



**Harmonized Use Case
for
Biosurveillance
(Visit, Utilization and Lab Result Data)**

March 19, 2006

Office of the National Coordinator for Health Information Technology (ONC)

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American Health Information Community
Initial Biosurveillance Use Case Area
December 12, 2005

Background:

The threat of significant natural or man-made health events is a critical issue for the nation. The ability to detect events rapidly, manage the events and appropriately mobilize resources in response can save lives. Information from hospitals, other providers and ancillary facilities can be electronically reported and monitored without identifying patients and serve to provide a near real-time view of the health of our communities. These data can be shared with and among local, state, and federal public authorities to support shared and unique needs at all levels of government.

Broad Area:

Implement real-time nationwide public health event monitoring and support rapid response management across public health and care delivery communities and other authorized government agencies.

Specific Use Case Area:

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.

1. Introduction to Biosurveillance (Visit, Utilization and Lab Result Data) Harmonized Use Case

In order to advance the Administration's goal of expanded adoption of health information technology (HIT), the Department of Health and Human Services (HHS) released a series of contracts in the fall of 2005 to support critical processes in the areas of standard harmonization, certification of HIT, and the development of a Nationwide Health Information Network.

A key step to ensure coordination of these processes was the identification and development of use cases. The use cases provide a common focus for the different activities and help lead to specific requirements, architecture, standards and policy discussions. Analysts typically develop use cases to convey specific business processes and indicate ways that systems should interact with users and with other systems to achieve specific goals. These harmonized use cases do not define policies and strive to not define technical approaches any more than is necessary. The harmonized use cases are intended to help structure subsequent work in these areas.

The American Health Information Community helped frame these use cases by defining "breakthrough areas" in which specific, near term value to the health care consumer could be realized. Based on this guidance, the Office of the National Coordinator for Health Information Technology (ONC) directed its portfolio of contractors to develop and submit for review use case areas in: (1) biosurveillance, (2) consumer empowerment, and (3) electronic health records.

Following the submission of the contractor's use cases on January 18, 2006, ONC launched a process to integrate the individual contributions into "harmonized" use cases. With the assistance of health information technology experts from across the federal government and guidance from the American Health Information Community and its Workgroups, ONC has completed the harmonization of the three use cases. While leaving flexibility for different implementation models, the harmonized use cases provide detailed guidance on the functions needed to advance critical efforts for the accelerated adoption of health information technology.

From the American Health Information Community's perspective, the harmonized use cases will yield valuable insights into the Community's continuing efforts to identify and remove barriers to adoption of health information technology.

For the nationwide health information network consortia, the harmonized use cases provide a foundation for the identification of critical architecture elements and establish the expectations of their prototype architectures.

For the Health Information Technology Standards Panel, the harmonized use cases scope its efforts to develop named standards and implementation level guidance necessary for interoperable solutions.

For the Certification Commission for Health Information Technology, the harmonized use cases provide insight into criteria for the certification of electronic health records and other aspects of the health IT landscape.

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2. Description of Biosurveillance (Visit, Utilization and Lab Result Data) Harmonized Use Case

In July 2004, the Department of Health and Human Services released a Strategic Framework report entitled *The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care*. The framework outlines four major goals to be pursued by public and private health sectors in order to shape a vision to utilize information technology in health. Simply, these four goals are as follows: (1) inform clinical practice, (2) interconnect clinicians, (3) personalize care, and (4) improve population health.

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 and care delivery communities and other authorized Government agencies.

The use case describes the process or interaction that each primary stakeholder will invoke in the capture, discovery, anonymization, and transmission of relevant data.

The use case addressed in this document is for the 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 format to authorized Public Health Agencies with less than one day lag time. The system and processes must also support the ability for authorized public health personnel to go back to the data source to seek to re-link the biosurveillance data to the data source as part of 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 data a data or network system such as a multi-faculty system or supporting organization that uses data in the course of providing other services and sends data to all appropriate public health agencies. Other permutations of these two models can also be considered. The role of the data or network system can be accomplished by several different stakeholders, including hospital systems, health plans, independent laboratories, and other possibilities. It is anticipated that Nationwide Health Information Network efforts will develop supporting approaches an infrastructure that may offer other solutions as well.

3. Scope of Biosurveillance (Visit, Utilization and Lab Result Data) Harmonized Use Case

This use case primarily includes the actions that are required to identify specific clinical care information used in the context of care and share these data with public health organizations to support Biosurveillance needs including initial event detection, situational awareness, outbreak management and response support. There are activities that occur inside of Public Health Agencies and some health care organizations related to biosurveillance functions and processing. These functions are not portrayed in this document since the use case is focused on the exchange of data from clinical sources to Public Health Agencies, rather than how the data are employed by Public Health Agencies in the execution of their missions.

Wherever possible, existing data, workflows, and systems shall be leveraged to minimize the barriers to participation in data sharing. Further, while this use case describes delivering clinical care data to Public Health Agencies, the policies, processes and standards may be applicable to many types of public health surveillance, including communicable disease, injury, and cancer surveillance. The use case scope includes the following:

1. Data routinely entered into hospital, ambulatory care, and other ancillary care data systems. These may include patient demographics; diagnostic data; chief complaints; triage data; laboratory orders and results; physician orders; healthcare facilities' capacity information; and admission, discharge and transfer data.
2. Hospital systems and affiliated clinical personnel who have clinical data of public health significance or oversee response management responsibilities.
3. The legally authorized local, regional, state, and federal public health personnel who monitor and manage public health surveillance data.

The scope of this use case excludes the following:

1. Sources other than those described in the "includes" section above, such as EMS run data, school absenteeism reports, poison center calls, and other sources of potentially relevant data.
2. The modeling of many interactions between the perspectives in this use case that occur as part of conducting normal business functions related to patient care. For example, physicians who order lab tests relevant to biosurveillance activities may interact with laboratories that are captured in the Integrated Health Care Data Suppliers perspective. However, the processes for ordering of the test (and modeling to reflect it) are not within the scope of this use case. The return of the results to the ordering physician is similarly out of scope. The collection and transmission of the relevant lab results to Public Health Agencies is the action of interest, and is therefore included in the model.
3. Policies for other use or sharing of data for non-Biosurveillance purposes.

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4. The specific processes and algorithms used by public health to manage and respond to public health crises.
5. The processes through which alerts and other information are communicated from Public Health Agencies to physicians and hospitals in the event of an outbreak or other situation of public health significance.

The scope of this use case excludes the following organizations and types of individuals:

1. First responders such as police or EMS.
2. The press and the general public (as a recipient of public health alerts when applicable).

The scope of this use case excludes the following Public Health Agency activities:

1. Surveillance data management.
2. Surveillance analytical methods for determining trends and event correlation.
3. Identifying populations at risk.
4. Public health and public notification mechanisms.
5. Routine health promotion and environmental health promotion programs.

To accomplish the charge, two broad categories of essential data shall be provided to Public Health Agencies: data used in the process of patient care and dynamic resource utilization data.

Data Used in the Process of Patient Care:

Within the health care data category, a minimum of four subcategories of essential data shall be provided in electronic format, as follows:

1. Limited Patient Demographic Data: may include but is not limited to encounter date, patient information (date of birth, age, gender, resident zip code, state of residence), date/time of last record update, and randomized data linker. All data will be anonymized before transmission to Public Health Agencies. Once anonymized, a randomized data linker provides the ability to re-identify the patient, through the data provider as part of an authorized public health investigation.
2. Clinical Data: may include but is not limited to patient class (outpatient, inpatient, and ER), diagnosis/injury code, diagnosis type, diagnosis date and time, and discharge disposition, chief complaint, date and time of first symptoms of illness.
3. Laboratory and Radiology Test Orders: may include but is not limited to order number, order test, and randomized data linker.
4. Laboratory and Radiology Test Results: may include but is not limited to reporting lab ID, performing lab ID, report date/time, report status, collection date, collection method, specimen, specimen site, test ordered, test results, organism identified / result other than organism, method type, result unit, test interpretation, susceptibility test interpretation, test status, and randomized data linker.

Dynamic Resource Utilization Data:

Utilization data should be captured and provided to Public Health Agencies so that officials can determine the status and available capacities of participating health care facilities. Within the Utilization Data category, a minimum of three subcategories of essential data shall be provided in electronic format, as follows:

1. Institution Data: includes but is not limited to Hospital System, Main Facility ID/name, physical facility address, and total number of beds in institution.
2. Unit-level Census Data: includes but is not limited to unit name, number of patients by unit, number of beds available by unit, and emergency room triage marginal capacity as a percentage and head-count.
3. Facility Utilization Data: includes but is not limited to admissions in last 24 hours at institution, discharges in last 24 hours at institution, deaths in last 24 hours at institution, date and time of report.

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4. Stakeholders for Biosurveillance (Visit, Utilization and Lab Result Data) Harmonized Use Case

The following list of stakeholders and their definitions are for discussion purposes within the context of the use case.

Stakeholders	Working Definition
Patient	Members of the public who require healthcare services from ambulatory and emergency department environments.
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, clinical supervisors.
Healthcare delivery organization	Organizations, such as hospitals, physician practices, which manage the delivery of care.
Laboratory organization	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.
Public Health Agencies (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.
Resource suppliers	Private and government organizations and personnel, other than Public Health Agencies, who have a stake in public health by supporting public health processes (e.g., USDA food inspectors, American Red Cross, pharmacies, Department of Homeland Security) and help address public health events.
Public	Consumers of health care services and information; stakeholders in the overall health care system.

5. Pre-Conditions for Biosurveillance (Visit, Utilization and Lab Result Data) Harmonized Use Case

Pre-conditions are the conditions that must be in place before the start of the use case. This includes, but is not limited to, the state of a stakeholder, data that must be available somewhere, or an action that must have occurred. This section also includes triggers for the initiation of the use case and discussions of important assumptions made about the use case during its development.

A variety of preconditions are necessary for this use case, including the existence of policies and agreements among stakeholders associated with information exchange, and a level of technical capability among participants in information sharing and analysis. Essential preconditions include:

1. Established network and policy infrastructures to enable secure, consistent, appropriate, reliable, and accurate information exchange.
2. Procedures and agreements supporting data exchange, including privacy protections, security or confidentiality breaches or misuses, secondary data uses and appropriate data sharing agreements/business associate agreements.
3. Agreed to method(s) for data categorization, and defined criteria for sharing data of public health significance.
4. Efforts to minimize “double counting.” For example, if a physician orders a lab test for a patient, it is desirable to determine that independent reports by the physician and lab are referring to the same case.
5. A consistent approach for data anonymization including method(s) for connecting related data elements for an encounter and/or multiple encounters at an organization and supporting needs for an authorized public health investigation to seek to re-link the data by going back to the data provider. For this use case, the implementation of the randomized data linker will support these needs
6. Healthcare facilities’ (i.e., hospitals, clinics, laboratories, ancillary clinical facilities) ability to electronically collect, process, and transmit pertinent public health data in a secure fashion, in less than 1 day, using existing data exchange and vocabulary standards.

6. Obstacles to Implementation of Biosurveillance (Visit, Utilization and Lab Result Data) Harmonized Use Case

In general, the absence of the prerequisites described in the previous section presents obstacles to implementation of the use case. Additional obstacles include an unwillingness to participate in activities that contribute to biosurveillance due to perceived security and privacy concerns or to

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the lack of perceived value. These obstacles could affect several groups including:

1. Consumers/the general public. Consumers must also be adequately educated about the value of biosurveillance and the security safeguards that are in place to protect their privacy and confidentiality.
2. Health facilities. Some health facilities may lack resources to implement the technology necessary to send secure, timely, standardized messages or otherwise participate in biosurveillance.
3. Perceived regulatory conflicts. There currently exists a patchwork of local, state and national approaches for the transmission of clinical data for public health purposes. These regional variations can cause conflicts or perceived conflicts that are obstacles to implementation of data sharing.

Additional obstacles include:

1. Inability of clinicians, laboratories, or healthcare delivery organizations to transform the data, using accepted standards into filtered, normalized, and anonymized form without external implementation assistance.
2. Limited access to connectivity capabilities for of clinicians', laboratories', or healthcare delivery organizations' systems to securely share data across the Internet.
3. Incomplete data within the local EHR systems. Key surveillance elements are not available.
4. Unwillingness of healthcare delivery organizations to provide data management, including review of patient information to identify data elements necessary for biosurveillance, potential manual data entry, etc.
5. Limited collection and availability of meaningful utilization data (e.g., clinician availability, stockpile inventory, pharmacy inventory, hospital bed availability).

7. Post-Conditions for Biosurveillance (Visit, Utilization and Lab Result Data) Harmonized Use Case

Post-conditions are the conditions that will be a result or output of the use case. This includes, but is not limited to, the state a stakeholder upon conclusion of the use case, data that was created or now available, and identification of actions that may serve as pre-conditions for other use cases. General post-conditions include:

1. Clinical ER data, ambulatory data, laboratory data, and utilization data sources will be able to automatically share biosurveillance-relevant patient event data with Public Health Agencies.

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2. Biosurveillance data messages will be formulated following a standard structure, coding, and minimal required set of information.
3. Surveillance data will be transmitted in real-time, when feasible, but with a periodicity of no longer than 24 hours.
4. Data provided will support the privacy and security of patient health information, and also be responsive to requirements for re-identification for authorized public health investigations.
5. When appropriate, a biosurveillance transmission message data and/or alert is generated, sent to and received by the appropriate users.
6. Appropriate entities are registered to send or receive biosurveillance data;
7. System transactions are auditable.

8. Detail of Biosurveillance (Visit, Utilization and Lab Result Data) Harmonized Use Case Perspectives and Scenarios

The following entity-driven perspectives will be part of the use case:

1. **Individual health care delivery organizations** denote stand-alone hospitals and clinics that provide ambulatory and/or emergency departments care and/or in-house laboratories. Although some actions and events to transmit relevant data to public health agencies are similar (or the same) to those used by the large integrated health care data suppliers perspective, this perspective is called out separately to highlight a different set of business rules necessary to adhere to public health reporting requirements.
2. **Integrated health care data suppliers** are organizations that span jurisdictional or functional boundaries (e.g., interstate hospital organizations) and may require a different reporting structure to transmit relevant biosurveillance data to requisite public health agencies. Because these organizations frequently cross jurisdictional boundaries, the identification of all correct local or state public health agencies to involve may be a complicated process. Some of these organizations include regional or nationwide laboratory organizations, integrated delivery networks claims clearing houses, payer systems, some utilization data sources and other relevant data sources.
3. **Public Health Agencies** are the relevant local, state, and public health agencies that are authorized to receive and use data to perform biosurveillance.

Note: Other permutations of the data flow models required to accomplish this use case can be considered; for example information exchanges may form through which individual health care delivery organization may provide aggregated information. Another example of a data flow permutation is the organization of a network of information exchanges, regional health information organizations, or affiliations of large integrated health care data suppliers that may collaborate to provide data to public health agencies.

The visual below depicts a combination of all events, primary and alternate, used in the scenario flow described in further detail in the tables that follow.

Biosurveillance

1.1.0.0 Individual Health Care Delivery Organizations

1.1.1.0 Event: Filter data for information required by Public Health Agencies

1.1.1.1 Filter collected data records to identify biosurveillance data

1.1.1.2 Aggregate identified data

1.1.2.0 Event: Anonymize data required by Public Health Agencies

1.1.2.1 Review identified data to ensure full privacy compliance

1.1.2.2 Embed randomized data linker to allow authorized re-identification

1.1.3.0 Event: Format data required by Public Health Agencies

1.1.3.1 Transform data into approved standards

1.1.4.0 Event: Identify Public Health Agencies that must be notified

1.1.4.1. Determine which Public Health Agencies require notification

1.1.5.0 Event: Transmit relevant data

1.1.5.1 Send results to Public Health Agencies

1.1.5.2 Log interaction between organization systems and Public Health Agencies

1.2.0.0 Integrated Health Care Data Suppliers

1.2.1.0 Event: Filter data for information required by Public Health Agencies

1.2.1.1 Filter collected data records to identify biosurveillance data

1.2.1.2 Aggregate identified data

1.2.2.0 Event: Anonymize data required by Public Health Agencies

1.2.2.1 Review identified data to ensure full privacy compliance

1.2.2.2 Embed randomized data linker to allow authorized re-identification

1.2.3.0 Event: Format data required by Public Health Agencies

1.2.3.1 Transform data into approved standards

1.2.4.0 Event: Identify Public Health Agencies that must be notified

1.2.4.1. Determine which Public Health Agencies require notification

1.2.5.0 Event: Transmit relevant data

1.2.5.1 Send results to Public Health Agencies

1.2.5.2 Log interaction between organization systems and Public Health Agencies

1.3.0.0 Public Health Agencies

1.3.1.0 Event: Provide listing of required biosurveillance data

1.3.1.1 Notify involved organizations of data that must be transmitted to Public Health Agencies

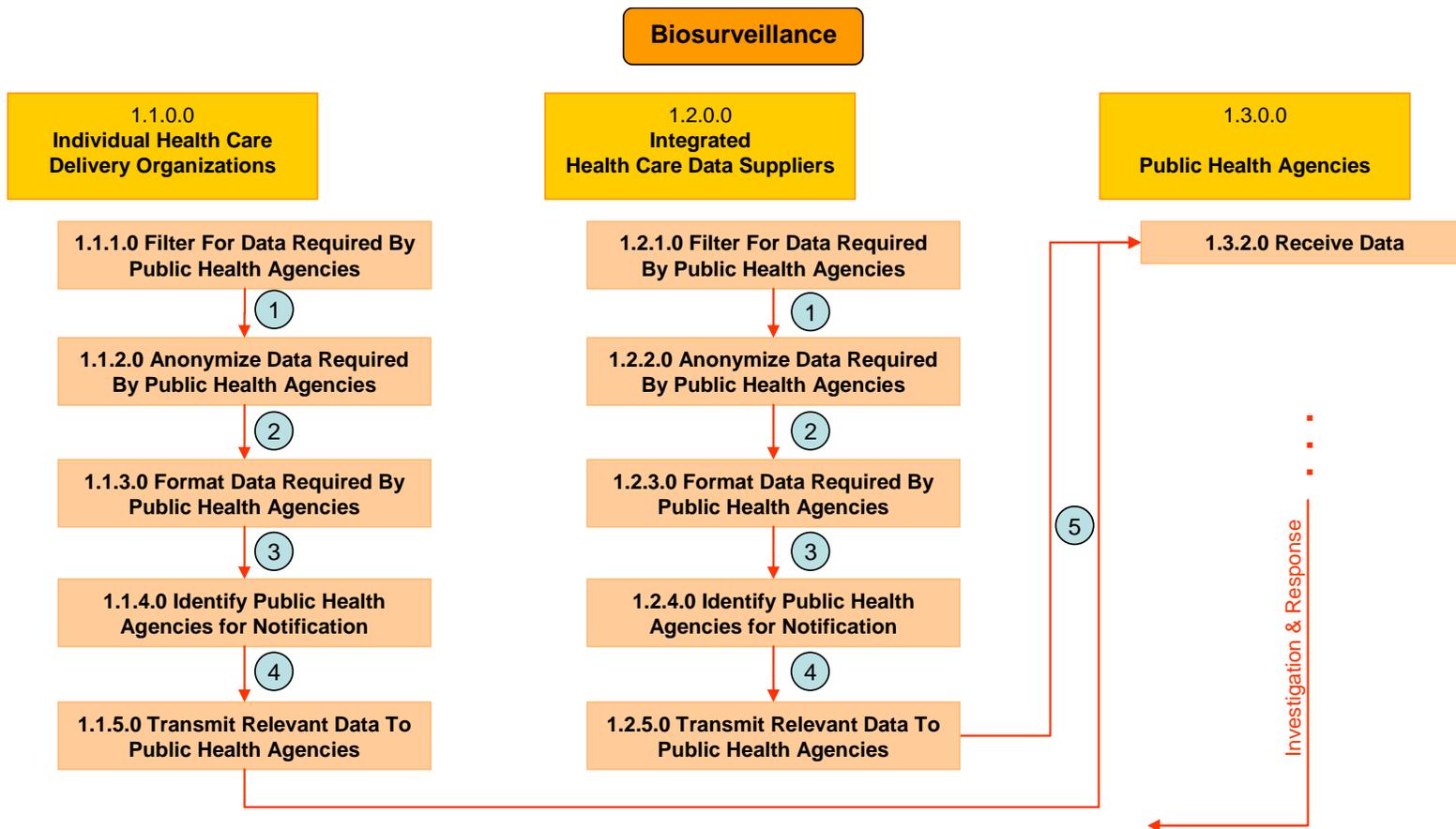
1.3.2.0 Event: Receive biosurveillance data

1.3.2.1 Receive biosurveillance data

1.3.2.2 Verify authenticity of transmission content

1.3.2.3 Acknowledge receipt of data

1.3.2.4 Log receipt of data



**Scenario Flow 1:
Transmission and Receipt of Relevant Biosurveillance Data**

1. Data from patient-clinician encounters in individual facilities (ambulatory, ER, and local labs) and from integrated healthcare data suppliers are filtered to identify the data relevant to biosurveillance. Integrated Health Care Data Suppliers include organizations such as laboratories, payer systems, claims clearing houses, integrated healthcare delivery networks, health information exchanges, et al.
2. Data are anonymized to meet privacy requirements but retain the ability to be “re-linked” to support public health investigations.
3. Data are formatted for transmission using approved standards.
4. Public Health Agencies that require data are identified
5. Data are transmitted to authorized public health agencies.

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1.1 Individual Health Care Delivery Organizations Perspective

Code	Description	Comment
1.1.1.0	Event: Filter existing data to identify data required by public health agencies	Referencing data requirements communicated by Public Health Agencies in Event 1.3.1.0, all data that is appropriate to provide to public health agencies is identified so that it can be formatted using the approved data and technology standards to allow processing across the stakeholders in this use case.
1.1.1.1	Action: Filter collected data records to identify biosurveillance data	Relevant data are marked for inclusion in a transmission, via EHR or web-enabled system, to public health agencies.
1.1.1.2	Action: Aggregate identified data	All essential data are aggregated.
1.1.2.0	Event: Anonymize data required by public health agencies	Data readied for transmission is anonymized to withhold direct patient identifiers. The process should allow for the data to be re-linked to a specific patient if required for and authorized public health investigation. All associated, randomized links are included with the data package.
1.1.2.1	Action: Required data are checked to ensure full privacy requirement compliance	Ensure that all data included in biosurveillance package are anonymized and meet all applicable privacy and security considerations.
1.1.2.2	Action: A randomized data linker is provided to allow authorized entities to re-link to patient data	Functionality is provided to re-link data to patient when required as part of an authorized public health investigation.
1.1.3.0	Event: Format data required by public health agencies	Anonymized data are formatted using approved technology and data standards.
1.1.3.1	Action: Transform data using approved standards	

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Code	Description	Comment
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.
1.1.4.1	Action: Determine which Public Health Agencies require notification	Apply business rules to determine which public agencies (which local, which state, and which federal agencies) need to be notified.
1.1.5.0	Event: Transmit relevant data to public health agencies	Anonymized data are transmitted to public health agencies using approved data and technology standards.
1.1.5.1	Action: Send results to public health agencies	Transmit the record to public health agencies. Any appropriate metadata will also be sent.
1.1.5.2	Action: Log interaction between organization systems and public health agencies	

1.2 Integrated Health Care Data Suppliers Perspective

Code	Description	Comment
1.2.1.0	Event: Filter existing data to identify data required by public health agencies	Within the data repositories of these entities, all data that is appropriate to provide to public health agencies is identified so that it can be formatted using the approved data and technology standards to allow processing across the stakeholders in this use case.
1.2.1.1	Action: Filter stored data to identify biosurveillance data	Relevant data are marked for inclusion in electronic format to public health agencies.
1.2.1.2	Action: Aggregate identified data	All essential data are aggregated.
1.2.2.0	Event: Anonymize data required by public health agencies	Data readied for transmission is anonymized to withhold direct patient identifiers. The process should allow for the data to be re-linked to a specific patient if required for an authorized public health investigation. All associated, randomized links are included with the data package.
1.2.2.1	Action: Required data are checked to ensure full privacy requirement compliance	Ensure that all data included in biosurveillance package are anonymized and meet all applicable privacy and security considerations.
1.2.2.2	Action: A randomized data linker is provided to allow authorized entities to re-link to patient data	Functionality is provided to re-link data to patient when required as part of an authorized public health investigation.
1.2.3.0	Event: Format data required by public health agencies	Anonymized data are formatted using approved technology and data standards.
1.2.3.1	Action: Transform data using approved standards	

Code	Description	Comment
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 Public Health Agencies (local/state/federal) Perspective

Code	Description	Comment
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	