; 2. For PH human review may be done by PH agency	1. CDS Reporting/trigger criteria for PH Reporting/trigger criteria for AE



**HITSP Public Health Case Reporting Use Case Requirements,
Design and Standards Selection**

Review Copy
20080627 V1.0

Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				7.1.3.2 Action: View report for selected possible PH Cases or AEs	1. Form Pre-population 2. Auto-report option 3. Workflow management: optionality for human review; review /comment/ modification option before sending 4. Support various reporting users: User may be clinician or office staff/hospital staff (infection control)	3. Data Mapping for Form Population 4. Case Report
			7.1.4 Event: May perform initial notification	7.1.4.1 Action: (If Applicable) Communicate initial notification to Public Health	1. Communication mechanism(s) (e.g. Case notification message 2. Anonymize (AE) 3. Pseudonymize (AE): <i>Patient</i> : Protected information for the patient safety report (NOTE: CDS - Patient Safety Organization process - discoverable information may need to be protected re: malpractice; <i>Provider/Organization</i> : Pseudonymization of provider or other protections (e.g. human intervention/review prior to reporting) for protecting PSO process data 4. Case Report workflow: preliminary report with detailed follow-up	1. CDS 4. Case Report
				7.1.4.2 Action: (If Applicable) Communicate initial notification to Manufacturers	Human review: Communication to report outside institution – provider input as to whether or not to report	
			7.1.5 Event: Complete and/or queue report	7.1.5.1 Action: Automatically send PH Case Reports or AE Reports which meet all reporting criteria. Reporting criteria include: trigger data and reporting specifications.	Workflow management (data management/communication queueing)	1. CDS Reporting/trigger criteria for PH Reporting/trigger criteria for AE 4. Case Report



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				7.1.5.2 Action: Send PH Case Reports or AE Reports which meet all reporting criteria to a review or approval queue. Reporting criteria include: trigger data and reporting specifications.	Workflow management e.g. HITSP/TP50 to create forms that are interoperable between all parties – contained in a package where people can incrementally add data in an iterative mechanism	1. CDS Reporting/trigger criteria for PH Reporting/trigger criteria for AE 4. Case Report
				7.1.5.3 Action: Send PH Case Reports or AE Reports which do not meet all reporting criteria to a completion queue. Reporting criteria include: trigger data and reporting specifications.	Workflow management (initial report, followed by investigation or complete report submission) NOTE: Data Validation at different points of the workflow may be different	1. CDS Reporting/trigger criteria for PH Reporting/trigger criteria for AE 4. Case Report
			7.1.6 Event: Augment EHR Information and update report	7.1.6.1 Action: Information related to possible PH Cases or AEs that is not available through an EHR is manually gathered	1. Augmentation mechanisms (TP50) 2. Linked/case-associated records (e.g. mom/baby supplement data, food borne outbreak, vaccine failure) NOTE: Case finding vs case investigation are not well distinguished from this step/Use Case – data requirements consideration	1. CDS Reporting supplement /trigger criteria for PH Reporting supplement /trigger criteria for AE 2. Terminology service 4. Case Report
				7.1.6.2 Action: Information related to possible PH Cases or AEs that is not available through an EHR may be gained through electronic information exchanges	1. Augmentation mechanisms (HITSP/TP50) 2. HITSP/TP21 Query for existing data: Format of the query – can be standard – ‘rationalized services’ against the HL7 – format of query may be standards-based (patient, provider, vocabulary) 3. Augmentation mechanisms require appropriate authorizations NOTE: Not just PH agencies, but providers that may be reaching out in various ways to capture data that may not have been available in original data source	2. Terminology service



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				7.1.6.3 Action: Update PH Case Report or AE Report.	<p>1. Augmentation mechanisms (HITSP/TP50)</p> <p>2. HITSP/TP21 Query for existing data: Format of the query – can be standard – ‘rationalized services’ against the HL7’ – format of query may be standards-based (patient, provider, vocabulary)</p> <p>3. Augmentation mechanisms require appropriate authorizations</p> <p>4. Linked/case-associated records (e.g. mom/baby supplement data, food borne outbreak, vaccine failure)</p> <p>NOTE: Case finding vs case investigation are not well distinguished from this step/Use Case – data requirements consideration</p> <p>NOTE: Example of overlap for food contamination – sharing across and all federal agencies (e.g. PH and FDA, customs, homeland security)</p>	<p>1. CDS Reporting supplement /trigger criteria for PH Reporting supplement /trigger criteria for AE</p> <p>2. Terminology service</p> <p>4. Case Report</p>
			7.1.7 Event: Finalize and Send Report	7.1.7.1 Action: Confirm PH Case Report or AE Report	<p>Support the iterative nature of building this report; e.g. for a device, the report completion may be provided by manufacturer. e.g. lab: preliminary report for a reportable condition (organism); provide a final once organism is confirmed; Need to model types of interactions that happen to build the case; this step is a misrepresentation of the actual workflow</p> <p>NOTE: Assume that confirm means that provider confirms transmission in that point in time. Provider may be able to gather info from a PHR</p>	<p>1. CDS Reporting supplement /trigger criteria for PH Reporting supplement /trigger criteria for AE</p> <p>2. Terminology service</p> <p>4. Case Report</p>



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
		Public Health Case Investigation and Information Sharing	7.1.6 Event: Augment EHR Information and update report	7.1.7.2 Action: Transmit confirmed PH Case Reports or AE Reports to public health	Candidate communication options (HITSP/TP50, HITSP/TP13, HITSP/T31, HITSP/T33, HL7) traditional messages; no anticipation to add additional transports; because of the variety of sources sending/receiving, depending on security and privacy restrictions, we want to support a broad set of transport requirements/options	1. CDS Reporting supplement /trigger criteria for PH Reporting supplement /trigger criteria for AE 2. Terminology service 4. Case Report
				7.1.6.1 Action: Information related to possible PH Cases or AEs that is not available through an EHR is manually gathered	1. Augmentation mechanisms (TP50) 2. Linked/case-associated records (e.g. mom/baby supplement data, food borne outbreak, vaccine failure) NOTE: Case finding vs case investigation are not well distinguished from this step/Use Case – data requirements consideration	1. CDS Reporting supplement /trigger criteria for PH Reporting supplement /trigger criteria for AE 2. Terminology service 3. Data Mapping for Form Population 4. Case Report
				7.1.6.2 Action: Information related to possible PH Cases or AEs that is not available through an EHR may be gained through electronic information exchanges	1. Augmentation mechanisms (HITSP/TP50) 2. HITSP/TP21 Query for existing data. Format of the query – can be standard – ‘rationalized services’ against the HL7 – format of query may be standards-based (patient, provider, vocabulary) 3. Augmentation mechanisms require appropriate authorizations 4. Not just PH agencies, but providers that may be reaching out in various way s to capture data that may not have been available in original data source	2. Terminology service



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				7.1.6.3 Action: Update PH Case Report or AE Report.	1. Augmentation mechanisms (HITSP/TP50) 2. HITSP/TP21 Query for existing data: Format of the query – can be standard – ‘rationalized services’ against the HL7 – format of query may be standards-based (patient, provider, vocabulary) 3. Augmentation mechanisms require appropriate authorizations 4. Linked/case-associated records (e.g. mom/baby supplement data, food borne outbreak, vaccine failure) NOTE: Example of overlap for food contamination – sharing across and all federal agencies (e.g. PH and FDA, customs, homeland security)	1. CDS Reporting supplement /trigger criteria for PH Reporting supplement /trigger criteria for AE 2. Terminology service 4. Case Report
			8.2.1 Event: Send Additional Information	8.2.1.1 Action: Receive request for additional information from Public Health	1. Workflow issue – human interaction 2. Needs authorization for the requests. – the receiver needs to be able validate the source of the request; 3. Communication issue – human, machine, human interface (e.g. phone, mail, messaging) HITSP/TP50	2. Terminology service 5. Unstructured Document Component
				8.2.1.2 Action: Send information to public health related to previously reported PH Cases and/or other information	1. HITSP/TP50 2. PHR interoperability for reports from patients (e.g. food diary) 3. Security issues should be the same as the original send to PH/AE	2. Terminology service 4. Case Report
			8.2.2 Event: Receive Public Health Information	8.2.2.1 Action: Receive case or patient specific information	1. Communication Mechanism 2. Security information should be the same as initial; if information has been pseudonymized, may require an additional re-id step	5. Unstructured Document Component
				8.2.2.2 Action: Receive specific clinically relevant Public Health information	1. Secure Communication Mechanism 2. Notification to EHR systems 3. Small Cell Size considerations	5. Unstructured Document Component



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				8.2.2.3 Action: Receive Publicly Available Information.	Communication Mechanism	6. Generic alert to identified providers
			8.2.3 Event: Manage and treat PH Cases	8.2.3.1 Action: Identify and manage additional possible PH Cases	Not applicable to AE No interoperability issue Edge System Workflow considerations	
				8.2.3.2 Action: Treat confirmed and additional possible PH Cases	Not applicable to AE Not interoperability issue Edge System Workflow considerations	
	Laboratory	Public Health Case Investigation and Information Sharing	8.3.1 Event: Send information/report	8.3.1.1 Action: Incorporate and utilize Public Health reporting specifications	NOTE: Not currently done electronically	1. CDS Reporting supplement /trigger criteria for PH Reporting supplement /trigger criteria for AE
				8.3.1.2 Action: Identify and send information/report	HITSP/T29 NOTE: The feed for the results reporting is not necessarily the same as the report to PH – be sure this note is included in the IS	1. CDS (identify reportable information: Report lab results on patients where test results meet criteria:) 4 Case Report (Lab Feed (HITSP/C35, HITSP/C36)



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				8.3.1.2a Alternate Action: Send information related to previously reported PH Cases and/or other information may be sent to Public Health	NOTE: May be a non-data request (e.g. send isolate)	4. Case Report
			8.3.2 Event: Receive Public Health Information	8.3.2.1 Action: Receive specimen status information or patient specific information		4. Case Report (Lab Feed (HITSP/C35, HITSP/C36)
				8.3.2.1a Alternate Action: Receive specific clinically relevant public health information or publicly available information	NOTE: Currently private sector labs are excluded from this information	5. Unstructured Document Component 6. Generic alert to identified providers
	Public Health	Reporting from EHRs	7.2.1 Event: Determine and communicate reporting criteria including: trigger data and reporting specifications	7.2.1.1 Action: Determine PH Case Criteria	1. Formalism for case definitions – need to create the formalism for every reportable disease - scoped to (TB, Hep B, Tuleremia, anthrax) which were presented to and accepted by AHIC for formalism recommendations – see scope of design; 2. Leverage an outside professional body, for PH - CSTE. A mechanism is started – extend this to cover the 50-60 nationally notifiable diseases NOTE: See standards-based requirements forms/standards to report the conditions. These are well-defined, well-modeled, and bound to specific terminologies;	1. CDS Disease-specific Reporting /trigger criteria for PH 4. Case Report



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				7.2.1.2 Action: Determine PH trigger data and reporting specifications.	1. Augmentation mechanisms (HITSP/TP50) 2. Identification of communication recipients (routing/recipients)	1. CDS CDS Disease- specific Reporting /trigger criteria for 3. Data Mapping for Form Population
				7.2.1.3 Action: Determine AE trigger data and reporting specifications.	1. Augmentation mechanisms (HITSP/TP50) 2. Identification of communication recipients (routing/recipients)	1. CDS Disease/treatment -specific or Event- type drug/drug- class;
				7.2.1.4 Action: Communicate reporting criteria for both PH Cases and AEs. Reporting criteria include: trigger data and reporting specifications.	1. Human readable and machine readable – problematic to choose which is wanted – for certain classes should have commonality – e.g. define ph case – a standard way to represent that definition e.g. text sections, list of standards/data elements 2. Transport mechanisms – some human readable, may involve both computable transmission, may have repositories of the information; 3. HITSP/TP50, HITSP/TP13, HITSP/T31, HITSP/T33, HL7 traditional messages; need additional communication mechanisms – e.g. remotely programmable/modifiable detectors? Email, PPT? No bounding on communication types – standard transports that can be invoked, but not precluding other approaches. Beware that the content of the transport mechanism may have meaning implied by the selected transport; NOTE: FDA – if AE defined better – can get standardized in this area	2. Terminology service 5. Unstructured Document Component 6. Generic alert to identified providers 7. Reporting Criteria Content (structured)



**HITSP Public Health Case Reporting Use Case Requirements,
Design and Standards Selection**

Review Copy
20080627 V1.0

Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
			7.2.2 Event: May receive initial notification	7.2.2.1 Action: (If Applicable) Receive initial notification from Providers	1. Identify communication recipients (e.g. border state) 2. Need multiple communication/transmission vehicles: fax, phone, and in some cases electronic exchanges 3. Support multiple sources of report: HC provider, Investigator, patient, other jurisdiction, lab, manufacturer (particularly for drug/device) 4. Need to distinguish preliminary notification from confirmed case 5. PH does not receive initial notification – all notifications are considered	4. Case Report
				7.2.2.2 Action: (If Applicable) Respond to initial notifications requiring immediate attention		1. CDS prioritize/report prioritization
			7.2.3 Event: Receive report and determine need for further action	7.2.3.1 Action: Public Health receives and evaluates reports	1. Identify communication recipients (e.g. border state) 2. Need multiple communication/transmission vehicles: fax, phone, and in some cases electronic exchanges 3. Support multiple sources of report: HC provider, Investigator, patient, other jurisdiction, lab, manufacturer (particularly for drug/device) 4. Need to distinguish preliminary notification from confirmed case PH does not receive initial notification – all notifications are considered	1. CDS prioritize/respond e time criticality
				7.2.3.2 Action: Public Health determines need for further action	No Interoperability Requirement	



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
		Public Health Case Investigation and Information Sharing	7.2.3 Event: Receive report and determine need for further action	7.2.3.1 Action: Public Health receives and evaluates reports		
				7.2.3.2 Action: Public Health determines need for further action	Workflow considerations: Feedback loop to go back and clarify with provider	
			8.1.1 Event: Access additional information and investigate	8.1.1.1 Action: Request information from submitters of reports/information	1. HITSP/TP29 Notification initiation 2. Augmentation mechanisms (HITSP/TP50)	2. Terminology service 5. Unstructured Document Component 6. Generic alert to identified providers 7. Reporting Criteria Content (structured)
				8.1.1.1a Alternate Action: Request information by utilizing information exchanges. Public Health may query for existing public health reportable data.	1. Workflow considerations (HITSP/TP21, HITSP/TP13, HITSP/TP50) 2. Augmentation mechanisms (HITSP/TP50) 3. Consent/permissions NOTE: HepB – example – need trans-aminase to verify – can leverage HIE rather than going back to the provider for this detail.	2. Terminology service 5. Unstructured Document Component 6. Generic alert to identified providers 7. Reporting Criteria Content (structured)
				8.1.1.2 Action: Receive additional information to assist in investigation activities	Augmentation mechanisms (HITSP/TP50)	2. Terminology service 5. Unstructured Document Component 6. Generic alert to identified providers
				8.1.1.3 Action: Perform investigation activities	No interoperability requirement	



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
			8.1.2 Event: Determine Case Status	8.1.2.1 Action: Evaluate and classify PH Cases	Human Validation	1. CDS Case Classification
				8.1.2.2 Action: Determine status of PH Case reports	Reporting from HITSP/TP13 Case finding from aggregate databases NOTE: For AE not as formal	1. CDS: Case Classification Data Input
			8.1.3 Event: Perform Contact Tracing	8.1.3.1 Action: Identify those who may have come in contact.	1. Contact Tracing – applies to both cases, may be the same in some instances and different in others 2. See HITSP/IS02, HITSPTP13 constraints for query 3. AE Devices Notification via provider Manufacturer	1. CDS: Levels of contact tracing 5. Unstructured Document Component 6. Generic alert to identified providers
				8.1.3.2 Action: Identify additional possible PH Cases	No specific interoperability requirement	1. CDS Reporting supplement /trigger criteria for PH Reporting supplement /trigger criteria for AE
			8.1.4 Event: Assess Impact and Determine Management Plan	8.1.4.1 Action: Assess and understand impact	Need standard way to transfer the case reports – standards for inter- jurisdiction case report/transfer message; from management perspective, issues of If a protocol is needed the protocol may need interoperability (e.g. CAP protocol between networks between HANs NOTE: Not interoperability – possibly (for AE is likely locally defined process/edge system issue)	1. NOTE: CDS – is a local consideration



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				8.1.4.2 Action: Determine management plan	No interoperability requirement	1. CDS – Management plan
			8.1.5 Event: Communicate public health information	8.1.5.1 Action: Communicate case or patient specific information	<p>1. Security and Privacy considerations: sensitive, identifiable, specific, need to be exchanged via secure methods.</p> <p>2. Re-identification: If anonymize/pseudonymize</p> <p>3. Identify communication recipients</p> <p>4. Reporting entity needs to be identified in a standard way</p> <p>5. Organization Role or POC/authorized recipient needs to be identified: Internal/external reporting practices may have a primary source reporter (e.g. nurse/individual). Some organizations may have a Risk manager to handle communications. When a PH agency does an investigation, the information flow is back to reporting facility; Typically, communications are to the risk manager, contact office, or to the primary source reporter. The contact office may be specific to the report type e.g. FDA, PH, etc. If the communication is to the patient where the patient is under 18 it is the guardian/parent. For AE, it is an agency-specific POC. For a device, it may be the device administrator by product type; For PH it may be an infection control practitioner.</p>	<p>5. Unstructured Document Component</p> <p>6. Generic alert to identified providers</p> <p>1. CDS – responsible party</p>



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				8.1.5.2 Action: Communicate specific clinically relevant Public Health information	1. Identify authorized communication recipients 2. IRB/research authorization (policy consideration) 3. Data anonymization 4. Considerations for small cell size; statistical methods for small cell size – complex in that it is more computational than – at-risk, incidence, prevalence in community, - formula needs to be addressed; Individual IRB decisions and consistency in decision-making 5. Policy considerations 6. Exposure notifications (policy considerations)	5. Unstructured Document Component 6. Generic alert to identified providers
				8.1.5.3 Action: Communicate publicly available information	1. Authorization of information release 2. Anonymize 3. Pseudonymize 4. Process for communicating information 5. Identify communication recipient (e.g. depends upon individual agency) - out of scope; typically manual/internal - not an interoperability issue	6. Generic alert to identified providers
	Information Exchange	Reporting from EHRs		9.1 Data provisioning – including support for secondary uses – data provisioning and distribution of data transmission parameters	No new requirements – see above requirements	
				9.2 Data pseudonymization and re-identification as well as HIPAA de-identification	1. Anonymize, 2. Pseudonymize – not for PH, but AE and Patient Safety would apply; Provider and patient de-id; Report-specific/policy determined	



Use Case	Perspective/ Business Actor	Scenario	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
				9.3 Data delivery – including secure data delivery, data receipt and confirmation of delivery to EHRs, personally controlled health records, other systems and networks	1. ID Communication Recipients 2. Data Receipt/Confirmation of delivery – policy driven – Digital Receipt (not done today): 21CFR Part 11	5. Unstructured Document Component 6. Generic alert to identified providers
	Information Exchange	Public Health Case Investigation and Information Sharing				

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 Clinical Decision Support Content (AE)	<p>Data elements for CDS-based triggers may include:</p> <p>Lab result</p> <p>Order</p> <p>Diagnosis</p> <p>7.1.1.1 Medical Devices/drugs – usually no trigger event or it is specified in great detail. Depends upon event/type of event reported – for med error might ask about what prescribed vs what given – that could be a trigger where there are differences. If taking certain drugs, may ask certain questions. It takes a HC provider or someone in the care process to make the judgment that an AE occurred. For Med devices, could be a device failure that triggers report.</p> <p>7.1.1.1 Automation opportunity: Potential triggers could be presented to ask if reportable – case definition with human attestation. Some aspects could be automated – could do some portion of the business rules that could guide a clinician to step through certain questions to validate the event as AE (e.g contraindications/warnings – could take the label data + business rules = flag to clinician)</p> <p>7.1.1.1 Could add statistical anomaly as a trigger: AE that occurs out of statistical data – add clinical judgment to validate the AE;</p> <p>7.1.1.1 AHRQ may have trigger events.</p> <p>7.1.2.1 Data requirements include: chief complaint/reason for visit, medical history, medication history, assessment, orders, tests, results, diagnosis, etc. The inclusion of lab results in an EHR is addressed in the 2006 EHR – Lab Results Use Case.</p> <p>7.1.3.1 Need a list of conditions/criteria that bypass or prioritize this action – action may be more of a prioritization for the human; Flag may be a threshold of events (e.g. 20 cases)</p> <p>7.1.5.1 Text processing: e.g occupation, food history – may be in text</p> <p>7.2.1.1 Disease-specific Reporting /trigger criteria for PH: Case Definition Standard (to be followed by CSTE/CDC or other professional society)</p> <p>7.2.1.3 Drug/treatment purposes; /medical device; patient-safety Reporting supplement /trigger criteria for AE</p> <p>7.2.2.2 Some PH events or AEs are more important than others –need defined procedures/prioritization and expedite review procedures; Prioritization classification – codification?</p> <p>If outbreak investigation then higher prioritization is defined; unusual disease with disastrous consequences; -</p> <p>Many states have regulation regarding the rapidity of report (e.g. 1 hour, 2 hours, 24 hours, etc) – classification of disease vs timeliness; - this is a provider perspective requirement;</p> <p>7.2.2.2 PH response requirements: if this is a message-based/notification response – defined threshold considerations – type of response can range from ACK to mobilization of homeland security resources; - classification of response level is needed; need some type of CDS to determine appropriate responses; need modeling in this area; weighted actions; applies to PH and AE – influence by public concern (external influences beyond the condition itself- e.g. CNN/media attention);</p> <p>7.2.3.1 CDS – to triage – part of 7.2.2; Data element is a standard threshold specification classified by policy;</p>



Requirement Number	Description
1 Clinical Decision Support (PH)	<p>8.1.2.1 Needs the human validation to evaluate/classify; classification vocabulary; accountability system (exists at local level for representing suspected/confirmed – attestation);</p> <p>Classification codification scheme – policy may define degree of investigation – decision tree may be handled by algorithm before coming into this point – CDS- if there are case definition level criteria, may help to triage workflow</p> <p>If there is access to the data set, then machine computation could be beneficial; machine-definition of a case – need confidence measurement – GAP ;Case Classification</p> <p>8.1.2.2 Status values (suspected, confirmed)</p> <p>8.1.3.1 Alerts for characteristics that identify populations at risk for communication of alerts;</p> <p>8.1.3.2 Impact considerations: GIS to transfer/track disease: location; referencing to facilities (facility identifiers – facility types; facility types between OIDs, coded vocabularies – HL7 V3 for facility types: see HL7 ; V2 specific vocabularies for facility types (CDC-assigned OID; may be a locally identified OID)? (Cecil and Margaret to check out V2 and V3 OIDs/facility types (see appendix A – table HL7 0331 – not sufficiently granularity) – facilities in a generic sense; for ICSR looking to start work with AHRQ for service location coded values – looking to see if current work will be sufficient for the ICSR reference guide; CDC – Dan P. – codes for location within a HC facility (e.g. ICU, etc)); OID for ; ASTM E1633;); effected entities; AE – may not be relevant to AE reporting – not necessarily a formalized management plan to deal with certain events (e.g. a lot identified that is suspect: would go into a separate internal tracing/investigation – work with reg affairs for alerts – AE is looking for organization ID numbers – is looking at implementation guide considerations for assignment of OID); National identifier for individuals – for organizations it may have more than one; for transfer of information, a facility may have more than one OID, but need to be able to find that OID – for HL7 conformance – must be registered in the HL7 OID registry for this to be a conformant message; for prior to HL7 V2.6 – no requirement to OID – requirement from 2.6 moving forward (to be validated); Impact assessment needs to know where the event occurred (facility identifiers)</p> <p>8.1.4.1 Undefined decision tree (or minimally defined then human intervention)</p> <p>8.1.5.1 CDS issue - know what role is responsible for this – for communications back to reporting entity: Identify Communication Recipients; Patient safety may also have a criteria, but not typically involving a communication back to the reporting entity;</p>
2 Terminology Service	<p>Translate from local vocabulary to standard vocabulary (e.g. Drug Reporting may be using MEDRA though LOINC has been specified by CHI; NOTE: SNOMED meaning may be different from CDC/CSTE meanings;)</p> <p>(Text processing: occupation, food history – may be in text)</p> <p>TP50- vocabulary can be bound to the schema; FDA has implemented SPL in XFORMS; Vocabulary is the challenge; Clinician wants to use the vocabulary that supports their workflow; Terminology service may be needed to provide the mapping from local vocabulary to the standard vocabulary; challenge in harmonizing the vocabulary to service the multiple stakeholders and multi-purpose the data elements; to adopt a terminology service, the workforce needs to think in terms of the result; risk is that the terminology service changes the meaning; read codes - incorporated incorrectly into SNOMED; Look at Canada's approach of standardization of required and optional components; Need to define what is important to standardize and what should be left to local decisions. e.g. patient demographics, medical HX, procedures can be standardized, but other elements need optionality.</p>
3 Case Report Pre-populate	<p>For AE report, senders/receivers decide which elements are mandatory/optional – from standards perspective, need to be careful about optionality in standard – don't want to fail validation if data is missing. (e.g. can't leave blank by standard vs populating with a valid /meaningful response – flavors of null); Rules for what could/should be blank is between sender/receiver.</p> <p>Data requirement: Report status – (e.g. preliminary, final, notification)</p> <p>PH: Abstract trigger events can be bound to standard vocabulary</p> <p>Common Case Report Content can be mapped to EHR elements to optimize data capture from EHR through form manager. See Tables 2.2.2.1 for common and domain specific data elements for pre-population mapping.</p>



Requirement Number	Description
4 Case Report	<p>General:</p> <p>Adverse Event Reports: FDA – MedWatch, Vaccine Reporting (VAERS)</p> <p>Adverse Event Reports: CDC – Healthcare Associated Infection Reporting</p> <p>Adverse Event Reports: AHRQ – Sentinel Event / Adverse Reaction Reporting</p> <p>Adverse Event Reports: Reporting: NHSN – National Hospital Safety Network</p> <p>Adverse Event Reports: Public Health Case Reporting</p> <p>If there were a requirement for CDC and FDA to go to one type of message, could create so that it fits into one international - Structured documents/CDA document is already underway for structured product label; internationalization is important; HL7 has ISO liason to fast track standards;</p> <p>AHRQ is currently working with other agencies to identify a common format for patient safety reporting</p> <p>follow-up report: Patient Safety might also request additional data with possible manual intervention;</p> <p>Need to identify preliminary report content vs comprehensive report;</p> <p>The information content should be close to the same for PH and AE (med HX, clincial HX; prior clinical encounters (e.g. disease surveillance), pre-disposed, exposed (e.g. family member of communicable disease treatment)</p> <p>Data requirement: Report status – (e.g. preliminary, final, notification)</p> <p>See Tables 2.2.2.1 for common and domain specific data elements for pre-population mapping.</p>
	<p>FDA AE – a limited subset of reports to go to FDA – encompasses several of their paper forms; FDA initial work will differ from initial CDA work from CDC; Once more information in this area, we would harmonize;</p> <p>Need to identify preliminary report content vs comprehensive report;</p> <p>FDA has unique requirements that are not required of other government agencies which have a US-centric domain. FDA has to deal with international AE exchanges;</p> <p>Other kinds of adverse events need to be considered and whether there are standards (e.g. HL7 V2 messages).</p>
	<p>Healthcare Associated Infection Reporting: QRDA HL7 DSTU - possibly scoped applicability.</p>
	<p>Sentinel event /Patient Safety may have specific data associated with some reports (e.g. fall); patient safety common format, but the content may have varying degrees of comprehensive content submitted. Patient Safety Report may be de-identified; amount of information sent at this step is highly variable;</p> <p>Need to identify preliminary report content vs comprehensive report;</p> <p>Further detail anticipated as a result of current harmonization efforts under way.</p>
	<p>Public Health Case Reporting: One payload for all PH case reporting is still a challenge (see data detail in Tables 2.2.2.1)</p> <p>Need to identify preliminary report content vs comprehensive report;</p> <p>PH may have unique data elements associated with a particular event; Like Quality – the data elements will have some common sets and others associated with specific events which may be maintained by another source (e.g. AHRQ, PH).</p> <p>Until analysis is conducted, the AE may be treated as a consumer complaint before being considered/promoted a confirmed AE until confirmed (may want a status indicator of 'confirmed' by HC professionals); If non-provider initiated, may want a status indicator;</p> <p>Formats/mechanisms defer to professional society; reference style guide from CSTE; FDA – product labeling may be considered a style guide – lists the things FDA and manufacturer listed as known problems;</p> <p>Support for Lab Feed (C35, C36)</p>



Requirement Number	Description
5 Unstructured Document Component	Presentation Preserving Text/Scanned document support Need to accommodate/consider privacy issues in small data sets Type of clinical data conveyed depends on what is being conveyed – disease-specific; AE – depends on AE Common/basic; case-specific Patient Specific Report (AE/PH – same report – content is specific to case and situation – don't know what the data are to identify standards – resulting GAP) e.g. TB: need to represent cases identified by a clinician to researchers looking to investigate a particular strain; Case notification/finding – heads up to PH about suspicious events – need to report incomplete data to support early notification and workflow considerations
6 Generic alert to identified providers	Presentation Preserving Text/Scanned document support Type of clinical data conveyed depends on what is being conveyed – disease-specific; AE – depends on AE Common/basic; case-specific Data requirements: (AE, PH) - case counts, other information; - case notifications - data elements; anonymization is defined; CDC has OMB approved data elements (HIPAA identifiers - only applies to covered entities - only required to remove the 18 where it is a covered entity; OMB approves the list of data elements which may exceed the HIPAA list (e.g. DOB); many PH entities are not exempt from HIPAA PH exemption); Small Cell Size considerations
7 Reporting Criteria Content:	Structured content – machine processable

Public Health Case Reporting Data Elements

In fulfillment of data and information requirements for case reporting, the following provisional data dictionary was generated by the HITSP Population Perspective Technical Committee (TC) based upon analysis of minimally common data requirements provided by the AHIC Ad-hoc Case Report Standardization workgroup for Initial Common Data Elements. 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. Options to be considered for these have been supplied by USHIK and can be found in the appendix in Section 6.3 of this document. The list of constraints is harmonized with that provided by the existing 2006 and 2007 HITSP Interoperability Specifications. If there is a deviation from identified concepts and standards from data requirements, it is important to identify if there is a difference in terms or a difference in concepts. If there is a concept difference, it is important to determine whether the concept needs to be preserved. Some of the data elements have a legacy introduction that may not be needed.

Moving forward, the HITSP Population Perspective TC has identified active industry bodies to which we defer for data requirements for this Use Case:

For Public Health reporting, the Council of State and Territorial Epidemiologists (CSTE) should be the body to adjudicate the reporting content. CSTE has ongoing efforts to harmonize these data and reporting



requirements across the state and territorial public health jurisdictions. These efforts will further inform the HITSP data requirements.

For Adverse Event Reporting, there are 3 bodies:

- 1) FDA, which has various groups within it depending upon the report type (e.g. drugs, food/dietary supplements, cosmetics, and devices)
- 2) Patient Safety Organizations or other professional organizations: in the future, PSOs may serve as a source for data elements and AE reporting, particularly in the area of AEs not related to drugs, devices, food/dietary supplements, cosmetics
- 3) Healthcare Associated Infections (HAI) this has traditionally been CDC, but PSOs could eventually become a source for this as well

There are three tiers of data for case reporting. The first tier includes those data elements that are cross-cutting in nature across all case reports. These are identified in the tables below as 'Universal' (U). The Next Tier is a set of domain-specific common elements which are unique to the report type. In the tables below, these are identified as 'Adverse Events' (AE) and 'Public Health' (PH). For public health, these data elements include the non-condition specific data elements maintained by CSTE. The third tier of data includes data elements that are report-specific. This document includes examples of these for public health based upon disease specific data elements maintained also by CSTE. These are identified as 'Anthrax' (RSAX), 'Hepatitis B' (RSHB), Tuberculosis (RSTB), and 'Tularemia' (RSTU). Some of the data elements included in these examples may be candidates for generalization resulting from the analysis for HITSP construct development.

Trigger rules and decision support rules should focus on the second tier of data elements. This second tier may be triaged further depending upon how general the trigger is. Once in the third tier, the context is known and detailed criteria may be applied. First tier trigger rules can leverage the following data elements:

- event status
- condition
- date/time
- public health event
- event outcome

Specific review and feedback of the following section in public comment is requested by the Population Health Perspective TC:

Table 2.2.2-2 Data Elements Cross Reference for High-level cross-cutting tables

DATA ELEMENTS CROSS REFERENCE	
Column	Definition
Data Element	Data element name/identifier as listed by the PH/CCC PH Initial Common Data Elements Ad-hoc workgroup
Definition	Data element description as listed by USHIK for the selected standard for the data element



Data Type	Type of data that is collected with this data element (coded, numeric, text, date/time)
Usage	Indicates which case reporting purposes leverage the data variable: U=Universal PH=Unique to Public Health Reporting AE=Unique to Adverse Event Reporting RSTB=Report-specific Tuberculosis RSAX=Report-specific Anthrax RSHB=Report-specific Hep B RSTU=Report-specific Tularemia
Data Requirement Standards	Expected standards/data values if data element has finite values. CHI-domain recommendations were followed if available
Optionality	Indicates optionality of the attribute: (R=Required, O=Optional, RE=Required if known);
Comments	Pertinent comments and usage

Table 2.2.2-3 Facility Data Elements

Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Facility/Importer Name	The name of the facility that the health care provider diagnosed the subject of the Case Report.	String	U, PH		R	Manufacturer/processor organization placing the report; For PH, one of the minimum number of variables requested for initial case reporting.
Facility Identifier	Unique facility identifier.	Numeric	U	CMS IDs	O	Federal Project under way to used DUNS number for companies that import products – global business
Address						
Address	The address (Street, City, State, Zip Code) of the person or facility that diagnosed the subject of the Case Report		U, PH	FIPS for city/state	R	The electronic transmission of the minimum data set requests either facility/provider telephone or address, preferably both, to be reported. For PH, one of the minimum number of variables requested for initial case reporting. Can be used for practice location
Telephone	The phone number of the person or facility that diagnosed the subject of the Case Report.		U	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O, PH: R	The electronic transmission of the minimum data set requests either facility/provider telephone or address, preferably both, to be report. For PH, one of the minimum number of variables requested for initial case reporting.
Contact						



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Contact Person	Definitions pending - see appendix for detail to be considered		U	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Comment and input appreciated
Contact Phone Number	Definitions pending - see appendix for detail to be considered		U, PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O, PH: R	The electronic transmission of the minimum data set requests either facility/provider telephone or address, preferably both, to be reported. For PH, one of the minimum number of variables requested for initial case reporting. comment and input appreciated
Responsible physician/Health care provider name	The name of the person that diagnosed the subject		U, PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered	PH: R	For PH, one of the minimum number of variables requested for initial case reporting. comment and input appreciated

Table 2.2.2-4 Report Data Elements

Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
User Facility / Importer Report Number	Definitions pending - see appendix for detail to be considered		U	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Type of Report	Definitions pending - see appendix for detail to be considered		U	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	review - as a general descriptor/content <i>comment and input appreciated</i>
Report Date	The date that the Case Report is being sent	Timestamp	U, PH	HL7 Timestamp	O,PH:R	For PH, one of the minimum number of variables requested for initial case reporting.
Reported Previously	Definitions pending - see appendix for detail to be considered		U	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Report sent to	Definitions pending - see appendix for detail to be considered		U	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Report sent to FDA	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Date User Facility/Importer Became Aware of Event	Definitions pending - see appendix for detail to be considered	Timestamp	U	HL7 Timestamp	O, PH:R	For PH, one of the minimum number of variables requested for initial case reporting. <i>comment and input appreciated</i>
Date report sent	Definitions pending - see appendix for detail to be considered	Timestamp	U	HL7 Timestamp	O,PH:R	For PH, one of the minimum number of variables requested for initial case reporting. <i>comment and input appreciated</i>
Date Sent to Manufacturer (Change to date report Sent)	Definitions pending - see appendix for detail to be considered	Timestamp	U	HL7 Timestamp	O	<i>comment and input appreciated</i>
Date sent to FDA	Definitions pending - see appendix for detail to be considered	Timestamp	AE	HL7 Timestamp	O	<i>comment and input appreciated</i>
Report Source	Definitions pending - see appendix for detail to be considered		U	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
REPORTER INFORMATION						
Reporter Name	The name of the person or facility sending the Case Report		U, PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O;PH:R, AE:R	For PH, one of the minimum number of variables requested for initial case reporting. For AE, one of the minimum number of variables required for valid electronic report



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Occupation of Reporter	Definitions pending - see appendix for detail to be considered		U	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Telephone	The phone number of the person or facility sending the Case Report		U, PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O;PH:R	For PH, one of the minimum number of variables requested for initial case reporting.
Reporter Email	Definitions pending - see appendix for detail to be considered		U	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Type of Reporter	Definitions pending - see appendix for detail to be considered		U	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Reporter Address (street name, city, state, zip code)	Definitions pending - see appendix for detail to be considered		U, PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered	PH: R	For PH, one of the minimum number of variables requested for initial case reporting

Table 2.2.2-5 Patient Data Elements

Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Patient identifier	Definitions pending - see appendix for detail to be considered	Alphanumeric	U	Standards to be selected pending further domain analysis - see appendix for detail to be considered	RE, AE:R	RE; NOTE: for PHCR, the patient identifier may be a pseudo-id For AE, one of the minimum number of variables required for valid electronic report <i>comment and input appreciated</i>
Patient Name (first, MI, Last)	The name (preferably legal) of the subject of the case report.		U	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O, PH: R	For PH, one of the minimum number of variables requested for initial case reporting <i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Date of Birth	Date of birth	Date field	U	HL7 Timestamp HL7 V3 flavors of null for DOB	O; PH: R	NOTE: May not be passing DOB for age over 89 due to HIPAA requirements For PH, one of the minimum number of variables requested for initial case reporting
Age	The age of the subject of the case report at time of diagnosis	Numeric	U, PH	Unified Code for Units of Measure (UCUM) for Age Units	O, PH: R	For PH, one of the minimum number of variables requested for initial case reporting <i>comment and input appreciated</i>
Gender	Patient sex	Coded	U, PH	HL7 2.5 Table 001 Administrative Sex M Male F Female U Undifferentiated	O, PH: R	For PH, one of the minimum number of variables requested for initial case reporting
Pregnancy Status	Whether the subject of the case report was pregnant at time of diagnosis.		PH, AE	Yes/No	O	This may apply to specific conditions. Report-specific requirements; Public health only. for AE - part of relevant medical history
Estimated Deliver Date	Estimated date of delivery (or est. date of confinement [EDC])		PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Only for certain reports <i>comment and input appreciated</i>
Weight	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Only for certain reports <i>comment and input appreciated</i>
Birth Weight	Definitions pending - see appendix for detail to be considered		AE, PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Only for certain reports <i>comment and input appreciated</i>
Number of Siblings	Definitions pending - see appendix for detail to be considered		PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Only for certain reports <i>comment and input appreciated</i>
Patient Address (street name, city, state, zip code)	The address of the subject of the case report.		U, PH	FIPS	O, PH: R	For PH, one of the minimum number of variables requested for initial case reporting



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Patient Telephone	The telephone of the subject of the case report.		U, PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O;PH: R	For PH, one of the minimum number of variables requested for initial case reporting <i>comment and input appreciated</i>
Patient County	The county of the address of the subject of the case report	String	U, PH	FIPS	O	
Patient Country	The country of the address of the subject of the case report.		U	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Race	The race(s) of the subject of the case report.		U, PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	May be restricted by jurisdiction <i>comment and input appreciated</i>
Ethnicity	The ethnicity of the subject of the case report		U, PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	May be restricted by jurisdiction <i>comment and input appreciated</i>
Occupation	The occupation of subject of the case report. Enter as much detail as possible (e.g. Teacher in Pre-School facility)		PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Only for certain reports <i>comment and input appreciated</i>
Date of Death	If patient has died, deceased date/time		U, PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Patient Country of Birth	The subject's country of birth.		PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Only for certain reports; This may apply to specific conditions <i>comment and input appreciated</i>
Patient Country of Origin	The subject's country of origin.		PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Only for certain reports; This may apply to specific conditions. May not necessarily be the subject's country of birth <i>comment and input appreciated</i>



**HITSP Public Health Case Reporting Use Case Requirements,
Design and Standards Selection**

Review Copy
20080627 V1.0

Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Time arrived in the US	The date that the subject most recently arrived into the US		PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Only for certain reports; This may apply to specific conditions <i>comment and input appreciated</i>

Table 2.2.2-6 Clinical Data Elements

Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
EVENT INFORMATION						
Date of Event	Definitions pending - see appendix for detail to be considered	Date field	AE	HL7 Timestamp HL7 V3 flavors of null for DOB	PH: R	For PH, one of the minimum number of variables requested for initial case reporting <i>comment and input appreciated</i>
Description of Event	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Name of Condition	The name of the condition diagnosed for the subject of the Case Report		PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered	PH: R	Might be combined with the concept of 'description of event' For PH, one of the minimum number of variables requested for initial case reporting <i>comment and input appreciated</i>
Event Patient Problem Code	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Might be combined with the concept of 'description of event' <i>comment and input appreciated</i>
Event Device Problem Code	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Might be combined with the concept of 'description of event' <i>comment and input appreciated</i>
Type of Reportable Event	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Might be combined with the concept of 'description of event' For AE, one of the minimum number of variables required for valid electronic report <i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Type of Event and/or Issue	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Might be combined with the concept of 'description of event' For AE, one of the minimum number of variables required for valid electronic report <i>comment and input appreciated</i>
Approximate Age of Device	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Outcome attributed to AE	Definitions pending - see appendix for detail to be considered.		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Patient Recovered Diagnosis	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Location where Event Occurred	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Adverse Event Terms	Definitions pending - see appendix for detail to be considered.		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Event Abated after use stopped or dose reduced?	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Event Reappeared after reintroduction	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
MEDICATION HISTORY						
Concomitant Medical Product Name	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	For AE, one of the minimum number of variables required for valid electronic report <i>comment and input appreciated</i>
Therapy Dates	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Pre-existing physician diagnosed allergies, birth defects. Medical conditions	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Current Medications (Medwatch concomitant meds)	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Previous Vaccine Type	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Vaccination Only <i>comment and input appreciated</i>
Previous Vaccine Manufacturer	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Vaccination Only <i>comment and input appreciated</i>
Previous Vaccine Lot #	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Vaccination Only <i>comment and input appreciated</i>
Previous Vaccine Route/Site	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Vaccination Only <i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Vaccine # Previous Doses	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Vaccination Only <i>comment and input appreciated</i>
Previous Vaccine Date Given	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Vaccination Only <i>comment and input appreciated</i>
AE Following Prior Vaccination	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Vaccination Only <i>comment and input appreciated</i>
Vaccine Purchased With	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Vaccination Only <i>comment and input appreciated</i>
Suspect Product Name	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Product Dose	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Product Frequency	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Product Route Used	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Product Therapy Dates	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Product Diagnosis for Use	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Product Lot #	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Expiration Date	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
NDC# or Unique ID	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Event Abated after use stopped or dose reduced?	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Event Reappeared after reintroduction?	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Suspect Medical Device Brand Name	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Common Device Name	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Manuf. name, City and State	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Medical Device Model #	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Medical Device Catalog #	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Medical Device Serial #	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Medical Device Lot #	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Medical Device Other #	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Operator of Device	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
If implanted give date	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
If explanted give date	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Is this a single use device that was reprocessed and reused on patient?	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Name and Address of Reprocessor	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Product available for evaluation?	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Date product returned to manuf.	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Concomitant Medical Products & Therapy Dates	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
PREVIOUS HISTORY						
Signs and Symptoms	Definitions pending - see appendix for detail to be considered		U, PH	SNOMED-CT ICD9-CM	O;	This may apply to specific conditions. <i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Types of Anthrax	Definitions pending – see appendix for detail to be considered		RSAX	Value Set: Cutaneous anthrax Inhalation anthrax Gastrointestinal anthrax	O	<i>comment and input appreciated</i>
Anthrax Signs and Symptoms	Definitions pending - see appendix for detail to be considered		RSAX	Question subset: Fever Chills Cough Chest pain Difficulty breathing Headache Vomiting Diarrhea Abdominal cramps or pain Edema Cutaneous ulcer with edema and black eschar Regional lymphadenopathy	R	Edema: Should be defined - pulmonary, lower extremity, and how does this differ from the ulcer definition <i>comment and input appreciated</i>
Hep B Signs and Symptoms	Definitions pending - see appendix for detail to be considered		RSHB	Question Subset: Symptomatic Jaundice	R	<i>comment and input appreciated</i>
TB Signs and Symptoms	Definitions pending - see appendix for detail to be considered		RSTB	Question Subset: Asymptomatic Fever Chills Cough Productive cough Hemoptysis Night sweat Weight loss Chest pain	R	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Tularemia signs and symptoms	Definitions pending - see appendix for detail to be considered		RSTU	Question subset: Abdominal cramps or pain Bloody sputum Chest pain Chills Conjunctivitis Cough Cutaneous ulcer Diarrhea Fever Headache Joint pain Lymphadenopathy Malaise Meningitis Muscle aches Nausea Pharyngitis Pneumonia Sepsis Shortness of breath Sore throat Vomiting Weight loss	R	<i>comment and input appreciated</i>
TB Major body site of TB	The subject's anatomic site where the disease is located		RSTB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	R	<i>comment and input appreciated</i>
TB Status of Patient at Diagnosis	At the time of diagnosis, was the subject alive or deceased?		RSTB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	R	<i>comment and input appreciated</i>
Tularemia Location of Lesion	Definitions pending - see appendix for detail to be considered		RSTU	Value Set: Ulceroglandular Pneumonic Glandular Oropharyngeal Oculoglandular Typhoidal	R	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Symptom/ Illness Onset Date/Time	This is the range of time of which the problem was active for the patient; for PH: The date that the subject began having symptoms of condition being reported	Date field	U	HL7 Timestamp	O	<i>comment and input appreciated</i>
Patient Class	General type of patient, e.g., Inpatient, Outpatient, Emergency	Coded	AE	HL7 2.5.5 Table 0004 Patient Class, ActEncounterCode subset of HL7 V3 ActCode, limited to IMP, AMB, EMER corresponding to HL7 V2.X I,O,E	O	<i>comment and input appreciated</i>
LAB RESULTS						
Reporting Laboratory Identifier	Identifier for laboratory that is sending the result. This laboratory may be sending results received back from reference laboratories	Alphanumeric	AE	CLIA Unique Laboratory ID	O	
Performing Laboratory	Laboratory that produced the test result. This may be a reference laboratory identifier.	Alphanumeric	AE	CLIA Unique Laboratory ID	O	
Report Date/Time	Date/time of report	Date	AE	HL7 Timestamp	O	
Results Status	Status of report (preliminary, final, corrected)	Coded	AE	HL70123 Result Status	O	
Ordered Test Code	The identifier code for the requested observation/test/battery	Coded	AE	Recommend SNOMED-CT, LOINC, CPT, HCPCS and others (encouraging commercial vendor participation) get together to establish a suitable vocabulary	O	Major GAP – lack of a universal vocabulary for identifying ordered tests; Referral made to SDOs by Population Perspective TC



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Resulted Test	"The identifier code for the specific test component resulted	Coded	AE	LOINC Laboratory Test Identifiers include analytes, specimen source, methods, and sensitivity tests for drugs.	O	
Result Unit	Unit for numeric result context	Alphanumeric	AE	Unified Code for Units of Measure (UCUM) Expressions	O	
Test Interpretation	Interpretation of test result, including the susceptibility test interpretation	Coded	AE	HL70078 Abnormal Flags	O	
Test Status	Status of the test result	Coded	AE	HL70123 Result Status	O	
CLINICAL TEST (Different from Diagnostic)						
TB Test Method	Testing method used to arrive at the specific result :Tuberculin Skin Test (TST)	Alphanumeric	RSTB	V3 Observation Method as a starter set. May be extended locally	R	May also be referred as Purified Protein Derivative (Mantoux)
TB Collection Date	Date TST was placed	Date	RSTB	HL7 Timestamp	R	
TB Test Result	Test result of TST	Coded	RSTB	Recommend SNOMED-CT	R	Includes all test results including susceptibilities, serologies, non-organisms; Additional value sets (e.g., +/-)
DIAGNOSTIC INFORMATION						
The following data element will include condition specific value sets.						
Date of Test	The date that the laboratory test was performed for the subject of the Case Report.	Date	AE, PH, RSAX, RSHB, RSTB, RSTU	HL7 Timestamp	O, O, R, R, R, R	
Test Method	Testing method used to arrive at the specific result :The name of the laboratory test.	Alphanumeric	AE, PH, RSAX, RSHB, RSTB, RSTU	V3 Observation Method as a starter set. May be extended locally	O, O, R, R, R, R	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Anthrax Test Method	Testing method used to arrive at the specific result :The name of the laboratory test.	Alphanumeric	RSAX	Value set: B. Anthracis culture Anthrax electrophoretic immunotransblot (EITB) reaction to protective antigen and/or lethal factor bands B. Anthracis direct fluorescent antibody assay (DFA) B. Anthracis time-resolved fluorescence (TRF) B. Anthracis by PCR x-ray	R	<i>comment and input appreciated</i>
HepB Test Method	Testing method used to arrive at the specific result :The name of the laboratory test.	Alphanumeric	RSHB	Value set: ALT (SGPT) AST (SGOT) Bilirubin IgM anti-HBc IgM anti-HAV Total anti-HBc Anti-HBs HBsAg HBeAg Anti-HBe HBV-DNA	R	<i>comment and input appreciated</i>
TB Test Method	Testing method used to arrive at the specific result :The name of the laboratory test.	Alphanumeric	RSTB	Value set: X-ray Smear - Acid fast bacilli Culture - Acid fast bacilli Nucleic Acid Amplification Test (NAAT) Polymerase chain reaction Interferon Gamma Release Assay (IGRA) QuantiFERON	R	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Tularemia Test Method	Testing method used to arrive at the specific result: The name of the laboratory test	Alphanumeric	RSTU	Value set: F. tularensis fluorescent assay F. tularensis antibody F. tularensis culture x-ray	R	<i>comment and input appreciated</i>
Test Result	The test result of the laboratory test including any applicable result units of measure	Coded	AE, PH, RSAX, RSHB, RSTB, RSTU	Recommend SNOMED-CT	O, O, R, R, R, R	
Specimen Collection Date	The date that the specimen for the laboratory test was taken from the subject of the Case Report	Date	AE, PH, RSAX, RSHB, RSTB, RSTU	HL7 Timestamp	O, O, R, R, R, R	
Source of Specimen	The physical body location from where the specimen for the lab report was taken from the subject	Coded	AE, PH, RSAX, RSHB, RSTB, RSTU	SNOMED –CT	O, O, R, R, R, R	<i>comment and input appreciated</i>
Anthrax Source of Specimen	The physical body location from where the specimen for the lab report was taken from the subject	Coded	RSAX	SNOMED –CT Value set: Blood Chest CSF Lesion swab Lymph node biopsy Skin biopsy Sputum Stool		<i>comment and input appreciated</i>
HepB Source of Specimen	The physical body location from where the specimen for the lab report was taken from the subject	Coded	RSHB	SNOMED –CT Value set: Blood	R	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
TB Source of Specimen	The physical body location from where the specimen for the lab report was taken from the subject	Coded	RSTB	SNOMED –CT Value set: Chest Abdominal Sputum Cerebrospinal fluid Biopsied tissue		<i>comment and input appreciated</i>
Tularemia Source of Specimen	The physical body location from where the specimen for the lab report was taken from the subject	Coded	RSTU	SNOMED –CT Value set: Blood Chest CSF Lesion swab Lymph node biopsy Skin biopsy Sputum Stool	R	<i>comment and input appreciated</i>
Name of Organization Collecting Specimen	Name of organization collecting specimen which may be different from the organization performing the laboratory analysis		AE, PH, RSAX, RSHB, RSTB, RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O, O, R, R, R, R	<i>comment and input appreciated</i>
HepB Lab Referencing Range	Upper limit normal??		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	This applies to liver enzyme levels, for the above test methods ALT and AST, at time of diagnosis <i>comment and input appreciated</i>
HepB Abnormal Flag	Definitions pending - see appendix for detail to be considered		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
HepB Previously tested HBsAg +	Has the subject previously tested positive for hepatitis B surface antigen?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	R	Include date of test <i>comment and input appreciated</i>
HBsAg Date of test	Date of previous HBsAg test performed		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	R	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Diagnosis/Injury Code	Diagnosis or diagnoses assigned as a result of the encounter	Coded	AE	ICD-9/10 CM Or SNOMED CT	O;	Only for certain Reports Review public health and AE use
Diagnosis Type	Type of diagnosis being sent (admitting, working, final)	IS (coded)	AE	HL7 2.5 User-defined Table 0052 - Diagnosis Type	O;	Only for certain Reports Review public health and AE use
Diagnosis Date/Time	The date that the subject of the Case Report was diagnosed with Condition above	Date field	AE, PH	HL7 Timestamp	O;	Only for certain Reports Review public health and AE use
Previous Event Report Details	Definitions pending - see appendix for detail to be considered		AE?	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Reason for Non-Evaluation	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Type of Follow-Up	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Type of Remedial Action	Definitions pending - see appendix for detail to be considered		AE	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
MEDICAL TREATMENT						
Administration of Treatment	Was treatment administered?		AE, PH, RSAX, RSHB, RSTB, RSTU	PH: Y/N	O, R, R, R, R	This may apply to specific conditions and may have different question sets applied. This can include administration of antibiotics, vaccine, or other substances used to treat for a specific condition



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Date of Admin of Treatment	The date treatment was administered. For HepB, Date HBV vaccine administered	Date	AE, PH, RSAX, RSHB, RSTB, RSTU	HL7 Timestamp	O, R, O, R, R	This may apply to specific conditions
Name of Treatment	Name of the treatment		AE, PH, RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O, R	This may apply to specific conditions. This can include name of antibiotics, vaccine, or other substances used to treat for a specific condition <i>comment and input appreciated</i>
Anthrax Name of Treatment	Name of the treatment used to treat the Anthrax.		RSAX	Value set: Amoxicillin Ciprofloxacin Doxycycline	O	<i>comment and input appreciated</i>
HepB Name of Treatment	Name of HBV vaccine		RSHB	HBV Vaccine	O	<i>comment and input appreciated</i>
TB Name of Treatment	The list of medications prescribed for the subject's treatment of TB		RSTB	Value set: Isonaizid (INH) Rifampin Rifamate Rifater Pyrazinamide Ethambutol Streptomycin Ethionamide Kanamycin Cycloserine Capreomycin Para-Amino Salicylic Acid Amikacin Rifabutin Ciprofloxacin Levofloxacin Moxifloxacin Ofloxacin Rifapentine Other	O	This data element is found in the non-condition specific list, but has specific value set associated with this condition <i>comment and input appreciated</i>
HepB Year of last HBV Vaccine Dose	In what year was the last shot received		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
HepB Number of doses of HBV vaccine in the past	If yes, how many shots		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Anti HBs test 1-2 months after the last dose of vaccine	Was the patient tested for antibody to HBsAg (anti-HBs) [within 1-2 months] after the last dose?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
HepB Positive anti-HBs	Did the patient test positive for Anti-HBs ("reactive", "positive", or anti-HBs \geq 10 mIU/ml) after the last dose of HBV vaccine?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Positive (or "reactive") for antibody HBsAg as defined by anti-HBs \geq 10mIU/ml <i>comment and input appreciated</i>
HepB Serum anti-HBs \geq 10mIU/ml	Was serum anti-HBs \geq 10mIU/ml?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	If patient tested positive for antibody to HBsAg (anti-HBs) after the last dose of HBV vaccine <i>comment and input appreciated</i>
Hospitalization	If the subject of the case report was hospitalized		U	Standards to be selected pending further domain analysis - see appendix for detail to be considered		<i>comment and input appreciated</i>
Admission Date	Enter the date that the subject of the Case Report was Admitted to the hospital.	Date	U	HL7 Timestamp		
Discharge Date	Enter the date that the subject of the Case Report was Discharged from the hospital		U	Standards to be selected pending further domain analysis - see appendix for detail to be considered		
Hospital Name	Name of hospital the case was admitted.	String	PH			<i>comment and input appreciated</i>
Recovered	Did the subject recover from the disease?		PH	Standards to be selected pending further domain analysis - see appendix for detail to be considered		<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Death	Did the subject die as a result of the disease?	Boolean	PH	HL7 Table 0136Yes/No Indicator		<i>comment and input appreciated</i>
EPIDEMIOLOGIC INFORMATION						
Contact with Person with Similar Symptoms	Definitions pending - see appendix for detail to be considered		RSAX	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Contact with Animal or Animal Products	Definitions pending - see appendix for detail to be considered		RSAX	Standards to be selected pending further domain analysis - see appendix for detail to be considered Question Subset: Animal Exposure type Current location Exposure date	O	<i>comment and input appreciated</i>
Handled suspicious mail	Definitions pending - see appendix for detail to be considered		RSAX	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Exposed to suspicious powder	Definitions pending - see appendix for detail to be considered		RSAX	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Travel Information	Definitions pending - see appendix for detail to be considered		RSAX	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Date Travel	Definitions pending - see appendix for detail to be considered	Date	RSAX	HL7 Timestamp	O	
Location of Travel	Definitions pending - see appendix for detail to be considered		RSAX	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Occupational Risk Factors	Definitions pending - see appendix for detail to be considered		RSAX	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Occupation	Definitions pending - see appendix for detail to be considered		RSAX	Standards to be selected pending further domain analysis - see appendix for detail to be considered Question Subset: Mail Handler	R	<i>comment and input appreciated</i>
EPIDEMIOLOGIC DATA – HEP B						
Environmental Risk Factors	Are environmental risk factors present?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Travel Information	Has the subject traveled out of state/country/out of routine?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Date Travel	Definitions pending - see appendix for detail to be considered	Date	RSHB	HL7 Timestamp	O	<i>comment and input appreciated</i>
Location of Travel	Definitions pending - see appendix for detail to be considered		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
DURING 6 WEEKS-6MONTHS PRIOR TO ONSET OF SYMPTOMS						
Contact with confirmed or suspect HBV case	[During 6 weeks-6 months prior to onset of symptoms] was the patient a contact of a person with confirmed or suspected acute or chronic hepatitis B virus infection?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered Question Subset: Casual Household [non-sexual] Sexual Needle use Perinatal Other	O	<i>comment and input appreciated</i>
Hemodialysis	Did the patient undergo hemodialysis		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Receive blood or blood products	Did the patient receive blood or blood products [transfusion]		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Date of receiving blood or blood products	If yes [to receiving blood or blood products], date of transfusion		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
IV infusion or injection in the outpatient setting	Did the patient receive any IV infusions and/or injections in the outpatient setting		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Surgery	Did the patient have surgery		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Organ or tissue transplant recipient	Did the patient have an organ or tissue transplant		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Dental work or oral surgery	Did the patient have dental work or oral surgery		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Acupuncture	Did the patient have puncture with a needle contaminated with blood		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Hospitalized	Was the patient hospitalized?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	This is different from the data element hospitalization in the non-condition specific list <i>comment and input appreciated</i>
Long-term Care	Was the patient a resident of a long term care facility?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Incarcerated	Was the patient incarcerated for longer than 24 hours?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Medical Risk Factors	Are medical risk factors present?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
History of Viral Hepatitis	Patient has a history of viral hepatitis?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered Question Subset: Hepatitis A Hepatitis B Hepatitis C Hepatitis D Other viral hepatitis	O	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Diagnosed STD	Definitions pending - see appendix for detail to be considered		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Treated STD	Was the patient EVER treated for a sexually transmitted disease		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Year of the most Recent Treatment	If yes to treated for STD, in what year was the most recent treatment		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Perinatal	Definitions pending - see appendix for detail to be considered		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Occupational Risk Factors	Are occupational risk factors present?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Occupation	The Occupation of subject of the case report		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	This data element is include in the non-condition specific, but has a specific value tied for this condition <i>comment and input appreciated</i>
Public Safety Worker	Was the patient employed as a public safety worker (fire fighter, law enforcement or correctional officer) having direct contact with human blood?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Medical or Dental Field	Was the patient employed in a medical or dental field involving direct contact with human blood?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Job involving direct contact with human blood	Definitions pending - see appendix for detail to be considered		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Frequency of direct blood or body fluid exposure	Frequency of direct blood contact or body fluids exposure?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered Value set: Frequent (several times weekly) Infrequent	O	This follow-up question applies to above questions for public safety worker, employed in medical or dental field, and generic question of job involving direct contact with human blood <i>comment and input appreciated</i>
Sociobehavioral Risk Factors	Are sociobehavioral risk factors present?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Sociobehavioral risk factors <i>comment and input appreciated</i>
Male Sexual Partners	In the 6 months before symptom onset how many male sex partners did the patient have?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Male sexual partners <i>comment and input appreciated</i>
Female Sexual Partners	In the 6 months before symptom onset how many female sex partners did the patient have?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Female sexual partners <i>comment and input appreciated</i>
Lifetime Total Sexual Partners	Definitions pending - see appendix for detail to be considered		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Lifetime total sexual partners <i>comment and input appreciated</i>
DURING 6 WEEKS - 6 MONTHS PRIOR TO ONSET OF SYMPTOMS						
Use of Injection Street Drugs	During the 6 weeks- 6 months prior to onset of symptoms inject drugs not prescribed by a doctor?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Shared Injection Equipment	Definitions pending - see appendix for detail to be considered		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Use of street drugs but not inject	During the 6 weeks- 6 months prior to onset of symptoms use street drugs but not inject?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Tattooing	Definitions pending - see appendix for detail to be considered		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Place the tattoo placement was performed	Definitions pending - see appendix for detail to be considered		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Body Piercing (other than ear)	Did the patient have any part of their body pierced (other than ear)?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Place the body piercing was performed	Where was the piercing performed?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Physical assault on exposed person involving blood or semen	Definitions pending - see appendix for detail to be considered		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Shared razor, toothbrushes or nail care items	Definitions pending - see appendix for detail to be considered		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
An accidental stick or puncture with a needle or other object contaminated with blood	Definitions pending - see appendix for detail to be considered		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Exposure to some else's blood	Definitions pending - see appendix for detail to be considered		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Incarcerated	Incarcerated for longer than 24 hours?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Incarceration	During his/her lifetime, was the patient EVER incarcerated for longer than 6 months?		RSHB	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
EPIDEMIOLOGIC INFORMATION - TB						
Environmental Risk Factors	Are environmental risk factors present?		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Location of Probable Exposure	Places that the subject may have been exposed to TB		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered Question subset: Day care Home School College Workplace Long term care facility Type of long term care facility Hospital Correctional facility Type of correctional facility Airplane or Public transportation Homeless shelter Other public gathering place	Conditional: R for Correctional and Homeless, O for remainder	The location when a person is diagnosed doesn't relate to the exposure site. Many of the cases are related to reactivation of latent TB infection and the exposure occurred many years before. These settings have more impact for the contact tracings to identify converts; NOTE: Workplace may include office; Airplane may include the parameter of 8 hour; <i>comment and input appreciated</i>
Travel Information	Has the subject traveled out of state/country/out of routine?		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Date Travel	Definitions pending - see appendix for detail to be considered	Date	RSTU	HL7 Timestamp	O	
Location of Travel	Definitions pending - see appendix for detail to be considered		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Medical Risk Factors	Are medical risk factors present?		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
HIV Status	Does the patient have a history of being HIV positive?		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Occupational Risk Factors	Are occupational risk factors present?		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered Question Subset: Health care worker Correctional employee	O	<i>comment and input appreciated</i>
Sociobehavioral Risk Factors	Are sociobehavioral risk factors present?		RSTU	Question Subset: Homeless within the past year Incarcerated Excess alcohol use within past year Injection drug use within past year Non-injection drug use within past year	O	<i>comment and input appreciated</i>
EPIDEMIOLOGIC INFORMATION – TULERAMIA						
Environmental Risk Factors	Are environmental risk factors present?		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Contact with person with similar symptoms	Definitions pending - see appendix for detail to be considered		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Contact with animal or animal products	Contact with livestock (dead or alive), animal products, insect		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Has the patient been bitten by ticks or deer flies in the three weeks prior to illness? May also ask is patient has consumed high-risk animal. (or this also define a recreational exposure) <i>comment and input appreciated</i>



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Animal/Insect	Type of animal/insect		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Exposure Type	Exposure type		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Also can be used to describe insect bite <i>comment and input appreciated</i>
Current Location	Location of exposure		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Can include ticks or deer flies <i>comment and input appreciated</i>
Exposure Date	Date of exposure		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	Date of bite
Exposed to Suspicious Powder	Was the Subject exposed to suspicious powder		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Travel Information	Has the subject traveled out of state/country/out of routine?		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	(Different periods of interests depending on state, also for time line, e.g., within XX days of onset) <i>comment and input appreciated</i>
Date Travel	Definitions pending - see appendix for detail to be considered	Date	RSTU	HL7 Timestamp	O	<i>comment and input appreciated</i>
Location	Definitions pending - see appendix for detail to be considered		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>
Occupational Risk Factors	Are occupational risk factors present?		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered	O	<i>comment and input appreciated</i>



**HITSP Public Health Case Reporting Use Case Requirements,
Design and Standards Selection**

Review Copy
20080627 V1.0

Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Occupation	The Occupation of subject of the case report		RSTU	Standards to be selected pending further domain analysis - see appendix for detail to be considered Question subset: Laboratory Landscape Work with animals or animal products	O	This data element is included in the non-condition specific, but has a specific value tied for this condition. <i>comment and input appreciated</i>

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
Clinical Information System (or HIS, EHR) (Healthcare Delivery Organizations, Ancillary Entities, Clinicians) [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.	1, 2
Laboratory Information Systems (Message Sender/ Bio Data Sender, Document Source)	Information system supporting the testing, analysis, and information management for laboratory organizations. Medical laboratories, in either in a hospital or ambulatory environment, which analyze specimens as ordered by clinicians to assess the health status of patients. Laboratories, depending on how they are affiliated with hospitals, can be part of either Individual Healthcare Facilities or Integrated Healthcare Data Suppliers. These business actors are responsible for updating interface engine rules and triggers in response to Use Case modifications of requested data feeds.	1,2
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)	1,2



Business Actor	Description	Use Case Scenario
Public Health Agencies (local/state/federal) (Message Receiver/ Bio Data Receiver, Document Consumer)	<p>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.</p> <p>NOTE: This business actor also includes other agencies and professional societies receiving PH information and agencies receiving AE/patient safety reports (e.g. CDC, CSTE, FDA, AHRQ)</p>	1,2

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 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 Public Health Case Reporting (PHCR) Business Sequence – Part 1

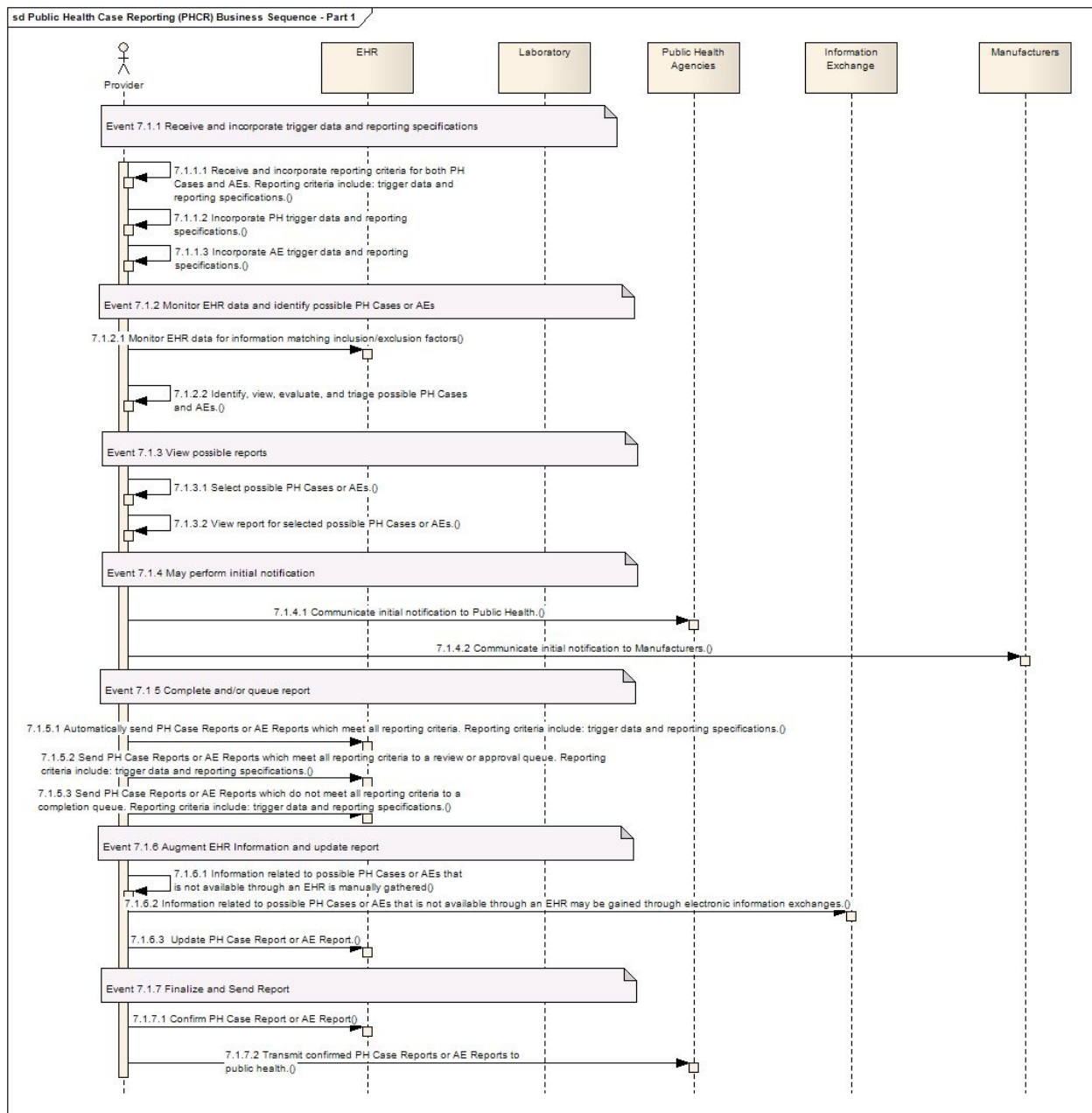


Figure 2.2.4-1 Public Health Case Reporting (PHCR) Business Sequence – Part 2

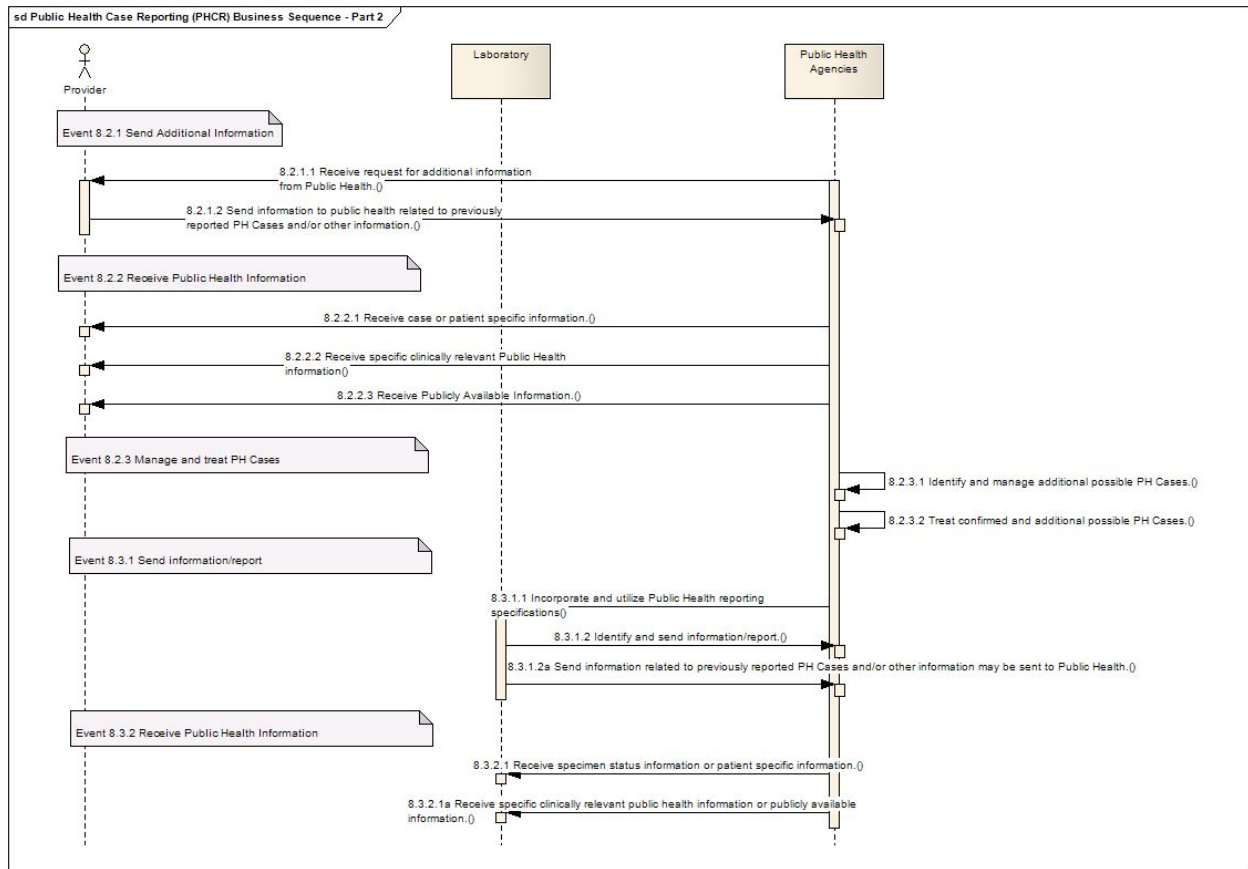
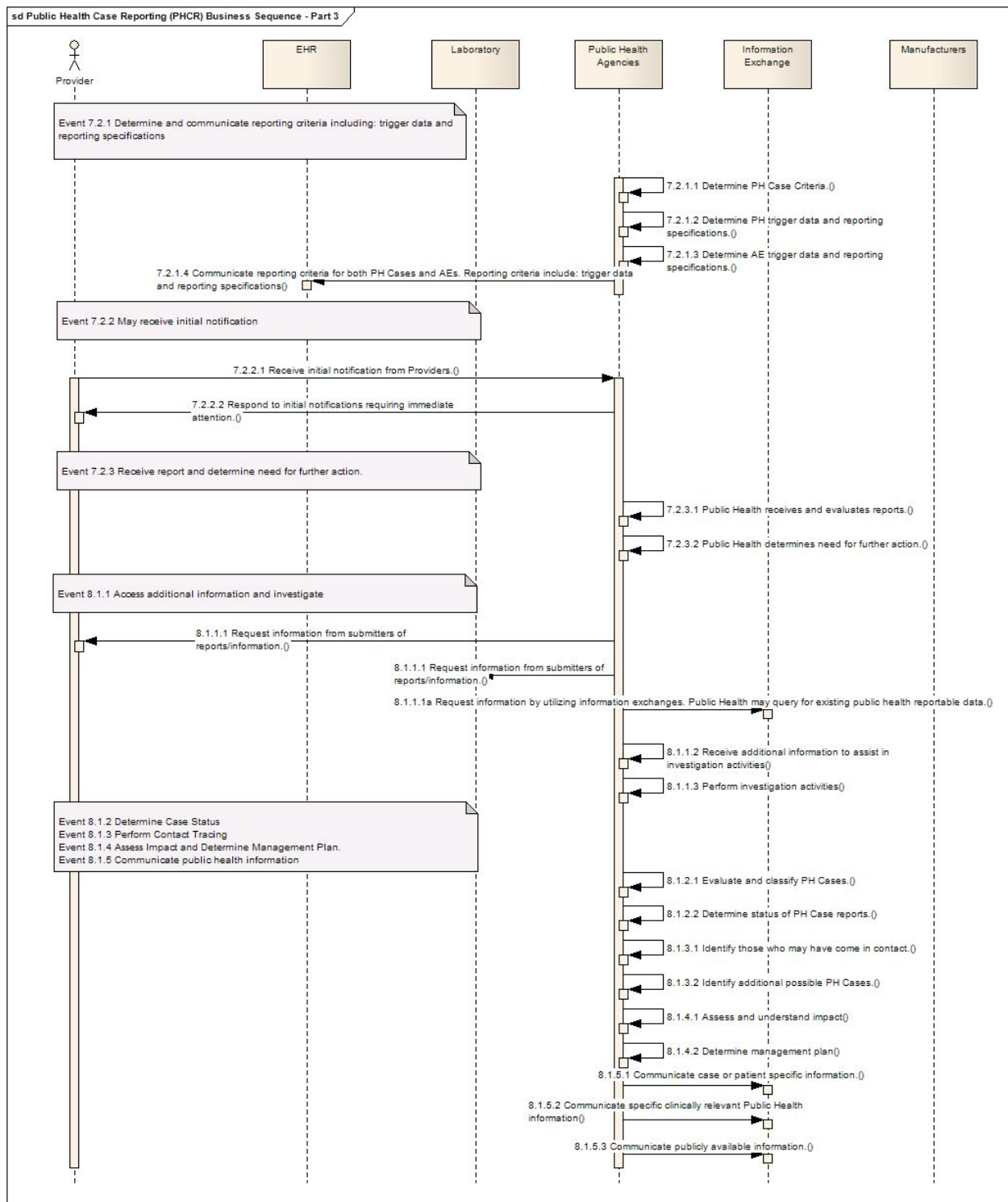


Figure 2.2.4-1 Public Health Case Reporting (PHCR) Business Sequence – Part 3



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 optimize electronic data capture of Public Health Case Reporting and adverse event data from electronic health records. This will be accomplished through the mapping of data elements that are cross-cutting among the multiple reporting purposes to electronic health record data elements. This mapping will enable pre-population of data within the context of HITSP TP50 Retrieve Form for Data Capture which can then be leveraged for the capture of supplemental reporting criteria not typically maintained as part of the electronic health record.

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 reporting, and triggering criteria for both public health adverse event cases. It also includes support for prioritization of responses.

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 Public Health Case Reporting 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 I:

- Establish Transaction Packages, Transactions, and components to complete the Use Case requirements related to the electronic data capture of report content from the electronic health record



- Communication of structured content for Healthcare Associated Infections (HAI) to public health authorities
- Leverage existing HITSP constructs to enable EHR compilation of augmented data surrounding case reporting for a given patient leveraging common data elements identified that across the multiple case reporting domains, those common within the domains, and detailed case reporting examples. Detailed case reporting examples in public health will be limited to Tuberculosis, Hepatitis B, Tularemia, and Anthrax
- Establish one component (Case Report Pre-populate) to enable mapping of common case reporting data elements from EHR to enable pre-population of forms from the TP50 form manager

While there are workflow commonalities between public health case reporting and adverse event reporting, there are differences in workflow policy and data elements routinely captured today. As harmonization is under way through cross-agency initiatives to align data and terminology requirements for case reporting to support both public health and varying adverse event reporting needs, the HITSP Population Perspective TC will identify, observe, and contribute to harmonization efforts and defer content specification for non-HAI communications until the standardization/harmonization is completed.

For the purpose of submitting a case report, we will develop the Case Report Pre-populate component based upon our common data requirements that will work in conjunction with HITSP/TP50 to enable pre-population, but which WILL NOT be specified as a component for the communication of the populated payload to the end agency recipient. This very important consensus construct (component) is deferred until such time as we have a consensus-based content /transport that can be specified and generated from a variety of architectures for submission to the agency. There is no determination at this time whether that construct will be a message, a CDA document or some other content construct. The content that we have discussed can be mapped to an HL7 message, CDA, HITSP/C32, or HITSP/C48 as a way that the EHR can send to the TP50 Form manager for pre-population and minimize data entry. The resulting construct to be sent from the form manager (or directly from a conformant EHR) to the end agency is a deferred construct and we will remain silent on specifying this in the Interoperability Specification (IS) until we have the consensus document. The one exception to the format that was identified was the HL7 HAI which is specified as a provisional construct pending the consensus document. The approach and IS resulting from this RDSS should be considered 'for implementation testing' only until we have the remaining construct defined, given that the final construct could impact the data capture and transport options.

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

- No consolidation of overlapping methods for case reporting and adverse event reporting. The second release will leverage harmonization efforts currently underway to specify common structured content for communication of public health and adverse event reporting data.
- Availability of constructs supporting clinical decision support



The following table identifies constructs that the Population Perspective Technical Committee plans to specify for Releases 1 and 2:

Table 3.1-1 Scope for Releases 1 and 2

Activity	Topic	Scoped to:	Reason for Deferral	Requirement
Case Reports	FDA – MedWatch, Vaccine Reporting (VAERS)	Year 2	Immature, standards in progress. Pending harmonization of case reporting content	Case Report (VAERS)
	CDC – Healthcare Associated Infection Reporting	Year 1	NA	Case Report (HAI)
	AHRQ – Sentinel Event / Adverse Reaction Reporting	Year 2	Immature, standards in progress. Pending harmonization of case reporting content.	Case Report (Patient Safety, AE)
	Public Health Case Reporting	Year 2	Immature, standards in progress. Pending harmonization of case reporting content	Case Report (Public Health Case Report)
	Standard Case Report Construct	Year 2	NOTE: There are currently multiple studies underway to propagate the information about an adverse event from source to the recipient. Specification will be deferred to leverage the outcome of these efforts.	Case Report (all)
Case Report Pre-populate	Mapping of common data elements to EHR data			
Reporting Criteria Content	Common/basic	Year 1	NA	
	Case-specific	Year 2	Immature, standards in progress	Reporting Criteria
Clinical Decision Support Content	Trigger Events Clinical Decision Support Content(Report triggers, prioritization)	Year 2	(Domain TC to flesh out)	CDS: Reporting Criteria Triggers Prioritization
Generic Alert to Identified Providers	Clinical Report	Year 2+	Immature Standards	
	Public Report	Year 2+	Immature Standards	
Unstructured Report Document	Content, Transport	Year 1 (see Alert and Reporting Criteria discussion below) Year 2 pending CDS	Pending CDS support	
Identify Communication Recipients	Support communication of non-PHI alerts and notifications	Year 1		



Alerts and Reporting Criteria:

Year 1 scope is limited to the use of the Unstructured Document Component for patient identifiable communications and to the use of Generic Alerts to Identified Providers with Identify Communication Recipients for non-patient identifiable communications. Further refinement of structured content may be provided in subsequent releases of the Interoperability Specification pending Standards Development Organization (SDO) generation of supporting content constructs and HITSP development of Clinical Decision Support constructs.

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
7.1.1.1 This event for AE invokes an investigation by regulation	1: AE
7.1.1.1 For PH the decision to investigate may be more subjective	1: PH
7.1.1.1 Assume that AE is limited to post-marketing not to clinical trials (note Drug Safety report from IHE is ICHE E2b – is pre/post market)	1: AE
7.1.1.2, 7.1.1.3 Forms is a very ambiguous word – we may have assumptions surrounding the interpretations. The common aspect is XML	1: All
7.1.4.1 Behavior and Policy of PSO is defined by jurisdiction	1: AE
7.1.5.3 The Use Case description does not necessarily represent the workflow of what actually happens	1: All
7.1.6.2 Authorizations for capture of supplemental data are defined by jurisdiction	1: All
7.1.7.1 Lab reporting to PH is included despite the lack of specified actor in scenario 1: state reporting requirements for condition reporting when a lab value results in a required report	1: PH
7.2.1.1 This perspective also represents that of other agencies and professional societies receiving PH information; and agencies AE/patient safety reports (e.g. CDC, CSTE, FDA, AHRQ)	1: All
7.2.2.1 if it is a required report, the report is filed; if not required (e.g. AE is not required), does not exist until it is reported	1: All
7.2.2.1 Until the case is reported, the AE or event is not known	1: AE
7.2.2.1 An unreported event may fall under quality Use Case	1: All
7.2.2.1 The entity that needs to receive/file the report is determined by jurisdiction or domain policy agreements	1: All
7.2.2.1 Trans-border communication expectations/specifications and mutual reporting are specified by policy	1: PH
7.2.3.1 PH (FDA and AHRQ are also PH agencies in this case along with state/local/tribal PH)	1,2: All
7.2.3.1 State-level responses are in place for many state preparedness planning	1,2: PH



Assumption	Use Case Scenario
7.2.3.1 Criticality may require no response other than tallying – no investigation typically conducted (e.g. chlamydia)	1,2: PH
8.1.1 Assumption is made that this is operating in an acceptably secure environment	2: All
8.1.1.1 There is a triage system; (e.g. there are some conditions that do not trigger a case investigation such as chlamydia)	2: PH
8.1.1.2 Implies inter-jurisdiction exchanges	2: All
8.1.1.2 Same type of information is appropriate to AEs. This is how AEs often work; Odds of information coming in an electronically standardized fashion is not good (follow-up may be an autopsy report – e.g. validating cause of death – not necessarily mortality report – autopsy report may be used for contributing factors or organ systems/biological changes, discharge summary); no need to have a standardized autopsy report for a data requirement; notification of death is of interest	2: All
8.1.1.3 Implication is that the prior information collection events include collection of data that can represent: PH Cases onset, symptoms, risk factors, laboratory results, procedures, diagnosis, health status, counts, trends, patterns, etc.	2: PH
8.1.2.1 Case definition can be defined and can be provided in an unambiguous format;	2: All
8.1.2.2 PH event may impact a community; from EHR point of view, may not be enough cases to trigger the PH event – at community level can detect the event	2: PH
8.1.2.2 Implication that there is an oversight mechanism for refining the definitions; if want a national definition, this needs to be handles with professional society oversight	2: All
8.1.3.1 PH investigation purpose is to identify populations at risk and to contact patients to see if they need to be investigated. Also to do queries on population characteristics	2: All
8.1.3.1 Drug manufacturer may need to ID patients that are similar for Medical devices/drugs; need to add language to extend the definition of 'contact tracing' to apply to population characteristic for drug/med devices etc (e.g. teens/antidepressants; implant in a population at risk)	2: AE
8.1.3.2 Case count is not the priority/purpose here – goal is to manage/contain event not to produce a case count	2: All
8.1.3.2 PH case workers may act in notification process from 7.1; these exposures may not be identified by a provider – may be identified by PH and referred to provider for treatment;	2: PH
8.1.4.1 Assume that the perspective addresses both National and local jurisdiction; Local PH jurisdiction perspective may differ from CDC perspective: Local PH jurisdiction – will have internal tools based on standardization of input data (using CHI vocabularies); Passes through local PH jurisdiction to CDC – data is using CHI standards; Many of these cases are cross-jurisdiction; e.g. in CA: if LA county PH in a train derailment chlorine gas issue, may cross multiple counties/jurisdictions – need to transfer case reports	2: PH
8.1.4.2 Management plan is not an interoperability requirement; AE will not be the same as PH; depending on the nature of event, the management plan will be different depending upon event; This step is not necessarily an automated process and it depends on the issue/agency involved (e.g. FBI) Multiple agencies may be involved, may be an inter-agency management plan involved; This is outside scope HITSP effort	2: All
8.1.4.2 Assumption: Needs human intervention for a management plan	2: All
8.1.4.2 Assumption: agency-specific, situation-specific determination and is not yet a candidate for automation	2: All
8.1.5.1 The initial communication may differ in the level of detail (depending on PH and AE) confirmation of the 'disease'; for PH it may already be well defined during report event; for AE it may still be undefined that there is an event and this may be a simple confirmation	2: All



Assumption	Use Case Scenario
8.1.5.2 An example would be: TB: need to represent cases identified by a clinician to researchers looking to investigate a particular strain	2: PH
8.2.1.1 Jurisdiction or HIE Policy may impose information exchange restrictions for some of these communications if electronic	2: All
8.3.1.2 Lab report content constraints are defined by policy	2: All

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/T16 - Consistent Time SHALL be implemented for each system grouping of actors.	1 and 2
HITSP/T17 - Secured Communication Channel SHALL be implemented for each system grouping of actors.	1 and 2
The policy of the implementation environment MAY require HITSP/C26 - Nonrepudiation of Origin for one or more information sources initiating a HITSP Transaction with a payload of: Case Report Reporting Criteria Unstructured Document Component	1 and 2
HITSP/T15 - Collect and Communicate Audit Trail SHALL be implemented for each information source initiating a HITSP Transaction with a payload of: Case Report Reporting Criteria 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 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

3.1.3 PRE-CONDITIONS

This section describes the necessary conditions that must be in place prior to the start of each scenario. The preconditions 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 preconditions are not met, the behavior of the Use Case should be considered uncertain.

Table 3.1.3-1 Pre-conditions

Pre-condition	Use Case Scenario
Support the technical measures to ensure security and privacy of consumer/patient health information	All
Authentication service to authenticate requestors and/or data submissions from various locations	All
Security and privacy policies, procedures and practices are commonly implemented to support acceptable levels of consumer/patient 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 Secured 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
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
There is an existing electronic record from which reports can be generated	All
8.1.1.1 Pre-condition – (for this scenario, there are rules in place that guide the prioritization and workflow considerations) NOTE: Challenging pre-condition as these do not exist in any electronic processable format; cases subject to investigation are designated notifiable would be the pre-condition – may be some cases (AE included) where it is always subject to a case investigation	2
Scenario 1 – Cases for investigation have been communicated	2
Immunizations and Response Management Use Case reporting of an adverse event	2

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
Appropriate case report information has been communicated and acted upon by Public Health	1
The case investigation has been concluded	2
Informing the PH decision making process	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
Various sources may communicate information which assists public health in determining criteria including: trigger data and reporting specifications: An update to the decision process rules. These may be event-driven or routine updates.	1
Providers may initially notify Public Health of possible PH Cases or Adverse Events through information exchange activities or in an ad-hoc manner. Providers may also notify Manufacturers of possible AEs through information exchange activities or in an ad-hoc manner A possible reportable event is detected or suspected. Human review is performed on possible events to make the final decision on reporting. Lab: Requirement for reporting to public health met – typically either a positive result or a required measured result (e.g. blood lead)	1
Possible AEs may be communicated to providers which may be internal or external to a public health setting. Specifics are addressed in the 2008 Immunizations and Response Management Detailed Use Case An external report was received by Public Health that indicates a detected or suspected adverse event. Human review is performed by public health on possible events to make the final decision on reporting.	1
Possible PH Cases or AE reports may be communicated via information exchange activities to public health A possible reportable event is detected or suspected. Human review is performed on possible events to make the final decision on reporting. NOTE: Triggers for AE, may have a broad category and add human intervention; sensitivity is high, and specificity is low - err on the side of false positives; Re-training the workforce will enable more specificity;	1
Public Health accesses additional information to assist in their investigations. Therefore, additional Information is requested by PH, the request is received by providers, and additional information is provided to Public Health via health information exchange activities. Information reported to Public Health is sufficient to begin a case investigation. Public Health investigates the report and finds that it needs additional information to develop the case investigation.	2
Public Health communicates case and/or patient specific information to providers and laboratories via health information exchange activities. Public Health decides it needs to communicate information to the provider community and chooses the appropriate means to do community.	2



Process Trigger	Use Case Scenario
Public Health communicates specific information supporting clinical care to other public health agencies/ organizations via information exchange activities. Public Health decides it needs to communicate information to the public health community and chooses the appropriate means to do community. NOTE: Intra-government issues – trigger events may cause the need to involve another federal agency – same issue for state/local government	2
Public Health communicates publicly available information to other entities via information exchange activities. Public Health decides it needs to communicate information to the general public and chooses the appropriate means to do community.	2
Based on Public Health information received via health information exchanges, providers may manage and treat PH Cases. Specifics are addressed in the 2008 Immunizations and Response Management Detailed Use Case. The provider has patients or patients with contacts that are subject to a Public Health notification.	2

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).

- Step 1: Gathering the case report data from existing health information systems

The clinician system may, in order to acquire data available electronically for reporting, retrieve patient data from other clinical systems using HITSP/TP21 or HITSP/TP13

- Step 2: Pre-population of the data

The clinician system sends common case reporting data elements to the form manager to allow for pre-population of the electronic data capture form from existing clinical data known to the clinician EHR (either directly or through the query mechanisms listed in step 1)

- Step 3: Completing the form and sending the data



The clinician or support staff fill in the remaining data elements in the case reporting data collection form supplied by the Form Manager. The Form Manager requests confirmation that the data submitted is accurate (human review), and upon confirmation, formats the data as required to send the resulting electronic report to the receiving agency or entity. At this time, the only case report component that is specified is for Healthcare Associated Infection reports. Other case report constructs will remain unspecified and implementations unconstrained until the deferred harmonized 'Standard Case Report Component' construct is available or other domain-specific component is specified.

Safety and Health Alert Functionality

For notification of reporting requirements, safety warnings, public health alerts, and patient-specific case investigation communications, there are two types of communications:

- Option 1 – The alert is generic and not specific to a particular patient (e.g. suspect lot, possible public health threat), 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 – 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 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).



Technical Actor(s)	Actor Role
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 both the persistent storage of documents as well as for their registration with the appropriate Document Registry. It assigns a URI to documents for subsequent retrieval by a Document Consumer. 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 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.
Form Archiver	The actor responsible for receiving form instance data for archival purposes. For Quality, supports the option to enable manual or cut/paste information capture of patient level quality data content.
Form Filler	The actor responsible for retrieving a form from a Form Manager and for submitting form instance data to a Form Receiver. The mechanism by which a unique identification of a form is obtained is outside the scope of the Retrieve Form for Data Capture profile. For Quality, used as an option to enable manual or cut/paste information capture of patient level quality data content. For Quality, Option for CIS to enable manual or cut/paste information capture.
Form Manager	The actor that supplies a form based upon a request that supplies unique form identification. For Quality, used as an option to enable manual or cut/paste information capture of patient level quality data content.
Form Receiver	The actor that receives form instance data. For Quality, supports the option to enable manual or cut/paste information capture of patient level quality data content.
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.
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).



HITSP Public Health Case Reporting Use Case Requirements, Design and Standards Selection

Review Copy
20080627 V1.0

Technical Actor(s)	Actor Role
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 acknowledgements 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 requester 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.
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.



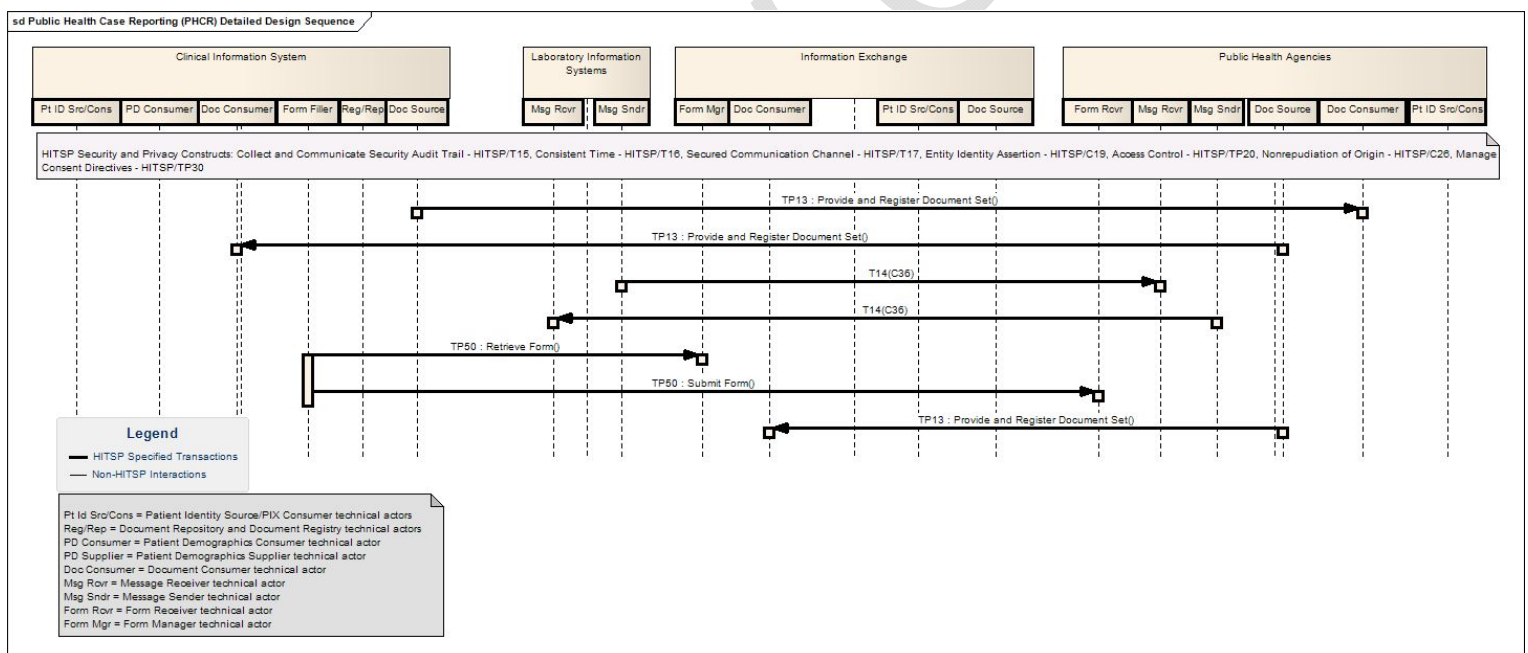
Technical Actor(s)	Actor Role
User Access Control Service (UACS)	The enterprise security service that supports and implements user-side access control capabilities. This is an initiator actor.
Value Set Consumer	An actor who retrieves a specific new or updated Value Sets based on its OID.
Value Set Repository	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.

Figure 3.2.2-1 Detailed Sequence Diagram for Scenario 1



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*
Laboratory Information Systems (Message Sender/Bio Data Sender, Document Source)	Content Creator	R	HITSP/C35	Lab Result Terminology	R
		R	HITSP/C36	Lab Result Message	R
		C [108]	HITSP/T24	Pseudonymization Request	R
		C [109]	HITSP/C25	Anonymize	R
	Message Sender	C [104]	HITSP/C35	Lab Result Terminology	R
		C [105]	HITSP/C36	Lab Result Message	R
	Message Receiver	C [104]	HITSP/C35	Lab Result Terminology	R
		C [106]	HITSP/C36	Lab Result Message	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



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	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
Clinical Information System (or HIS, EHR-S) (Healthcare Delivery Organizations, Ancillary Entities, Clinicians, Pharmacies) [Care Delivery Actor]	Service Provider Access Control Service (SP ACS)	C [102]	HITSP/TP20	Access Control Request	O
	Patient Identity Source	C [101]	HITSP/T23	Patient Demographics Query	R
	PIX Consumer	C [101]	HITSP/TP22	PIX Identity Feed	R
				PIX Query	R
	Patient Demographics Consumer	C [101]	HITSP/T23	Patient Demographics Query	R
	Message Sender	C [104]	HITSP/C35	Lab Result Terminology	R
		C [105]	HITSP/C36	Lab Result Message	R
	Message Receiver	C [104]	HITSP/C35	Lab Result Terminology	R
		C [106]	HITSP/C36	Lab Result Message	R
	Document Source	C [102] C [105]	HITSP/TP13	Provide & Register Document Set-b	C [202]
				Provide & Register Document Set	C [202]
	Document Consumer	C [102] C [106]	HITSP/TP13	Registry Stored Query	C [203]
				Retrieve Document Set	C [203]
				Stored Query	C [203]
				Retrieve Document	C [203]
	Document Repository	O	HITSP/TP13	Provide and Register Document Set-b	C [204]
				Register Document Set-b	C [204]
				Retrieve Document Set	C [204]
				Register Document Set	C [204]
				Provide & Register Document Set	C [204]
	Document Registry	O	HITSP/TP13	Retrieve Document	C [204]
				Patient Identity Feed	R
				Registry Stored Query	C [205]
				Provide & Register Document Set-b	C [205]
				Stored Query	C [205]
				Provide & Register Document Set	C [205]



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)	C [202]
				Provide & Register Document Set (offline mode)	C [202]
	Document Recipient	C [103] C [106]	HITSP/T31	Provide & Register Document Set.b (online mode)	C [202]
				Provide & Register Document Set (offline mode)	C [202]
	Clinical Data Consumer	C [107]	HITSP/TP21	Query Immunizations	C [202]
				Query Problems and Allergies	C [202]
				Query Diagnostic Data	C [202]
				Query Medications	C [202]
				Query Immunizations	C [202]
				Query Professional Services	C [202]
	Vital Signs Data Repository	O	HITSP/TP21	Query Vital signs	R
	Problems and Allergies Data Repository	O	HITSP/TP21	Query Problems and Allergies	R
	Diagnostic Data Repository	O	HITSP/TP21	Query Diagnostic Data	R
	Medications Data Repository	O	HITSP/TP21	Query Medications	R
	Immunizations Data Repository	O	HITSP/TP21	Query Immunizations	R
	Professional Services Data Repository	O	HITSP/TP21	Query Professional Services	R
	Form Manager	O	HITSP/TP50	Retrieve Form	R
				Retrieve Clarifications	R
	Form Receiver	O	HITSP/TP50	Submit Form	R
	Form Archiver	O	HITSP/TP50	Archive Form	R
	Content Creator	O	HITSP/C75	Adverse Event Reports: CDC - Healthcare Associated Infection Reporting	C [201]
		R	HITSP/TP30	Consent Document	R
		O	HITSP/C76	Case Reporting Terminology	R
		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
	Content Consumer	R	HITSP/C62	Unstructured Document	O
		R	HITSP/TP30	Consent Document	R



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	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 Exchange (RHIO, HIE)	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/C35	Lab Result Terminology	R
		C [105]	HITSP/C36	Lab Result Message	R
	Message Receiver	C [104]	HITSP/C35	Lab Result Terminology	R
		C [106]	HITSP/C36	Lab Result Message	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



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	Document Consumer	R	HITSP/TP13	Query Registry	R
				Retrieve Documents	R
	Form Manager	O	HITSP/TP50	Retrieve Form	R
				Retrieve Clarifications	R
	Form Receiver	O	HITSP/TP50	Submit Form	R
	Form Archiver	O	HITSP/TP50	Archive Form	R
	Content Creator	O	HITSP/C75	Adverse Event Reports: CDC - Healthcare Associated Infection Reporting	C [201]
		R	HITSP/TP30	Consent Document	R
		O	HITSP/C76	Case Reporting Terminology	R
		O	HITSP/C35	Lab Terminology	R
		O	HITSP/C36	Lab Message	R
		C [108]	HITSP/T24	Pseudonymization Request	R
		C [109]	HITSP/C25	Anonymize	R
	Content Consumer	R	HITSP/C62	Unstructured Document Component	O
		R	HITSP/TP30	Consent Document Component	R
		O	HITSP/C76	Case Reporting Terminology Component	R
		O	HITSP/C75	Adverse Event Reports: CDC - Healthcare Associated Infection Reporting	C [201]
	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



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
				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/IS06	Send Message	R
				Receive Ack	R
	Message Receiver	C [104] C [106]	HITSP/IS06	Receive Message	R
				Send Ack	R
	Document Source	R	HITSP/TP13	Provide & Register Document Set	R
	Document Consumer	R	HITSP/TP13	Query Registry	R
				Retrieve Documents	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)	C [201]
				Provide & Register Document Set (offline mode)	C [201]
	Document Recipient	C [103] C [106]	HITSP/T31	Provide & Register Document Set.b (online mode)	C [201]
				Provide & Register Document Set (offline mode)	C [201]
	Form Manager	O	HITSP/TP50	Retrieve Form	R
				Retrieve Clarifications	R
	Form Receiver	O	HITSP/TP50	Submit Form	R
	Form Archiver	O	HITSP/TP50	Archive Form	R
	Content Creator		HITSP/C62	Unstructured Document	O
		C [108]	HITSP/T24	Pseudonymization Request	R
		C [109]	HITSP/C25	Anonymize	R
	Content Consumer	R	HITSP/C62	Unstructured Document	O
		R	HITSP/TP30	Consent Document	R
		O	HITSP/C76	Case Reporting Terminology	R
		O	HITSP/C75	Adverse Event Reports: CDC - Healthcare Associated Infection Reporting	C [201]



HITSP Public Health Case Reporting Use Case Requirements, Design and Standards Selection

Review Copy
20080627 V1.0

Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
		R	HITSP/C35	Lab Result Terminology	R
		R	HITSP/C36	Lab Result Message	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
	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

***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 [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 [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

Transaction/Content (T/C) Optionality Conditions

- C [201] – Shall support either form filler or case report construct.
- C [202] – The Actor shall support at least one of these transactions.
- C [203] – The Document Consumer shall support either XDS.a transactions, XDS.b transactions, or both. Where Identity Assertion is required, the Document Consumer shall support XDS.b (Registry Stored Query, Retrieve Document Set)
- C [204] – The Document Repository shall support either XDS.a transactions, XDS.b transactions, or both. Where Identity Assertion is required, the Document Repository shall support XDS.b (Provide & Register Document Set-b, Register Document Set-b, Retrieve Document Set)
- C [205] – The Document Registry shall support either XDS.a transactions, XDS.b transactions, or both. Where Identity Assertion is required, the Document Repository shall support XDS.b to query the registry (Registry Stored Query)

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)
HITSP/C35, HITSP/C36	Send Message	Constraints as per CDC/CSTE sponsored calls for electronic lab reporting (ELR) - are expected to be in the optionality rather than in the vocabulary. No new data elements expected	Pre-condition	Allow for communications with destination of Public Health rather than clinicians
	Require Acknowledgement	HITSP/T31, HITSP/TP30 : Need to be sure business actor binding messenger with sender – needs to bind with an Xform response back to the human	General	Enable Acknowledgement receipt for submission of case report
	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



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/C76 - Case Reporting Terminology	Supports Data Mapping from HITSP/C32 EHR terms for form pre-population in support of: Adverse Event Reports: FDA – MedWatch, Vaccine Reporting (VAERS) Adverse Event Reports: CDC – Healthcare Associated Infection Reporting Adverse Event Reports: AHRQ – Sentinel Event/Adverse Reaction Reporting Adverse Event Reports: Public Health Case Reporting Other FDA Reports	Content Creator Content Consumer	Case Report Pre-populate
HITSP/C75 - Adverse Event Reports: CDC – Healthcare Associated Infection Reporting	Structured content to communicate Healthcare Associated Infections using HL7 HAI CDA Structured Document	Content Creator Content Consumer	Case Report (HAI) NOTE: HL7 Structured Documents; Provisional
HITSP/T64 - Identify Communication Recipients	Leveraged for communications for specific report clarifications	Directory Service Directory Consumer	6 Generic alert to identified providers
HITSP/T66 - Terminology Service	May or not be deferred depending upon Tier 2	Value set Consumer Value set Repository	2 Terminology Service
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-EHR) population based	Content Creator Content Consumer	6 Generic Alert to identified providers NOTE: This cannot be a targeted communication as this would be PHI NOTE: Coupled with Identify communication recipients for this Design



New Construct	Construct Description	Technical Actors	Interoperability or Data Requirement
HITSP/C62 - Unstructured Document	<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.</p> <p>(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> <ul style="list-style-type: none"> Individual-Based Consumer communication Clinician communication Patient communication <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>Meta-data for the payload/image is required</p> <p>5 Unstructured Document Component</p>

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/TP50	Retrieve Form for Data Capture	<p>Form Manager</p> <p>Form Filler</p> <p>Form Receiver</p> <p>Form Archiver</p>	<p>7.1.1.2</p> <p>7.1.1.3</p> <p>7.1.6.1</p> <p>7.1.6.2</p> <p>7.1.7.2</p> <p>7.2.1.4</p> <p>8.1.1.1</p> <p>8.1.1.2</p> <p>8.2.1.1</p> <p>8.2.1.2</p>	<p>Form needs to support AE content and routine reporting</p> <p>Form MAY need digital signature</p>
HITSP/TP21	Query for Existing Data	<p>Clinical Data Consumer</p> <p>Data Repository:</p> <ul style="list-style-type: none"> Vital Signs Problems and Allergies Medications Immunizations Diagnostic Data Professional Services 	<p>7.1.6.2</p> <p>8.1.1.1a</p>	



HITSP Construct	Construct Description	Technical Actors	Interoperability or Data Requirement Number	Modification Required
HITSP/TP13	Manage Sharing of Documents	Document Source Document Consumer Registry Repository	7.1.7.2 7.2.1.4 8.1.1.1a 8.1.2.2 8.1.3.1	None anticipated – use considered to leverage Aggregate re-purposing constraints like BIO/Quality
HITSP/C32	Summary Documents Using HL7 Continuity of Care Document (CCD)	Content Creator Content Consumer	8.1.1.1a 8.1.2.2 8.1.3.1	Pending Domain TC document harmonization
HITSP/C48	Encounter Document Using IHE Medical Summary (XDS-MS)	Content Creator Content Consumer	8.1.1.1a 8.1.2.2 8.1.3.1	Pending Domain TC document harmonization
HITSP/C25	Anonymize	Content Creator Content Consumer	7.1.4.1 8.1.5.2 8.1.5.3 9.2	Update to assess new content considerations for Case Reporting Anonymize to address the public reporting data communication content (8.1.5.3)
HITSP/C35	Lab Result Terminology	Content Creator Content Consumer	8.3.1.2 8.3.2.1	None anticipated
HITSP/C36	Lab Result Message	Content Creator Content Consumer	8.3.1.2 8.3.2.1	None anticipated
HITSP/T24	Pseudonymize	Patient Identity Source Person Identification Service Pseudonymization Services Person Identity Consumer	7.1.4.1 8.1.5.2 8.1.5.3 9.2	None anticipated
HITSP/T23	Patient Demographics Query	Patient Demographics Consumer Patient Demographics Supplier	7.1.7.2 7.2.1.4 8.1.1.1a 8.1.2.2 8.1.3.1	None anticipated
HITSP/T29	Notification of Document Availability	Notification Sender Notification Receiver	8.2.2.2 8.1.1.1 8.1.3.1 8.1.5.2	None anticipated
HITSP/TP22	Patient ID Cross-Referencing	PIX Manager Patient Identity Source PIX Consumer	7.1.7.2 7.2.1.4 8.1.1.1a 8.1.2.2 8.1.3.1	None anticipated



HITSP Construct	Construct Description	Technical Actors	Interoperability or Data Requirement Number	Modification Required
HITSP/T16	Consistent Time	Time Client Time Server	7.1.1 7.1.3 7.1.4 7.1.5 7.1.6 7.1.7 7.2.1 7.2.2 7.2.3 8.1.1 8.1.5 8.2.1 8.2.2 8.3.1 8.3.2 9.3	None anticipated
HITSP/T17	Secured Communication Channel	Node	7.1.1 7.1.3 7.1.4 7.1.5 7.1.6 7.2.1 7.2.2 7.2.3 8.1.1 8.1.5 8.2.1 8.2.2 8.3.1 8.3.2 9.3	None anticipated
HITSP/C26	Nonrepudiation of Origin	Content Creator Content Consumer	7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 7.1.7.2 7.2.1.4 8.1.1.1 8.1.1.2 8.2.1.1 8.2.1.2	None anticipated



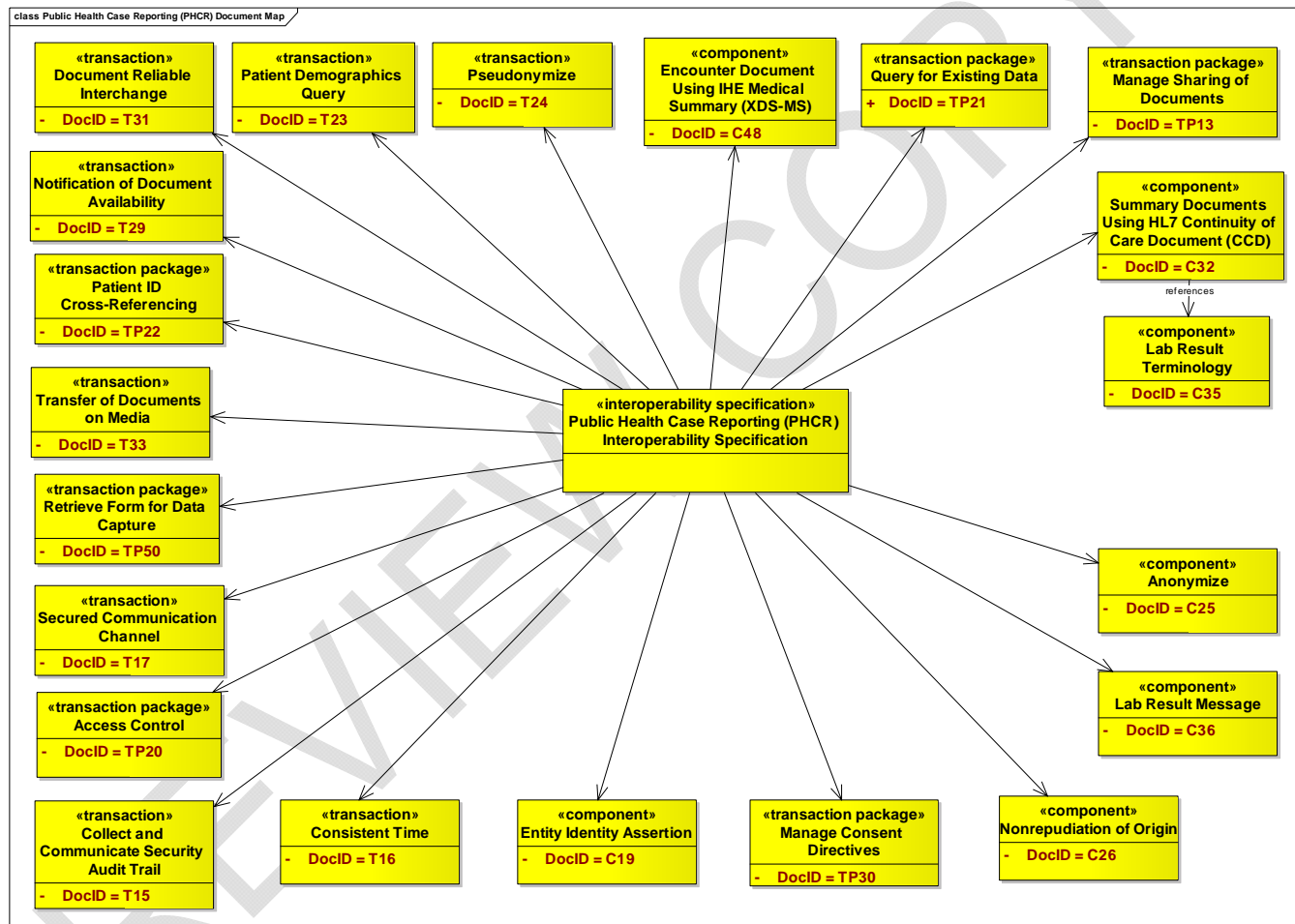
HITSP Construct	Construct Description	Technical Actors	Interoperability or Data Requirement Number	Modification Required
HITSP/C19	Entity Identity Assertion	Content Creator Content Consumer	7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 7.1.7.2 7.2.1.4 8.1.1.1 8.1.1.2 8.2.1.1 8.2.1.2	None anticipated
HITSP/T15	Collect and Communicate Security Audit Trail	Audit Record Source Audit Record Repository	7.1.1 7.1.3 7.1.4 7.1.5 7.1.6 7.1.7 7.2.1 7.2.2 7.2.3 8.1.1 8.1.5 8.2.1 8.2.2 8.3.1 8.3.2 9.3	None anticipated
HITSP/TP30	Manage Consent Directives	Consent Originator Consent Registry Consent Repository Consent Directive Requestor	8.1.1	None anticipated
HITSP/TP20	Access Control	User User Access Control Service (UACS) Service Provider (SP) Service Provider Access Control Service (SP ACS)	7.1.3 7.1.6 7.2.3 8.1.1 8.2.1	None anticipated
HITSP/T31	Document Reliable Interchange	Document Source Document Recipient	7.1.7.2 7.2.1.4	None anticipated
HITSP/T33	Transfer of Documents on Media	Portable Media Creator Portable Media Importer	7.1.7.2 7.2.1.4	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 Public Health Case Reporting 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



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

- has been agreed upon by a group of experts
- has been publicly vetted
- provides rules, guidelines, or characteristics
- helps to ensure that materials, products, processes, and services are fit for their intended purpose
- is available in an accessible format
- 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
American Society for Testing and Materials (ASTM) Standard Specification for Coded Values Used in the Electronic Health Record: # E1633-02	8.1.3.2 7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 7.1.7.2 7.2.1.4 8.1.1.1 8.1.1.2 8.2.1.1 8.2.1.2	HITSP/C76 - Case Reporting Terminology (supporting Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS))	Codes for location within a HC facility
Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN)	7.1.6.3 7.1.7.2 7.2.1.4 8.1.1.2 8.2.1.2	HITSP/C65 - Generic Alert to Identified Providers	
Consolidated Health Informatics (CHI) Domain: Allergy	7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 7.1.7.2 7.2.1.4 8.1.1.1 8.1.1.2 8.2.1.1 8.2.1.2	HITSP/C76 - Case Reporting Terminology (supporting Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS))	Previously selected by HITSP
Extensible Markup Language (XML) v1.0 (Fourth Edition)	7.1.1.2, 7.1.1.3.	HITSP/C75 - Adverse Event Reports: CDC – Healthcare Associated Infection Reporting	
Federal Medications Terminology	7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 7.1.7.2 7.2.1.4 8.1.1.1 8.1.1.2 8.2.1.1 8.2.1.2	HITSP/C76 - Case Reporting Terminology (supporting Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS))	Supported by HL7 ICSR; VA/Kaiser Problem List for adverse events/indication – subset of SNOMED



SDO and Standard Name	Event/Action Code	Category	Remarks/ Minor Gaps
Health Level Seven (HL7) Implementation Guide for CDA Release 2; National Healthcare Safety Network (NHSN) Healthcare Associated Infection (HAI) Reports, Release 1 (DSTU)	7.1.6.3 7.1.7.2 7.2.1.4 8.1.1.2 8.2.1.2	HITSP/C75 - Adverse Event Reports: CDC – Healthcare Associated Infection Reporting	DSTU for reporting Healthcare Associated Infection
Health Level Seven (HL7) Version 2+ (Table HL7 0331)	8.1.3.2	HITSP/C76 - Case Reporting Terminology (supporting Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS))	Facility Type
HL7 CDA Structure Document (HAI) Health Level Seven (HL7) Implementation Guide for CDA Release 2; National Healthcare Safety Network (NHSN) Healthcare Associated Infection (HAI) Reports, Release 1 (DSTU)	8.1.1.1a 8.1.2.2 8.1.3.1	HITSP/C75 - Adverse Event Reports: CDC – Healthcare Associated Infection Reporting	CDA – the XFORMS document vs the output of an XFORMS document – Forms is a very ambiguous word – we may have assumptions surrounding the interpretations. The common aspect is XML
Integrating the Healthcare Enterprise (IHE) Drug Safety Content Profile (DSC) Draft Profile from the IHE QRPH Domain	7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 7.1.7.2 7.2.1.4 8.1.1.1 8.1.1.2 8.2.1.1 8.2.1.2	HITSP/C76 - Case Reporting Terminology (supporting Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS))	Supports pre-population
International Classification of Diseases, 10th Revision, Related Health Problems (ICD-10-CM)	7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 7.1.7.2 7.2.1.4 8.1.1.1 8.1.1.2 8.2.1.1 8.2.1.2	HITSP/C76 - Case Reporting Terminology (supporting Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS))	Previously selected by HITSP



SDO and Standard Name	Event/Action Code	Category	Remarks/ Minor Gaps
International Classification of Diseases, 9th Revision, Clinical Modifications (ICD-9-CM)	7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 7.1.7.2 7.2.1.4 8.1.1.1 8.1.1.2 8.2.1.1 8.2.1.2	HITSP/C76 - Case Reporting Terminology (supporting Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS))	Previously selected by HITSP
International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 7.1.7.2 7.2.1.4 8.1.1.1 8.1.1.2 8.2.1.1 8.2.1.2	HITSP/C76 - Case Reporting Terminology (supporting Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS))	Previously selected by HITSP
International Organization for Standardization (ISO) Document Management – Portable Document Format (PDF) Part 1: PDF 1.7, ISO# 32000-1:2008 (Under Development)	7.1.5.2 (IRM)	HITSP/C62 - Unstructured Document	Need to review and check for revised needs;
LANGUAL International Framework for Food Description	7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 7.1.7.2 7.2.1.4 8.1.1.1 8.1.1.2 8.2.1.1 8.2.1.2	HITSP/C76 - Case Reporting Terminology (supporting Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS))	International Framework for Food Description; (not strongly supported from FDA, CDC has used in some cases)
Logical Observation Identifiers Names and Codes (LOINC®)	7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 7.1.7.2 7.2.1.4 8.1.1.1 8.1.1.2 8.2.1.1 8.2.1.2	HITSP/C76 - Case Reporting Terminology (supporting Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS))	Previously selected by HITSP



**HITSP Public Health Case Reporting Use Case Requirements,
Design and Standards Selection**

Review Copy
20080627 V1.0

SDO and Standard Name	Event/Action Code	Category	Remarks/ Minor Gaps
Medical Dictionary for Regulatory Activities (MedDRA)	7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 7.1.7.2 7.2.1.4 8.1.1.1 8.1.1.2 8.2.1.1 8.2.1.2	HITSP/C76 - Case Reporting Terminology (supporting Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS))	Terminology standards used for ICH ICSR; HL7 ICSR does not require this terminology; Problematic for tapping into Electronic Health Records
Structured Product Labeling Implementation Guide (SPL) Release 3 Implementation Guide for FDA Drug and Biological Products v1.1	7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 7.1.7.2 7.2.1.4 8.1.1.1 8.1.1.2 8.2.1.1 8.2.1.2	HITSP/C76 - Case Reporting Terminology (supporting Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS))	For Identifying Products SPL –and content is less structured and codified than optimal goal
U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health MEDWATCH Medical Device Reporting Code Instructions, Appendix - B Device and Patient Problem Codes	7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 7.1.7.2 7.2.1.4 8.1.1.1 8.1.1.2 8.2.1.1 8.2.1.2	HITSP/C76 - Case Reporting Terminology (supporting Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS))	Specified by FDA for related AE reports
US Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) Data Standards Manual	7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 7.1.7.2 7.2.1.4 8.1.1.1 8.1.1.2 8.2.1.1 8.2.1.2	HITSP/C76 - Case Reporting Terminology (supporting Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS))	Specified by FDA for related AE reports



SDO and Standard Name	Event/Action Code	Category	Remarks/ Minor Gaps
US Food and Drug Administration (FDA) Substance Registration System Manual - Unique Ingredient Identifier (UNII) assignment	7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 7.1.7.2 7.2.1.4 8.1.1.1 8.1.1.2 8.2.1.1 8.2.1.2	HITSP/C76 - Case Reporting Terminology (supporting Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS))	Specified by FDA for related AE reports
World Health Organization (WHO), World Alliance for Patient Safety International Classification for Patient Safety V1.0 for Field Testing 2007-2008 (ICPS)	7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 7.1.7.2 7.2.1.4 8.1.1.1 8.1.1.2 8.2.1.1 8.2.1.2	HITSP/C76 - Case Reporting Terminology (supporting Adverse Event Report (Overlap with Public Health Reporting) FDA – MedWatch, Vaccine Reporting (VAERS))	Classification of types of events; Available for field testing 2007-2008

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 Public Health Case Reporting 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
7.1.6.3 7.1.7.2 7.2.1.4 8.1.1.2 8.2.1.2 7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 8.1.1.1 8.2.1.1	<p>Action: Update PH Case Report or AE Report.</p> <p>Action: Transmit confirmed PH Case Reports or AE Reports to Public Health.</p> <p>Action: Communicate reporting criteria for both PH Cases and AEs. Reporting criteria include: trigger data and reporting specifications.</p> <p>Action: Receive additional information to assist in investigation activities.</p> <p>Action: Send information to Public Health related to previously reported PH Cases and/or other information.</p> <p>Action: Incorporate PH trigger data and reporting specifications.</p> <p>Action: Incorporate AE trigger data and reporting specifications.</p> <p>Action: Information related to possible PH Cases or AEs that is not available through an EHR is manually gathered.</p> <p>Action: Information related to possible PH Cases or AEs that is not available through an EHR may be gained through electronic information exchanges.</p> <p>Action: Request information from submitters of reports/information.</p> <p>Action: Receive request for additional information from Public Health.</p>	GAP: Need to refer maintenance of common data elements and harmonization effort	Recommend that a body to maintain this be identified
7.1.1.2, 7.1.1.3	Incorporate PH/AE trigger data and reporting specifications.	Not sufficient support in yet	HL7 EDCI – standard under ballot in progress
7.1.1.3	Incorporate AE trigger data and reporting specifications.	FDA – forms for SPL; Form structure is there, but not the logic behind it;	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting.
7.1.1.2, 7.1.1.3	Incorporate PH/AE trigger data and reporting specifications.	Forms section- HITSP – the industry recognized need for development of standardized forms, but the forms development is an area of gaps. Forms sections have some things to start with. LOINC is not complete for this.	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting.



Event Code	Event Description	Identified Gaps	Recommended Resolution
8.1.1.1	Action: Request information from submitters of reports/information.	In the PH side – an attempt is made to enumerate as much of the notifiable conditions possible – the opposite exists in AE reporting, but for AE the case is inverted – for PH it is doable, but for AE, it is not easily doable without tremendous human intervention to automate the classification; Alert may be programmable by class – trigger certain reporting events, but this is after the determination that this is an event.	Work with SDOs to create a minimum number of standards for PH case reporting requests and AE reporting requests.
8.1.1.2	Action: Request information from submitters of reports/information.	Gap in identifying supplemental detail needed from standards (e.g. using patient anti-TB drug as an indication of active TB to compare to known TB patients) – what standardized questions to ask;	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting.
8.1.1.2	Action: Request information from submitters of reports/information.	GAP in the specifics of what should be requested.	Leave to local definition via TP50
8.1.5.1	Action: Receive additional information to assist in investigation activities.	Possible gap for identifying party to whom to communicate this information; Policy consideration	Refer to policy specifications
8.2.2.2	Action: Communicate case or patient specific information.	No Standards for structure Clinical Reports sent from PH to HC Provider	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting.
8.2.2.3	Action: Receive specific clinically relevant Public Health information	No Standards for structure Reports sent from PH to Public	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting.
8.3.1.2a	Alternate Action: Send information related to previously reported PH Cases and/or other information may be sent to Public Health.	No standards for supplemental information reports	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting.



Event Code	Event Description	Identified Gaps	Recommended Resolution
7.1.6.3 7.1.7.2 7.2.1.4 8.1.1.2 8.2.1.2	Action: Update PH Case Report or AE Report. Action: Transmit confirmed PH Case Reports or AE Reports to Public Health. Action: Communicate reporting criteria for both PH Cases and AEs. Reporting criteria include: trigger data and reporting specifications. Action: Receive additional information to assist in investigation activities. Action: Send information to Public Health related to previously reported PH Cases and/or other information.	No consolidation of overlapping methods for Case reporting and AE reporting	Better harmonize the data elements across the Use Case which will make the generation of the standards easier. AHRQ in partnership with FDA, CDC, DOD, IHS, and VA is developing and will publish a set of data safety data elements in common format for use by the PSOs to exchange data. This should be reconciled with the dataset that will inform the development of a construct for communication of the adverse event data. Support efforts currently underway to create within the SDOs harmonized standards for the adverse event reports. Recommend that the SDOs prepare standards for the transmission of this payload.
7.1.6.3 7.1.7.2 7.2.1.4 8.1.1.2 8.2.1.2	Action: Update PH Case Report or AE Report. Action: Transmit confirmed PH Case Reports or AE Reports to public health. Action: Communicate reporting criteria for both PH Cases and AEs. Reporting criteria include: trigger data and reporting specifications. Action: Receive additional information to assist in investigation activities. Action: Send information to public health related to previously reported PH Cases and/or other information.	There are gaps for standards for AE reporting - Vocabularies to describe the event for regulatory domain are MedDRA, but not used by EHR It is not clear what organization is the owner of non-drug, device, hai or previously defined events.	Refer to AHIC and ONC or other appropriate bodies to identify some organization within this group to help deal with the policy and data and reporting requirements. Evaluate harmonized cross-agency data set to determine whether the result will support these data and reporting requirements. Listed Never Events: the category to capture falls, sores, non-infectious surgical complications; criminal events. Incident categories are not fully defined – efforts with WHO patient safety taxonomy, NQF NOTE: Messaging – do not see the point of introducing another AE message – deferring because there are discussions under way to address this issue.
7.1.6.3 7.1.7.2 7.2.1.4 8.1.1.2 8.2.1.2	Action: Update PH Case Report or AE Report. Action: Transmit confirmed PH Case Reports or AE Reports to public health. Action: Communicate reporting criteria for both PH Cases and AEs. Reporting criteria include: trigger data and reporting specifications. Action: Receive additional information to assist in investigation activities. Action: Send information to Public Health related to previously reported PH Cases and/or other information.	Vocabularies used across the models are not standardized in HL7;	HL7 is looking to standardized the vocabularies across HL7 internal and external Adopt SDO-defined vocabularies where possible.



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 Public Health Case Reporting event. 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
7.1.6.3 7.1.7.2 7.2.1.4 8.1.1.2 8.2.1.2 7.1.1.2 7.1.1.3 7.1.6.1 7.1.6.2 8.1.1.1 8.2.1.1	Action: Update PH Case Report or AE Report. Action: Transmit confirmed PH Case Reports or AE Reports to public health. Action: Communicate reporting criteria for both PH Cases and AEs. Reporting criteria include: trigger data and reporting specifications. Action: Receive additional information to assist in investigation activities. Action: Send information to Public Health related to previously reported PH Cases and/or other information. Action: Incorporate PH trigger data and reporting specifications. Action: Incorporate AE trigger data and reporting specifications. Action: Information related to possible PH Cases or AEs that is not available through an EHR is manually gathered. Action: Information related to possible PH Cases or AEs that is not available through an EHR may be gained through electronic information exchanges. Action: Request information from submitters of reports/information. Action: Receive request for additional information from Public Health.	CDISC Anatomical Site List – Overlap SNOMED –	Refer to Foundations



Event Code	Event Description	Standard Overlap	Recommended Resolution
7.1.6.3 7.1.7.2 7.2.1.4 8.1.1.2 8.2.1.2	<p>Action: Update PH Case Report or AE Report.</p> <p>Action: Transmit confirmed PH Case Reports or AE Reports to Public Health.</p> <p>Action: Communicate reporting criteria for both PH Cases and AEs. Reporting criteria include: trigger data and reporting specifications.</p> <p>Action: Receive additional information to assist in investigation activities.</p> <p>Action: Send information to Public Health related to previously reported PH Cases and/or other information.</p>	<p>There is an active migration/harmonization to enable the adoption of the same standards across multiple organizations for Patient Safety:</p> <p>ISO ICSR : HL7 ICSR 3 HL7 ICSR 2 ICH-E2B Notifiable Disease Condition Generic Incident Notification (GIN) Root cause and Underlying factors Message (RUM) ICSR – 2 flavors: 1) International conference of Harmonization E2B; does not cover vaccines, devices or food; does not include combination products (e.g. drug/device, drug/biologic) – only supports use of MEDRA; extends use of MEDRA to code surgical, disease conditions; discussion using to code lab; MEDRA has incorporated some of the lab code test names; AE; 2) HL7 ICSR – developed as a broader Use Case – next release is what FDA is trying to get international consensus; HL7 includes food, devices and medications, and vaccines</p>	<p>Harmonization effort is under way – Version 3 is expected to expand version 2 to include food, cosmetics, devices, drugs, and possibly veterinary. Work may be informed by ISO TR22224.</p> <p>Once SDO harmonization is complete, we should incorporate the resulting work into a HITSP construct to communicate the payload.</p>
7.1.6.3 7.1.7.2 7.2.1.4 8.1.1.2 8.2.1.2	<p>Action: Update PH Case Report or AE Report.</p> <p>Action: Transmit confirmed PH Case Reports or AE Reports to Public Health.</p> <p>Action: Communicate reporting criteria for both PH Cases and AEs. Reporting criteria include: trigger data and reporting specifications.</p> <p>Action: Receive additional information to assist in investigation activities.</p> <p>Action: Send information to Public Health related to previously reported PH Cases and/or other information.</p>	<p>Healthcare Associated Infections (HAI), CDC, CMS, AHRQ</p> <p>States don't necessarily align with the same definition and list of HAIs than those required by CDC.</p> <p>Over the last decade, difficulty on agreeing on standards for harmonizing adverse event reporting</p>	<p>Request harmonization of state and federal definitions for HAIs from the CSTE.</p> <p>HHS/PSOs may become appropriate bodies for managing standardization of reporting for Hospital/Institutional Acquired Infections.</p>



Event Code	Event Description	Standard Overlap	Recommended Resolution
7.1.6.3 7.1.7.2 7.2.1.4 8.1.1.2 8.2.1.2	<p>Action: Update PH Case Report or AE Report.</p> <p>Action: Transmit confirmed PH Case Reports or AE Reports to Public Health.</p> <p>Action: Communicate reporting criteria for both PH Cases and AEs. Reporting criteria include: trigger data and reporting specifications.</p> <p>Action: Receive additional information to assist in investigation activities.</p> <p>Action: Send information to public health related to previously reported PH Cases and/or other information.</p>	<p>PH Case Reporting</p> <p>No official standard, but there are numerous attempts to create one</p> <p>See Appendix 6.2 for details</p>	<p>standardization workgroup within CSTE – body to adjudication PHCS reporting standards</p> <p>Case Reporting WG reports to Surveillance Coordination Group which in turn reports to PH Informatics Team. The PH Informatics team passes it on to CSTE membership for approval.</p> <p>This should be reconciled with the dataset that will inform the development of a construct for communication of the public health case event data.</p> <p>Recommend that the SDOs prepare standards for the transmission of this payload. Monitor and contribute to these efforts.</p>



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 Public Health Case Reporting 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

Standard Name	Description
American Society for Testing and Materials (ASTM) Standard Specification for Coded Values Used in the Electronic Health Record: # E1633-02	Identifies the lexicons to be used for the data elements identified in ASTM's Standard Guide for Content and Structure of the Electronic Health Record (EHR): # E1384-02. E1633-02 "is intended to unify the representations for: (1) primary record of care data elements, (2) the data elements identified in other standard statistical data sets, (3) data elements used in other healthcare data message exchange format standards, or (4) in data gathering forms for this purpose, and (5) in data derived from these elements in order that data recorded in the course of patient care be exchangeable and be the source of accurate statistical and resource management data." {Source: ASTM E1633-02a, 2006} For more information visit www.astm.org .
Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN)	<p>The National Healthcare Safety Network (NHSN) is a secure, internet-based surveillance system that integrates patient and healthcare personnel safety surveillance systems managed by the Division of Healthcare Quality Promotion (DHQP) at CDC.</p> <p>The purposes of NHSN are to:</p> <ul style="list-style-type: none">Collect data from a sample of healthcare facilities in the United States to permit valid estimation of the magnitude of adverse events among patients and healthcare personnel.Collect data from a sample of healthcare facilities in the United States to permit valid estimation of the adherence to practices known to be associated with prevention of healthcare-associated infections (HAI).Analyze and report collected data to permit recognition of trends.Provide facilities with risk-adjusted data that can be used for interfacility comparisons and local quality improvement activities.Assist facilities in developing surveillance and analysis methods that permit timely recognition of patient and healthcare personnel safety problems and prompt intervention with appropriate measures.Conduct collaborative research studies with NHSN member facilities (e.g., describe the epidemiology of emerging HAI and pathogens, assess the importance of potential risk factors, further characterize HAI pathogens and their mechanisms of resistance, and evaluate alternative surveillance and prevention strategies). <p>For more information visit www.cdc.gov.</p>



Standard Name	Description
Consolidated Health Informatics (CHI) Domain: Allergy	The Consolidated Health Informatics (CHI) initiative is one of the Office of Management and Budget's (OMB) eGov initiatives. CHI is a collaborative effort to adopt health information interoperability standards, particularly health vocabulary and messaging standards, for implementation in federal government systems. Originally, CHI identified a portfolio of 24 health domains that later expanded to 27. CHI adopted 20 uniform standards for electronic exchange of clinical information to be used across the federal health enterprise. The standards in the Allergy Domain will be used to set requirements for "exchanging" allergy data across the federal health enterprise, using allergy information exchange requirements and several related allergy vocabulary standards for Allergen Code, Allergen Group, Allergy Type, Allergy Severity and Allergen Reaction. For more information visit www.hhs.gov .
Extensible Markup Language (XML) v1.0 (Fourth Edition)	The Extensible Markup Language (XML) is a subset of SGML that is completely described in this document. Its goal is to enable generic SGML to be served, received, and processed on the Web in the way that is now possible with HTML. XML has been designed for ease of implementation and for interoperability with both SGML and HTML. For more information, visit www.w3.org .
Federal Medications Terminology	<p>A set of controlled terminologies and code sets developed and maintained as part of a collaboration between the Food and Drug Administration, National Library of Medicine, Veterans Health Administration, National Cancer Institute and Agency for Healthcare Research and Quality related to medications, including medication proprietary and nonproprietary names, clinical drug code (RxNorm); ingredient names and Unique Ingredient Identifiers (UNII); routes of administration, dosage forms, and units of presentation from the NCI Thesaurus (NCIt); and certain pharmacological drug classes from the National Drug File Reference Terminology (NDF-RT) .</p> <p>The Federal Medication Terminology leverages medication models maintained by the Food and Drug Administration (ex. UNII, NDC Codes), National Library of Medicine (RxNorm), the Veterans Health Administration (NDF-RT), and the National Cancer Institute (NCIt).</p> <p>Information on the Federal Medication Terminologies may be found and downloaded from the NCI Web portal terminology resources page at www.cancer.gov/cancertopics.</p>
Health Level Seven (HL7) Version 2+ (Table HL7 0331)	The HL7 Version 2.5 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. For more information visit www.hl7.org .
HL7 CDA Structure Document (HAI) Health Level Seven (HL7) Implementation Guide for CDA Release 2; National Healthcare Safety Network (NHSN) Healthcare Associated Infection (HAI) Reports, Release 1 (DSTU)	Specifies a standard for electronic submission of Healthcare Associated Infection (HAI) Reports to the National Healthcare Safety Network (NHSN) of the Centers for Disease Control and Prevention (CDC). This Draft Standard for Trial Use (DSTU) defines the overall approach and method of electronic submission and develops a set of appendices defining specific HAI report types. As reports are modified and new report types are defined, additional appendices will be developed and published by CDC and HL7. For more information visit www.hl7.org .
Integrating the Healthcare Enterprise (IHE) Drug Safety Content Profile (DSC) Draft Profile from the IHE QRPH Domain	DSC describes the content and format to be used within the Prepopulation Data transaction described within the RFD Integration Profile. The purpose of this profile is to support a standard set of data in CCD format which the Form Filler provides for use in reporting adverse events as it relates to Drug Safety. In addition this profile will reference the ability to convert this output into the ICH E2B(R3) standard. For more information visit www.ihe.net .



Standard Name	Description
International Classification of Diseases, 10th Revision, Related Health Problems (ICD-10-CM)	<p>The International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), describes the classification of morbidity information for statistical purposes and for the indexing of healthcare records by diseases. The National Center for Health Statistics (NCHS), the Federal agency responsible for use of the International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) in the United States, developed a clinical modification of the classification for morbidity purposes. For more information visit</p> <p>Note: While ICD-10 is not deployed in US installations, we recognize the need to move toward new releases of coded values. For more information visit, www.cdc.gov/nchs.</p>
International Classification of Diseases, 9th Revision, Clinical Modifications (ICD-9-CM)	<p>The International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM), Volumes I, II (diagnoses) and III (procedures) describes the classification of morbidity information for statistical purposes and for the indexing of healthcare records by diseases and procedures. For more information visit, www.cdc.gov/nchs.</p>
International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	<p>SNOMED CT consists of a technical design, core content architecture, and Core content. SNOMED CT Core content includes the technical specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content also includes a concepts table, description table, relationships table, history table, ICD-9-CM mapping, and Technical Reference Guide. Additionally, SNOMED CT provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms unique to particular organizations or localities. For more information visit, www.ihtsdo.com.</p>
International Organization for Standardization (ISO) Document Management -- Portable Document Format (PDF) Part 1: PDF 1.7, ISO# 32000-1:2008 (Under Development)	<p>PDF specifies a digital form for representing electronic documents to enable users to exchange and view electronic documents independent of the environment in which they were created or the environment in which they are viewed or printed. It is intended for the developer of software that creates PDF files (conforming writers), software that reads existing PDF files and interprets their contents for display and interaction (conforming readers) and PDF products that read and/or write PDF files for a variety of other purposes (conforming products). For more information, visit www.iso.org.</p>
LANGUAL International Framework for Food Description	<p>LanguaL is a Food Description Thesaurus. LanguaL stands for "Langua aLimentaria" or "language of food". It is an automated method for describing, capturing and retrieving data about food. The work on LanguaL was started in the late 1970's by the Center for Food Safety and Applied Nutrition (CFSAN) of the United States Food and Drug Administration as an ongoing co-operative effort of specialists in food technology, information science and nutrition. Since then, LanguaL has been developed in collaboration with the US National Cancer Institute (NCI), and, more recently, its European partners, notably in France, Denmark, Switzerland and Hungary. Since 1996, the European LanguaL Technical Committee has administered the thesaurus. The thesaurus provides a standardised language for describing foods, specifically for classifying food products for information retrieval. LanguaL is based on the concept that:</p> <p>Any food (or food product) can be systematically described by a combination of characteristics</p> <p>These characteristics can be categorised into viewpoints and coded for computer processing</p> <p>The resulting viewpoint/characteristic codes can be used to retrieve data about the food from external databases</p> <p>For more information, visit www.languaL.org.</p>



Standard Name	Description
Logical Observation Identifiers Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. For more information visit www.loinc.org .
Medical Dictionary for Regulatory Activities (MedDRA)	MedDRA - the Medical Dictionary for Regulatory Activities - is a pragmatic, medically valid terminology with an emphasis on ease of use for data entry, retrieval, analysis, and display, as well as a suitable balance between sensitivity and specificity within the regulatory environment. It was developed by the International Conference on Harmonisation (ICH) and is owned by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) acting as trustee for the ICH steering committee. MedDRA terminology applies to all phases of drug development, excluding animal toxicology. It also applies to the health effects and malfunction of devices. For more information visit, www.meddrasso.com .
Structured Product Labeling Implementation Guide (SPL) Release 3 Implementation Guide for FDA Drug and Biological Products v1.1	This document provides technical details (conformance criteria) on using Structured Product Labeling (SPL) for FDA Drug and Biological Products including the Content of Labeling, Drug Listing Data Elements and Highlights Data Elements. Outside the scope of this document is information on the creation of SPL for a specific product and instructions on the use of extensible mark up language (XML). For more information, visit www.fda.gov .
U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health MEDWATCH Medical Device Reporting Code Instructions, Appendix - B Device and Patient Problem Codes	The MedWatch Medical Device Reporting Code Manual contains codes to describe reportable device adverse event information. Patient codes describe the patient's condition during the reportable event, and the device codes describe the nature of the device failure or problem. For more information, visit www.fda.gov
US Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) Data Standards Manual	This is a compilation of standardized nomenclature monographs that have been reviewed and approved by the CDER Nomenclature Standards Committee (NSC). These CDER nomenclature standards are considered binding upon all new automated databases, and upon all existing automated databases when undergoing a major redesign. Use of the nomenclature standards are strictly voluntary for static existing databases. Some of the current CDER automated databases that use these nomenclature standards include the Center-wide Oracle Management Information System (COMIS), the Division Files System (DFS), the Drug Product Reference File (DPRF), the Drug Registration and Listing System (DRLS), the Developers and Distributors System (DADS), the Special Products On-Line Tracking System (SPOTS), and the Phase 4 Tracking System. For more information, visit www.fda.gov
US Food and Drug Administration (FDA) Substance Registration System Manual - Unique Ingredient Identifier (UNII) assignment	The overall purpose of the joint FDA/USP Substance Registration System (SRS) is to support health information technology initiatives by generating unique ingredient identifiers (UNIIs) for substances in drugs, biologics, foods, and devices. The UNII is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information. For more information, visit www.fda.gov



Standard Name	Description
World Health Organization (WHO), World Alliance for Patient Safety International Classification for Patient Safety V1.0 for Field Testing 2007-2008 (ICPS)	The aim of the ICPS is to “define, harmonize and group patient safety concepts into an internationally agreed classification in a way that is conducive to learning and improving patient safety across systems.” It is intended to enable the translation of data and information into a common (standardized) language and to allow for analysis which will result in awareness, accountability and knowledge building. In order to achieve its purpose, a conceptual framework with agreed concepts for the ICPS was designed. For more information visit www.who-icps.org .



6.2 HARMONIZATION EFFORTS FOR PUBLIC HEALTH CASE REPORTING

Data Element	Description	# NND Covered	Diseases and (Number in Production)
Generic	All Investigations start with the set of Generic elements - 176 are truly "Generic" then subtract out the Foodborne, Tetanus, Rabies, Lyme Disease, as we have not covered the extended questions - still send these records to NETSS, though, as "Core records". Foodborne (30), STD*MIS covered = 12 or so ==> not sure how you want to count these! Looks like Arbonet already deleted.	134	Aseptic meningitis (553) Ehrlichiosis, human monocytic (25) Flu activity Code (48) Influenza, Human Isolates (775) Legionellosis (55) Lyme Disease (81) Varicella Infection - Chickenpox (1364) VRE (1139) Foodborne-core investigation only Salmonellosis (1462) Foodborne -core investigation only Shigellosis (1762) Foodborne-core investigation only
BMIRD			
BMD Gen	these elements are also included in the Extended BMIRD Notifications	3	10650-Bacterial Meningitis, Other (70) 11715-Streptococcal disease, invasive, Group B (277) 1716-Streptococcal disease, other, invasive, beta-hemolytic (non-group A and non-group B) (44)
Extended			
	HIN-Haemophilus Influenzae	1	10590-62 H. flu Instances
	NMN-Meningococcal disease (Neisseria Meningitidis)	1	10510-54 N. meningitidis Instances
	STP-Streptococcal Pneumoniae	2	11720-Streptococcus pneumoniae, drug resistant, invasive disease (78) 11717-Streptococcus pneumoniae, invasive in children < 5 years (588)
	STA - Streptococcus, Group A	2	11710-Streptococcal disease, invasive, Group A (233) 11700-Streptococcal toxic-shock syndrome (2)
Hepatitis			
Hep Gen	these elements are also included in the Extended Hepatitis Notifications	4	10481-Hepatitis Non-ABC, Acute (0) 10105-Chronic Hepatitis B (1405) 10102-Hepatitis Delta co- or super-infection, acute (Hep D) (0) 10103-Hepatitis E, acute (0)
Extended			
	HAA-Hep A Acute	1	10110-Hepatitis A, acute (208)
	HBA-Hep B Acute	1	10100-Hepatitis B, acute (465)
	HCA-Hep C Acute	1	10101-Hepatitis C, acute (67)
	HCC-Hep C Chronic		10160-Hepatitis C virus infection (past or present) (6176)
	HPV-Hep Perinatal		10104-Hepatitis B virus, perinatal infection (0)
Vaccine Preventable	no VPD "generic" exists right now but could		
MUM - Mumps		1	10180-Mumps (16)
MEA - Measles		1	10140-Measles (Rubeola) (1)



	RUB - Rubella		1	10200-Rubella (1)
	CRS - Congenital Rubella Syndrome		1	10370-Rubella, congenital syndrome (0)
		Totals	154	

6.3 USHIK DATA ELEMENT DEFINITIONS FOR IDENTIFIED COMMON DATA ELEMENTS

The following table provides a list of standards available for selection for each of the potential common data elements identified by the HITSP Population Perspective TC. The list was compiled based upon the available standards listed in USHIK.

Data Elements	Organization	Data Element ID	Definition	Context	Data Type	Data Domain	Comments
Transaction Date & Time							
Transaction Date	HL7	0060-62-480-3235.77499.v1	The date of the transaction. E.g. this would be used to identify the date a procedure, item, or test was conducted or used. It may be defaulted to today's date.	Health Level Seven v 2.X	TS		
Transaction Posting Date	HL7	0060-62-480-3235.77503.v1	This field contains the date of the transaction that was sent to the financial system for posting.	Health Level Seven v 2.X	TS		
Transaction Creation Time	X12	0060-07-329-4837.28144.v1	Time file is created for transmission	X12 Health Care Data Element Dictionary	ID		
Facility/ Importer Information		Additional information required					
Facility/Importer Name/Address		Additional information required					
Facility Name	AHRQ	044012578.82895.v1	Name of facility Organization Name Used in HAVE message	Not Provided	Not Provided		
Facility Name	NCPDP	0060-02-166-0014.81367.v1	Name identifying the location of the service rendered.	NCPDP Data Dictionary V8.1 October 2005	Not Provided		



Facility Address	HL7	0060-62-480-3235.76874.v1	This field contains the facility's address. Components: In Version 2.3 and later, replaces the AD data type. < street address (SAD) > ^ < other designation (ST) > ^ < city (ST) > ^ < state or province (ST) > ^ < zip or postal code (ST) > ^ < country (ID) > ^ < address type (ID) > ^ < other geographic designation (ST) > ^ < county/parish code (IS) > ^ < census tract (IS) > ^ < address representation code (ID) > ^ < address validity range (DR) >	The HL7 v 2.4 Standard specification for electronic data exchange	Not Provided		
Street Name			:				
Facility Street Address	NCPDP	0060-02-166-0014.81369.v1	Free form text for Facility address information	NCPDP Data Dictionary V8.1 October 2005	Not Provided		
City							
Facility City Address	NCPDP	0060-02-166-0014.81366.v1	Free form text for facility city name	NCPD Data Dictionary V8.1	Not Provided		
Facility Zip/Postal Zone	NCPDP	0060-02-166-0014.81370v.1	Code defining international postal zone excluding punctuation and blanks	NCPD Data Dictionary V8.1	Not Provided		
Zip Code		See Patient Information below					
State		See Patient Information below					
Telephone		See Patient Information below					
Contact Person		See Patient Information below					
Contact Phone Number		See Patient Information below					
Contact Address	HL7	0060-62-480-3235.76683.v1	This field contains the address of the study contact identified in CM0-9 - Contact for study. Components: In Version 2.3 and later, replaces the AD data type. < street address (SAD) > ^ < other designation (ST) > ^ < city (ST) > ^ < state or province (ST) > ^ < zip or postal code (ST) > ^ < country (ID) > ^ < address type (ID) > ^ < other geographic designation (ST) > ^ < county/parish code (IS) > ^ < census tract (IS) > ^ < address representation code (ID) > ^ < address validity range (DR) > Subcomponents of street address: < street address (ST) > & < street name (ST) > & < dwelling number (ST) >	Health Level Seven v 2X	XAD		



Contact Communication Information	HL7	0060-62-480-3235.76684.v1	<p>This field contains the information, such as the phone number or electronic mail address, used to communicate with the contact person or organization.</p> <p>Components: [NNN] [(999)]999-9999 [X99999] [B99999] [C any text] ^ < telecommunication use code (ID) > ^ < telecommunication equipment type (ID) > ^ < email address (ST) > ^ < country code (NM) > ^ < area/city code (NM) > ^ < phone number (NM) > ^ < extension (NM) > ^ < any text (ST) ></p>	Health Level Seven v 2X	XTN		
Contact Location	HL7	0060-62-480-3235.76687.v1	<p>"This field contains the location of the contact, which is required when a contact that may be external to a given enterprise must be referenced. For example, if this contact represents the office manager of the referred-to physician, then the contact location should identify the clinic of the physician or provider to whom this referral has been sent. The identification of the contact's location is specified by an application and facility identifier carried in the facility field. The application identifier and the facility identifier would be used in the same manner as their corresponding fields in the MSH segment (MSH-3-Sending application, MSH-5-Receiving application, MSH-4-Sending facility, MSH-6-Receiving facility). That is, the facility field will contain an application identifier and facility identifier which describe the location of this contact. However, it should be noted that they may describe a different location because the contact location being referenced in this field may not be the location from which the message originated, which is being described by the MSH. Components: < point of care (IS) > ^ < room (IS) > ^ < bed (IS) > ^ < facility (HD) > ^ < location status (IS) > ^ < person location type (IS) > ^ < building (IS) > ^ < floor (IS) > ^ < location description (ST) > Subcomponents of facility: < namespace ID (IS) & < universal ID (ST) > & < universal ID type (ID) >"</p>	Health Level Seven v 2X	PL		



Contact Name	HL7	0060-62-480-3235.76688.v1	This field contains the name of the contact person identified in this segment. Generally, this field will describe a person or provider associated with the referral. If this contact name is a physician, you may refer to the CTD-7-Contact identifiers (Section 11.6.4.7) for the physician identifier. Components: In Version 2.3, replaces the PN data type. < family name (FN) > ^ < given name (ST) > ^ < second and further given names or initials thereof (ST) > ^ < suffix (e.g., JR or III) (ST) > ^ < prefix (e.g., DR) (ST) > ^ < degree (e.g., MD) (IS) > ^ < name type code (ID) > ^ < name representation code (ID) > ^ < name context (CE) > ^ < name validity range (DR) > ^ < name assembly order (ID) >	Health Level Seven v 2X	XPN		
Contact Person	HL7	0060-62-480-3235.76689.v1	This field contains the primary contact person's name. Components: In Version 2.3 and later, use instead of the CN data type. < ID number (ST) > ^ < family name (FN) > ^ < given name (ST) > ^ < second or further given names or initials thereof (ST) > ^ < suffix (e.g., JR or III) (ST) > ^ < prefix (e.g., DR) (ST) > ^ < degree (e.g., MD) (IS) > ^ < source table (IS) > ^ < assigning authority (HD) > ^ < name type code (ID) > ^ < identifier check digit (ST) > ^ < code identifying the check digit scheme employed (ID) > ^ < identifier type code (IS) > ^ < assigning facility (HD) > ^ < name representation code (ID) > ^ < name context (CE) > ^ < name validity range (DR) > ^ < name assembly order (ID) >. Subcomponents of assigning authority: < namespace ID (IS) > & < universal ID (ST) > & < universal ID type (ID) >. Subcomponents of assigning facility ID: < namespace ID (IS) > & < universal ID (ST) > & < universal ID type (ID) >	Health Level Seven v 2X	SCN		
Contact Person's Address	HL7	0060-62-480-3235.76691.v1	"This field contains the addresses of the contact person depending on the value of the relationship defined in NK1-3 - relationship. This field is typically used when the NK1 is an organization. When multiple addresses are sent, the mailing address must be sent first in the sequence. Components: In Version 2.3 and later, replaces the AD data type. < street address (ST) > ^ < other designation (ST) > ^ < city (ST) > ^ < state or province (ST) > ^ < zip or postal code (ST) > ^ < country (ID) > ^ < address type (ID) > ^ < other geographic designation (ST) > ^ < county/parish code (IS) > ^ < census tract (IS) > ^ < address representation code (ID) > ^ < address validity range (DR) > Subcomponents of	Health Level Seven v 2X	XAD		



			street address: < street address (ST) > & < street name (ST) > & < dwelling number (ST) >"				
Contact Person's Name	HL7	0060-62-480-3235.76692.v1	<p>This field contains the names of the people to contact, depending on the value of the relationship defined in NK1-3 - relationship. This field is typically needed when the NK1 is an organization. The legal name should be sent first in the sequence. Refer to HL7 Table 0200 - Name type for valid values. Components: In Version 2.3, replaces the PN data type. < family name (FN) > ^ < given name (ST) > ^ < second and further given names or initials thereof (ST) > ^ < suffix (e.g., JR or III) (ST) > ^ < prefix (e.g., DR) (ST) > ^ < degree (e.g., MD) (IS) > ^ < name type code (ID) > ^ < name representation code (ID) > ^ < name context (CE) > ^ < name validity range (DR) > ^ < name assembly order (ID) > Subcomponents of family name: < family name (ST) > & < own family name prefix (ST) > & < own family name (ST) > & < family name prefix from partner/spouse (ST) > & < family name from partner/spouse (ST) >"</p>	Health Level Seven v 2X	XPN		
Contact Person's Telephone Number	HL7	0060-62-480-3235.76693.v1	<p>"This field contains the telephone numbers of the contact person depending on the value of the relationship defined in NK1-3 - relationship. This field is typically needed when the NK1 is an organization. The primary telephone number must be sent in the first sequence. If the primary telephone number is not sent, then a repeat delimiter must be sent in the first sequence. Refer to HL7 Table 0201 - Telecommunication use code and HL7 Table 0202 - Telecommunication equipment type for valid values Components: [NNN] [(999)]999-9999 [X99999] [B99999] [C any text] ^ < telecommunication use code (ID) > ^ < telecommunication equipment type (ID) > ^ < email address (ST) > ^ < country code (NM) > ^ < area/city code (NM) > ^ < phone number (NM) > ^ < extension (NM) > ^ < any text (ST) >"</p>	Health Level Seven v 2X	XTN		



Contact Phone	HL7	0060-62-480-3235.76694.v1	This field contains the phone number to use to contact facility personnel about the patient location, in case of inquiries about the location. This phone is not necessarily within the named patient location. Components: [NNN] [(999)]999-9999 [X99999] [B99999] [C any text] ^ < telecommunication use code (ID) > ^ < telecommunication equipment type (ID) > ^ < email address (ST) > ^ < county code (NM) > ^ < area/city code (NM) > ^ < phone number (NM) ^ < extension (NM) > ^ < any text (ST) >	Health Level Seven v2X	XTN		*Move this to Facility Contact Phone (Location)
Facility Identifier							
Facility Identifier	AHRQ	044012578.82894.v1	Unique facility identifier CMM IDs OrganizationID uUsed in HAVE message	Not Provided	Data Element		
User Facility / Importer Report Number							
Admissions last 24 hours	AHRQ	044012578.82889.v1	Number of admission to facility in the last 24 hours Numeric observationObservation with HAVE SML tag: ?Admission^Admissions Past 24 hours? Once daily routine census report	Not Provided	Data Element		
Discharges last 24 hours	AHRQ	044012578.82900.v1	Number of discharges from the facility in the last 24 hours Numeric observation Observation with HAVE XML tag: ?Dishcarges^Discharges Past 24 hours? Once daily routine census report	Not Provided	Data Element		
Deaths last 24 hours	AHRQ	0440112578.82901.v1	Number of deaths recorded at facility in last 24 hours Numeric observatinObservation with HAVE XML tag: ?Deaths^Deaths Past 24 hours? Once daily routine census report	Not Provided	Data Element		
Clinical Status							



Problems ccr:Health Status	ASTM	0060-00-199- 3369.81803.v1	Used to define the of the Actor to whom the problem applies (used more commonly in < Family History >). < HealthStatus > has children < DateTime >, < Description >, < CauseOfDeath >. < DateTime > can be an Exact DateTime, an age, an approximate DateTime, or a DateTime range. < Description > and < CauseOfDeath > are instances of Coded DescriptionType with restricted content that must be one of the defined structured text values. < Description > Alive And Well, In Remission, Symptom Free, Chronically Ill, Severely Ill, Disabled, Severely Disabled, Deceased; < CauseOfDeath > Yes, No, Unknown. Note that under < HealthStatus > the CCR can record the current health status relative to this problem as well as if the problem was or was not the and a Time Of Death as a < Type > under < DateTime >. Optional	The information from ASTM standard and other documents.	Data Element		
Problems ccr:Status	ASTM	0060-00-199- 3369.81798.v1	Defines the < Status > of the < Problem >. This is a CodedDescription Type with restricted content that must be one of the defined structured text values. Active, Inactive, chronic, Intermittent, Recurrent, Rule Out, Ruled Out, Resolved. Optional.	The information from ASTM standards and other documents.	Data Element		
Clinical Investigation Subject Outcome.Di agnosis Code	ADA	0060-07-442- 5216.74190.v1	This attribute contains encoded data which specified a health diagnosis.	Standard Clinical Data Architecture for the Structure and Content of an Electric Health Record	Data Element		
Clinical Progress Note	ASTM	0060-00-199-3369- 72412.v1	A textual description of the physician's observations, their interpretations and conclusions about the clinical course of the patient or the steps taken, or to be taken, in the care of the patient.	The information from ASTM standard and other documents	Data Element	*Clinical Progress Note Date-Time (ASTM)	
Facility Status							
Facility Type	HL7	0060-62-480- 3235.76383.v1	"This field contains the type of facility. Refer to HL7 Table 0330 - Facility type for valid values. HL7 Table 0331-Facility type"	The HL7 V 2.4 Standard specification for electronic	Data Element		



				data exchang e			
*Facility type code X12							
facility category descriptive tx	HA						
Facility Operations							
facility operational status cd	HA	0060-02-670- 0448.39741.v1	The code that denotes a condition of a specific facility in a military operations environment.	Health Affairs data Dictionar y	Data Element		
facility operational status dt	HA	0060-02-670- 0448.39759.v1	The date of the facility-Operation-Status	Health Affairs data Dictionar y	Data Element		
facility operational status tm	HA	0060-02-670- 0448.39761.v1	The time of a facility-operation-status	Health Affairs data Dictionar y	Data Element		
facility plan operation duration qy	HA	0060-02-670- 0448.39767.v1	The quantity of days that a FACILITY- PLAN will be in effect.	Health Affairs data Dictionar y	Data Element		
facility type skill cd	HA	0060-02-670- 0448.39931.v1	The code that represents a facility -type skill	Health Affairs data Dictionar y	Data Element		
Responsible Physician Contact Information							



Ordering Provider	HL7	0060-62-480-3235.77108.v1	<p>" This field identifies the provider who ordered the test. Either the ID code or the name, or both, may be present. This is the same as ORC-12-Ordering provider.</p> <p>Components: In Version 2.3 and later, use instead of the CN data type. < ID number (ST) > ^ < family name (FN) > ^ < given name (ST) > ^ < second or further given names or initials thereof (ST) > ^ < suffix (e.g., JR or III) (ST) > ^ < prefix (e.g., DR) (ST) > ^ < degree (e.g., MD) (IS) > ^ < source table (IS) > ^ < assigning authority (HD) > ^ < name type code (ID) > ^ < identifier check digit (ST) > ^ < code identifying the check digit scheme employed (ID) > ^ < identifier type code (IS) > ^ < assigning facility (HD) > ^ < name representation code (ID) > ^ < name context (CE) > ^ < name validity range (DR) > ^ < name assembly order (ID) > Subcomponents of assigning authority: < namespace ID (IS) > & < universal ID (ST) > & < universal ID type (ID) > Subcomponents of assigning facility ID: < namespace ID (IS) > & < universal ID (ST) > & < universal ID type (ID) >"</p>	Health Level Seven v 2.X	XCN		
Other Healthcare Provider	HL7	0060-62-480-3235.76053.v1	<p>"This field has been retained for backward compatibility only. Use the ROL-Role Segment to communicate providers not specified elsewhere. Refer to section 12.3.3 for the definition of the ROL segment. This field contains the other healthcare providers (e.g. nurse care practitioner, midwife, physician assistant). Multiple healthcare providers can be sent. Depending on local agreements, either the ID or the name may be absent from this field. Use values in User-defined Table 0010 - Physician ID for first component. Components: < ID number (ST) > ^ < family name (ST) > ^ < given name (ST) > ^ < second and further given names or initials thereof (ST) > ^ < suffix (e.g., JR or III) (ST) > ^ < prefix (e.g., DR) (ST) > ^ < degree (e.g., MD) (IS) > ^ < source table (IS) > ^ < assigning authority (HD) > ^ < name type code (ID) > ^ < identifier check digit (ST) > ^ < code identifying the check digit scheme employed (ID) > ^ < identifier type code (IS) > ^ < assigning facility (HD) > ^ < name representation code (ID) > ^ < name context (CE) > ^ < name validity range (DR) > Subcomponents of family name: < family name (ST) > & < own family name prefix (ST) > & < own family name (ST) > & < family name prefix from partner/spouse (ST) > & < family name from partner/spouse (ST) ></p>	Health Level Seven v 2.X	CV		



			Subcomponents of assigning authority: < namespace ID (IS) > & < universal ID (ST) > & < universal ID type (ID) > Subcomponents of assigning facility: < namespace ID (IS) > & < universal ID (ST) > & < universal ID type (ID) >"				
Ordering Provider Identification	X12	0060-07-329-4837.26484.v1	The identifier assigned by the Payer to the provider who ordered or prescribed this service	X12N health Care Data Element Dictionary	ID		
Ordering Provider Contact Name	X12	0060-07-329-4837.26480.v1	Contact person to whom inquires should be directed at the provider ordering services for the patient.	X12N health Care Data Element Dictionary	ID		
Ordering Provider First Name	X12	0060-07-329-4837.26482.v1	The first name of the provider who ordered or prescribed this service	X12N health Care Data Element Dictionary	ID		
Ordering Provider Last Name	X12	0060-07-329-4837.26486.v1	The last name of the provider who ordered or prescribed this service	X12N health Care Data Element Dictionary	ID		
Ordering Provider Address Line	X12	0060-07-329-4837.26476.v1	Address line of the provider ordering services for the patient.	X12N health Care Data Element Dictionary	ID		
Ordering Provider City Name	X12	0060-07-329-4837.26478.v1	City of provider ordering services for the patient	X12N health Care Data Element Dictionary	ID		
Ordering Provider State Code	X12	0060-07-329-4837.26500.v1	The State Postal Code of the provider ordering services for the patient.	X12N health Care Data Element Dictionary	ID		
Ordering Provider Postal Zone ZIP	X12	0060-07-329-4837.26496.v1	The ZIP code of the provider ordering services for the patient	X12N health Care Data	ID		



**HITSP Public Health Case Reporting Use Case Requirements,
Design and Standards Selection**

Review Copy
20080627 V1.0

Code				Element Dictionary			
Healthcare Provider Name							
Healthcare Providers ccr:Providers	ASTM	0060-00-199-3369.81879.v1	Used to define all healthcare providers involved in the current or pertinent historical care of the patient. This is a link to an < Actor > with an <Actor Role >. This data object is not used for listing a patients non-healthcare <Support > providers. <Support > providers are listed under the < Support > section of the CCR> At a minimum the patient's key healthcare providers should be listed, particularly their primary physician and any active consulting physicians, therapist and counselors. Examples: Physicians, PAs, NPs, nurses, therapists, counselors, etc. Optional.	The information from ASTM standards and other documents	Data element		
Personnel							
personnel resource status information tx	HA	0060-02-670-0448.54981.v1	The text of the details of a PERSONNEL-RESOURCE-STATUS	Health Affairs Dictionary	Data element	*dt, tx, cd and type available (HA)	
Decontamination Capacity			No current data elements				
EMS Traffic Status	AHRQ	044012578.82908.v1	Ability of this emergency department to receive patients via emergency medical services. Value must be one of : Normal - Accepting all EMS traffic Advisory - Experiencing specific resource limitations which may affect transport of some EMS traffic. Closed - Requesting re-route of EMS traffic to other facilities. NotApplicable - Not Applicable. This hospital does not have an emergency department. Observation with HAVE SML tag: ?EMSTrafficStatus? Associate comments may also be passed.	Not Provided	Data element		
EMS Capacity							
Emergency Department Status - EMS Capacity	AHRQ	044012578.82909.v1	The number of each triage patient type the hospital can accept. Capacity TriageRed count CapacityTriageYellow count CapacityTriageGreen count CapacityTriageBlack count Observationwith HAVE SML tag:?CapacityTriageRed?Associate comment may also be passed.	Not Provided	Data element		
EMS Census							



Emergency Department Status - EMS Census	AHRQ	044012578.82910.v 1	The number of each triage patient type the hospital currently has. CensusTriageRed count CensusTriageYellow count CensusTriageGreen count CensusTriageBlack count Observation with HAVE SML tag: ?CensusTriageRed? Associated comment may also be passed.	Not Provided	Data element		
Adult ICU Beds							
HospitalBedCapacityStatus - Available Adult ICU Beds	AHRQ	044012578.82912.v 1	Number of physically available and staffed Adult ICU beds. These beds can support critically ill or injured patients, including ventilator support. Category includes all major subtypes of ICU beds, including neuro, cardiac, trauma, or medical, with the exception that this category does not include burn ICU beds.	Not Provided	Data element		
Medical Surgical Beds							
HospitalBedCapacityStatus - Available Adult General Beds	AHRQ	044012578.82913.v 1	Number of physically available and staffed Adult General beds. These are also thought of as ward beds. These beds may or may not include cardiac telemetry capability. Numeric Observation with HAVE XML tag: AdultICUAvailableCount	Not Provided	Not Provided		
Burn Beds							
HospitalBedCapacityStatus - Available Burn Beds	AHRQ	044012578.82914.v 1	These are thought of as burn ICU beds, either approved by the American Burn Association or self-designated. These beds are NOT to be included in other ICU bed counts. Numeric Observation with HAVE XML tag: BurnAvailableCount	Not Provided	Not Provided		
Pediatrics ICU Beds							
HospitalBedCapacityStatus - Available Peds ICU Beds	AHRQ	044012578.82915.v 1	Capacity status for pediatric ICU beds. This is similar to adult ICU beds, but for patients 17-years-old and younger. Numeric Observation with HAVE XML tag: PediatricICUAvailableCount	Not Provided	Not Provided		
Pediatrics Beds							
HospitalBedCapacityStatus - Available Peds General Beds	AHRQ	044012578.82916.v 1	Capacity status for pediatrics beds. These are ward medical/surgical beds for patients 17-years-old and younger. Numeric Observation with HAVE XML tag: PediatricAvailableCount	Not Provided	Not Provided		
Negative Flow Isolation Beds							



HospitalBedCapacityStatus - Available Negative Pressure Rooms	AHRQ	044012758.82917.v1	Capacity status for negative airflow isolation beds. These provide respiratory isolation. NOTE: This value may represent available beds included in the counts of other types. Numeric Observation with HAVE XML tag: ζNegativeFlowIsolationAvailableCountζ	Not Provided	Not Provided		
Available Ventilators							
HospitalBedCapacityStatus- Available Ventilators	AHRQ	044212578.82918.v1	Number of available ventilators. Numeric Observation with HAVE XML tag: ζVentilatorAvailableCountζ	Not Provided	Not Provided		
Number of Facility Beds							
Number of Facility Beds	AHRQ	044012578.82897.v1	All facility beds regardless of licensing status. N/A Not routinely messaged	Not Provided	Not Provided		
Number of Licensed Beds							
Number of Licensed Beds	AHRQ	044012578.82898.v1	Number of Licensed Beds	Not Provided	Not Provided		
Reported previously?							
Date of Report							
Event Report Date	HL7	0060-62-480-3235.76858.v1	This field contains the date the message was originally sent to the regulatory agency.	Health Level Seven v 2.X	TS		
Report Date	HL7	0060-62-480-3235.77315.v1	This field contains the date as assigned by the sender.	Health Level Seven v 2.X	TS		
Reported Date/Time	HL7	0060-62-480-3235.77323.v1	This field contains the date/time the allergy was reported to a caregiver.	Health Level Seven v 2.X	TS		
Report Date/Time	AHRQ	044012578.82919.v1	Date/time the data on this report is relevant. Specific HL7 attribute: OBR-22 Results/Rpt Status Chg Dt/time	Not Provided	Not Provided		
Date User Facility/Importer Became Aware of Event							
Report Submitters Name		No results found on reporter/ submitter refers to claims not tests. Additional information required.					
Reporter Name							
Reporter's Telephone							
Reporter's Address							
Reporter's Email							
Report Sent to ?							



Event Report Source	HL7	0060-62-480-3235.76302.v1	"This field identifies the source from which the sender learned about the event. Multiple sources may be reported by repeating the element. If the source of the report is a clinical trial, the CSR and CSP segments can be included to define the study. Refer to HL7 Table 0235 - Report source for valid values. HL7 Table 0235 - Report source "	Health Level Seven v 2.X	CV		
Event Reported To	HL7	0060-62-480-3235.76303.v1	"This field indicates all the entities to whom the entity submitting the report has reported the event. Repeat the element if the report was submitted to more than one entity. Refer to HL7 Table 0236 - Event reported to for valid values. HL7 Table 0236 - Event reported to "	Health Level Seven v 2.X	ID		
Reported By	HL7	0060-62-480-3235.77322.v1	"This field contains the name of the person reporting the allergy to a caregiver at the time reported in IAM-14 - reported date/time. Components: In Version 2.3, replaces the PN data type. < family name (FN) > ^ < given name (ST) > ^ < second and further given names or initials thereof (ST) > ^ < suffix (e.g., JR or III) (ST) > ^ < prefix (e.g., DR) (ST) > ^ < degree (e.g., MD) (IS) > ^ < name type code (ID) > ^ < name representation code (ID) > ^ < name context (CE) > ^ < name validity range (DR) > ^ < name assembly order (ID) > Subcomponents of family name: < family name (ST) > & < own family name prefix (ST) > & < own family name (ST) > & < family name prefix from partner/spouse (ST) > & < family name from partner/spouse (ST) > "	Health Level Seven v 2.X	XPN		
Report Priority	HL7	0060-62-480-3235.76132.v1	This field contains the priority associated with this report or update. Refer to HL7 Table 0109 - Report priority for valid values. HL7 Table 0109 - Report priority "	Health Level Seven v 2.X	ID		
Reporting Priority	HL7	0060-62-480-3235.76250.v1	"This field contains the available priorities reporting the test results when the user is asked to specify the reporting priority independent of the processing priority. Refer to HL7 Table 0169 - Reporting priority for valid values. HL7 Table 0169 - Reporting priority "	Health Level Seven v 2.X	ID		



Reporting Lab Identifier	AHRQ	044012578.82942.v1	CLIA Specific HL7 attribute: MSH-4 Sending Facility	Not Provided	Not Provided		
Date Sent to Manufacturer							
Report Sent to FDA							
Date Sent to FDA							
Type of Reporter							
Occupation of Reporter							
Vaccine Purchased With							
Type of Report							
Attachment Report Type Code	X12	0060-07-329-4837.26394.v1	Code to specify the type of attachment that is related to the claim	X12N Health Care Data Element Dictionary			
Report Type	HL7	0060-62-480-3235.77321.v1	This field contains the name, title, or other description of the report. Typically, the field will include the agency name (e.g., FDA), agency component if applicable (e.g., CDRH) and the report type (e.g., Medical Device Reporting Baseline Report).	Health Level Seven v 2.X			
Report Type Code	X12	0060-07-329-4837.1790.v1	Code indicating the title or contents of a document, report or supporting item	X12 Data Dictionary			
Report Source							
Event Report Source	HL7	0060-62-480-3235.76302.v1	"This field identifies the source from which the sender learned about the event. Multiple sources may be reported by repeating the element. If the source of the report is a clinical trial, the CSR and CSP segments can be included to define the study. Refer to HL7 Table 0235 - Report source for valid values. HL7 Table 0235 - Report source "	The HL7 v 2.4 Standard specification for electronic data exchange	Data element		
Event From Original Reporter	HL7	0060-62-480-3235.7680.v1	This field contains a summary narrative text description of the event provided by the original reporter. Note that laboratory results can be encoded as OBX segments reather then including them in the narrative.	The HL7 v 2.4 Standard specification for electronic data exchange	Data element		



Patient Identifier		See Patient Name Below					
Patient First name		See Patient Name Below					
Patient Middle name		See Patient Name Below					
Patient Last name		See Patient Name Below					
Patient Name	HL7	0060-62-480-3235.77144.v1	<p>This field contains the names of the patient, the primary or legal name of the patient is reported first. Therefore, the name type code in this field should be ""L - Legal"". Refer to HL7 Table 0200 - Name type for valid values. Repetition of this field is allowed for representing the same name in different character sets.</p> <p>Note that ""last name prefix"" is synonymous to ""own family name prefix"" of previous versions of HL7, as is ""second and further given names or initials thereof"" to ""middle initial or name"". Multiple given names and/or initials are separated by spaces. HL7 Table 0200 - Name type Components: In Version 2.3, replaces the PN data type. < family name (FN) > ^ < given name (ST) > ^ < second and further given names or initials thereof (ST) > ^ < suffix (e.g., JR or III) (ST) > ^ < prefix (e.g., DR) (ST) > ^ < degree (e.g., MD) (IS) > ^ < name type code (ID) > ^ < name representation code (ID) > ^ < name context (CE) > ^ < name validity range (DR) > ^ < name assembly order (ID) > Subcomponents of family name: < family name (ST) > & < own family name prefix (ST) > & < own family name (ST) > & < family name prefix from partner/spouse (ST) > & < family name from partner/spouse (ST) > "</p>	Health Level Seven v 2X	XPN	*Suffix/Pref X12	
Prior Patient Name	HL7	0060-62-480-3235.77218.v1	<p>This field contains the prior name of the patient. This field is not used to change a patient name. Refer to HL7 Table 0200 - Name type for valid values. Components: In Version 2.3, replaces the PN data type. < family name (FN) > ^ < given name (ST) > ^ < second and further given names or initials thereof (ST) > ^ < suffix (e.g., JR or III) (ST) > ^ < prefix (e.g., DR) (ST) > ^ < degree (e.g., MD) (IS) > ^ < name type code (ID) > ^ < name representation code (ID) > ^ < name context (CE) > ^ < name validity range (DR) > ^ < name assembly order (ID) > Subcomponents of family name: < family name (ST) > & < own family name prefix (ST) > & < own family name (ST) > & < family name prefix from partner/spouse (ST) > & < family name from partner/spouse (ST) > "</p>				



Patient Name	CMS	0060-92-764-5622.74309.v1	This field contains the names of the patient, the primary or legal name of the patient is reported first. Therefore, the name type code in this field should be "L - Legal". Refer to HL7 Table 0200 - Name type for valid values. Repetition of this field is allowed for representing the same name in different character sets. Note that "last name prefix" is synonymous to "own family name prefix" of previous versions of HL7, as is "second and further given names or initials thereof" to "middle initial or name". Multiple given names and/or initials are separated by spaces.	Consolidated Health Informatics Initiative	PN		
Patient Name Prefix	X12	0060-07-329-4837.26733.v1	The name prefix of the individual to whom the services were provided.	X12N Health Care Data Element Dictionary	ID		
Patient Name Suffix	X12	0060-07-329-4837.26735.v1	Suffix to the name of the individual to whom the services were provided.	X12N Health Care Data Element Dictionary	ID		
Patient Telephone							
Other Patient Names (??)	NEMA	00-0000049.82692.v1	Telephone numbers at which the patient can be reached	National Electrical Manufacturers Association Standard	Not Provided		
Patient Phone Number	NCPDP	0060-02-166-0014.61508.v1	Ten digit phone number of patient	NCPDP Data Dictionary	Integer		
Patient's Telephone Number	NEMA	00-0000049.79360.v1	Telephone numbers at which the patient can be reached	National Electrical Manufacturers Association Standard	Not Provided		
Person's Telephone Numbers	NEMA	00-0000049.79403.V1	TBD	National Electrical Manufacturers Association Standard	Not Provided		



Phone Number	HL7	0060-62-4480-3235.77162.V1	"This field contains the telephone number of the next of kin/associated party. Multiple phone numbers are allowed for the same person. The primary telephone number must be sent in the first sequence. If the primary telephone number is not sent, then the repeat delimiter must be sent in the first sequence. Refer to HL7 Table 0201 - Telecommunication use code and HL7 Table 0202 - Telecommunication equipment type for valid values. Components: [NNN] [(999)]999-9999 [X99999] [B99999] [C any text] ^ < telecommunication use code (ID) > ^ < telecommunication equipment type (ID) > ^ < email address (ST) > ^ < country code (NM) > ^ < area/city code (NM) > ^ < phone number (NM) > ^ < extension (NM) > ^ < any text (ST) >"	Health Level Seven v 2.X	XTN		
Phone Number (Business)	CMS	0060-92-764-5622.74322.V1	This field contains the patient's business telephone numbers. All business numbers for the patient are sent in the following sequence. The first sequence is considered the patient's primary business phone number (for backward compatibility). If the primary business phone number is not sent, then a repeat delimiter must be sent in the first sequence	Consolidated Health Informatics Initiative	TN		
Phone Number (Home)	CMS	0060-92-764-5622.74321.V1	This field contains the patient's personal phone numbers. All personal phone numbers for the patient are sent in the following sequence. The first sequence is considered the primary number (for backward compatibility). If the primary number is not sent, then a repeat delimiter is sent in the first sequence. [(999)]999-9999 [X99999] [B99999] .	Consolidated Health Informatics Initiative	TN		
Phone Number-Business	HL7	0060-62-480-3235.77162.V1	"This field contains the patient's business telephone numbers. All business numbers for the patient are sent in the following sequence. The first sequence is considered the patient's primary business phone number (for backward compatibility). If the primary business phone number is not sent, then a repeat delimiter must be sent in the first sequence. Refer to HL7 Table 0201 - Telecommunication use code and HL7 Table 0202 - Telecommunication equipment type for valid values. Components: [NNN] [(999)]999-9999 [X99999] [B99999] [C any text] ^ < telecommunication use code (ID) > ^ < telecommunication equipment type (ID) > ^ < e-mail address (ST) > ^ < country code (NM) > ^ < area/city code (NM) > ^ < phone number (NM) > ^ < extension (NM) > ^ < any text (ST) >"	Health Level Seven v 2.x	XTN		



Phone Number - Business	HL7	0060-62-480-3235.77162.V2	This field contains the patient's business telephone numbers. All business numbers for the patient are sent in the following sequence. The first sequence is considered the patient's primary business phone number (for backward compatibility). If the primary business phone number is not sent, then a repeat delimiter must be sent in the first sequence. Refer to HL7 Table 0201 - Telecommunication Use Code and HL7 Table 0202 - Telecommunication Equipment Type for valid values.	Health Level Seven v 2.5	XTN		
Phone Number-Home	HL7	0060-62-480-3235.77163.V1	"This field contains the patient's personal phone numbers. All personal phone numbers for the patient are sent in the following sequence. The first sequence is considered the primary number (for backward compatibility). If the primary number is not sent, then a repeat delimiter is sent in the first sequence. Refer to HL7 Table 0201 - Telecommunication use code and HL7 Table 0202 - Telecommunication equipment type for valid values. Components: [NNN] [(999)]999-9999 [X99999] [B99999] [C any text] ^ < telecommunication use code (ID) > ^ < telecommunication equipment type (ID) > ^ < e-mail address (ST) > ^ < country code (NM) > ^ < area/city code (NM) > ^ < phone number (NM) > ^ < extension (NM) > ^ < any text (ST) > "	Health Level Seven v 2.X	XTN		
Phone Number - Home	HL7	0060-62-480-3235.77163.V2	This field contains the patient's personal phone numbers. All personal phone numbers for the patient are sent in the following sequence. The first sequence is considered the primary number (for backward compatibility). If the primary number is not sent, then a repeat delimiter is sent in the first sequence. Refer to HL7 Table 0201 - Telecommunication Use Code and HL7 Table 0202 - Telecommunication Equipment Type for valid values.	Health Level Seven v 2.5	XTN		
Telephone Number	NCPDP	0060-02-166-0014.62740.V1	Telephone number of the member.	NCPDP Data Dictionary	Integer		
Patient Address							



Patient Address	CMS	0060-92-764-5622.74316.v1	This field contains the mailing address of the patient. Multiple addresses for the same person may be sent in the following sequence: The primary mailing address must be sent first in the sequence (for backward compatibility); if the mailing address is not sent, then a repeat delimiter must be sent in the first sequence. Contains street address (ST), other designation (ST), city (ST), state or province (ST), zip or postal code (ST), country (ID), address type (ID), other geographic designation (ST), county/parish code (IS), census tract (IS), address representation code (ID), and address validity range (DR).	Consolidated Health Informatics Initiative	AD		
Patient Address	HL7	0060-62-480-3235.77136.v1	"This field contains the mailing address of the patient. Address type codes are defined by HL7 Table 0190 - Address type. Multiple addresses for the same person may be sent in the following sequence: The primary mailing address must be sent first in the sequence (for backward compatibility) - if the mailing address is not sent, then a repeat delimiter must be sent in the first sequence. Components: In Version 2.3 and later, replaces the AD data type. < street address (ST) > ^ < other designation (ST) > ^ < city (ST) > ^ < state or province (ST) > ^ < zip or postal code (ST) > ^ < country (ID) > ^ < address type (ID) > ^ < other geographic designation (ST) > ^ < county/parish code (IS) > ^ < census tract (IS) > ^ < address representation code (ID) > ^ < address validity range (DR) > Subcomponents of street address: < street address (ST) > & < street name (ST) > & < dwelling number (ST) > "	Health Level Seven v 2.X	XAD		
Patient Address	HL7	0060-62-480-3235.77136.v2	This field contains the mailing address of the patient. Address type codes are defined by HL7 Table 0190 - Address Type. Multiple addresses for the same person may be sent in the following sequence: The primary mailing address must be sent first in the sequence (for backward compatibility); if the mailing address is not sent, then a repeat delimiter must be sent in the first sequence	Health Level Seven v 25	XAD		
Patient Address Line	X12	0060-07-329-4837.26667.v1	Address line of the street mailing address of the patient.	X12N Health Care Data Element Dictionary	ID		



Patient Address Line -1	X12	0060-07-329-4837.78316.v1	The basis of this data element is the X12 data element Patient Address Line - 1. For detail X12 information see http://www.wpc-edi.com/reportingguides/detail.aspx?ns=TS837A1_2010CA_N301_PatientAddressLine	Health Care Standards Reporting Guide	Not Provided		
Patient Address Line -2	X12	0060-07-329-4837.78315.v1	The basis of this data element is the X12 data element Patient Address Line - 2. For detail X12 information see http://www.wpc-edi.com/reportingguides/detail.aspx?ns=TS837A1_2010CA_N302_PatientAddressLine	Health Care Standards Reporting Guide	Not Provided		
Patient City		See Patient Address Above					
Patient County		See Patient Address Above					
State		See Patient Address Above					
Zip Code		See Patient Address Above					
Patient Country		See Patient Address Above					
Patient Country of Origin							
Requester Country Code	HL7	0060-07-329-4837.27445.v1	Code identifying the country on the address of the requester	X12N Health Care Data Element Dictionary	Data Element		
Patient Country of Birth	HL7	0060-62-480-3235.76626.v1	This field indicates the location of the patient's birth, for example "St. Francis Community Hospital of Lower South Side". The actual address is reported in PID-11 with an identifier of "N".	Health Level Seven v 2.X	ST		
Birth Place	HL7	0060-62-480-3235.76626.v1	This field indicates the location of the patient's birth, for example "St. Francis Community Hospital of Lower South Side". The actual address is reported in PID-11 with an identifier of "N".	Health Level Seven v 2.X	ST		
Place Of Birth (City)	CMS	0060-92-764-5622.74314.v1	This field indicates the location of the persons birth, for example "St. Francis Community Hospital of Lower South Side". The actual address is reported in PID-11 (Patient Address) with an identifier of "N".	Consolidated Health Informatics Initiative	ST		
Place Of Birth (State)	CMS	0060-92-764-5622.74315.v1	This field indicates the location of the persons birth, for example "St. Francis Community Hospital of Lower South Side". The actual address is reported in PID-11 (Patient Address) with an identifier of "N".	Consolidated Health Informatics Initiative	Not Provided		
Time arrived in the USA		No data element found					
Date of Birth (DOB)							



Date of Birth	ARHQ	044012578.82922.v1	Patient's year and month of birth (day is not included for privacy purposes). Date field Specific HL7 attribute: PID-7 Date of Birth Most ADT and many other messages carry the date of birth in PID-7. Expected format is YYYYMM. NOTE: May not be passing DOB for age over 89 due to HIPAA requirements.	Not Provided	Not Provided		
Date of Birth	CMS	0060-92-764-5622.83039.v1	Year, month and day of birth. It is recommended that the year of birth be recorded in four digits to make the data element more reliable for the increasing number of persons of 100 years and older. It will also serve as a quality check as the date of birth approaches the new century mark.	NCVHS Core Health Data Elements	NM		
Date of Birth	CMS	0060-92-764-5622.65753.v1	Year (in four digits), Month, Day as recommended by the Uniform Hospital Discharge Data Set	NCVHS Core Health Data Elements	NM		
Date of Birth	CMS	0060-92-764-5622.74308.v1	This field contains the patient's date and time of birth. Consists of first 8 characters of YYYYMMDD[HHMM[SS]].	Consolidated Health Informatics Initiative	DT		
Date of Birth	NCPDP	0060-02-166-0014.60519.v1	Date of birth of patient.	NCPDP Data Dictionary	Integer		
Age							
Patient Age	ARHQ	044012578.82923.v1	Patient's age as reported in an application at the source. Age may be available if DOB was not populated. UCUM Age Units Observation with LOINC code: 21612-7*Reported Patient Age^LN; Not an HL7 attribute in any segment but may exist as an observations collected with specimen or when x-ray done	Not Provided	Data Element		
Age Units		no data element found - further specifications required					
Number of Siblings		no data element found					
Gender							
Actors ccr:Gender	ASTM	0060-00-199-3369.81203.v1	Defines < Gender > . This is a CodedDescriptionType with restricted content that must be one of the defined structured text values. Examples: Male, Female, Other, Unknown Optional	ASTM Data Dictionary	Not Provided		
AdministrativeGender	HL7	0060-62-480-3235.82326.v1	The gender of a person used for administrative purposes (as opposed to clinical gender)	Clinical Document Architecture	CE		
administrative_gender_cd	HL7	0060-62-480-3235.29222.v1	A code depicting the gender (sex) of a person (e.g., female, male). This code is used for administrative purposes. ExtRef: This information is reported on UB FL 15.	Data Dictionary - HL7	CE		



CCD Header < Actor > < Person > < Gender >	HL7	0060-62-480-3235.80781.v1	Defines < Gender >. This is a CodedDescriptionType with restricted content that must be one of the defined structured text values. Examples: Male, Female, Other, Unknown Optional	Health Level Seven	Not Provided		
GENDER	ASTM	0060-00-199-3369.72673.v1	Distinction of gender.	ASTM Data Dictionary	Not Provided		
Gender	CMS	0060-92-764-5622.65902.v1	1 = Male; 2 = Female; 3 = Unknown/not stated as recommended by the Uniform Hospital Discharge Data Set and the Uniform Ambulatory Care Data Set.	NCVHS Core Health Data Elements	Not Provided		
Gender Code	NCPDP	0060-02-166-0014.60872.v1	For eligibility, and identifying the gender of the individual member.	NCPDP Data Dictionary	Numeric Extension		
Gender Code	X12	0060-07-329-4837.19605.v1	Code indicating the sex of the individual	X12 Data Dictionary	ID		
Gender Code	X12	0060-07-329-4837.25320.v1	A code indicating the gender of the patient or insured.	X12N Health Care Data Element Dictionary	ID		
Gender, Coded	NCPDP	0060-02-166-0014.74920.v1	Gender of the patient. X-12 DE 1069. Field Number/Alias: 040-9703. PTT.	NCPDP SCRIPT Standard 4.2	Not Provided		
GenderStatus	HL7	0060-62-480-3235.82241.v1	A value representing whether the primary reproductive organs of NonPersonLivingSubject are present.	CDA	CE		
gender_status_cd	HL7	0060-62-480-3235.29312.v1	A code indicating whether the reproductive organs of Non_person_living_subject have been surgically removed.	Data Dictionary - HL7	CE		
Patient Gender Code	HL7	0060-02-166-0014.61472.v1	Code indicating the gender of the individual.	NCPDP Data Dictionary	Integer		
Patient Gender Code	X12	0060-07-329-4837.26722.v1	A code indicating the sex of the patient.	X12N Health Care Data Element Dictionary	ID		
Sex/Gender	CMS	0060-92-764-5622.74312.v1	This field contains the sex identifier. M for Males, F for Females, O for Other, U for Unknown, A for Ambiguous, N for Not Applicable.	Consolidated Health Informatics Initiative	IS		
Race							
RACE	ASTM	0060-00-199-3369.72839.v1	The region of the world from which the patient's ancestors came generally indicating possible inherited biologic diversity.	ASTM Data Dictionary	Not Provided		
Race	CMS	0060-92-764-5622.7435.v1	This field refers to the persons race. The second triplet of the CE data type for race (alternate identifier, alternate text, and name of alternate coding system) is reserved for governmentally assigned codes. Use 1002-5 for American Indian or Alaskan Native, 2028-9 for Asian, 2054-5 for Black or African American, 2076-8 for Native Hawaiian or Other Pacific Islander, 2106-3 for White, 2131-1 for Other Race.	Consolidated Health Informatics Initiative	CE		



Race	HL7	0060-62-480-3235.82227.v1	<p>In the United States, federal standards for classifying data on race determine the categories used by federal agencies and exert a strong influence on categorization by state and local agencies and private sector organizations. The federal standards do not conceptually define race, and they recognize the absence of an anthropological or scientific basis for racial classification. Instead, the federal standards acknowledge that race is a social-political construct in which an individual's own identification with one more race categories is preferred to observer identification. The standards use a variety of features to define five minimum race categories. Among these features are descent from "the original peoples" of a specified region or nation. The minimum race categories are American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. The federal standards stipulate that race data need not be limited to the five minimum categories, but any expansion must be collapsible to those categories.</p>	Clinical Document Architecture	CE		
Race	HL7	0060-62-480-3235.76044.v1	<p>"This field refers to the patient's race. Refer to User-defined Table 0005 - Race for suggested values. The second triplet of the CE data type for race (alternate identifier, alternate text, and name of alternate coding system) is reserved for governmentally assigned codes. User-defined Table 0005 - Race Components: < identifier (ST) > ^ < text (ST) > ^ < name of coding system (IS) > ^ < alternate identifier (ST) > ^ < alternate text (ST) > ^ < name of alternate coding system (IS) >"</p>	Health Level Seven v s.X	CE		



Race	HL7	0060-62-480-3235.76044.v2	This field refers to the patient's race. Refer to User-defined Table 0005 - Race for suggested values. The second triplet of the CE data type for race (alternate identifier, alternate text, and name of alternate coding system) is reserved for governmentally assigned codes. This field identifies the race of the next of kin/associated party. Refer to User-defined Table 0005 - Race for suggested values. The second triplet of the CE data type for race (alternate identifier, alternate text, and name of alternate coding system) is reserved for governmentally assigned codes. This field refers to the person's race. Refer to User-defined Table 0005 - Race for suggested values. The second triplet of the CE data type for race (alternate identifier, alternate text, and name of alternate coding system) is reserved for governmentally assigned codes.	Health Level Seven v 2.5	CE		
race cd	HA	0060-02-670-0448.55774.v1	A code that represents a race	Data Dictionary -HA	CHARACTER-STRING		
race nm	HA	0060-02-670-0448.55780.v1	The name of a RACE	Data Dictionary- HA	Character		
RACE.Race Name	ADA	0060-07-442-5216.73902.v1	This attribute contains text data used to name the human race	ANSI/ASA Specification N. 1000	Character		
race_cd	HL7	0060-62-480-3235.29446.v1	A code depicting the race of a person	Data Dictionary HL7	SET CV		
Ethnicity							
Race and Ethnicity	CMS	0060-92-764-5622.65755.v1	Slightly expanded from the Office of Management and Budget Directive 15: Race: 1 American Indian/Eskimo/Aleut, 2 Asian, 3 Black, 4 White, 5 Other (specify), Unknown/not stated. Ethnicity: 1 Hispanic Origin (specify), 2 Other (specify), 3 Unknown/not stated	NCVHS Core Health Data Element	AN		



Race and Ethnicity	CMS	0060-92-764-5622.83070.v1	The collection of race and ethnicity have a required definition for Federal data collection in Office of Management and Budget (OMB) Directive 15. The definition has been expanded slightly from the OMB requirement: A. Race 1. American Indian/Eskimo/Aleut 2. Asian or Pacific Islander (specify) 3. Black 4. White 5. Other (specify) 6. Unknown/not stated. B. Ethnicity 1. Hispanic Origin (specify) 2. Other (specify) 3. Unknown/not stated. It is recommended that this item be self-reported, not based on visual judgment or surnames. Whenever possible, the Committee and participants recommended collecting more detailed information on Asian and Pacific Islanders, as well as persons of Hispanic Origin.	NCVHS Core Health Data Element	AN		
Race or Ethnicity Code	X12	0060-07-329-4837.19850.v1	Code indicating the racial or ethnic background of a person; it is normally self-reported; Under certain circumstances this information is collected for United States Government statistical purposes	X12 Data Dictionary	ID		
Race or Ethnicity Code	X12	0060-07-329-4837.27112.v1	Code indicating the racial or ethnic background of a person.	X12 Data Dictionary	ID		
Occupation							
OCCUPATION	ASTM	0060-00-199-3369.72200.v1	The employment, business, or a course of action which the patient is engaged (i.e. "student")	ASTM Data Dictionary	Not Provided		
Occupation	NEMA	00-0000049.79348.v1	Occupation of the Patient	National Electrical Manufacturers Associate Standard	Not Provided		*codes /dt, etc available
Previous Vaccine Type							
	vaccine search rendered: Administered, Manufacturer, cd, immunity cd, duration, series, source & type.						
Previous Vaccine Manufacturer							



Previous Vaccine Lot #							
Previous Vaccine Route/Site							
Vaccine # Previous Doses							
Previous Vaccine Date Given							
AE following prior vaccinations							
Relevant Tests/Laboratory Data (including dates)							
Illness at time of Vaccine							
Pre-existing physician diagnosed allergies, birth defects or medical conditions							
Current Medications							
Medications Prescribed	CMS	0060-92-764-5622.83055.v1	All medications prescribed or provided by health care practitioner at the encounter or given at discharge; includes National Drug Codes, dose, strength, and total amount prescribed.	NCVHS Core Health Data Elements	Not Provided		
Medications Prescribed	CMS	0060-92-764-5622.65835.65935.v1	All medications prescribed or provided by health care practitioner at the encounter or given at discharge; includes National Drug Codes, dose, strength, and total amount prescribed.	NCVHS Core Health Data Elements	Not Provided		
Weight							
Member Weight	X12	0060-07-329-4837.23928.v1	Weight of member	x12N Health Care Data Element Dictionary	ID		
Patient Weight	NCPDP	0060-02-166-0014.62877.v1	The patients weight in standard pounds	NCPDP Data Dictionary Version 5.0 Deleted Data	Integer		



**HITSP Public Health Case Reporting Use Case Requirements,
Design and Standards Selection**

Review Copy
20080627 V1.0

				Element			
Patient Weight	X12	0060-047-329-4837.26758.v1	Weight of the patient at time of treatment or transport.	x12N Health Care Data Element Dictionary	ID		
Patient-Weight	IEEE-1073	00-0000050.77817.v1	N/A	IEEE 1073 Standard	Not Provided		
Patient's Weight	NEMA	00-0000049.79361.v1	Weight for the patient in kilograms	National Electrical Manufacturers Association Standard	DS 1		
Weight	X12	0060-07-329-4837.5151.v1	Numeric value of weight	X12 Data Dictionary	R		
Birth Weight							
Birth Weight of Newborn	CMS	0060-92-764-5622.83037.v1	Birth Weight of Newborn	NCVHS Core Health Data Elements	Not Provided		
Birth Weight of Newborn	CMS	0060-92-764-5622.65892.v1	Birth Weight of Newborn	NCVHS Core Health Data Elements	Not Provided		
Newborn Birth Weight	X12	0060-07-329-4837.78317.v1	The basis of this data element is the X12 data element Value Code - 1. For detail X12 information see http://www.wpc-edi.com/reportingguides/detail.aspx?Ns=TS837A1_2300_H101_C02202U667_ValueCode	Health Care Standards Reporting Guide	Not Provided		
Patient-Birth-Weight	IEEE-1073	00-0000050.77819.v1	for neonatal	IEEE 1073 Standard	Not Provided		
Pregnancy Status							
Pregnancy Indicator	NCPDP	0060-02-166-0014.61800.v1	Code indicating the patient as pregnant or non-pregnant	NCPDP Data Dictionary	Character		
Pregnancy Indicator	X12	0060-07-329-4837.28290.v1	A yes/no code indicating whether a patient is pregnant	X12N Health Care Data Element Dictionary	ID		
Pregnancy Status	NEMA	00-0000049.82702.v1	User-defined comments about the patient	National Electrical Manufacturers Association Standard	Not Provided		
Pregnancy Status	NEMA	00-0000049.79376.v1	Describes pregnancy state of patient	National Electrical Manufacturers Association Standard	US 1		
Estimated Delivery Date							



Estimated Birth Date	X12	0060-07-329-4837.28309.v1	Date delivery is expected	X12N Health Care Data Element Dictionary	ID		
ESTIMATE D DATE OF DELIVERY	ASTM	0060-00-199-3369.72647.v1	The date on which it is estimated that delivery will occur	ASTM Data Dictionary	Not Provided		
Name of Condition							
Will return to this with further clarification of context. There are over 50 data elements pertinent to condition.							
Diagnosis/Injury Code							
Admitting Diagnosis Code	X12	0060-07-329-4837.78330.v1	Admitting Diagnosis Code	Health Care Standards Reporting Guide	Not Provided		
Associated Diagnosis Code	HL7	0060-62-480-3235.76078.v1	Associated Diagnosis Code	Health Level Seven v 2.X	Not Provided		
CLINICAL INVESTIGATION SUBJECT OUTCOME .Diagnosis Code	ADA	0060-07-442-5216.74190.v1	This attribute contains encoded data which specifies a health diagnosis	ANSI/ADA Specification No. 1000	character		
Diagnosis Code	NCPDP	0060-02-166-0014.60551.v1	Code identifying the diagnosis of the patient.	NCPDP Data Dictionary	character		
Diagnosis Code	X12	0060-07-329-4837.24827.v1	An ICD-9-CM Diagnosis Code identifying a diagnosed medical condition.	X12N Health Care Data Element Dictionary	ID		
Diagnosis Code -DG1	HL7	0060-62-480-3235.76079.v1	<p>"Use this field instead of DG1-2 - diagnosis coding method and DG1-4 - diagnosis description. (Those two fields have been retained for backward compatibility only.) DG1-3 - diagnosis code DG1 contains the diagnosis code assigned to this diagnosis. Refer to User-defined Table 0051 - Diagnosis code for suggested values. This field is a CE data type for compatibility with clinical and ancillary systems. See Chapter 7 for suggested diagnosis codes. For the name of the coding system, refer to Chapter 7, Section 7.2.5, ""Coding schemes.""</p> <p>Components: < identifier (ST) > ^ < text (ST) > ^ < name of coding system (IS) > ^ < alternate identifier (ST) > ^ < alternate text (ST) > ^ < name of alternate coding system (IS) ></p>	Health Level Seven v 2.X	Not Provided		



Diagnosis Code -FT1	HL7	0060-62-480-3235.76080.v1	"This field contains the primary diagnosis code for billing purposes. ICD9-CM is assumed for all diagnosis codes. This is the most current diagnosis code that has been assigned to the patient. ICD10 can also be used. The name of coding system (third component) indicates which coding system is used. Refer to User-defined Table 0051 - Diagnosis code for suggested values. User-defined Table 0051 - Diagnosis code Components: < identifier (ST) > ^ < text (ST) > ^ < name of coding system (IS) > ^ < alternate identifier (ST) > ^ < alternate text (ST) > ^ < name of alternate coding system (IS) > "	Health Level Seven v 2.X	Not Provided		
DIAGNOSIS Diagnosis Code	ADA	0060-07-442-5216.73911.v1	This attribute contains encoded data which specifies a health diagnosis.	ANSI/ADA Specification No. 1000	character		
Event Symptom/Diagnosis Code	HL7	0060-62-480-3235.76859.v1	This field is the coded diagnosis or problem description which best describes the event. A text representation of the coded item should routinely be included. MEDDRA and WHO-ART are examples of appropriate coding schemes, as are the patient and device codes included in the FDA Center for Devices and Radiologic Health's coding manual for Form 3500A. Components: < identifier (ST) > ^ < text (ST) > ^ < name of coding system (IS) > ^ < alternate identifier (ST) > ^ < alternate text (ST) > ^ < name of alternate coding system (IS) > "	Health Level Seven v 2.X	CE		
Other Diagnosis Code	X12	0060-07-329-4837-4837.78328.v1	The basis of this data element is the X12 data element Industry Code (Other Diagnosis - 1). For detail X12 information http://www.wpc-edi.com/reportingguides/detail.aspx?ns=TS837A1_2300_HI01_C02202U166_IndustryCode	Health Care Standards Reporting Guide	Not Provided		
POPULATION HEALTH CONDITION Diagnosis Code	ADA	0060-07-442-5216.74015.v1	This attribute contains encoded data which specifies a health diagnosis.	ANSI/ADA Specification No. 1000	Character		
Principal Diagnosis Code	X12	0060-07-329-4837.78323.v1	The basis of this data element is the X12 data element Industry Code (Principal Diagnosis). For detail X12 information http://www.wpc-edi.com/reportingguides/detail.aspx?ns=TS837A1_2300_HI01_C02202U25_IndustryCode	Health Care Standards Reporting Guide	Not Provided		
Diagnosis Type							
Diagnosis Date/Time							



Diagnosis Date	X12	0060-07-329-4837.24830.v1	Date the diagnosis was established or recorded	X12 Health Care Data Element Dictionary	ID		
Diagnosis Date/Time	AHRQ	044012578.82929.v1	Date/time the diagnosis was made Date/time field Specific HL7 attribute: DG-5 Diagnosis Date/Time is an optional attribute on the DG1 segment	Not Provided	Not Provided		
Diagnosis Date/Time	HL7	0060-62-480-3235.76774.v1	This field contains the date/time that the diagnosis was determined	Health Level Seven v 2.X	TS		
INDIVIDUAL HEALTH CONDITION Diagnosis Date/Time	ADA	0060-07-442-5216.73431.v1	This attribute contains data which specifies the date and time at which a patient health condition is diagnosed	ANSI/ADA Specification No.1000	Date-and-Time		
Discharge Disposition							
Discharge Disposition	AHRQ	044012578.82930.v1	Discharge Disposition ¿patient¿s anticipated location or status following the visit (admitted, sent home, etc.). Universal Billing codes (UB-92) Specific HL7 attribute: PV1-36 Discharge Disposition Expected attribute in ADT^A03 Discharge messages.	Not Provided	Not Provided		
Discharge Disposition	CMS	0060-92-764-5622.7462.v1	User-defined code representing the disposition of the patient at time of discharge (e.g., discharge to home or self care, left against medical advice.). In the US, this is UB92 FL22. CMS UB92 FL22 - Patient Status.	Consolidated Health Informatics Initiative	IS		
Discharge Disposition	HL7	0060-62-480-3235.76134.v1	This field contains the disposition of the patient at time of discharge (i.e., discharged to home, expired, etc.). Refer to User-defined Table 0112 - Discharge disposition for suggested values. In the US, this field is used on UB92 FL22. The UB codes listed as examples are not an exhaustive or current list - refer to a UB specification for additional information. User-defined Table 0112 - Discharge disposition"	Health Level Seven v 2.X	IS		
Expected Discharge Disposition	CMS	0060-92-764-5622.74608.v1	User-defined code representing the what the patient's disposition is expected to be at the end of the visit. CMS UB92 FL22.	Consolidated Health Informatics Initiative	IS		
Expected Discharge Disposition	HL7	0060-62-480-3235.76135.v1	This field describes what the patient's disposition is expected to be at the end of the visit. Refer to User-defined Table 0112 - Discharge disposition for suggested values.	Health Level Seven v 2.X	Not Provided		
Date/Time of Death							
Date of Death	CMS	0060-92-764-5622.74371.v1	This field contains the date and time at which the person death occurred. Consist of first 8 characters of YYYYMMDD[HHMM[SS]]	CHI Standard	Generic Data Element		



Time of Death	CMS	0060-92-764-5622.74373.v1	This field contains the date and time at which the person death occurred. Consists of characters 9 through 14 of YYYYMMDD[HHMM[SS]]	CHI Standard	DTM		
DATE-TIME OF DEATH	ASTM	0060-00-199-3369.72609.v1	The recorded date and time of the patient's death; in cases where death was unobserved it is the best estimate of such date and time.	ASTM Data Dictionary	Not Provided		
deceased_time	HL7	0060-62-480-3235.29232.v1	The date and time that a living subject's death occurred	Data Dictionary - HL7	TS		
Patient Death Date and Time	HL7	0060-62-480-3235.77138.v2	This field contains the date and time at which the patient death occurred.	Health Level Seven v 2.5	TS		
Patient Death Date and Time	HL7	0060-480-3235.77138.v1	This field contains the date and time at which the patient death occurred.	Health Level Seven v 2.5	TS		
Patient Class							
Patient Class	AHRQ	044012578.82931.v1	General type of patient, e.g., Inpatient, Outpatient, Emergency. HL7 2.5 Patient Class Codes constrained to EIO Specific HL7 attribute: PV1-2 Patient Class Required for all Patient Visit information segment (PV1) usage.	Not Provided	Not Provided		
Patient Class	CMS	0060-92-764-5622.74544.v1	User-defined code to categorize patients by site (e.g., inpatient, outpatient, emergency). It does not have a consistent industry-wide definition. HL7® v2.4 Table HL0004 - Patient Class.	Consolidated Health Informatics Initiative	IS		
Patient Class	HL7	0060-62-480-3235.76022.v1	"This field is used by systems to categorize patients by site. It does not have a consistent industry-wide definition. It is subject to site-specific variations. Refer to User-defined Table 0004 - Patient class for suggested values. User-defined Table 0004 - Patient class"	Health Level Seven v 2.X	IS		



Valid Patient Classes	HL7	0060-62-480-3235.76041.v1	This field contains the patient types for which this charge description is valid. For example, Inpatient, Outpatient, Series, Clinic, ER, Ambulatory, Observation, etc. These values should be the same set of values as those used for PV1-3 - Patient class, which is site defined. Use only when the price is not valid for all patient types, that is, a null value indicates that this pricing is valid for all patient classes. When two PRC segments are sent the same key values but with different valid patient classes, the second is sent in addition to the first, not to replace the first. The effective unique identifier is the charge code (PRC-1 - PRC primary key) plus the facility ID (PRC-2 - Facility ID) plus the department (PRC-3 - Department) plus the patient class (PRC-4 - Valid patient classes). Multiple patient classes can be sent in the same segment to indicate that those patient classes use the same pricing.	Health Level Seven v 2.X	IS		
Signs and Symptoms							
Symptom/ Illness Onset Date/Time							
Date/time of illness onset	AHRQ	044012578.82932.v1	Date and time of illness onset Date/time field Observation tagged with LOINC code: 11368-8^Illness/Injury Onset Date/time^LN. There is a gap because illness onset date and time is not currently captured in a consistent manner at data sources. It is not always a date/time field and does not lend itself to responses such as 3 three days or 2 two weeks ago.	Not Provided	Not Provided		
PROBLEM ESTD DATE ONSET	ASTM	0060-00-199-3369.72833.v1	The estimated date that the problem first occurred.	ASTM Data Dictionary	Not Provided		
Event Onset Date/Time	HL7	0060-62-480-3235.76856.v1	This field contains a report or best estimate of the date/time of onset of the event. The date/time can be recorded to any level of precision it is known (hour, day, month, year).	Health Level Seven v 2.X	TS		
Onset Date	HL7	0060-62-480-3235.77096.v1	This field contains the actual date of the first reaction.	Health Level Seven v 2.X	DT		
Onset Date Text	HL7	0060-62-480-3235.77097.v1	This field contains a text description of the time period of the first reaction when an exact date is not known. (e.g., adolescence, childhood, spring 1990).	Health Level Seven v 2.X	ST		
Problem Date of Onset	HL7	0060-62-480-3235.77229.v1	This field contains the date/time when the problem began. "	Health Level Seven v 2.X	TS		



Problem Onset Text	HL7	0060-62-480-3235.77237.v1	"This field allows for a textual representation of the time when the problem began. "	Health Level Seven v 2.X	ST		
Onset Date	X12	0060-07-329-4837.26455.v1	Date of onset of indicated patient condition.	X12 Health Care Data Element Dictionary	ID		
Onset of Current Illness or Injury Date	X12	0060-07-329-4837.28307.v1	Date of onset of indicated patient condition.	X12 Health Care Data Element Dictionary	ID		
Chief Complaint							
Chief Complaint	AHRQ	044012578.82933.v1	Patient-reported reason for visit or admission reason. It may have been entered as text or may make use of drop-down lists to enter canned text. SNOMED-CT and/or Clinical Care Classification recommended for codifying of free-form text Specific HL7 attribute: PV2-3 Admit Reason May also be collected as a LOINC-tagged observation: ¿ 11292-0 ED Chief Complaint ¿ Patient Reported^LN¿. ADT^A04 for outpatient/ED ADT^A01 for inpatient	Not Provided	Not Provided		
CHIEF COMPLAINT	ASTM	0060-00-199-3369.72503.v1	The reason for the episode/encounter and patient's complaints and symptoms reflecting his/her own perceptions of his needs. The nature and duration of symptoms that caused the patient to seek medical attention, as stated in the patient's own words	ASTM Data Dictionary	Not Provided		
Patient's Stated Reason for Visit or Chief Complaint	CMS	0060-92-764-5622.83062.v1	Outpatient: Includes the patient's stated reason at the time of the encounter for seeking attention or care. This item attempts to define what actually motivated the patient to seek care and has utility for analyzing the demand for health care services, evaluating quality of care and performing risk adjustment.	NCVHS Core Health Data Elements	Not Provided		
Patient's Stated Reason for Visit or Chief Complaint	CMS	0060-92-764-5622.65888.v1	Outpatient: What motivated the patient to seek care at the time of the encounter. Needs considerable study and testing.	NCVHS Core Health Data Elements	Not Provided		
symptom hse observation chief complaint indctr cd	HA	0060-02-670-0448.57381.v1	The code that indicates whether a SYMPTOM-HEALTH-SERVICE-ENCOUNTER-OBSERVATION is reported by the recipient to be the most problematic.	Data Dictionary - HA	character		
Temperature							



Temperature	HL7	0060-62-480-3235.77481.v1	"This field identifies the specimen temperature in degrees Celsius [°C] at the time of the transaction specified in the EQU segment. Components: < comparator (ST) > ^ < num1 (NM) > ^ < separator/suffix (ST) > ^ < num2 (NM) > "	Health Level Seven v 2.X	SN		
Temperature Date/time of temperature	AHRQ	044012578.82935.v1	Body temperature measurement, including the reference to Celsius or Fahrenheit. The temperature taken on initial assessment/triage is the vital sign of interest. Numeric observation that uses UCUM Temperature units Observation tagged with LOINC code 8310-5^ BODY TEMPERATURE^ LN, including timestamp	Not Provided	Not Provided		
Pulse Oximetry							
Pulse Oximetry Pulse Ox Date/Time	AHRQ	044012578.82937.v1	Pulse oximetry reading and the date/time that it was performed. The pulse ox reading at triage assessment time is the vital sign of interest. Numeric observation Observation tagged with LOINC code: 19960-4^PULSE OXIMETRY^LN, including timestamp	Not Provided	Not Provided		
Nursing/Triage Notes	AHRQ	044012578.82938.v1	Provider notes documented in the process of sorting patients based on need for or likely benefit from immediate medical treatment. SNOMED-CT and/or Clinical Care Classification recommended for codifying of free-form text Observation tagged with LOINC code: 34120-6^INITIAL EVALUATION NOTE^LN, including timestamp	Not Provided	Data Element		
Reason for Non-Evaluation	No data element found						
Type of Follow-Up							
ENCOUNTER FOLLOW UP STATUS	ASTM	0060-00-199-3369-72084.v1	A list of terms depicting the current status of the follow-up action	ASTM Data Dictionary	Not Provided		
Follow-up Action Code	X12	0060-07-329-4837.80881.v1	Code identifying follow-up actions allowed	X12 Health Care Data Element Dictionary	Not Provided		
Follow-up Action Code	X12	0060-07-329-4837.18786.v1	Code identifying follow-up actions allowed	X12 Health Care Data Element Dictionary	ID		
Follow-up Action Code	X12	0060-07-329-4837.25230.v1	Code identifying follow-up actions allowed	X12 Health Care Data Element Dictionary	ID		



Type of Remedial Action	No data element found containing remedial. Another search?						
Medical Treatment	ADA	0060-07-442-5216.73373.v1	This attribute contains encoded data which identifies a specific health care procedure	ANSI/ADA Specification No. 1000	character		
Administration of Treatment							
ADMISSION TREATMENT	ASTM	0060-00-199-3369.v1	Identifier of treatment given in this admission	ASTM	data element		
Date of Admin of Treatment							
Name of Treatment							
Hospitalization							
Date of admission							
Admission Date	CMS	0060-92-764-5622.65815.v1	Inpatient: Year, month, and day of admission.	NCVHS Core Health Data Elements	DT		
Admission Date	CMS	0060-92-764-5622.83035.v1	Inpatient: An inpatient admission begins with the formal acceptance by a hospital of a patient who is to receive health care practitioner or other services while receiving room, board, and continuous nursing services. Year, month, and day of admission. It is recommended that the year of admission contain 4 digits to accommodate problems surrounding the turn of the century.	NCVHS Core Health Data Elements	DT		
Admission Date and Hour	X12	0060-07-329-4837.24504.v1	The date and time of the admission to the facility.	X12 Health Care Data Element Dictionary	ID		
Admission Date/Start of Care	X12	0060-07-329-4837.78362.v1	The basis of this data element is the X12 data element Admission Date and Hour. For detail X12 information see http://www.wpc-edi.com/reportingguides/detail.aspx?ns=TS837A1_2300_DTP03__AdmissionDateAndHour	Health Care Standards Reporting Guide	Not Provided		
Admission Hour	X12	0060-07-329-4837.78361.v1	The basis of this data element is the X12 data element Admission Date and Hour. For detail X12 information see http://www.wpc-edi.com/reportingguides/detail.aspx?ns=TS837A1_2300_DTP03__AdmissionDateAndHour	Health Care Standards Reporting Guide	Not Provided		
Admit Date/Time	HL7	0060-62-480-3235.76572.v2	This field contains the admit date/time. It is to be used if the event date/time is different than the admit date and time, i.e., a retroactive update. This field is also used to reflect the date/time of an out-patient/emergency patient registration.	Health Level Seven v 2.5	TS		



Admit Date/Time	HL7	0060-62-480-3235.76572.v1	This field contains the admit date/time. It is to be used if the event date/time is different than the admit date and time, i.e., a retroactive update. This field is also used to reflect the date/time of an outpatient/emergency patient registration.	Health Level Seven v 2.X	TS		
Admit Date/Time	CMS	0060-92-764-5622.74571.v1	The admit date/time. It is to be used if the event date/time is different than the admit date and time, i.e., a retroactive update. This field is also used to reflect the date/time of an outpatient/emergency patient registration.	Consolidated Health Informatics Initiative	Not Provided		
Admitting Date	NEMA	00-0000049.80290.v1	TBD	National Electrical Manufacturers Association Standard	Not Provided		
Admitting Time	NEMA	00-0000049.80291.v1	TBD	National Electrical Manufacturers Association Standard	Not Provided		
Discharge Date							
Discharge Date	CMS		Inpatient: Year, month, and day of discharge.	NCVHSS Core Health Data Elements	DT		
Discharge Date	CMS		Inpatient: An inpatient discharge occurs with the termination of the room, board, and continuous nursing services, and the formal release of an inpatient by the hospital. Year, month, and day of discharge. Four digits are recommended for the discharge year.	NCVHS Core Health Data Elements	DT		
Discharge Date	NEMA		Date patient visit ended or is scheduled to end.	National Electrical Manufacturers Association Standard	Not Provided		
Discharge Date - Derived from Statement From Date & Type of Bill	X12		The basis of this data element is the X12 data element Statement From or To Date. For detail X12 information see http://www.wpc-edi.com/reportingguides/detail.aspx?ns=TS837A1_2300_DTP03_StatementFromOrToDate	Consolidated Health Informatics Initiative	Not Provided		
Discharge Date/Time	CMS		The discharge date/time. It is to be used if the event date/time is different than the discharge date and time, i.e., a retroactive update. This field is also used to reflect the date/time of an outpatient/emergency patient discharge.	Health Level Seven v 2.X	TS		



Discharge Date/Time	HL7		This field contains the discharge date/time. It is to be used if the event date/time is different than the discharge date and time, that is, a retroactive update. This field is also used to reflect the date/time of an outpatient/emergency patient discharge	Health Level Seven v 2.5	TS		
Supplementary clinician report comments							
Event Patient Problem Code							
Event Device Problem Code							
Approximate Age of Device	No result found in data search.						
Type of Event and/or Issue	See Type of Reportable Event below						
Outcome attributed to AE							
Event Outcome	HL7	0060-62-480-3235.76307.v1	This field identifies the consequence of the event on the patient. If the consequence of the event is not understood or not available, the patient outcome element may be used although neither is required. May be repeated if more than one is appropriate. Refer to HL7 Table 0240 - Event consequence for valid values.	Health Level Seven v 2.X	CV		
Patient Recovered?							
Date of Event							
Event Date/Time	HL7	0060-62-480-3235.76842.v1	This field is the date/time that the event (e.g., state transition, issuing of command, finishing of command execution) occurred.	Health Level Seven v 2.X	TS		
Event Occurred	CMS	0060-92-764-5622.74529	The date/time that the event actually occurred. For example, on a transfer (A02 transfer a patient), this field would contain the date/time the patient was actually transferred. On a cancellation event, this field should contain the date/time that the event being cancelled occurred.	Consolidated Health Informatics Initiative	Not Provided		
Event Occurred	HL7	0060-62-480-3235.76302.v1	This field contains the date/time that the event actually occurred. For example, on a transfer (A02 transfer a patient), this field would contain the date/time the patient was actually transferred. On a cancellation event, this field should contain the date/time that the event being cancelled occurred.	Health Level Seven v 2.X	TS		



Event Onset Date/Time	HL7	0060-62-480-3235.76856.v1	This field contains a report or best estimate of the date/time of onset of the event. The date/time can be recorded to any level of precision it is known (hour, day, month, year).	Health Level Seven v 2.X	TS		
Event Time -UIB	NCPDP	0060-02-166-0014.74919.v1	The time of the interchange. Field Number/Alias: Ø8Ø-S3ØØ-Ø2-Ø114. UIB	NDPDP SCRIPT Standard 4.2	DTM		
Description of Event or Report/ Result							
EVENT.Event Description	ADA	0060-07-442-5216.73752.v1	This attribute contains narrative data which describes the health care event.	ANSI/ADA Specification No. 1000	Character		
EVENT TYPE.Event Type Description	ADA	0060-07-442-5216.73984.v1	This attribute contains textual data which describes the health care event.	ANSI/ADA Specification No. 1000	Character		
Sender Event Discription	HL7	0060-62-480-3235.77384.v1	This field contains the summary narrative text description of the event that occurred written by the sender, which may include a description of the nature of the event, how the product was involved, any environmental conditions that may have influenced the event, and patient follow-up or required treatment. Note that laboratory results can be encoded as OBX segments rather than including them in the narrative. By representing clinical information in OBX segments rather than in the narrative, these data become much more useful and flexible	Health Level Seven v 2.X	FT		
Location Where Event Occurred							
County where vaccine administered							
Adverse Event Terms							
Type of Reportable Event							
Event Type	HL7	0060-62-480-3235.76490.v1	This field identifies the type of event of the message. Refer to HL7 Table 0450 - Event type for valid values. Components: < identifier (ST) > ^ < text (ST) > ^ < name of coding system (IS) > ^ < alternate identifier (ST) > ^ < alternate text (ST) > ^ < name of alternate coding system (IS) > HL7 Table 0450-Event type	Health Level Seven v 2.X	ID		



Event Type Code	HL7	0060-62-480-3235.76040.v1	This field has been retained for backward compatibility only. We recommend using the second component (trigger event) of MSH-9 - Message Type to transmit event type code information. This field contains the events corresponding to the trigger events described in this section, e.g., admission, transfer, or registration. Refer to HL7 Table 0003 - Event type for valid values.	Health Level Seven v 2.X	ID		
EVENT Type.Event Type	ADA	0060-07-442-5216.73751.v1	This attribute contains data which identifies the type of health care event.	ANSI/ADA Specification No. 1000	Character		
Previous Event Report Details							
Date/Time of Issued Vaccine							
Vaccine Type							
Vaccine Manufacturer							
Vaccine Lot #							
Vaccine Route/Site							
Vaccine # Previous Doses							
Vaccine Administered By							
Suspect Product Name							
Product Dose							
Product Frequency							
Product Route Used							
Product Therapy Dates							
Product Diagnosis for Use							
Product Lot #							
Expiration Date							
NDC# or Unique ID							
Event abated after use stopped or dose reduced?							
Event reappeared after reintroduction?							



Suspect Medical Device Brand Name							
Common Device Name							
Manuf. name, city and state							
Medical Device Model #							
Medical Device Catalog #							
Medical Device Serial #							
Medical Device Lot #							
Medical Device Other #							
Operator of Device							
If implanted give date							
If explanted give date							
Is this a single use device that was reprocessed and reused on patient?							
Name and address of reprocessor							
Product available for evaluation?							
Date product returned to manuf.							
Concomitant Medical Products & Therapy Dates							
Type of Manufacturer							
Order Number							
Order Number	AHRQ	044012578.82939.v1	This is a unique identifier for the laboratory or radiology order used for tracking of order execution by the ancillary department. Specific HL7 attribute: ORC-2 Placer Order Number Usually assigned by the Order Entry system GAP: Universally agreed upon meaning of order number; Request clarification from HL7	Not Provided	Not Provided		
Test/Procedure Name							
Test/Procedure Code							



Reporting Laboratory Identifier							
Performing Laboratory							
Name of organization collecting specimen							
Report Date/Time							
Test Date							
Results Status							
Collection Date/Time							
Specimen Source							
Ordered Test Code							
Resulted Test							
Test Method							
Result							
Result Unit							
Test Interpretation							
Test Status							



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.

