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HITSP Interoperability Specification Biosurveillance

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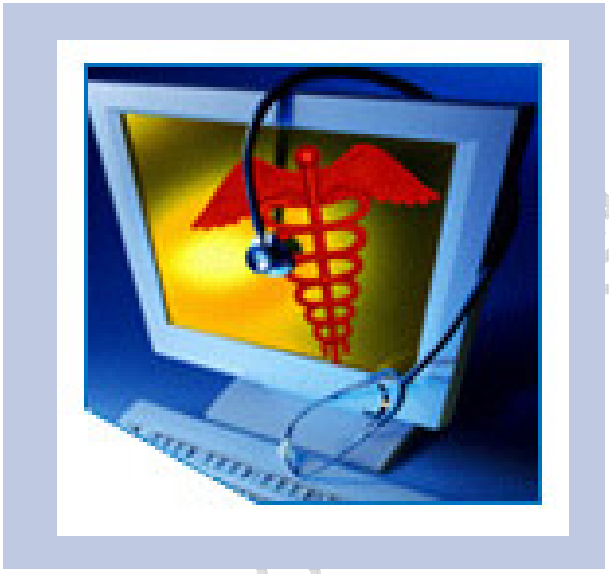

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DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
1.0	Final Draft	Biosurveillance Technical Committee	August 18, 2006

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1.0 FOREWORD

Healthcare Information Technology Standards Panel (HITSP) 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. HITSP functions as a partnership of the public and private sectors and operate 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 documents). 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 informatics to ensure that the resulting standards are globally relevant.

Be use-case driven, utilize information from stakeholders and base its decisions on industry needs.

The HITSP shall serve the public good by working to ensure that the combined work of various healthcare information standards organizations supports interoperability, accurate use, access, privacy and security of shared health information.

In order to advance the goal of expanding harmonized interoperability specifications and information policies, HITSP was tasked with developing interoperability specifications for three main use case “breakthroughs areas” in which specific, near term value to the health care consumer could be realized. The harmonized use case areas are:

1.	Biosurveillance	Transmit essential ambulatory care and emergency department visit, utilization, and lab result data from electronically enabled health care delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time.
2.	Consumer Empowerment	Allow consumers to establish and manage permissions access rights and informed consent for authorized and secure exchange, viewing, and querying of their linked patient registration summaries and medication histories between designated caregivers and other health professionals.
3.	Electronic Health Record	Allow ordering clinicians to electronically access laboratory results, and allow non-ordering authorized clinicians to electronically access historical and other laboratory results for clinical care.

The interoperability specification provides a detailed mapping of existing standards and specifications such as implementation guides and integration profiles to actions and actors that

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satisfy the requirements imposed by the relevant use cases. It identifies and constrains standards where necessary, and creates groupings of specific actions and actors to further describe the relevant contexts. Where gaps and overlaps are identified, the interoperability specification provides recommendations and a roadmap for corrections to be made.

2.0 INTRODUCTION

This document, the HITSP Biosurveillance Interoperability Specification (BIO IS), defines specific implementations of established standards. The BIO IS is intended to promote appropriate exchange of biosurveillance information to coordinate the optimal detection, event monitoring, and event management among health care providers, public health authorities, resource managers, and the public. This initial specification is scoped to populate the Biosurveillance Information System. The HITSP Biosurveillance Interoperability Specification identifies a subset of the functional components of the healthcare enterprises and health information networks, called HITSP actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions.

2.1 OVERVIEW

The Interoperability Specification focuses on a set of constrained standards for information interchange that address the core requirements of the Use Case described herein. It does not define all functions, constructs and standards necessary to implement a conforming system in a real world environment. 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.

This document refers to 2006 cycle of the HITSP Biosurveillance initiative. It is the basis for the testing of implementations performed.

Related Documents	Document Description	Document Name and Location
HITSP-ISTP-13	Manage Sharing of Documents Transaction Package	ISTP_HITSP_13_v1.0_2006 Manage Sharing of Dos 060810-A
HITSP-IST-22	Uniquely identify a Patient across enterprises	IST_HITSP_22_v0.B_2006 Patient ID Cross-Referencing and Patient Identity Feed Transactions 20060815
HITSP-IST-23	Patient Demographics Query (PDQ) Transaction	IST_HITSP_23_v1.0_2006 Patient Demographics Query Transaction 20060811 V0.A
HITSP-ISC-45	Acknowledgements Component	ISC_HITSP_45_v1.0_2006 Acknowledgements Component 20060728 V0.A
HITSP-ISC-29	Notification of Document Availability	ISC_HITSP_29_v1.0_2006 Notification of Document Availability

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Related Documents	Document Description	Document Name and Location
HITSP-ISC-25	Component Anonymize Data	ISC_HITSP_25_v0.1 Anonymize IP19b 081506
HITSP- IST-24	Pseudonymize Data	IST_HITSP_24_v0.1_2006 Pseudonymize 08152006
HITSP-ISC-37	Laboratory Report Document	ISC_HITSP_37_v1.0_2006 Lab Report Document
HITSP-ISC-36	Laboratory Result Message Component	ISC_HITSP_36_v1.0_2006_Sunday Lab Result Message
HITSP-ISC-35	Laboratory Result Terminology Component	ISC_HITSP_35_v1.0_2006 Lab Result Terminology
IHE/XDS-MS	Medical Summary Document	IHE Patient Care Coordination: Medical Summary Document
HITSP-ISC-39	Encounter Message	ISC_HITSP_39_v1.0_2006 ISC_HITSP_39_v1.0_2006_Ct-Encounter-Msgs
HITSP-ISC-41	Radiology Result Message	ISC_HITSP_41_v1.0_2006 Radiology Result Message
HITSP-ISC-47	Utilization Message	ISC_HITSP_47_v1.0_2006 ComponentSpecification_Draft Resource Avail_IP55a_8-4
IHE-RFD	Retrieve Form for Data Capture	IHE IT Infrastructure Technical Framework Supplement: Retrieve Form for Data Capture

2.2 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 interoperability set of specifications is a key requirement for establishing interoperability compliance.

2.3 TERMS AND DEFINITIONS

The definitions used for the purposes of this document can be found in the glossary. Refer to appendix 6.3 for the Common Terms and Definitions Document

2.4 CONVENTIONS

This specification uses the following to convey the full descriptions and usage of standards:

UML sequence and activity diagrams

In these diagrams, the actors and transactions are highlighted within the framework of the specific scenario or context. The actors involved in the specified use-scenario or context are mapped out, and the interactions between each action and actor for a particular context, and the flow of data are provided through the use of arrows. Diagrams are named according to the section in which they reside, and will use the following naming convention:

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Figure <section number>-<consecutive number for the diagram, e.g. 1, 2, 3, etc.>. <Short name/description of diagram>. For example, a diagram residing in section 3.1.3 showing the Actor Interactions for the Send Lab Results transaction package is named:
Figure 3.1.3-1. Send Lab Results Transaction Package

Tables

Tables are used to indicate standards categorizations, as well as dependencies and constraints between constructs. Tables are named according to the section in which they reside, and will use the following naming convention:
Table <section number>-<consecutive number for the table, e.g. 1, 2, 3, etc.>. <Short name/description of table>. For example, a table residing in section 2.7.1 showing the Dependencies between the transactions for the Send Lab Results transaction package is named:
Table 2.7.1-1. Send Lab Results Transaction Package dependencies

References

When references are made to another section within an Interoperability Specification a section number is used by itself. When references are made to other constructs that are related to the Interoperability Specification, such as Transaction Packages, Components or Composite Standards, the HITSP document short name and section number are displayed as follows:

<HITSP Document short name or Composite Standard Short Name>-<Volume Number>: <section number>

where:
<HITSP document short name> is a short designator for the construct (e.g. HITSP/ISTP-013)
<Composite Standard Short Name> is a short designator for the composite standard (e.g. IHE-ITI TF)
<Volume Number> is the applicable volume within the given composite standard (e.g. 1)
<section number> is the applicable section number (e.g. 3.1)

For example: HITSP/ISTP-013: 3.1 refers to Section 3.1 in the Interoperability Specification for a Transaction Package, IHE-ITI TF-2: 4.33 refers to Section 4.33 in volume 2 of the IHE IT Infrastructure Technical Framework.

Reproductions

Where large sections of composite standards or base standards are reproduced within a HITSP specification, the reproduced sections are cited with introductory text containing the reference information for the composite or base standard. In addition, the beginning and ending of the reproduced text are respectively shown using a beginning statement:

The text for the <composite or base standard name> specification begins here:

And an ending statement:

The text for the <composite or base standard name> ends here.

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2.5 COMMENTS

To submit comments for this interoperability specification, please download the Comment Submission sheet from the HITSP site at www.hitsp.org and provide all relevant information, and then email the completed document to hitspcomments@ansi.org. Comments are consolidated periodically and sent to the Technical Committees for review.

2.6 COPYRIGHT PERMISSIONS

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3.0 STANDARDS REFERENCES

It is HITSP's policy to only incorporate standards that have been approved according to the formal policy of the standards development organization that publishes the standard. HITSP interprets approval to include standards for trial use. The objective is to incorporate only standards that are managed within a formal life cycle process as defined by the SDO. In some cases, where we believe a not yet approved standard best meets the requirements of an Interoperability Specification, HITSP may provisionally select and conditionally use such standard subject to the following:

- The standard is approved by the time that the Interoperability Specification is released by HITSP.

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- The standard approved is substantially the same as it was when provisionally used.

If either condition is not met at the date of the HITSP Interoperability Specification release, HITSP may continue to use the "standard" as it was in its provisional state until such time as HITSP can replace it with a more suitable artifact. In this circumstance, the SDO would have no responsibility to maintain or correct this artifact.

The Biosurveillance Technical Committee (Bio TC) has focused its work on the Harmonized Biosurveillance Use Case provided by the American Health Information Community (AHIC). This work has also been informed by the proceedings of the AHIC Biosurveillance Workgroup Data Steering Committee (BDSC).

The Bio TC has selected standards first in accordance with HITSP Tier 1 and Tier 2 processes. 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. The results and the resource will be used in extension of this interoperability specification to additional domains and clinical data information exchange standards.

The Bio 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 Biosurveillance Data Steering Committee.

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3.1 LIST OF BASE STANDARDS

The following base standards are used to implement this interoperability specification:

Context Standards	
Standard	Description
HL7 ORU R01 v2.5	Notification of Unsolicited Observation Result
Information Interchange Standards	
Standard	Description
IETF RFC 2616	IETF RFC2616 HyperText Transfer Protocol HTTP/1.1
IETF RFC2616 HTTP/1.1	HyperText Transfer Protocol HTTP/1.1 ()
SQL ISO/IEC 9075	Database Language SQL
ISO 15000/1	Electronic business eXtensible Markup Language (ebXML) -- Part 1: Collaboration-protocol profile and agreement specification (ebCPP) (available in English only)
ISO 15000/2	Electronic business eXtensible Markup Language (ebXML) -- Part 2: Message service specification (ebMS) (available in English only)
ISO 15000/3	Electronic business eXtensible Markup Language (ebXML) -- Part 3: Registry information model specification (ebRIM)
ISO 15000/4	Electronic business eXtensible Markup Language (ebXML) -- Part 4: Registry services specification (ebRS) (available in English only)
SOAP 1.1	Web Services Security: Soap Message Security 1.1
W3C XML	Recommendation: Extensible Markup Language (XML) 1.0
RFC-822	Standard for the format of ARPA Internet Text Messages
RFC-1521	Multi-purpose internet mail extensions
RFC-1738	Uniform Resource Locators
RFC-2368	Mailto URL Scheme
RFC-2821	Simple Mail Transfer Protocol
RFC-3001	A URN Namespace of Object Identifiers, 2000, IETF
RFC-3629	UTF-8, a transformation format of ISO 10646
ANSI X9.30 Part 2:	Public Key Cryptography for the Financial Services Industry - Part 2: The Secure Hash Algorithm (SHA-1)
IETF RFC 3066	Tags for the Identification of Languages
RFC-2821	Simple Mail Transfer Protocol
W3C XML 1.0	Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October 2000
W3C WSDL 1.1	Web Services Description Language (WSDL) 1.1. W3C Note 15 March 2001
W3C XForms 1.0	XForms 1.0 (Second Edition)
WS	Web Services
Health Level Seven (HL7) version 2.5	ANSI approved standard for information interchange
HL7 CDA	Clinical Document Architecture
Terminology Standards	
Standard	Description
IETF RFC 1738	IETF RFC1738, Uniform Resource Locators (URL), December 1994
Logical Observation Identifiers Names and Codes (LOINC®)	A database of Universal identifiers for laboratory and other clinical observations maintained by Regenstrief Institute. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), toxicology; etc. Contact the Regenstrief Institute

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	at e-mail: loinc@regenstrief.org or visit www.regenstrief..org/loinc for more information.
Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT®)	A validated clinical health care terminology and infrastructure that makes health care knowledge more usable and accessible. The SNOMED CT Core terminology provides a common language that enables a consistent way of capturing, sharing and aggregating health data across specialties and sites of care. Among the applications for SNOMED CT are electronic medical records, ICU monitoring, clinical decision support, medical research studies, clinical trials, computerized physician order entry, disease surveillance, image indexing and consumer health information services. Maintained by the College of American Pathologists (CAP), information is available at www.snomed.org/snomedct/index.html.
CPT® (Current Procedural Terminology)	A numeric coding system maintained by the American Medical Association (AMA). The CPT is a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. These health care professionals use the CPT to identify services and procedures for which they bill public or private health insurance programs. Visit www.ama-assn.org/ama/pub/category/3113.html for more information.
HL7 V2.5	The HL7 Version 2 Messaging Standard is an application protocol for electronic data exchange in healthcare that is maintained by HL7, an (ANSI) -accredited Standards Developing Organizations (SDOs) operating in the healthcare arena. In support of the HL7 messaging standard, HL7 also publishes value sets or code tables for use with specified fields in an HL7 message. Visit www.hl7.org for more information
HL7 V3.0	HL7 Version 3 represents a significant departure from "business as usual" for HL7. It uses an object-oriented development methodology and a Reference Information Model (RIM) to create messages. The RIM is an essential part of the HL7 Version 3 development methodology, as it provides an explicit representation of the semantic and lexical connections that exist between the information carried in the fields of HL7 messages. The HL7 Vocabulary TC and the domain TCs maintain a vocabulary for use with Version 3 messages. Visit www.hl7.org for more information.
LOINC	Logical Object Identifiers Names and Codes - Clinical Labs
UCUM	Unified Codes for Units of Measure
HAVE terminology	Description: HAVE specification contains terminology that is specific to utilization information and allows the communication of the status of a hospital and its resources to other emergency agencies, including bed capacity and availability, emergency department status, the available service coverage, and the status of a hospital's facility and operations. Reasoning: The Bio TC has identified the Hospital Availability Exchange (HAVE) dataset as being closely aligned with the data elements identified by the Biosurveillance Data Steering Committee. The HAVE specification is being proposed as an Organization for the Advancement of Structure Information Standards (OASIS) standard, but has not yet

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	been fully reviewed and adopted. HAVE was derived from the results of the HAVBed project sponsored by the Agency for Health Resources and Quality. While it is anticipated that the HAVE specification will soon be approved by Oasis, and is likely to meet the requirements for reporting the data elements for hospitals and health resource availability identified by the BDSC, pending this formal approval the choice of a specific standard to represent these data elements remains a gap as defined in the HITSP policies.
HAVE Messaging Specification	Description: HAVE specification is an XML document that is is specific to utilization information and allows the communication of the status of a hospital and its resources to other emergency agencies, including bed capacity and availability, emergency department status, the available service coverage, and the status of a hospital's facility and operations. Reasoning: The Bio TC has identified the Hospital Availability Exchange (HAVE) dataset as being closely aligned with the data elements identified by the Biosurveillance Data Steering Committee. The HAVE specification is being proposed as an Organization for the Advancement of Structure Information Standards (OASIS) standard, but has not yet been fully reviewed and adopted. HAVE was derived from the results of the HAVBed project sponsored by the Agency for Health Resources and Quality. While it is anticipated that the HAVE specification will soon be approved by Oasis, and is likely to meet the requirements for reporting the data elements for hospitals and health resource availability identified by the BDSC, pending this formal approval the choice of a specific standard to represent these data elements remains a gap as defined in the HITSP policies.
EDXL DE	Description: This Distribution Element DE specification describes a standard message distribution framework for data sharing among emergency information systems using the XML-based Emergency Data Exchange Language (EDXL). This format may be used over any data transmission system, including but not limited to the SOAP HTTP binding. The EDXL-DE was ratified as an Oasis standard in June, 2006. Reasoning: The Emergency Data Exchange Language (EDXL) is a suite of specific XML based standards intended as a suite of emergency data message types including resource queries and requests, situation status, message routing instructions and the like, needed in the context of cross-disciplinary, cross-jurisdictional communications related to emergency response. It is the result of a project of the Disaster Management eGov Initiative of the Department of Homeland Security (DHS) as a means to enhance XML based inter-agency emergency data communications. DHS partnered with industry members of the Emergency Interoperability Consortium (EIC) to bring the work to OASIS for advancement and standardization. Reference: http://www.oasis-open.org/committees/download.php/17227/EDXL-DE_Spec_v1.0.html
HL7 v2.5 ORU	Description: The HL7 version 2.5 Observation Result Unsolicited (HL7 ORU) message constrained to transmit the Resource Utilization Information.

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	Reasoning: HL7 has a wide range of healthcare information interchange standards but has no standards specific to conveying healthcare utilization information. Hospital utilization information can be conveyed in an HL7 Observation Result message as general observations. In the HL7 ORU message each hospital utilization statistic becomes an observation. The HL7 ORU message has been implemented in existing biosurveillance systems. This approach accommodates the large installed base of health information technology systems that rely on HL7 messaging methods. Reference: See ANSI/HL7 V2.5-2003, Chapter 7, dated 06/26/2003
HL-7 2.5	HL0001
FIPS 5-2	Federal Information Processing System Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States and Associated Areas
ICD-9/10 CM	Diagnoses and Procedures
HL-7 2.5	HL0052
HL-7 2.5	Timestamp
UB-92	Universal Billing codes
HL-7 2.5	HL0004
CCC	Clinical Care Classification
CPT	Current Procedural Terminology
HL-7 2.5	HL70123
HL-7 2.5	HL70488
HL-7 2.5	HL70078
HL-7 2.5	HL70085
HCPCS	Healthcare Common Procedure Coding System
NCCLS	National Committee for Clinical Laboratory Standards
RxNorm	National Library of Medicine RxNorm
Security Standards	
Standard	Description
ISO/DTS 25237	Health Informatics – Pseudonymisation
DICOM Supplement 55	Attribute Level Confidentiality (including De-identification)
Identifier Standards	
Standard	Description
CLIA	Clinical Laboratory Improvement Amendments
Functionality and Process/Process and Workflow Standards	
Standard	Description
NTP	Network Time Protocol Version 3. RFC1305
SNTP	Simple Network Time Protocol (SNTP) RFC2030
Legislative Standards	
Standard	Description
HIPAA	Reference: NIH Publication Number 003-5388. 'Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule.'
Other Standards	
Standard	Description

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3.2 LIST OF COMPOSITE STANDARDS

The following composite standards are referenced by this Interoperability Specification.

Composite Standard	Description	Relationships
IHE XDS	Cross-Enterprise Document Sharing	ISO 15000/ebRIM OASIS/ebXML Registry Information Model v2.0, 3.0 ISO 15000/ebRS OASIS/ebXML Registry Services Specifications v2.0, 3.0 ISO 15000/3 ISO 15000/4 SQL ISO/IEC 9075 Database Language SQL SOAP 1.1 HTTP HyperText Transfer Protocol HTTP/1.1 (IETF RFC2616) SHA-1 (FIPS 180-1) IETF Language Identifiers UTF-8
IHE XDS-LAB	Laboratory Report Document	This in an implementation profile that references: HL7 CDA2, LOINC, and SNOMED-CT
IHE-ITI-RFD	Retrieve Form for Data Capture	IETF RFC 2616 IETF RFC2616 HyperText Transfer Protocol HTTP/1.1 W3C XML 1.0 Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October 2000 W3C WSDL 1.1 Web Services Description Language (WSDL) 1.1. W3C Note 15 March 2001 W3C XForms 1.0 (Second Edition)
IHE-PIX	Patient Identification Cross-Referencing	This is an implementation profile referencing the following standards: HL7 V2.5 Patient Mgt HL7 V3.0 Person Management and Patient Registry HL7/OMG Entity Identifier Service (EIS) HL7 V2.5 Patient Mgt & HL7 V3.0 Person Management OMG Patient Identification Services (PIDS)

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Composite Standard	Description	Relationships
IHE-PDQ	Patient Demographics Query	This is an implementation profile referencing the following standards: HL7 V2.5 Patient Mgt HL7 V3.0 Person Management and Patient Registry HL7/OMG Entity Identifier Service (EIS) HL7 V2.5 Patient Mgt & HL7 V3.0 Person Management OMG Patient Identification Services (PIDS)
IHE-RAD-XDS-I	Cross-Enterprise Sharing of Imaging	This is an implementation profile that references DICOM 2003 PS3.4 Query/Retrieve Service Class, DICOM 2003 PS 3.4: Storage SOP Class , DICOM 2003 PS 3.16: Content Mapping Resource
IHE-XDS-MS	Medical Summary Document	Implementation guide based on OASIS ebRS - ebRIM 2.0/3.0 (ISO 15000-3&4) and CDA-2

3.3 BASE 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 Bio 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.

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USE CASE EVENTS AND ASSOCIATED GAPS TABLE

Event Code	Event Description	Identified Gaps	Recommended Resolution
1.1.1.0	Filter existing data to identify data required by public health agencies	1. LAB *Terminology –* • Orders/Results (Test Batteries) • Possible Gap: indication /presumptive diagnosis/ reason for test - NOT a gap for current data dictionary, gap for domain 2. LAB, VISIT, UTILIZATION *Functionality/ workflow/ process* - Filtering process	1. Work with LOINC and SNOMED to achieve the appropriate level of granularity link test orders to test results. 1. 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) 2. Approach HL7 and OASIS IHC to coordinate standards development efforts for formalizing rule specification for consistent screening of cohort selection 2. 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 Pseudonymnization standard – Refer to AHIC Security/Privacy group.
1.2.2.0	Anonymize data required by public health agencies		

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1.1.3.0	Format data required by public health agencies	1. LAB *Terminology* - need for • 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 2. VISIT *2.a 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 biosurveilance data set.
1.2.3.0	Format data required by public health agencies		
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	Work with AHIC to define dataflow between clinical care and local, state and federal public health agencies for biosurveillance

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1.2.4.0	Identify Public Health Agencies that must be notified	federal public health agencies for biosurveillance	
1.1.5.0	Transmit relevant data to public health agencies	Additional security standards refinement and profiling are needed.	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	LAB, VISIT, UTILIZATION Need to define biosurveillance data set	
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

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STANDARDS OVERLAPS TABLE:

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	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	1. Work with HL7 to assess recommendations for bed/resource availability: o address at the next meeting of HL7 o name a liaison to carry the issue o compare to OASIS HAVE 2. HL7 Order Result is recommended for human results interpretation, whereas DICOM is recommended for machine - generated results 3. Review and assess relevant work to express o Specimen Site and o Presumptive DX 4. Work with SDOs to harmonize standards (e.g. define mapping translations from one message-type to the other 5. Identify the appropriate information model 6. Review best practices in lab 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	7. 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	8. Recommend review and harmonization of ASTM E1985 with ANSI/INCITS 359

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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			

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RESOLUTION PLAN

Date	Task to be Accomplished/Who is involved
Filter data Required by Public Health Authorities	
2005/2006	Monitor / contribute/ review IHE Retrieve Form for Data Capture (RFD) to assure biosurveillance needs are 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 BIO TC contribution and clinical use cases. Work product adopted as part of this specification. Recommend to work with continuing efforts in the next cycle 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
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 Bio 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	

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Date	Task to be Accomplished/Who is involved
2005/2006	Liaisons from the Biosurveillance 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	This approach has been incorporated into this interoperability specification.
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.
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 Biosurveillance TC. These two groups worked in parallel to comply with early data dictionary requirements in the current implementation specification. The HITSP Biosurveillance 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 next cycle.
2006/2007+	The HITSP Biosurveillance 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 Biosurveillance 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 Biosurveillance 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 is currently in freeform text or standardized, machine-readable format.'

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Date	Task to be Accomplished/Who is involved
2006/2007+	The HITSP BIO 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 cycle of interoperability specification development to embrace these standards as they are developed. The usefulness of 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 cycle of the 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.
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	
2006/2006	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	

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Date	Task to be Accomplished/Who is involved
2005/2006	The HITSP Biosurveillance 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 is often recorded in an unstructured, freeform text format. In order to maximize the value of freeform text data for use in biosurvellance systems, translation into standardized, machine-readable codes is necessary. As a near-term incremental proposal, the HITSP Biosurveillance TC recommends that the edge systems (sending or receiving) 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 is 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 is 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 BIO 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 BIO 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.
2006/2007+	The HITSP Biosurveillance 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 cycle of interoperability specification development to embrace these standards as they are developed.
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 Our assumption is that there is more than 1 recipient of biosurveillance data. 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 health care process in biosurveillance and for other secondary use and semantic interoperability efforts.
Radiology/Lab Order Message	

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Date	Task to be Accomplished/Who is involved
2005/2006	The HITSP Biosurveillance 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 deprecated 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 Biosurveillance 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
Lab 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
	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
	Organism identified :This remains an overlap for which HITSP issues a recommendation to create a harmonized finer granularity to NCCLS (has some of the needed granularity) and SNOMED-CT so that SNOMED-CT + NCCLS would suffice for granularity expression. A specific area where granularity is needed is the addition of local codes for newly identified organisms that are not yet assigned codes
	Standards evaluation Process

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Date	Task to be Accomplished/Who is involved
2005/2006	The Biosurveillance 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

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4.0 INTEROPERABILITY REQUIREMENTS

4.1 USE CASE OVERVIEW

Biosurveillance is an American Health Information Community breakthrough area defined as implementation of real-time, nationwide public health event monitoring to support early detection, situational awareness, and rapid response management across public health, care delivery, 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 use case addressed in this document is for transmission of essential data from ambulatory care and emergency department visits, utilization, and lab result data from electronically enabled healthcare delivery and public health systems in a standardized and anonymized form, to authorized Public Health Agencies with less than one day lag time. The system and processes must enable authorized public health personnel to go to the data source to re-link anonymized biosurveillance data to the data source in an appropriate public health investigation.

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 network such as a multi-faculty system or supporting organization that uses data to provide 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 others. It is anticipated that Nationwide Health Information Network efforts will develop supporting approaches and infrastructure that may offer other solutions as well.

Clinical Exemplar Scenarios:

To maintain context and perspective, the Biosurveillance Technical Committee (BIO TC) approached the creation of an interoperability specification using clinical exemplar scenarios. These exemplars were consistent with the 15 National Planning Scenarios created by the US 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.

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

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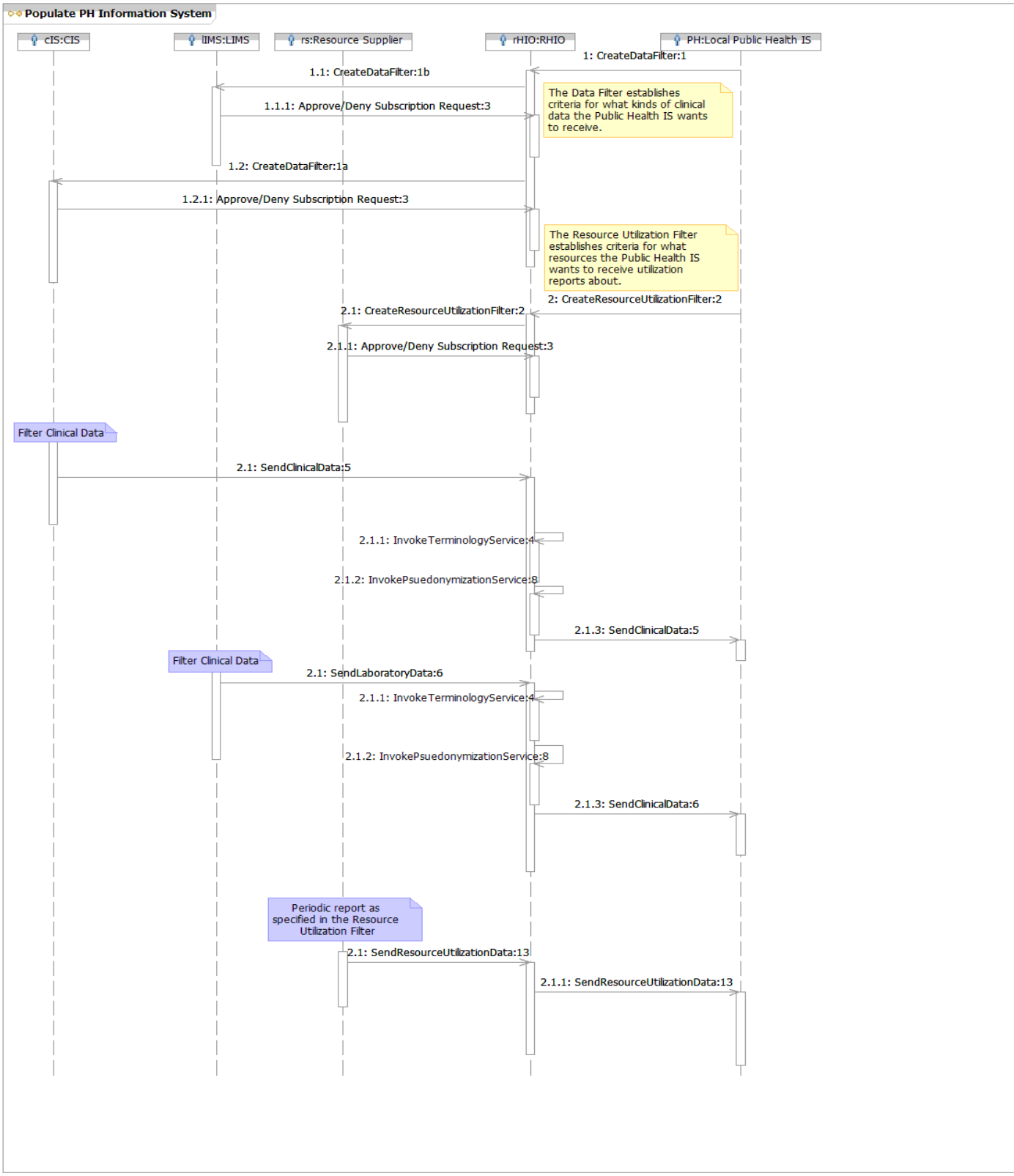
Populate PH Information System
cIS:CIS
lIMS:LIMS
rs:Resource Supplier
rHIO:RHIO
PH:Local Public Health IS
1: CreateDataFilter:1
1.1: CreateDataFilter:1b
1.1.1: Approve/Deny Subscription Request:3
The Data Filter establishes criteria for what kinds of clinical data the Public Health IS wants to receive.
1.2: CreateDataFilter:1a
1.2.1: Approve/Deny Subscription Request:3
The Resource Utilization Filter establishes criteria for what resources the Public Health IS wants to receive utilization reports about.
2: CreateResourceUtilizationFilter:2
2.1: CreateResourceUtilizationFilter:2
2.1.1: Approve/Deny Subscription Request:3
Filter Clinical Data
2.1: SendClinicalData:5
2.1.1: InvokeTerminologyService:4
2.1.2: InvokePsuedonymizationService:8
2.1.3: SendClinicalData:5
Filter Clinical Data
2.1: SendLaboratoryData:6
2.1.1: InvokeTerminologyService:4
2.1.2: InvokePsuedonymizationService:8
2.1.3: SendClinicalData:6
Periodic report as specified in the Resource Utilization Filter
2.1: SendResourceUtilizationData:13
2.1.1: SendResourceUtilizationData:13

Figure 1

The BIO 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.

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 ability to comply with those formats. As such, the requirements are somewhat less prescriptive than those that are associated with clinical systems integration.

The BIO 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 BIO TC has defined three separate functional flow scenarios. The BIO 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:

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, and authorized interested parties to identify and manage public health threats.

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 public health authority 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.

Resource Management Data Transfer (Document-based and Message-based) (HITSP- RM) – a mechanism to automate the communication of resource availability from a resource provider to a resource management information service. This is intended to communicate this data in near-real-time and within 24 hours to Biosurveillance Information Systems (BIS) to identify and manage public health threats.

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

The first 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:

- It leverages an approach that is also utilized for clinical document sharing servicing patient care, and as such, will facilitate the capture of biosurveillance data from source systems.
- By using a shared document resource, access to regional information can be offered to neighboring regions and other public health authorities with a need to extend investigative and monitoring actions beyond its own region.
- Since many local public health departments have limited computing resources, this offers a means by which these stakeholders can leverage the biosurveillance resource with minimal additional investment.
- By providing a resource that maintains persistent, human readable documents, strong support for case investigation can be offered.

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.

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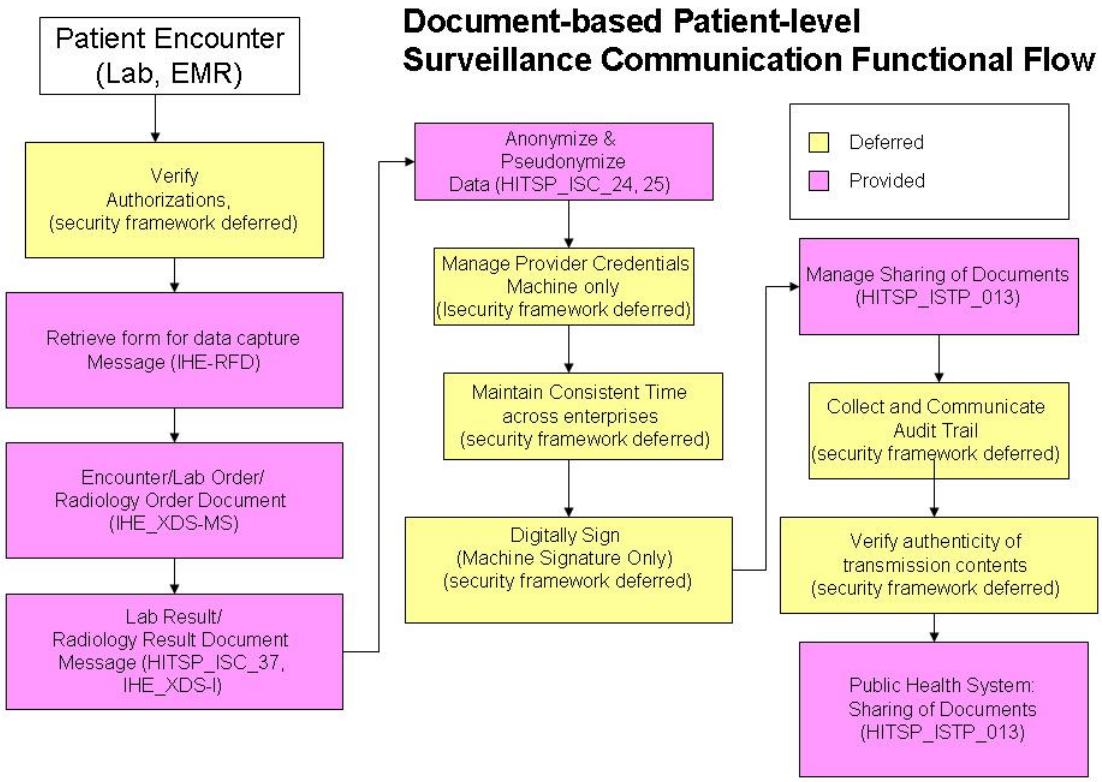
Document-based Patient-level Surveillance Data Sharing (Biosurveillance Documents)

Functional Flow Scenario diagram:



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 public health authority. 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 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. 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

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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 Lab Report Document specification (See *ISC_HITSP_37_v1.0_2006 Lab Report Document)*.

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 public health authority.

The preconditions 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-XDS-MS, 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 public health authority. 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 preconditions 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 XDS-I without further constraint. Therefore, no additional HITSP component specification is provided in support of this scenario option.

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4.1.1.1 SCENARIO CONSTRAINTS

The Scenario is constrained to the following:

- AHIC Data Steering Committee Data set: See Appendix 6.4
- AHIC Biosurveillance Use Case
- Document constraints: Laboratory Report Document, IHE-XDS-I, XDS-MS
- Vocabulary Constraints: See Appendix 6.5

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 differs 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. Two key communication options are available to the BIS using this shared document resource option:

1. Notification/retrieve (See *ISC_HITSP_29_v1.0_2006 Notification of Document Availability*):

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 highly limited, but this is an area for expansion opportunities to incorporate more semantically sophisticated notifications. While IHE-NAV 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 public health authority can subscribe to data of interest. The HITSP BIO TC recommends that IHE review and identify a mechanism to enhance this profile to include publish and subscribe options in support to public health

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2. Query Option (See HITSP-ISTP-013: Manage Shared 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 Biosurveilance documents to Query Neighboring Jurisdiction for Event Detection, Monitor a Suspected Event, or for Case Management purposes.

In many cases, the public health authority 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 4.1-1 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 assumes that the healthcare provider information systems are able to translate local codes into standard terminology.

4.1.1.2 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 insure 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

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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 preconditions 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.

4.1.1.3 SCENARIO TRIGGERS

None

4.1.1.4 SCENARIO POST-CONDITIONS

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

4.1.1.5 SCENARIO OUTPUTS

None

4.1.1.6 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 and radiology service 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 Health Care Facilities or Integrated Health Care 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 Health Care Facilities or Integrated Health Care 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.

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Actor	Description
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.

4.1.1.7 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 identification (IHE-PIX & IHE-PDQ), security and privacy (IHE-CT, IHE-ATNA, IHE-XUA), and notification of availability of documents (NAV). (See the IHE IT Infrastructure Interoperability Specification, http://www.ihe.net/Technical_Framework/). These profiles have been further constrained by HITSP common component 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.

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.

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Actor	Description
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 Demographics Supplier	A repository of patient information that can be searched on demographic or visit-related fields.
Patient Demographics Consumer	This actor allows a user to associate information with a patient at the point of care.
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 a unique form identification.
Document Vault	Repository of permanent source records of clinical trials.

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4.1.1.8 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:

1. Notification/retrieve
2. Query Option

The functional workflow for information retrieval is listed in Figure 4.1-1.

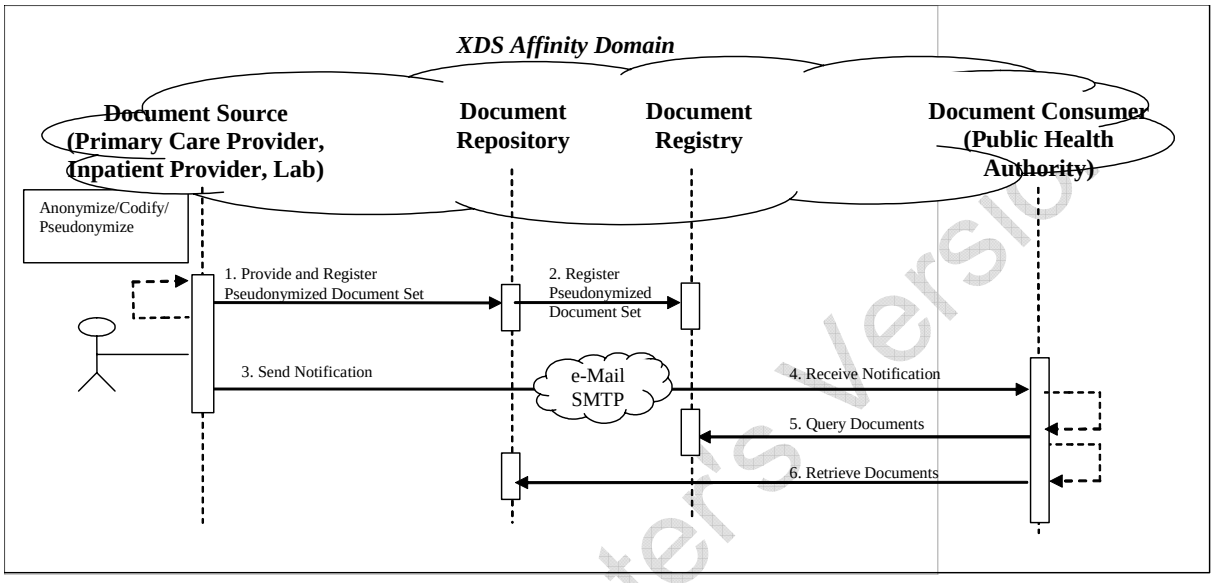

Figure 4.1-1 Message-based Patient Scenario Process Flow Diagram

These steps are:

1. Extract/capture a collection of records into a set of documents packaged as an IHE-XDS Submission Set. This submission contains a Biosurveillance Report, 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 is anonymized and pseudonymized and structured as a document of the options described (Laboratory Report, Encounter Summary, and Radiology Report) and constrained as described by this interoperability specification.
2. This step uses the transactions provided by the IHE-ITI XDS profile to place the records in an IHE-XDS Repository (local or shared).
3. The Repository ensures that the documents of the submission set are registered with the IHE-XDS Registry of the Affinity Domain (set of cooperating care delivery institutions).
4. Notify the public health authority that documents are now available for review or download. This step utilizes the transactions provided by the IHE-ITI NAV profile to perform the e-mail notification.
5. The e-mail notification that contains no patient identified information is received by the public health authority BIS system.

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6. The receiving public health authority can then utilize existing query transactions from the IHE-XDS profile to find the URL of the Documents.

Finally, the receiving public health authority may choose to import relevant information from these records into their own BIS system.

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

The second 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 public health authority 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 designated recipients. 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.

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:

1. Laboratory Orders
2. Laboratory Results including preliminary, interim, and final results
3. Encounter messages from Electronic Medical Records Systems
4. Radiology Orders
5. 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

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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 deprecated 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.

Message-Based Patient-level Surveillance Data Communication (HITSP-MS), Functional Flow Scenario:

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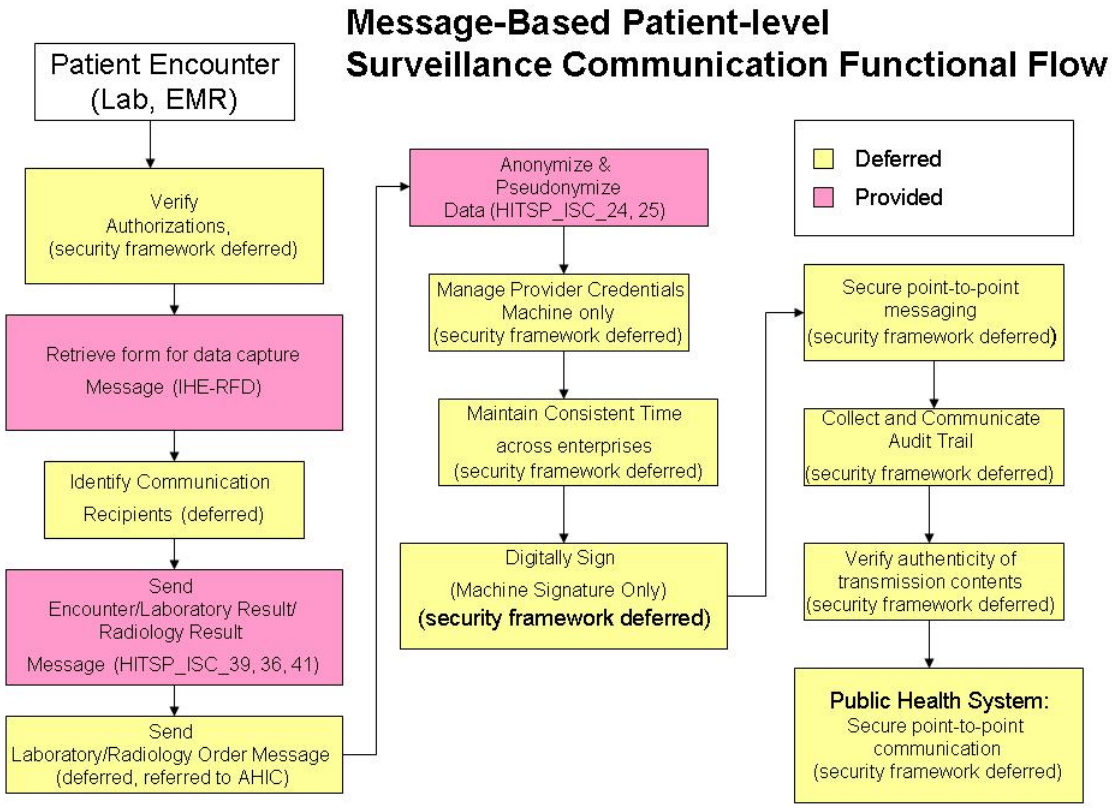

Figure 4.1-2 Functional Flow Diagram

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Scenario Option 1: Laboratory Order Message

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

The preconditions 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 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 orders defined to be of interest to the public health authorities for biosurveillance purposes. An assumption is made that the health care 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 *ISC_HITSP_36_v1.0_2006_sunday Lab Result Message*).

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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 preconditions 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 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 *ISC_HITSP_39_v1.0_2006_Ct-Encounter-Msgs*).

Scenario Option 4: Radiology Order Message

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

The preconditions 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 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 radiology orders defined to be of interest to the public health authorities for biosurveillance purposes. An assumption is made that the health care 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 Results Messages

This scenario option involves generation of Radiology Result messages.

The preconditions 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

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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 radiology results defined to be of interest to the public health authorities for biosurveillance purposes. An assumption is made that the radiology system with 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 *ISC_HITSP_41_v1.0_2006 Radiology Result Message).*

4.1.2.1 SCENARIO CONSTRAINTS

The Scenario is constrained to the following:

- AHIC Data Steering Committee Data set: See Appendix 6.4
- AHIC Biosurveillance Use Case
- Document constraints: Laboratory Report Document, IHE-XDS-I, XDS-MS
- Vocabulary Constraints: See Appendix 6.5

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 assumes 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 insure that the implementing systems operate within a secure infrastructure that insures the privacy, integrity and availability of

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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 preconditions for this scenario include:

For the current HITSP 2006 cycle, the acknowledgements are limited to those provided by the IHE ITI Infrastructure used to implement this functional flow scenario (see gap analysis in section 3.3 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:

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.

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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 and radiology service 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 Health Care Facilities or Integrated Health Care 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 Health Care Facilities or Integrated Health Care 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 and manage these threats once manifested. Staff of these agencies interacts with the BIS to verify and validate system indications of public health threats, and to assert acknowledgements that may be required by system processes.

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.

Some IHE Integration Profiles are leveraged for supporting services as well. These include patient identification (PIX & PDQ), and Consistent Time (CT). (See the IHE IT Infrastructure Interoperability Specification, http://www.ihe.net/Technical_Framework/). These 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.

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Actor	Description
Bio Message Sender	Clinical Information System sending biosurveillance message
Bio Message Receiver	BIS receiving the Biosurveillance message
Patient Demographics Supplier	A repository of patient information that can be searched on demographic or visit-related fields.
Patient Demographics Consumer	This actor allows a user to associate information with a patient at the point of care.
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.
Document Vault	Repository of permanent source records of clinical trials.

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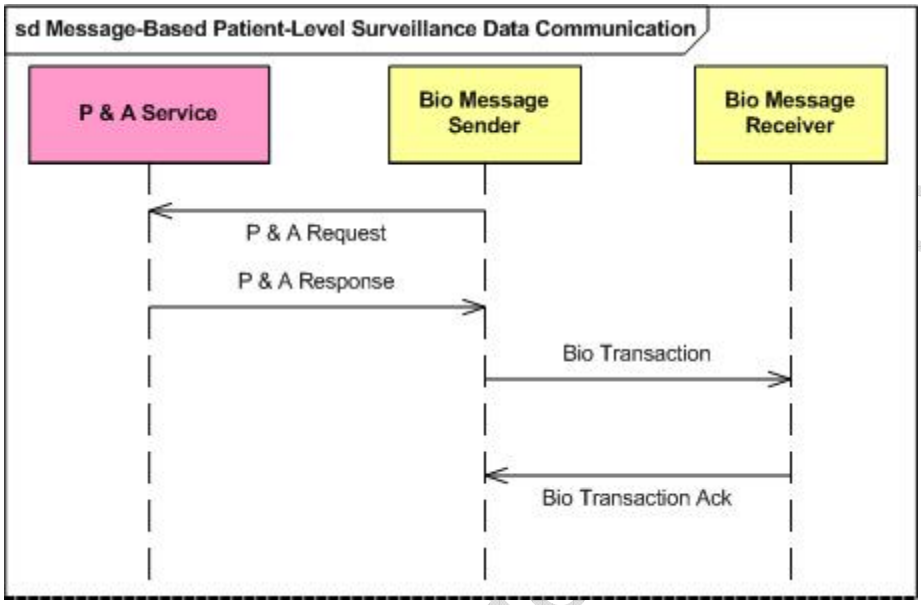
4.1.2.8 SCENARIO ACTOR INTERACTIONS



800 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 4.1.2 of this document.

For the current HITSP 2006 cycle, the acknowledgement is limited to traditional HL7 ACK messages (see gap analysis in section 3.3 above for discussion regarding Biosurveillance use-
805 case-specific acknowledgment requirements).

4.1.3 RESOURCE MANAGEMENT DATA TRANSFER (DOCUMENT-BASED AND MESSAGE-BASED) (HITSP- RM) 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.
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The Health Information Technology Standards Panel (HITSP) Biosurveillance Technical Committee (Bio TC) 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
815 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 Committee (BDSC) which in turn reports to the Biosurveillance Work Group of the AHIC.

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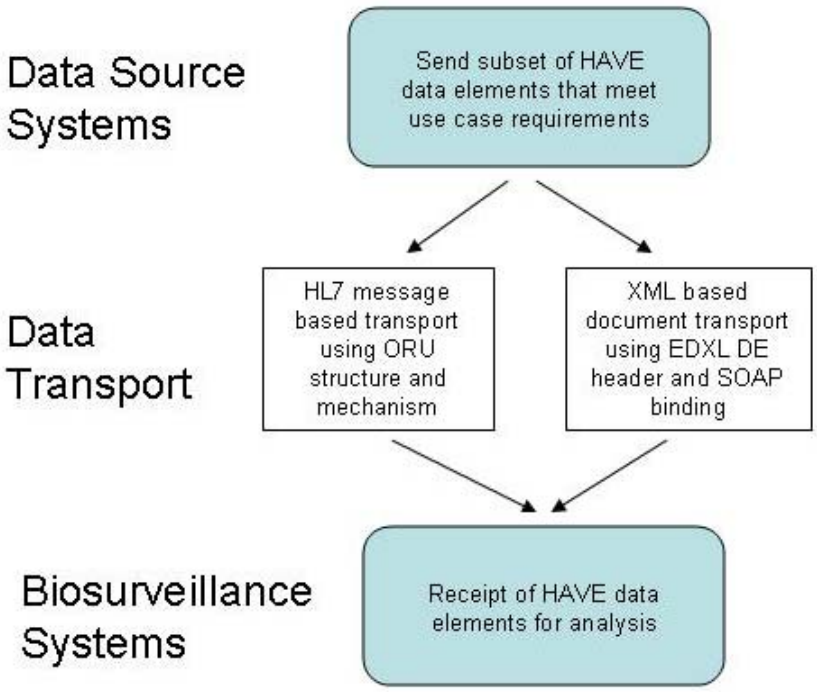

With regard to the messaging approach to support the exchange of hospital and health resource availability information, the Bio TC recommends that either of two acceptable specifications be utilized. The two specifications are the Emergency Data Exchange Language Distribution Element (EDXL-DE) version 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.

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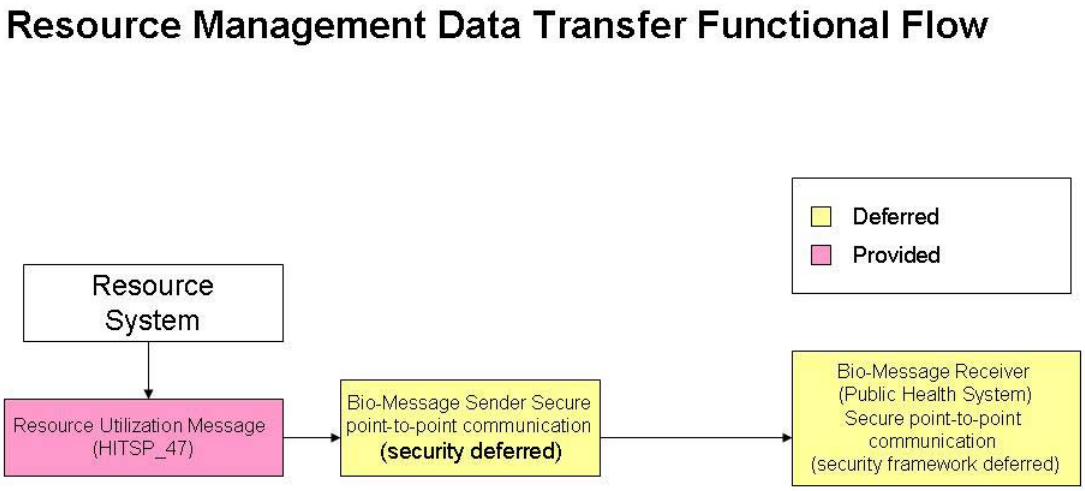
Figure 4.1.3-a Process flow for Bed Availability Monitoring



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 preconditions assume the existence of the secure transport mechanisms, and that the bed availability data is 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 health care 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 component specification (See *ISC_HITSP_47_v1.0_2006 ComponentSpecification_Draft Resource Avail_IP55a_8-4).*

Scenario Option 2: Bed Availability Message

This scenario option involves generation of bed availability messages from inpatient healthcare provider administrative systems.

The preconditions assume the existence of the secure transport mechanisms, and that the bed availability data is available to the system generating the resource availability data. This option

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defines the content of the message to be delivered over that transport to communicate bed availability documents defined. An assumption is made that the health care 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 component specification (See *ISC_HITSP_47_v1.0_2006 ComponentSpecification_Draft Resource Avail_IP55a_8-4).*

4.1.3.1 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 3.3 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.

4.1.3.2 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 insure that the implementing systems operate within a secure infrastructure that insures the privacy, integrity and availability of

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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 preconditions 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.

4.1.3.3 SCENARIO TRIGGERS

None

4.1.3.4 SCENARIO POST-CONDITIONS

The Biosurveillance Information System has received the submitted data.

4.1.3.5 SCENARIO OUTPUTS

None

4.1.3.6 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.
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.

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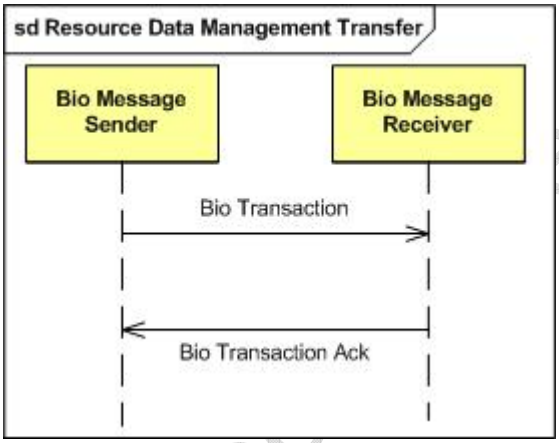
4.1.3.7 SCENARIO TECHNICAL ACTORS

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.

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)

4.1.3.8 SCENARIO ACTOR INTERACTIONS



4.2 LIST OF TRANSACTION PACKAGES AND INDEPENDENT TRANSACTIONS

The following list of transaction packages, transactions, and their definitions are used by the interoperability specification.

Transaction Package/Independent Transaction	Description	Document References	Date Added
Manage Sharing of Documents	Specification for a data locator and repository for shared storage of documents	HITSP/ISTP-13	8-2006

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Transaction Package/Independent Transaction	Description	Document References	Date Added
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.	IHE/RFD	8-2006
Pseudonymize Data	Apply a common standard to Codify Document Content, Anonymize or Pseudonymize patient data to protect patient identity form undesired disclosure when communicating care data to/from external parties.	HITSP/IST-24	8-2006
Patient ID Cross Referencing	Uniquely identify a patient through query and/or matching of key elements. Query and retrieve any patient demographic	HITSP/ISTP-22	8-2006
Patient Demographics Query	Provides ways for multiple distributed applications to query a central patient information server for a list of patients, based on user-defined search criteria, and retrieve a patient's demographic (and, optionally, visit or visit-related) information directly into the application.	HITSP/ISTP-23	8-2006
Acknowledgements	Automated assertion that the information was received and correct	HITSP/ISC-25	8-2006
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/IST-29	8-2006

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4.2.1 DEPENDENCIES

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The following table shows a list of transaction packages with their existing dependencies.

935 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:

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)	IHE-XDS-MS Share Medical Summaries across enterprises	Each HITSP-DS Actor shall support the IHE-XDS-MS content profile 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 (Lab Document Sources)	HITSP-ISC-37	HITSP-DS Actor shall support the HITSP-ISC-37-Laboratory Report content profile	Required for communication of discharge summary information from hospital and ambulatory EMRs
Shared Document Resource/Provide and Register (Document Sources)	HITSP-IST-22 PIX Uniquely identify a Patient across enterprises	HITSP-DS Actor shall support the HITSP-IST-22 PIX as part of the HITSP-IST-24 Pseudonymisation	Required for consistently assigning the pseudo-identity to a patient across multiple provider locations
Shared Document Resource/Provide and Register (Document Source)	HITSP-IST-24 - Anonymize and Pseudonymize Data,	Each actor implementing HITSP-DS shall be grouped with the HITSP-IST-24 Pseudonymisation	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-IST-24 Pseudonymize Data	Each HITSP-Surveillance Message-Based Data Submission Actor shall be grouped with the HITSP--IST-24 Pseudonymisation	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.

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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)
HITSP-IST-24 Pseudonymize	HITSP-IST-PIX Uniquely identify a Patient across enterprises	HITSP-IST-24 Actor shall support the IHE-PIX Integration Profile as part of the HITSP-Pseudonymisation building block	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 are associated with this use case implementation specification:

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
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

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Transaction Package/Transaction	Constraint	Constraint Type (Pre-condition, post-condition, general)	Purpose (Reason for this constraint)
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 6.5)	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 Retrieve Document Transaction	Support to return multiple documents for stored Query	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

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Transaction Package/Transaction	Constraint	Constraint Type (Pre-condition, post-condition, general)	Purpose (Reason for this constraint)
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'
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	BPPC should be referenced to record the OID of the authorization policy under which the patient data is disclosed to the authorized public health authority.	Post-condition	Asserted to record authorized disclosure in compliance with HIPAA
Manage Shared Docs/provide and register;	BPPC should be referenced to record the OID of the authorization policy under which the patient data is 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	ATNA should be constrained to record the OID of the authorization policy under which the patient data is 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	Add new registry metadata value for: Attribute: reportableCondition. Optionality: R2 Vocabulary: SNOMED-CT See Appendix 6.6 for values for reportable conditions	Pre-condition	The list of codes aims to represent the main clinical acts documented. The attribute has a requirement level of O, which is acceptable in the case of biosurveillance.
	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.

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Transaction Package/Transaction	Constraint	Constraint Type (Pre-condition, post-condition, general)	Purpose (Reason for this constraint)
	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	
	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.
	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.
	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.

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The following XDS Metadata elements are to be added in support of Biosurveillance. This does not extend XDS Metadata to accommodate non-patient data sources as these are not in the current AHIC Biosurveillance use case. The HITSP Biosurveillance TC does anticipate that should we need to accommodate such information in the future, that this metadata will be further extended to add a "dataSourceId" to better distinguish non-patient information:

XDSSubmissionSet attribute	Optional?	Constrained?	Extended Discussion?	Source Type	Source/ Value
reportableConditions	R2	Vocabulary: SNOMED-CT	Yes	CAD	See IHE-ITI-TF Metadata 1.4.1.2.1
pseudoID	R2*		Yes	CAD	See IHE-ITI-TF Metadata 1.4.1.2.1
sourcePseudoID	R2**		Yes	CAD	See IHE-ITI-TF Metadata 1.4.1.2.1

* Either pseudoID or patientID must be present. It is expected that pseudoID is to be used for the pseudonymized linker, and that patientID will not be populated (or alternatively will be populated with a consistent dummy value) unless the affinity domain is operating under circumstances where patient identifiable information is not of concern.

** Either sourcePatientID or sourcePseudoID must be present. It is expected that sourcePseudoID is to be used for the local pseudonymized linker, and that sourcePatientID will not be populated (or alternatively will be populated with a consistent dummy value) unless the affinity domain is operating under circumstances . It is expected that sourcePseudoID is available only to the source organization through query constraints. Some implementations may populate both of these values with a dummy value so as to protect the local identities.

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.

6.0 APPENDIX

6.1 HITSP HARMONIZATION FRAMEWORK

There are several constructs that are being used to define the interoperability specification, with each level providing more granularity to the standards applicable for fulfillment of the Use Case. The table below describes the current framework within which the interoperability specification is being built, the relationships between each construct, and further illustrative examples.

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CONSTRUCT	**DEFINITION**	EXAMPLE	**RULES**
Use Case Harmonization Request	Defines business/functional requirements and specifies the relevant context	ONC Harmonized ONC Harmonized EHR Use Case	
Interoperability Specification	Models the business/functional requirements, identifies technical/system requirements to meet the specified use-case, and then identifies how to use one or more standards to meet the use-case	HITSP EHR Interoperability Specification	Based on UML diagram to identify actors and actions Sets context Testable functional requirements Identifies transaction(s) or packages of transactions
Transaction Package	Defines how two or more transactions are used to support a stand-alone information exchange within a defined context between two or more systems	Record Locator Service, Entity Identification Service	Thin context and functional requirements Testable Based on analysis of like actors, context and content harmonized across the transactions May be fulfilled by one or more complex standards Expresses constraints on how the transactions are used together
Transaction	Logical grouping of actions, including necessary content and context, that must all succeed or fail as a group.	Query lab result, Send lab result	Fulfills all actions between two systems that meet one or more functional requirements Testable Expresses constraints on how the components and/or standards are used together
Component	An atomic construct used to support an information interchange or to meet an infrastructure requirement (e.g., security, logging/audit)	Lab result message, Lab result context	Typically will use one “primary” standard and may have other “secondary” standards May express constraints on how the standards are used
Base Standard	A standard capable of fulfilling a discrete function within a single category produced and maintained by a single standards organization.	Messaging standard, Security standard, Code set.	Per HITSP definition the term “standard” refers to (and is not limited to): –Specifications –Implementation Guides –Code Sets –Terminologies –Integration Profiles

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CONSTRUCT	**DEFINITION**	EXAMPLE	**RULES**
Composite Standard	Grouping of coordinated base standards, often from multiple standards organizations, maintained by a single organization. In HITSP, it can serve as a component, transaction or transaction package functional requirements.	Integration profiles Implementation guides Health transaction services	Per HITSP Definition

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6.2 USE CASE ACTIONS AND EVENTS

6.2.1 1.1 INDIVIDUAL HEALTH CARE DELIVERY ORGANIZATIONS PERSPECTIVE

Code	Description	Comment	Addressed In
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.	Addressed in HITSP/IS-02, HITSP/ISC-39, HITSP/ISC-40, HITSP/ISC-41, IHE/XDS-MS, IHE/XDS-Lab, IHE/XDS-I
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.	HITSP/IS-02
1.1.1.2	Action: Aggregate identified data	All essential data are aggregated.	HITSP/IS-02
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.	HITSP/IST-24, HITSP/IST-25
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.	HITSP/IST-25, HITSP/IST-22
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.	HITSP/IST-24
1.1.3.0	Event: Format data required by public health agencies	Anonymized data are formatted using approved technology and data standards.	HITSP/IS-02, HITSP/ISC-39, HITSP/ISC-40, HITSP/ISC-41, IHE/XDS-MS, IHE/XDS-Lab, IHE/XDS-I
1.1.3.1	Action: Transform data using approved standards		HITSP/IS-02, HITSP/ISC-39, HITSP/ISC-40, HITSP/ISC-41, HITSP/ISC-42, IHE/XDS-MS, IHE/XDS-Lab, IHE/XDS-I

Code	Description	Comment	Addressed In
1.1.4.0	Event: Identify Public Health Agencies that must be notified	For individual health care delivery organizations, the process to determine Public Health Agency jurisdiction and the requirement to notify is less complex than for multi-jurisdictional integrated health care data suppliers.	HITSP/IS-02
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.	HITSP/IS-02
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.	HITSP/IS-02, HITSP/ISTP-13, HITSP/IST-29 HITSP/ISC-42
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.	HITSP/IS-02, HITSP/ISTP-13, HITSP/IST-29 HITSP/ISC-42
1.1.5.2	Action: Log interaction between organization systems and public health agencies		IHE/ATNA

6.2.2 1.2 INTEGRATED HEALTH CARE DATA SUPPLIERS PERSPECTIVE

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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.

Code	Description	Comment
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 health care delivery organizations, the process to determine Public Health Agency jurisdiction and the requirement to notify is less complex than for multi-jurisdictional integrated health care 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.
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 lab test results	

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6.3 GLOSSARY

This is the HITSP glossary that spans all the interoperability specifications, which can be found in the following folder on the HITSP site:
http://publicaa.ansi.org/sites/apdl/Documents/Forms/AllItems.aspx?RootFolder=http%3a%2f%2fpublicaa%2eansi%2eorg%2fsites%2fapdl%2fDocuments%2fStandards%20Activities%2fHealthcare%20Informatics%20Technology%20Standards%20Panel

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6.4 AHIC Data Dictionary

No.	BDSG	HITSP-TC	No.	BDSG Official Name (merge)	No.	HAVE
	Institution Data	Base Facility Data Elements				OrganizationInformation
1	Hospital Medicare Number	Hospital Medicare Number	1	Hospital Medicare Number	1	OrganizationID
2	Hospital System*	Hospital System	2	Hospital System*	2	NA
3	Main facility ID/name*	Main Facility ID / Name	3	Main facility ID/Name*	3	OrganizationName
4	Location address*	Location Address	4	Location address*	4	OrganizationLocation
5	Number of facility beds*	Number of Licensed Beds	5			see below
6	Type of bed*					see below
	Specific Bed/Room Types (ICU, Peds)					see below
	# of Ventilators					see below
						HospitalFacilityStatus
	Is facility Open?					see below
	Infrastructure Problems					see below
	Staffing Problems					see below
	Supply Problems					see below

* These elements may be available from other sources related to Hospital Medicare numbers. This will be explored more. (per BSV WG)

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	BDSG	HITSP-TC		BDSG Official Name (merge)	No.	
No.	Daily Facility Summary	Daily Facility Summary Report Elements	No.			HospitalFacilityStatus
7	Date/time of report					Activity24Hr
8	Admissions last 24 hours	Admissions last 24 hours	6	Admissions last 24 hours		Admissions
9	Discharges last 24 hours	Discharges last 24 hours	7	Discharges last 24 hours		Discharges
10	Deaths last 24 hours	Deaths last 24 hours	8	Deaths last 24 hours		Deaths
		Date/Time of Message	9			LastUpdateTime
	BDSG	HITSP-TC		BDSG Official Name (merge)	No.	
		Dynamic Resource Availability Report Elements	No.			HospitalFacilityStatus
		Hospital Open?	10			ClinicalStatus
		Significant Infrastructure Problems?	11			FacilityStatus
						HospitalResourceStatus
		Significant Supply Problems?	12			FacilityOperations
		Significant Staffing Problems?	13			Staffing
		Decontam Capability?	15			DeconCapacity
						EmergencyDepartmentStatus
		Emergency Dept Capability?	14			EMSTrafficStatus
						EMSCapacity
						EMSCensus
						EMSOffloadMinutes
						HospitalBedCapacityStatus
						AvailableCount
		Available Adult ICU Beds	16			AdultICU
		Available Adult General Beds	17			MedicalSurgical
		Available Burn Beds	18			Burn
		Available Peds ICU Beds	19			PediatricICU
		Available Peds General Beds	20			Pediatrics
		Available Negative Pressure Rooms	21			NegativeFlowIsolation
		Available Ventilators	22			NA
		Date/Time of Message	23			LastUpdateTime

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	BDSG	HITSP-TC		BDSG Official Name (merge)	No.
No.	Patient Data	Patient Data Elements	No.		
11	Randomized data linker	Randomized data linker	24	Randomized data linker	
12	Encounter date	Encounter date/time	25		
13	DOB (month and year of birth)	Date of Birth	26		
14	Age (if DOB, not available)	Age	27		
15	Gender	Gender	28	Gender	
16	Zip (at Min 5 Digit Zip)	Zip	29		
17	State	State	30	State	
18	Date/time last update				
	Add time (HL7 = Time Stamp)	Date/Time of Message	31		

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	BDSG	HITSP-TC		BDSG Official Name (merge)	No.
No.	Clinical Data	Clinical Data	No.		
19	Diagnosis/Injury Code	Diagnosis/Injury Code	32	Diagnosis/Injury Code	
20	Diagnosis type	Diagnosis Type	33	Diagnosis type	
21	Diagnosis date/time	Diagnosis Date/Time	34	Diagnosis Date/Time	
22	Discharge disposition	Discharge disposition	35	Discharge disposition	
23	Patient class (Outpatient, Inpatient, ER)	Patient Class	36	Patient Class	
24	Date and time onset of illness	Date and Time Illness Onset	37	Date and Time Illness Onset	
25	Chief complaint	Chief Complaint	38	Chief complaint	
		Fever	39		
		Blood Pressure	40		
		Heart Rate	41		
		Pulse Ox	42		
	Nursing /Triage Notes	Nurse / Triage Note	43		
	BDSG	HITSP-TC		BDSG Official Name (merge)	No.
No.	Laboratory & Radiology - Orders	Lab and Radiology Test Orders	No.		
26	Order number	Order number	44	Order number	
27	Ordered test	Order test name	45		
	Frequency of Procedures				
	BDSG	HITSP-TC		BDSG Official Name (merge)	No.
No.	Laboratory/Microbiology Results	Laboratory/Microbiology Results	No.		
28	Reporting Lab ID	Reporting Lab ID	46	Reporting Lab ID	
29	Performing laboratory	Performing laboratory	47	Performing laboratory	
30	Report date/time	Report date/time	48	Report date/time	
31	Report status	Report status	49	Report status	
32	Collection date	Collection date	50	Collection date	
33	Collection method	Collection method	51	Collection method	
34	Specimen site	Specimen site	52	Specimen site	
35	Specimen	Specimen	53	Specimen	
36	Ordered test	Ordered test	54	Ordered test	
37	Resulted test	Resulted test	55	Resulted test	
38	Organism identified	Organism identified	56	Organism identified	
39	Method type	Method type	57	Method type	
40	Result other than organism	Result other than organism	58	Result other than organism	
41	Result unit	Result unit	59	Result unit	
42	Test interpretation	Test interpretation	60	Test interpretation	
43	Susceptibility test interpretation	Susceptibility test interpretation	61	Susceptibility test interpretation	
44	Test status	Test status	62	Test status	

6.5 AHIC Data Dictionary Vocabulary

All Biosurveillance message and documents will communicate the AHIC data elements below using the indicated vocabularies:

Patient Data Elements	Vocabulary/Standard Constraint
Demographics	
Randomized data linker	Alphanumeric
Encounter date/time	HL7 Timestamp
Date of Birth	HL7 Timestamp
Age	LOINC/UCUM
Gender	HL0001
Zip	Postal Zip Code
State	FIPS 5-2
Date/Time of Message	HL7 Timestamp
Clinical Data	
Diagnosis/Injury Code	ICD-9/10 CM Or SNOMED CT
Diagnosis Type	HL0052
Diagnosis Date/Time	HL7 Timestamp
Discharge disposition	Universal Billing codes (UB-92)
Patient Class	HL0004
Date and Time Illness Onset	GAP: harmonization to align concept with vocabulary: HL7 and ASTM
Chief Complaint	SNOMED-CT and/or Clinical Care Classification is suitable for codifying of free-form text
Fever	Clinical LOINC/UCUM
Blood Pressure	Clinical LOINC/UCUM
Heart Rate	Clinical LOINC/numeric
Pulse Ox	Clinical LOINC/numeric
Nurse / Triage Note	SNOMED-CT and/or Clinical Care Classification is suitable for codifying of free-form text
Lab and Radiology Test Orders	
Order number	GAP: Universally agreed upon meaning of order number; Request clarification from HL7

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Patient Data Elements	Vocabulary/Standard Constraint
Order test name	GAP: Recommend to LOINC, SNOMED-CT, and CPT to develop AND harmonize a suitable coded value set to express order test name
Laboratory/Microbiology Results	
Reporting Lab ID	CLIA
Performing laboratory	CLIA
Report date/time	HL7 Timestamp
Report status	HL70123
Collection date	HL7 Timestamp
Collection method	Overlap: HL70488 – Recommend to subset SNOMED-CT for clarification and align subset with Table 488
Specimen site	SNOMED –CT
Specimen	SNOMED –CT
Ordered test	Major GAP – lack of a universal vocabulary; Recommend SNOMED-CT, LOINC, CPT, HCPCS and others (encouraging commercial vendor participation) get together to establish a suitable vocabulary
Resulted test	Major GAP – lack of a universal vocabulary; Recommend SNOMED-CT, LOINC, CPT, HCPCS and others (encouraging commercial vendor participation) get together to establish a suitable vocabulary
Organism identified	Overlap – Need further granularity NCCLS provides granularity Recommend SNOMED-CT and NCCLS to harmonize; SNOMED-CT + NCCLS for granularity expression +Local codes for newly identified organisms that are not yet assigned codes
Method type	V3 Observation method AS a starter set. May be extended locally
Result other than organism	SNOMED for coded values + RxNorm Even SNOMED may be inadequate here.
Result unit	UCUM
Test interpretation	HL70078
Susceptibility test interpretation	HL70078
Test status	HL70085

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6.6 Coded SNOMED-CT Values for Reportable Conditions

SNOMED-CT was written and published in 2000, 2002 by the College of American Pathologists. The SNOMED-CT composite standard is reproduced in part in this specification with specific written permission from the College of American Pathologists, provides sample scenarios depicting how specific technical actors should comply with the proposed standards for interoperability. The entire SNOMED-CT composite standard is also available on the SNOMED Web site, http:// www.snomed.org

The text for the SNOMED-CT specification begins here:

CONCEPTID	FULLYSPECIFIEDNAME
235867002	acute hepatitis E
398102009	acute poliomyelitis
62479008	AIDS
111910009	Amoebiasis
31986002	animal bite
154295005	Anthrax
40610006	arbovirus infection
14175009	articular rheumatic fever
301770000	aseptic meningitis
408856003	autistic disorder
187241002	Babesiosis
95883001	bacterial meningitis
69996000	Blastomycosis
186110004	Botulism
154296006	Brucellosis
86500004	Campylobacteriosis
62576004	Carboxyhaemoglobin
79974007	cat scratch disease
128188000	cerebral palsy
266143009	Chancroid
154269008	Cholera
116560007	clostridium perfringens epsilon toxin
187025009	Coccidioidomycosis
1857005	congenital rubella syndrome
186126003	Cryptosporidiosis
240372001	Cyclosporiasis
38362002	Dengue
34348001	Dengue virus
373421000	diarrhea-associated haemolytic uraemic syndrome
154299004	Diphtheria
37203006	disease due to Calicivirus
53648006	disease due to Enterovirus
414015000	disease due to Orthopoxvirus
417702007	disorder due to Venezuelan equine encephalitis virus
243601002	eastern equine encephalitis virus

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CONCEPTID	FULLYSPECIFIEDNAME
416925005	Eastern equine encephalitis virus infection
77361002	Ehrlichiosis
45170000	Encephalitis
25668000	endemic typhus
103429008	enterohemorrhagic Escherichia coli, serotype O157:H7
198242009	female gonococcal pelvic inflammatory disease
75258004	food poisoning
266113007	genital warts
312099009	genitourinary chlamydia infection
58265007	Giardiasis
4639008	Glanders
28438004	gonococcal conjunctivitis neonatorum
236682002	gonococcal urethritis
15628003	Gonorrhea
28867007	granuloma inguinale
40956001	Guillain-Barre syndrome
111407006	haemolytic uraemic syndrome
120639003	Hantavirus pulmonary syndrome
408679000	healthcare associated pneumonia
128241005	Hepatitis
23513009	herpesvirus infection
12962009	Histoplasmosis
86406008	human immunodeficiency virus infection
398446008	human rabies
407152001	increased blood lead level
71057007	infection due to Escherichia coli
398557001	infection due to non-cholerae vibrio
406602003	infection due to Staphylococcus aureus
406575008	infection due to vancomycin resistant enterococcus
406621006	infection due to Vibrio
6142004	Influenza
78431007	influenza due to Influenza virus, type A, human
24662006	influenza due to Influenza virus, type B
406583002	invasive hemophilus influenzae disease
240373006	Isosporiasis
49937004	Kaposi's sarcoma
75053002	Kawasaki's syndrome
26726000	Legionellosis
81004002	Leprosy
186953000	Leptospirosis
186315001	Listeriosis
154376000	Lyme disease
186946009	lymphogranuloma venereum
154374002	Malaria
2963004	Marburg virus
77503002	Marburg virus disease

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CONCEPTID	FULLYSPECIFIEDNAME
14189004	Measles
34458001	Melioidosis
4089001	Meningococcaemia
23511006	meningococcal infectious disease
85180002	mercury poisoning
406593009	methaemoglobinaemia due to nitrate poisoning
61842000	Microsporidiosis
359814004	Monkeypox
154352008	Mumps
88415009	mycobacterial disease
398355005	non-human rabies
57607007	occupational asthma
34298002	ophthalmia neonatorum
416534008	Outbreak
77889005	paralytic shellfish poisoning
230681000	Paralytic shellfish poisoning
27836007	Pertussis
37131007	pesticide poisoning
198130006	PID - pelvic inflammatory disease
58750007	Plague
367318001	Poliomyelitis
20484008	Prion disease
75116005	Psittacosis
186788009	Q fever
406600006	rabies prophylaxis
406601005	rabies prophylaxis, post exposure
420079008	relapsing fever
105635000	retrovirus infection
74351001	Reye's syndrome
274095001	Rheumatic fever
30096004	Ricin
409617000	ricin poisoning
75096007	Rickettsialpox
186772009	Rocky Mountain spotted fever
36653000	Rubella
302231008	Salmonellosis
154303009	Scarlet fever
41229001	septicaemia of newborn
398447004	severe acute respiratory syndrome
36188001	Shigellosis
67924001	Smallpox
230284004	spongiform encephalopathy
22754005	staphylococcal pneumonia
3092008	staphylococcus aureus
418950004	Staphylococcus aureus enterotoxin A
419488004	Staphylococcus aureus enterotoxin B

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CONCEPTID	FULLYSPECIFIEDNAME
60875001	staphylococcus epidermidis
154379007	Syphilis
154312006	Tetanus
86068002	toxic effect of noxious substance eaten as food
18504008	toxic shock syndrome
187192000	Toxoplasmosis
2576002	Trachoma
88264003	Trichinosis
56717001	tuberculosis
19265001	Tularaemia
66071002	Type B viral hepatitis
4834000	typhoid fever
293095001	vaccine, immunoglobulins and antisera adverse reaction
111852003	Vaccinia
404680007	vancomycin resistant Staphylococcus aureus
38907003	Varicella
415822001	viral gastroenteritis due to Rotavirus
240523007	viral haemorrhagic fever
50711007	viral hepatitis C
40468003	viral hepatitis, type A
397575003	viral hepatitis, type G
87121004	visceral larva migrans syndrome
392662004	west Nile encephalitis
57311007	West Nile virus
16541001	yellow fever
83436008	Yersiniosis

The text for the SNOMED-CT specification ends here.

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6.7 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 Biosurveillance 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.

6.7.1 EXISTING ACTORS

6.7.1.1 Document Source

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

6.7.1.2 Document Consumer

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

6.7.1.3 Patient Identity Source

Currently feeds the registry with affinity domain level patient IDs. We need pseudoanonimized, ids. Additionally, non-patient centric data sources are needed for full biosurveillance functionality (lab 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.

6.7.1.4 Document Registry

Suitable with additional metadata recommendations

6.7.1.5 Document Repository

Suitable, and can be populated with existing document types: XDS-MS, XDS-Lab, XDS-I

6.7.2 EXISTING TRANSACTIONS

6.7.2.1 Provide and Register Document Set

Main issues here concern the metadata.

6.7.2.2 Register Document Set

Main issues here concern the metadata.

6.7.2.3 Query Registry

Most of the defined queries are patient-centric and require the patientId. 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.

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6.7.3 EXISTING METADATA

XDS metadata is inherently patient-centric and can potentially be difficult to adapt to biosurveillance use cases.

6.7.3.1 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 pseudoanonimized. 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

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- 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 plottable in on a map or useful for geographic simulation.

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

6.7.3.2 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").

6.7.3.3 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.

6.7.4 NEEDED ACTORS

6.7.4.1 Pseudoanonimizer? (or adapt PIX/PDQ, see below)

6.7.5 NEEDED TRANSACTIONS

6.7.5.1 Pseudoanonimization

Adapt XDS/PIX/PDQ Profiles

6.7.5.2 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 + Public Health Authority User,

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6.7.6 NEEDED METADATA

6.7.6.1 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.

6.7.6.2 'Plottable' Geographic Information – Document Entry

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

6.7.6.3 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").

6.7.7 DOCUMENT CONTENT PROFILES

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

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