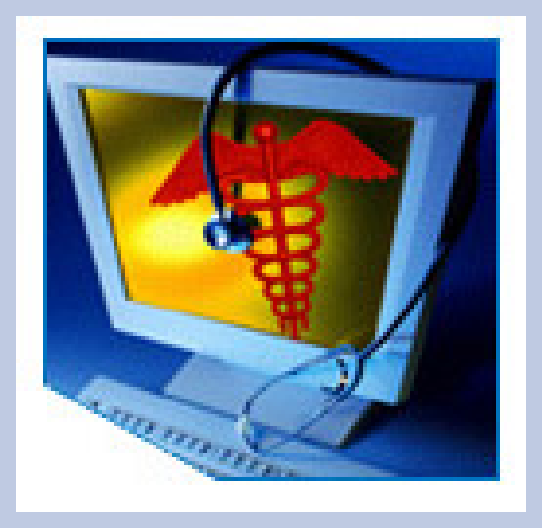
December 13, 2007
Version 2.1

HITSP Biosurveillance Interoperability Specification

HITSP/IS02



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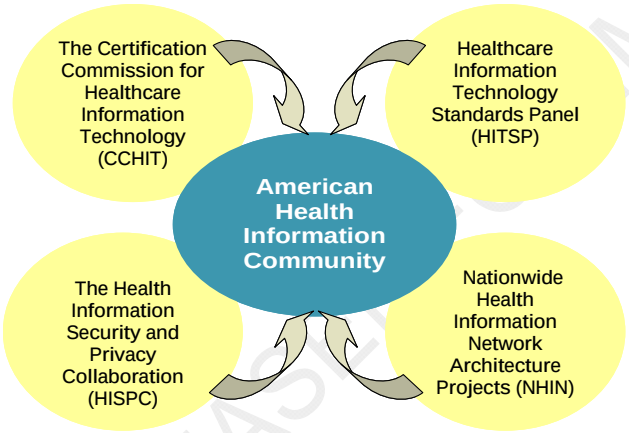
1.0 FOREWORD

This document is referred to as an Interoperability Specification and is an artifact of the Healthcare Information Technology Standards Panel (HITSP).

The following paragraphs provide background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. It also describes the HITSP process for healthcare standards harmonization and explains how to use this document and other related documents to inform your health IT product development or product refinement. If you are familiar with HITSP and HITSP artifacts, please proceed to Section 2.0.

U.S. Nationwide Health Information Interoperability

Studies published by the Institute of Medicine and others have raised awareness of the extent to which the fragmented nature of clinical information adversely impacts the quality of care across the U.S. Health Information Technology (IT) can be used to enable better integration of clinical information. However, as of 2007, only a small number of U.S. healthcare providers have fully adopted health IT due, in part, to technical barriers associated with a lack of unambiguous and nationally recognized interoperability standards.



The American Health Information Community[1] (AHIC), a 2005 federally-chartered commission made up of leaders from public and private health sectors, was formed to provide recommendations on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected, in a smooth, market-led way. At the same time, the Department of Health and Human Services, through the Office of the National Coordinator for Health IT (ONC) awarded contracts to 1) Identify Interoperability Standards to facilitate the exchange of patient data (HITSP), 2) define a process for certifying that health IT products comply with appropriate standards through the Certification Commission for Healthcare Information Technology (CCHIT), and 3) develop a series of prototypes to establish the requirements of a nationwide health information network (NHIN). These activities share the goal of widespread adoption of interoperable electronic health records within 10 years through public-private collaboration. Under a renewed second year contract, HITSP scheduled activities will include identifying and constraining the standards needed for a standards-based security framework that provides the mechanisms needed to protect patient privacy and maintain confidentiality of information about the patient, as well as further work in additional Use Case priority areas recommended by AHIC. This year,

[1] http://www.hhs.gov/healthit/ahic.html

CCHIT is expanding its certification efforts to inpatient, or hospital, electronic health record products. In January 2007, four NHIN prototypes were delivered based on the requirements for health information exchange. The next phase will be to connect the prototypes and state and regional health information exchange efforts in trial implementations.

HITSP's Role within Nationwide Interoperability Efforts

The HITSP[2] is a multi-stakeholder coordinating body designed to provide the process within which affected parties can identify, select, and harmonize standards for communicating healthcare information throughout the healthcare spectrum. As used by HITSP, the term "standard" refers, but is not limited to Specifications, Implementation Guides, Code Sets, Terminologies, and Integration Profiles. A standard should be produced through a well-defined approach that supports a business process and

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

HITSP functions as a partnership of the public and private sectors and operates with a neutral and inclusive governance model administered by the American National Standards Institute. The goal of the Panel is to:

- Facilitate the development of harmonized Interoperability Specifications and information policies, including SDO work products (e.g. standards, technical reports). These policies, profiles and work products are essential for establishing privacy, security and interoperability among healthcare software applications
- Coordinate, as appropriate, with other national, regional and international groups addressing healthcare information to ensure that the resulting standards are globally relevant
- Be Use Case driven, using information from stakeholders and basing decisions on industry needs

The work of HITSP is conducted through formally chartered Technical Committees and Work Groups. The artifact of the Technical Committee and Work Group activities is an Interoperability Specification (IS) and related constructs referred to as Transaction Packages, Transactions, or Components. For additional information on these constructs, please refer to the HITSP Harmonization Framework.

This HITSP document pertains to the Interoperability Specification for the following:

[2] www.hitsp.org

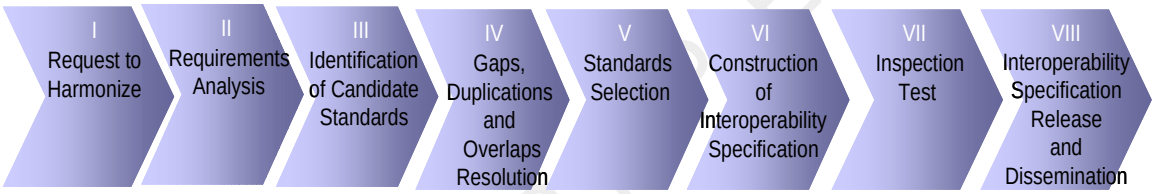
Use Case	Specific Scope of this Use Case
Biosurveillance	Transmit essential ambulatory care and emergency department visit, utilization, and laboratory result data from electronically enabled healthcare delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time.

In its final state, this Interoperability Specification provides unambiguous instructions for how two or more systems should exchange information within this specific context of the Use Case.

How Use Cases and HITSP Interoperability Specifications are Developed

The American Health Information Community, as the representative of public and private health sector stakeholders, identified the three Use Cases (available at hitsp.org) that drove the initial efforts of the HITSP. Nationwide public and private health sector priorities continue to focus the efforts of the HITSP. The Use Case driven HITSP harmonization process is implemented by formally chartered Technical Committees. The volunteers that comprise a Technical Committee followed an 8 step process, depicted below.

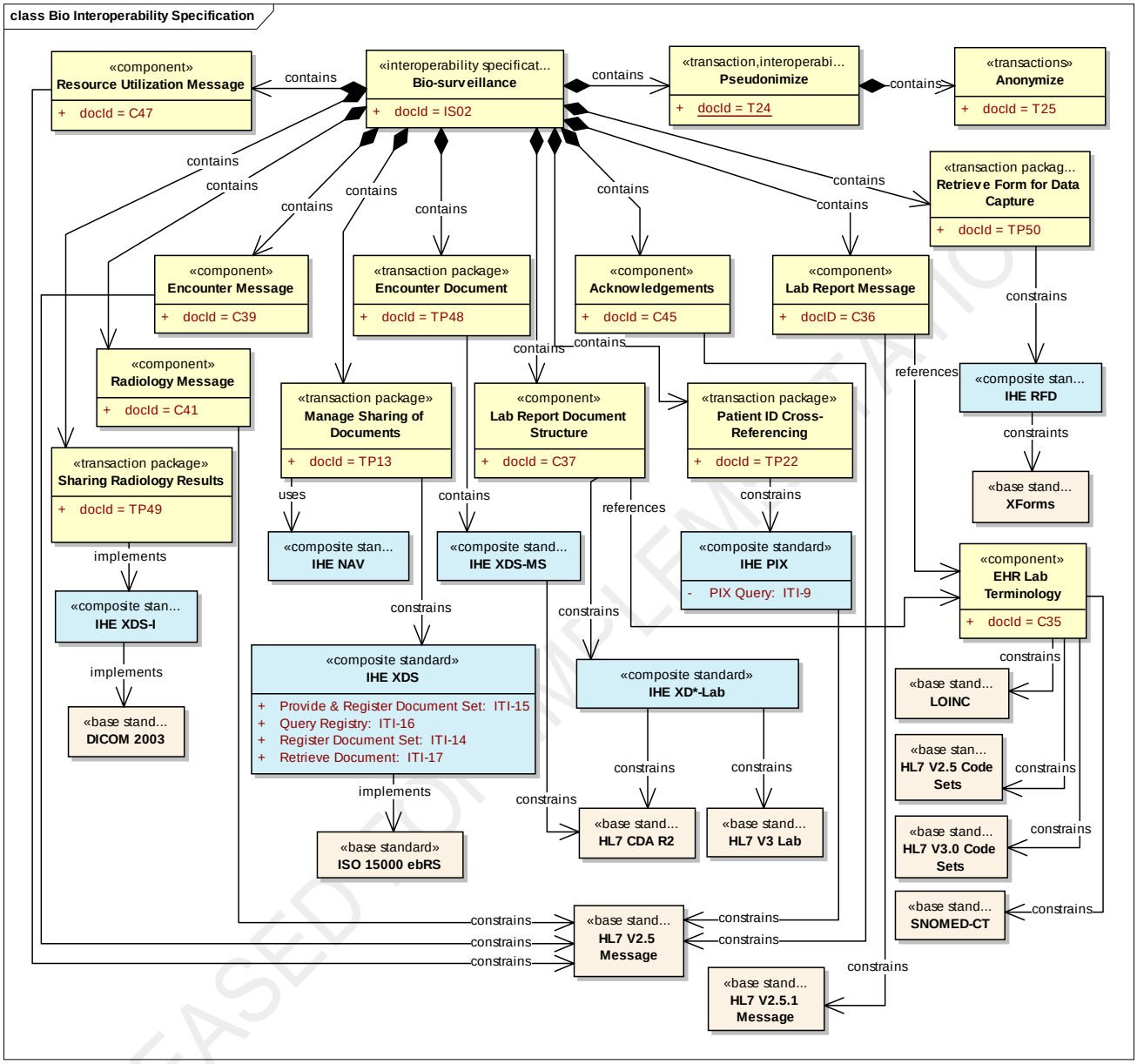
Figure 1.0-1 HITSP Harmonization Process Steps



How to Read this Interoperability Specification

Each HITSP Interoperability Specification (IS) is comprised of a suite of constructs that, taken as a whole, define how to integrate and constrain existing standards and specifications to satisfy the requirements imposed by a given Use Case. The IS groups specific actions and actors to describe the relevant context(s) for the use of HITSP constructs that further identify and constrain standards where necessary. In addition to ISs, there are three other types of HITSP constructs called Transaction Packages (TP), Transactions (T), and Components (C). The roadmap depicted in Figure 1.0-2 identifies the HITSP constructs used to meet the IS requirements. Implementers should read the documents that describe the constructs depicted in the diagram for their details and specific uses.

Figure 1.0-2 Interoperability Specification Roadmap



2.0 INTRODUCTION

As an introduction to the HITSP Biosurveillance Interoperability Specification, this section provides a high level overview of information sharing scenario enabled by following this specification, outlines the technical scope of the specification, describes the intended audience for the technical content of the document, acknowledges the copyright protections that pertain, provides Internet links to our acronym list and an explanation of the conventions we use to convey the full descriptions and usage of standards. If you are already familiar with this information, proceed to Section 3.0.

2.1 OVERVIEW

Biosurveillance is an American Health Information Community breakthrough area defined as implementation of near real-time, nationwide public health event monitoring to support early detection, situational awareness, and rapid response management across care delivery, public health, and other authorized Government agencies. The Use Case describes the process or interaction that each primary stakeholder will invoke to capture, discover, anonymize, and transmit relevant data.
The AHIC Biosurveillance Use Case that defines the scope of the Interoperability Specification describes the process or interaction that each primary stakeholder will invoke in the capture, discovery, anonymization, and transmission of relevant data. In particular, an implementer must provide the technical infrastructure and security framework necessary to support operations in accordance with law, regulation, best practices and business agreements.

Table 2.1-1 Related Documents

Related Documents	Document Description
HITSP/TP13	HITSP Manage Sharing of Documents Transaction Package
HITSP/TP22	HITSP Patient ID Cross-Referencing Transaction Package
HITSP/T29	HITSP Notification of Document Availability Transaction
HITSP/C25	HITSP Anonymize Component
HITSP/T24	HITSP Pseudonymize Transaction
HITSP/C37	HITSP Lab Report Document Using IHE XD* Lab Component
HITSP/C36	HITSP Lab Result Message Component
HITSP/C35	HITSP Lab Terminology Component
HITSP/C48	HITSP Encounter Document Using IHE Medical Summary Component
HITSP/C39	HITSP Encounter Message Component
HITSP/C41	HITSP Radiology Result Message Component
HITSP/TP49	HITSP Sharing Radiology Results Transaction Package
HITSP/C47	HITSP Resource Utilization Message Component
HITSP/TP50	HITSP Retrieve Form for Data Capture Transaction Package
	Biosurveillance Glossary of terms used for the Bio Interoperability Specifications

2.2 TECHNICAL ASSUMPTIONS AND SCOPE

This Interoperability Specification focuses on a set of constrained standards for information interchange that address the core requirements of the Use Case described above. It may not define all functions, constructs and standards necessary to implement a conforming system in a real world environment. The following paragraphs provide the HITSP principles with regard to several critical topics to ensure consistent interpretation of the Interoperability Specifications.

2.2.1 INTEROPERABILITY SPECIFICATIONS NOT FUNCTIONAL SPECIFICATIONS

The HITSP Interoperability Specification defines how two or more systems exchange standard data content in a standardized manner. Interoperability Specifications define the necessary business and technical actors, the transactions between them including the message, content and terminology standards for the actual information exchange. Interoperability Specifications do not specify the functional requirements or behaviors of the systems or applications.

2.2.2 ARCHITECTURAL NEUTRALITY

HITSP Interoperability Specifications, unless otherwise noted, are not intended to define or prescribe any system architecture or implementation. At the most basic level, the Interoperability Specifications define specific information exchange standards that are to be used by any two systems. Information exchange must be placed within the context of a transaction between defined technical actors which fulfill higher level business requirements derived from the Use Case. In some cases the necessary technical actors may require some architectural structure or make some assumptions involving synchronous or asynchronous data exchanges, or require specific type of exchange, such as a message or document. These requirements may constrain to some degree the total range of choices regarding system architectures. When constraints are necessary to meet the Use Case requirements, the Interoperability Specification will note this and will retain as much architectural neutrality as possible. When appropriate, the Interoperability Specifications may provide architectural examples and discuss considerations of such examples.

2.2.3 THE USE OF MESSAGES AND DOCUMENTS AS APPROPRIATE

Within healthcare information there is an ongoing debate concerning the proper role of messages and documents as methods of exchanging data. Messages are typically non-persistent encapsulations of highly structured data that require external context. Documents are persistent encapsulations of both data and context which may be authenticated to insure non-repudiation. Persistence as defined by Health Level Seven (HL7) means that a clinical document continues to exist in an unaltered state for a time period defined by local and regulatory requirements. Non-repudiation, as defined by ISO adapted from ASTM E31, means a service that provides proof of the integrity and origin of data, which can be verified by any party. HITSP recognizes that requirements for both messages and documents exist and where consistent with harmonization will support both. For example, depending on specific phases of the workflow, a laboratory result might be exchanged as a message, as a document, or both. Business requirements may define which format is more effective.

2.2.4 SECURITY AND PRIVACY

The Health Insurance Portability and Accountability Act (HIPAA) and its Administrative Simplification sections establish the minimum federal requirements for security and privacy of individually identifiable health information (IIHI). HIPAA requires that “covered entities” establish and maintain secure systems that protect IIHI from unauthorized disclosures while ensuring its availability for authorized uses. Most providers, health plans and intermediaries, and by contract their business associates, are covered by HIPAA regulation. However, HIPAA does not cover personal health records unless they are held by a covered entity, nor an individual’s use of their own health information.

Currently, HITSP is charged by ONC to harmonize standards based on Use Cases derived from AHIC requirements and priorities. Implicitly and in some cases explicitly, the Use Cases require a secure infrastructure and certain security or privacy functions. Because of time and resource constraints and the need for further information as described below, HITSP has decided to defer specifying most security requirements, instead treating these as a pre-condition for implementing the core information exchanges. The underlying premise is that HITSP**,** based upon prioritization by AHIC and ONC, will in the future identify and constrain the standards needed for a standards-based security framework that provides the mechanisms needed to protect patient privacy and maintain confidentiality of information about the patient. This standards-based security framework will need to accommodate federal, state, local, and healthcare enterprise security and privacy policies and processes. Exceptions to the deferred requirements that are addressed in this first release are secure web-based messaging, pseudonymization and anonymization.

There is a special case for the Consumer Empowerment (CE) Use Case. In the first year of HITSP's work, the Consumer Empowerment TC is to provide an Interoperability Specification for sharing of demographic data, medication lists, and allergies *based on patient consent*. Patient consent is clearly within the scope of the CE Use Case. However, HITSP requires further guidance on patient consent, particularly since patient consent is not addressed by HIPAA in the case of a personal health record (PHR) nor is it established within widely accepted PHR standards. Therefore HITSP identifies patient consent as a necessary pre-condition for successful implementation of a PHR that contains personal demographic data and medication histories. Patient consent will be documented as a pre-condition in the CE Interoperability Specification. Work on patient consent has been deferred until the second year of HITSP work.

2.3 AUDIENCE

The Interoperability Specification is designed to be used by analysts who need to understand the interoperability requirements for the described Use Case, and by implementers working to develop interoperable applications. Understanding and using the relevant set of Interoperability Specifications is a key requirement for establishing interoperability compliance.

2.4 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

Certain materials contained in this Interoperability Specification are reproduced from Health Level Seven (HL7) Version 2.5/2.5.1, Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2), and Health Level Seven (HL7) Version 3.0 with permission of Health Level Seven, Inc. No part of the material may be copied or reproduced in any form outside of the Interoperability Specification documents, including an electronic retrieval system, or made available on the Internet without the prior written permission of Health Level Seven, Inc. Copies of standards included in this Interoperability Specification may be purchased from the Health Level Seven, Inc. Material drawn from these standards is credited where used.

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2.5 ACRONYMS

The acronyms used in this document are contained in the HITSP Acronyms List.

2.6 CONVENTIONS

Conventions are used to convey the full descriptions and usage of standards in the Interoperability Specification and are contained in the HITSP Conventions List.

2.7 REFERENCE DOCUMENTS

The HITSP Glossary provides definitions for relevant terms used by HITSP documents.

3.0 REFERENCED STANDARDS

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

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

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

The Population Health Technical Committee has focused its work around an analysis of the Biosurveillance Use Case provided by the American Health Information Community (AHIC). This work has also been informed by the proceedings of the AHIC Biosurveillance Data Steering Group (BDSG).

The Population Health TC has selected standards first in accordance with HITSP Tier 1 and Tier 2 criteria. The TC worked with USHIK to evaluate the metadata and repository for use in standards selection using demographic and encounter data as a test case. Note that the United States Health Information Knowledgebase (USHIK) provides and maintains a metadata registry of health information data element definitions, values, and information models (www.ushik.org). The results and the resource will be used to extend this Interoperability Specification to additional domains and clinical data information exchange standards.

The Population Health TC has selected standards with more options than might otherwise be defined between communication partners. As biosurveillance is based upon secondary use of clinical data, the processes and data capture options are somewhat opportunistic, and associated data mining processes have more latitude in translation and data preparation processes. Since it is important to maximize the data sources to contribute data to the biosurveillance information system, information exchange selections include options for data capture from both legacy environments and emerging environments. Vocabulary, message, and content standards have been selected in consideration of providing the most comprehensive, machine processable fulfillment of the data requirements provided by the AHIC BDSG.

3.1 LIST OF STANDARDS

The following standards are used to implement this Interoperability Specification. It is important to understand that the standards selected here are within the context of the specific Use Case requirements and do not necessarily reflect selection in other contexts.

Table 3.1-1 List of Standards

Standard	Description
American Medical Association (AMA) Current Procedural Terminology (CPT®) Fourth Edition (CPT-4)	A uniform coding system used primarily to identify medical services and procedures furnished by physicians and other healthcare professionals. Visit www.ama-assn.org for more information.
Clinical Care Classification (CCC) Version 2.0 [formerly known as the Home Healthcare Classification (HHCC) System]	Provides a standardized framework and unique coding structure for assessing, documenting, and classifying patient care in all healthcare settings. CCC consists of two interrelated terminologies: CCC of Nursing Diagnoses and Outcomes and CCC of Nursing Interventions and Actions classified by 21 Care Components that represent the Functional, Health Behavioral, Physiological, and Psychological Patterns of patient care. The 21 Care components serve as the framework for mapping and linking the two interrelated terminologies to each other and to other health-related classifications. It was designed for computer processing and is free with permission. Visit www.sabacare.com for more information.
Clinical Laboratory Improvement Amendments (CLIA) of 1988	Establishes quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test is performed. The Centers for Medicare and Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. based on CLIA. Visit www.fda.gov and www.cms.hhs.gov for more information.
Digital Imaging and Communications in Medicine (DICOM) Attribute Level Confidentiality Supplement: # 55	Adds a mechanism for selective protection of individual attributes within arbitrary DICOM service-object pair (SOP) instances. It may be used to achieve protection of identifying information, e.g., a reversible anonymization or pseudonymization of DICOM SOP instances while continuing to use unmodified lower level message and protocol services for network transfer, storage, and media exchange of composite image information objects. Visit medical.nema.org for more information.

Standard	Description
Federal Information Processing Standards (FIPS) Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5-2, May, 1987	A set of two-digit numeric codes and a set of two-letter alphabetic codes for representing the 50 states, the District of Columbia and the outlying areas of the United States, and associated areas. The standard covers all land areas under the sovereignty of the United States, the freely associated states of Federated States of Micronesia and Marshall Islands, and the trust territory of Palau. Visit www.itl.nist.gov for more information. NOTE: ASC X12 transactions and ASC X12N Implementation Guides do not allow use of this standard; instead they require use of the U.S. Postal Service's National Zip Code and Post Office Directory -- which provides similar alphabetic code values.
Health Insurance Portability and Accountability Act (HIPAA) -- Administrative Simplification	A listing of national standards plus rules adopted by federal regulation for electronically communicating specified administrative and financial healthcare transactions, and protecting the security and privacy of healthcare information, as applied to the three types of defined covered entities: health plans, healthcare clearinghouses, and healthcare providers who conduct any of the specified healthcare transactions. See the Code of Federal Regulations, Title 45, Parts 160, et. seq. for more information.
Health Level Seven (HL7) Version 2.5	The HL7 Version 2.5 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 5, and 7 including patient demographic (ADT) and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. Visit www.hl7.org for more information.
Health Level Seven (HL7) Version 2.5/2.5.1[3]	The HL7 Version 2.5 and 2.5.1 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 4, 5, and 7 including patient demographic (ADT), Pharmacy/Treatment Orders and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. They are also used in HL7 order messages such as Visit www.hl7.org for more information.
Health Level Seven (HL7) Version 3.0	The HL7 Version 3.0 Messaging Standard is an application protocol for electronic data exchange in healthcare. Version 3.0 is based on a Reference Information Model (RIM); which is used to instantiate various message formats. Value sets / code tables are contained in the standard. Visit www.hl7.org for more information.

[3] HITSP references HL7 2.5.1 messaging for lab results reporting and HL7 2.5 for other messages. Future maintenance work will move toward referencing a single HL7 version across HITSP documents.

Standard	Description
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)	The HL7 Clinical Document Architecture is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. Of particular focus for HITSP Interoperability Specifications are message formats for Laboratory Results and Continuity of Care (CCD) documents. Release 2 of the HL7 Clinical Document Architecture (CDA) is an extension to the original CDA document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. CDA R2 further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and Structures. Visit www.hl7.org for more information.
Healthcare Common Procedure Coding System (HCPCS) Level II Code Set	Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes (Level I of HCPCS) for billing purposes. In some cases a HCPCS code may be used to identify a unusual ordered service mapped to the AHIC data set. CMS maintains HCPCS codes. Visit www.cms.hhs.gov for more information.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 3.0	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles, offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 3.0 for Final Text, specifies the IHE transactions defined and implemented as of December 9, 2006. The latest version of the IHE Technical Framework is available at www.ihe.net.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles, offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 4.0 for Final Text, specifies the IHE transactions defined and implemented as of August 22, 2007. The latest version of the IHE Technical Framework is available at www.ihe.net
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 - Registry Stored Query Transaction for XDS Profile Supplement	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles, offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The Registry Stored Query Transaction Trial Implementation Supplement specifies an IHE transaction that provides optimization and implementation simplification. This supplement is available at www.ihe.net.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 XCA Supplement	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles, offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The trial implementation version of the XCA Supplement to the ITI-TF, rev. 4.0 Final Text, specifies the IHE transactions that support access between communities in a manner compatible with the XDS Integration profile. This supplement is available at www.ihe.net.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement	Supplement (ITI TF-Supplement) ITI-25 Notification of Document Availability (NAV), IHE TF, Jun 28, 2005
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement	Supplement (ITI TF-Supplement) Retrieve Form for Data Capture (RFD), IHE TF Sep 25, 2006

Standard	Description
Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Supplement 2006-2007 Revision 1.0	The IHE Laboratory Technical Framework introduces a content Integration Profile Sharing Laboratory Reports (XD*-LAB) that describes a clinical laboratory report as a human-readable electronic document. This document, which may also contain data in a machine-readable format and contains the complete set of final results produced by a clinical laboratory in fulfillment of one or more test orders for a patient. This document is focused on the sharing of sets of laboratory results in the form of a laboratory report structured document, and is not intended to address ordering or return of laboratory results to the ordering provider. Visit www.ihe.net for more information.
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 3.0	The IHE Patient Care Coordination Technical Framework (PCC TF) defines specific implementations (called Integration Profiles) of established standards to deal with integration issues that cross providers, patient problems or time. The Cross Enterprise Document Sharing of Medical Summaries (XDS-MS) Integration Profile enables sharing of health information between enterprises of a regional health network, and further describes how to map content in a CDA medical document into registry metadata. In the registry, healthcare providers publish pointers to documents stored in distributed repositories. Other healthcare providers may search and retrieve these and other documents. Visit www.ihe.net for more information.
Integrating the Healthcare Enterprise (IHE) Radiology Technical Framework Revision 7.0	The IHE Radiology Technical Framework specifies the Cross Enterprise Document Sharing for Imaging (XDS-I) Integration Profile which enables sharing of imaging documents such as radiology images and reports across healthcare enterprises. XDS-I extends XDS by sharing, locating and accessing DICOM instances from its original local sources, e.g. for radiologists or oncologists. Visit www.ihe.net for more information.
International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS)	The International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS), describes the classification of inpatient procedures for statistical purposes and for the indexing of healthcare records by procedures. ICD-10-PCS is a procedural coding system managed by the Centers for Medicare and Medicaid Services (CMS). Visit www.cms.hhs.gov for more information.
International Classification of Diseases, 10th Revision, Related Health Problems (ICD-10-CM)	The International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), describes the classification of morbidity information for statistical purposes and for the indexing of healthcare records by diseases. The National Center for Health Statistics (NCHS), the Federal agency responsible for use of the International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) in the United States, developed a clinical modification of the classification for morbidity purposes. Visit www.cdc.gov/nchs for more information.
International Classification of Diseases, 9th Revision, Clinical Modifications (ICD-9-CM)	The International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM), Volumes I, II (diagnoses) and III (procedures) describes the classification of morbidity information for statistical purposes and for the indexing of healthcare records by diseases and procedures. Visit www.cdc.gov/nchs for more information.
International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	SNOMED CT consists of a technical design, core content architecture, and Core content. SNOMED CT Core content includes the technical specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content also includes a concepts table, description table, relationships table, history table, ICD-9-CM mapping, and Technical Reference Guide. Additionally, SNOMED CT provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms unique to particular organizations or localities. Visit www.snomed.org for more information.
International Organization for Standardization (ISO) Health informatics -- Pseudonymization, Unpublished Technical Specification # 25237	Health Informatics – Pseudonymization. Approved as a Technical Specification March, 2007. Visit www.iso.org for more information.
International Organization for Standardization (ISO) Electronic business eXtensible Markup Language (ebXML), Technical Specification # 15000 -- Part 4: Registry services specification (ebRS), May, 2004	Describes eXtensible Markup Language (XML) and its usage characteristics. Consists of 4 parts: ebCPP, ebMS, ebRIM, and ebRS. Part 4 ebRS defines the interface between the registry and the registry clients, as well as the interaction protocols, message definitions and XML schema. Visit www.iso.org for more information.

Standard	Description
Logical Observation Identifiers Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. Visit www.loinc.org for more information.
National Library of Medicine (NLM) Unified Medical Language System (UMLS) RxNorm	Provides standard names for (1) clinical drugs and (2) drug dose forms as administered to a patient. Also provides links from clinical drugs, both branded and generic, to their active ingredients, drug components (active ingredient + strength), and related brand names. Food and Drug Administration (FDA) National Drug Codes (NDCs) for specific drug products and many of the drug vocabularies commonly used in pharmacy management and drug interaction software are additionally linked to RxNorm. Visit www.nlm.nih.gov for more information.
National Uniform Billing Committee (NUBC) Uniform Bill Version 1992 (UB-92) Current UB Data Specification Manual Field 22, Patient Discharge Status, Codes	A code set identifying status of patient discharge on an institutional claim (e.g., inpatient, outpatient, hospice, home care). Visit www.nubc.org for more information.
Organization for the Advancement of Structured Information Standards (OASIS) Emergency Data Exchange Language (EDXL) Distribution Element (DE)	Describes a standard message distribution framework for data sharing among emergency information systems using the XML-based EDXL. This format may be used over any data transmission system. DE is initially intended for use in disaster or emergency situations. Visit www.oasis-open.org for more information.
Unified Code for Units of Measure (UCUM)	A code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans. Visit aurora.regenstrief.org for more information.

OASIS HAVE V1.0 is included in this Interoperability Specification as Intended for Use, and it is anticipated that the standard will be approved before the end of the first quarter of 2008. OASIS HAVE V1.0 will not be approved by the time this Interoperability Specification is released. However, the standard is sufficiently defined to enable detailed evaluation of how well it will meet technical and business requirements. The HL7 specifications and constraints provided by this Interoperability Specification are aligned with the OASIS HAVE V1.0 standard.

3.2 STANDARDS GAPS AND OVERLAPS

The following two tables portray gaps and overlaps in standards needed to fulfill this Use Case. These were identified during the initial HITSP Gap Analysis prepared for this Use Case. These are still gaps to implementation of optimal solutions for Biosurveillance. Because the standards development process for a given initiative involves significant manpower and time to establish a consensus-based solution, the HITSP Population Health TC continues to reference these as gaps and overlaps for resolution. In some cases, progress is already underway to resolve these gaps and overlaps. Such progress is identified in the resolution plan table that is provided in this document section.

Table 3.2-1 Use Case Events And Associated Gaps

Event Code	Event Description	Identified Gaps	Recommended Resolution
1.1.1.0	Filter existing data to identify data required by public health agencies	LAB Terminology Orders/Results (Test Batteries) Possible Gap: indication /presumptive diagnosis/ reason for test - NOT a gap for current data dictionary, gap for domain Standardization of data definitions to ensure accurate filtering	Work with LOINC and SNOMED to achieve the appropriate level of granularity Link test orders to test results. Work with ICD and SNOMED to review Vocabulary requirements for presumptive DX CMS-validated mapping between SNOMED-CT and ICD9-CM (while more clinical granularity as provided by SNOMED, current systems are using ICD-9-CM for morbidity coding) Approach HL7 and OASIS IHC to coordinate standards development efforts for formalizing rule specification for consistent screening of cohort selection Monitor/contribute/review IHE Retrieve Form for Data Capture (RFD) to assure biosurveillance needs are met for reportable filters.
1.2.1.0	Filter existing data to identify data required by public health agencies		
1.1.2.0	Anonymize data required by public health agencies	LAB, VISIT, UTILIZATION *Functionality/ workflow/ process* Freeform text records, e.g., notes, specimen description, etc. may contain information that can identify an individual. Method for abstracting concepts from freeform text records that will not effect anonymization is needed. We need additional guidance on policy that is inclusive of the entire U.S. needs.	Encourage open source and publicly available software contributions of free-text parsers to extract and encode data of interest (codify) at the source to protect the anonymity of the payload data, e.g., Eclipse Open Healthcare Frameworks Monitor / contribute / review ISO TC215 Health Informatics Pseudonymisation standard Refer to AHIC Security/Privacy group
1.2.2.0	Anonymize data required by public health agencies		

Event Code	Event Description	Identified Gaps	Recommended Resolution
1.1.3.0	Format data required by public health agencies	LAB Terminology Granular ontology of body sites Definitions for indication/ presumptive DX/reason for test Standardized use of laboratory terminology standards is a gap because laboratories and hospitals often use local codes to describe laboratory tests and test results instead of adhering to vocabulary standards such as LOINC and SNOMED *Functionality /workflow/ process* - need to define dataset to be send VISIT *Terminology* - Possible Gaps -need to have more detail on the essential data set. There may be gaps in the vocabulary (e.g. ED Acuity): LAB, VISIT, UTILIZATION *Context* – need for information model for visit data Message – there is a need for a message standard that can appropriately represent the required utilization data. *Functionality/ workflow/ process* - need for a method for transformation, mapping between different standards and local/custom codes. UMLS / SNOMED mapping may be incomplete for this Use Case need to define to whom to send data need to define term “transform” (i.e., from what to what?)	LAB Review context standards (see statements below) Monitor/ contribute / review the HL7 specimen segment development Review the data dictionary and volume/frequency requirements to better assess potential vocabulary gaps Encourage open source and publicly available software to help facilitate mapping from local codes to selected vocabulary standards Support both messaging and structured document approaches for submitting data to BIS Monitor/ contribute / review IHE Laboratory Documents (IHE CDA-2) to assure biosurveillance needs are met Provide tools and other services that assist hospitals and laboratories in standardizing their laboratory messaging and vocabulary. This includes properly mapping laboratory information into the agreed to standard messages and translating local codes to standardized codes Provide tools that can securely transport laboratory messages to the intended recipient. Example: Eclipse Open Healthcare Frameworks to identify status Define conformance measures for laboratory reporting standards. Regenstrief is developing a tool called "HL7-Lint" which examines messages for conformance to HL7, and identifies some of the most common HL7 errors (e.g. units in the wrong field, etc.). This tool is used to examine messages from new data providers as an initial step in the message-standardization and term-mapping process. Further steps are needed to review tool requirements for fulfillment of domain testing /coordinate with LOINC Work with LOINC to develop a richer set of orderable laboratory test panels within the LOINC coding system. Work with the Council of State Territorial Epidemiologists Public Health Informatics Subcommittee to define a common national standard specification for laboratory data reporting GENERAL Monitor / contribute / review HL7 CTS (Nascent Standard) and HL7 PHER SIG to assure that biosurveillance needs are met Work with CSTE/CDC to harmonize public health reporting requirements mandated by state laws (reportable conditions) and identified by CDC (notifiable conditions) with regards to presumptive or confirmed cases of diseases/conditions Work with AHIC to define biosurveillance data set.
1.2.3.0	Format data required by public health agencies		

Event Code	Event Description	Identified Gaps	Recommended Resolution
1.1.4.0	Identify Public Health Agencies that must be notified	LAB, VISIT UTILIZATION There is a need to define dataflow between clinical care and local, state and federal public health agencies for biosurveillance	Work with AHIC to define dataflow between clinical care and local, state and federal public health agencies for biosurveillance
1.2.4.0	Identify Public Health Agencies that must be notified		
1.1.5.0	Transmit relevant data to public health agencies	Additional security standards refinement and profiling are needed. LAB, VISIT, UTILIZATION Need to define biosurveillance data set	Monitor/contribute/review ISO TC215 Health Informatics WG4 NWIP Audit. Monitor/contribute/review IHE PCC Patient Consent/Authorizations profile for access to medical records in the current cycle to assure support for consent override for public health purposes, which would be included in a disclosure log
1.2.5.0	Transmit relevant data to public health agencies		
1.3.1.0	Provide listing of required biosurveillance data	LAB, VISIT, UTILIZATION Need to define biosurveillance data set Generation of required data listing is a paper/human process today Gaps in *Context, Information Exchange* and *Functionality /Process/ Workflow*	See Data Dictionary Recommendations above Work with HL7 V3 PH to review communication protocols between actors Communicate the gap to National Center for Health marketing at CDC to request a review of the problem
1.3.2.0	Receive biosurveillance data	LAB, VISIT, UTILIZATION - *Functionality/Process/Workflow*– need consistency in the level of acknowledgement (ACK).	Recommend that the biosurveillance technical framework include implementation guidance to assure a consistent process for ACK. Use RFC 2298 and RFC 2852 See security recommendations in 1.1.5.0 (overlaps)

RESOLVING GAPS: Work with SDOs /Profiling Organizations

When relevant *current work* is identified:

Establish Technical Committee (TC) Liaison to monitor, inform, and participate in the development process to assure that the work fills the gap

When relevant *pending work* is identified:

Work with organization to request acceleration

Establish TC Liaison to inform and contribute to the new standard/profile development process to assure that the work is established to fill the gap

Adjust the Biosurveillance Interoperability Specification roadmap to accommodate estimated timeline for completion

When *no current/pending efforts* are identified:

Work with organization(s) to request new standard/profile

Establish TC Liaison to inform, and contribute to the new standard/profile development process to assure that the work is established to fill the gap

Adjust the Biosurveillance Interoperability Specification roadmap to accommodate estimated timeline for completion of pending work

When *multiple organizations have current/pending* work:

Request joint development and concurrent harmonization to assure that the work is filling the gap and not introducing duplications

Establish TC Liaison with each affected organization to inform, harmonize, and contribute to the concurrent development process to assure that the work fills the gap without introducing duplications

Adjust the Biosurveillance Interoperability Specification roadmap to accommodate estimated timeline for completion of pending work

Table 3.2-2 Overlaps

Event Code	Event Description	Standard Duplication/ Overlap	Recommended Resolution
1.1.2.0 1.2.2.0	Anonymize data required by public health agencies	See access control below	See access control Below
1.1.3.0 1.2.3.0	Format data required by public health agencies Format data required by public health agencies	UTILIZATION *Information Exchange* - Bed availability - HL7 V2.x: 4 candidate messages - Potential overlap: OASIS HAVE LAB *Information Exchange* – Lab Results *Message* – Result Interpretation - DICOM / HL7 *Terminology* - Specimen / Body Site: - HL7 / foundational model of anatomy / LOINC / SNOMED / DICOM *Terminology* – Presumptive Diagnosis: - HL7 / SNOMED / ICD9/ ICD10 VISIT *Information Exchange* – Visit data messages - Potential Overlap HL7/X12 *Terminology* - Presumptive Diagnosis: - HL7 / SNOMED / ICD9/ ICD10 LAB, VISIT, UTILIZATION *Information Context* - Possible Overlap for information models - ASTM / HL7 / DICOM / ADA / ISO	Work with HL7 to assess recommendations for bed/resource availability: address at the next meeting of HL7 name a liaison to carry the issue compare to OASIS HAVE HL7 Order Result is recommended for human results interpretation, whereas DICOM is recommended for machine - generated results Review and assess relevant work to express Specimen Site and Presumptive DX Work with SDOs to harmonize standards (e.g. define mapping translations from one message-type to the other Identify the appropriate information model Review best practices in laboratory data management such as CAP, JCAHO, CDC, National Patient Safety Laboratory Guidelines, CMS, CLSI, NACB, and centers of laboratory excellence
1.1.5.0 1.2.5.0	Transmit relevant data to public health agencies Transmit relevant data to public health agencies	***Multiple security standards identified do not represent overlapping standards in security***. These standards and profiles may vary based upon architecture. ASTM E2085 and E2086 provide guidance for selection of engineering standards, but do not include guidance on newer technologies. See access control below	Review and update ASTM E2085 and E2086 to include guidance for new WS, ISO, and engineering standards. See access control below
access control	Manage and Control Data Access	Overlap: ANSI/INCITS 359 for RBAC Possible Overlap: ANSI/INCITS 359 with ASTM E1985	Recommend review and harmonization of ASTM E1985 with ANSI/INCITS 359

Event Code	Event Description	Standard Duplication/ Overlap	Recommended Resolution
RESOLVING DUPLICATION AND OVERLAPS: When overlap is *within* the standard: work with SDO to resolve internal issue (e.g. HL7 bed availability) When overlap is *across* standards: work with affected SDOs through joint meetings (e.g. SNOMED/LOINC) translation mapping for data standards (e.g. CCR/CDA-2) request SDOs to jointly conduct harmonization (e.g. SNOMED/LOINC) Apply evaluation criteria (e.g. current use, ease of implementation for Use Case, etc) to select standards for Interoperability Specification until harmonization between identified overlapping standards is complete Once harmonization is complete, update the Interoperability Specification accordingly			

Table 3.2-3 Resolution Plan

Date	Task to be Accomplished/Who is involved
HL7 v3.0 is included even though their use is emerging – it is a current version of HL7. Industry use of standards is evolving, and the expectation is that these standards will become more broadly used. A change management plan is needed to adopt new versions and/or standards as appropriate. Semantic interoperability is a developmental process that needs to continue and gain adoption.	
Filter Data Required by Public Health Authorities	
2005/2006	Monitored / contributed/ reviewed IHE Retrieve Form for Data Capture (RFD) to assure biosurveillance needs were met for reportable filters and supplemental data elements for conditions reported to public health agencies
2006/2007	IHE-RFD work product was developed in full consideration of Population Health TC contribution and clinical Use Cases. Work product adopted as part of this specification. Recommend to work with continuing efforts in the 2006-2007 project year to automate mapping of source data elements from Clinical Information System to form content. Work with LOINC and SNOMED to Achieve the appropriate level of granularity Link test orders to test results Work with ICD and SNOMED to review Vocabulary requirements for presumptive DX CMS-validated mapping between SNOMED-CT and ICD9-CM (while more clinical granularity as provided by SNOMED, current systems are using ICD-9-CM for morbidity coding) Approach HL7 and OASIS IHC to coordinate standards development efforts for formalizing rule specification for consistent screening of cohort selection Monitor and contribute to IHE efforts to establish tracking capabilities for specimens as they move from the local level to the state level and federal level (IHE PCC Case Management PH Lab profile; Also will need to monitor and contribute to the IHE-XCA through HITSP Cross-TC efforts and IHE-RFD tagging items.), Refer the SNOMED/Reportable conditions mapping request to Foundations Committee, including clarification of reportable conditions definition. An IHE RFD profile update regarding security considerations for RFD is under way. The TC will monitor and contribute to this IHE effort.

Date	Task to be Accomplished/Who is involved
Anonymize Data Required by Public Health Agencies	
2005/2006	While DICOM Supplement 55 is published, it but references radiology research within an organization; The pseudonymization and anonymization principles addressed in this specification conform to the ISO TC215 /DTS 25237. The Population Health TC recognizes that ISO/DTS 25237 is a draft standard and informal Liaison relationship is established to Monitor, contribute, and review the development of the ISO TC215 Health Informatics Pseudonymisation technical specification. Re-identification out of scope in current Use Case, and given the interim status of DTS 25237, re-identification specification is deferred. The Population Health TC anticipates that this ISO TC215 technical specification will address re-identification methodologies for re-identification.
2006/2007+	The Population Health TC will continue to monitor, contribute, and review the development of the ISO TC215 Health Informatics Pseudonymisation technical specification ISO/DTS 25237. Updates will be made to this HITSP specification to conform to any changes that impact this specification. Re-identification is a policy issue and that the action be the responsibility of the pseudonymization services. ISO TC215/DTS 25237 is expected to address re-identification. This HITSP specification will be updated to include re-identification methodologies in conformance with the ISO TC215 specification.
Harmonize OASIS HAVE and HL7	
2005/2006	Joint meetings were started in May 2006. As a result, a plan was developed to integrate the HAVE Concepts into the HL7 messaging structure to capture bed availability from HL7 enabled environments. This approach has been detailed in this Interoperability Specification
2006/2007+	OASIS HAVE Specification is under public comment and review. Anticipate this to be a final approved standard by year end *Need for Further Harmonization* In order to facilitate improvements in future healthcare utilization information interchange standards, the HITSP Population Health TC recommends that OASIS and HL7 work collaboratively to develop a single, unified resource utilization Interoperability Specification, including both information exchange and terminology standards, to meet the needs of Biosurveillance and other stakeholders.
Laboratory Report Document Support for Biosurveillance	
2005/2006	Liaisons from the Population Health TC worked with IHE to develop the Laboratory Report Document HL7-CDA-2 implementation specification. The committee has reviewed the document out now for public comment, and updates will be made to account for these contributions in September. The results of this initiative have been incorporated into this Interoperability Specification. No additional gap is identified at this time for this document.
Support Both Messaging and Structured Document Approaches for Submitting Data to BIS	
2005/2006	Both messaging and structured document approaches have been incorporated into this Interoperability Specification. Document-based information sharing is included in this Interoperability Specification to align and maintain consistency with other HITSP efforts in Electronic Health Record and Consumer Empowerment. The document-based information sharing approach has not previously been considered for secondary use of data as required by Biosurveillance or other secondary use systems (e.g., clinical trials, aggregate performance measurements, disease management and population health).
2006/2007+	Evaluate expansion of specification to support additional messaging and document structures so as to enable broader options and sources for collecting Biosurveillance data. The Technical Committee identified several areas for further evaluation prior to endorsing full document-based data sharing for Biosurveillance activities. These areas for evaluation include: Methodology and criteria for publish and subscribe capability such that subscription filtering can be modified in real time as the situation requires. Document Sharing Service requirements to meet the needs of public health and, potentially other forms of secondary data use. Extent of usable information within documents; i.e., structured Vs human readable text, and the extent of natural language processing required to enable document sharing as a viable Biosurveillance solution. The evaluation should include the extent to which document-based sharing encapsulates message-based standards that correlate with the message-based functional flow as detailed elsewhere in this document. Implementation sites are encouraged to explore and research these areas of concern to provide additional evidence for more robust usage of document-based information sharing for secondary usage of data.

Date	Task to be Accomplished/Who is involved
Need to Have More Detail on the Essential Data Set	
2005/2006	HITSP communicated the need for a Biosurveillance Data Dictionary to ONC. In response to this request, the AHIC Biosurveillance Data Steering Committee has been established. This group began meeting in June 2006. Liaisons were established between this steering committee and the Population Health TC. These two groups worked in parallel to comply with early data dictionary requirements in the current implementation specification. The HITSP Population Health TC has indicated through the liaisons that further specificity is needed to accommodate the request for Laboratory and Radiology Orders. These will be moved to address in the 2006-2007 project year.
2006/2007+	The HITSP Population Health TC will work with the AHIC Biosurveillance Data Steering Committee to expand the data dictionary and to expand the Interoperability Specification to address additional data elements and data sources identified by this steering committee. The HITSP Population Health TC will work with the AHIC Biosurveillance Data Steering Committee to identify more sophisticated query support for the shared document resource functional flow scenario to enhance the functionality of the implementation in support of identification, monitoring, and management of public health threats. Monitor / contribute/ review IHE PCC Patient Consent/Authorizations profile for access to medical records in the current cycle to assure support for consent override for public health purposes, which would be included in a disclosure log.
2005/2006	This work has been completed. The resulting IHE-BPPC has been included in this technical specification for the purposes of supporting audit and verification of authorization to collect PHI for biosurveillance purposes.
Resolve an Overlap between HL7 and DICOM	
2005/2006	This work is completed: HITSP Guideline developed to address this overlap as follows: When human analysis is to be provided, an HL7 Order Result is the appropriate means to deliver the data. When machine analysis is to be provided, DICOM is the most appropriate. For attachments to Order Results, use HL7 for human analysis and DICOM for machine analysis and for images. DICOM has a variety of image object specifications, ranging from the "Secondary Capture" object used as the most generic container through specific objects for CT and MR to highly specialized objects such as the Ophthalmic OCT image and Intravascular Ultrasound objects. The specific object type to be used depends on the kind of image being attached. More specific guidance as to appropriate DICOM content can typically be found in part 3, and more specific guidance as to appropriate vocabulary for that content can be found in part 16 - e.g., Basic Diagnostic Imaging Report (TID 2000), Chest CAD analysis (TID 4100), etc.
Semantic Interoperability	
2005/2006	The HITSP Population Health TC has identified semantic interoperability to be highly important to the progress of work in Biosurveillance having developed the following statement: 'Improving data standardization processes is a crucial step in achieving the long-term goal of semantic interoperability. An initial step toward achieving this goal is to establish a framework for exchanging clinical information, whether the data are currently in freeform text or standardized, machine-readable format.'
2006/2007+	The HITSP Population Health TC recognizes that this is a highly complex area, with a long-term timeline. This TC will establish Liaisons with existing efforts in semantic interoperability. These liaisons will work through HL7 and OASIS to propagate this work into standards. Continuous evaluation will be done for each new Interoperability Specification development to embrace these standards as they are developed. The usefulness of near real-time biosurveillance information depends on the degree to which data collected from disparate sources are semantically interoperable. Semantic interoperability – the communication of full and commonly understood meaning across systems – will be optimized through achievement of the following objectives: Precise definition of the concepts being communicated, taking context into account where appropriate; Identification of common term sets used to communicate those concepts; Where multiple term sets exist for a concept, mapping of identical or synonymous terms across term sets. These objectives can be achieved in phases, the first of which is the enumeration of standards for messaging between actors in the biosurveillance scenarios, which has been done in the 2006 HITSP Biosurveillance initiative. On an ongoing basis, concepts within these messaging standards should be enumerated, and appropriate vocabulary selection and mapping performed. This identification and mapping process will not be completed within the first annual cycle. The steps needed to achieve these ultimate objectives must be integrated into the HITSP development roadmap.

Date	Task to be Accomplished/Who is involved
Publish and Subscribe	
2005/2006	Recommend that IHE review and identify a mechanism for publish and subscribe in support to public health
2006/2007	Work with IHE to develop a mechanism for publish and subscribe in support to public health
XDS Stored Query Gap	
2005/2006	Gap - Request IHE-ITI Change Proposal to add stored query support; Add constraint for 2005/2006 cycle
Penetration of Clinical Information Systems	
2006/2007+	Gap - Process issue – gap is in clinical systems – clinical systems are in ordering/administrative issues/process – system investment issue/clinical – identified as a challenge in original Use Case – penetration of clinical systems is an issue.: Continue to expand support for additional clinical data information exchange standards and document types
Codify Data from Freeform Text	
2005/2006	The HITSP Population Health TC has identified codification of freeform text to be highly important to the progress of work in Biosurveillance having developed the following statement: Clinical data are often recorded in an unstructured, freeform text format. In order to maximize the value of freeform text data for use in biosurveillance systems, translation into standardized, machine-readable codes is necessary. As a near-term incremental proposal, the HITSP Population Health TC recommends that sending or receiving systems assume responsibility for translating freeform text data for the AHIC -defined biosurveillance data set. Improving data standardization processes is a crucial step in achieving the long-term goal of semantic interoperability. An initial step toward achieving this goal is to establish a framework for exchanging clinical information, whether the data are currently in freeform text or standardized, machine-readable format. The data elements identified in the AHIC Biosurveillance Use Case that are routinely captured as freeform text include: • Chief complaints • Nursing / Triage Notes • Radiology impressions • Microbiology results Due to the volume of freeform text data requiring standardization, human review of all data are infeasible and automated text processing techniques, such as natural language processing (NLP) are needed to translate data into standardized formats. Further research addressing the challenges inherent in automated mapping of freeform text to SNOMED, ICD-9/10, LOINC and other terminologies is needed. The Population Health TC recommends that developing and disseminating standards and best practices for automated text processing techniques should be a priority. This technology has applicability to other areas outside of Biosurveillance, and would include processes for establishing semantic context, negation, exclusion criteria, and others.' Methods for standardizing chief complaints and nursing notes are needed. A nursing terminology that provides a standardized terminology framework, such as the Clinical Care Classification, for documenting coding and tracking nursing care in any healthcare setting may be applicable for this purpose. The Population Health TC recommends that SDOs in nursing and other clinical domains harmonize and present the benefits for biosurveillance and other secondary use efforts to provide value in long term semantic interoperability efforts. Diagnosis/injury code and associated cause may be addressed in ICD-9 and associated E-codes, but further study is needed.
2006/2007+	The HITSP Population Health TC recognizes that this is a highly complex area, with a long-term timeline. This TC will establish Liaisons with existing efforts in semantic interoperability. These liaisons will work through HL7 and OASIS and other SDOs to propagate this work into standards. Continuous evaluation will be done for each new Interoperability Specification development to embrace these standards as they are developed. Monitor and contribute to IHE Patient Care Coordination Technical Framework update to release 2.0. Update relevant references and constraints to these documents.

Date	Task to be Accomplished/Who is involved
Identify Communication Recipients	
2005/2006	Our specification assumes point-to-point and as a result is not applicable. Our assumption is that there is more than 1 recipient of biosurveillance data in subsequent HITSP cycles Scoped out as an architecture/infrastructure issue.
2006/2007+	Assess use of ISO TC215 ISO/TS21091 and other standards to facilitate communication among recipients
Nursing Terminology	Recommend to provide a patient care documentation terminology by nursing SDOs and other clinical domains for the representation of the benefits of the healthcare process in biosurveillance and for other secondary use and semantic interoperability efforts.
Radiology/Laboratory Order Message	
2005/2006	The HITSP Population Health TC has developed the following statement for review and consideration by the AHIC Biosurveillance Data Steering Committee: Pre-existing information contained in clinical orders may be used as early warning indicators for events of public health significance. Because clinical orders contain information describing patients and the types of clinical tests requested, the Biosurveillance Use Case for laboratory and radiology orders seeks to "re-use" this pre-existing information, and consequently represents a "secondary" use of such data. The Biosurveillance order Use Case is dependent on the primary Use Case developed for Laboratory and Radiology ordering. The selection of messages to be used for Laboratory and Radiology orders should be driven by the primary Use Case for orders, not a more limited secondary Biosurveillance Use Case. Consequently, we advocate that Biosurveillance should not dictate the order message(s) used to convey Laboratory and Radiology orders. Rather, the Biosurveillance work group should ensure that the information necessary for public health surveillance is included in order messages. We propose that any preliminary document developed for the Biosurveillance Use Case would maximally identify candidate messages that could contain the information of interest, and the location of the desired information in each transaction. Also of crucial importance is that the most common order message used for both Laboratory and Radiology orders today (the ORM^O01) has been temporarily retained for backward compatibility, but not recommended for use in HL7 2.5. Subsequently, the 2.5 order messages that may be selected by HITSP may *not* be the most universally implemented message for orders. For Biosurveillance to take advantage of the information found in orders, we must focus on where surveillance information can be found in a variety of order message types, not just a single order message type that is dictated for a Biosurveillance Use Case. To be broadly applicable, the Biosurveillance Use Case should leverage clinical order transactions commonly exchanged among clinical healthcare stakeholders, as well as public health entities. It should be noted that the laboratory order message selected by PHIN is intended for a narrow Use Case for messaging orders between public health laboratories, which has limited application to the Biosurveillance and EHR Use Cases.
2006/2007+	The HITSP Population Health TC will continue to work with AHIC Biosurveillance Data Steering Committee to enhance support for additional data element added to the data dictionary.
Terminology and Data Value Issues	
2005/2006	Identified issues
2006/2007+	Work with SDOs to resolve gaps and overlaps in this area:
	Date and Time Illness Onset : This remains a gap for which HITSP issues a recommendation to HL7 and ASTM to align concepts and vocabulary and produce a harmonized result
Laboratory and Radiology Test Orders	
	Order number :This remains a gap for which HITSP issues a clarification request from HL7 to attain a broadly accepted meaning for order number;
	Order test name :This remains a gap for which HITSP issues a recommendation to LOINC, SNOMED-CT, and CPT to develop and harmonize a suitable coded value set to express order test name
	Collection method :This remains an overlap for which HITSP issues a recommendation to subset SNOMED-CT for clarification and for SNOMED and HL7 to align subset with HL7 Table 488

Date	Task to be Accomplished/Who is involved
	Ordered test and Resulted test :Lack of a universal vocabulary remains a major gap for which HITSP issues a recommendation that SNOMED-CT, LOINC, CPT, HCPCS and others (encouraging commercial vendor participation) work together to establish a suitable and harmonized vocabulary
	Standards evaluation Process
2005/2006	The Population Health TC conducted assessment of demographic and clinical encounter data using the USHIK metadata registry. The TC Recommends further use of USHIK metadata registry in comparison and evaluation of standards in future work as part of the standards evaluation/selection process. (www.ushik.org/hitsp)
2006/2007+	Utilize the USHIK metadata registry to assist in comparison and evaluation of standards as part of the standards evaluation/selection process.
Policy Gap	
2005/2006	This approach has been incorporated into this Interoperability Specification. Refer to AHIC Security/Privacy group
2006/2007	Identify a liaison to the AHIC Security/Privacy group to carry the policy gap issue forward and to harmonize with TC efforts

4.0 INTEROPERABILITY REQUIREMENTS

4.1 USE CASE OVERVIEW

The AHIC Biosurveillance Use Case that defines the scope of this Interoperability Specification describes the process or interaction that each primary stakeholder will invoke in the capture, discovery, anonymization, and transmission of relevant data.

The scope addressed in this document is the transmission of essential data from ambulatory care and emergency department visits, utilization, and laboratory result data from electronically enabled healthcare delivery and public health systems in a standardized and anonymized format, to authorized Public Health Agencies with less than one day lag time. While the system and processes ultimately must also support the ability for authorized public health personnel to go back to the data source to seek to re-link the anonymized biosurveillance data to the data source as part of an appropriate public health investigation, such re-linking has been deferred for future effort and is not addressed in this IS. The anonymization and pseudonymization processes may require product engineering and external calls not specified in this document. This document will not specify where these calls are to be made in order to remain architecturally neutral.

The management of data to ensure proper routing, security, privacy, and timely reporting is critical to enabling biosurveillance activities. Potential architectural solutions to data flow issues include using individual facility data sources (e.g., single hospitals or ambulatory care sites) or networked system such as a multi-facility system or supporting organization that uses data in the course of providing other services and sends data to all appropriate public health agencies. Other permutations of these two models can also be considered. The role of the data or network system can be accomplished by several different stakeholders, including hospital systems, health plans, independent laboratories, and other possibilities. However, this IS was defined to be independent of architecture choice and is intended to support any variant of the architectural choices identified above.

National Planning Scenarios

1. Nuclear detonation – 10–Kiloton Improvised Nuclear Device
2. Biological Attack – Aerosol Anthrax
3. Biological Disease Outbreak – Pandemic Influenza
4. Biological Attack – Plague
5. Chemical Attack – Blister Agent
6. Chemical Attack – Toxic Industrial Chemicals
7. Chemical Attack – Nerve Agent
8. Chemical Attack – Chlorine Tank Explosion
9. Natural Disaster – Major Earthquake
10. Natural Disaster – Major Hurricane
11. Radiological Attack – Radiological Dispersal Devices
12. Explosives Attack – Bombing Using Improvised Explosive Devices
13. Biological Attack – Food Contamination
14. Biological Attack – Foreign Animal Disease (Foot and Mouth Disease)
15. Cyber Attack

4.1.1 CLINICAL EXAMPLES

To maintain context and perspective, the Population Health Technical Committee approached the creation of an Interoperability Specification using clinical exemplar scenarios. These exemplars were consistent with the 15 National Planning Scenarios created by the U.S. Department of Homeland Security listed in the text box to the right of this paragraph. Specific attention was given to biological attack with aerosol anthrax and biological disease outbreak with pandemic influenza. To

establish utility of interoperability for routine public health syndromic surveillance and situational awareness efforts, sexually transmitted disease (Chlamydia) and food-borne illness (Salmonella) were considered among clinical exemplars.

The Population Health TC has developed this Interoperability Specification in conformance with the AHIC Harmonized Biosurveillance Use Case to the extent that there are current standards and options with which to accomplish the requirements set forth in that Use Case. The TC has further worked in parallel with the AHIC Biosurveillance Data Steering Committee to adopt the initial work from the newly formed group to inform the work of this Interoperability Specification.

Except for secure web connection and pseudonymization/anonymization, security and privacy efforts have been deferred. Although the Use Case specifies a requirement for anonymization some Biosurveillance systems may be exempt from such requirements due to Public Health Law, contracts or legal agreements. This specification utilizes the Pseudonymization Service to implement the Randomized Data Linker functionality. In some cases today, pseudonymization has been done as a cross-reference table at the data source. This, however, can pose a burden on the data source system. As such, the Population Health TC recommends establishing regional and/or national services for patient pseudonymization for biosurveillance. This would allow for tracking of patients across institutions for better biosurveillance reporting/analysis:

- Reducing duplicate counts
- Reduce the work effort on any individual sending system

While this is not yet pervasively available, we recommend this as a roadmap to accomplish this goal.

There are a number of challenges related to automated capture of Biosurveillance data that have been considered in the development of this specification. Because the Biosurveillance capture relies on routine processes, the ability to require conformance with the specified formats is limited to the organization's ability to comply with those formats. As such, the requirements are somewhat less prescriptive than those that are associated with clinical systems integration.

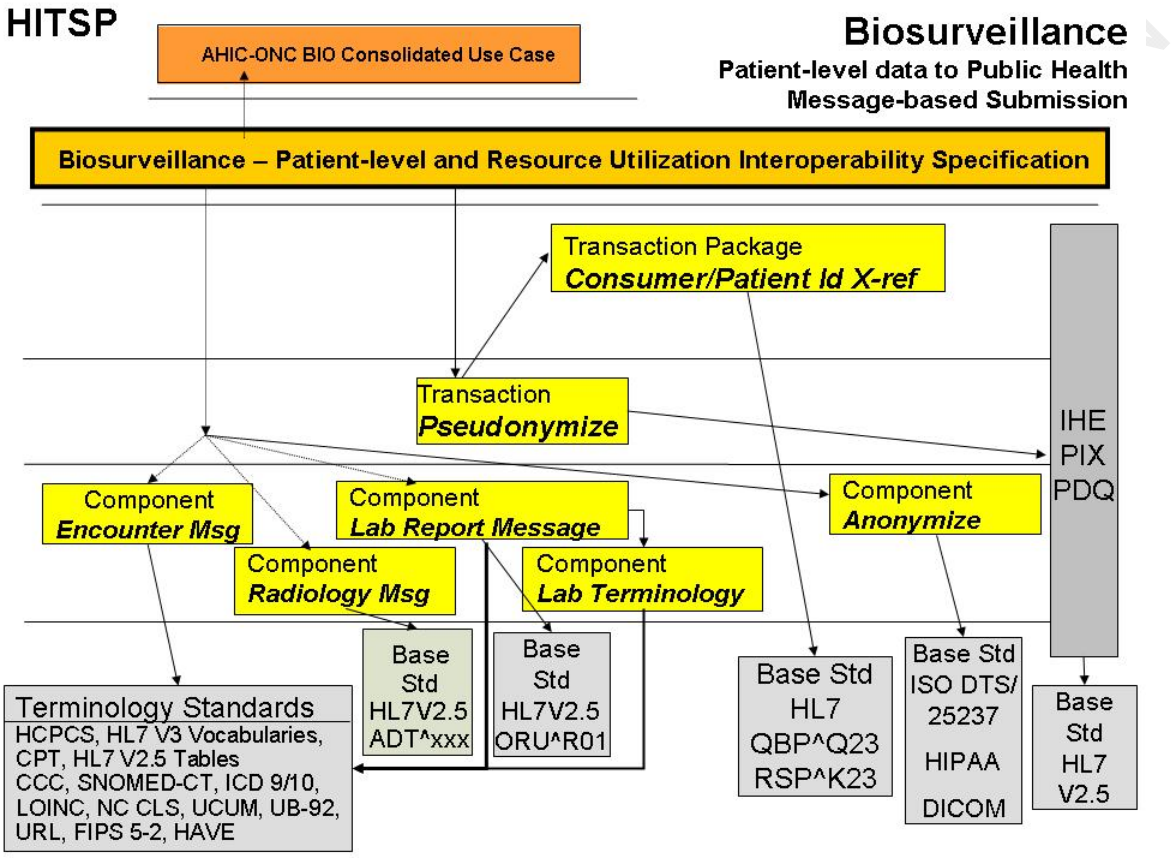
The Population Health TC recognizes that current systems used by stakeholders with an interest in resource availability data may differ from systems used for individual patient information. Therefore, Interoperability Specifications that support resource utilization also differ from those primarily concerned with patient specific data.

To reflect the nuances of managing the various data types as identified in the AHIC Biosurveillance Use Case, the Population Health TC has defined three separate functional flow scenarios. The TC has identified two functional flow scenarios for exchanging patient specific data, one described as message based and the other as document based. A third functional flow scenario has been defined for managing resource data. The three functional flow scenarios are:

Message-Based Patient-Level Surveillance Data Communication (HITSP-MS) – a mechanism to automate the communication of near real-time message-based data from the clinical care provider to the

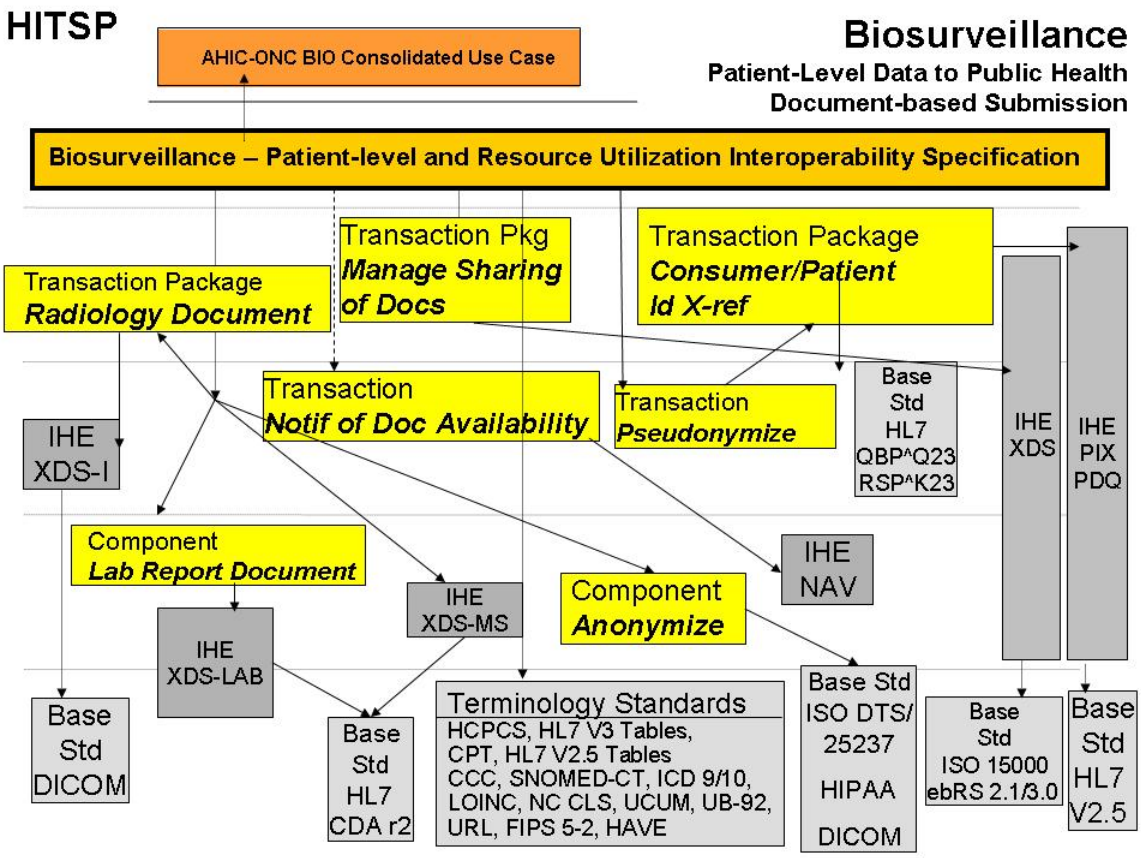
Biosurveillance Information System through integration with the local clinical information system. This is intended to communicate this data in near-real-time and within 24 hours to Biosurveillance systems to identify and manage public health threats. Figure 4.1.1-1 depicts the documents referenced for this implementation.

Figure 4.1.1-1 Document Map for Message-based Submissions



Document-based Patient-level Surveillance Data Sharing (Biosurveillance Documents) (HITSP-DS) – a mechanism to automate sharing between care providers of Biosurveillance documents, a class of clinical documents that contain the most relevant portions of information about pseudonymized patient encounter or laboratory testing. This is intended to enable sharing of these documents in near-real time and within 24 hours for a use by Biosurveillance systems, clinicians, epidemiologists and case managers to identify and manage public health threats. Figure 4.1.1-2 depicts the documents referenced for this implementation.

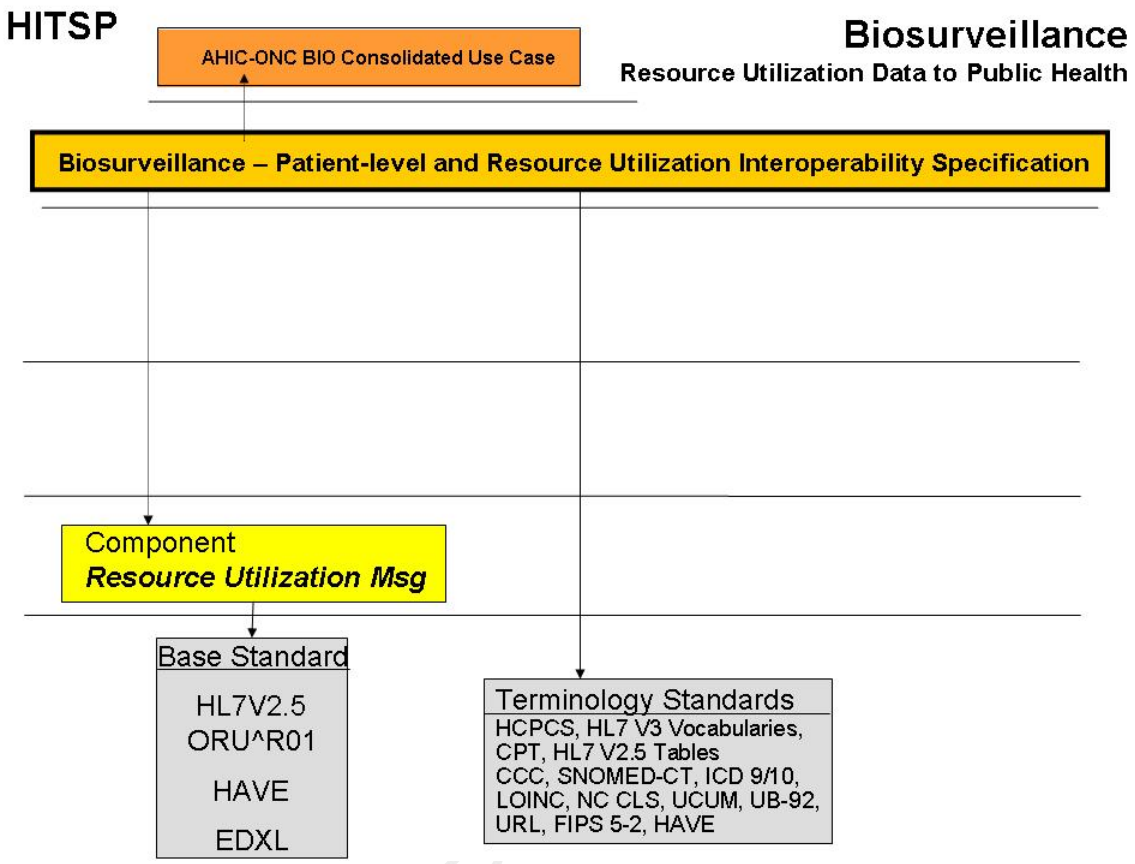
Figure 4.1.1-2 Document map for Document-based Submissions



Resource Management Data Transfer (Document-based and Message-based) (HITSP- RM) – a mechanism to automate the communication of resource availability from a BIO-Data sender to a BIO-Data Receiver. This is intended to communication of this data in near-real-time and within 24 hours to Biosurveillance systems to identify and manage public health threats.

Figure 4.1.1-3 depicts the documents referenced for this implementation.

Figure 4.1.1-3 Document Map for Resource Utilization Submissions



We have adopted the patient demographics definition from HL7 (a CHI standard) as an interim step and will conform to a HITSP harmonized approach for patient demographics once it becomes available.

This IS references Patient ID cross reference services. The HITSP Population Health TC recognizes that such services are not broadly available, nor is there a national service. There are some available now and more are expected. It is also recognized that cross reference services will be limited to the scope of the service provided - local, regional, etc. We expect these services to be cost-effective. This IS references exchanges between clinical providers and public health authorities. This term is used because the Use Case is expected to expand to include bi-directional information sharing

The following table reflects a mapping from the Use Case events to the implementation specification approaches:

Table 4.1.1-1 Use Case Events Mapping

Code	Event Description	Comment	Addressed In
1.1.1.0 1.2.1.0	Event: Filter existing data to identify data required by public health agencies	Referencing data requirements communicated by Public Health Agencies in Event 1.3.1.0, all data that is appropriate to provide to public health agencies is identified so that it can be formatted using the approved data and technology standards to allow processing across the stakeholders in this Use Case.	Addressed somewhat in HITSP/TP50 options; Noted as a GAP and deferred to roadmap efforts
1.1.2.0 1.2.2.0	Event: Anonymize data required by public health agencies	Data readied for transmission is anonymized to withhold direct patient identifiers. The process should allow for the data to be re-linked to a specific patient if required for and authorized public health investigation. All associated, randomized links are included with the data package.	HITSP/T24, HITSP/T25
1.1.3.0 1,2,3.0	Event: Format data required by public health agencies	Anonymized data are formatted using approved technology and data standards.	HITSP/IS02, HITSP/C36, HITSP/C39, HITSP/C41, HITSP/C47, HITSP/C48, HITSP/C37, HITSP/TP49
1.1.4.0 1.2.4.0	Event: Identify Public Health Agencies that must be notified	For individual healthcare delivery organizations, the process to determine Public Health Agency jurisdiction and the requirement to notify is less complex than for multi-jurisdictional integrated healthcare data suppliers.	HITSP/IS02 (Identified as a Gap)
1.1.5.0 1.2.5.0	Event: Transmit relevant data to public health agencies	Anonymized data are transmitted to public health agencies using approved data and technology standards.	HITSP/IS02, HITSP/TP13, HITSP/T29
1.3.1.0	Event: Provide listing of required biosurveillance data	Public health agencies provide the listing of essential data for reporting, and specific field information.	Addressed somewhat in HITSP/TP50 options; HITSP/IS02 Noted as a GAP and deferred to roadmap efforts
1.3.2.0	Event: Receive biosurveillance data	Public health agencies electronically receive anonymized data that is relevant to authorized biosurveillance activities. The data are anonymized, but the data contain randomized data linking capabilities to allow public health agencies to request that the sending organizations be able to support authorized public health investigators' need for more information. In cases where the message does not meet all the integrity rules, a retransmission request will be generated.	HITSP/IS02, HITSP/TP13, HITSP/TP50

AHIC Minimum Data Set Cross-Reference

The IS is informed by and the IS scope of data elements is constrained by the data element list provided by AHIC. The following tables reflect the data variables provided to the HITSP Population Health

Technical Committee by the American Health Information Community and the Biosurveillance Data Steering Group (BDSG) along with associated data types and selected terminologies. This table will be updated in subsequent releases based upon the ongoing work of the AHIC BDSG. Further specificity regarding the following selected data standards is provided in appendix 6.3: AHIC Minimum Data Set USHIK Cross-Reference.

Table 4.1.1-2 Data Elements Cross Reference

DATA ELEMENTS CROSS REFERENCE	
Data Element	Definition
AHIC Data Element	Data element name/identifier as listed by American Health Information Community and the Biosurveillance Data Steering Group (BDSG).
Definition	Data element description as listed by American Health Information Community and the Biosurveillance Data Steering Group (BDSG).
Data Type	Type of data that is collected with this data element (coded, numeric, text, date/time).
Terminology	Expected data values if data element has finite values. CHI-domain recommendations were followed if available.
Comments	Pertinent comments and usage.

Table 4.1.1-3 Base Facility Data Elements

BASE FACILITY DATA ELEMENTS *[Submitted at baseline and when changes occur]*				
AHIC Data Element	Definition	Data Type	Selected Standards	Comments
Facility Identifier	Unique facility identifier.	Numeric	CMS IDs	"Organization ID" in HAVE document This is not necessarily a numeric data type.
Facility Name	Name of facility	String		"Organization Name" in HAVE document
Facility Location	City and State *[May use FIPS county codes]*	String	FIPS	"Organization Location" in HAVE document City and State are Coded data type.
Number of Facility Beds	All facility beds regardless of licensing status.	Numeric		Not routinely messaged
Number of Licensed Beds	All facility beds considered licensed in that jurisdiction.	Numeric		Not routinely messaged

Table 4.1.1-4 Daily Facility Summary Report Elements

DAILY FACILITY SUMMARY REPORT ELEMENTS *[Specific data capture mechanisms may be required without HL7 message structures that support these concepts]*				
AHIC Data Element	Definition	Data Type	Selected Standards	Comments
Admissions last 24 hours	Number of admissions to facility in the last 24 hours *[Determine if daily aggregate report prepared by facility or may be calculated by data recipient]*	Numeric		Passed as observation with OASIS/HAVE XML tag: 'Admissions'

DAILY FACILITY SUMMARY REPORT ELEMENTS *[Specific data capture mechanisms may be required without HL7 message structures that support these concepts]*				
AHIC Data Element	Definition	Data Type	Selected Standards	Comments
Discharges last 24 hours	Number of discharges from the facility in the last 24 hours *[Determine if daily aggregate report prepared by facility or may be calculated by data recipient]*	Numeric		Passed as observation with OASIS/HAVE XML tag: 'Discharges'
Deaths last 24 hours	Number of deaths recorded at facility in last 24 hours *[Determine if daily aggregate report prepared by facility or may be calculated by data recipient]*	Numeric		Passed as observation with OASIS/HAVE XML tag: 'Deaths'
Clinical Status	Facility's clinical resources are operating: Normal: Within normal limits Level-1: At Level-1 surge conditions. Level-2: At Level-2 surge conditions. Full: Exceeded; acceptable care cannot be provided to additional patients. Diversion or community surge response is required.	Coded	OASIS/HAVE Values as in definition	Passed as observation with OASIS/HAVE XML tag: 'ClinicalStatus' Associated comment may also be passed.
Facility Status	Facility resources are operating under: Normal - No conditions exist that adversely affect the general operations of the facility. Compromised - General operations of the facility have been affected due to damage, operating on emergency backup systems, or facility contamination. Evacuating - Indicates that a hospital is in the process of a partial or full evacuation. Closed – Closure; facility no longer capable of providing services and only emergency services/restoration personnel may remain in the facility.	Coded	OASIS/HAVE Values as in definition	Passed as observation with OASIS/HAVE XML tag: 'HospitalFacilityStatus' Associated comment may also be passed.
Facility Operations	Status of supplies necessary for facility operations. Adequate - Meets the current needs. Insufficient – Current needs are not being met.	Coded	OASIS/HAVE Values as in definition	Passed as observation with OASIS/HAVE XML tag: 'FacilityOperations' Associated comment may also be passed.
Staffing	Available personnel to support facility operations. Adequate - Meets the current needs. Insufficient – Current needs are not being met	Coded	OASIS/HAVE Values as in definition	Passed as observation with OASIS/HAVE XML tag:'Staffing' Associated comment may also be passed.

DAILY FACILITY SUMMARY REPORT ELEMENTS *[Specific data capture mechanisms may be required without HL7 message structures that support these concepts]*				
AHIC Data Element	Definition	Data Type	Selected Standards	Comments
Decontamination Capacity	Capacity for chemical/biological/ radiological patient decontamination. Inactive - Not being used, but available if needed Open - In use and able to accept additional patients Full - In use at maximum capacity Exceeded - Needs exceed available capacity	Coded	OASIS/HAVE Values as in definition	Passed as observation with OASIS/HAVE XML tag: 'DeconCapacity' Associated comment may also be passed.
EMS Traffic Status	Facility capable of: Normal - Accepting all EMS traffic Advisory - Experiencing specific resource limitations which may affect transport of some EMS traffic. Closed - Requesting re-route of EMS traffic to other facilities. Not Applicable - Not Applicable. This hospital does not have an emergency department.	Coded	OASIS/HAVE Values as in definition	Passed as observation with OASIS/HAVE XML tag: 'EMSTrafficStatus' Associated comment may also be passed.
EMS Capacity	The number of each triage patient type the hospital can accept. triageRed (numeric) triageYellow (numeric) triageGreen (numeric) triageBlack (numeric) commentText (string)	Numeric with text/ comments	OASIS/HAVE Values:	Passed as observation with OASIS/HAVE XML tags: 'CapacityTriageRed' 'CapacityTriageYellow' 'CapacityTriageGreen' 'CapacityTriageBlack' Associated comment may also be passed.
EMS Census	The number of each triage patient type the overall hospital currently has. triageRed (numeric) triageYellow (numeric) triageGreen (numeric) triageBlack (numeric) commentText (string)	Numeric with text/ comments	OASIS/HAVE Values:	Passed as observation with OASIS/HAVE XML tags: 'CensusTriageRed' 'CensusTriageYellow' 'CensusTriageGreen' 'CensusTriageBlack' Associated comment may also be passed.
Adult ICU	Capacity Status for adult ICU beds. *[These can support critically ill or injured patients, including ventilator support. This category includes all major subtypes of ICU beds, including neuro, cardiac, trauma, or medical, with the exception that this category does not include burn ICU beds.]*	Numeric		

DAILY FACILITY SUMMARY REPORT ELEMENTS *[Specific data capture mechanisms may be required without HL7 message structures that support these concepts]*				
AHIC Data Element	Definition	Data Type	Selected Standards	Comments
Medical Surgical	Capacity Status for adult medical-surgical beds. *[These are also thought of as ward beds. These beds may or may not include cardiac telemetry capability.]*	Numeric		
Burn	Capacity Status for burn beds. *[These are thought of as Burn ICU beds, either approved by the American Burn Association or self-designated. These beds are NOT to be included in other ICU bed counts.]*	Numeric		
Pediatric ICU	Capacity Status for pediatric ICU beds. *[Similar to adult ICU beds, but for patients 17-years-old and younger.]*	Numeric		
Pediatrics	Capacity Status for pediatrics beds. *[These are ward medical/surgical beds for patients 17-years-old and younger.]*	Numeric		
Negative Flow Isolation	Capacity status for negative airflow isolation beds. *[These provide respiratory isolation. NOTE: This value may represent available beds included in the counts of other types.]*	Numeric		
Available Ventilators	Functional ventilators not in current use.	Numeric		

Table 4.1.1-5 Patient Data Elements

PATIENT DATA ELEMENTS *[To be transmitted for each admission, discharge and transfer at a facility. Need to determine if daily messages expected for all hospitalized patients. Presumes that data are obtained by monitoring HL7 messages]*				
AHIC Data Element	Definition	Data Type	Selected Standards	Comments
Pseudonymized Data Linker	A unique, randomly generated, encoded number that links to patient-level information (i.e., name and address) retained at the facility.	Alphanumeric		Patient ID/MRN used to create the randomized linker patient ID.
Encounter Date/Time	Time of the patient presentation for care. *[Encounter has meaning only for outpatient settings.]**	Date/time field		Expected on ADT^A04 Registration and ADT^A01 Admit transactions TC does not necessarily agree with the encounter comment.
DOB (month and year of birth)	*[limited to month and year]*	Date field		Proposed definition: "Date of Birth, limited to month and year for privacy purposes" May not be passing DOB for age over 89 due to HIPAA requirements.

PATIENT DATA ELEMENTS *[To be transmitted for each admission, discharge and transfer at a facility. Need to determine if daily messages expected for all hospitalized patients. Presumes that data are obtained by monitoring HL7 messages]*				
AHIC Data Element	Definition	Data Type	Selected Standards	Comments
Age	*[could be calculated]*	Numeric value	Unified Code for Units of Measure (UCUM) for Age Units	Proposed definition: Patient age, which may be calculated from full date of birth before the days are removed.
Gender	*[Use standard codeset (e.g., Census)]*	Coded	HL7 2.5 Administrative Sex Codes	Proposed definition: "Patient sex" May want to limit to M, F, U
Zip	Home address *[minimum 5 Digit Zip]*	String		Not ZIP plus Four, but will not aggregate to the first 3 characters
State	Home address *[2 character abbreviation]*	String	FIPS State codes	Data type should be coded.
Date/time last update	Expected date/time stamp for all registration (ADT) system transactions	Date		

Table 4.1.1-6 Clinical Data Elements

CLINICAL DATA *[To be transmitted for each admission, discharge and transfer at a facility. Need to determine if daily messages expected for all hospitalized patients. Presumes 1) data are obtained by monitoring HL7 messages and 2) facility identifier and pseudonymized linker have been associated with the clinical data element record]*				
AHIC Data Element	Definition	Data Type	Selected Standards	Comments
Diagnosis/Injury Code	ICD-9 code *[may vary as more information is acquired]*	String	ICD-9/10 CM Or SNOMED CT	Proposed definition: "Diagnosis or diagnoses assigned as a result of the encounter" Industry uses mostly ICD-9 diagnosis codes used for billing purposes. The previously available SNOMED CT to ICD 9 CM statistical mapping has been enhanced to include a SNOMED CT to ICD-9-CM rule based reimbursement map. The mapping has been completed and is currently being evaluated by the NLM and vendor community. Further validation will be done by AHIMA

CLINICAL DATA *[To be transmitted for each admission, discharge and transfer at a facility. Need to determine if daily messages expected for all hospitalized patients. Presumes 1) data are obtained by monitoring HL7 messages and 2) facility identifier and pseudonymized linker have been associated with the clinical data element record]*				
AHIC Data Element	Definition	Data Type	Selected Standards	Comments
Diagnosis Type	Preliminary, Interim, final	String	HL7 2.5 Diagnosis Type Codes	Proposed definition: "Type of diagnosis being sent (admitting, working, final)" Data type should be Coded. Values are site-defined but typically are "working", "admission", and "final".
Diagnosis Date/Time	*[System time stamp of data entry likely to be only associated date and time+E94]*	Date		Proposed definition: "Date/time the diagnosis was made"
Discharge Disposition	If discharged, place to where patient was released. [*Need to develop a standardized list – does BioSense have one]*	String	Universal Billing codes (UB-92/NUBC CURRENT UB DATA SPECIFICATIONS MANUAL)	Proposed definition: "Patient's anticipated location or status following the encounter." Data type should be Coded. Expected in Discharge transactions only.
Patient Class	[*Need to develop a standardized list – does BioSense have one]*	String	HL7 2.5 Patient Class Codes	Proposed definition: "General type of patient, *e.g.*, Inpatient, Outpatient, Emergency." Data type should be Coded. May want to constrain to Emergency, Inpatient, and Outpatient.
Date and Time Illness Onset	Recorded by triage or clinician *[may not be coded value]*	Date		Proposed definition: Date and time of illness onset as recorded by triage or clinician Passed as observation tagged with LOINC code: '11368-8^Illness/Injury Onset Date/time^LN' There is a gap because illness onset date and time is not currently captured in a consistent manner at data sources. It is not always a date/time field and does not lend itself to responses such as "three days" or "two weeks ago".
Chief Complaint	Short description, recorded during triage, for seeking care. *[may have text string or coded (e.g., ICD-9) values]*	String	SNOMED-CT and/or Clinical Care Classification recommended for codifying of free-form text	May be collected as a LOINC-tagged observation: '11292-0^ED Chief Complaint – Patient Reported^LN' Expected to be available with Registration and Admission transactions

CLINICAL DATA *[To be transmitted for each admission, discharge and transfer at a facility. Need to determine if daily messages expected for all hospitalized patients. Presumes 1) data are obtained by monitoring HL7 messages and 2) facility identifier and pseudonymized linker have been associated with the clinical data element record]*				
AHIC Data Element	Definition	Data Type	Selected Standards	Comments
Temperature	Recorded temperature during triage.	Numeric	Unified Code for Units of Measure (UCUM) for Temperature units	Passed as observation tagged with LOINC code '8310-5^BODY TEMPERATURE^LN', including timestamp for when it was done
Pulse Oximetry	Record pulse oximetry value during triage.	Numeric		Passed as observation tagged with LOINC code: '19960-4^PULSE OXIMETRY^LN' including timestamp for when it was done
Nursing/Triage Notes	Text string written by nurse or healthcare partner *[may have implications for privacy and security]*	String	SNOMED-CT and/or Clinical Care Classification recommended for codifying of free-form text	Passed as observation tagged with LOINC code: '34120-6^INITIAL EVALUATION NOTE^LN'
Provider Identifier	Unique facility-specific provider identifier	Alpha-numeric		Proposed definition: "Unique provider (clinician) identifier. This data element is assumed to meet local biosurveillance needs." Need clarification from AHIC regarding provider role(s): (e.g., attending, primary).

Table 4.1.1-7 Laboratory and Radiology Test Orders

The TC has indicated through the liaison that further specificity is needed to accommodate the request for laboratory and radiology orders. Refer to Radiology/Laboratory Order Message section of Table 3.2-3 Resolution Plan.

LABORATORY/MICROBIOLOGY TEST ORDER ELEMENTS *[To be transmitted for a subset of all laboratory and radiology tests. Need to determine if messages include all hospitalized patients. Presumes 1) data are obtained by monitoring HL7 messages and 2) facility identifier and pseudonymized linker have been associated with the laboratory/radiology test order element record]*				
AHIC Data Element	Definition	Data Type	Selected Standards	Comments
Order number	Accession number as defined by reporting laboratory *[HITSP may use the term "specimen ID"]*	Alpha-numeric		<scoped out> TC Comment: This number is usually assigned by the Order Entry system. Order number is NOT the accession or specimen number. GAP: Universally agreed upon meaning of order number; Request clarification from HL7

LABORATORY/MICROBIOLOGY TEST ORDER ELEMENTS *[To be transmitted for a subset of all laboratory and radiology tests. Need to determine if messages include all hospitalized patients. Presumes 1) data are obtained by monitoring HL7 messages and 2) facility identifier and pseudonymized linker have been associated with the laboratory/radiology test order element record]*				
AHIC Data Element	Definition	Data Type	Selected Standards	Comments
Test/Procedure Name	Procedure name from reporting laboratory	String		<scoped out> TC Comment: This will be the name of the ordered radiology or laboratory service as the ordering system knows it.
Test/Procedure Code	LOINC/DICOM code associated with test/procedure	Alpha-numeric		<scoped out> GAP: Recommend to LOINC, SNOMED-CT, and CPT to develop AND harmonize a suitable coded value set to express order test name and code values.

Table 4.1.1-8 Laboratory/Microbiology Result Data

LABORATORY/MICROBIOLOGY RESULTS *[To be transmitted for a subset of all laboratory and radiology tests. Presumes: 1) include all hospitalized patients, 2) data are obtained by monitoring HL7 messages 3) accession number, facility identifier, and pseudonymized linker have been associated with the clinical data element record]*				
AHIC Data Element	Definition	Data Type	Selected Standards	Comments
Reporting Laboratory Identifier	Standard national identifier value *[e.g., CLIA or CAP laboratory number]*	Alphanumeric	CLIA Unique Laboratory ID	Proposed Definition: "Identifier for laboratory that is sending the result. This laboratory may be sending results received back from reference laboratories."
Performing laboratory	Standard national identifier value *[e.g., CLIA or CAP laboratory number]*	Alphanumeric	CLIA Unique Laboratory ID	Proposed Definition: "Laboratory that produced the test result. This may be a reference laboratory identifier."
Report date/time		Date	HL7 Timestamp	Proposed Definition: "Date/time of report"
Report status	Coded value *[Need method to convert to a standard codeset, e.g., SNOMED]*	Coded	HL70123 Result Status	Proposed Definition: "Status of report (preliminary, final, corrected)"
Collection date		Date	HL7 Timestamp	Proposed Definition: "Date/time of specimen collection"
Collection method	Coded value *[Need method to convert to a standard codeset, e.g., SNOMED]*	Coded	Overlap: HL70488 – Recommend to subset SNOMED-CT for clarification and align subset with Table 488	Proposed Definition: "Method of specimen collection." Not collected that often as a data element for results.

LABORATORY/MICROBIOLOGY RESULTS *[To be transmitted for a subset of all laboratory and radiology tests. Presumes: 1) include all hospitalized patients, 2) data are obtained by monitoring HL7 messages 3) accession number, facility identifier, and pseudonymized linker have been associated with the clinical data element record]*				
AHIC Data Element	Definition	Data Type	Selected Standards	Comments
Specimen Source	Coded value *[Need method to convert to a standard codeset, e.g., SNOMED]*	Coded	SNOMED –CT	Proposed Definition: "Body site of specimen collection." Not collected that often as a data element for results.
Specimen	Coded value *[Need method to convert to a standard codeset, e.g., SNOMED]*	Coded	HL70487 Specimen or SNOMED-CT	Proposed Definition: "Type of specimen the test was run against." Not collected that often as a separate data element, since the LOINC test code specifies the specimen type as one of the axes.
Ordered test code	LOINC code associated with test/procedure	Coded	Recommend SNOMED-CT, LOINC, CPT, HCPCS and others (encouraging commercial vendor participation) get together to establish a suitable vocabulary	Proposed Definition: "The identifier code for the requested observation/test/battery." Major GAP – lack of a universal vocabulary for identifying ordered tests
Resulted test		Coded	LOINC Laboratory Test Identifiers include analytes, specimen source, methods, and sensitivity tests for drugs.	Proposed Definition: "The identifier code for the specific test component resulted."
Result	Includes all test results including susceptibilities, serologies, non-organisms; coded value *[Need method to convert to a standard codeset, e.g., SNOMED]*		Recommend SNOMED-CT	
Method type	Coded value *[Need method to convert to a standard codeset, e.g., SNOMED]*	Alphanumeric	V3 Observation Method as a starter set. May be extended locally	Proposed Definition: "Testing method used to arrive at the specific result."
Result unit	Coded value *[Need method to convert to a standard codeset, e.g., SNOMED]*	Alphanumeric	Unified Code for Units of Measure (UCUM) Expressions	Proposed Definition: "Unit for numeric result context."
Test interpretation	Coded value *[Need method to convert to a standard codeset, e.g., SNOMED]*	String	HL70078 Abnormal Flags	Proposed Definition: "Interpretation of test result, including the susceptibility test interpretation."
Test status	Coded value *[Need method to convert to a standard codeset, e.g., SNOMED]*	Alphanumeric	HL70123 Result Status	Proposed Definition: "Status of the test result."
Ordering Provider Identifier	Provider of record for the test result that is being reported.	Alphanumeric		Newly added and has not been previously considered.

Table 4.1.1-9 Radiology Result Data

Note that the AHIC minimum data set did not specify radiology report-specific data elements. These are the ones that the HITSP TC developed.

RADIOLOGY RESULT DATA				
AHIC Data Element	Definition	Data Type	Selected Standards	Comments
Study ID/Radiology Number		String		Proposed Definition: "Unique identifier for the radiological study, so that report revisions can be linked with the original report."
Study date and time		Date/time		Proposed Definition: "Date / time the exam was performed."
Report date/time		Date/time		Proposed Definition: "Report/Reading Date. This date is updated with report corrections and addendums."
Report Status		Coded	HL70123 Result Status	Proposed Definition: "Status of the report (preliminary, final, corrected) is required in a result message."
Test Performed		Coded	CPT+ Textual Description which can include modification	Proposed Definition: "Radiology test code/description."
Impressions		Alphanumeric	SNOMED CT Or ICD9-CM	Proposed Definition: "Radiologist's diagnosis and impressions." May be passed as an observation with LOINC tag: '19005-8^X-RAY IMPRESSION^LN'
Date / Time Revised		Date/time		Proposed Definition: "Date and time of the report revision"

4.1.2 MESSAGE-BASED PATIENT-LEVEL SURVEILLANCE DATA COMMUNICATION (HITSP-MS) FUNCTIONAL FLOW SCENARIO OVERVIEW

The first scenario, Message-Based Patient-level Surveillance Data Communication (HITSP-MS), is a mechanism to automate the communication of near real-time message-based data from the clinical care provider to the Biosurveillance Information System through integration with the local clinical information system. This approach leverages the traditional message-based communications, typically facilitated through an organization's interface engine, to capture messages of interest to public health surveillance, and to transmit these messages to a designated recipient. If multiple recipients are to be supported, they have to be configured at each of the sources or an infrastructure duplicating these messages needs to be managed with knowledge of these destinations. The clinical information sources in this functional flow scenario send anonymized and pseudonymized clinical messages to support public health surveillance

needs. This is intended to enable communication of this message data in near-real-time and within 24 hours for a use by Biosurveillance systems (BIS). The BIS provides support to, clinicians, epidemiologists and case managers to identify and manage public health threats using data received from the clinical information systems.

Message-based Advantages and Disadvantages

- It leverages an approach that is utilized for information sharing which is currently functional in hospitals and Emergency Departments such that data can be submitted for Biosurveillance efforts using existing mechanisms of data transfer
- Existing healthcare message-based transmission standards provide a baseline for the interpretation of the data in aggregate for Syndromic surveillance and situational awareness
- The basic data submission standards, through harmonization, provide a reasonable incremental approach to provide public health with required data elements

Disadvantages

- Ambulatory systems have variable penetration of message-based data transmission capabilities. A single methodology for managing information sharing from resource-challenged ambulatory facilities is preferable and alignment with patient record-sharing initiatives is beneficial

This functional flow scenario includes the specification of multiple Biosurveillance messages to capture data from healthcare providers and laboratory systems, which contain data that can be used by the epidemiologist to assess the health of the population. Operationally, they are typically collected at any point in time, including admission, clinical order, transfer or discharge. While it is anticipated that information sources and content will expand for biosurveillance purposes in support of the current Use Case, the following types of clinical messages are defined:

- Laboratory Orders
- Laboratory Results including preliminary, interim, and final results
- Encounter messages from Electronic Medical Records Systems
- Radiology Orders
- Radiology Results

Pre-existing information contained in clinical orders may be used as early warning indicators for events of public health significance. Because clinical orders contain information describing patients and the types of clinical tests requested, the Biosurveillance Use Case for laboratory and radiology orders seeks to “re-use” this pre-existing information, and consequently represents a “secondary” use of such data.

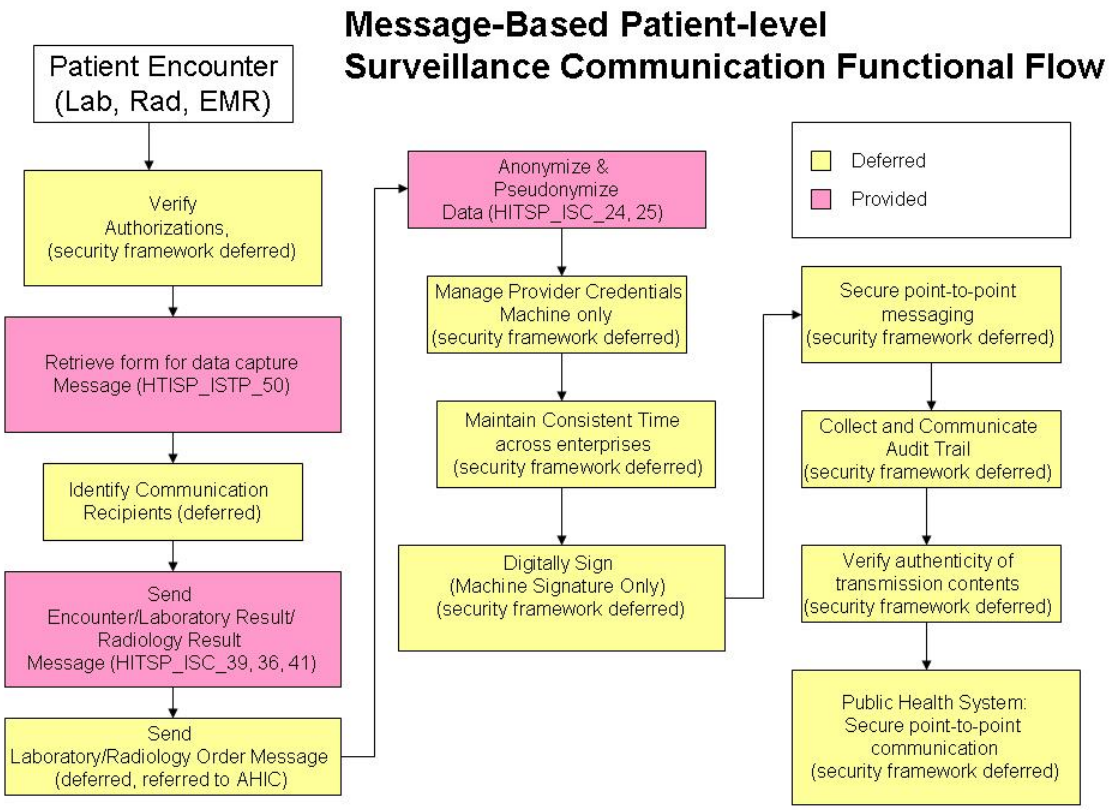
The Biosurveillance order Use Case is dependent on the primary Use Case developed for Laboratory and Radiology ordering. The selection of messages to be used for Laboratory and Radiology orders should be driven by the primary Use Case for orders, not a more limited secondary Biosurveillance Use Case. Consequently, we advocate that Biosurveillance should not dictate the order message(s) used to convey Laboratory and Radiology orders. Rather, the Biosurveillance work group should ensure that the information necessary for public health surveillance is included in order messages. We propose that any

preliminary document developed for the Biosurveillance Use Case would maximally identify candidate messages that could contain the information of interest, and the location of the desired information in each transaction.

Also of crucial importance is that the most common order message used for both Laboratory and Radiology orders today (the ORM^O01) has been temporarily retained for backward compatibility, but not recommended for use in HL7 2.5. Subsequently, the 2.5 order messages that may be selected by HITSP may *not* be the most universally implemented message for orders. For Biosurveillance to take advantage of the information found in orders, we must focus on where surveillance information can be found in a variety of order message types, not just a single order message type that is dictated for a Biosurveillance Use Case.

To be broadly applicable, the Biosurveillance Use Case should leverage clinical order transactions commonly exchanged among clinical healthcare stakeholders, as well as public health entities. It should be noted that the laboratory order message selected by PHIN is intended for a narrow Use Case for messaging orders between public health laboratories, which has limited application to the Biosurveillance and EHR Use Cases.

Figure 4.1.2-1 Functional Flow Diagram for Message-Based Patient-level Surveillance Data Communication (HITSP-MS)



Scenario Option 1: Laboratory Order Message

This scenario option involves generation of laboratory order messages from clinical healthcare provider systems.

The pre-conditions assume the existence of the secure transport mechanisms, and that an order for laboratory testing has been entered into the clinical information system that is within the category of interest for biosurveillance reporting as required by federal, state, or local health departments. It is also assumed that the healthcare provider information system is able to generate standard terminology. This option defines the content of the message to be delivered over that transport to communicate laboratory orders defined to be of interest to the public health authorities for biosurveillance purposes. An assumption is made that the healthcare provider has a computer information system with capability to capture the information required to generate the message.

The specific data elements managed by the provider clinical information system are expected to be the source for the information used in creating the biosurveillance laboratory order message. A variety of clinical information system implementations and usage by clinicians may result in some variability in the content of the biosurveillance laboratory order message.

There is no specification provided for the 2006 HITSP cycle (see functional flow overview discussion)

Scenario Option 2: Laboratory Results Message including preliminary, interim, and final results

This scenario option involves generation of laboratory result messages from Laboratory Information Management systems (LIMs).

The preconditions assume a laboratory has processed a sample, and the test result is within the range and category of interest for biosurveillance reporting as required by federal, state or local health departments. It is also assumes that the healthcare provider information system is able to generate standard terminology. This option defines the content of the message to be delivered over that transport to communicate laboratory results defined to be of interest to the public health authorities for biosurveillance purposes. An assumption is made that the laboratory has a LIM system with capability to capture the information required to generate the message.

The specific data elements managed by the laboratory's LIM are expected to be the source for the information used in creating the biosurveillance message. A variety of LIMS implementations and usage by clinicians may result in some variability in the content of the biosurveillance message.
The detailed content of the biosurveillance report to support this Use Case will be detailed as part of the HITSP Component specification (See HITSP/C36 - Lab Result Message).

Scenario Option 3: Encounter messages from Electronic Medical Records Systems

This Use Case involves a generation of encounter summary messages from clinical healthcare provider systems.

The pre-conditions assume a patient has presented to a healthcare provider. After examination and evaluation of the patient condition, the provider (or provider EMR) determines that the case is within the range and category of interest for biosurveillance reporting as required by federal, state or local health departments. An assumption is made that the provider has an EMR system with capability to capture the information required to generate the message.

The specific data elements managed by the provider EMR are expected to be the source for the information used in creating the biosurveillance message. A variety of EMR implementations and usage by clinicians may result in some variability in the content of the biosurveillance message.
The detailed content of the biosurveillance encounter message to support this Use Case will be detailed as part of the HITSP Component specification (See HITSP/C39 - Encounter Message Component).

Scenario Option 4: Radiology Order Message

This scenario option involves generation of radiology order messages from clinical healthcare provider systems.

The pre-conditions assume the existence of the secure transport mechanisms, and that an order for radiology testing has been entered into the clinical information system that is within the category of interest for biosurveillance reporting as required by federal, state, or local health departments. It is also assumed that the healthcare provider information system is able to generate standard terminology. This option defines the content of the message to be delivered over that transport to communicate radiology orders defined to be of interest to the public health authorities for biosurveillance purposes. An assumption is made that the healthcare provider has a computer information system with capability to capture the information required to generate the message.

The specific data elements managed by the provider clinical information system are expected to be the source for the information used in creating the biosurveillance laboratory order message. A variety of clinical information system implementations and usage by clinicians may result in some variability in the content of the biosurveillance radiology order message.

There is no specification provided for the 2006 HITSP cycle (see functional flow overview discussion)

Scenario Option 5: Radiology Result Messages

This scenario option involves generation of Radiology Result messages.

The pre-conditions assume a radiology clinic has processed a sample, and the interpretation is within the range and category of interest for biosurveillance reporting as required by federal, state or local health

departments. It is also assumed that the healthcare provider information system is able to generate standard terminology. This option defines the content of the message to be delivered over that transport to communicate radiology results defined to be of interest to the public health authorities for biosurveillance purposes. An assumption is made that the radiology system has the capability to capture the information required to generate the message.

The specific data elements managed by the radiology system are expected to be the source for the information used in creating the biosurveillance message. A variety of radiology system implementations and usage by clinicians may result in some variability in the content of the biosurveillance message.

The detailed content of the biosurveillance report to support this Use Case will be detailed as part of the HITSP Component specification (See HITSP/C41 - Radiology Result Message).

4.1.2.1 SCENARIO CONSTRAINTS

The Scenario is constrained to the following:

- AHIC Data Steering Committee Data set: See AHIC Minimum Data Set Cross-reference table in Section 4.1
- AHIC Biosurveillance Use Case
- Message constraints: HITSP/C36 Lab Result Message, HITSP/C39 Encounter Message, and HITSP/C41 Radiology Results message
- Vocabulary Constraints: Laboratory Terminology, and See AHIC Minimum Data Set Cross-reference table in Section 4.1

This functional flow scenario leverages the common messaging approach used in intra-organizational communications. A number of constraints are added as part of this Interoperability Specification so as to assert common content and assure authenticity of transmission contents. These constraints address privacy protection, authenticity, and message content.

In support of this functional flow scenario, this Interoperability Specification provides constraints to the Use Case for those topics that merit significant additional biosurveillance workflow and semantic interoperability consideration. These key constraints are with respect to terminology, and support for content specification for the varying reportable conditions forms required by state public health departments to collect supplemental data relevant to support detection and monitoring of public health threats for the local environment. Some of these areas need additional consideration and in some cases harmonization efforts before HITSP can fully specify a robust implementation. While this specification defines the fit for these constructs, detailed specification in some cases will be deferred to enable sufficient consideration for the complexity of the subject matter. It is also assumed that the healthcare provider information systems are able to translate local codes into standard terminology.

4.1.2.2 SCENARIO PRE-CONDITIONS

In order to implement the information interchange conforming to this Interoperability Specification and its constructs in a real world environment, the implementer must ensure that the implementing systems

operate within a secure infrastructure that insures the privacy, integrity and availability of all personally identifiable health information as prescribed by the Health Insurance Portability and Accountability Act, and all other applicable laws and regulations and terms of any contracts and agreements. The information interchange standards may also assume that certain information technology infrastructure and functions are in place. These assumptions collectively are the general pre-conditions for conforming to this Interoperability Specification and its constructs.

Specific pre-conditions for this scenario include:

- For the current HITSP 2006-2007 cycle, the acknowledgements are limited to those provided by HITSP/C36 to implement this functional flow scenario (see gap analysis in section 3.2 above for discussion regarding Biosurveillance Use Case-specific acknowledgment requirements).
- A secure communication channel (e.g. VPN) is negotiated and established and all policy, compliance, and authorization issues are addressed through automated or manual means.
- Configuration of communication and identification of communication exchanges partners.
- Communication of biosurveillance messages occurs in an environment where public health authorities, clinical offices, laboratories, resource suppliers and hospitals have secured point-to-point network connections. This may include VPN, S/MIME, or other approaches.
- Radiology and laboratory clinical orders are available electronically, may be used, and contain information describing patients and the types of clinical tests requested.

4.1.2.3 SCENARIO TRIGGERS

None

4.1.2.4 SCENARIO POST-CONDITIONS

The Biosurveillance Information System has received the submitted data.

4.1.2.5 SCENARIO OUTPUTS

None

4.1.2.6 SCENARIO BUSINESS ACTORS

The following business actors are involved in this functional flow scenario:

Table 4.1.2.6-1 Message-Based Patient-level Surveillance Data Communication Scenario Business Actors

Actor	Description
Clinician (Bio Message Sender)	In ambulatory and emergency department settings, the healthcare providers within Healthcare Delivery Organizations with direct patient interface in the delivery of care, including physicians, nurses, and clinical supervisors. These business actors are involved in the entry of source data into the system. In the case of reportable conditions, these business actors will also enter supplemental public health data elements into the data capture form.

Actor	Description
Message Source (Bio Message Sender)	Information system supporting the clinical care and information management for Ambulatory, inpatient, and emergency department settings for organizations, such as hospitals, physician practices, which manage the delivery of care and submission of utilization resource information.
Laboratory Information Systems (Bio Message Sender)	Information system supporting the testing, analysis, and information management for laboratory organizations. Medical laboratories, in either in a hospital or ambulatory environment, which analyze specimens as ordered by clinicians to assess the health status of patients. Laboratories, depending on how they are affiliated with hospitals, can be part of either Individual Healthcare Facilities or Integrated Healthcare Data Suppliers. These business actors are responsible for updating interface engine rules and triggers in response to Use Case modifications of requested data feeds.
Healthcare delivery organization (Bio Message Sender)	Organizations, such as hospitals, physician practices, which manage the delivery of care and submission of utilization resource information. These business actors are responsible for updating interface engine rules and triggers in response to Use Case modifications of requested data feeds.
Radiology Information Systems (Bio Message Sender)	Information system supporting the testing, analysis, and information management for radiology service organizations. Radiology services, depending on how they are affiliated with hospitals, can be part of either Individual Healthcare Facilities or Integrated Healthcare Data Suppliers. These business actors are responsible for updating interface engine rules and triggers in response to Use Case modifications of requested data feeds.
Public Health Agencies (local/state/federal) (Bio Message Receiver)	Local, state, and federal government organizations and personnel that exist to help protect and improve the health of their respective constituents. A critical effort under this charge is collecting health information to monitor for the existence of emerging health threats appearing in the population, as well as managing these threats once manifested. Staff of these agencies interact with the BIS to verify and validate system indications of public health threats, and to assert acknowledgements that may be required by system processes.

4.1.2.7 SCENARIO TECHNICAL ACTORS

It is expected that the communication of biosurveillance messages in this functional flow scenario will occur in an environment where the public health authorities, physician offices, laboratories, resource suppliers and hospitals establish secured point-to-point network connections. This may be achieved through either VPN or S/MIME approaches. There is no sharing in this functional flow scenario.
This functional flow scenario leverages message-based communications. The content of these messages are defined in the associated components.

Several IHE Integration Profiles are leveraged for supporting services as well. These include Patient Identifier Cross-Referencing (PIX), and Consistent Time (CT). See the IHE IT Infrastructure Technical Framework (ITI-TF) Revision 2.0. These Integration Profiles have been further constrained by HITSP Transaction Package specifications, but the associated infrastructure actors are the same and referenced directly in the tables below. Other actors that may be indirectly involved due to their participation in related dependent transactions such as Audit Trail and Node Authentication and Consistent Time are not shown.

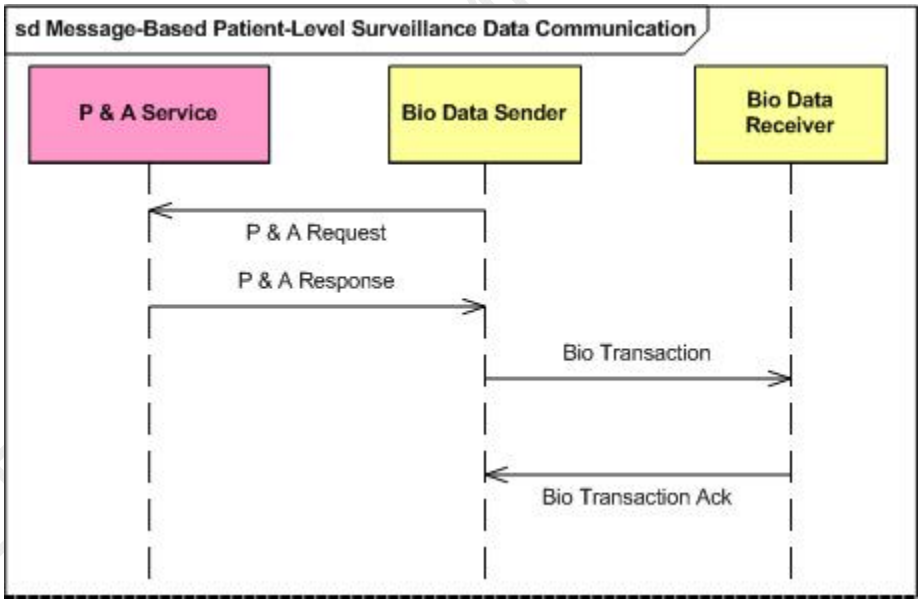
Table 4.1.2.7-1 Message-Based Patient-level Surveillance Data Communication Scenario Technical Actors

Actor	Description
Bio-Data Sender	BIO- Data Sender The holder of resource data who is communicating that data to the message receiver, typically the resource management information system (e.g. Census System/Bed Capacity System) .
Bio-Data Receiver	An authorized entity that is receiving resource availability data (e.g. BIS/Emergency Operations Center).

Actor	Description
Patient Identifier Cross-reference manager	Serves a well-defined set of Patient Identifier Domains. Based on information provided in each Patient Identifier Domain by a Patient Identification Source Actor, it manages the cross-referencing of patient identifiers across Patient Identifier Domains.
Patient Identifier Cross-reference consumer	This actor allows a system in a Patient Identifier Domain to determine the identification of a patient in a different Patient Identifier Domain by using the services of a Patient Identifier Cross-Reference Manager Actor.
Patient Identity Source	The Patient Identity Source Actor is a provider of unique identifier for each patient and maintains a collection of identity traits. Each Patient Identifier Domain requires this Actor to assign patient identities and to notify other Actors (e.g. a Patient Identifier Cross-reference Manager or a Registry Actor) of all events related to patient identification (creation, update, merge, etc.).
Pseudonymization Service (P & A Service)	Supplier of alternative identification information that permits a patient to be referred to by a key that suppresses his/her actual identification information.
Form Filler	The actor responsible for retrieving a form from a Form Manager, and for submitting form instance data to a Form Receiver. The mechanism by which a unique identification of a form is obtained is outside the scope of the Retrieve Form for Data Capture profile.
Form Manager	The actor that supplies a form based upon a request that supplies a unique form of identification.
Form Receiver (Biosurveillance Information System)	Repository of permanent source records of public health reports.

4.1.2.8 SCENARIO ACTOR INTERACTIONS

Figure 4.1.2.8-1 Scenario Actor Interaction Diagram



The Bio Message Sender may first process pseudonymization and anonymization to assure privacy protection of the patient identifiable data within the message. This functional flow scenario can send any of the message options described in section 4.1.1 of this document.

For the current HITSP 2006 cycle, the acknowledgement is limited to traditional HL7 ACK messages (see gap analysis in section 3.2 above for discussion regarding Biosurveillance use-case-specific acknowledgment requirements).

Transmission Option:

Retrieve Form For Data Capture Option (See HITSP/TP50 Retrieve Form for Data Capture Transaction Package)

In support of public health authority reportable conditions monitoring and management, the clinical or laboratory information source may optionally implement HITSP/TP50. This option allows for capture of supplemental data variables not typically maintained in an electronic health record or laboratory information system through a more seamless integration with the local electronic management system. This option allows for the local system to retrieve a form specific to the identified potential public health threat. This is one option currently available for reportable conditions which may need additional local configuration and architectural constraints or considerations for implementation architectures.

4.1.3 DOCUMENT-BASED PATIENT-LEVEL SURVEILLANCE DATA SHARING (BIOSURVEILLANCE DOCUMENTS) (HITSP-DS) FUNCTIONAL FLOW SCENARIO OVERVIEW

The second scenario, Document-based Patient-level Surveillance Data Sharing (Biosurveillance Documents) (HITSP-DS), is the shared document resource data submission model. This approach leverages a shared registry and repository resource to which the clinical information sources can send anonymized and pseudonymized biosurveillance documents to support public health surveillance needs. This is intended to enable sharing of these documents in near-real-time and within 24 hours for a use by Biosurveillance systems, clinicians, epidemiologists and case managers to identify and manage public health threats. This functional scenario offers several advantages.

Advantages

Document-based information sharing is included in this Interoperability Specification to align and maintain consistency with other HITSP efforts in Electronic Health Record and Consumer Empowerment. The document-based information sharing approach has not previously been considered for secondary use of data as required by Biosurveillance or other secondary use systems (e.g., clinical trials, aggregate performance measurements, disease management and population health). The Technical Committee identified several areas for further evaluation prior to endorsing full document-based data sharing for Biosurveillance activities. These areas for evaluation include:

- Methodology and criteria for publish and subscribe capability such that subscription filtering can be modified in real time as the situation requires
- Document Sharing Service requirements to meet the needs of public health and, potentially other forms of secondary data use
- Extent of usable information within documents; i.e., structured *vs* human readable text, and the extent of natural language processing required to enable document sharing as a viable Biosurveillance solution

- Extent to which document-based sharing encapsulates message-based standards that correlate with the message-based functional flow as detailed elsewhere in this document

Implementation sites are encouraged to explore and research these areas of concern to provide additional evidence for more robust usage of document-based information sharing for secondary usage of data.

Document-based Advantages and Disadvantages

This functional scenario offers several advantages and disadvantages.

Advantages

- It leverages an emerging approach of sharing patient care clinical document, and as such, could facilitate the capture of information from source systems, especially in the ambulatory setting
- A shared document resource could provide access to regional information allowing authorized neighboring public health authorities access to patient care clinical documents when there is a need to extend investigative and monitoring actions across public health jurisdictions
- Since many local public health departments have limited computing resources, this offers a means by which these stakeholders can leverage patient care clinical documents to support a largely manual approach to biosurveillance with minimal additional investment
- By providing a resource that maintains persistent, human readable documents, support for case investigation can be offered

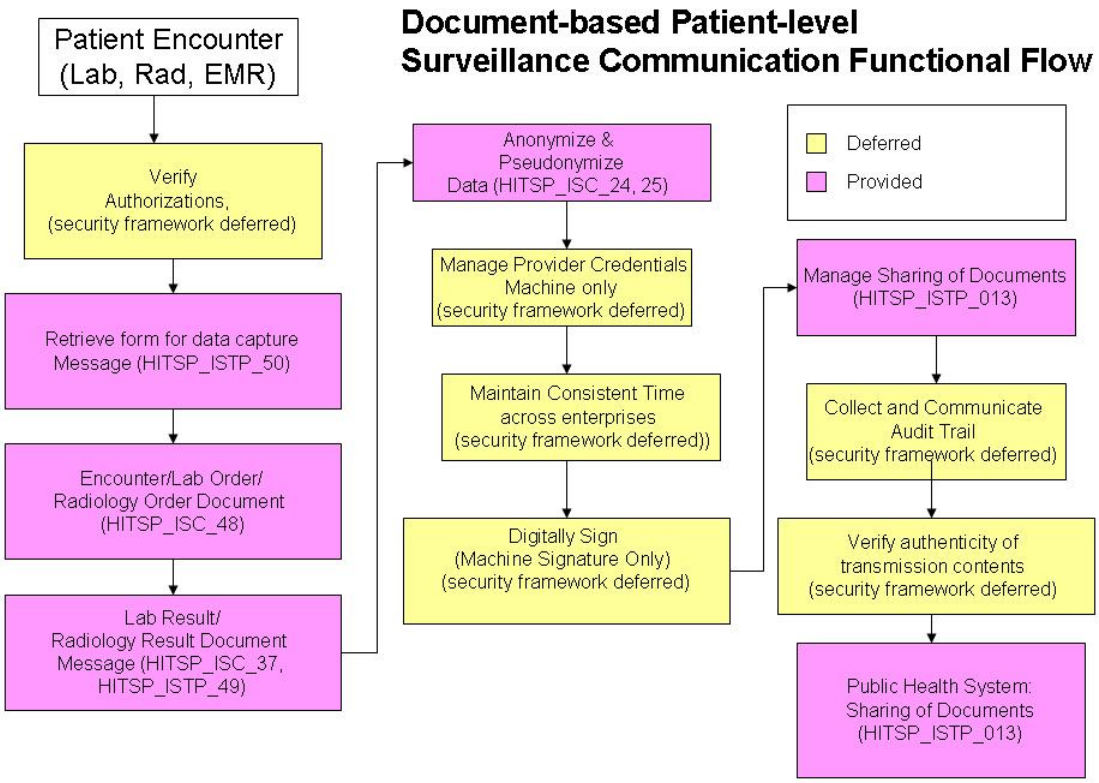
Disadvantages

- HL7 Clinical Document Architecture (CDA R2) is required for more fully structured content within the document; it has not yet been implemented
- The intent of the document-based information is to facilitate the sharing of human readable transfer of care information between providers
- These documents are not tailored for Biosurveillance; the Use Cases for which document-based data sharing have been developed are based on sharing of data about individual patients from one provider to another
- End of encounter submission of documents for hospital admissions, and to some extent Emergency Departments, would be compiled too late to meet the Biosurveillance Use Case requirement for Syndromic surveillance and situational awareness
- A document share must enable publish and subscribe capability to allow public health useful access to required information
- Hospitals and Emergency Departments have existing message-based data transmission capabilities that can be leveraged in the near term
- Document-based transmission is not in general use by healthcare organizations and requires significant additional resource expense with limited additional benefit to the facility

Preconditions include configuration of communication and identification of communication exchanges partners. This functional flow scenario includes the specification of multiple Biosurveillance documents, which form a class of clinical documents that contain information and data that can provide the epidemiologist with sufficient data on the health of the population. Operationally, they can be created at any point in time, including admission, clinical order, transfer or discharge. While it is anticipated that information sources and content will expand for biosurveillance purposes, in support of the current Use Case, the following types of clinical Biosurveillance Documents should be collected:

- Laboratory Results Documents, including preliminary, interim, and final result documents.
- Encounter summaries from Electronic Medical Records Systems (including orders for laboratory and radiology testing).
- Radiology Results Documents, particularly interpretation reports.

Figure 4.1.3-1 Functional Flow Scenario diagram for Document-based Patient-level Surveillance Data Sharing (HITSP-DS)



Because content, business rules, and electronic capture of data from LIMS and EMRs differ significantly, these are defined as separate scenario options. Users or implementers of this functional flow scenario are offered several options.

Scenario Option 1: Submission of Laboratory Biosurveillance Document

This scenario option involves a submission of laboratory biosurveillance documents from a laboratory to a Biosurveillance Information System. This scenario option is a central component of routine public health reporting processes, which typically requires an established trusted communication channel prior to the actual transfer of biosurveillance documents being initiated.

The pre-conditions assume a laboratory has processed a sample, and the test result is within the range and category of interest for biosurveillance reporting as required by federal, state or local health departments. The laboratory is also assumed to have a Laboratory Information Management (LIM) system that can capture the information required to generate the document.

The specific data elements managed by the laboratory's LIM are expected to be the source for the information used in creating the biosurveillance document. A variety of LIM implementations and usage by clinicians may result in some variability in the content of the biosurveillance document.

Detailed contents of the biosurveillance report to support this Use Case are included in the HITSP/C37 Lab Report Document Using IHE XD* Lab Component specification.

Scenario Option 2: Submission of EMR-Generated Biosurveillance Document

This Use Case involves a submission of healthcare provider generated biosurveillance documents from a Hospital/ED/Ambulatory clinic to a Biosurveillance Information System.

The pre-conditions assume a patient having presented to a healthcare provider. After examination and evaluation of the patient condition, the provider (or provider EMR) determines that the case is within the range and category of interest for biosurveillance reporting as required by federal, state or local health departments. An assumption is made that the provider has an EMR system with capability to capture the information required to generate the report.

The specific data elements managed by the provider EMR are expected to be the source for the information used in creating the biosurveillance report related to this reportable condition. A variety of EMR implementations and usage by clinicians may result in some variability in the content of the biosurveillance report.

The detailed content of the biosurveillance report are in accordance with IHE Cross-Enterprise Document Sharing of Medical Summaries (XDS-MS) Integration Profile, as described in HITSP/C48 Encounter Document Using IHE Medical Summary (XDS-MS) Component subject to the constraints listed in section 4.2.4 of this document.

Scenario Option 3: Submission of Radiology Result Biosurveillance Document

The AHIC Use Case includes capture of Radiology Results. This scenario option involves a submission of radiology result biosurveillance documents from radiology systems to a Biosurveillance Information

System. While this scenario option is not a central component of routine public health reporting processes existing work will be leveraged to accommodate this document type.
The pre-conditions assume a radiologist has captured the data of interest and provided an interpretation of that data into the radiology information system and the test result is within the range and category of interest for biosurveillance reporting as required by federal, state or local health departments. An assumption is made that the radiologist has a system with capability to capture the information required to generate the document.
The specific data elements managed by the radiology system are expected to be the source for the information used in creating the biosurveillance document. A variety of radiology information system implementations and usage by clinicians may result in some variability in the content of the biosurveillance document.
Until further specification requirements are defined to enable additional constraints, the Radiology Result Biosurveillance Document references IHE Cross-Enterprise Document Sharing for Imaging (XDS-I) Integration Profile without further constraint as described by the HITSP/TP49 Sharing Radiology Results Transaction Package.

4.1.3.1 SCENARIO CONSTRAINTS

The Scenario is constrained to the following:

- AHIC Data Steering Committee Data set: See AHIC Minimum Data Set Cross-reference table in Section 4.1
- AHIC Biosurveillance Use Case
- Document constraints are described in HITSP/C37 - Lab Report Document Using IHE XD* Lab, HITSP/C48 - Encounter Document Using IHE Medical Summary (XDS-MS), and HITSP/TP49 - Sharing Radiology Results
- Vocabulary Constraints: See AHIC Minimum Data Set Cross-reference table in Section 4.1

This functional flow scenario leverages the shared document resource approach common to each of the current HITSP Use Cases. The use of this type of shared resource for Biosurveillance differs from the use of the resource to support sharing of clinical care records primarily in that the information is anonymized, and in that the resource is used to support secondary use. To support secondary use functions, query support must be included that supports retrieval of multiple records at one time, and to support retrieval of subsets of interest to public health. A number of constraints are added which are specific to Biosurveillance use of such a resource, and will be included as a part of this Interoperability Specification. These constraints address privacy protection, authenticity, query, and polling considerations associated with event detection uses, and with secondary use of clinical data for analytical purposes.
Notification of Document Availability and associated actors are optional in this functional flow scenario.

Transmission Options

Note that the Use Cases above use the same set of transactions and differ only by the content of the Biosurveillance Report. This scenario describes the use of a common document repository to enable communication of biosurveillance data with one or many public health authorities. Four key

communication options are available to the Biosurveillance Information System (BIS) using this shared document resource option:

Notification/retrieve (HITSP/C29 Notification of Document Availability Component)

The first transmission option is to enable interested parties (e.g. local, state, federal public health authorities) to subscribe to notification events for published data. Neighboring states, for instance, may be interested in notification for conditions that are registered of a particular type or source. Filtering options for this cycle will be limited, but this is an area for expansion opportunities to incorporate more semantically sophisticated notifications. While the IHE Notification of Document Availability (NAV) Integration Profile is referenced to accomplish this goal, it is still insufficient, and this is an area where additional work is needed. What is actually needed is the ability to subscribe to data of interest in fulfillment of the Use Case requirement to filter existing data such that the Biosurveillance Information System can subscribe to data of interest. The HITSP Population Health TC recommends that IHE review and identify a mechanism to enhance this profile to include publish and subscribe options in support to public health

Query Option (HITSP/TP13 Manage Sharing of Documents Component)

The query option is included in this case to enable communication with Biosurveillance Information Systems (BIS) through an option to poll or query the content of the shared document resource. In some cases, this may be routine polling. For instance, the state and local public health department may wish to poll the resource on an incremental basis so as to retrieve all new records (possibly with a defined time overlap) since the last query. This approach is suited to enable routine access to multiple parties. The query option may also be used to enable access to Biosurveillance documents in order to Query Neighboring Jurisdiction for Event Detection, Monitor a Suspected Event, or for Case Management purposes.

In many cases, the Biosurveillance Information System may need to assess information from the patient care history, and patients may have Biosurveillance case documents in the IHE-XDS repository from prior visits to other providers. For example, if a patient is diagnosed with a new strain of flu, the epidemiologist may want to collect the medical history associated with the case to identify trends in symptoms for early detection. Figure 4.1.3.8-1 shows the transactions required for this Use Case.

A query option will be defined as part of this functional flow scenario in order to complete the Biosurveillance Use Case requirement to populate the BIS. A shared information resource environment with query options enables an organization BIS to access and populate its own resource from one or many shared document resources. This serves to accomplish the goals of the Use Case, while better enabling more robust support for the BIS to gather data of interest for multiple regions and information types.

In support of this functional flow scenario, this Interoperability Specification provides constraints to the Use Case for those topics that merit significant additional biosurveillance workflow consideration. These

key constraints are with respect to terminology, notifications, and support for content specification for the varying reportable conditions forms required by state public health departments to collect supplemental data relevant to support detection and monitoring of public health threats for the local environment. Some of these areas need additional consideration and in some cases harmonization efforts before HITSP can fully specify a robust implementation. While this specification defines the fit for these constructs, detailed specification in some cases will be deferred to enable sufficient consideration for the complexity of the subject matter. It is also assumed that the healthcare provider information systems are able to translate local codes into standard terminology.

Data Monitor Option

A data monitor option will be available to enable retrieval from the document repository or additional feed from the document source. This will enable a service to be defined with optional rules for selecting and sending data of interest to the BIS.

Retrieve Form For Data Capture Option (See HITSP/TP50 Retrieve Form for Data Capture Transaction Package)

In support of public health authority reportable conditions monitoring and management, the clinical or laboratory information source may optionally implement HITSP/TP50 Retrieve Form for Data Capture Transaction Package. This option allows for capture of supplemental data variables not typically maintained in an electronic health record or laboratory information system through a more seamless integration with the local electronic management system. This option allows for the local system to retrieve a form specific to the identified potential public health threat. This is one option currently available for reportable conditions which may need additional local configuration and architectural constraints or considerations for implementation architectures.

4.1.3.2 SCENARIO PRE-CONDITIONS

In order to implement the information interchange conforming to this Interoperability Specification and its constructs in a real world environment, the implementer must ensure that the implementing systems operate within a secure infrastructure that insures the privacy, integrity and availability of all personally identifiable health information as prescribed by the Health Insurance Portability and Accountability Act, all other applicable laws and regulations and terms of any contracts and agreements. The information interchange standards may also assume that certain information technology infrastructure and functions are in place. These assumptions collectively are the general pre-conditions for conforming to this Interoperability Specification and its constructs.

Specific pre-conditions for this scenario include:

- Secure communications are in place, and all policy, compliance, and authorization issues are addressed through automated or manual means
- Configuration of communication and identification of communication exchanges partners

4.1.3.3 SCENARIO TRIGGERS

None

4.1.3.4 SCENARIO POST-CONDITIONS

The Shared Document Resource is available to all authorized Public Health Agencies.

4.1.3.5 SCENARIO OUTPUTS

None

4.1.3.6 SCENARIO BUSINESS ACTORS

Table 4.1.3.6-1 Document-based Patient-level Surveillance Data Sharing Scenario Business Actors

Actor	Description
Clinician	In ambulatory and emergency department settings, the healthcare providers within Healthcare Delivery Organizations with direct patient interface in the delivery of care, including physicians, nurses, and clinical supervisors. These business actors are involved in the entry of source data into the system. In the case of reportable conditions, these business actors will also enter supplemental public health data elements into the data capture form.
Clinical Information Systems (Document Source)	Information system supporting the clinical care and information management for Ambulatory, inpatient, and emergency department settings for organizations, such as hospitals, physician practices, which manage the delivery of care and submission of utilization resource information.
Laboratory Information Systems (Document Source)	Information system supporting the testing, analysis, and information management for laboratory. Medical laboratories, in either in a hospital or ambulatory environment, which analyze specimens as ordered by clinicians to assess the health status of patients. Laboratories, depending on how they are affiliated with hospitals, can be part of either Individual Healthcare Facilities or Integrated Healthcare Data Suppliers. These business actors are responsible for updating interface engine rules and triggers in response to Use Case modifications of requested data feeds.
Radiology Information Systems	Information system supporting the testing, analysis, and information management for radiology service organizations. Radiology services, depending on how they are affiliated with hospitals, can be part of either Individual Healthcare Facilities or Integrated Healthcare Data Suppliers. These business actors are responsible for updating interface engine rules and triggers in response to Use Case modifications of requested data feeds.
Healthcare delivery organization	Organizations, such as hospitals, physician practices, which manage the delivery of care and submission of utilization resource information. These business actors are responsible for updating interface engine rules and triggers in response to Use Case modifications of requested data feeds.
Public Health Agencies BIS (local/state/federal)	Local, state, and federal government organizations and personnel that exist to help protect and improve the health of their respective constituents. A critical effort under this charge is collecting health information to monitor for the existence of emerging health threats appearing in the population and manage these threats once manifested. Staff of these agencies interact with the BIS to verify and validate system indications of public health threats, and to assert acknowledgements that may be required by system processes.

4.1.3.7 SCENARIO TECHNICAL ACTORS

It is expected that the communication of biosurveillance documents in this functional flow scenario will occur in an environment where the public health authorities, physician offices, laboratories, resource suppliers and hospitals are coordinated within a regional health information organization that serves the information sharing needs of a community of care settings.

This functional flow scenario leverages the registry/repository-based infrastructure specified by the IHE-XDS Cross-Enterprise Document Sharing and related IHE Integration Profiles such as Patient Identifier Cross-Referencing (IHE-PIX), security and privacy (IHE-CT, IHE-ATNA, IHE-XUA), and Notification of Availability of Documents (NAV). (See the IHE IT Infrastructure Technical Framework). These IHE Integration Profiles have been further constrained by HITSP common component specifications, but the associated actors are the same and referenced directly in the tables below. Other actors that may be indirectly involved due to their participation in related dependent transactions such as Audit trail and Node Authentication and Consistent Time are not shown.

Table 4.1.3.7-1 Document-based Patient-level Surveillance Data Sharing Scenario Technical Actors

Actor	Description
Document Consumer	The Document Consumer Actor queries a Document Registry Actor for documents meeting certain criteria, and retrieves selected documents from one or more Document Repository actors.
Document Source	The Document Source Actor is the producer and publisher of documents. It is responsible for sending documents to a Document Repository Actor. It also supplies metadata to the Document Repository Actor for subsequent registration of the documents with the Document Registry Actor.
Document Repository	The Document Repository is responsible for both the persistent storage of these documents as well as for their registration with the appropriate Document Registry. It assigns a URI to documents for subsequent retrieval by a Document Consumer.
Document Registry	The Document Registry Actor maintains metadata about each registered document in a document entry. This includes a link to the Document in the Repository where it is stored. The Document Registry responds to queries from Document Consumer actors about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration.
Notification Sender	This actor sends notifications of availability for documents in an XDS registry, and receives acknowledgements of these notifications.
Notification Receiver	This actor receives notifications of availability for documents in an XDS registry, and may optionally send acknowledgments of them.
Patient Identifier Cross-reference manager	Serves a well-defined set of Patient Identifier Domains. Based on information provided in each Patient Identifier Domain by a Patient Identification Source Actor, it manages the cross-referencing of patient identifiers across Patient Identifier Domains.
Patient Identifier Cross-reference consumer	This actor allows a system in a Patient Identifier Domain to determine the identification of a patient in a different Patient Identifier Domain by using the services of a Patient Identifier Cross-Reference Manager Actor.
Patient Identity Source	The Patient Identity Source Actor is a provider of unique identifier for each patient and maintains a collection of identity traits. Each Patient Identifier Domain requires this Actor to assign patient identities and to notify other Actors (e.g. a Patient Identifier Cross-Reference Manager or a Registry Actor) of all events related to patient identification (creation, update, merge, etc.).
Pseudonymization Service	Supplier of alternative identification information that permits a patient to be referred to by a key that suppresses his/her actual identification information.
Form Filler	The actor responsible for retrieving a form from a Form Manager, and for submitting form instance data to a Form Receiver. The mechanism by which a unique identification of a form is obtained is outside the scope of the Retrieve Form for Data Capture profile.
Form Manager	The actor that supplies a form based upon a request that supplies unique form identification.
Form Receiver (Biosurveillance Information System)	Repository of permanent source records of public health reports.

4.1.3.8 SCENARIO ACTOR INTERACTIONS

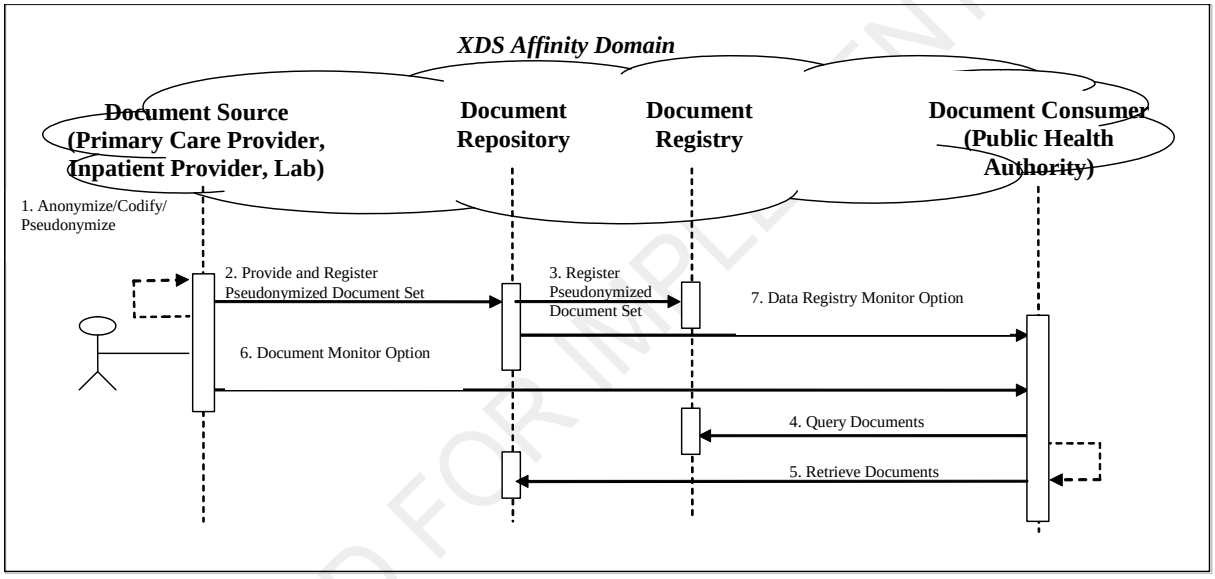
Transmission Options

As described in the constraints section above, key communication options are available to the BIS using this shared document resource option:

- Notification/retrieve
- Query Option
- Data Monitor Option

The functional workflow for information retrieval is listed below.

Figure 4.1.3.8-1 Document-based Patient Scenario Process Flow Diagram



These steps are:

- Extract/capture a collection of records into a set of documents packaged as an IHE-XDS Submission Set. This submission contains a Biosurveillance Document, and may contain a number of other related documents. Biosurveillance documents include data sent to public health authorities for the purposes of detection, monitoring, and managing threats to the public health. This data are anonymized and pseudonymized and structured as a document of the options described (Laboratory Report, Encounter Summary, and Radiology Report Document) and constrained as described by this Interoperability Specification.
- This step uses the transactions provided by the IHE-ITI XDS profile to place the records in an IHE-XDS Repository (local or shared).
- The Repository ensures that the documents of the submission set are registered with the IHE-XDS Registry of the XDS Affinity Domain (set of cooperating care delivery institutions).

- The receiving Biosurveillance Information System can then utilize existing query transactions from the IHE-XDS profile to find the URL of the Documents.
- Finally, the receiving Biosurveillance Information System may choose to import relevant information from these records into its own BIS system.

Alternatively:

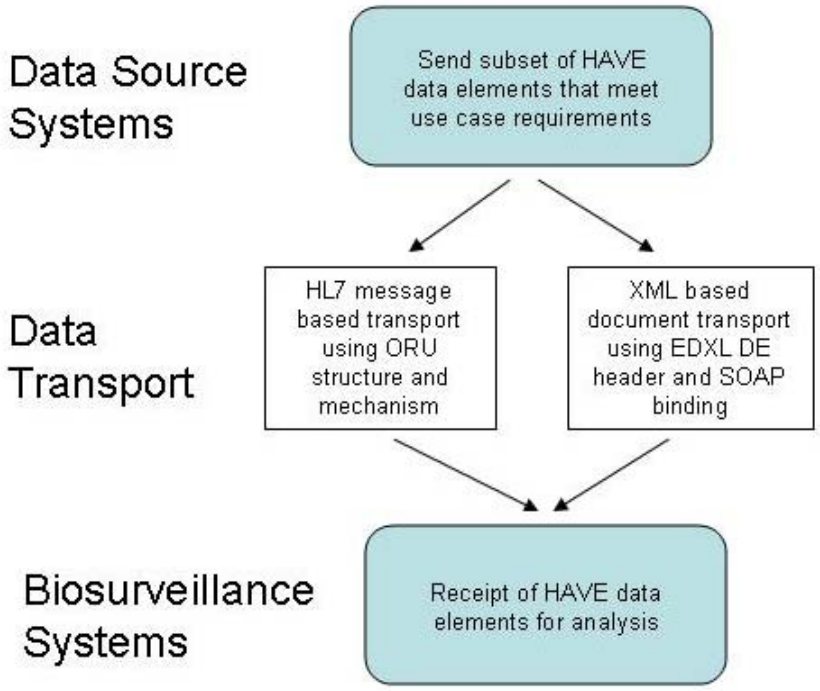
- A document source monitor option will be available to enable sending document and registry data from the document source to the public health authority;
- A registry monitor option will be available to enable sending registry data from the document repository actor to the public health authority so that a query may be later issued from the public health authority.
- This will enable a service to be defined with optional rules for selecting and sending data of interest to the BIS.

4.1.4 RESOURCE MANAGEMENT DATA TRANSFER (DOCUMENT-BASED AND MESSAGE-BASED) FUNCTIONAL FLOW SCENARIO OVERVIEW

The third functional flow scenario provides a mechanism to automate the communication of resource availability from a resource provider to a resource management information service. In this Use Case, utilization data only goes to Public Health Authorities.

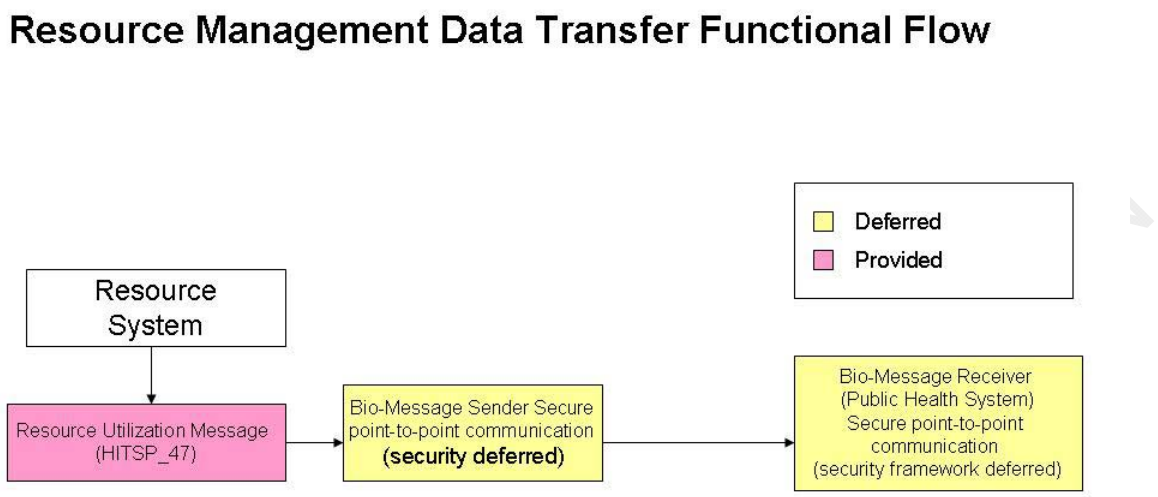
The Population Health Technical Committee has identified a need for both data element definition and a messaging schema to support the exchange of information for reporting the utilization and availability of hospitals and health resources. The TC is informed by the Harmonized Biosurveillance Use Case provided by American Health Information Community (AHIC). The TC is further informed with regard to the desirable set of data elements relevant to this purpose by the Biosurveillance Data Steering Group which in turn reports to the Biosurveillance Work Group of the AHIC.

Figure 4.1.4-1 Information Flows for Bed Availability



With regard to the messaging approach to support the exchange of hospital and health resource availability information, the Population Health TC recommends that either of two acceptable specifications be utilized. The two specifications are the Emergency Data Exchange Language Distribution Element (EDXL-DE) version 1.0 for information exchange in an XML/SOAP/Web services environment, or the HL7 version 2.5 Observation Result Unsolicited (HL7 ORU) message constrained to transmit the Hospital Availability Exchange (HAVE) format dataset.

Figure 4.1.4-2 Process flow for Bed Availability Monitoring



Scenario Option 1: Bed Availability Document

This scenario option involves generation of a bed resource availability document from the healthcare provider environment. This document is defined specifically to represent the characteristics and breadth of specificity desired for optimal use by Emergency Operations Centers. This information may be generated through manual input, or from existing systems, or from a combined integrated system with supplemental data entry.

The pre-conditions assume the existence of the secure transport mechanisms, and that the bed availability data are available to the system and/or individual generating the resource availability data. This option defines the content of the message to be delivered over that transport to communicate bed availability documents defined. An assumption is made that the healthcare provider has a computer information system with capability to capture the information required to generate the document.

No assumption is made as to the source of the bed availability information. A variety of administrative classifications for bed type, provider specialty, and usage by provider organizations may result in some variability in the content and detail of the bed availability document.
The detailed content of the associated bed availability document to support this Use Case will be detailed as part of the HITSP/C47 - Resource Utilization Message.

Scenario Option 2: Bed Availability Message

This scenario option involves generation of bed availability messages from inpatient healthcare provider administrative systems.
The pre-conditions assume the existence of the secure transport mechanisms, and that the bed availability data are available to the system generating the resource availability data. This option defines the content of the message to be delivered over that transport to communicate bed availability documents

defined. An assumption is made that the healthcare provider has a computer information system with capability to capture the information required to generate the message.
It is assumed that the bed availability message will be captured from the organization admitting/discharge system. A variety of administrative classifications for bed type, provider specialty, and usage by provider organizations may result in some variability in the content and detail of the bed availability document.
The detailed content of the associated bed availability document to support this Use Case will be detailed as part of the HITSP/C47 - Resource Utilization Message.

4.1.4.1 SCENARIO CONSTRAINTS

- Constrained just to the data needed from provider to public health
- Constraining data elements to the overall messaged defined by HAVE –
- Regular vs. Emergency
- This functional flow scenario assumes a point-to-point communication from the source to the recipient. No constraints are included at this time with respect to information or processes otherwise needed to support the Emergency Operations Center system. However, as the resource content and sources will likely be expanded in future iterations, it is anticipated that additional constraints will be added at that time to support infrastructure and emergency response needs.
- Constraints are included primarily to assert interoperable data communications. In particular, this Interoperability Specification has constrained HL7 messages so as to be able to communicate the resource management information so as to better support integration with existing system capabilities at inpatient locations. As HAVE was specifically designed to support the Emergency Operations Center system, few additional constraints are added to accommodate this standard.
- These standards have been identified in section 3.2 of this document as an overlap. As a result of the HITSP Biosurveillance Gap Analysis deliverable, harmonization between these two standards is more formally underway between the two standards bodies. As a result, subsequent versions of the Biosurveillance Interoperability Specification may be modified so as to accommodate any updates and resolutions resulting from the harmonization effort.

4.1.4.2 SCENARIO PRE-CONDITIONS

In order to implement the information interchange conforming to this Interoperability Specification and its constructs in a real world environment, the implementer must ensure that the implementing systems operate within a secure infrastructure that insures the privacy, integrity and availability of all individually identifiable health information as prescribed by the Health Insurance Portability and Accountability Act, all other applicable laws and regulations and terms of any contracts and agreements. The information interchange standards may also assume that certain information technology infrastructure and functions are in place. These assumptions collectively are the general pre-conditions for conforming to this Interoperability Specification and its constructs.

Specific pre-conditions for this scenario include:

- Communication of biosurveillance messages occurs in an environment where public health authorities, clinical offices, laboratories, resource suppliers and hospitals have secured point-to-point network connections. This may be through either VPN or S/MIME approaches
- A Regional Capture Center (Data Source System) exists
- Configuration of communication and identification of communication exchanges partners.
- This functional flow scenario leverages message-based communications. The content of these messages are defined in the associated components

4.1.4.3 SCENARIO TRIGGERS

None

4.1.4.4 SCENARIO POST-CONDITIONS

The Biosurveillance Information System has received the submitted data.

4.1.4.5 SCENARIO OUTPUTS

None

4.1.4.6 SCENARIO BUSINESS ACTORS

Table 4.1.4.6-1 Resource Management Data Transfer (Document-based and Message-based) Scenario Business Actors

Actor	Description
Inpatient Healthcare delivery organization (Data Source System)	Organizations, such as hospitals, Skilled Nursing Facilities, and other inpatient healthcare providers, which manage the delivery of care and submission of utilization resource information.
Regional Capture Center (Data Source System)	Network or collaborative of regional inpatient healthcare delivery organizations utilizing a common service to capture and forward on resource availability information to BIS Emergency Operations Centers. This may be a service facilitated by a RHIO/HIE.
Emergency Operations Center (Biosurveillance System)	Local, state, and federal government organizations and personnel that exist to help protect and improve the health of their respective constituents. A critical effort under this charge is collecting health information to monitor for the existence of emerging health threats appearing in the population and manage these threats once manifested.

4.1.4.7 SCENARIO TECHNICAL ACTORS

It is expected that the communication of biosurveillance messages in this functional flow scenario will occur in an environment where, organizations, such as public health authorities' hospitals, Skilled Nursing Facilities, and other inpatient healthcare providers establish secured point-to-point network connections. This may be achieved through either VPN or S/MIME approaches. There is no sharing in this functional flow scenario.

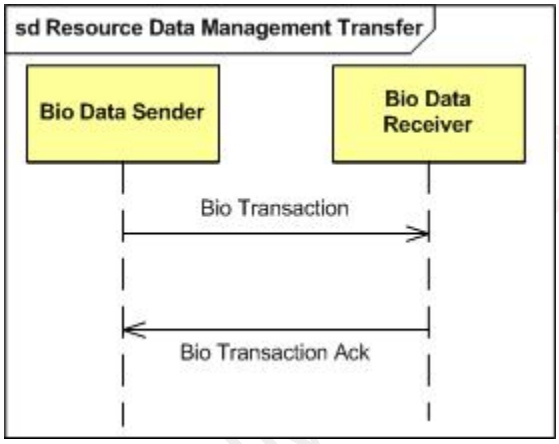
This functional flow scenario leverages message-based communications. The content of these messages are defined in the associated components.

Table 4.1.4.7-1 Resource Management Data Transfer (Document-based and Message-based) Scenario Technical Actors

Actor	Description
Message Sender	The holder of resource data who is communicating that data to the message receiver, typically the resource management information system (e.g. Census System/Bed Capacity System)
Message Receiver	An authorized entity that is receiving resource availability data (e.g. BIS/Emergency Operations Center)

4.1.4.8 SCENARIO ACTOR INTERACTIONS

Figure 4.1.4.8-1 Scenario Actor Interaction Diagram



4.2 LIST OF TRANSACTION PACKAGES, INDEPENDENT TRANSACTIONS AND COMPONENTS

The following list of Transaction Packages, Transactions, Components and their definitions are used by the Interoperability Specification:

Table 4.2-1 Transaction Packages, Transactions and Components

Transaction Package/ Independent Transaction	Description	Document References
Manage Sharing of Documents	Specification for a data locator and repository for shared storage of documents	HITSP/TP13
Retrieve Form for Data Capture	A data capture mechanism to support the gathering of additional information for reporting. This will be used to enable public health required reporting with supplemental data capture requirements.	HITSP/TP50
Pseudonymize Data	Apply a common standard to Codify Document Content, Anonymize or Pseudonymize patient data to protect patient identity from undesired disclosure when communicating care data to/from external parties.	HITSP/T24

Transaction Package/ Independent Transaction	Description	Document References
Anonymize Data	Apply a common standard to Codify Document Content, Anonymize or Pseudonymize patient data to protect patient identity from undesired disclosure when communicating care data to/from external parties.	HITSP/C25
Patient ID Cross-Referencing	Uniquely identify a patient through query and/or matching of key elements.	HITSP/TP22
Acknowledgements	Automated assertion that the information was received and correct	HITSP/C36[4]
Notification of Document Availability	Defines a mechanism for point-to-point notifications between systems or users within an XDS Affinity Domain. These notifications can be used to trigger various activities within applications that implement both XDS and NAV.	HITSP/T29

4.2.1 DEPENDENCIES

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

Table 4.2.1-1 Dependencies

Transaction Package/Independent Transaction	Depends On (Name of Transaction or Transaction Package that it depends on)	Dependency Type (Pre-requisite, grouping)	Purpose (Reason for this dependency)
Shared Document Resource/ Provide and Register (EMR Document Sources)	HITSP/C48 Encounter Document Using IHE Medical Summary (XDS-MS)	Each HITSP-Document Sharing (DS) Actor shall support the HITSP/C48 Encounter Document with additional constraints as specified to support the biosurveillance requirements	Required for the communication of biosurveillance encounter report information and lab/radiology order information from hospital and ambulatory EMRs
Shared Document Resource/Provide and Register (Laboratory Document Sources)	HITSP/C37 Lab Report Document Using IHE XD* Lab	HITSP-DS Actor shall support the HITSP/C37-Lab Report Document content profile	Required for communication of discharge summary information from hospital and ambulatory EMRs
Shared Document Resource/Provide and Register (Document Sources)	HITSP/TP22 Patient ID Cross-Referencing	HITSP-DS Actor shall support the HITSP/TP22 PIX as part of the HITSP/T24 Pseudonymize	Required for consistently assigning the pseudo-identity to a patient across multiple provider locations

[4] Acknowledgements are now part of the HL7 Lab Implementation Guide. See HITSP/C36 – Lab Result Message for further details.)

Transaction Package/Independent Transaction	Depends On (Name of Transaction or Transaction Package that it depends on)	Dependency Type (Pre-requisite, grouping)	Purpose (Reason for this dependency)
Shared Document Resource/Provide and Register (Document Source)	HITSP/T24 Pseudonymize	Each actor implementing HITSP-DS shall be grouped with the HITSP/T24 Pseudonymize	Used to protect confidentiality of patients whose personal health information is sent to the BIS while assuring that patients can be re-identified if needed to manage public health threats
Surveillance Message-Based Data Submission	HITSP/T24 Pseudonymize	Each HITSP-Surveillance Message-Based Data Submission Actor shall be grouped with the HITSP/T24 Pseudonymize	Used to protect the confidentiality of the patients whose personal health information is sent to the BIS such that the patients can be re-identified as needed to manage public health threats. Reportable conditions sent to local public health authorities may necessarily need to be identified and as such, this is to be supported as an option.
HITSP/T24 Pseudonymize	HITSP/TP22 PIX Uniquely identify a Patient across enterprises	HITSP/T24 Actor shall support the IHE-PIX Integration Profile as part of the HITSP-Pseudonymize construct	Required for consistently assigning the pseudo-identity to a patient across multiple provider locations

To support a dependent construct, an actor must implement all required Transactions in the prerequisite construct in addition to those in the dependent construct. In some cases, the prerequisite is that the actor selects any one of a given set of constructs.

4.2.2 CONSTRAINTS

The following constraints and/or enhancements are associated with this Use Case implementation specification:

Table 4.2.2-1 Constraints

Transaction Package/ Transaction	Constraint	Constraint Type (Pre-condition, post-condition, general)	Purpose (Reason for this constraint)
Shared Document Resource/provide and register	Constrain Medical Summary documents to minimal clinical and anonymized demographic dataset from AHIC Data Steering Committee data dictionary clinical data elements	Pre-condition	Required to conform to the AHIC domain requirements for Biosurveillance data
Shared Document Resource/provide and register	Constrain Laboratory Report Document to minimal laboratory result dataset from AHIC Data Steering Committee data dictionary laboratory result data elements	Pre-condition	Required to conform to the AHIC domain requirements for Biosurveillance data

Transaction Package/ Transaction	Constraint	Constraint Type (Pre-condition, post-condition, general)	Purpose (Reason for this constraint)
Bio Transaction	Constrain Encounter Summary message to minimal clinical and anonymized demographic dataset from AHIC Data Steering Committee data dictionary clinical data elements	Pre-condition	Required to conform to the AHIC domain requirements for Biosurveillance data
Bio Transaction	Constrain Laboratory Result Message to minimal laboratory result dataset from AHIC Data Steering Committee data dictionary laboratory result data elements	Pre-condition	Required to conform to the AHIC domain requirements for Biosurveillance data
Manage Shared Docs/provide and register	Data sent to the shared document repository and recorded in the shared registry must be Anonymized 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 BIS such that the patients can be re-identified as needed to manage public health threats
BIO Transaction	Data sent from the Bio Message Sender to the Bio Message Receiver must be Anonymized 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 BIS such that the patients can be re-identified as needed to manage public health threats
Shared Document Resource/Provide and Register /provide and register / Submission of EMR-Generated Biosurveillance Document	Medical Summary Document Constraints – Vocabulary (See Section 4.1)	Pre-condition	Required for optimum harmonization and interoperability of document content
Shared Document Resource/Provide and Register /provide and register / Submission of EMR-Generated Biosurveillance Document	Medical Summary Documents may be generated at any time during the patient visit, and not restricted to patient discharge	Pre-condition	Required to conform to Use Case constraint of providing biosurveillance information in with a periodicity of no longer than 24 hours.
Shared Document Resource/Provide and Register /provide and register / Submission of EMR-Generated Biosurveillance Document	Medical Summary Documents should contain some machine-readable content	Pre-condition	Used to assure machine-consumable information for large volume information exchange and processing
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.	General	Asserted to enable public health information retrieval support to enable pull of repository data to the BIS or to ask public health questions of the data
Manage Shared Docs/provide and register	IHE-DSG - This assures the validity of the information source, submitter, data transmission, and authorization; Document Consumer of the query registry is responsible fore verification of integrity, authenticity,	Pre-condition	Asserted to fulfill the Use Case requirement to 'Verify authenticity of transmission contents'

Transaction Package/ Transaction	Constraint	Constraint Type (Pre-condition, post-condition, general)	Purpose (Reason for this constraint)
Manage Shared Docs/query registry	IHE-DSG - This assures the validity of the information source, submitter, data transmission, and authorization; Document Consumer of the query registry is responsible for verification of integrity, authenticity, using OCSP, ANSI X9.31, and CRL	Post-condition	Asserted to fulfill the Use Case requirement to 'Verify authenticity of transmission contents'
Manage Shared Docs/query registry	IHE-BPPC 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
Manage Shared Docs/provide and register;	IHE-BPPC 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
Manage Shared Docs/ATNA	IHE-ATNA 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
Uniquely identify a Patient across enterprises	Constrain to return single value for pseudonymization steps	General	In order to link pseudo identifiers across entities
Manage Shared Docs/provide and register	The XDSDocumentEntry.eventCodeList 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.
Manage Shared Docs/provide and register	Extend the usage of the XDSDocumentEntry 'confidentialityCode' to signify when patient information in the document and corresponding metadata has been pseudonymized. Attribute: confidentialityCode Optionality: R[5] Vocabulary: Need to assign a unique OID and code values to indicate pseudonyminization.	Pre-condition	This code indicates the level of confidentiality for the corresponding document.
Manage Shared Docs/provide and register	In object type XDSDocumentEntry, attributes 'healthcareFacilityTypeCode' and 'practiceSettingCode' both have requirement level of R. This could potentially be a problem, unless we can expand the definition of these attributes.	Pre-condition	These attributes do not quite conceptually align with all possible data sources for biosurveillance data.
Manage Shared Docs/provide and register	In object type XDSDocumentEntry, attributes 'parentDocumentId' and 'parentDocumentRelationship' are potentially applicable to biosurveillance, useful in the general sense for document management. Requirement level of R2 suits the biosurveillance Use Case.	Pre-condition	These attributes are useful in the general sense for document management.

[5] Per IHE Metadata source/query codes, R2 refers to 'Required if Known'

Transaction Package/ Transaction	Constraint	Constraint Type (Pre-condition, post-condition, general)	Purpose (Reason for this constraint)
Manage Shared Docs/provide and register	In object type XDSDocumentEntry, the requirement for attributes 'patientId' and 'sourcePatientID' is a problem.	Pre-condition	In many data sources for biosurveillance, patients may not be involved at all. If they are, the id should be pseudonymized. We need something like 'sourceId' in this case as a substitute.
Manage Shared Docs/provide and register	In object type XDSDocumentEntry, attributes 'serviceStartTime' and 'serviceStopTime' do not have an intuitive context for all biosurveillance data sources.	Pre-condition	We'd need to expand/explain their definition when the data source is not from an EMR system.
Manage Shared Docs/provide and register	In object type XDSDocumentEntry, several sub-attributes are required for attribute 'sourcePatientInfo': source patient id list, patient name, patient gender, patient birthdate, patient address. This is a problem.	Pre-condition	When the biosurveillance data source does not pertain to a patient, most of these are useless. Other sub-attributes of the HL7 v2.5 PID Segment can come into play: Species Code, Breed Code, Strain, Production Class Code, County Code (assuming this is equivalent to UN – level 2 region identification). In the case of patients, XDS does not enforce many requirements on the sub-components for these sub attributes. Address could contain nothing more than a street name or a country. In this case, data from XDS would not be plottable on a map or useful for geographic simulation.

In support of Biosurveillance, the following XDS Metadata elements are constrained as follows.

XDS Metadata Attribute	Optionality	Extended Discussion	Source Type
XDSDocumentEntry.eventCodeList	R[6]	See 0	CADT
XDSDocumentEntry.confidentialityCode	R	See 4.2.2.2	FAD
XDSDocumentEntry.patientID and XDSSubmissionSet.patientID	R	See 4.2.2.3	SAT
XDSDocumentEntry.sourcePatientID and XDSSubmissionSet.sourcePatientID	R	See 4.2.2.4	SAT

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

4.2.2.1 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 if this guide. 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. Vocabularies and reporting compliance needs to be validated and audited independent of this specification.

4.2.2.2 XDSDocumentEntry.confidentialityCode

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

4.2.2.3 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 Transaction.

4.2.2.4 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 Transaction.

5.0 TECHNICAL IMPLEMENTATION

5.1 CONFORMANCE

To conform to this specification, a system must implement all parts of this specification that are relevant to the interfaces for which conformance is claimed. A system conforming to this specification for the purposes of representing an EHR system must implement this complete specification and must implement a model consistent with the model specified in this specification. The system must implement an information interchange, and security model that is consistent with the intent of this specification

5.2 SUPPORTING DOCUMENTS

The following documents were used to support the creation of this Interoperability Specification.

Table 5.2-1 Supporting Documents

Document Title	Relationship
Harmonized Use Case for Biosurveillance (Visit, Utilization, and Lab Result Message), March 19, 2006	ONC harmonized Use Case that describes the requirements for the HITSP specifications

6.0 APPENDIX

6.1 USE CASE ACTIONS AND EVENTS

6.1.1 INDIVIDUAL HEALTHCARE DELIVERY ORGANIZATIONS PERSPECTIVE

Table 6.1.1-1 Individual Healthcare Delivery Organizations Perspective

Code	Description	Comment
1.1.1.0	Event: Filter existing data to identify data required by public health agencies	Referencing data requirements communicated by Public Health Agencies in Event 1.3.1.0, all data that is appropriate to provide to public health agencies is identified so that it can be formatted using the approved data and technology standards to allow processing across the stakeholders in this Use Case.
1.1.1.1	Action: Filter collected data records to identify biosurveillance data	Relevant data are marked for inclusion in a transmission, via EHR or web-enabled system, to public health agencies.
1.1.1.2	Action: Aggregate identified data	All essential data are aggregated.
1.1.2.0	Event: Anonymize data required by public health agencies	Data readied for transmission is anonymized to withhold direct patient identifiers. The process should allow for the data to be re-linked to a specific patient if required for and authorized public health investigation. All associated, randomized links are included with the data package.
1.1.2.1	Action: Required data are checked to ensure full privacy requirement compliance	Ensure that all data included in biosurveillance package are anonymized and meet all applicable privacy and security considerations.
1.1.2.2	Action: A randomized data linker is provided to allow authorized entities to re-link to patient data	Functionality is provided to re-link data to patient when required as part of an authorized public health investigation.
1.1.3.0	Event: Format data required by public health agencies	Anonymized data are formatted using approved technology and data standards.
1.1.3.1	Action: Transform data using approved standards	
1.1.4.0	Event: Identify Public Health Agencies that must be notified	For individual healthcare delivery organizations, the process to determine Public Health Agency jurisdiction and the requirement to notify is less complex than for multi-jurisdictional integrated healthcare data suppliers.
1.1.4.1	Action: Determine which Public Health Agencies require notification	Apply business rules to determine which public agencies (which local, which state, and which federal agencies) need to be notified.
1.1.5.0	Event: Transmit relevant data to public health agencies	Anonymized data are transmitted to public health agencies using approved data and technology standards.
1.1.5.1	Action: Send results to public health agencies	Transmit the record to public health agencies. Any appropriate metadata will also be sent.
1.1.5.2	Action: Log interaction between organization systems and public health agencies	

6.1.2 INTEGRATED HEALTHCARE DATA SUPPLIERS PERSPECTIVE

Table 6.1.2-1 Integrated Healthcare Data Suppliers Perspective

Code	Description	Comment
1.2.1.0	Event: Filter existing data to identify data required by public health agencies	Within the data repositories of these entities, all data that is appropriate to provide to public health agencies is identified so that it can be formatted using the approved data and technology standards to allow processing across the stakeholders in this Use Case.
1.2.1.1	Action: Filter stored data to identify biosurveillance data	Relevant data are marked for inclusion in electronic format to public health agencies.
1.2.1.2	Action: Aggregate identified data	All essential data are aggregated.
1.2.2.0	Event: Anonymize data required by public health agencies	Data readied for transmission is anonymized to withhold direct patient identifiers. The process should allow for the data to be re-linked to a specific patient if required for an authorized public health investigation. All associated, randomized links are included with the data package.
1.2.2.1	Action: Required data are checked to ensure full privacy requirement compliance	Ensure that all data included in biosurveillance package are anonymized and meet all applicable privacy and security considerations.
1.2.2.2	Action: A randomized data linker is provided to allow authorized entities to re-link to patient data	Functionality is provided to re-link data to patient when required as part of an authorized public health investigation.
1.2.3.0	Event: Format data required by public health agencies	Anonymized data are formatted using approved technology and data standards.
1.2.3.1	Action: Transform data using approved standards	
1.2.4.0	Event: Identify Public Health Agencies that must be notified	For individual healthcare delivery organizations, the process to determine Public Health Agency jurisdiction and the requirement to notify is less complex than for multi-jurisdictional integrated healthcare data suppliers.
1.2.4.1	Action: Determine which Public Health Agencies require notification	Apply business rules to determine which public agencies (which local, which state, and which federal agencies) need to be notified.
1.2.5.0	Event: Transmit relevant data to public health agencies	Anonymized data are transmitted to public health agencies using approved data and technology standards.
1.2.5.1	Action: Send results to public health agencies	Transmit the record to public health agencies. Any appropriate metadata may also be sent.
1.2.5.2	Action: Log interaction between organization systems and public health agencies	
1.3.1.0	Event: Provide listing of required biosurveillance data	Public health agencies provide the listing of essential data for reporting, and specific field information.
1.3.1.1	Action: Notify involved organizations of data that must be transmitted to Public Health Agencies	A variety of methods for this notification may be necessary, including electronic or fax.
1.3.2.0	Event: Receive biosurveillance data	Public health agencies electronically receive anonymized data that is relevant to authorized biosurveillance activities. The data are anonymized, but the data contain randomized data linking capabilities to allow public health agencies to request that the sending organizations be able to support authorized public health investigators' need for more information. In cases where the message does not meet all the integrity rules, a retransmission request will be generated.

Code	Description	Comment
1.3.2.1	Action: Receive clinical data from the all data sources.	The data as well as any pertinent information necessary for indexing and query is being provided.
1.3.2.2	Action: Verify authenticity of transmission contents	Verify integrity of the transmission contents from the identified source. The data should contain appropriate anonymized patient information and other information per agreed to standards and policies.
1.3.2.3	Action: Acknowledge receipt of clinical data	Send acknowledgment to senders that integrity, authenticity and completeness of results are acceptable.
1.3.2.4	Action: Log receipt and storage of laboratory test results	

6.2 BIOSURVEILLANCE GLOSSARY

There is an additional glossary for the Biosurveillance Interoperability Specifications that may be obtained through the Population Health Technical Committee.

6.3 AHIC MINIMUMDATA SET USHIK CROSS-REFERENCE

6.3.1 CROSS-REFERENCE TABLE KEY

Table 6.3.1-1 Data Elements Cross-Reference

DATA ELEMENTS CROSS REFERENCE	
Data Element	Definition
AHIC Data Element	Data element name/identifier as listed by American Health Information Community and the Biosurveillance Data Steering Group (BDSG).
HITSP-Selected Standards	The Standard(s) from which the element(s) chosen by HITSP originate
SDO Name	SDO's Name for the elements(s) or Terminology(ies) chosen by HITSP
Link	If not loaded into USHIK, the link to other online source
SDO Source Definition	Definition or description of the elements(s) or Terminologies chosen by HITSP
SDO Datatype	Datatype of the intended standard element
SDO Codes & Representations	Chosen Standard's representation or code set for the element

6.3.2 BASE FACILITY DATA ELEMENTS

Table 6.3.2-1 Base Facility Data Elements

BASE FACILITY DATA ELEMENTS						
AHIC Data Element	HITSP- Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
Facility Identifier	HIPAA National Provider Identifier	National Provider Identifier	http://www.cms.hhs.gov/NationalProvIdentStand/	10-position all-numeric identification number assigned by the NPS to uniquely identify a healthcare provider.	Numeric	N10
Facility Name		None Available			String	Example: St. Joseph's Hospital
Facility Location	FIPS 55-3 [NIST] GNIS [USGS]	None Available	http://www.itl.nist.gov/fipspubs/fip55-3.htm	None	2 character alpha	Example: TX
Number of Facility Beds	HL7-defined	None Available	http://www.hl7.org	None	HL7-defined numeric data type	Example: 530
Number of Licensed Beds	HL7-defined	None Available	http://www.hl7.org	None	HL7-defined numeric data type	Example: 205

6.3.3 DAILY FACILITY SUMMARY REPORT ELEMENTS

Table 6.3.3-1 Daily Facility Summary Report Elements

DAILY FACILITY SUMMARY REPORT ELEMENTS						
AHIC Data Element	HITSP- Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
Admissions last 24 hours	HL7-defined	None Available	http://www.hl7.org	None	HL7-defined numeric data type	Example: 150
Discharges last 24 hours	HL7-defined	None Available	http://www.hl7.org	None	HL7-defined numeric data type	Example: 150
Deaths last 24 hours	HL7-defined	None Available	http://www.hl7.org	None	HL7-defined numeric data type	Example: 4
Clinical Status	HAVE values as in AHIC definition [OASIS]				To be determined when HAVE becomes a final standard	

DAILY FACILITY SUMMARY REPORT ELEMENTS						
AHIC Data Element	HITSP- Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
Facility Status	HAVE values as in AHIC definition [OASIS]				To be determined when HAVE becomes a final standard	
Facility Operations	HAVE values as in AHIC definition [OASIS]				To be determined when HAVE becomes a final standard	
Staffing	HAVE values as in AHIC definition [OASIS]				To be determined when HAVE becomes a final standard	
Decontamination Capacity	HAVE values as in AHIC definition [OASIS]				To be determined when HAVE becomes a final standard	
EMS Traffic Status	HAVE values as in AHIC definition [OASIS]				To be determined when HAVE becomes a final standard	
EMS Capacity	HL7-defined	None Available	http://www.hl7.org	None	HL7-defined numeric data type	Example: triageRed 5 triageYellow 10 triageGreen 30 triageBlack 50 commentText None
EMS Census	HL7-defined	None Available	http://www.hl7.org	None	HL7-defined numeric data type	Example: triageRed 3 triageYellow 7 triageGreen 25 triageBlack 45 commentText None
Adult ICU	HL7-defined	None Available	http://www.hl7.org	None	HL7-defined numeric data type	Example: 50
Medical Surgical	HL7-defined	None Available	http://www.hl7.org	None	HL7-defined numeric data type	Example: 100

DAILY FACILITY SUMMARY REPORT ELEMENTS						
AHIC Data Element	HITSP- Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
Burn	HL7-defined	None Available	http://www.hl7.org	None	HL7-defined numeric data type	Example: 40
Pediatric ICU	HL7-defined	None Available	http://www.hl7.org	None	HL7-defined numeric data type	Example: 50
Pediatrics	HL7-defined	None Available	http://www.hl7.org	None	HL7-defined numeric data type	Example: 100
Negative Flow Isolation	HL7-defined	None Available	http://www.hl7.org	None	HL7-defined numeric data type	Example: 15
Available Ventilators	HL7-defined	None Available	http://www.hl7.org	None	HL7-defined numeric data type	Example: 200

6.3.4 PATIENT DATA ELEMENTS

Table 6.3.4-1 Patient Data Elements

PATIENT DATA ELEMENTS						
AHIC Data Element	HITSP- Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
Pseudonymized Data Linker	None Available	None Available	None	None	Alphanumeric	Example: 123ABC
Encounter Date/Time	HL7 V2.5	None Available	http://www.hl7.org	None	HL7 Timestamp (TS)	Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] Examples: 19700101 197001010000 19700101000000
DOB (month and year of birth)	HL7 V2.5	None Available	http://www.hl7.org	None	HL7 Timestamp (TS)	Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] Examples: 19700101 197001010000 19700101000000
Age	UCUM	None Available	http://aurora.regenstrief.org/UCUM/	None	None	Examples: 40 a 18 mo
Gender	HL7 V2.5	Administrative Sex	http://tinyurl.com/zbhls	This field contains the patient's sex. Refer to User-defined Table 0001 - Administrative Sex for suggested values.	IS (Coded value for user defined tables)	A Ambiguous F Female M Male N NOT APPLICABLE O OTHER U Unknown
Zip	U.S. Postal Service Zip Code	None Available	http://zip4.usps.com/zip4/	None	String	Examples: 12345 12345-1234
State	Federal Information Processing Standards (FIPS 55-3) [NIST]	None Available	http://www.itl.nist.gov/fipspubs/fip55-3.htm	None	2-character alpha	Examples TX

PATIENT DATA ELEMENTS						
AHIC Data Element	HITSP- Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
Date/time last update	HL7 V2.5	None Available	http://www.hl7.org	None	HL7 Timestamp (TS)	Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] Examples: 19700101 197001010000 19700101000000

6.3.5 CLINICAL DATA ELEMENTS

Table 6.3.5-1 Clinical Data Elements

CLINICAL DATA						
AHIC Data Element	HITSP- Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
Diagnosis/Injury Code	ICD9-CM, SNOMED-CT	None Available	http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/07_summarytables.asp http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html	None	Code	ICD9-CM Examples: 0010 00581
Diagnosis Type	HL7 V2.5	Diagnosis Type	http://tinyurl.com/enojf	This field contains a code that identifies the type of diagnosis being sent. Refer to User-defined Table 0052 - Diagnosis type for suggested values. This field should no longer be used to indicate ""DRG"" because the DRG fields have moved to the new DRG segment. User-defined Table 0052 - Diagnosis type	IS (Coded value for user defined tables)	A - Admitting F - Final W – Working

CLINICAL DATA						
AHIC Data Element	HITSP-Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
Diagnosis Date/Time	HL7 V2.5	None Available	http://www.hl7.org	None	HL7 Timestamp (TS)	Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] Examples: 19700101 197001010000 19700101000000
Discharge Disposition	Universal Billing Codes (UB-92/NUBC CURRENT UB DATA SPECIFICATIONS MANUAL)	None Available	http://www.nubc.org	None	Code	
Patient Class	HL7 V2.5	Patient Class	http://tinyurl.com/ezyhd	This field is used by systems to categorize patients by site. It does not have a consistent industry-wide definition. It is subject to site specific variations. Refer to User-defined Table 0004 - Patient Class for suggested values.	IS (Coded value for user defined tables)	B Obstetrics C Commercial Account E Emergency I Inpatient N Not applicable O Outpatient P Preadmit R Recurring patient U Unknown
Date and Time Illness Onset	LOINC code: '11368-8^Illness/Injury Onset Date/time^LN'	None Selected	http://www.regenstrief.org/loinc/	None	String	LOINC String with an HL7 formatted Time Stamp or a textual explanation. Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] Examples: 19700101 197001010000 19700101000000
Chief Complaint	SNOMED-CT, CCC	None Available	http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html http://www.regenstrief.org/loinc/	None	Free-Form String or LOINC Tagged	Example: 11292-0^ED Chief Complaint – Patient Reported^LN'

CLINICAL DATA						
AHIC Data Element	HITSP-Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
Temperature	LOINC code '8310-5^BODY TEMPERATURE ^LN'; UCUM	None Available	http://www.regenstrief.org/loinc/ http://www.hl7.org http://aurora.regenstrief.org/UCUM	None	HL7-defined numeric data type	Example: 37 CEL
Pulse Oximetry	LOINC code: '19960-4^PULSE OXIMETRY^LN'; UCUM	None Available	http://www.regenstrief.org/loinc/ http://www.hl7.org http://aurora.regenstrief.org/UCUM	None	HL7-defined numeric data type	Example: 93.9
Nursing/Triage Notes	SNOMED-CT, CCC	None Available	http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html http://www.regenstrief.org/loinc/	None	String	Example: 34120-6^INITIAL EVALUATION NOTE^LN Patient skipped lunch.
Provider Identifier	None Available	None Available	None	None	Alpha-numeric	Example: 123ABC

6.3.6 LABORATORY AND RADIOLOGY TEST ORDERS

Table 6.3.6-1 Laboratory/Microbiology Test Order Elements

LABORATORY/MICROBIOLOGY TEST ORDER ELEMENTS						
AHIC Data Element	HITSP- Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
Order number	None Available	None Available	None	None	None	None
Test/Procedure Name	None Available	None Available	None	None	None	None
Test/Procedure Code	LOINC DICOM	None Available	http://www.regenstrief.org/loinc/	None	Alpha-numeric	None

6.3.7 LABORATORY/MICROBIOLOGY RESULT DATA

Table 6.3.7-1 Laboratory/Microbiology Result Data

LABORATORY/MICROBIOLOGY RESULTS						
AHIC Data Element	HITSP- Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
Reporting Laboratory Identifier	CLIA Unique Laboratory ID [FDA]	CLIA ID#	http://www.fda.gov/cdrh/clia/ http://www.cms.hhs.gov/CLIA/18_Laboratory_Registry.asp	None	Alpha-numeric	Example: 05D0571145
Performing laboratory	CLIA Unique Laboratory ID [FDA]	CLIA ID#	http://www.fda.gov/cdrh/clia/ http://www.cms.hhs.gov/CLIA/18_Laboratory_Registry.asp	None	Alpha-numeric	Example: 05D0571145
Report date/time	Hl7 defined	None	None	None	HL7 Timestamp (TS)	Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] Examples: 19700101 197001010000 19700101000000
Report status	HL7 V2.5	Result Status	http://tinyurl.com/mzyyl	This field contains the status of results for this order. This conditional field is required whenever the OBR is contained in a report message. It is not required as part of an initial order. There are two methods of sending status information. If the status is that of the entire order, use ORC-15-order effective date/time and ORC-5-order status. If the status pertains to the order detail segment, use OBR-25-result status and OBR-	ID (Coded Value)	A Some, but not all, results available C Correction to results F Final results; results stored and verified. Can only be changed with a corrected result. I No results available; specimen received, procedure incomplete O Order received; specimen not yet received P Preliminary: A verified early result is available, final results not yet obtained R Results stored; not yet verified S No results available; procedure scheduled, but not done X No results available; Order canceled. Y No order on record for this test.

LABORATORY/MICROBIOLOGY RESULTS						
AHIC Data Element	HITSP- Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
				22-results rpt/status chng - date/time. If both are present, the OBR values override the ORC values. This field would typically be used in a response to an order status query where the level of detail requested does not include the OBX segments. When the individual status of each result is necessary, OBX-11-observ result status may be used.		(Used only on queries) Z No record of this patient. (Used only on queries)
Collection date	None specified	None	None	None	HL7 Timestamp (TS)	Format: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]]]][+/-ZZZZ] Examples: 19700101 197001010000 19700101000000
Collection method	HL7 V2.5 SNOMED-CT	Specimen Collection Method	http://tinyurl.com/qyb7z http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html	Describes the procedure or process by which the specimen was collected. Any nationally recognized coding system might be used for this field including SNOMED; alternatively the HL7 defined table 0488 may be used. Veterinary medicine may choose the tables supported for the components of this field as decided by their industry.	CWE (coded with exceptions)	ANP Plates, Anaerobic BAP Plates, Blood Agar BCAE Blood Culture, Aerobic Bottle BCAN Blood Culture, Anaerobic Bottle BCPD Blood Culture, Pediatric Bottle BIO Biopsy CAP Capillary Specimen CATH Catheterized CVP Line, CVP EPLA Environmental, Plate ESWA Environmental, Swab FNA Aspiration, Fine Needle KOFFP Plate, Cough LNA Line, Arterial LNV Line, Venous MARTL Martin-Lewis Agar ML11 Mod. Martin-Lewis Agar MLP Plate, Martin-Lewis NYP Plate, New York City PACE Pace, Gen-Probe PIN Pinworm Prep PNA Aterial puncture

LABORATORY/MICROBIOLOGY RESULTS						
AHIC Data Element	HITSP- Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
						PRIME Pump Prime PUMP Pump Specimen QC5 Quality Control For Micro SCLP Scalp, Fetal Vein SCRAPS Scrapings SHA Shaving SWA Swab SWD Swab, Dacron tipped TMAN Transport Media, Anaerobic TMCH Transport Media, Chlamydia TMM4 Transport Media, M4 TMMY Transport Media, Mycoplasma TMOT Transport Media, TMP Plate, Thayer-Martin TMPV Transport Media, PVA TMSC Transport Media, Stool Culture TMUP Transport Media, Ureaplasma TMVI Transport Media, Viral VENIP Venipuncture WOOD Swab, Wooden Shaft
Specimen Source	SNOMED –CT	None Available	http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html	None	None	

Specimen	HL7 V2.5 Specimen Type Codes OR
	SNOMED-CT Specimen Codes
		Specimen Type	http://tinyurl.com/owx7w	This field describes the precise nature of the entity that will be the source material for the observation.
				
				Any physical entity that may have observations made about it may qualify as a specimen. The entry in this attribute describes the specific entity as precisely as possible, whether that is a complex organism (e.g., an ostrich) or a specific cellular mass (e.g., a specific muscle biopsy).
					CWE (coded with exceptions)	ABS Abscess
						PELVA Abscess, Pelvic
						PERIA Abscess, Perianal
						RECTA Abscess, Rectal
						SCROA Abscess, Scrotal
						SUBMA Abscess, Submandibular
						SUBMX Abscess, Submaxillary
						TSTES Abscess, Testicular
						AIRS Air Sample
						ALL Allograft
						AMP Amputation
						GASAN Antrum, Gastric

LABORATORY/MICROBIOLOGY RESULTS						
AHIC Data Element	HITSP- Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
				This attribute corresponds to the first component of OBR.15 – Specimen Source and SAC.6 – Specimen Source component 1 – Specimen source name or code. These components, and the SPS data type, were deprecated upon the development of this segment.		…
Ordered test code	LOINC code associated with test/procedure	None Available	http://www.regenstrief.org/loinc/ http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html	None	Code	None
Resulted test	LOINC Laboratory Test Identifiers	None Available	http://www.regenstrief.org/loinc/	None	Code	None
Result	SNOMED-CT,	None Available	http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html	None	Code, Numeric (hl7 TS), or Text	None
Method type	HL7 V3	Observation Method	http://www.hl7.org	A code that provides additional detail about the means or technique used to ascertain the observation.	HL7 Coded (CE)	Example: For Microbiology Sensitivity testing methods, MIC (Minimum Inhibitory Concentration) or KB for Kirby-Bauer (example provided by the Technical Committee)
Result unit	UCUM	None Available	http://aurora.regenstrief.org/UCUM	None	None	None
Test interpretation	HL7 V2.5	Abnormal Flags	http://tinyurl.com/k28v2	This field contains a table lookup indicating the normalcy status of the result. We strongly recommend sending this value when applicable. (See ASTM 1238 - review for more details). Refer to	IS (Coded value for user defined tables)	< Below absolute low-off instrument scale > Above absolute high-off instrument scale A Abnormal (applies to non-numeric results) AA Very abnormal (applies to

LABORATORY/MICROBIOLOGY RESULTS						
AHIC Data Element	HITSP- Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
				User-defined Table 0078 - Abnormal flags for valid entries. When the laboratory can discern the normal status of a textual report, such as chest X-ray reports or microbiologic culture, these should be reported as N when normal and A when abnormal. Multiple codes, e.g., abnormal and worse, would be separated by a repeat delimiter, e.g., A~W. User-defined Table 0078 - Abnormal flags		non-numeric units, analogous to panic limits for numeric units) B Better--use when direction not relevant D Significant change down H Above high normal HH Above upper panic limits I Intermediate. Indicates for microbiology susceptibilities only. L Below low normal LL Below lower panic limits MS Moderately susceptible. Indicates for microbiology susceptibilities only. N Normal (applies to non-numeric results) Null No range defined, or normal ranges don't apply R Resistant. Indicates for microbiology susceptibilities only. S Susceptible. Indicates for microbiology susceptibilities only. U Significant change up VS Very susceptible. Indicates for microbiology susceptibilities only. W Worse--use when direction not relevant
Test status	HL7 V2.5	Result Status	http://tinyurl.com/mzyyl	This field contains the status of results for this order. This conditional field is required whenever the OBR is contained in a report message. It is not required as part of an initial order. There are two methods of sending status information. If the status is that of the entire order, use ORC-15-order effective date/time and ORC-5-order status. If the status pertains to the order detail segment, use OBR-25-result status and OBR-22-results rpt/status chng - date/time. If both are present, the OBR values override the ORC values. This field would typically be used in a response to an order status query where the level of detail	ID (Coded Value)	A Some, but not all, results available C Correction to results F Final results; results stored and verified. Can only be changed with a corrected result. I No results available; specimen received, procedure incomplete O Order received; specimen not yet received P Preliminary: A verified early result is available, final results not yet obtained R Results stored; not yet verified S No results available; procedure scheduled, but not done X No results available; Order canceled. Y No order on record for this test. (Used only on queries) Z No record of this patient. (Used

LABORATORY/MICROBIOLOGY RESULTS						
AHIC Data Element	HITSP- Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
				requested does not include the OBX segments. When the individual status of each result is necessary, OBX-11-observ result status may be used.		only on queries)
Ordering Provider Identifier	HIPAA National Provider Identifier	National Provider Identifier	http://www.cms.hhs.gov/NationalProvIdentStand/	10-position all-numeric identification number assigned by the NPS to uniquely identify a healthcare provider.	Numeric	N10

6.3.8 RADIOLOGY RESULT DATA

Table 6.3.8-1 Radiology Result Data

RADIOLOGY RESULT DATA						
AHIC Data Element	HITSP- Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
Study ID/Radiology Number	None Available	None	None	None	String	None
Study date and time	None Available	None	http://www.hl7.org	None	HL7 Timestamp (TS)	Format: YYYY[MM[DD[HH[MM[SS[.S[S[S]]]]]]]][+/-ZZZZ] Examples: 19700101 197001010000 19700101000000
Report date/time	None Available	None	http://www.hl7.org	None	HL7 Timestamp (TS)	Format: YYYY[MM[DD[HH[MM[SS[.S[S[S]]]]]]]][+/-ZZZZ] Examples: 19700101 197001010000 19700101000000
Report Status	HL7 V2.5	Result Status	http://tinyurl.com/mzyyl	This field contains the status of results for this order. This conditional field is required whenever the OBR is contained in a report message. It is not required as part of an initial order.	ID (Coded Value)	A Some, but not all, results available C Correction to results F Final results; results stored and verified. Can only be changed with a

RADIOLOGY RESULT DATA						
AHIC Data Element	HITSP- Selected Standards	SDO Name	Link	SDO Definition	SDO Datatype	SDO Codes & Representations
				There are two methods of sending status information. If the status is that of the entire order, use ORC-15-order effective date/time and ORC-5-order status. If the status pertains to the order detail segment, use OBR-25-result status and OBR-22-results rpt/status chng - date/time. If both are present, the OBR values override the ORC values. This field would typically be used in a response to an order status query where the level of detail requested does not include the OBX segments. When the individual status of each result is necessary, OBX-11-observ result status may be used.		corrected result. I No results available; specimen received, procedure incomplete O Order received; specimen not yet received P Preliminary: A verified early result is available, final results not yet obtained R Results stored; not yet verified S No results available; procedure scheduled, but not done X No results available; Order canceled. Y No order on record for this test. (Used only on queries) Z No record of this patient. (Used only on queries)
Test Performed	AMA CPT+ Textual Description which can include modification					
Impressions	LOINC tag: '19005-8^X-RAY IMPRESSION^LN'	None Available	http://www.regenstrief.org/loinc/	None	String	None
Date / Time Revised	HL7	None Available	http://www.hl7.org	None	HL7 Time-stamp (TS)	Format: YYYY[MM[DD[HH[MM[SS[.S[S[S]]]]]]]][+/-ZZZZ] Examples: 19700101 197001010000 19700101000000

6.4 MANAGE DOCUMENT SHARING – BIOSURVEILLANCE GAP ANALYSIS

This Gap Analysis addresses considerations of using IHE-XDS to support the needs of Biosurveillance. The scope of this analysis is somewhat broader than the AHIC Use Case requirements in that it also addresses the unique considerations for using the resource for sample and results from non-human sources such as animals and environmental subjects (e.g. water samples). The HITSP Population Health

TC has adopted its constraints to Managed Shared Documents based upon this analysis, but in the context of the AHIC Data Steering Committee data dictionary requirements.

6.4.1 EXISTING ACTORS

6.4.1.1 DOCUMENT SOURCE

Main issues concern metadata. Actor itself seems to be re-usable. On and Off-line communication methods are enabled.

6.4.1.2 DOCUMENT CONSUMER

Main issues concern query function. Actor itself seems to be re-usable.

6.4.1.3 PATIENT IDENTITY SOURCE

Currently feeds the registry with XDS affinity domain level patient IDs. We need pseudonymized, identifiers. Additionally, non-patient centric data sources are needed for full biosurveillance functionality (laboratory microbial, water, air, soil, substance, animal data, etc.). In such cases as these, the “source” needs to be identified, but there really is not a need for cross-enterprise identity validation.

6.4.1.4 DOCUMENT REGISTRY

Suitable with additional metadata recommendations

6.4.1.5 DOCUMENT REPOSITORY

Suitable, and can be populated with existing document types: HITSP/C48 Encounter Document Using IHE Medical Summary (XDS-MS) Component, HITSP/C37 Lab Report Document Using IHE XD* Lab Component, and those described by HITSP/TP49 Sharing Radiology Results Transaction Package.

6.4.2 EXISTING TRANSACTIONS

6.4.2.1 PROVIDE AND REGISTER DOCUMENT SET

Main issues here concern the metadata.

6.4.2.2 REGISTER DOCUMENT SET

Main issues here concern the metadata.

6.4.2.3 QUERY REGISTRY

Most of the defined queries are patient-centric and require the patient ID. Many data source for biosurveillance may not come from patients. This requirement would have to be lifted for XDS-BSV queries, unless specifically searching for patient related information.

6.4.3 EXISTING METADATA

XDS metadata are inherently patient-centric and can potentially be difficult to adapt to biosurveillance Use Cases.

6.4.3.1 DOCUMENT ENTRY

- authorInstitution, authorPerson, authorRole, authorSpeciality – applicable attributes, though not essential. All have requirement level of R2, which is acceptable in the case of Biosurveillance
- availabilityStatus, classCode, confidentialityCode, creationTime, entryUUID - applicable attributes, and essential for functionality. All have requirement level of R, which is acceptable in the case of Biosurveillance
- eventCodeList – this list of codes aims to represent the main clinical acts documented. Possibly this could be “stretched” to cover reportable conditions, though it would be better to have reportable conditions as a separate attribute. It has a requirement level of O, which is acceptable in the case of Biosurveillance
- formatCode, hash - applicable attributes, and essential for functionality. All have requirement level of R, which is acceptable in the case of biosurveillance
- healthcareFacilityTypeCode and practiceSettingCode do not quite conceptually align with all possible data sources for biosurveillance data. They both have requirement level of R. This could potentially be a problem, unless we can expand the definition of these attributes
- languageCode, legalAuthenticator and mimeType - applicable attributes and their requirement levels suit biosurveillance Use Case R,O,R (respectively)
- parentDocumentId and parentDocumentRelationship – potentially applicable to boisurveillance, useful in the general sense for document management. Requirement level of R2 suits the biosurveillance Use Case
- patientId – this is a problem, since in many data sources for biosurveillance, patients may not be involved at all. If they are, the id should is pseudonymized. We need something like “sourceId” in this case as a substitute
- serviceStartTime and serviceStopTime do not have an intuitive context for all biosurveillance data sources. We’d need to expand/explain their definition when the data source is not from an EMR system
- size - applicable attribute, and essential for functionality. Has requirement level of R, which is acceptable in the case of biosurveillance
- sourcePatientId – same issues as with patientId
- sourcePatientInfo – XDS requires several sub-attributes here: source patient id list, patent name, patient gender, patient birthdate, patient address. When the biosurveillance data source does not pertain to a patient, most of these are useless. Other sub-attributes of the HL7 v2.5 PID Segment can come into play: Species Code, Breed Code, Strain, Production Class Code, County Code (assuming this is equivalent to UN – level 2 region identification). In the case of patients, XDS does not enforce many requirements on the sub-components for these sub attributes. Address could contain nothing more than a street name or a country. In this case, data from XDS would not be plotted on a map or useful for geographic simulation

- title, typeCode, uniqueId, URI – these are all ok

6.4.3.2 SUBMISSION SET

All attributes are ok, except the patientId, for reasons noted above. Also, if the document concerns data that is not particular to a patient, there may be more than one “source” (specimen/animal) to which the document pertains. Maintaining the patientId connectivity among the metadata types (document entry, submission set, folder) may not be useful in cases as these. We may need to define an equivalent centering concept for XDS-BSV to replace patientId, but where patientId can be used in its place (“dataSourceId”).

6.4.3.3 FOLDER

All attributes are ok, except the patientId, for reasons noted above, and codeList. Code list, like document entry event codes, are focused around clinical activities, which may not be relevant to particular sources of biosurveillance data. We’d need to expand the definition of codeList for XDS-BSV.

6.4.4 NEEDED ACTORS

6.4.4.1 PSEUDONYMIZATION SERVICE (OR ADAPT PIX/PDQ, SEE BELOW)

6.4.5 NEEDED TRANSACTIONS

6.4.5.1 PSEUDONYMIZATION

6.4.5.2 ADAPTED XDS/PIX/PDQ PROFILES

6.4.5.3 PROCESSING OF AUTHORIZATION AND PATIENT CONSENT

Processing of authorizations/Patient Consent: A legal policy – Public Health Reportable Condition, is an authorization to override patient consent which can be filed with registry/repository. Re-identification authorization – investigation + Biosurveillance Information System User,

6.4.6 NEEDED METADATA

6.4.6.1 REPORTABLE CONDITION(S) – DOCUMENT ENTRY

Need metadata that clearly identifies, for a particular document, the (or the set of) reportable condition(s) to which the document pertains. This value should be a coded value and should be required.

6.4.6.2 ‘PLOTTABLE’ GEOGRAPHIC INFORMATION – DOCUMENT ENTRY

Needed in order for data to be fed into geographic simulations, or for alerts and intervention. Need accurate locations.

6.4.6.3 SOURCE ID SUBSTITUTE FOR PATIENT ID

We may need to define an equivalent centering concept for XDS-BSV to replace patientId, but where patientId can be used in its place (“dataSourceId”).

6.4.7 DOCUMENT CONTENT PROFILES

- IHE-XDS-MS
- IHE-XDS-Lab (Micro-bacterial data)
- Animal/Veterinary data
- Environmental/Substance data (water, air, soil)

7.0 CHANGE HISTORY

7.1 MAY 11, 2007

This document is now Released for Implementation.

7.2 DECEMBER 5, 2007

The changes in this cycle address the following updates:

- Updates for adoption of OASIS HAVE specification
- Updates for use of HITSP/C36 – Lab Result Message for Acknowledgements (acknowledgements are part of the HL7 Lab IG which is used by HITSP/C36)

7.3 DECEMBER 13, 2007

Upon approval by the HITSP Panel on December 13, 2007, this document is now Released for Implementation.