

HITSP Public Health Case Reporting Interoperability Specification

HITSP/IS11



Healthcare Information Technology Standards Panel

Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Population Perspective Technical Committee



DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
	Template V2.4	Project Team	July 31, 2008
0.0.1	Review Copy	Population Perspective Technical Committee	September 26, 2008
0.0.2	Review Copy	Population Perspective Technical Committee	December 10, 2008
1.0	Released for Implementation	Population Perspective Technical Committee	December 18, 2008
1.0.1	Review Copy	Population Perspective Technical Committee	January 31, 2010



TABLE OF CONTENTS

1.0	INTRODUCTION.....	5
1.1	Interoperability Specification Overview	5
1.2	Document Scope	6
1.3	Copyright Permissions	8
1.4	Reference Documents	8
1.5	Conformance	8
1.5.1	Conformance Criteria	9
1.5.2	Conformance Scoping, Subsetting and Options	9
1.5.3	Test Methods	9
2.0	REQUIREMENTS	10
2.1	Synopsis of Requirements	10
2.2	Reporting from EHRs	13
2.2.1	Information Exchange Requirements for Reporting from EHRs	13
2.3	Public Health Case Investigation and Information Sharing	14
2.3.1	Information Exchange Requirements for Public Health Case Investigation and Information Sharing	14
2.4	Consumer Adverse Event Reporting	15
2.5	System Description	16
3.0	DESIGN SPECIFICATION	18
3.1	Capabilities Used	20
3.2	Capability Orchestration	25
3.2.1	Constraints on Required Capabilities	32
4.0	CAPABILITY GAPS.....	41
5.0	APPENDIX	49
5.1	Provisional Exchange Content Descriptions	49
5.2	Provisional Data Requirements	49
5.3	Harmonization Request Traceability	56
5.4	Public Health Case Reporting Data Elements	71
6.0	DOCUMENT UPDATES.....	101
6.1	December 10, 2008	101
6.2	December 18, 2008	101
6.3	January 31, 2010	101



FIGURES AND TABLES

Figure 3-1 Diagram Showing Capabilities Used Between Systems.....	23
Table 1-1 Reader's Guide for Interoperability Specification	5
Table 1-2 Reference Documents	8
Table 2-1 Reader's Guide for Section 2.0.....	10
Table 2-2 Description of Information Exchange Requirements	12
Table 2-3 Description of Scenarios	12
Table 2-4 Reporting from EHRs Information Exchange Requirements.....	13
Table 2-5 Public Health Case Investigation and Information Sharing Information Exchange Requirements	14
Table 2-6 Consumer Adverse Event Reporting Information Exchange Requirements	15
Table 2-7 System Names and Descriptions.....	16
Table 3-1 Reader's Guide for Section 3.0.....	18
Table 3-2 Capabilities Used.....	20
Table 3-3 Orchestration of Capabilities by System	25
Table 3-4 Conditions.....	27
Table 3-5 Orchestration Constraints.....	28
Table 3-6 Additional Constraints on Required Capabilities	33
Table 3-7 Additional Constraints on XDS Metadata Elements	39
Table 4-1 Reader's Guide for Section 4.0.....	41
Table 4-2 Capability Gaps	41
Table 5-1 Reader's Guide for Section 5.0.....	49
Table 5-2 New Exchange Content Data Requirements.....	49
Table 5-3 Data Requirements	50
Table 5-4 Harmonization Request Events and Actions Analysis Table	57
Table 5-5 Data Elements Cross Reference for High-level Cross-Cutting Tables	72
Table 5-6 Facility Data Elements	73
Table 5-7 Facility Data Elements: Address.....	73
Table 5-8 Facility Data Elements: Contact.....	73
Table 5-9 Report Data Elements.....	74
Table 5-10 Report Data Elements: Reporter Information	76
Table 5-11 Patient Data Elements	76
Table 5-12 Clinical Data Elements.....	79



1.0 INTRODUCTION

This Healthcare Information Technology Standards Panel (HITSP) document is divided into Requirements, Design and Capabilities sections which may be used by analysts, architects and implementers. Analysts might use this document to refer to the requirements of a particular Harmonization Request. Architects and system implementers might refer to this document as the top level architectural specification for a system design while software developers will use the Interoperability Specification as a source of requirements for interoperable information exchange.

The following table details specific sections of this Interoperability Specification template and how specific sections of this document are targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 1-1 Reader's Guide for Interoperability Specification

Document Section	Section Number	Intended Audience	Information Contained
Section 2.0 Requirements	2.1 Synopsis of Requirements	Policy Managers Policy Analysts Executive Leadership	Used to provide an overview (using a scenario-based approach) of the requirements applicable to this document. Readers should start here to learn more about what specific requirements this Interoperability Specification is intended to address
	2.2 – 2.3 Scenarios	Program Managers Policy Analysts Executive Leadership	Each of the scenarios specific to the Interoperability Specification are outlined and described using a HITSP concept known as an Information Exchange Requirement (IER). HITSP uses IER's to outline requirements for HITSP work products
	2.4 System Description	Architects Business Analysts Policy Analysts Program Managers	The systems assigned to the system roles (as defined in the HITSP Capabilities used by this Interoperability Specification) are identified and described here. Readers can learn which systems have been included as part of this HITSP Interoperability Specification
Section 3.0 Design Specification	3.1 Capabilities Used	Architects Business Analysts Development Team	For each Information Exchange Requirement (IER) identified in Section 2.0, a corresponding HITSP Capability is associated and mapped. A reader can review how specific HITSP Capabilities meet information exchange needs. A diagram is also provided to show the interchange of data among systems identified in this Interoperability Specification
	3.2 Capability Orchestration	Architects Development Team	The core of the design in the Interoperability Specification is documented here. This solution shows orchestration of Capabilities to meet the specific Information Exchange Requirements (IER) in Section 3.1. The design also identifies conditions and constraints, as well as any content subsets specific to the solution
Section 4.0 Capability Gaps	4.0 Capability Gaps	Business Analysts Development Team Architects	Gaps specific to Capabilities used as part of this Interoperability Specification are reviewed in this section to determine why specific information exchange requirements may not yet be met or defined. Readers should check this section to track the progress of gap resolution
Section 5.0 Appendix	5.1 Harmonization Request Traceability	Architects Business Analysts	A complete mapping of information exchange requirements to functional requirements is provided in this section. Readers can trace IER's to underlying Harmonization Request events and actions (in those instances where a Use Case exists) or to functional requirements defined as part of an official standards Harmonization Request

1.1 INTEROPERABILITY SPECIFICATION OVERVIEW

The HITSP Public Health Case Reporting Interoperability Specification supports the bi-directional information exchanges of the Public Health Case Reporting process. The Public Health Case Reporting Use Case addresses numerous domains which have similar content and processes at a high level, but



which also are dissimilar in report content details and case management processes when considering any specific report.

This Interoperability Specification focuses on enabling more efficient data capture at the point of care while allowing for optimal information delivery format and content while waiting for current standard development organization (SDO) efforts to be finalized. In the absence of standards in structured content and associated clinical decision support (CDS) for alerts and information reporting criteria, this Interoperability Specification provides options for the secure communication of basic presentation preserving content to better automate the current paper-based information flows.

1.2 DOCUMENT SCOPE

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 personal health information (PHI).

Harmonization Request actions requiring clinical decision support capabilities are limited to the HITSP Capability HITSP/CAP122 Request Medical Knowledge. Further efforts in clinical decision support 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 case reporting and adverse event cases. It also includes support for prioritization of responses.

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, HITSP will identify, observe, and contribute to harmonization efforts and defer content specification for non-Healthcare Associated Infection (HAI) communications until the standardization/harmonization is completed. This decision is supported by Tier 2 Readiness Criteria Assessment efforts.

For the purpose of submitting a case report, we will leverage HITSP/CAP135 Retrieve and Populate Form using HITSP/C76 Case Report Pre-populate, which was created based upon common data requirements of Public Health and Adverse Event reporting. This Interoperability Specification WILL NOT specify at this time a component for the communication of the populated payload to the end agency recipient. This very important construct 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. The report construct specified for communication of the case report to the report recipient will vary by report type. For HAI reports, this Interoperability Specification specifies an HL7 structured document specifically established for this purpose (HITSP/C75 Healthcare Associated Infection (HAI) Report). For Drug Safety reporting, this Interoperability Specification will provisionally select ICSR V3, which is pending ballot in both HL7 and ISO TC215 as an international harmonized effort addressing drug safety reporting. Development of the associated HITSP construct will be deferred in order to adopt this work. Constructs for other case report types are similarly pending SDO and domain harmonization efforts.

Mapping of common data elements specified in this Interoperability Specification to CDA documents is specified by HITSP/C76 Case Report Pre-populate enabling the EHR to send data for pre-population of the Case Report Form and to minimize data entry. The resulting construct to be sent to the end agency is a deferred construct and we will remain silent on specifying this in the Interoperability Specification 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 in this



Interoperability Specification should be considered 'for implementation testing' only until we have the remaining case report constructs defined, given that the final constructs could impact the data capture and transport options.

Alerts and Reporting Criteria:

The scope is limited to the use of the HITSP/CAP122 Request for Medical Knowledge, and HITSP/CAP120 Communicate Unstructured Document for patient identifiable communications and to the use of HITSP/CAP136 Communicate Emergency Alert and HITSP/CAP142 Retrieve Communication Recipients for generic alerts to identified clinicians for non-patient identifiable communications. Further refinement of structured content may be provided in subsequent releases of the Interoperability Specification pending SDO development of supporting content constructs and HITSP development of CDS constructs.

Patient Safety Roadmap:

The AHIC Quality Workgroup established a sub-group to define a data set for use by HITSP for the Public Health Case Reporting Use Case. That data set is provided in this Interoperability Specification and HITSP/C76 Case Report Pre-populate. Although this effort is valuable for identifying EHR-generated data elements for use with reporting, harmonization with other government and industry efforts is important. The Agency for Healthcare Research and Quality (AHRQ) initiated a similar effort represented by the AHRQ Common Formats. The AHRQ effort results from the Patient Safety and Quality Improvement Act of 2005 which establishes a framework by which doctors, hospitals, and other healthcare providers may voluntarily report information on a privileged and confidential basis regarding patient safety events and quality of care.

The Statute authorizes the collection of this information in a standardized manner. The AHRQ has coordinated the development of a set of common definitions and reporting formats (AHRQ Common Formats) that facilitate the voluntary collection of patient safety event information and the reporting of this information to Patient Safety Organizations. The AHRQ Common Formats effort provides an ongoing methodology to establish a standardized data set for patient safety reporting.

The AHRQ Common Formats delineate definitions, data elements, and reporting formats that allow healthcare providers to collect and submit standardized information regarding patient safety events. They are event focused in contradistinction to EHR records, which are patient focused. Patient safety reporting is also a function of a reporting system and not an EHR document. However, to the extent that EHR captured data can feed the reporting system, significant value will be generated. This HITSP Interoperability Specification identifies a mechanism for filling required information in a form automatically from EHR data and enabling clinicians to add additional information and then return the form to the reporting system. A human Risk Manager will almost always be required to validate the information before actual reporting to any agency or Patient Safety Organization. To the extent possible, EHRs may be able to trigger the need for reporting based on a standard data set of triggers. Such a standard data set has not been established to date.

In establishing interoperability using this HITSP Interoperability Specification, there are three main categorizations of the AHRQ Common Formats elements to consider:

- AHRQ Common Formats data elements which may correspond directly to EHR elements
 - Patient's Name
 - Patient's Date of Birth
 - Patient's Gender
- AHRQ Common Formats data elements which may appear to correspond directly to EHR elements, but have different usage in the Patient Safety arena
 - Location
 - This is the location where the unsafe event or condition occurred. This does not necessarily correspond to the patient's location as customarily documented in an EHR



- Date
 - This is the date the event occurred, and can be documented validly as “unknown.” This does not correspond to the date the patient first noted symptoms (or was admitted to a facility), as customarily documented in an EHR
- Device Type
 - The type of device involved in an event may be documented as: Implantable device, non-implantable device, or any other type of medical equipment or medical/surgical supply. These categorizations are less concrete than device information customarily documented in an EHR. An EHR usually contains details of the procedure during which the device was used/implanted, etc.
- AHRQ Common Formats data elements which are assumed not to exist in an EHR. Most of the AHRQ Common Formats data elements fall under this category
 - Number of Patients (How many patients the incident reached)
 - Rescue Attempted (Whether or not “rescue” was attempted following the discovery of an incident)
 - Level of Preventability (How preventable the event or unsafe condition was)

Notifiable disease information is captured in a common format defined in concert by the Council of State and Territorial Epidemiologists (CSTE) and the Centers for Disease Control and Prevention (CDC). The Association of Public Health Laboratories (APHL) also evaluates codes used for laboratory reporting of these reportable conditions. The effort is also expected to list triggers that can enable EHRs to generate information for national notifiable conditions. The results of this effort will also be harmonized with data available within EHRs future releases of this Interoperability Specification.

1.3 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

© 2010 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.

1.4 REFERENCE DOCUMENTS

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

Table 1-2 Reference Documents

Reference Documents	Document Description
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents
TN900 – Security and Privacy	TN900 is a reference document that provides the overall context for use of the HITSP Security and Privacy constructs
TN901 - Clinical Documents	TN901 is a reference document that provides the overall context for use of the HITSP Care Management and Health Records constructs
TN903 – Data Architecture	TN903 is a reference document that provides the overall context for use of the HITSP Data Architecture constructs
TN904 – Harmonization Framework and Exchange Architecture	TN904 is a reference document that provides the overall context for use of the HITSP Harmonization Framework and Exchange Architecture constructs

1.5 CONFORMANCE

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



1.5.1 CONFORMANCE CRITERIA

For an implementation to claim conformance to a HITSP Interoperability Specification, it must be implemented in its entirety or within a limited scope or subset as defined within the Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must be constrained as specified in this Interoperability Specification, and implement all of the required interfaces within the scope, subset or implementation options as described.

1.5.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

HITSP may define the permissibility for system scoping, subsetting or implementation options by which the specification may be implemented in a limited manner. The selected scope, subset or options shall specifically be stated, and implementations must include all requirements within the selected scope, subset or options to claim conformance.

For this Interoperability Specification, conformance may be declared by a participating system for any Capability provided that all declared constraints, conditions and requirements imposed by the Capability and its referenced HITSP constructs are satisfied.

1.5.3 TEST METHODS

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

An [HIT Implementation Testing and Support](#) Web Site has been developed in collaboration with HITSP, the National Institute of Standards and Testing (NIST), the Certification Commission for Healthcare Information Technology (CCHIT), and the Office of the National Coordinator for Health Information Technology (ONC) to advance conformance and interoperability testing capabilities. This Web Site provides HIT implementers with the necessary resources to support and test their implementation of standards-based health systems..



2.0 REQUIREMENTS

Section 2.0 identifies the requirements from the Harmonization Request for which information exchanges are necessary. The following table details how this section and other sections of the document are targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 2-1 Reader's Guide for Section 2.0

Document Section	Section Number	Intended Audience	Information Contained
Section 2.0 Requirements	2.1 Synopsis of Requirements	Policy Managers Policy Analysts Executive Leadership	Used to provide an overview (using a scenario-based approach) of the requirements applicable to this document. Readers should start here to learn more about what specific requirements this Interoperability Specification is intended to address
	2.2 – 2.3 Scenarios	Program Managers Policy Analysts Executive Leadership	Each of the scenarios specific to the Interoperability Specification are outlined and described using a HITSP concept known as an Information Exchange Requirement (IER). HITSP uses IER's to outline requirements for HITSP work products
	2.4 System Description	Architects Business Analysts Policy Analysts Program Managers	The systems assigned to the system roles (as defined in the Capabilities used by this Interoperability Specification) are identified and described here. Readers can learn which systems have been included as part of this Interoperability Specification

2.1 SYNOPSIS OF REQUIREMENTS

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 Table 5-4 Harmonization Request Events and Actions Analysis Table actions 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 was 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.

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 for most notifiable conditions, 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.

The following table describes the information exchange requirements needed to accomplish the Harmonization Request for which information exchange is necessary.



Table 2-2 Description of Information Exchange Requirements

Information Exchange Requirement Number (IER)	Description
IER1	Query/Retrieve Communication Recipients from PH
IER2	Send DR17 Decision Support Data Content from PH
IER3	Query/Retrieve DR17 Decision Support Data Content from EHR
IER4	Send DR59 Generic Alert Data - Public Health from PH
IER5	Query/Retrieve DR59 Generic Alert Data - Public Health from EHR
IER6	Send DR8 Unstructured Data from PH
IER7	Query/Retrieve DR8 Unstructured Data from EHR
IER8	Send Notification of Document Availability from PH
IER9	Query/Retrieve EC66 Value Set from EHR
IER10	Pre-Populate Form EC76 Case Report Pre-Populate from EHR
IER11	Send DR25 Case Report Content from EHR
IER12	Send EC87 Anonymous Case Report from EHR
IER13	Query/Retrieve EC24 Pseudo Identity from PH (re-identify)
IER14	Send EC62 (Report Confirmation) from Manufacturer
IER15	Send EC62 (Report Confirmation, Request for Additional Information) from PH
IER16	Query Existing Data DR25 from EHR
IER17	Query/Retrieve DR25 from EHR
IER18	Provide/Register EC30 from EHR
IER19	Query/Retrieve EC30 from PH
IER20	Send EC36 Laboratory Message from LAB
IER21	Publish/Register EC37 Laboratory Report Document from LAB
IER22	Send EC37 Laboratory Report Document from LAB
IER23	Query/Retrieve EC37 Laboratory Report Document from PH
IER24	Query/Retrieve DR17 Decision Support Data Content from PH
IER25	Subscribe EC62 (Generic Alert) from PHR
IER26	Query/Retrieve DR17 Decision Support Data Content from PHR
IER27	Query/Retrieve DR59 Generic Alert Data -from Public Health
IER28	Query/Retrieve DR8 Unstructured Data from PHR
IER29	Subscribe EC62 (Report Confirmation) from PHR
IER30	Query/Retrieve EC62 (Report Confirmation) from PHR
IER31	Query/Retrieve EC66 Value Set from EHR
IER32	Pre-Populate Form EC76 Case Report Pre-Populate from EHR
IER33	Send DR25 Case Report Content from PHR
IER34	Provide/Register EC30 Patient Consent Document from EHR
IER35	Query/Retrieve EC24 Pseudo Identity from PHR
IER36	Send EC87 Anonymous Case Report from PHR

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:

Table 2-3 lists and describes the major subdivisions of a Harmonization Request, called Scenarios.

Table 2-3 Description of Scenarios

Scenario Name	Scenario Description
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



Scenario Name	Scenario Description
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
Consumer Adverse Event Reporting	In the case of the consumer adverse event reporting, a similar capability for communicating adverse event reports from PHRs or other systems may be needed to allow consumers to complete a potential adverse event report and communicate it via information exchange to appropriate organizations

2.2 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 Use Case Sections 7.0 and 8.0.

2.2.1 INFORMATION EXCHANGE REQUIREMENTS FOR REPORTING FROM EHRs

Table 2-4 Reporting from EHRs Information Exchange Requirements summarizes the relationship between the Exchange Action, Exchange Content, and the Initiating and Responding System(s) along with Exchange Attributes.

Table 2-4 Reporting from EHRs Information Exchange Requirements

IER Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER1	Query/Retrieve	Communication Recipients	PH	HIE	
IER2	Send	DR17 Decision Support Data Content	PH	EHR	
IER2	Send	DR17 Decision Support Data Content	PH	PH	
IER3	Query/Retrieve	DR17 Decision Support Data Content	EHR	PH	
IER4	Send	DR59 Generic Alert Data - Public Health	PH	EHR	
IER5	Query/Retrieve	DR59 Generic Alert Data - Public Health	EHR	PH	
IER6	Send	DR8 Unstructured Data	PH	EHR	
IER7	Query/Retrieve	DR8 Unstructured Data	EHR	PH	
IER8	Send	Notification of Document Availability	PH	EHR	
IER9	Query/Retrieve	EC66 Value Set	EHR	HIE	
IER10	Pre-Populate Form	EC76 Case Report Pre-Populate	EHR	Manufacturer PH PHR	



IER Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER11	Send	DR25 Case Report Content	EHR	Manufacturer PH	
IER12	Send	EC87 Anonymous Case Report	EHR	Manufacturer	
IER13	Query/Retrieve	EC24 Pseudo Identity	PH	HIE	(Re-identify)
IER14	Send	EC62 Unstructured Document	Manufacturer	EHR	(Report Confirmation)
IER15	Send	EC62 Unstructured Document	PH	EHR	(Report Confirmation) (Request for Additional Information)
IER16	Query Existing Data	DR25 Case Report Content	EHR	EHR	
IER17	Query/Retrieve	DR25 Case Report Content	EHR	HIE	
IER18	Provide/Register	EC30 Consent Document	EHR	HIE	
IER19	Query/Retrieve	EC30 Consent Document	PH	HIE	

2.3 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.

2.3.1 INFORMATION EXCHANGE REQUIREMENTS FOR PUBLIC HEALTH CASE INVESTIGATION AND INFORMATION SHARING

Table 2-5 Public Health Case Investigation and Information Sharing Information Exchange Requirements summarizes the relationship between the Exchange Action, Exchange Content, and the Initiating and Responding Systems along with Exchange Attributes.

Table 2-5 Public Health Case Investigation and Information Sharing Information Exchange Requirements

Information Exchange Requirement Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER1	Query/Retrieve	Communication Recipients	PH	HIE	
IER2	Send	DR17 Decision Support Data Content	PH	EHR	
IER2	Send	DR17 Decision Support Data Content	PH	PH	
IER3	Query/Retrieve	DR17 Decision Support Data Content	EHR	PH	
IER4	Send	DR59 Generic Alert Data - Public Health	PH	EHR	
IER5	Query/Retrieve	DR59 Generic Alert Data - Public Health	EHR	PH	



IER6	Send	DR8 Unstructured Data	PH	EHR	
IER7	Query/Retrieve	DR8 Unstructured Data	EHR	PH	
IER8	Send	Notification of Document Availability	PH	EHR	
IER9	Query/Retrieve	EC66 Value Set	EHR	HIE	
IER10	Pre-Populate Form	EC76 Case Report Pre-Populate	EHR	Manufacturer PH PHR	
IER11	Send	DR25 Case Report Content	EHR	Manufacturer PH	
IER12	Send	EC87 Anonymous Case Report	EHR	Manufacturer	
IER13	Query/Retrieve	EC24 Pseudo Identity	PH	HIE	(Re-identify)
IER14	Send	EC62 Unstructured Document	Manufacturer	EHR	(Report Confirmation)
IER15	Send	EC62 Unstructured Document	PH	EHR	(Report Confirmation) (Request for Additional Information)
IER16	Query Existing Data	DR25 Case Report Content	EHR	EHR	
IER17	Query/Retrieve	DR25 Case Report Content	EHR	HIE	
IER18	Provide/Register	EC30 Consent Document	EHR	HIE	
IER19	Query/Retrieve	EC30 Consent Document	PH	HIE	
IER20	Send	EC36 Laboratory Message	LAB	PH	
IER21	Publish/Register	EC37 Laboratory Report Document	LAB	HIE	
IER22	Send	EC37 Laboratory Report Document	LAB	PH	
IER23	Query/Retrieve	EC37 Laboratory Report Document	PH	HIE	
IER24	Query/Retrieve	DR17 Decision Support Data Content	PH	PH	

2.4 CONSUMER ADVERSE EVENT REPORTING

In the case of the Consumer Adverse Event Reporting, a similar Capability for communicating adverse event reports from PHRs or other systems may be needed to allow consumers to complete a potential adverse event report and communicate it via information exchange to appropriate organizations.

Table 2-5 Consumer Adverse Event Reporting Information Exchange Requirements summarizes the relationship between the Exchange Action, Exchange Content, and the Initiating and Responding Systems along with Exchange Attributes.

Table 2-6 Consumer Adverse Event Reporting Information Exchange Requirements

Information Exchange Requirement Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER25	Subscribe	EC62 Unstructured Document	PHR	PH	(Generic Alert)
IER26	Query/Retrieve	DR17 Decision Support Data Content	PHR	PH	



IER27	Query/Retrieve	DR59 Generic Alert Data - Public Health	PHR	PH	
IER28	Query/Retrieve	DR8 Unstructured Data	PHR	PH	
IER29	Subscribe	EC62 Unstructured Document	PHR	PH	(Report Confirmation)
IER30	Query/Retrieve	EC62 Unstructured Document	PHR	HIE	(Report Confirmation)
IER31	Query/Retrieve	EC66 Value Set	PHR	HIE	
IER32	Pre-Populate Form	EC76 Case Report Pre-Populate	PHR	PH	
IER33	Send	DR25 Case Report Content	PHR	PH	
IER34	Provide/Register	EC30 Consent Document	PHR	HIE	
IER35	Query/Retrieve	EC24 Pseudo Identity	PHR	HIE	
IER36	Send	EC87 Anonymous Case Report	PHR	Manufacturer	

2.5 SYSTEM DESCRIPTION

The following table lists systems involved in the above listed scenarios, and identifies the stakeholders served by those involved systems.

Table 2-7 System Names and Descriptions

System Name	System Description	Stakeholders
Electronic Health Record (EHR) System	The Electronic Health Record (EHR) System is a secure, real-time, point-of-care, patient-centric information resource for clinicians	HIS, EHR Healthcare Delivery Organizations, Ancillary Entities, Clinicians Care Delivery Actor Providers, Clinicians, Healthcare Entities
Health Information Exchange (HIE)	A Health Information Exchange (HIE) is a multi-stakeholder system that enables the exchange and use of health information, in a secure manner, for the purpose of promoting the improvement of health quality, safety and efficiency	RHIO, Health Information Exchange Organizations
Laboratory Information Systems	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 systems are responsible for updating interface engine rules and triggers in response to Use Case modifications of requested data feeds	Laboratories



System Name	System Description	Stakeholders
Public Health Information System	An automated and integrated system used to document and address information of interest to public health. Local, state, and federal government organizations and personnel use these systems to help protect and improve the health of their respective constituents. A critical effort under this charge is collecting health information to monitor for the existence of emerging health threats appearing in the population and manage these threats once manifested. Staff of these agencies interacts with the public health information system to verify and validate system indications of public health threats, and to assert acknowledgements that may be required by system processes	Local/state/federal public health agencies including FDA, CDC Manufacturers/Distributors, Government Agencies, and other appropriate organizations, Knowledge Suppliers
Personal Health Record (PHR) Systems	A healthcare record system used to create, review, annotate and maintain records by the patient or the caregiver for a patient. The PHR may include any aspect(s) of the health condition, medications, medical problems, allergies, vaccination history, visit history or communications with healthcare providers	Patients, Consumers, PHR System Suppliers Other supporting stakeholders represented by different systems: Health Information Exchange Organizations, Clinicians, Healthcare Entities, and Knowledge Suppliers



3.0 DESIGN SPECIFICATION

Section 3.0 identifies the Capabilities used to meet the requirements identified in Section 2.0 Requirements and describes how to orchestrate this set of Capabilities to meet those requirements. The following table details how this section of the document is targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 3-1 Reader's Guide for Section 3.0

Document Section	Section Number	Intended Audience	Information Contained
Section 3.0 Design Specification	3.1 Capabilities Used	Architects Business Analysts Development Team	For each Information Exchange Requirement (IER) identified in Section 2.0, a corresponding Capability is associated and mapped. A reader can review how specific Capabilities meet information exchange needs. A diagram is also provided to show the interchange of data among systems identified in this Interoperability Specification
	3.2 Capability Orchestration	Architects Development Team	The core of the design in the Interoperability Specification is documented here. This solution shows orchestration of Capabilities to meet the specific Information Exchange Requirements (IER) in Section 3.1. The design also identifies conditions and constraints, as well as any content subsets specific to the solution

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

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

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

Examples:

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

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



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

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

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 Query for Existing Data or HITSP/TP13 Manage Sharing of Documents.

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 fills 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: Non-patient-specific push – Where the alert is generic and not specific to a particular patient (e.g. an increase in incidence of a communicable disease has been noticed by public health which needs to notify local providers) and the communication requires presentation preserving properties. The communication recipients are identified using HITSP/T64 Identify Communication Recipients, and the generic alert is sent to those providers leveraging HITSP/T63 Emergency Message Distribution Element with HITSP/C82 Emergency Common Alerting Protocol. The communication itself may be conducted using email, Health Alert Network (HAN), or FAX as specified by the implementation. Communication recipients may be identified using HITSP/T64 Identify Communication Recipients
- Option 2 - Where the alert is generic and not specific to a particular patient (e.g. an increase in incidence of a communicable disease has been noticed by public health which needs to notify local providers) and the communication is text-based, the communication recipients are identified using HITSP/T64 Identify Communication Recipients, and the generic alert is sent to those providers using HITSP/T63
- Option 3 – Where the alert is patient-specific in nature, HITSP/T29 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 using HITSP/C62 Unstructured Document which will contain the immunization notification alert and instructions for the clinician or patient
- Option 4 – Context specific information may be requested by the EHR or PHR using HITSP/T81 Retrieval of Medical Knowledge as part of the user interface or pre-fetching options. This approach may be used to address the request of alerts and reporting requirements. This option leverages a retrieval model and cannot be leveraged for a distribution only approach



Consumer Adverse Event Reporting Extension

Consumer Adverse Event Reporting includes consumers identifying potential adverse events and communicating relevant information about these events to relevant organizations, providers, and other entities such as manufacturers. Therefore, requirements for the 2009 Consumer Adverse Events Reporting Extension/Gap document can be summarized as:

- The ability for consumers to report adverse events to appropriate organizations using Personal Health Records (PHRs) or other systems
- The ability for relevant organizations to send standardized consumer adverse event reporting information and specifications to PHRs and other systems, and
- The ability for PHRs and other systems to receive standardized consumer adverse event reporting information and specifications from appropriate organizations, and incorporate and use this information within PHRs and other systems

This document supports the need for incorporation of adverse event reporting capabilities into PHRs and other systems to enhance the communication between consumers' PHRs and the systems that support organizations concerned with potential adverse events. The communication of adverse events from a consumer to various stakeholders will depend on standardized data elements, datasets, message structures, and message transport considerations.

3.1 CAPABILITIES USED

Table 3-2 Capabilities Used

Capability	Capability Summary	Capability IE Used	IEs Satisfied
HITSP/CAP120 - Communicate Unstructured Document	This Capability addresses interoperability requirements that support the communication of a set of unstructured health data related to a patient in a context set by the source of the document who is attesting to its content. Two types of specific unstructured content are supported, both with a structured CDA header: <ol style="list-style-type: none">1. PDF-A supporting long-term archival2. UTF-8 text	Send and Receive Unstructured Document	IER6 IER7 IER8 IER14 IER15 IER25 IER28 IER29 IER30
HITSP/CAP126 – Communicate Lab Results Message	This Capability addresses interoperability requirements that support the sending of a set of laboratory test results. Ordering Providers of Care receive results as a laboratory results message. The communication of the order is Out of scope for this Capability. The content of these test results may be either or both: General Laboratory Test Results; Microbiology Test Results This Capability may use content anonymization	Send Lab Result Message	IER20
HITSP/CAP127 – Communicate Lab Results Document	This Capability addresses interoperability requirements that support the communication of a set of structured laboratory results related to a patient in a context set by the source of the document who is attesting to its content. Non-ordering Providers of Care access historical laboratory results as documents and "copy-to" Providers of Care may receive document availability notifications to retrieve such lab report documents. Lab Report content creators shall support HITSP specified coded terminologies as defined by specific content subsets specified in this Capability for: General Laboratory Test Results; Microbiology Test Results. This Capability may use content anonymization	Send and Receive Lab Report Document	IER21 IER22 IER23
HITSP/CAP135 – Retrieve and Populate Form	This Capability addresses interoperability requirements to support the upload of specific captured data (e.g. public	Send Pre-population data	IER10 IER32



Capability	Capability Summary	Capability IE Used	IEs Satisfied
	<p>health surveillance reportable conditions, healthcare associated infection reporting) to Public Health Monitoring Systems and Quality Organizations Systems. The forms presented may be pre-populated by information provided by the clinical or laboratory information systems to avoid manual re-entry. A number of supplemental information variables may be captured from within the user's clinical information system to improve the workflow and timeliness of required reporting. One or more types of form content may be supported:</p> <ul style="list-style-type: none"> • Pre-population for Public Health Case Reports from Structured Documents using CDA • Pre-population for Quality Data from Structured Documents using CDA • No pre-population content <p>Systems may optionally support the means to retrieve request for clarifications</p>	Receive Pre-population data	IER10 IER32
		Send Pre-populated form	IER10 IER32
		Receive Pre-populated form	IER10 IER32
HITSP/CAP122 - Retrieve Medical Knowledge	<p>This Capability addresses the requirements to retrieve medical knowledge that is not patient-specific based on context parameters. The actual content delivered is not constrained by this Capability; this Capability focuses on providing the mechanism to ask for (query) and receive the medical knowledge</p>	Request & Response HITSP/T81 – Retrieval of Medical Knowledge	IER3 IER5 IER24 IER26 IER27
		Request & Response HITSP/T66 – Retrieve Value Set	IER9 IER31
HITSP/CAP136 - Communicate Emergency Alert	<p>This Capability addresses interoperability requirements to support multicast of non-patient specific notification messages about emergencies events, alerts concerning incidence of communicable diseases, alerts concerning population needs for vaccines and other generic alerts sent to an identified channel. The intended recipients are populations such as “all emergency departments in XXX county”, “within a geographic area”, etc. Note that this Capability is not used to communicate patient-specific or identifiable data</p>	Send Emergency Alert	IER2 IER4
HITSP/CAP138 – Retrieve Pseudonym	<p>This Capability addresses interoperability requirements to support a particular type of anonymization that both removes the association with a data subject, and adds an association between a particular set of characteristics relating to the data subject and one or more pseudonyms. This enables a process of supplying an alternative identifier, which permits a patient to be referred to by a key that suppresses his/her actual identification information. The purpose of this Capability is to offer a pseudonymization framework for situations that require the use of specific data without disclosing the specific identity of patients or providers. Pseudo-identifiers are intended to allow accessibility to clinical information, while safeguarding any information that may compromise the privacy of the individual patient or provider. However, unlike anonymization, the alternative identifier key can be used to re-identify the individuals whose data was used</p>	Request & Response Pseudo Identity	IER13 IER35

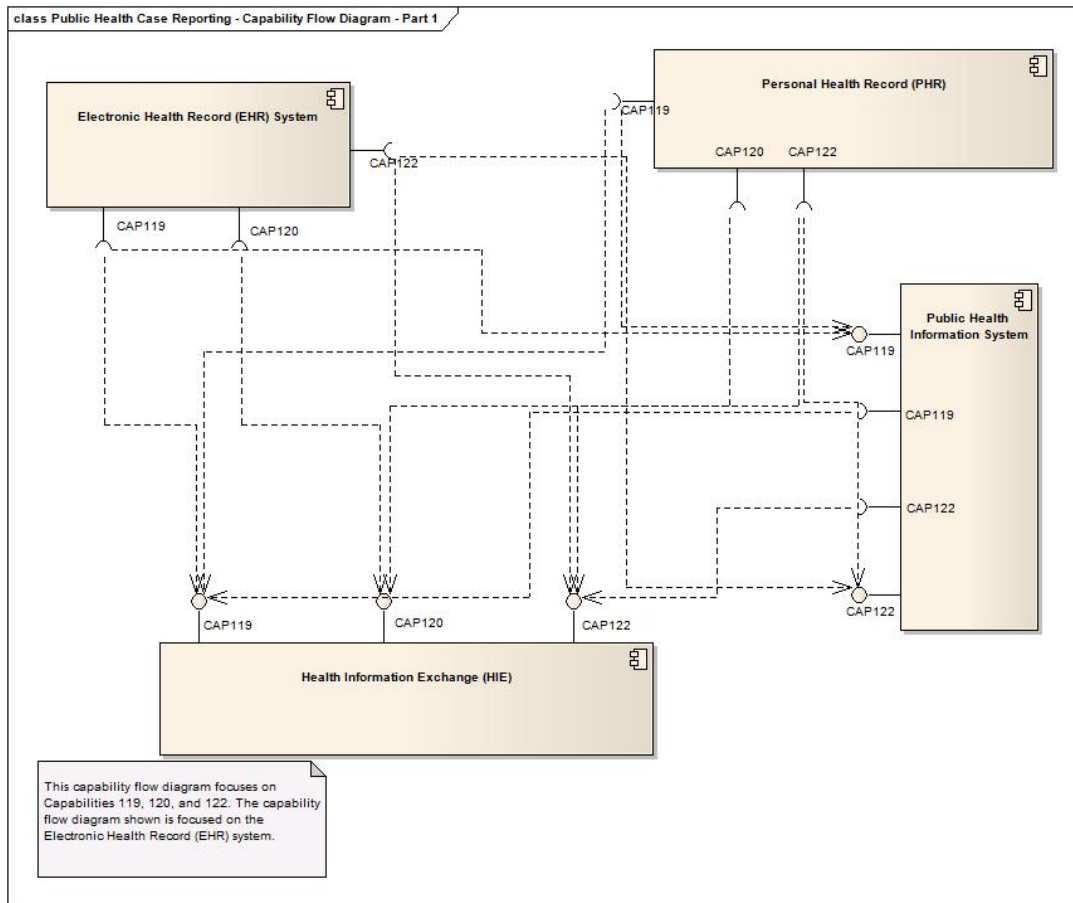


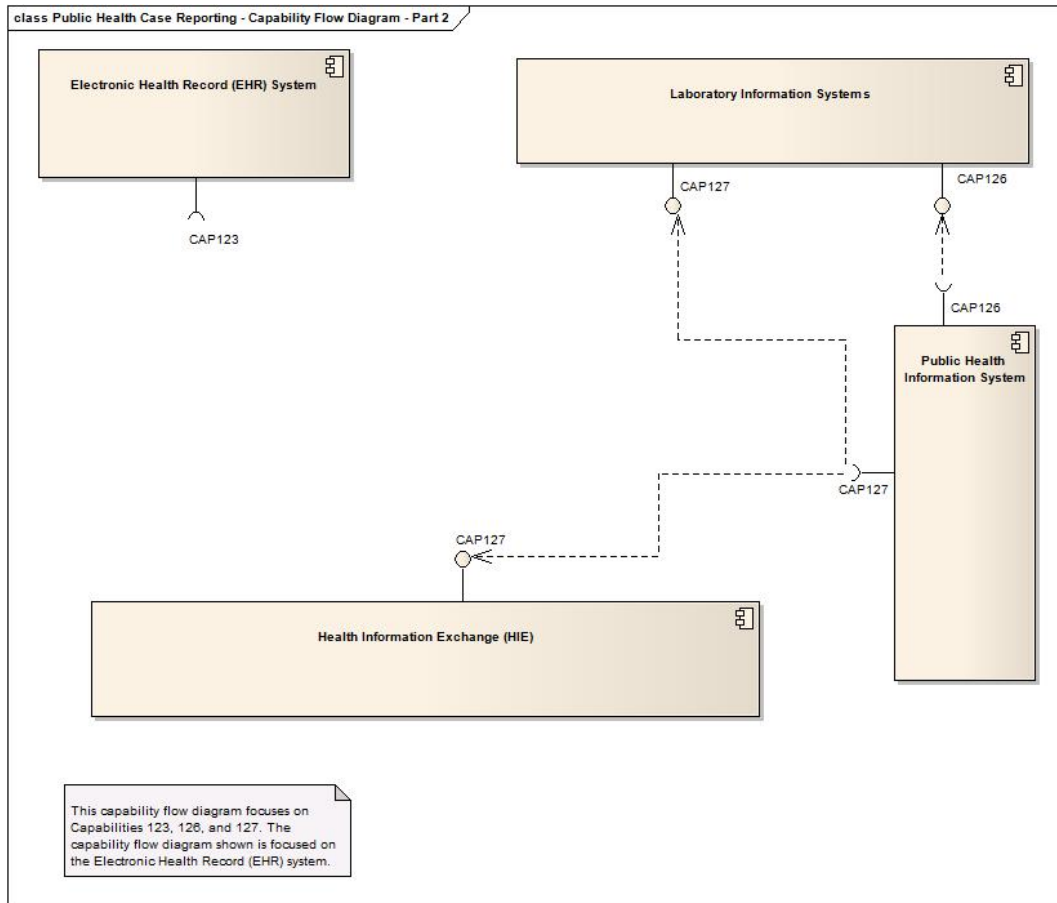
Capability	Capability Summary	Capability IE Used	IEs Satisfied
HITSP/CAP142 – Retrieve Communications Recipient	This Capability addresses interoperability requirements that support access to a directory to identify one or more communication recipients in order to deliver alerts and bi-directional communications (e.g., public health agencies notifying a specific group of service providers about an event). The method and criteria by which individuals are added to a directory is a policy decision, which is Out of scope for this construct	Request & Response HITSP/T64 – Identify Communication Recipients	IER1
HITSP/CAP119 - Communicate Structured Document	This Capability addresses interoperability requirements that support the communication of structured health data related to a patient in a context set by the source of the document who is attesting to its content. Several document content subsets, structured according to the HL7 CDA standard, are supported by this Capability. The following are examples of the type of structured data that may be used: <ol style="list-style-type: none"> 1. Continuity of Care Document (CCD) 2. Emergency Department Encounter Summary 3. Discharge Summary (In-patient encounter and/or episodes of care) 4. Referral Summary Ambulatory (encounter and/or episodes of care) 5. Consultation Notes 6. History and Physical 7. Personal Health Device Monitoring Document 8. Healthcare Associated Infection (HAI) Report Document Document creators shall support a number of the HITSP specified coded terminologies as defined by specific content subsets specified in this Capability	Send and Receive Document	IER11 IER12 IER17 IER33 IER36
HITSP/CAP123 – Retrieve Existing Data	This Capability supports queries for clinical data (e.g., common observations, vital signs, problems, medications, allergies, immunizations, diagnostic results, professional services, procedures and visit history)	Request & Response Query for Existing Data	IER16
HITSP/CAP143 – Manage Consumer Preference and Consents	This Capability addresses management of consumer preference and consents as an acknowledgement of a privacy policy. This Capability is used to capture a patient or consumer agreement to one or more privacy policies; where examples of a privacy policy may represent a consent, dissent, authorization for data use, authorization for organizational access, or authorization for a specific clinical trial. This Capability also supports the recording of changes to prior privacy policies such as when a patient changes their level of participation or requests that data no-longer be made available because they have left the region	Request & Response Consent Directives	IER18 IER19 IER34

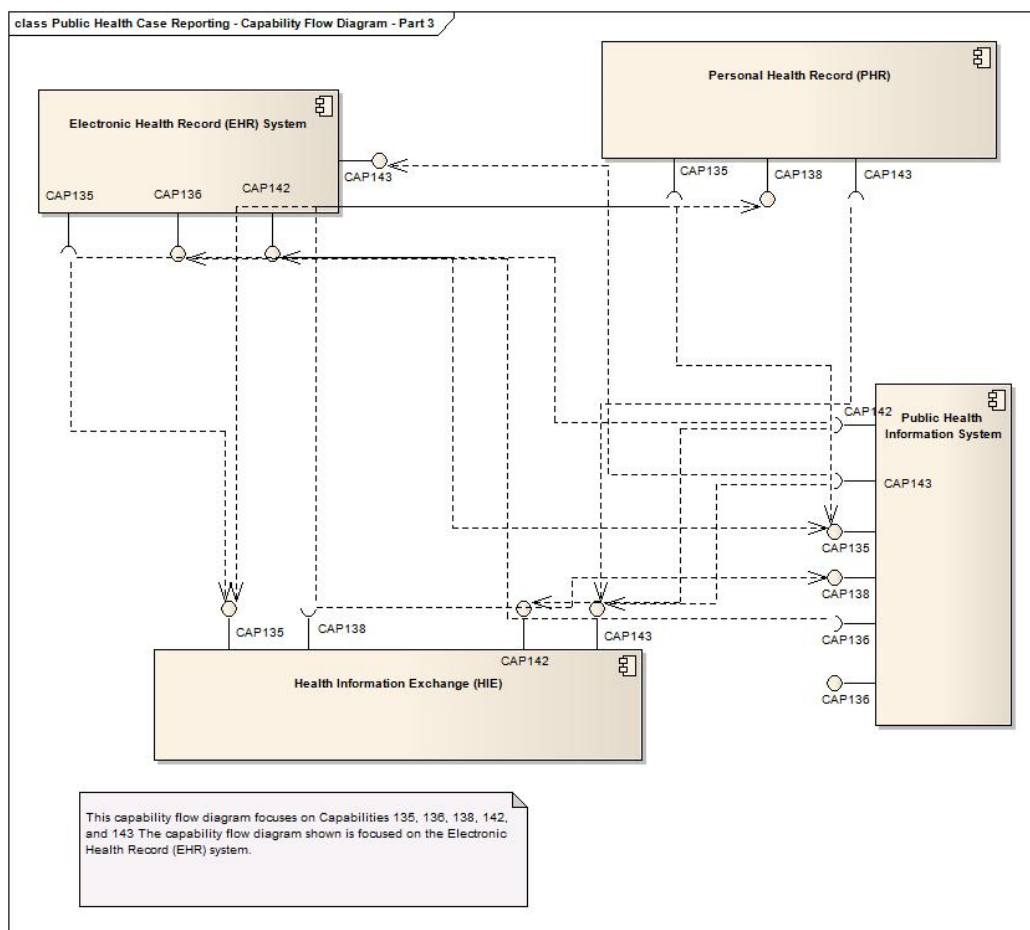
The following diagram shows how systems use Capabilities to complete the full Interoperability Specification. The diagram is purposely created to be architecturally neutral. In some settings a given system role within a Capability will be filled by more than one system in the Interoperability Specification. In many settings, one system may implement multiple Capabilities as shown in the diagram. There are many potential combinations of systems using these Capabilities in different architectures. The diagram therefore uses one example that includes all systems.



Figure 3-1 Diagram Showing Capabilities Used Between Systems







3.2 CAPABILITY ORCHESTRATION

This section describes how the Capabilities identified above are orchestrated to achieve the aims of the Harmonization Request (such as a Use Case) addressed by this Interoperability Specification. The orchestration identifies systems that fill the system roles in the Capabilities to achieve the desired data flows.

Table 3-3 lists the orchestration of Capabilities by system to meet the information exchange requirements described in Section 2.0. Subsets of these systems perform information exchanges according to one or more of the Capabilities identified in this specification. The Capabilities are annotated on the diagrams. The in-scope requirements are supported by Capabilities either previously specified by HITSP or new Capabilities introduced in this section. Optionality is expressed as Required (R), Optional (O) or Conditional (C). If the optionality is Conditional, the applicable conditions are given in Table 3-4 below.

Table 3-3 Orchestration of Capabilities by System

System	Capability	System Role	System Role Option	Condition
Laboratory Information Systems (Message Sender/Bio Data Sender, Document Source)	HITSP/CAP126 – Communicate Lab Results Message	Result Sender	O	C[102]
	HITSP/CAP127 – Communicate Lab Results Document	Document Sender	O	C[102]



System	Capability	System Role	System Role Option	Condition
Electronic Health Record (EHR) System	HITSP/CAP119 – Communicate Structured Document	Document Consumer	R	R
	HITSP/CAP120 – Communicate Unstructured Document	Document Consumer	R	R
	HITSP/CAP122 – Retrieve Medical Knowledge	Knowledge Requestor	O	C[104]
	HITSP/CAP122 – Retrieve Medical Knowledge	Value Set Consumer	O	
	HITSP/CAP123 – Retrieve Existing Data	Clinical Data Consumer	O	
	HITSP/CAP135 – Retrieve and Populate Form	Form Filler	R	
	HITSP/CAP136 – Communicate Emergency Alert	Alert Message Receiver	R	
	HITSP/CAP138 – Retrieve Pseudonym	Request Patient Identity	O	C[103]
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Sender	R	
Health Information Exchange (HIE)	HITSP/CAP119 – Communicate Structured Document	Document Registry	O	C[105]
	HITSP/CAP119 – Communicate Structured Document	Document Repository	O	C[101]
	HITSP/CAP120 – Communicate Unstructured Document	Document Registry	O	C[105]
	HITSP/CAP120 – Communicate Unstructured Document	Document Repository	O	C[101]
	HITSP/CAP122 – Retrieve Medical Knowledge	Value Set Repository	O	
	HITSP/CAP127 – Communicate Lab Results Document	Document Registry	O	C[105]
	HITSP/CAP127 – Communicate Lab Results Document	Document Repository	O	C[101]
	HITSP/CAP135 – Retrieve and Populate Form	Form Manager	O	
	HITSP/CAP135 – Retrieve and Populate Form	Form Receiver	O	
	HITSP/CAP135 – Retrieve and Populate Form	Form Archiver	O	
	HITSP/CAP138 – Retrieve Pseudonym	Pseudonymization Service	O	C[103]
	HITSP/CAP142 – Retrieve Communications Recipient	Personnel White Pages Directory	O	
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Registry and Repository	O	C[101] C[105]
Public Health Information System	HITSP/CAP119 – Communicate Structured Document	Document Sender	O	C[102]
	HITSP/CAP119 – Communicate Structured Document	Document Consumer	O	C[102]
	HITSP/CAP122 – Retrieve Medical Knowledge	Knowledge Resource	O	



System	Capability	System Role	System Role Option	Condition
	HITSP/CAP122 – Retrieve Medical Knowledge	Knowledge Requestor	O	
	HITSP/CAP122 – Retrieve Medical Knowledge	Value Set Repository	O	
	HITSP/CAP126 – Communicate Lab Results Message	Result Receiver	O	C[102]
	HITSP/CAP127 – Communicate Lab Results Document	Document Receiver	O	C[102]
	HITSP/CAP135 – Retrieve and Populate Form	Form Manager	O	
	HITSP/CAP135 – Retrieve and Populate Form	Form Receiver	O	
	HITSP/CAP135 – Retrieve and Populate Form	Form Archiver	O	
	HITSP/CAP136 - Communicate Emergency Alert	Alert Message Receiver	O	
	HITSP/CAP136 - Communicate Emergency Alert	Alert Message Sender	R	
	HITSP/CAP138 – Retrieve Pseudonym	Request Patient Identity	O	C[103]
	HITSP/CAP142 – Retrieve Communications Recipient	Personnel White Pages Consumer	O	
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Receiver	R	
Personal Health Record (PHR)	HITSP/CAP119 – Communicate Structured Document	Document Consumer	R	R
	HITSP/CAP120 – Communicate Unstructured Document	Document Consumer	R	R
	HITSP/CAP122 – Retrieve Medical Knowledge	Knowledge Requestor	O	C[104]
	HITSP/CAP122 – Retrieve Medical Knowledge	Value Set Consumer	O	
	HITSP/CAP135 – Retrieve and Populate Form	Form Filler	R	
	HITSP/CAP138 – Retrieve Pseudonym	Request Patient Identity	O	C[103]
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Sender	R	

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

Table 3-4 below lists the conditions applicable to the orchestration (see above table) of the Capabilities engaged in this Interoperability Specification.

Table 3-4 Conditions

Condition Code	Condition Description
C[101]	Conditional on HIE model (e.g. Federated, centralized, hybrid)
C[102]	Shall support at least one of these Capabilities
C[103]	Required where pseudonymization is required by the jurisdiction or information sharing agreements
C[104]	Knowledge Consumer may be used to retrieve guideline and educational material. E mail or Web-based retrieval alternatives may be use. At least one of these methods must be supported. Jurisdiction implementations may require the use of one or more methods



Condition Code	Condition Description
C[105]	For document sharing, at least one Registry Shall exist.

Table 3-5 Orchestration Constraints

Constraint ID	Constraint	Type of Constraint
1	(Consumer Perspective) Consumer considering potential adverse events, MAY use a PHR to help complete a report, and notify others of a potential adverse event for potential follow-up and investigation. This communication MAY be directed to the appropriate organizations such as providers, manufacturers, public health, government agencies, and other organizations	Assumption
2	(Consumer Perspective) Alerts to the patient MAY include recall data sent to subscribe	Assumption
3	(Consumer Perspective) There SHALL be a service that is available to provide the notifications	Assumption
4	(Consumer Perspective) Case reports MAY be made available from patient to provider and from provider to patient	Assumption
5	(Consumer Perspective) There MAY be a notification from EHR/clinician to patient. This is subject to policy	Assumption
6	(Consumer Perspective) Adverse Event Reports includes VAERS	Assumption
7	(Consumer Perspective) The identity of information source (system) SHALL be verified	Assumption
8	(Consumer Perspective) Validation if identity is done at the time registration	Assumption
9	(Consumer Perspective) Assertion of identity SHALL be provided in the header of the transmission (TLS with system certificate rather than the end user)	Assumption
10	The Adverse event report invokes an investigation by regulation	Assumption
11	For Public Health, the decision to investigate may be more subjective	Assumption
12	HC provider or someone in the care process SHALL make the judgment that an AE occurred	Assumption
13	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	Assumption
14	In some states, the case reporting process may be varied or perhaps regulated (funding, distribution, schedule) differently	Assumption
15	Handling between PH/AE may be different	Assumption
16	An implementation MAY implement an auto-report option	Assumption
17	Workflow management MAY support options for human review; review /comment/modification option before sending	Assumption
18	Reporting MAY support various reporting users: User may be clinician or office staff/hospital staff (e.g. stand-alone infection control applications, clinical registries, etc.)	Assumption
19	Behavior and Policy of PSO is defined by jurisdiction	Assumption
20	Human review is supported: Communication to report outside institution – clinician input as to whether or not to report	Assumption
21	The Harmonization Request description does not necessarily represent the workflow of what actually happens	Assumption
22	Authorizations for capture of supplemental data are defined by jurisdiction	Assumption
23	Augmentation mechanisms require appropriate authorizations: Not just PH agencies, but clinicians that may be reaching out in various ways to capture data that may not have been available in original data source	Assumption



Constraint ID	Constraint	Type of Constraint
24	Lab reporting to PH is included despite the lack of specified interface in scenario 1: State reporting requirements for condition reporting when a lab value results in a required report	Assumption
25	Assume that confirm means that clinician confirms transmission in that point in time. Clinician may be able to gather info from a PHR	Assumption
26	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)	Assumption
27	The entity that needs to receive/file the report is determined by jurisdiction or domain policy agreements	Assumption
28	Trans-border communication expectations/specifications and mutual reporting are specified by policy	Assumption
29	PH does not receive initial notification – all notifications are to be considered	Assumption
30	PH (FDA and AHRQ are also PH agencies in this case along with state/local/tribal PH)	Assumption
31	State-level responses are in place for many state preparedness planning	Assumption
32	Criticality may require no response other than tallying – no investigation typically conducted (e.g. Chlamydia)	Assumption
33	Assumption is made that this is operating in an acceptably secure environment	Assumption
34	There is a triage system; (e.g. there are some conditions that do not trigger a case investigation such as Chlamydia)	Assumption
35	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	Assumption
36	Case definition can be defined and can be provided in an unambiguous format	Assumption
37	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	Assumption
38	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)	Assumption
39	Contact Tracing – applies to both cases, may be the same in some instances and different in others: AE, Devices, Notification via Clinician, Manufacturer	Assumption
40	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 are 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	Assumption
41	Possibly (for AE is likely locally defined process/edge system issue). 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)	Assumption
42	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 of HITSP effort	Assumption
43	Assumption: Needs human intervention for a management plan	Assumption
44	Assumption: Agency-specific, situation-specific determination and is not yet a candidate for automation	Assumption



Constraint ID	Constraint	Type of Constraint
45	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	Assumption
46	Policy considerations apply to exposure notifications and IRB/research authorization	Assumption
47	Jurisdiction or HIE Policy may impose information exchange restrictions for some of these communications if electronic	Assumption
48	Lab report content constraints are defined by policy	Assumption
49	The feed for the results reporting is not necessarily the same as the report to PH	Assumption
50	Currently private sector labs are excluded from this information	Assumption
51	Assumption – for different types of reports, assume report creators will create a sufficiently unique code – assumption that assigning authority would want something unique	Assumption
52	This Use Case assumes the developing presence of electronic systems such as Electronic Health Records (EHRs), Personal Health Records (PHRs), and other local or Web-based solutions supporting consumers and clinicians, while recognizing the issues and obstacles associated with these assumptions. This approach helps promote the development of longer-term efforts. Reference: HITSP Immunizations and Response Management Use Case Requirements, Design and Standards Selection, pg 10, Section 2.2	Assumption
53	(Consumer Perspective) Generic alert data does not contain patient-specific information	Assumption
54	(Consumer Perspective) Both Generic and patient-specific communications – subscribe to patient-specific communications	Assumption
55	(Consumer Perspective) Note that this may not be part of the current workflow	Assumption
56	(Consumer Perspective) FDA may be a PIX or PDQ consumer	Assumption
57	(Consumer Perspective) Anonymization of certain data elements (e.g. description of event or name of drug) would preclude some information flows e.g. Receiver can share the case with manufacturer, but sharing may be limited	Assumption
58	(Consumer Perspective) Patient is the reporter and consent may not allow onward forwarding of patient identity to other entities	Assumption
59	(Consumer Perspective) Consumer may make an anonymous report through a third party system that would mask their identity on their behalf	Assumption
60	(Consumer Perspective) Agency has measures to handle bogus data that may be submitted by the patient	Assumption
61	Support the technical measures to ensure Security and Privacy of consumer/patient health information	Pre-condition
62	Authentication service to authenticate requestors and/or data submissions from various locations	Pre-condition
63	Security and Privacy policies, procedures and practices are commonly implemented to support acceptable levels of consumer/patient security and privacy	Pre-condition
64	Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect	Pre-condition
65	All pre-conditions from the lower level constructs are incorporated	Pre-condition
66	When needed, the patient is uniquely registered with the Patient Identity Cross-Referencing service	Pre-condition
67	Patient Identities (name, demographics etc.) are known and are consistent with policies	Pre-condition
68	There is an existing electronic record from which reports can be generated	Pre-condition



Constraint ID	Constraint	Type of Constraint
69	Pre-condition – (for this scenario, there are rules in place that guide the prioritization and workflow considerations). NOTE: Challenging pre-conditions 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	Pre-condition
70	Scenario 1 – Cases for investigation have been communicated	Pre-condition
71	Immunizations and Response Management Use Case reporting of an adverse event	Pre-condition
72	(Consumer Perspective) Reporting criteria (trigger data and reporting specifications) are available to the consumer through the system (PHR, Third party reporting tool)	Pre-condition
73	(Consumer Perspective) (flow 2) Patient perceives that they have experienced an adverse event	Pre-condition
74	<ul style="list-style-type: none"> Various sources may communicate information which assists public health in determining criteria including: trigger data and reporting specifications: <ul style="list-style-type: none"> – An update to the decision process rules. These may be event-driven or routine updates 	Trigger
75	<ul style="list-style-type: none"> Clinicians may initially notify Public Health of possible PH Cases or Adverse Events through information exchange activities or in an ad-hoc manner. Clinicians 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: <ul style="list-style-type: none"> – Requirement for reporting to public health met – typically either a positive result or a required measured result (e.g. blood lead) 	Trigger
76	<ul style="list-style-type: none"> Possible AEs may be communicated to clinicians who 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 	Trigger
77	<ul style="list-style-type: none"> 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 	Trigger
78	<ul style="list-style-type: none"> Public Health accesses additional information to assist in their investigations. Therefore, additional Information is requested by PH, the request is received by clinicians, 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 	Trigger
79	<ul style="list-style-type: none"> Public Health communicates case and/or patient specific information to clinicians and laboratories via health information exchange activities Public Health decides it needs to communicate information to the clinician community and chooses the appropriate means to do community 	Trigger
80	<ul style="list-style-type: none"> 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 	Trigger



Constraint ID	Constraint	Type of Constraint
81	<ul style="list-style-type: none"> 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 	Trigger
82	<ul style="list-style-type: none"> Based on Public Health information received via health information exchanges, clinicians may manage and treat PH Cases. Specifics are addressed in the 2008 Immunizations and Response Management Detailed Use Case The clinician has patients or patients with contacts that are subject to a Public Health notification 	Trigger
83	(Consumer Perspective) New reporting forms, criteria, guidelines, and other communications are available	Trigger
84	(Consumer Perspective) A report is completed and ready for submission by the consumer	Trigger
85	Appropriate case report information has been communicated and acted upon by Public Health	Post-condition
86	The case investigation has been concluded	Post-condition
87	Informing the PH decision making process	Post-condition
88	(Consumer Perspective) Acknowledgement of the report has been received by the consumer and/or provider	Post-condition
89	The policy of the implementation environment MAY require - Nonrepudiation of Origin for one or more information sources initiating a HITSP Transaction with a payload of <ul style="list-style-type: none"> Case Report Reporting Criteria Unstructured Document 	Assumption
90	The policy of the implementation environment MAY require Entity Identity Assertion	Assumption
91	The policy of the implementation environment MAY require Anonymize for analytical data uses	Assumption
92	The policy of the implementation environment MAY require - Pseudonymization for analytical data uses	Assumption
93	The policy of the implementation environment MAY require Access Control	Assumption
94	The policy of the implementation environment WILL require the - Manage Consent Directives wherever access to IIHI is required	Assumption

3.2.1 CONSTRAINTS ON REQUIRED CAPABILITIES

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



Table 3-6 Additional Constraints on Required Capabilities

Constraint ID	Data Element	Capability	Constraint	Constraint Type	Purpose (Reason for this constraint)
IS11-1	Contact Person: The name of the person to be contacted for further information	HITSP/CAP135	HL7 Name	General	Coded interoperable content
IS11-2	Contact Phone Number: The telephone number for the contact person	HITSP/CAP135	HL7 Phone	General	Coded interoperable content
IS11-3	Report Date: The date that the Case Report is being sent	HITSP/CAP135	HL7 Timestamp	General	Coded interoperable content
IS11-4	Reported Previously: Indication if the information is supplemental to update in event already reported	HITSP/CAP135	Boolean datatype Y/N/U	General	Coded interoperable content
IS11-5	Report sent to FDA: Indication if the report is submitted to the Food and Drug Administration (FDA)	HITSP/CAP135	Boolean datatype Y/N/U	General	Coded interoperable content
IS11-6	Date User Facility/Importer Became Aware of Event: The date the event was first recognized by an observer	HITSP/CAP135	HL7 Timestamp	General	Coded interoperable content
IS11-7	Date report sent: The date the report is submitted	HITSP/CAP135	HL7 Timestamp	General	Coded interoperable content
IS11-8	Date sent to FDA: The date the report was submitted to the FDA – U.S.	HITSP/CAP135	HL7 Timestamp	General	Coded interoperable content
IS11-9	Report Source: The originator of the report	HITSP/CAP135	Where possible, use HL7 Table 0235 – Report source Value C Clinical trial L Literature H Health professional R Regulatory agency D Database/registry/ poison control center N Non-healthcare professional P Patient M Manufacturer/ marketing authority holder E Distributor O Other -	General	Coded interoperable content (may be updated in future IS11 Releases pending additional C80 review)
IS11-10	Reporter Name: The name of the person or facility sending the Case Report	HITSP/CAP135	HL7 Name	General	Coded interoperable content
IS11-11	Occupation of Reporter: The role of the reporter (e.g., physician, nurse, administrator, etc.)	HITSP/CAP135	North American Industry Classification System	General	Coded interoperable content
IS11-12	Telephone: The phone number of the person or facility sending the Case Report	HITSP/CAP135	HL7 Phone	General	Coded interoperable content



Constraint ID	Data Element	Capability	Constraint	Constraint Type	Purpose (Reason for this constraint)
IS11-13	Reporter Email: The email contact information for the reporter	HITSP/CAP135	HL7 email	General	Coded interoperable content
IS11-14	Patient Country: The country of the address of the subject of the case report	HITSP/CAP135	ISO 3166-1	General	Coded interoperable content
IS11-15	Occupation: The occupation of subject of the case report	HITSP/CAP135	North American Industry Classification System	General	Coded interoperable content
IS11-16	Location where Event Occurred: The location of the event – e.g., home, hospital, other facility, etc	HITSP/CAP135	HAI Service Delivery Location – HL7, Home, Work	General	Coded interoperable content
IS11-17	Event Abated after use stopped or dose reduced: Indication that the event resolved/abated after usage stopped or dose reduced	HITSP/CAP135	Boolean datatype Y/N/U	General	Coded interoperable content
IS11-18	Event Reappeared after reintroduction: Indication if the reaction reoccurred after rechallenging the patient to the suspected substance	HITSP/CAP135	Boolean datatype Y/N/U	General	Coded interoperable content
IS11-19	Immunization Services Funding Eligibility: Indication of vaccination source (e.g., special program such as Vaccine for Children, state or provincial programs, etc)	HITSP/CAP135	C80 data element for financial class – 2.2.3.5.5 "Immunization Services Funding Eligibility"	General	Coded interoperable content
IS11-20	Product Diagnosis for Use: The reason the product was initially used	HITSP/CAP135	Shall be coded as specified in HITSP/C80 Section 2.2. 3.1.3 Diagnosis	General	Coded interoperable content
IS11-21	Expiration Date: The expiration date of the product	HITSP/CAP135	HL7 Timestamp	General	Coded interoperable content
IS11-22	Manufacturer name, City and State: Manufacturer of the device	HITSP/CAP135	The State component shall be coded as specified in HITSP/C80 Section 2.2.1.1.1 State	General	Coded interoperable content
IS11-23	Operator of Device: The individual managing the device – (e.g. Health professional, lay user, patient, other)	HITSP/CAP135	North American Industry Classification System	General	Coded interoperable content
IS11-24	If implanted give date: Date of implantation of the device (if implanted)	HITSP/CAP135	HL7 Timestamp	General	Coded interoperable content
IS11-25	If explanted give date: Date device was removed (if removed)	HITSP/CAP135	HL7 Timestamp	General	Coded interoperable content
IS11-26	Is this a single use device that was reprocessed and reused on patient?: Indication if the device is a single-use device that was cleaned/reprocessed and is reused on the affected patient	HITSP/CAP135	Boolean datatype Y/N/U	General	Coded interoperable content



Constraint ID	Data Element	Capability	Constraint	Constraint Type	Purpose (Reason for this constraint)
IS11-27	Administration of Treatment: Was treatment administered?	HITSP/CAP135	Boolean datatype Y/N/U	General	Coded interoperable content
IS11-28	Name and Address of Reprocessor: Name and address of the individual/organization reprocessing the single use device	HITSP/CAP135	The State component shall be coded as specified in HITSP/C80 Section 2.2.1.1.1 State	General	Coded interoperable content
IS11-29	Product available for evaluation: Indication if the product is still available to be evaluated	HITSP/CAP135	Boolean datatype Y/N/U	General	Coded interoperable content
IS11-30	Date product returned to manuf.: If returned to the manufacturer, date of return	HITSP/CAP135	HL7 Timestamp	General	Coded interoperable content
IS11-31	Concomitant Medical Products & Therapy Dates: Other medical products and treatment used proximal to the event	HITSP/CAP135	Medications should reference NDC and RxNorm as identified in HITSP/C80. Vaccines are represented by CVX codes (also identified in HITSP/C80). Non-medication product terms are to be represented with ICSR 3 and therefore, these are a GAP for this release. In the user interface, the user will need to select one or more (n) of a list.	General	Coded interoperable content
IS11-32	AE Following Prior Vaccination: Description of the adverse event	HITSP/CAP135	In HITSP/C80, the VAKP SNOMED Subset identifies adverse events (e.g., hives, difficulty breathing) and is selected for reporting adverse events (from the Allergy/Adverse Event section of a document).	General	Coded interoperable content
IS11-33	Suspect Product Name: Product name	HITSP/CAP135	Medications should reference NDC and RxNorm as identified in HITSP/C80. Vaccines are represented by CVX codes (also identified in HITSP/C80). Non-medication product terms are to be represented with ICSR 3 and therefore, these are a GAP for this release. In the user interface, the user will need to select one or more (n) of a list.	General	Coded interoperable content



Constraint ID	Data Element	Capability	Constraint	Constraint Type	Purpose (Reason for this constraint)
IS11-34	Reporting Laboratory Identifier: Identifier for laboratory that is sending the result. This laboratory may be sending results received back from reference laboratories	HITSP/CAP135	See HITSP/C35	General	Coded interoperable content
IS11-35	Performing Laboratory: Laboratory that produced the test result. This may be a reference laboratory identifier	HITSP/CAP135	See HITSP/C35	General	Coded interoperable content
IS11-36	Ordered Test Code: The identifier code for the requested observation/test/battery	HITSP/CAP135	See HITSP/C35	General	Coded interoperable content
IS11-37	Date of Test: The date that the laboratory test was performed for the subject of the Case Report	HITSP/CAP135	See HITSP/C35	General	Coded interoperable content
IS11-38	Specimen Collection Date: The date that the specimen for the laboratory test was taken from the subject of the Case Report	HITSP/CAP135	See HITSP/C35	General	Coded interoperable content
IS11-39	Source of Specimen: The physical body location from where the specimen for the lab report was taken from the subject	HITSP/CAP135	See HITSP/C35	General	Coded interoperable content
IS11-40	Name of Organization Collecting Specimen: Name of organization collecting specimen which may be different from the organization performing the laboratory analysis	HITSP/CAP135	See HITSP/C35	General	Coded interoperable content
IS11-41	Diagnosis Date/Time: The date that the subject of the Case Report was diagnosed with Condition above	HITSP/CAP135	HL7 Timestamp	General	Coded interoperable content
IS11-42	Previous Event Report Details	HITSP/CAP135	Shall be coded as specified in HITSP/C80 Section 2.2. 3.1.1 Problem	General	Coded interoperable content
IS11-43	Hospitalization: If the subject of the case report was hospitalized	HITSP/CAP135	Boolean datatype Y/N/U	General	Coded interoperable content
IS11-44	Recovered: Did the subject recover from the disease?	HITSP/CAP135	Boolean datatype Y/N/U	General	Coded interoperable content
IS11-45	All	HITSP/CAP126, HITSP/CAP127	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



Constraint ID	Data Element	Capability	Constraint	Constraint Type	Purpose (Reason for this constraint)
IS11-46	N/A	Require Acknowledgement	HITSP/T31, HITSP/TP30 : Need to be sure System binding messenger with sender – needs to bind with an Xform response back to the human	General	Enable Acknowledgement receipt for submission of case report
IS11-47	N/A	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
IS11-48	N/A	HITSP/CAP119 – Communicate Structured Document	Data sent to the shared document repository and recorded in the shared registry used for analytical purposes must be Anonymized and Pseudonymized unless otherwise permitted through legal and out-of-band arrangements	Pre-condition	Required to protect the confidentiality of the patients whose personal health information is sent to the Public Health Information System such that the patients can be re-identified as needed to manage public health threats
IS11-49	N/A	HITSP/CAP119 – Communicate Structured Document (Shared Document Resource)/ Query Registry Transaction Stored Query Transaction Retrieve Document Transaction	Support queries and stored queries for documents which do not require a patient id as a query parameter – Support for Multi-patient Query	General	Asserted to enable public health information retrieval support to enable pull of repository data to the Public Health Information System or to ask public health questions of the data
IS11-50	N/A	HITSP/CAP119 – Communicate Structured Document (Query Registry)	HITSP/TP30 – Manage Consent Directives should be referenced to record the OID of the authorization policy under which the patient data are disclosed to the authorized public health authority	Post-condition	Asserted to record authorized disclosure in compliance with HIPAA



Constraint ID	Data Element	Capability	Constraint	Constraint Type	Purpose (Reason for this constraint)
IS11-51	N/A	HITSP/CAP119 – Communicate Structured Document (Provide and Register)	HITSP/TP30 – Manage Consent Directives should be referenced to record the OID of the authorization policy under which the patient data are disclosed to the authorized public health authority	Pre-condition	Asserted to record authorized disclosure to public health authority in audit logs
IS11-52	N/A	HITSP/CAP119 – Communicate Structured Document	HITSP/T15 should be constrained to record the OID of the authorization policy under which the patient data are disclosed to the authorized public health authority	Post-condition	Asserted to record authorized disclosure to public health authority in audit logs
IS11-53	NA	HITSP/CAP119 – Communicate Structured Document (Uniquely identify a Patient across enterprises)	Constrain to return single value for pseudonymization steps	General	In order to link pseudo identifiers across entities
IS11-54	XSDDocumentEntry.eventCodeList	HITSP/CAP119 – Communicate Structured Document (Provide and Register)	The metadata element should be required when there is a known condition as required by or of interest to public health authorities, and must contain a value from a controlled vocabulary describing the reportable condition.	Pre-condition	The list of codes aims to represent the main clinical acts documented
IS11-55	XSDDocumentEntry 'confidentialityCode'	HITSP/CAP119 – Communicate Structured Document (Provide and Register)	Extend the usage to signify when patient information in the document and corresponding metadata has been pseudonymized Attribute: confidentialityCode Optionality: R2 Vocabulary: Need to assign a unique OID and code values to indicate pseudonymization	Pre-condition	This code indicates the level of confidentiality for the corresponding document

In support of public health investigation, Table 3-7 describes the constraints placed on several of the elements of the XSDDocumentEntry object type from HITSP/TP13 Manage Sharing of Documents where the document sharing resource is leveraged for analytical purposes.



Table 3-7 Additional Constraints on XDS Metadata Elements

XDS Metadata Attribute	Optionality	Extended Discussion	Source Type
XDSDocumentEntry.eventCodeList	R ¹	See 3.2.5.1	Coded in Affinity Domain with Transform (CADT)
XDSDocumentEntry.confidentialityCode	R	See 3.2.1.2	Fixed by Affinity Domain (FAD)
XDSDocumentEntry.patientID and XDSSubmissionSet.patientID	R	See 3.2.1.3	Source document Attribute with Transformation (SAT)
XDSDocumentEntry.sourcePatientID and XDSSubmissionSet.sourcePatientID	R	See 3.2.1.4	Source document Attribute with Transformation (SAT)

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

3.2.1.1 XDSDOCUMENTENTRY.EVENTCODELIST

An XDSDocumentEntry.eventCodeList metadata element that contains a value from a controlled vocabulary describing reportable conditions should be required when there is a known condition as required by, or of interest to, public health authorities. Other XDSDocumentEntry.eventCodeList metadata elements may also be present using local codes or other controlled terminology; however, these are outside of the scope of this specification. The eventCodeList could contain, for instance, a value from the Nationally Notifiable Diseases and Other Conditions of Public Health Importance Event Code List published by the Centers for Disease Control and Prevention. See www.cdc.gov for more details.

The vocabulary shall be identified by the OID representing the coding system from which these events are pulled present in the codingScheme data element.

```
<rim:Classification
  classificationScheme="urn:uuid:2c6b8cb7-8b2a-4051-b291-b1ae6a575ef4"
  classifiedObject="theDocument" nodeRepresentation="eventCode">
  <rim:Name>
    <rim:LocalizedString value="eventCodeDisplayName" />
  </rim:Name>
  <rim:Slot name="codingScheme">
    <rim:ValueList>
      <rim:Value>2.16.840.1.114222.4.5.255</rim:Value>
    </rim:ValueList>
  </rim:Slot>
</rim:Classification>
```

The population of this code is not in any way circumventing, defining, or changing state/federal requirements reporting. Vocabulary and reporting compliance need to be validated and audited independent of this specification.

3.2.1.2 XDSDOCUMENTENTRY.CONFIDENTIALITYCODE

The confidentialityCode attribute shall contain the following OID when the submitted document has been pseudonymized according to HITSP/T24 Pseudonymize: 2.16.840.1.113883.3.88.5.2.1

¹ This metadata element is optional in the XDS Provide and Register Transaction, but required for use with the Biosurveillance specifications.



3.2.1.3 XDSDOCUMENTENTRY.PATIENTID AND XDSSUBMISSIONSET.PATIENTID

The XDSDocumentEntry.patientID and XDSSubmissionSet.patientID attributes shall contain either the actual patient identifier used by the XDS registry, or shall contain a pseudonymized identifier generated during the HITSP/T24 Pseudonymize.

3.2.1.4 XDSDOCUMENTENTRY.SOURCEPATIENTID AND XDSSUBMISSIONSET.SOURCEPATIENTID

The XDSDocumentEntry.sourcePatientID and XDSSubmissionSet.sourcePatientID attributes shall contain either the actual patient identifier used by the document source, or shall contain a pseudonymized identifier generated during the HITSP/T24 Pseudonymize.



4.0 CAPABILITY GAPS

Section 4.0 identifies gaps not met by existing Capabilities but needed to achieve the aims of the Harmonization Request for which this Interoperability Specification is written. This includes overlaps in Capabilities as well. The following table details how this section of the document is targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 4-1 Reader's Guide for Section 4.0

Document Section	Section Number	Intended Audience	Information Contained
Section 4.0	4.0 Capability Gaps	Business Analysts Development Team Architects	Gaps specific to Capabilities used as part of this Interoperability Specification are reviewed in this section to determine why specific information exchange requirements may not yet be met or defined. Readers should check this section to track the progress of gap resolution

The following table identifies gaps not met by or overlapping with existing Capabilities as described above.

Table 4-2 Capability Gaps

IER Gap Description	Responsible HITSP Technical Committee	Design Approach	Required Standards Now Unavailable for Constructs	SDO Working on Unavailable Standards	Expected Availability
Standard data requirements for notifiable conditions	Population Perspective Technical Committee	Work with SDOs to create a minimum number of standards for PH case reporting requests and AE reporting requests	Specification Terminology	CSTE HL7 IHE	Some in 2010
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	Population Perspective Technical Committee	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting	Specification Terminology	CSTE HL7 IHE	Pending SDO Evaluation
Facility Identifier, Send Report to: <ul style="list-style-type: none"> Federal Project under way to used DUNS number for companies that import products – global business – Not sufficient for this Use Case – doesn't cover: PH Agency requesting information back PH Clinic – may 	Population Perspective Technical Committee	Pending policy and assigning authority recommendations	Identifier Specification	Assigning Authorities	Pending Policy



IER Gap Description	Responsible HITSP Technical Committee	Design Approach	Required Standards Now Unavailable for Constructs	SDO Working on Unavailable Standards	Expected Availability
<p>not have one, manufacturers won't, food importers – DUNS</p> <ul style="list-style-type: none"> Satellite clinic may not have a separate ID from Hospital <p>May need to be more than one data element to distinguish the concept</p>					
<p>Event Device Problem Code : Not using a structured terminology</p>	Population Perspective Technical Committee	Monitor MedDRA/CDRH discussion to align terminologies; Reconcile structured terminology for device AE reporting. Work with SDOs to update the standards to conform to the data requirements	Terminology	MedDRA/CDRH	Pending SDO evaluation
<p>Type of Reportable Event It should represent the coded adverse event term. Events/incidents for internal reporting (e.g. falls) Reportable events for non-FDA; <ul style="list-style-type: none"> WHO taxonomy Joint Commission list CDC FDA (form) VAERS – vaccine injury CMS Never list Terminology Service opportunity; Broadest list may reflect a GAP Multiple lists reflect OVERLAP It is a vocabulary issue to be addressed with ICSR 3</p>	Population Perspective Technical Committee	Work with SDOs to update the standards to conform to the data requirements	Terminology	WHO ISO/TC215	Pending SDO Evaluation
<p>Type of Follow-Up MedWatch form – follow-up info – corrected, etc – no structured vocabulary</p>	Population Perspective Technical Committee	Work with SDOs to update the standards to conform to the data requirements	Terminology	HL7 ISO/TC215	Pending SDO Evaluation



IER Gap Description	Responsible HITSP Technical Committee	Design Approach	Required Standards Now Unavailable for Constructs	SDO Working on Unavailable Standards	Expected Availability
Type of Remedial Action Not coded today; could be coded depending on type of report (e.g. medical device – refurbished)	Population Perspective Technical Committee	Work with SDOs to update the standards to conform to the data requirements	Terminology	HL7 ISO/TC215	Pending SDO Evaluation
Occupational Risk FactorsGAP for detail– some in, but not all in SNOMED-CT Y/N/U/Not Asked null flavor options	Population Perspective Technical Committee	Work with SDOs to update the standards to conform to the data requirements	Terminology	SNOMED-CT	Pending SDO Evaluation
Contact with confirmed or suspect HBV case – Need contact type coded	Population Perspective Technical Committee	Work with SDOs to update the standards to conform to the data requirements	Terminology	SNOMED-CT	Pending SDO Evaluation
Frequency of direct blood or body fluid exposure Frequent, several times/week, infrequent	Population Perspective Technical Committee	Work with SDOs to update the standards to conform to the data requirements	Terminology	FDA	Pending Evaluation
Concomitant Medical Products & Therapy Dates: Other medical products and treatment used proximal to the event: Non-medication product terms are to be represented with ICSR 3 and therefore, these are a GAP for this release. In the user interface, the user will need to select one or more (n) of a list	Population Perspective Technical Committee	Work with SDOs to update the standards to conform to the data requirements	Terminology	HL7 ISO/TC215	Pending SDO Evaluation
Type of Reporter: The role of the reporter with respect to the patient (e.g., treating or consulting clinician, case manager, etc.)	Population Perspective Technical Committee	Work with SDOs to update the standards to conform to the data requirements	Terminology	HL7 ISO/TC215	Pending SDO Evaluation
Suspect Product Name: Product	Population Perspective	Work with SDOs to update the standards to conform to the data requirements	Terminology	HL7 ISO/TC215	Pending SDO Evaluation



IER Gap Description	Responsible HITSP Technical Committee	Design Approach	Required Standards Now Unavailable for Constructs	SDO Working on Unavailable Standards	Expected Availability
name - Medications should reference NDC and RxNorm as identified in C80. Vaccines are represented by CVX codes (also identified in C80). Non-medication product terms are to be represented with ICSR 3 and therefore, these are a GAP for this release. In the user interface, the user will need to select one or more (n) of a list	Technical Committee	requirements			
Patient Recovered Diagnosis: Final determination of reaction – diagnosis; Captures reported signs and symptoms that have been combined into a succinct diagnosis that captures the patient state at the end of the adverse event	Population Perspective Technical Committee	Recovery terminology will be determined as part of the ICSR 3 effort. Some terms are identified in ICH which will be reviewed for ICSR 3. Some harmonization is also required with Public Health reporting for other uses of the term “recovered”. For now, the vocabulary is a GAP	Terminology	HL7 ISO/TC215	Pending SDO Evaluation
Name of Treatment	Population Perspective Technical Committee	Medications should reference NDC and RxNorm as identified in C80. Vaccines are represented by CVX codes (also identified in C80). Non-medication product terms and actions are to be represented with ICSR 3 and therefore, these are GAPS for this release. In the user interface, the user will need to select one or more (n) of a list	Terminology	HL7 ISO/TC215	Pending SDO Evaluation
Incorporate PH/AE trigger data and reporting specifications. Not sufficient support yet	Population Perspective Technical Committee	HL7 EDCI – standard under ballot in progress	Terminology	HL7	Pending SDO Evaluation
Incorporate AE trigger data and reporting specifications. FDA – forms for	Population Perspective Technical Committee	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting	Terminology	HL7 ISO/TC215	Pending SDO Evaluation



IER Gap Description	Responsible HITSP Technical Committee	Design Approach	Required Standards Now Unavailable for Constructs	SDO Working on Unavailable Standards	Expected Availability
SPL; Form structure is there, but not the logic behind it					
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	Population Perspective Technical Committee	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting	Terminology	LOINC	Pending SDO Evaluation
Communicate case or patient specific information. No Standards for structured Clinical Reports sent from PH to HC Provider	Population Perspective Technical Committee	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting	Specification	HL7 ISO/TC215	Pending SDO Evaluation
Receive specific clinically relevant Public Health information. No Standards for structured Reports sent from PH to Public	Population Perspective Technical Committee	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting	Specification	HL7 ISO/TC215	Pending SDO Evaluation
Send information related to previously reported PH Cases and/or other information may be sent to Public Health. No standards for supplemental information reports	Population Perspective Technical Committee	Work with SDOs to create a minimum number of standards for PH case reporting and AE reporting	Specification	HL7 ISO/TC215	Pending SDO Evaluation
No consolidation of overlapping methods for Case reporting and AE reporting	Population Perspective Technical Committee	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	Terminology	HL7 ISO/TC215	Pending SDO Evaluation



IER Gap Description	Responsible HITSP Technical Committee	Design Approach	Required Standards Now Unavailable for Constructs	SDO Working on Unavailable Standards	Expected Availability
		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			
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	Population Perspective Technical Committee	Refer to 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	Policy	ONC	Pending Evaluation
Vocabularies used across the models are not standardized in HL7	Population Perspective Technical Committee	HL7 is looking to standardized the vocabularies across HL7 internal and external Adopt SDO-defined vocabularies where possible 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 Once SDO harmonization is complete, we should incorporate the resulting work into a HITSP construct to communicate the payload	Terminology	HL7 ISO/TC215	2010
CDISC Anatomical Site List – Overlap SNOMED	Population Perspective Technical Committee	Refer to SDO for Harmonization	Terminology	CDISC SNOMED-CT	Pending SDO Evaluation
Notifiable Disease Condition	Population Perspective	There is an active migration/harmonization to enable	Terminology	ISO ICSR : HL7 ICSR 3	Pending SDO activities



IER Gap Description	Responsible HITSP Technical Committee	Design Approach	Required Standards Now Unavailable for Constructs	SDO Working on Unavailable Standards	Expected Availability
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	Technical Committee	the adoption of the same standards across multiple organizations for Patient Safety		HL7 ICSR 2 ICH-E2B	
States don't necessarily align with the same definition and list of HAls than those required by CDC Over the last decade, difficulty on agreeing on standards for harmonizing adverse event reporting	Population Perspective Technical Committee	Request harmonization of state and federal definitions for HAls from the CSTE HHS/PSOs may become appropriate bodies for managing standardization of reporting for Hospital/Institutional Acquired Infections	Terminology	CSTE, HHS	Pending SDO Evaluation
PH Case Reporting No official standard, but there are numerous attempts to create one See Appendix 6.2 for details	Population Perspective Technical Committee	Standardization workgroup within CSTE – body to adjudication PHCS reporting standards 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 This should be reconciled with the dataset that will inform the development of a construct for communication of the public health case event data Recommend that the SDOs prepare	Terminology	CSTE	Pending SDO Evaluation



IER Gap Description	Responsible HITSP Technical Committee	Design Approach	Required Standards Now Unavailable for Constructs	SDO Working on Unavailable Standards	Expected Availability
		standards for the transmission of this payload. Monitor and contribute to these efforts			
CDISC has started a list of ~300 anatomical sites; Looking for 100 +/-sites (e.g. upper right arm) Overlap possible – HL7 Bodysite/CDISC Want major gross anatomical sites involved with clinical procedures	Population Perspective Technical Committee	Recommend harmonization between CDISC and HL7 (RCRIM, OO referral)	Terminology	CDISC, HL7	Pending SDO Evaluation



5.0 APPENDIX

The following section includes relevant materials referenced throughout this document. The following table details how this section of the document is targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 5-1 Reader's Guide for Section 5.0

Document Section	Section Number	Intended Audience	Information Contained
Section 5.0	5.1 Harmonization Request Traceability	Architects Business Analysts	A complete mapping of information exchange requirements to functional requirements is provided in this section. Readers can trace IER's to underlying Harmonization Request events and actions (in those instances where a Use Case exists) or to functional requirements defined as part of an official standards Harmonization Request

5.1 PROVISIONAL EXCHANGE CONTENT DESCRIPTIONS

The exchange content descriptions answer one or more data requirements, and map to existing or planned HITSP constructs. In this section, any provisional exchange content descriptions identified for IERs that address gaps are described.

Table 5-2 New Exchange Content Data Requirements

Exchange Content Number	Exchange Content Name	Exchange Content Definition	Data Requirements	Qualifier
EC 28	Emergency Encounter Summary	Data from multiple sources (such as physicians, nurses, technologists, etc.) Recording the assessments and care delivered by the ED team in response to an ED visit. It is a summary of the patient's current health status and care tendered in the ED between arrival and ED departure. Includes triage note, nursing note, composite triage and nursing note, and ED physician note	<ul style="list-style-type: none">• PDR50 - Fully Coded Lab Results• PDR 67 - ED Triage Note• ED Nursing Note• Composite ED Triage and ED Nursing Note• ED Physician Note• Prehospital Care Report• EDR (Emergency Department Referral)• Diagnostic Imaging Reports• Consultations – future document type specification• Transfer Summary – future document type specification• Summary of Death – future document type specification	

5.2 PROVISIONAL DATA REQUIREMENTS

In this section, any provisional data requirement descriptions identified for provisional exchange contents listed above are described.



Table 5-3 Data Requirements

Data Requirement Number (DR)	Description	Data
DR08	Unstructured Data: Document that contains simple text such as a note to the patient, about a patient, or a note from the patient (e.g. camp form immunization summary, patient-specific immunization alert, patient listing alert to providers of patients needing vaccination). This document could include an unstructured, presentation preserved format, such as PDF. In the context of this Use Case, an example would be: For TB: need to represent cases identified by a clinician to researchers looking to investigate a particular strain) Metadata may include but is not limited to:	<ul style="list-style-type: none"> • Title • Clinic ID • Date
DR17	Decision support data: Employed to evaluate a given clinical situation to suggest a course of action, or to set up criteria to trigger one or more actions when a clinical event meets those criteria. NOTE: Component Specification Deferred due to standards gaps (see scope and gaps) In general, the data may include, but is not limited to:	<ul style="list-style-type: none"> • Medication reconciliation • Clinical protocols • Administrative protocols (E.g., Insurance) • Diagnosis • Laboratory results <p>Within the Public Health (PH) context, data may include, but is not limited to:</p> <ul style="list-style-type: none"> • Decision support data input • Age range • Sex • Race • Risk Location of the exposure • Date/time of exposure • Type of exposure, • Occupation (e.g. first responders) • Clinical history • Patient Birth Date • Decision support feedback (pending further analysis) • Logic • Contraindications • Policy • Trigger Criteria
DR21	Terminology Data: Used to transform human or computer vocabularies. Data attributes may be specified based upon implementation. Within the context of this Use Case, 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) For example, the Clinician wants to use the vocabulary that supports their workflow. A 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	



Data Requirement Number (DR)	Description	Data
DR24	Case Report Pre-populate Data: Supports a standard set of data, terminology constraints, and associated mapping to EHR elements for pre-population within a Form Filler to optimize data capture from EHR for use in Public Health Case Reporting	<ul style="list-style-type: none"> • Facility/Importer Name • Facility Identifier • Address • Telephone • Contact Person • Contact Phone Number • Responsible Physician/Healthcare provider name • User Facility/Importer Report Number • Type of Report • Report Date • Reported Previously • Report sent to • Report sent to FDA • Date User Facility/Importer Became Aware of Event • Date report sent • Date sent to FDA • Report Source • Reporter Name • Occupation of Reporter • Telephone • Reporter Email • Type of Reporter • Reporter Address (street name, city, state, zip) • Patient Identifier • Patient Name (First, MI, Last) • Patient Alias Name: First, Middle, Last • Date of Birth • Age • Gender • Pregnancy Status • Estimated Deliver Date • Weight • Birth Weight • Number of Siblings • Name of Treatment • Admission Date • Discharge Date • Hospital Name • Death • Patient Address (street name, city, state, zip)



Data Requirement Number (DR)	Description	Data
		<ul style="list-style-type: none"> • Patient County • Patient Country • Race • Ethnicity • Date of Death • Date of Event • Description of Event • Name of Condition • Event Patient Problem Code • Type of Event and/or Issue • Concomitant Medical Product Name • Therapy Dates • Pre-existing clinician diagnosed allergies, birth defects • Current Medications (concomitant meds) • Previous Vaccine Type • Previous Vaccine Manufacturer • Previous Vaccine Lot # • Previous Vaccine Route/Site • Previous Vaccine Date Given • Suspect Product Name • Product Dose • Product Frequency • Product Route Used • Product Therapy Dates • NDC# or Unique ID • Suspect Medical Device Brand Name • Common Device Name • Signs and Symptoms • Symptom/Illness Onset Date/Time • Patient Class • Report Date/Time • Results Status • Resulted Test • Result Unit • Test Interpretation • Test Status • Test Method • Test Result • Diagnosis/Injury Code • Diagnosis Type • Administration of Treatment



Data Requirement Number (DR)	Description	Data
DR25	<p>Case Report Content: Case data of the report to be submitted. For this Use Case, there are multiple reporting types:</p> <ul style="list-style-type: none"> • Biovigilance (blood, organ, and tissue) reporting to include post-marketing surveillance • Drug Safety (AE related to drug) (see tier 2) • Device Safety Report • Drug administration management • Vaccine AE report • Food safety • Reportable disease reports • HAI • Other HC safety reports other than Infection (e.g. falls) (including Sentinel events; all never-events, anything that may become a never-event; AHRQ) <p>Many of the attributes are common across these report types. The data requirements below are listed as 3 subsets: Case data captured universally, data requirements that are specific to public health reporting, and those that are specific to adverse event reports. Report-specific attributes are not identified here, though an example of these can be found in Section 6.2. The complete list of attributes and associated detail is summarized in Section 6.2</p>	<p>Universal data requirements supporting all case report types:</p> <ul style="list-style-type: none"> • Facility/Importer Name • Facility Identifier • Address • Telephone • Contact • Contact Person • Contact Phone Number • Responsible Clinician/Healthcare provider name • User Facility/Importer Report Number • Type of Report • Report Date • Reported Previously • Report Sent To • Date User Facility/Importer Became Aware of Event • Date Report Sent • Date Sent to Manufacturer • Report Source • Reporter Name • Occupation of Reporter • Telephone • Reporter Email • Report Date/Time • Type of Reporter • Reporter Address (street name, city, state, zip) • Patient Identifier • Patient Name (First, MI, Last) • Patient Alias Name: First, Middle, Last • Date of Birth • Age • Physiological Sex • Pregnancy Status • Birth Weight • Patient Address (street name, city, state, zip)



Data Requirement Number (DR)	Description	Data
		<ul style="list-style-type: none"> • Patient Telephone • Patient County • Patient Country • Race • Ethnicity • Date of Death • Date of Event • Description of Event • Name of Condition • Signs and Symptoms • Symptom/Illness Onset Date/Time • Reporting Laboratory Identifier • Performing Laboratory • Results Status • Ordered Test Code • Resulted Test • Result Unit • Test Interpretation • Test Status • Date of Test • Test Method • Test Result • Specimen Collection Date • Source of Specimen • Name of Organization Collecting Specimen • Diagnosis Date/Time • Administration of Treatment • Date of Admin of Treatment • Name of Treatment • Hospitalization • Admission Date • Discharge Date • Recovered
		<p>Data requirements for Public Health reporting:</p> <ul style="list-style-type: none"> • Estimated Deliver Date • Number of Siblings • Occupation <p>Patient Country of Birth:</p> <ul style="list-style-type: none"> • Patient Country of Origin • Time arrived in the U.S. • Hospital Name • Death



Data Requirement Number (DR)	Description	Data
		<p>Data requirements for Adverse Event Reports:</p> <ul style="list-style-type: none"> • Report Sent to FDA • Date sent to FDA • Weight • Event Patient Problem Code • Event Device Problem Code • Type of Reportable Event • Type of Event and/or Issue • Approximate Age of Device • Outcome Attributed to AE • Patient Recovered • Diagnosis • Location where Event Occurred • Adverse Event Terms • Event Abated after use stopped or dose reduced? • Event Reappeared after reintroduction • Concomitant Medical Product Name • Therapy Dates • Pre-existing clinician diagnosed allergies, birth defects. Medical conditions • Current Medications (concomitant meds) • Previous Vaccine Type • Previous Vaccine Manufacturer • Previous Vaccine Lot # • Previous Vaccine Route/Site • Vaccine # Previous Doses • Previous Vaccine Date Given • AE Following Prior Vaccination • Immunization Services Funding Eligibility • Suspect Product Name • Product Dose



Data Requirement Number (DR)	Description	Data
		<ul style="list-style-type: none"> • Product Frequency • Product Route Used • Product Therapy Dates • Product Diagnosis for Use • Product Lot # • Expiration Date • NDC# or Unique ID • 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 • Patient Class • Diagnosis/Injury Code • Diagnosis Type • Previous Event Report Details • Reason for Non-Evaluation • Type of Follow-Up • Type of Remedial Action
DR26	Reporting Criteria Content - Structured content – machine processable. Data requirements pending further analysis and SDO development. (see GAPS)	
DR59	Generic Alert Data – Public Health: A non-patient identifiable alert (message or presentation preserving document) sent to an identified set of recipients. This may be used to communicate unstructured reporting requirements, and alerts. Data requirements include but are not limited to:	<ul style="list-style-type: none"> • Target population <ul style="list-style-type: none"> – A descriptive directive • Severity <ul style="list-style-type: none"> – Source/Author

5.3 HARMONIZATION REQUEST TRACEABILITY

This section describes the traceability to the Harmonization Request for which this Interoperability Specification is written. The traceability may be described in terms of events and actions, or in terms of functional requirements.

This table relates the events of a Harmonization Request to the actions taken and information exchanges required.



Table 5-4 Harmonization Request Events and Actions Analysis Table

Event	Action	Information Exchange Requirement(s) (includes security requirements)
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	IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
		IER7 Query/Retrieve DR8 Unstructured Data EHR to PH
		IER8 Send Notification of Document Availability PH to EHR
		IER4 Send DR59 Generic Alert Data – Public Health PH to EHR
		IER6 Send DR8 Unstructured Data PH to EHR
	7.1.1.2 Action: Incorporate PH trigger data and reporting specifications	IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
		IER4 Send DR59 Generic Alert Data – Public Health PH to EHR
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
		IER6 Send DR8 Unstructured Data PH to EHR
		IER7 Query/Retrieve DR8 Unstructured Data EHR to PH
	7.1.1.3 Action: Incorporate AE trigger data and reporting specifications	IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
		IER4 Send DR59 Generic Alert Data – Public Health PH EHR
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
		IER6 Send DR8 Unstructured Data PH to EHR
		IER7 Query/Retrieve DR8 Unstructured Data EHR to PH
		IER9 Query/Retrieve EC66 Value Set EHR to HIE



Event	Action	Information Exchange Requirement(s) (includes security requirements)
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
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	IER9 Query/Retrieve EC66 Value Set EHR HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
	7.1.2.2 Action: Identify, view, evaluate, and triage possible PH Cases and AEs	IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
7.1.3 Event: View possible reports	7.1.3.1 Action: Select possible PH Cases or AEs	No Interoperability requirement – edge system function
	7.1.3.2 Action: View report for selected possible PH Cases or AEs	IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
7.1.4 Event: May perform initial notification	7.1.4.1 Action: (If Applicable) Communicate initial notification to Public Health	IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER11 Send DR25 Case Report Content EHR to PH
	7.1.4.2 Action: (If Applicable) Communicate initial notification to Manufacturers	IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR Manufacturer
		IER11 Send DR25 Case Report Content EHR Manufacturer
		IER12 Send EC87 Anonymous Case Report EHR Manufacturer
		IER13 Query/Retrieve EC24 Pseudoidentity EHR to HIE
		IER14 Send EC62 (Report Confirmation) Manufacturer EHR
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	IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
	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	IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER11 Send DR25 Case Report Content EHR to PH
	7.1.5.3 Action: Send PH Case Reports or AE Reports which	IER15 Send EC62 (Report Confirmation) PH to EHR
		IER9 Query/Retrieve EC66 Value Set EHR to HIE



Event	Action	Information Exchange Requirement(s) (includes security requirements)
	do not meet all reporting criteria to a completion queue. Reporting criteria include: Trigger data and reporting specifications	IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH IER15 Send EC62 (Report Confirmation) PH to EHR
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	IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
	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	IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER16 Query Existing Data DR25 EHR to EHR
		IER17 Query/Retrieve DR25 EHR to HIE
		IER18 Provide/Register EC30 EHR to HIE
		IER19 Query/Retrieve EC30 PH to HIE
		IER9 Query/Retrieve EC66 Value Set EHR to HIE
	7.1.6.3 Action: Update PH Case Report or AE Report	IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER16 Query Existing Data DR25 EHR to EHR
		IER17 Query/Retrieve DR25 EHR to HIE
		IER18 Provide/Register EC30 EHR to HIE
		IER19 Query/Retrieve EC30 PH to HIE
7.1.7 Event: Finalize and Send Report	7.1.7.1 Action: Confirm PH Case Report or AE Report	IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER11 Send DR25 Case Report Content EHR to PH
		IER15 Send EC62 (Report Confirmation) PH to EHR
	7.1.7.2 Action: Transmit confirmed PH Case Reports or AE Reports to public health	IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER11 Send DR25 Case Report Content EHR to PH
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	IER15 Send EC62 (Report Confirmation) PH to EHR
		IER9 Query/Retrieve EC66 Value Set EHR to HIE
	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	IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER9 Query/Retrieve EC66 Value Set EHR HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER16 Query Existing Data DR25 EHR to EHR
		IER17 Query/Retrieve DR25 EHR to HIE
		IER18 Provide/Register EC30 EHR to HIE
		IER19 Query/Retrieve EC30 PH to HIE



Event	Action	Information Exchange Requirement(s) (includes security requirements)
	7.1.6.3 Action: Update PH Case Report or AE Report	IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER16 Query Existing Data DR25 EHR to EHR
		IER17 Query/Retrieve DR25 EHR to HIE
		IER11 Send DR25 Case Report Content EHR to PH
		IER15 Send EC62 (Report Confirmation) PH to EHR
		IER18 Provide/Register EC30 EHR to HIE
		IER19 Query/Retrieve EC30 PH to HIE
8.2.1 Event: Send Additional Information	8.2.1.1 Action: Receive request for additional information from Public Health	IER15 Send EC62 (Request for Additional Information) PH to EHR
		IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
		IER4 Send DR59 Generic Alert Data – Public Health PH to EHR
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
		IER6 Send DR8 Unstructured Data PH to EHR
		IER7 Query/Retrieve DR8 Unstructured Data EHR to PH
		IER8 Send Notification of Document Availability PH EHR
	8.2.1.2 Action: Send information to public health related to previously reported PH Cases and/or other information	IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER11 Send DR25 Case Report Content EHR to PH
		IER15 Send EC62 (Report Confirmation) PH to EHR
		IER18 Provide/Register EC30 EHR to HIE
		IER19 Query/Retrieve EC30 PH to HIE
8.2.2 Event: Receive Public Health Information	8.2.2.1 Action: Receive case or patient specific information	IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER11 Send DR25 Case Report Content EHR to PH
		IER15 Send EC62 (Report Confirmation) PH to EHR
		IER18 Provide/Register EC30 EHR to HIE
		IER19 Query/Retrieve EC30 PH to HIE
	8.2.2.2 Action: Receive specific clinically relevant Public Health information	IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH



Event	Action	Information Exchange Requirement(s) (includes security requirements)
		IER11 Send DR25 Case Report Content EHR to PH
		IER15 Send EC62 (Report Confirmation) PH to EHR
		IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
		IER4 Send DR59 Generic Alert Data – Public Health PH to EHR
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
		IER6 Send DR8 Unstructured Data PH to EHR
		IER7 Query/Retrieve DR8 Unstructured Data EHR to PH
		IER8 Send Notification of Document Availability PH to EHR
	8.2.2.3 Action: Receive Publicly Available Information	IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
		IER4 Send DR59 Generic Alert Data – Public Health PH to EHR
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
		IER6 Send DR8 Unstructured Data PH to EHR
		IER7 Query/Retrieve DR8 Unstructured Data EHR to PH
		IER8 Send Notification of Document Availability PH to EHR
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
8.3.1 Event: Send information/report	8.3.1.1 Action: Incorporate and utilize Public Health reporting specifications	NOTE: Not currently done electronically IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
	8.3.1.2 Action: Identify and send information/report	IER20 Send EC36 LAB to PH
		IER21 Publish/Register EC37 LAB to HIE
		IER22 Send EC37 LAB to PH
		IER23 Query/Retrieve EC37 PH to HIE



Event	Action	Information Exchange Requirement(s) (includes security requirements)
	8.3.1.2a Alternate Action: Send information related to previously reported PH Cases and/or other information may be sent to Public Health	IER20 Send EC36 LAB to PH NOTE: May be a non-data request (e.g. send isolate)
		IER21 Publish/Register EC37 LAB to HIE
		IER22 Send EC37 LAB to PH
		IER23 Query/Retrieve EC37 PH to HIE
8.3.2 Event: Receive Public Health Information	8.3.2.1 Action: Receive specimen status information or patient specific information	IER6 Send DR8 Unstructured Data PH to EHR
		IER7 Query/Retrieve DR8 Unstructured Data EHR to PH
		IER8 Send Notification of Document Availability PH to EHR
	8.3.2.1a Alternate Action: Receive specific clinically relevant public health information or publicly available information	IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR PH
		IER4 Send DR59 Generic Alert Data – Public Health PH to EHR
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
7.2.1 Event: Determine and communicate reporting criteria including: trigger data and reporting specifications	7.2.1.1 Action: Determine PH Case Criteria	IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
		IER4 Send DR59 Generic Alert Data – Public Health PH to EHR
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
		IER6 Send DR8 Unstructured Data PH to EHR
		IER7 Query/Retrieve DR8 Unstructured Data EHR to PH
		IER8 Send Notification of Document Availability PH to EHR
		IER15 Send EC62 (Report Confirmation) PH to EHR
	7.2.1.2 Action: Determine PH trigger data and reporting specifications	IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
		IER4 Send DR59 Generic Alert Data – Public Health PH to EHR



Event	Action	Information Exchange Requirement(s) (includes security requirements)
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
		IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
	7.2.1.3 Action: Determine AE trigger data and reporting specifications	IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
		IER4 Send DR59 Generic Alert Data – Public Health PH to EHR
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
		IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
	7.2.1.4 Action: Communicate reporting criteria for both PH Cases and AEs. Reporting criteria include: trigger data and reporting specifications	IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
		IER4 Send DR59 Generic Alert Data – Public Health PH to EHR
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
		IER9 Query/Retrieve EC66 Value Set EHR to HIE
7.2.2 Event: May receive initial notification	7.2.2.1 Action: (If Applicable) Receive initial notification from Providers	IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER11 Send DR25 Case Report Content EHR to PH
7.2.3 Event: Receive report and determine need for further action	7.2.2.2 Action: (If Applicable) Respond to initial notifications requiring immediate attention	No Interoperability Requirement. NOTE: Depends upon information received in 7.2.2.1
	7.2.3.1 Action: Public Health receives and evaluates reports	No Interoperability Requirement. NOTE: Depends upon information received in 7.2.2.1
	7.2.3.2 Action: Public Health determines need for further action	No Interoperability Requirement
7.2.3 Event: Receive report and determine need for further	7.2.3.1 Action: Public Health receives and evaluates reports	No Interoperability Requirement. NOTE: Depends upon information received in 7.2.2.1



Event	Action	Information Exchange Requirement(s) (includes security requirements)
action	7.2.3.2 Action: Public Health determines need for further action	NOTE: No Interoperability Requirement;
8.1.1 Event: Access additional information and investigate	8.1.1.1 Action: Request information from submitters of reports/information	IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER11 Send DR25 Case Report Content EHR to PH
		IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
		IER4 Send DR59 Generic Alert Data – Public Health PH to EHR
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
		IER6 Send DR8 Unstructured Data PH to EHR
		IER7 Query/Retrieve DR8 Unstructured Data EHR to PH
		IER8 Send Notification of Document Availability PH to EHR
	8.1.1.1a Alternate Action: Request information by utilizing information exchanges. Public Health may query for existing public health reportable data	IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER11 Send DR25 Case Report Content EHR to PH
		IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
		IER4 Send DR59 Generic Alert Data – Public Health PH to EHR
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
		IER6 Send DR8 Unstructured Data PH to EHR
		IER7 Query/Retrieve DR8 Unstructured Data EHR to PH
		IER8 Send Notification of Document Availability PH to EHR
	8.1.1.2 Action: Receive additional information to assist in investigation activities	IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER11 Send DR25 Case Report Content EHR to PH
	8.1.1.3 Action: Perform investigation activities	No Interoperability Requirement



Event	Action	Information Exchange Requirement(s) (includes security requirements)
8.1.2 Event: Determine Case Status	8.1.2.1 Action: Evaluate and classify PH Cases	IER2 Send DR17 Decision Support Data Content PH to PH
		IER24 Query/Retrieve DR17 Decision Support Data Content PH to PH
	8.1.2.2 Action: Determine status of PH Case reports	IER2 Send DR17 Decision Support Data Content PH to PH
		IER24 Query/Retrieve DR17 Decision Support Data Content PH to PH
		IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER11 Send DR25 Case Report Content EHR to PH
8.1.3 Event: Perform Contact Tracing	8.1.3.1 Action: Identify those who may have come in contact.	IER2 Send DR17 Decision Support Data Content PH to PH
		IER24 Query/Retrieve DR17 Decision Support Data Content PH to PH
		IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER11 Send DR25 Case Report Content EHR to PH
	8.1.3.2 Action: Identify additional possible PH Cases	No Interoperability Requirement
8.1.4 Event: Assess Impact and Determine Management Plan	8.1.4.1 Action: Assess and understand impact	No Interoperability Requirement NOTE: CDS – is a local consideration
	8.1.4.2 Action: Determine management plan	No Interoperability Requirement
8.1.5 Event: Communicate public health information	8.1.5.1 Action: Communicate case or patient specific information	IER6 Send DR8 Unstructured Data PH to EHR
		IER7 Query/Retrieve DR8 Unstructured Data EHR to PH
		IER8 Send Notification of Document Availability PH to EHR
		IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
		IER4 Send DR59 Generic Alert Data – Public Health PH to EHR
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
		IER6 Send DR8 Unstructured Data PH to EHR
		IER7 Query/Retrieve DR8 Unstructured Data EHR to PH
		IER8 Send Notification of Document Availability PH to EHR



Event	Action	Information Exchange Requirement(s) (includes security requirements)
	8.1.5.2 Action: Communicate specific clinically relevant Public Health information	IER13 Query/Retrieve EC24 Pseudoidentity PH to HIE (re-identify)
		IER9 Query/Retrieve EC66 Value Set EHR to HIE
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER11 Send DR25 Case Report Content EHR to PH
		IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
		IER4 Send DR59 Generic Alert Data – Public Health PH to EHR
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
		IER6 Send DR8 Unstructured Data PH to EHR
		IER7 Query/Retrieve DR8 Unstructured Data EHR to PH
		IER8 Send Notification of Document Availability PH to EHR
		IER18 Provide/Register EC30 EHR to HIE
		IER19 Query/Retrieve EC30 PH to HIE
		IER13 Query/Retrieve EC24 Pseudoidentity EHR to HIE
		IER12 Send EC87 Anonymous Case Report EHR Manufacturer
	8.1.5.3 Action: Communicate publicly available information	IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
		IER4 Send DR59 Generic Alert Data – Public Health PH to EHR
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
		IER6 Send DR8 Unstructured Data PH to EHR
		IER7 Query/Retrieve DR8 Unstructured Data EHR to PH
		IER13 Query/Retrieve EC24 Pseudoidentity EHR to HIE
		IER12 Send EC87 Anonymous Case Report EHR Manufacturer
		IER18 Provide/Register EC30 EHR to HIE
		IER19 Query/Retrieve EC30 PH to HIE



Event	Action	Information Exchange Requirement(s) (includes security requirements)
	9.1 Data provisioning – including support for secondary uses – data provisioning and distribution of data transmission parameters	IER9 Query/Retrieve EC66 Value Set EHR to HIE IER28
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PH
		IER12 Send EC87 Anonymous Case Report EHR Manufacturer
		IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
		IER4 Send DR59 Generic Alert Data – Public Health PH to EHR
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
		IER6 Send DR8 Unstructured Data PH to EHR
		IER7 Query/Retrieve DR8 Unstructured Data EHR to PH
		IER8 Send Notification of Document Availability PH to EHR
		IER13 Query/Retrieve EC24 Pseudoidentity EHR to HIE
		IER11 Send DR25 Case Report Content EHR to PH
	9.2 Data pseudonymization and re-identification as well as HIPAA de-identification	IER13 Query/Retrieve EC24 Pseudoidentity EHR to HIE
		IER12 Send EC87 Anonymous Case Report EHR Manufacturer
	9.3 Data delivery – including secure data delivery, data receipt and confirmation of delivery to EHRs, personally controlled health records, other systems and networks	IER1 Query/Retrieve Communication Recipients PH to HIE
		IER2 Send DR17 Decision Support Data Content PH to EHR
		IER3 Query/Retrieve DR17 Decision Support Data Content EHR to PH
		IER4 Send DR59 Generic Alert Data – Public Health PH to EHR
		IER5 Query/Retrieve DR59 Generic Alert Data – Public Health EHR to PH
		IER6 Send DR8 Unstructured Data PH to EHR
		IER7 Query/Retrieve DR8 Unstructured Data EHR to PH
		IER8 Send Notification of Document Availability PH to EHR
		IER11 Send DR25 Case Report Content EHR to PH
		IER15 Send EC62 (Report Confirmation) PH to EH
		IER9 Query/Retrieve EC66 Value Set EHR to HIE



Event	Action	Information Exchange Requirement(s) (includes security requirements)
		IER10 Pre-Populate Form EC76 Case Report Pre-Populate EHR to PHR
		IER18 Provide/Register EC30 EHR to HIE
		IER19 Query/Retrieve EC30 PH to HIE
Consumer perspective		
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	IER25 Subscribe EC62 (Generic Alert) PHR to PH
		IER26 Query/Retrieve DR17 Decision Support Data Content PHR to PH
		IER27 Query/Retrieve DR59 Generic Alert Data – Public Health PHR to PH
		IER28 Query/Retrieve DR8 Unstructured Data PHR to PH
		IER30 Query/Retrieve EC62 (Report Confirmation) PHR to HIE
	7.1.1.2 Action: Incorporate PH trigger data and reporting specifications	IER25 Subscribe EC62 (Generic Alert) PHR to PH
		IER26 Query/Retrieve DR17 Decision Support Data Content PHR to PH
		IER27 Query/Retrieve DR59 Generic Alert Data – Public Health PHR to PH
		IER28 Query/Retrieve DR8 Unstructured Data PHR to PH
		IER30 Query/Retrieve EC62 (Report Confirmation) PHR to HIE
	7.1.1.3 Action: Incorporate AE trigger data and reporting specifications	IER25 Subscribe EC62 (Generic Alert) PHR to PH
		IER26 Query/Retrieve DR17 Decision Support Data Content PHR to PH
		IER27 Query/Retrieve DR59 Generic Alert Data – Public Health PHR to PH
		IER28 Query/Retrieve DR8 Unstructured Data PHR to PH
		IER30 Query/Retrieve EC62 (Report Confirmation) PHR to HIE
7.1.2 Event: Monitor PHR data and identify possible PH Cases or AEs	7.1.2.1 Action: Monitor PHR data for information matching inclusion/exclusion factors	No Interoperability Requirement – edge system function
		Not Interoperability Requirement – edge system function
	7.1.2.2 Action: Identify, view, evaluate, and triage possible PH Cases and AEs	No Interoperability Requirement – edge system function
7.1.3 Event: View possible reports	7.1.3.1 Action: Select possible PH Cases or AEs	No Interoperability Requirement – edge system function
		IER31 Query/Retrieve EC66 Value Set PHR to HIE
		IER32 Pre-Populate Form EC76 Case Report Pre-Populate PHR to PH
	7.1.3.2 Action: View report for selected possible PH Cases or AEs	IER33 Send DR25 Case Report Content PHR to PH
7.1.4 Event: Perform Notification		
7.1.4 Event: Perform	7.1.4.1 Action: (If Applicable) Communicate initial	IER31 Query/Retrieve EC66 Value Set PHR to HIE



Event	Action	Information Exchange Requirement(s) (includes security requirements)
Notification	notification to Public Health	IER32 Pre-Populate Form EC76 Case Report Pre-Populate PHR to PH
		IER33 Send DR25 Case Report Content PHR to PH
	7.1.4.2 Action: (If Applicable) Communicate initial notification to Manufacturers	IER31 Query/Retrieve EC66 Value Set PHR to HIE
		IER32 Pre-Populate Form EC76 Case Report Pre-Populate PHR to PH
		IER33 Send DR25 Case Report Content PHR to PH
		IER34 Provide/Register EC30 PHR to HIE
		IER19 Query/Retrieve EC30 PHR to HIE
		IER36 Send EC87 Anonymous Case Report PHR Manufacturer
		IER35 Query/Retrieve EC24 Pseudoidentity PHR to HIE
		IER25 Subscribe EC62 (Generic Alert) PHR to PH
Public Health Case Reporting: Public Health – Reporting from PHRs		
7.2.1 Event: Determine and communicate reporting criteria including: trigger data and reporting specifications	7.2.1.1 Action: Determine PH Case Criteria	IER25 Subscribe EC62 (Generic Alert) PHR to PH
		IER26 Query/Retrieve DR17 Decision Support Data Content PHR to PH
		IER27 Query/Retrieve DR59 Generic Alert Data – Public Health PHR to PH
		IER28 Query/Retrieve DR8 Unstructured Data PHR to PH
		IER29 Subscribe EC62 (Report Confirmation) PHR to PH
		IER30 Query/Retrieve EC62 (Report Confirmation) PHR to HIE
	7.2.1.2 Action: Determine PH trigger data and reporting specifications	IER25 Subscribe EC62 (Generic Alert) PHR to PH
		IER26 Query/Retrieve DR17 Decision Support Data Content PHR to PH
		IER27 Query/Retrieve DR59 Generic Alert Data – Public Health PHR to PH
		IER28 Query/Retrieve DR8 Unstructured Data PHR to PH
	7.2.1.3 Action: Determine AE trigger data and reporting specifications	IER25 Subscribe EC62 (Generic Alert) PHR to PH
		IER26 Query/Retrieve DR17 Decision Support Data Content PHR to PH
		IER27 Query/Retrieve DR59 Generic Alert Data – Public Health PHR to PH
		IER28 Query/Retrieve DR8 Unstructured Data PHR to PH
	7.2.1.4 Action: Communicate reporting criteria for both PH Cases and AEs. Reporting criteria include: trigger data and reporting specifications	IER29 Subscribe EC62 (Report Confirmation) PHR to PH
		IER30 Query/Retrieve EC62 (Report Confirmation) PHR to HIE
		IER25 Subscribe EC62 (Generic Alert) PHR to PH
		IER26 Query/Retrieve DR17 Decision Support Data Content PHR to PH



Event	Action	Information Exchange Requirement(s) (includes security requirements)
7.2.2 Event: May receive initial notification	7.2.2.1 Action: (If Applicable) Receive initial notification from PHR – or agent	IER27 Query/Retrieve DR59 Generic Alert Data – Public Health PHR to PH
		IER29 Query/Retrieve DR8 Unstructured Data PHR to PH
		IER25 Subscribe EC62 (Generic Alert) PHR to PH
		IER26 Query/Retrieve DR17 Decision Support Data Content PHR to PH
	7.2.2.2 Action: (If Applicable) Respond to initial notifications requiring immediate attention	IER27 Query/Retrieve DR59 Generic Alert Data – Public Health PHR to PH
		IER28 Query/Retrieve DR8 Unstructured Data PHR to PH
		IER25 Subscribe EC62 (Generic Alert) PHR to PH
		IER26 Query/Retrieve DR17 Decision Support Data Content PHR to PH
		IER27 Query/Retrieve DR59 Generic Alert Data – Public Health PHR to PH
		IER28 Query/Retrieve DR8 Unstructured Data PHR to PH
Public Health Case Reporting: Information Exchange – Reporting from PHRs		
	9.1 Data provisioning – including support for secondary uses – data provisioning and distribution of data transmission parameters	IER31 Query/Retrieve EC66 Value Set PHR to HIE
		IER32 Pre-Populate Form EC76 Case Report Pre-Populate PHR to PH
		IER35 Query/Retrieve EC24 Pseudoidentity PHR to HIE
		IER36 Send EC87 Anonymous Case Report PHR Manufacturer
		IER25 Subscribe EC62 (Generic Alert) PHR to PH
		IER26 Query/Retrieve DR17 Decision Support Data Content PHR to PH
		IER27 Query/Retrieve DR59 Generic Alert Data – Public Health PHR to PH
		IER28 Query/Retrieve DR8 Unstructured Data PHR to PH
		IER29 Subscribe EC62 (Report Confirmation) PHR to PH
		IER30 Query/Retrieve EC62 (Report Confirmation) PHR to HIE
	9.2 Data pseudonymization and re-identification as well as HIPAA de-identification	IER35 Query/Retrieve EC24 Pseudoidentity PHR to HIE
		IER36 Send EC87 Anonymous Case Report PHR Manufacturer
	9.3 Data delivery – including secure data delivery, data receipt and confirmation of delivery to EHRs, personally controlled health records, other systems and networks	IER25 Subscribe EC62 (Generic Alert) PHR to PH
		IER26 Query/Retrieve DR17 Decision Support Data Content PHR to PH



Event	Action	Information Exchange Requirement(s) (includes security requirements)
		IER27 Query/Retrieve DR59 Generic Alert Data – Public Health PHR to PH
		IER28 Query/Retrieve DR8 Unstructured Data PHR to PH
		IER29 Subscribe EC62 (Report Confirmation) PHR to PH
		IER30 Query/Retrieve EC62 (Report Confirmation) PHR to HIE
		IER31 Query/Retrieve EC66 Value Set PHR to HIE
		IER32 Pre-Populate Form EC76 Case Report Pre-Populate PHR to PH

5.4 PUBLIC HEALTH CASE REPORTING DATA ELEMENTS

In fulfillment of data and information requirements for case reporting, the following provisional data dictionary was generated HITSP 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 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 AHRQ-USHIK and can be found in the Appendix in Section 5.0 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, HITSP 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) 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

Table 5-5 Data Elements Cross Reference for High-level Cross-Cutting Tables

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 AHRO-USHIK for the selected standard for the data element. NOTE: many of the Public Health-specific terms, defined or not in this table, are informative only in this document and will be maintained by CSTE
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 C=Consumer Adverse Event Reporting 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 5-6 Facility Data Elements

Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Facility Identifier	Unique facility identifier	Numeric	AE PH	CMS IDs	O	Federal Project under way to use DUNS number for companies that import products – global business – Not sufficient for this Use Case – doesn't cover: PH Agency requesting information back PH Clinic – May not have one, manufacturers won't, food importers – DUNS Satellite clinic may not have a separate ID from Hospital May need to be more than one data element to distinguish the concept
Facility/Importer Name	The name of the facility that the healthcare provider diagnosed the subject of the Case Report	String	AE PH		C	Manufacturer/processor organization placing the report; For PH, one of the minimum number of variables requested for initial case reporting

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

Table 5-7 Facility Data Elements: Address

Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Address	The address (Street, City, State, Zip Code) of the person or facility that diagnosed the subject of the Case Report	XAD-106	AE PH	FIPS for city/state	R	The electronic transmission of the minimum data set requests either facility/clinician 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	XTN-40	AE PH	HL7 Phone	O PH: R	The electronic transmission of the minimum data set requests either facility/clinician telephone or address, preferably both, to be report. For PH, one of the minimum number of variables requested for initial Case Reporting

Optionality = "R" for Required, "R2" for Required if Known or "O" for Optional, or "C" for Conditional

Table 5-8 Facility Data Elements: Contact

Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Contact Person	The name of the person to be contacted for further information		AE PH	HL7	O	
Contact Phone Number	The telephone number for the contact person	XTN-40	AE PH	HL7	O PH: R	The electronic transmission of the minimum data set requests either facility/clinician telephone or address, preferably both, to be reported 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
Responsible clinician/ Healthcare provider name	The name of the person that diagnosed the subject		C AE PH	HL7	C:RE O PH: R	For Consumer, may be Primary Care Physician, Clinician, Pharmacist, Dispenser For PH, one of the minimum number of variables requested for initial Case Reporting

Optionality = "R" for Required, "R2" for Required if Known or "O" for Optional, or "C" for Conditional

Table 5-9 Report Data Elements

Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Date Report Sent	The date the report is submitted	Timestamp	AE PH	HL7 Timestamp	O PH:R	For PH, one of the minimum number of variables requested for initial Case Reporting
Date Sent to FDA	The date the report was submitted to the FDA – U.S.	Timestamp	AE	HL7 Timestamp	O	
Date Sent to Manufacturer (Change to date report Sent)	Date report sent to manufacturer of suspected product	Timestamp	AE PH	HL7 Timestamp	O	
Date User Facility/Importer Became Aware of Event	The date the event was first recognized by an observer	Timestamp	AE PH	HL7 Timestamp	O PH:R	For PH, one of the minimum number of variables requested for initial Case Reporting
Report Date	The date that the Case Report is being sent	Timestamp	U	HL7 Timestamp	O PH:R	For PH, one of the minimum number of variables requested for initial Case Reporting
Report Sent To	The organization to which the report is submitted		AE PH		O	For PH – report sent to PH Entity – Facility Identifier (see above)
Report Sent to FDA	Indication if the report is submitted to the Food and Drug Administration (FDA) – U.S.		AE	Y/N/U	O	



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Report Source	The originator of the report		AE PH	HL7 Table 0235 – Report source Value C Clinical trial L Literature H Health professional R Regulatory agency D Database/registry/poison control center N Non-healthcare professional P Patient M Manufacturer/marketing authority holder E Distributor O Other	O	
Reported Previously	Indication if the information is supplemental to update in event already reported	Coded	U	Y/N/U	O	
Type of Report	The type of report (e.g., Drug Event Report, Healthcare Associated Infection Report, etc.)	Alphanumeric	U		O	List of report types – typically text (e.g. MedWatch, HAI, Case Notification) – may have formal number assigned by report recipient
User Facility/Importer Report Number	The number of the report assigned by the reporting facility		AE PH		O	May be a standard way to constructing the ID (e.g. assigning authority:ID) – Candidate: HL7 Entity Identifier? Need to be as neutral as possible May need to identify an assigning authority e.g., PH – CDC is an assigning authority for this element, statePH, LocalPH is an assigning authority

Optionality = “R” for Required, “R2” for Required if Known or “O” for Optional, or “C” for Conditional



Table 5-10 Report Data Elements: Reporter Information

Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Occupation of Reporter	The role of the reporter (e.g., physician, nurse, administrator, etc.)		U	North American Industry Classification System – derived from the above – a formal name for the Census List	O	
Reporter Address (street name, city, state, zip code)	The address of the reporter		U	HL7	O PH: R	For PH, one of the minimum number of variables requested for initial Case Reporting For Consumer, <ul style="list-style-type: none"> • May be patient or agent • Subject to Privacy Enhancement
Reporter Email	The email contact information for the reporter		U	HL7	O	For Consumer, <ul style="list-style-type: none"> • May be patient or agent • Subject to Privacy Enhancement
Reporter Name	The name of the person or facility sending the Case Report		U		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 For Consumer, <ul style="list-style-type: none"> • May be patient or agent • Subject to Privacy Enhancement
Telephone	The phone number of the person or facility sending the Case Report	XTN-40	U PH	HL7	O PH:R	For PH, one of the minimum number of variables requested for initial Case Reporting For Consumer, <ul style="list-style-type: none"> • May be patient or agent • Subject to Privacy Enhancement
Type of Reporter	The role of the reporter with respect to the patient (e.g., treating or consulting clinician, case manager, etc.)		U	E.g., reported by self, clinician-reported, PH nurse	O C=R	For Consumer, <ul style="list-style-type: none"> • Patient or agent

Optionality = “R” for Required, “R2” for Required if Known or “O” for Optional, or “C” for Conditional

Table 5-11 Patient Data Elements

Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
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 For Consumer, Subject to Privacy Enhancement
Birth Weight	The weight of the patient at birth		U	UCUM units	O O	Only for certain reports (absolute) For Consumer, Optional, but encouraged



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Date of Birth	Date of birth	Date field	U PH	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 For Consumer, Subject to Privacy Enhancement
Date of Death	If patient has died, deceased date/time		AE PH C	HL7 date	O O C:R	
Estimated Deliver Date	Estimated date of delivery (or est. date of confinement [EDC])		PH		O	Only for certain reports
Ethnicity	The ethnicity of the subject of the Case Report		U	Shall be coded as specified in HITSP/C80 Section 2.2.1.1.2.2 Ethnicity CDC Race and Ethnicity Code Set	O	May be restricted by jurisdiction NOTE: This may repeat For Consumer, Subject to Privacy Enhancement
Number of Siblings	The number of siblings in a multiple birth	Numeric	PH		O	Only for certain reports
Occupation	The occupation of subject of the case report. Enter as much detail as possible (e.g. Teacher in Pre-School facility)		PH	North American Industry Classification System – derived from the above –a formal name for the Census List	O	Only for certain reports
Patient Address (street name, city, state, zip code)	The address of the subject of the Case Report	XAD-106	U	FIPS	O PH: R C:O	For PH, one of the minimum number of variables requested for initial Case Reporting For Consumer, Subject to Privacy Enhancement
Patient Alias Name: First, Middle, Last	This field contains names by which the patient has been known at some time	XPN-48	U	HL7	O	(Former names for management of adoptions and name changes)
Patient Country	The country of the address of the subject of the Case Report		U	ISO 3166-3	O	For Consumer, Subject to Privacy Enhancement
Patient Country of Birth	The subject's country of birth		PH	ISO 3166-3	O	Only for certain reports; This may apply to specific conditions
Patient Country of Origin	The subject's country of origin		PH	ISO 3166-3	O	Only for certain reports; This may apply to specific conditions. May not necessarily be the subject's country of birth
Patient County	The county of the address of the subject of the Case Report	String	U	FIPS	O	For Consumer, Subject to Privacy Enhancement



Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Patient Identifier	The identifier for the patient, may be a pseudonymized identifier	Alphanumeric	U		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 For Consumer, <ul style="list-style-type: none"> May not exist Subject to Privacy Enhancement
Patient Name (First, MI, Last)	The name (preferably legal) of the subject of the Case Report		AE	HL7	O PH: R	For PH, one of the minimum number of variables requested for initial Case Reporting For Consumer, <ul style="list-style-type: none"> Subject to Privacy Enhancement
Patient Telephone	The telephone of the subject of the Case Report	XTN-40	U	HL7	O PH: R C:O	For PH, one of the minimum number of variables requested for initial Case Reporting For Consumer, Subject to Privacy Enhancement
Physiological Sex	Patient sex	Coded	U	Full list of codes from CDC	O PH: R C: 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 C	Yes/No	O O C:R	This may apply to specific conditions. Report-specific requirements; Public health only. For AE – part of relevant medical history
Race	The race(s) of the subject of the Case Report.		U	Shall be coded as specified in HITSP/C80 Section 2.2.1.1..2.7 RACE CDC Race and Ethnicity Code Set	O C:R	May be restricted by jurisdiction NOTE: this may repeat For Consumer, Subject to Privacy Enhancement
Time arrived in the U.S.	The date that the subject most recently arrived into the U.S.		PH	HL7 Timestamp	O	Only for certain reports; This may apply to specific conditions
Weight	The weight of the patient at the time of the report		C AE	UCUM units	C: O O	Consumer: Encourage Only for certain reports (absolute)

Optionality = "R" for Required, "R2" for Required if Known or "O" for Optional, or "C" for Conditional



Table 5-12 Clinical Data Elements

Scenario	Data Element	Definition	Data Type	Usage	Data Requirement Standards	Optionality	Comments
Event Information	Adverse Event Terms	Definition pending		C AE		O	Consumer User interface may need to provide additional guidance in capturing this in a consumer friendly manner NOTE: Narrative description of the event – translate into coded value of the narrative
	Approximate Age of Device	The length of time the device has been in use for the patient		C AE	UCUM + absolute	O	Consumer User interface may need to provide additional guidance in capturing this in a consumer friendly manner Same as Patient age –Can be derived from product manufacture date
	Date of Event	The date the event first occurred	Date Field	U PH C	HL7 Timestamp HL7 V3 flavors of null for DOB	U PH: R C:R	For PH, one of the minimum number of variables requested for initial Case Reporting
	Description of Event	A textual description of the event	Free Text	U C		O C:R	Consumer User interface may need to provide additional guidance in capturing this in a consumer friendly manner
	Event Abated after use stopped or dose reduced?	Indication that the event resolved/abated after usage stopped or dose reduced		C AE	Y/N/U	C:R O	
	Event Device Problem Code	The locally determined code to identify the problem for subsequent follow up		AE	See Gaps	O	Might be combined with the concept of 'description of event'
	Event Patient Problem Code	The locally determined code to identify the problem for subsequent follow up		AE	Codes from center for devices	O	Might be combined with the concept of 'description of event'
	Event Reappeared after reintroduction	Indication if the reaction reoccurred after rechallenging the patient to the suspected substance		C AE	Y/N/U	C:R O	
	Location where Event Occurred	The location of the event – e.g., home, hospital, other facility, etc.		C AE	HAI Service Delivery Location – HL7, Home, Work	O	



Event Information	Name of Condition	The name of the condition diagnosed for the subject of the Case Report		AE PH	SNOMED-CT (This HITSP Interoperability Specification will use the CHI recommended SNOMED CT as a reference terminology to communicate interoperable information among and between systems, with the HITSP Interoperability Specification Pre-condition that the sending and using systems must use formal coded nursing terminologies such as the Clinical Care Classification (CCC) System and the Omaha System that are integrated in SNOMED CT)	O 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
	Outcome attributed to AE	Textual description of the outcome associated with the adverse event		C AE	Terminology mapping to a constrained set. HL7 event outcome HL7 Table 0240	C:R O	E.g., Died, Hospitalized, disabled/permanent injury
	Patient Recovered Diagnosis	Final determination of reaction – diagnosis		C AE	ICH – B2B guide – short list	C:R O	Consumer User interface may need to provide additional guidance in capturing this in a consumer friendly manner e.g., Patient recovered, recovering, recovered with sequella



Event Information	Type of Event and/or Issue	Definition pending		C AE	See Gaps	O	Consumer User interface may need to provide additional guidance in capturing this in a consumer friendly manner Might be combined with the concept of 'description of event' For AE, one of the minimum number of variables required for valid electronic report Next level detail from type of reportable event; Hierarchy type relationship; (e.g. a subset of TRLI, a lab error), Expect the same standard set as selected for 'Type of Reportable Event' Could have a 1:1 match; to classify by incident type – Information model relationship between this term and 'Type of Reportable Event'
	Type of Reportable Event	Seriousness of the event		C AE	See Gaps	O	Consumer User interface may need to provide additional guidance in capturing this in a consumer friendly manner Might be combined with the concept of 'description of event' For AE, one of the minimum number of variables required for valid electronic report
Medication History	AE Following Prior Vaccination	Description of the adverse event		C AE	Y/N/Y with Free text description	C:RE O	Consumer: Assuming PHR-populated Vaccination Only NOTE: Could say add free-text description or coded value from above selection: add a separate field for this – this could appear as part of the medical HX;
	Common Device Name	Common name of the device	Alphanumeric	C AE		C:R (if reporting device) O	How referred to in institution; (e.g. MRI, CT Scan);



Medication History	Concomitant Medical Product Name	Other medical products in use for the patient to determine proximal relationships		C AE	NDC; RxNorm; FDA lists; ISO Medicinal Product Identifiers – an international drug dictionary	RE O	For AE, one of the minimum number of variables required for valid electronic report NOTE: Devices: Global Medical Device Nomenclature (Pending); licensing issues
	Concomitant Medical Products & Therapy Dates	Other medical products and treatment used proximal to the event		C AE	HL7 Timestamp	C:RE O	Need to capture date+product
	Current Medications (Medwatch concomitant meds)	Other medications in use		C AE	RxNorm (harmonize with other Use Cases)	C:RE O	
	Date product returned to manuf.	If returned to the manufacturer, date of return		C AE	HL7 Timestamp	O	
	Expiration Date	The expiration date of the product		C AE	HL7 Timestamp	O	
	If explanted give date	Date device was removed (if removed)		C AE	HL7 Timestamp	C:R O	
	If implanted give date	Date of implantation of the device (if implanted)		C AE	HL7 Timestamp	C:R O	
	Immunization Services Funding Eligibility	Indication of vaccination source (e.g., special program such as Vaccine for Children, state or provincial programs, etc)		AE	HL7 2.5 Table 0064 – Financial class	O	Vaccination Only
	Is this a single use device that was reprocessed and reused on patient?	Indication if the device is a single-use device that was cleaned/ reprocessed and is reused on the affected patient		C AE	Y/N/U	O	
	Manuf. Name, City and State	Manufacturer of the device	XAD-106	C AE	HL7	C:RE O	
	Medical Device Catalog #	Catalog number of the device	Alphanumeric	C AE		C:RE O	
	Medical Device Lot #	Lot number of the device	Alphanumeric	C AE		C:RE O	
	Medical Device Model #	Model number of the device	Alphanumeric	C AE		C:RE O	



Medication History	Medical Device Other #	Other identifiers for the device	Alphanumeric	C AE		C:RE O	
	Medical Device Serial #	Serial number of the device	Alphanumeric	C AE		C:RE O	
	Name and Address of Reprocessor	Name and address of the individual/ organization reprocessing the single use device	XAD-106	C AE	HL7	O	
	NDC# or Unique ID	The unique identifier for the product		C AE	Complete NDC number – down to the package level detail	O	
	Operator of Device	The individual managing the device		C AE	Health professional, lay user, patient, other	C O	Aligns with occupation of operator (e.g. radiologist, radiation therapist, parent): Terminology mapping
	Pre-existing clinician diagnosed allergies, birth defects. Medical conditions	Allergies, conditions existing prior to the use of the suspected agent		C AE	SNOMED list harmonized with other Use Cases; CHI Allergies	C:RE O	Consumer User interface may need to provide additional guidance in capturing this in a consumer friendly manner
	Previous Vaccine Date Given	The date the vaccination dose suspected was administered		C AE	HL7 Timestamp	C:RE O	Vaccination Only
	Previous Vaccine Lot #	The lot number of the vaccine dose	Alphanumeric	C AE		C:RE O	Vaccination Only
	Previous Vaccine Manufacturer	The manufacturer of the vaccine dose		C AE	MXV	C:RE O	Consumer: Assuming PHR-populated Vaccination Only
	Previous Vaccine Route/Site	The route of administration of the vaccine dose		C AE	HL7 V 2.5 Table 0163 – Administrative site	C:RE O	Consumer: Assuming PHR-populated Vaccination Only NOTE: Need to distinguish route (e.g. intramuscular) and site (e.g. left hip) Route may be determined by type of vaccine
	Previous Vaccine Type	The type of vaccine		C AE	CVX	C:RE O	Consumer: Assuming PHR-populated Vaccination Only



Medication History	Product available for evaluation?	Indication if the product is still available to be evaluated		C AE	Y/N/U	O	
	Product Diagnosis for Use	The reason the product was initially used		C AE	SNOMED-CT	C:R O	Condition for which the product was used Align with med management 'Reason for use' – use the same term (check term)
	Product Dose	The dose of the product administered		C AE	Align with med management dose	C:R O	
	Product Frequency	The frequency with which the product was administered		C AE	Align with med management	C:R O	
	Product Lot #	The product lot number	Alphanumeric	C AE		O	
	Product Route Used	The route of administration of the product (e.g., oral, intravenous, intramuscular, etc.)		C AE	Align with med management	C:R O	
	Product Therapy Dates	Duration of therapy with the product		C AE	HL7 Timestamp	C:R O	
	Suspect Product Name	Product name		C AE	CVX for vaccine, are for vaccine AE; NDC: Text description or brand name or trade name; Devices: GAP or possibly UPC codes	C:R O	
	Therapy Dates	Dates of treatment with the suspected agent		C AE	HL7 timestamp	C:R O	
	Vaccine # Previous Doses	The number of previous doses of the vaccine type	numeric	C AE		C:RE O	Consumer: Assuming PHR-populated Vaccination Only



Previous History	Anthrax Signs and Symptoms	The signs and symptoms experienced by the patient pertaining to Anthrax		RSAX	SNOMED-CT 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 NOTE: Terminology Service mapping to SNOMED-CT terms; if there is a term not in SNOMED that the term be added. Not for HITSP to do the mapping. Point to CSTE to provide this mapping/value set for the SNOMED-CT codes
	Hep B Signs and Symptoms	The signs and symptoms experienced by the patient pertaining to Hep B		RSHB	SNOMED-CT Question Subset: Symptomatic Jaundice	R	NOTE: Terminology Service mapping to SNOMED-CT terms; if there is a term not in SNOMED that the term be added. Not for HITSP to do the mapping. Point to CSTE to provide this mapping/value set for the SNOMED-CT codes
	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	
	Signs and Symptoms	The signs and symptoms experienced by the patient		U PH C	SNOMED-CT (This HITSP Interoperability Specification will use the CHI recommended SNOMED CT as a reference terminology to communicate interoperable information among and between systems, with the HITSP Interoperability Specification Pre-condition that the sending and using systems must use formal coded nursing terminologies such as the Clinical Care Classification (CCC) System and the Omaha System that are integrated in SNOMED CT)	O C:R	This may apply to specific conditions. ICD9-CM – does not cover in sufficient detail Consumer User interface may need to provide additional guidance in capturing this in a consumer friendly manner



Previous History	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 C:R	
	TB Major body site of TB	The subject's anatomic site where the disease is located		RSTB	See Overlaps	R	NOTE: One terminology for this IS, probably even across HITSP; may need expansion or constraint by CHI standard is SNOMED, but recommended – table for body site comes from HL7 – HL7 value set be developed from SNOMED content – Use HL7 Body Site table; Possible Gap – need to check mapping to SNOMED – verify
	TB Signs and Symptoms	The signs and symptoms experienced by the patient pertaining to TB		RSTB	SNOMED-CT Question Subset: Asymptomatic Fever Chills Cough Productive cough Hemoptysis Night sweat Weight loss Chest pain	R	NOTE: Terminology Service mapping to SNOMED-CT terms; if there is a term not in SNOMED that the term be added. Not for HITSP to do the mapping. Point to CSTE to provide this mapping/value set for the SNOMED-CT codes
	TB Status of Patient at Diagnosis – Alive	At the time of diagnosis, was the subject alive or deceased?		RSTB	consider Y/N	R	
	Tularemia Location of Lesion	Anatomical location of Tularemia lesion		RSTU	(See Overlaps) Value Set: Ulceroglandular Pneumonic Glandular Oropharyngeal Oculoglandular Typhoidal	R	CDISC has started a list of ~300 anatomical sites; Looking for 100 +/-sites (e.g. upper right arm) Overlap possible – HL7 Bodysite/CDISC Want major gross anatomical sites involved with clinical procedures



Previous History	Tularemia signs and symptoms	The signs and symptoms experienced by the patient pertaining to Tularemia		RSTU	SNOMED-CT 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	NOTE: Terminology Service mapping to SNOMED-CT terms; if there is a term not in SNOMED that the term be added. Not for HITSP to do the mapping. Point to CSTE to provide this mapping/value set for the SNOMED-CT codes
	Types of Anthrax	Mode or site of the introduction of the anthrax bacilli		RSAX	SNOMED-CT Value Set: Cutaneous anthrax Inhalation anthrax Gastrointestinal anthrax	O	
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	



Lab Results	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
	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 Collection Date	Date TST was placed	Date	RSTB	HL7 Timestamp	R	
	TB Test Method	Testing method used to arrive at the specific result: Tuberculin Skin Test (TST)	Alphanumeric	RSTB	HL7 V3 Observation Method as a starter set. May be extended locally	R	May also be referred as Purified Protein Derivative (Mantoux) NOTE: Need language from TB experts to differentiate this data element from diagnostic test method below Clinical test may be a screening test; May need to select specific subset terms; need definition of terms for which tests can appear in which classification
	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	C AE, PH, RSAX, RSHB, RSTB, RSTU	HL7 Timestamp	C:O O O R R R R	



Diagnostic Information (The following data element will include condition specific value sets)	Test Method	Testing method used to arrive at the specific result: The name of the laboratory test	Alphanumeric	C AE, PH, RSAX, RSHB, RSTB, RSTU	HL7 V3 Observation Method as a starter set. May be extended locally	C: O O R R R R	LOINC – code may already indicate the method if already specified within LOINC that this field may be left unspecified (NOTE: HL7 Observation Method Table – refers to CDC maintained value set)
	Anthrax Test Method	Testing method used to arrive at the specific result: The name of the laboratory test	Alphanumeric	RSAX	All select HL7 Observation Method for lab tests, including domain subsets. 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	
	HepB Test Method	Testing method used to arrive at the specific result: The name of the laboratory test	Alphanumeric	RSHB	All select HL7 Observation Method for lab tests, including domain subsets. 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	



Diagnostic Information (The following data element will include condition specific value sets)	TB Test Method	Testing method used to arrive at the specific result: The name of the laboratory test	Alphanumeric	RSTB	All select HL7 Observation Method for lab tests, including domain subsets. 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	
	Tularemia Test Method	Testing method used to arrive at the specific result: The name of the laboratory test	Alphanumeric	RSTAE	All select HL7 Observation Method for lab tests, including domain subsets. Value set: F. tularensis fluorescent assay F. tularensis antibody F. tularensis culture x-ray	R	
	Test Result	The test result of the laboratory test including any applicable result units of measure	Coded	C AE, PH, RSAX, RSHB, RSTB, RSTU	SNOMED-CT	C:O 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	C AE, PH, RSAX, RSHB, RSTB, RSTU	HL7 Timestamp	C:O 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	C AE, PH, RSAX, RSHB, RSTB, RSTU	SNOMED –CT	C:O O O R R R R	



Diagnostic Information (The following data element will include condition specific value sets)	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		Terminology Service mapping to SNOMED-CT terms; if there is a term not in SNOMED that the term be added. Not for HITSP to do the mapping Point to CSTE to provide this mapping/value set for the SNOMED-CT codes
	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	Terminology Service mapping to SNOMED-CT terms; if there is a term not in SNOMED that the term be added. Not for HITSP to do the mapping Point to CSTE to provide this mapping/value set for the SNOMED-CT codes
	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		Terminology Service mapping to SNOMED-CT terms; if there is a term not in SNOMED that the term be added. Not for HITSP to do the mapping Point to CSTE to provide this mapping/value set for the SNOMED-CT codes
	Tularemia Source of Specimen	The physical body location from where the specimen for the lab report was taken from the subject	Coded	RST	SNOMED –CT Value set: Blood Chest CSF Lesion swab Lymph node biopsy Skin biopsy Sputum Stool	R	Terminology Service mapping to SNOMED-CT terms; if there is a term not in SNOMED that the term be added. Not for HITSP to do the mapping Point to CSTE to provide this mapping/value set for the SNOMED-CT codes
	Name of Organization Collecting Specimen	Name of organization collecting specimen which may be different from the organization performing the laboratory analysis	Alphanumeric	C AE, PH, RSAX, RSHB, RSTB, RSTU	Facility identifier as discussed above	C: O O R R R	



Diagnostic Information (The following data element will include condition specific value sets)	HepB Lab Referencing Range	Upper limit normal?	Free-text	RSHB		O	This applies to liver enzyme levels, for the above test methods ALT and AST, at time of diagnosis
	HepB Abnormal Flag	Interpretative result of HbsAg lab test		RSHB	(HL7 table) 0078	O	
	HepB Previously tested HbsAg +	Has the subject previously tested positive for hepatitis B surface antigen?		RSHB	Y/N/U	R	Include date of test
	HbsAg Date of test	Date of previous HbsAg test performed		RSHB	HL7 Timestamp	R	
	Diagnosis/ Injury Code	Diagnosis or diagnoses assigned as a result of the encounter	Coded	C AE	ICD-9/10 CM Or SNOMED CT	C:O O;	Only for certain Reports Review public health and AE use Constrain to ICD9/10 Would need good SNOMED CT to ICD maps Consumer User interface may need to provide additional guidance in capturing this in a consumer friendly manner
	Diagnosis Type	Type of diagnosis being sent (admitting, working, final)	IS (coded)	C AE	HL7 2.5 User-defined Table 0052 – Diagnosis Type	C:RE O	Assuming available through PHR 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	C AE, PH	HL7 Timestamp	C:O O	Only for certain Reports Review public health and AE use
	Previous Event Report Details	Definition pending		AE	SNOMED-CT	O	
	Reason for Non-Evaluation	Definition pending	Free-text	AE		O	
	Type of Follow-Up	Definition pending		AE	See gaps	O	
	Type of Remedial Action	Definition pending		AE	See Gaps	O	



Medical Treatment	Administration of Treatment	Was treatment administered?		C AE, PH, RSAX, RSHB, RSTB, RST	PH: Y/N	C:RE O 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
	Admission Date	Enter the date that the subject of the Case Report was Admitted to the hospital	Date	U	HL7 Timestamp	C:RE O	
	Anthrax Name of Treatment	Name of the treatment used to treat the Anthrax		RSAX	Subset of values for Name of treatment/intervention Value set: Amoxicillin Ciprofloxacin Doxycycline	O	
	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	Y/N	O	
	Date of Admin of Treatment	The date treatment was administered. For HepB, Date HBV vaccine administered	Date	C AE, PH, RSAX, RSHB, RSTB, RST	HL7 Timestamp	C:RE O R O R R	This may apply to specific conditions
	Death	Did the subject die as a result of the disease?	Boolean	PH	HL7 Table 0136Yes/No Indicator	O	
	Discharge Date	Enter the date that the subject of the Case Report was Discharged from the hospital		U	HL7 Timestamp	C:RE O	
	HepB Name of Treatment	Name of HBV vaccine		RSHB	HBV Vaccine	O	Subset of values for Name of treatment/intervention
	HepB Number of doses of HBV vaccine in the past	If yes, how many shots	Numeric	RSHB		O	



Medical Treatment	HepB Positive anti-HBs	Did the patient test positive for Anti-HBs ("reactive", "positive", or anti-HBs >= 10 mIU/ml) after the last dose of HBV vaccine?		RSHB	Y/N/U	O	Positive (or "reactive") for antibody HbsAg as defined by anti-HBs >= 10mIU/ml
	HepB Serum anti-HBs >=10mIU/ml	Was serum anti-HBs >= 10mIU/ml?		RSHB	Y/N/U	O	If patient tested positive for antibody to HbsAg (anti-HBs) after the last dose of HBV vaccine
	HepB Year of last HBV Vaccine Dose	In what year was the last shot received?		RSHB	HL7 Timestamp	O	
	Hospital Name	Name of hospital the case was admitted	String	PH	Same discussion as facility name/id	O	
	Hospitalization	If the subject of the case report was hospitalized		U	Y/N/U	C:RE O	
	Name of Treatment	Name of the treatment		C AE, PH, RST	SNOMED-CT; RxNorm; CVX	C:RE O R	<p>Consumer User interface may need to provide additional guidance in capturing this in a consumer friendly manner This may apply to specific conditions. This can include name of antibiotics, vaccine, or other substances used to treat for a specific condition</p> <p>NOTE: Patient may have received as a result of the harm/incident</p> <p>Context of use – may be 2 attributes –</p> <p>Intervention (substance intervention, clinical intervention) :</p> <p>What additional substances were administered (CVX, MVX)</p> <p>Name of treatment for clinical, dx, procedure (SNOMED)</p> <p>Actions take to mitigate harm (could be clinical procedure or substance administration)</p> <p>Actions taken with the drug (e.g. stop drug) – HL7 ICSR – not PH</p>



Medical Treatment	Recovered	Did the subject recover from the disease?		AE, PH C	Recovered, recovered with sequelae	O C:RE	Combine with Patient Recovered Diagnosis
	TB Name of Treatment	The list of medications prescribed for the subject's treatment of TB		RSTB	Value set: Isoniazid (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 Subset of values for Name of treatment/intervention
Epidemiologic Information	Contact with Animal or Animal Products	Definition pending		RSAX	Y/N/U/Not Asked null flavor options Question Subset: Animal Exposure type Current location Exposure date	O	
	Contact with Person with Similar Symptoms	Definition pending		RSAX	Y/N/U/Not Asked null flavor options	O	
	Exposed to suspicious powder	Definition pending		RSAX	Y/N/U/Not Asked null flavor options	O	
	Handled suspicious mail	Definition pending		RSAX	Y/N/U/Not Asked null flavor options	O	
Travel Information	Date Travel	Definition pending	Date	RSAX	HL7 Timestamp	O	
	Location of Travel	Definition pending		RSAX	International – ISO country codes, Local – could be GPS location – situation dependent	O	
	Occupational Risk Factors	Definition pending		RSAX	SNOMED-CT (See Gaps)	O	



Epidemiologic Data – Hep B	Environmental Risk Factors	Are environmental risk factors present?		RSHB	Y/N/U/Not Asked null flavor options	0	
During 6 Weeks – 6 Months prior to onset of symptoms	Acupuncture	Did the patient have puncture with a needle contaminated with blood?		RSHB	Y/N/U/Not Asked null flavor options	0	Terminology Service
	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	Y/N/U/Not Asked null flavor options Question Subset: Casual Household [non-sexual] Sexual Needle use Perinatal Other	0	
	Date of receiving blood or blood products	If yes [to receiving blood or blood products], date of transfusion		RSHB	HL7 Timestamp	0	
	Dental work or oral surgery	Did the patient have dental work or oral surgery?		RSHB	Y/N/U/Not Asked null flavor options	0	Terminology Service
	Hemodialysis	Did the patient undergo hemodialysis?		RSHB	Y/N/U/Not Asked null flavor options	0	
	Hospitalized	Was the patient hospitalized?		RSHB	Y/N/U/Not Asked null flavor options	0	This is different from the data element hospitalization in the non-condition specific list
	Incarcerated	Was the patient incarcerated for longer than 24 hours?		RSHB	Y/N/U/Not Asked null flavor options	0	
	IV infusion or injection in the outpatient setting	Did the patient receive any IV infusions and/or injections in the outpatient setting?		RSHB	Y/N/U/Not Asked null flavor options	0	Terminology Service
	Long-term Care	Was the patient a resident of a long term care facility?		RSHB	Y/N/U/Not Asked null flavor options	0	
	Organ or tissue transplant recipient	Did the patient have an organ or tissue transplant?		RSHB	Y/N/U/Not Asked null flavor options	0	Terminology Service
	Receive blood or blood products	Did the patient receive blood or blood products [transfusion]?		RSHB	Y/N/U/Not Asked null flavor options	0	
	Surgery	Did the patient have surgery?		RSHB	Y/N/U/Not Asked null flavor options	0	Terminology Service
Medical Risk Factors	Diagnosed STD	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	0	Terminology Service



Medical Risk Factors	History of Viral Hepatitis	Patient has a history of viral hepatitis?		RSHB	Y/N/U/Not Asked null flavor options Question Subset: Hepatitis A Hepatitis B Hepatitis C Hepatitis D Other viral hepatitis	0	Terminology Service
	Perinatal	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	0	
	Treated STD	Was the patient EVER treated for a sexually transmitted disease?		RSHB	Y/N/U/Not Asked null flavor options	0	Terminology Service
	Year of the most Recent Treatment	If yes to treated for STD, in what year was the most recent treatment		RSHB	HL7 Timestamp	0	
Occupational Risk Factors	Female Sexual Partners	In the 6 months before symptom onset how many female sex partners did the patient have?		RSHB	Y/N/U/Not Asked null flavor options	0	Female sexual partners
	Frequency of direct blood or body fluid exposure	Frequency of direct blood contact or body fluids exposure?		RSHB	See gaps Value set: Frequent (several times weekly) Infrequent	0	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 Frequent/several times per week, infrequent; GAP – CDC value set
	Job involving direct contact with human blood	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	0	Terminology Service CSTE mapping
	Lifetime Total Sexual Partners	Definition pending	numeric	RSHB		0	Lifetime total sexual partners
	Male Sexual Partners	In the 6 months before symptom onset how many male sex partners did the patient have?		RSHB	CDC 0 1 2-5 Unknown >5	0	Male sexual partners Numeric or grouped CDC has a value set – number of sex partners SNOMED – incomplete – local CDC



Occupational Risk Factors	Medical or Dental Field	Was the patient employed in a medical or dental field involving direct contact with human blood?		RSHB	Y/N/U/Not Asked null flavor options	0	Terminology Service
	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	Y/N/U/Not Asked null flavor options	0	Terminology Service
	Socio-behavioral Risk Factors	Are socio-behavioral risk factors present?		RSHB	Y/N/U/Not Asked null flavor options	0	Socio-behavioral risk factors
During 6 Weeks – 6 Months prior to onset of symptoms	An accidental stick or puncture with a needle or other object contaminated with blood	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	0	
	Body Piercing (other than ear)	Did the patient have any part of their body pierced (other than ear)?		RSHB	Y/N/U/Not Asked null flavor options	0	
	Exposure to some else's blood	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	0	
	Incarcerated	Incarcerated for longer than 24 hours?		RSHB	Y/N/U/Not Asked null flavor options	0	
	Incarceration	During his/her lifetime, was the patient EVER incarcerated for longer than 6 months?		RSHB	Y/N/U/Not Asked null flavor options	0	
	Physical assault on exposed person involving blood or semen	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	0	
	Place the body piercing was performed	Where was the piercing performed?		RSHB		0	
	Place the tattoo placement was performed	Definition pending		RSHB	Standards to be selected pending further domain analysis – see appendix for detail to be considered	0	
	Shared Injection Equipment	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	0	



During 6 Weeks – 6 Months prior to onset of symptoms	Shared razor, toothbrushes or nail care items	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	O	
	Tattooing	Definition pending		RSHB	Y/N/U/Not Asked null flavor options	O	
	Use of Injection Street Drugs	During the 6 weeks- 6 months prior to onset of symptoms inject drugs not prescribed by a doctor?		RSHB	Y/N/U/Not Asked null flavor options	O	
	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	Y/N/U/Not Asked null flavor options	O	
Epidemiologic Information	HIV Status	Does the patient have a history of being HIV positive?		RSTU	Y/N/U/Not Asked null flavor options	O	
	Location of Probable Exposure	Places that the subject may have been exposed to TB		RSTU	HAI Service Delivery Location – HL7, Home, Work 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 of a person 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 NOTE: Repeat from location of event – remove /qualify subset in Appendix
	Medical Risk Factors	Are medical risk factors present?		RSTU	Y/N/U/Not Asked null flavor options	O	
	Occupational Risk Factors	Are occupational risk factors present?		RSTU	Y/N/U/Not Asked null flavor options Question Subset: Healthcare worker Correctional employee	O	CSTE – may want to spell this out for mapping



Epidemiologic Information	Sociobehavioral Risk Factors	Are sociobehavioral risk factors present?		RSTU	Y/N/U/Not Asked null flavor options 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	CSTE – may want to spell this out for mapping
Epidemiologic Information - Tularemia	Animal/Insect	Type of animal/insect		RSTU	SNOMED-CT	O	
	Contact with animal or animal products	Contact with livestock (dead or alive), animal products, insect		RSTU	Y/N/U/Not Asked null flavor options	O	Has the patient been bitten by ticks or deer flies in the three weeks prior to illness? May also ask if patient has consumed high-risk animal. (or this also define a recreational exposure)
	Contact with person with similar symptoms	Definition pending		RSTU	Y/N/U/Not Asked null flavor options	O	
	Current Location	Location of exposure		RSTU	Field, Zoo, descriptive location; may be in SNOMED-CT	O	Can include ticks or deer flies
	Exposed to Suspicious Powder	Was the Subject exposed to suspicious powder		RSTU	Field, Zoo, descriptive location; may be in SNOMED-CT	O	
	Exposure Date	Date of exposure		RSTU	HL7 Timestamp	O	Date of bite
	Exposure Type	Exposure type		RSTU	SNOMED-CT	O	Also can be used to describe insect bite

Optionality = "R" for Required, "R2" for Required if Known or "O" for Optional, or "C" for Conditional



6.0 DOCUMENT UPDATES

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

6.1 DECEMBER 10, 2008

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

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

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

Changes also reflect the following:

- Renamed Business actors and adopted cross-IS harmonized descriptions, adjusting diagrams to align with the renaming
- Adjusted all Data Requirements and IERs to use cross-IS harmonized concepts and descriptions
- Moved the Detailed Data Requirements table to the Appendix as an informative reference and propagated the data elements to the Data Requirements Table
- Modified descriptions of constructs in Table 1-1 List of Constructs
- Added HITSP/C80, HITSP/C83, HITSP/C37, HITSP/C32 and HITSP/C48 to Table 3-8 and made several updates to optionality in this table as well
- Updated the technical actor role descriptions in Table 3-7
- Updated the Business Actor table to include IER03 and IER04
- Updated Table 3-8 to correct references to HITSP/TP20 and HITSP/C19
- Updated HITSP/TP21 Technical Actors and references to reflect updated HITSP/TP21

Minor editorial changes were made to this construct.

6.2 DECEMBER 18, 2008

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

6.3 JANUARY 31, 2010

Updated to reflect the HITSP Interoperability Specification Template Version 2.0.

Updated for public comment input to fulfill the requirements of Consumer Adverse Event Reporting.

