

U.S. Department of Health and Human Services
Office of the National Coordinator for Health Information Technology



Public Health Case Reporting

Detailed Use Case

March 21, 2008



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1.0 Preface

Use cases developed for the American Health Information Community (AHIC) are based on the priorities expressed by the AHIC, which include needs expressed by the AHIC Workgroups. These high-level use cases focus on the needs of many individuals, organizations, and systems rather than the development of a specific software system. The use cases describe involved stakeholders, information flows, issues, and system needs that apply to the multiple participants in these arenas.

The use cases strive to provide enough detail and context for standards harmonization, certification considerations, architecture specifications and detailed policy discussions to advance the national health information technology (HIT) agenda. These high-level use cases focus, to a significant degree, on the exchange of information between organizations and systems rather than the internal activities of a particular organization or system.

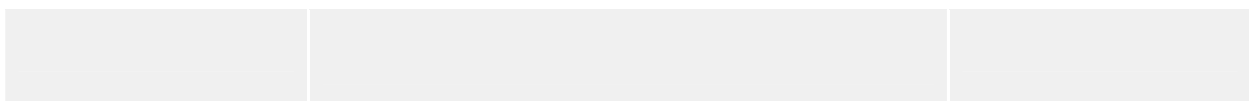
During the January 2007 AHIC meeting, nine priority areas (representing over 200 identified AHIC and AHIC workgroup detailed issues and needs) were discussed and considered. Three of these areas (Consumer Access to Clinical Information, Medication Management, and Quality) were selected for use case development and the final 2007 Detailed Use Cases were published in June, 2007.

The remaining six priority areas from the January 2007 AHIC meeting (Remote Monitoring, Patient-Provider Secure Messaging, Personalized Healthcare, Consultations & Transfers of Care, Public Health Case Reporting, and Immunizations & Response Management) have been developed as the 2008 Use Cases which will be processed in the national HIT agenda activities in 2008.

The 2008 Use Cases have been developed by the Office of the National Coordinator for Health Information Technology (ONC) with previous opportunities for review and feedback by interested stakeholders within both the private and public sectors. To facilitate this process, the use cases were developed in two stages:

- The **Prototype Use Case** describes the candidate workflows for the use case at a high level, and facilitate initial discussion with stakeholders; and
- The **Detailed Use Case** documents all of the events and actions within the use case at a detailed level.

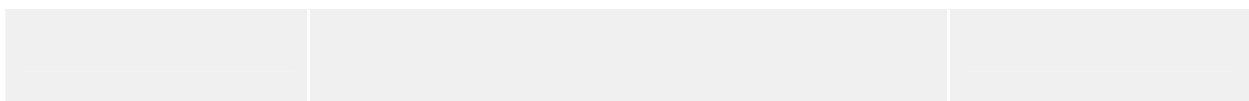
This document is the Detailed Use Case. Feedback received on the Draft Detailed Use Case have been considered and incorporated where applicable into this document.





This Detailed Use Case is divided into the following sections:

- Section 2.0, Introduction and Scope, describes the priority needs identified by one or more AHIC workgroups and includes decisions made regarding the scope of the use case.
- Section 3.0, Use Case Stakeholders, describes individuals and organizations that participate in activities related to the use case and its components.
- Section 4.0, Issues and Obstacles, describes issues or obstacles which may need to be resolved in order to achieve the capabilities described in the use case.
- Section 5.0, Use Case Perspectives, describes how the use case combines similar roles (or actors) to describe their common needs and activities. The roles are intended to describe functional roles rather than organizations or physical entities.
- Section 6.0, Use Case Scenarios, describes how various perspectives interact and exchange information within the context of a workflow. Use case scenarios provide a context for understanding information needs and are not meant to be prescriptive.
- Sections 7.0 and 8.0 provide a greater level of detail for each scenario and include information flows. Specific events and actions for each perspective and scenario are presented and discussed. These are also not intended to be prescriptive.
- Section 9.0, Information Exchange, describes the role of information exchange in the use case at a high level.
- Section 10.0, Dataset Considerations, identifies specific information opportunities relevant to this use case that may support future standardization and harmonization activities.
- Appendix A, the Glossary, provides descriptions of key concepts and terms contained in the detailed use case.
- Appendix B, Bi-Directional Communication: Information Sharing with Clinicians, provides categories of information sharing which may occur between public health and clinicians.





2.0 Introduction and Scope

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

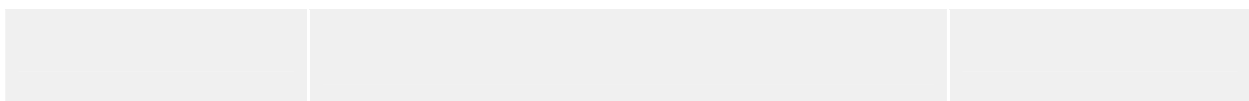
This use case also discusses the incorporation of reporting criteria into EHRs which may assist in the possible identification and reporting of PH Cases and AEs. Reporting criteria which are incorporated and utilized by EHRs may include: general and specific reporting considerations, as well as the identification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

Following the reporting of possible PH Cases, investigation and information sharing may occur by public health personnel in clinical care settings or public health agencies. There may be similar processes which support AE investigation and follow-up, but due to the presence of different information flows and stakeholders, AE investigations and recalls are not addressed in the scope of this use case.

Leveraging electronic clinical information to address population health data needs can also support providers in their decision making. Specifically, providers may benefit from having access to population health data (sometimes called bi-directional communication in reference to data flowing back from public health to clinical care personnel) to support decision support. As expressed in Section 10.0, Data Set Considerations and Appendix B, capabilities for data flowing back to clinical care personnel from public health may include communications which are: case-specific or patient-specific, generalized to clinically relevant public health functions, or broad enough to be publicly available.

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

- Providers and Public Health will benefit from having the ability to electronically integrate reporting criteria into EHRs and/or other systems;





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

One of the goals of AHIC is to establish a pathway, based on common data and technical standards that facilitates and incorporates interoperable reporting criteria including trigger data and events and reporting specifications into EHRs and/or other tools. This approach can support the reporting of AEs, as well as support the reporting, investigation, and information sharing associated with PH Cases. This use case was developed to support the various stakeholders who are active in the development and implementation of EHRs and those facilitating health information exchange activities, including those engaged in activities related to standards, interoperability, harmonization, architecture, policy development, and certification. Some of these stakeholders and their initiatives are further discussed in section 10.0 Data Set Considerations.

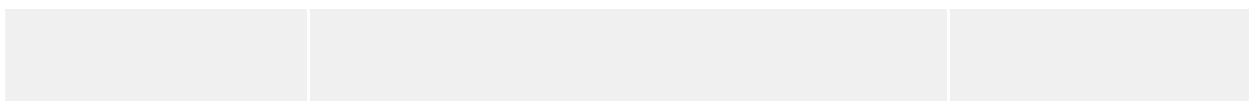
This Public Health Case Reporting Detailed Use Case focuses on the exchange of information between providers' EHRs, public health organizations, manufacturers, laboratories, and describes the following scenarios:

- **Reporting from EHRs**

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

- **Public Health Case Investigation and Information Sharing**

In evaluating the need for further actions, those performing public health functions may request and receive various types of appropriate authorized information when



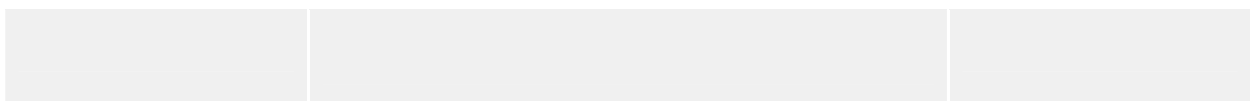


performing their investigations. The information exchanges and analysis conducted during investigations will assist public health in case status, refining reporting criteria, performing contact tracing to determine who else may have been exposed, assessing impact, determining management and response plans, and communicating appropriate public health information.

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

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

For reporting of AEs, both mandatory, as designated by the statutes and regulations of the Food and Drug Administration (FDA), and voluntary reporting exists. While acknowledging the issues and obstacles associated with this environment, this use case recognizes current efforts to standardize reporting requirements as well as reporting criteria, including those being focused on by Council of State and Territorial Epidemiologists (CSTE), Centers for Disease Control and Prevention (CDC), FDA, and others to advance these and other initiatives, which promote improved population health.

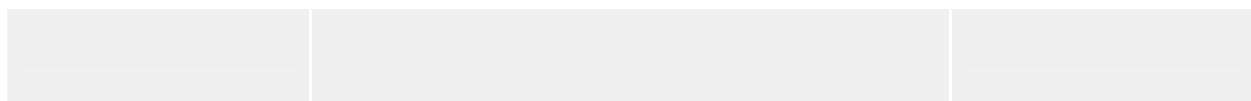




3.0 Use Case Stakeholders

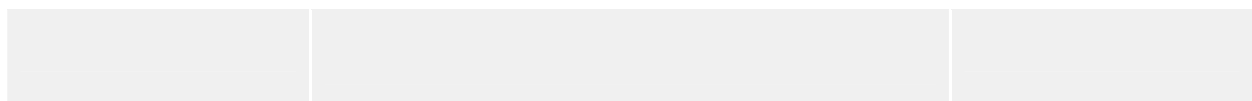
Figure 3-1. Public Health Case Reporting Use Case Stakeholders Table

Stakeholder	Contextual Description
Consumers	Members of the public that include: patients, caregivers, patient advocates, surrogates, family members, and other parties who may be acting for, or in support of, a patient receiving or potentially receiving healthcare services.
Electronic Health Record (EHR)/Personal Health Record (PHR) System Suppliers	Organizations which provide specific EHR and PHR solutions to clinicians and patients such as software applications and software services. These suppliers may include developers, providers, resellers, operators, and others who may provide these or similar capabilities.
Geographic Health Information Exchange/ Regional Health Information Organizations	A multi-stakeholder entity, which may be a free-standing organization (e.g., hospital, healthcare system, partnership organization) that supports health information exchange and enables the movement of health-related data within state, local, territorial, tribal, or jurisdictional participant groups. Activities supporting health information exchanges may also be provided by entities that are separate from geographic health information exchanges/Regional Health Information Organizations including integrated delivery networks, health record banks, and others.
Government Agencies	Federal, state, local, territorial, or tribal departments within the United States government responsible for the oversight and administration of a specific function; government agencies may include: Department of Health and Human Services (DHHS), Food & Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Drug Enforcement Agency (DEA), Centers for Medicare & Medicaid Services (CMS), Department of Defense (DoD), Department of Veterans Affairs (VA), Indian Health Services (IHS), Department of Homeland Security (DHS), non-Federal public health departments/agencies, Agency for Healthcare Research and Quality (AHRQ), and Department of Agriculture (USDA).



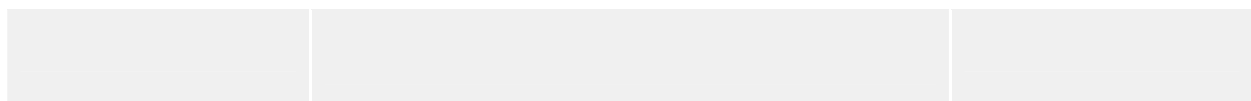


Stakeholder	Contextual Description
Healthcare Entities	Organizations that are engaged in or support the delivery of healthcare; these organizations include hospitals, ambulatory clinics, long-term care facilities, community-based healthcare organizations, employers/occupational health programs, school health programs, dental clinics, psychology clinics, care delivery organizations, pharmacies, home health agencies, hospice care providers, and other public health/healthcare entities.
Healthcare Payors	Insurers, including health plans, self-insured employer plans, and third party administrators, providing healthcare benefits to enrolled members and reimbursing provider organizations.
Laboratories	A laboratory (often abbreviated lab) is a setting where specimens are sent for testing and analysis, are resulted, and then results communicated back to the requestor. The types of laboratories may include anatomical pathology, clinical/medical, environmental, and veterinarian, and may be both private and/or public.
Laboratory Information System (LIS) Suppliers	Organizations which provide specific laboratory information system solutions. A laboratory information system is a class of software which handles receiving, processing, transmitting, and storing information generated by medical laboratory processes. These systems often must interface with instruments and other information systems such as hospital information systems. An LIS is a highly configurable application which is customized to facilitate a wide variety of laboratory workflow models.
Manufacturers/Distributors	Entities which may be involved in the following activities: research, development, testing, production, storage, distribution, surveillance, and communication regarding medical/healthcare products at the community, regional, and national level. Examples include: pharmaceutical manufacturers, drug wholesalers, medical device suppliers, etc.
Patients	Members of the public who receive healthcare services
Providers	The healthcare clinicians within healthcare delivery organizations with direct patient interaction in the delivery of care, including physicians, nurses, psychologists, and other clinicians. This can also refer to healthcare delivery organizations.





Stakeholder	Contextual Description
<p>Public Health Agencies/Organizations (federal/state/local/territorial/tribal)</p>	<p>Federal, state, local, territorial, and tribal government organizations and clinical care personnel that exist to help protect and improve the health of their respective constituents.</p>
<p>Public Health Knowledge Providers</p>	<p>Associations of public health individuals/organizations who provide technical advice and assistance to state and local health agencies in a broad range of areas including: occupational health, infectious diseases, immunization, environmental health, chronic diseases, injury control, and maternal and child health. These associations may include Council of State and Territorial Epidemiologists (CSTE), Association of Public Health Laboratories (APHL), Association of State and Territorial Health Officials (ASTHO), National Association of County and City Health Officials (NACCHO), etc.</p>
<p>Registries</p>	<p>Organized systems for the collection, storage, retrieval, analysis, and dissemination of information on individual persons to support health needs. This also includes government agencies and professional associations which define, develop, and support registries.</p>
<p>Reporting Entities</p>	<p>Organizations and/or individual clinicians that report possible public health cases or adverse events to Public Health.</p>
<p>Research Entities</p>	<p>Organizations that are engaged in or support healthcare research that include those entities performing research, clinical trials, or other research activities (e.g., National Institutes of Health, academic centers).</p>
<p>Response Management Organizations</p>	<p>Organizations that are responsible for emergency evaluation and response to natural disasters (e.g., public health and emergency management organizations (Federal Emergency Management Agency, Red Cross)).</p>



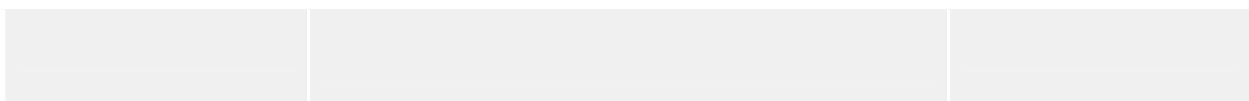


4.0 Issues and Obstacles

Realizing the full benefits of HIT is dependent on overcoming a number of issues and obstacles in today's environment. Inherent is the premise that some of these issues and obstacles are cross-cutting and therefore shown in all use cases, while others are unique to this specific use case. Some of these topics appear in both the cross-cutting and use case-specific sections so that, in addition to the shared characteristics of the issue, considerations specific to a use case may be addressed.

Issues and Obstacles which are applicable across use cases appear below in problem and consequence form:

- **Confidentiality, privacy, and security:**
 - In order for consumers to accept electronic health records, appropriate privacy and security protections may be needed to manage access to personal health information. Consumers may also want to decide who will view and communicate their personal health information. Privacy and security controls and the means of restricting data access are not standardized or regulated.
 - Without permissions and controls, consumer participation in the act of electronic health information exchange may be limited.
 - There are regulations concerning the storage, transmission, or destruction of electronic health information. These regulations are inconsistent across federal, state, and local jurisdictions.
 - Without consistent standards, the viewing, accessing, or transmitting of electronic health information may be inhibited.
- **Information integrity, interoperability, and exchange:**
 - Incomplete, inaccurate, or proprietarily-formatted information prevents efficient health information exchange activities or utilization of electronic health information.
 - Without data standards that promote compatibility and interoperability, longitudinal patient medical records may be incomplete or of questionable integrity.
- **EHR and HIT adoption:**
 - The processes identified in the use cases rely upon successful integration of EHRs into clinical activities. Because this integration may not align with



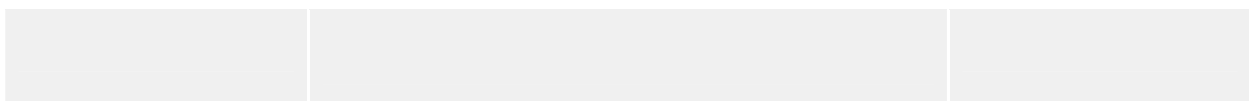


current workflow and may require additional upfront costs, it may not be widely pursued or implemented.

- Low adoption of HIT, particularly within rural areas and long-term care settings, may create disparate service levels and may adversely affect healthcare for these populations.
- **Lack of business model and infrastructure:**
 - Financial incentives are not currently sufficient to promote the business practices necessary for sustainable HIT.
 - If sufficient reimbursement policies and other financial incentives are not established, HIT adoption may be difficult or unsustainable.
 - Activities involving health information exchange will require additional technical infrastructure, functionality, and robustness, beyond what is currently available.
 - Unless the requisite infrastructure for health information exchange capabilities is established, improved upon, and sustained, these capabilities may have limited success and provide few benefits.
- **Clinical Decision Support:**
 - The capabilities, requirements, and standards needed for consistent development, implementation, and maintenance of Clinical Decision Support have not been identified.
 - The utility and benefits of Clinical Decision Support cannot be fully realized without the development of workflows and standards demonstrating benefits for consumers, patients, and providers.

In addition to the cross-cutting issues and obstacles described above, there are several other issues or obstacles that are specific to this use case.

- **Confidentiality, privacy, and security:**
 - There is currently no consistent approach for supporting patient confidentiality within public health case reporting and investigation.
 - Mandatory reporting, as well as patient protections within public health entities is in place for many local, state, tribal, and territorial jurisdictions. However, without the ability to ensure patient confidentiality, across public health entities, voluntary population





health information exchange between entities and local, state, tribal, territorial, and federal governments may be limited.

- **Public Health Reporting Criteria, Specifications, and Communications**

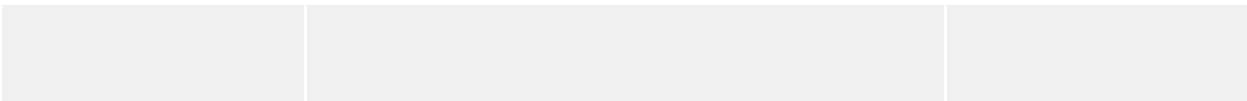
- Today, PH Case and AE detection criteria and reporting specifications may not be defined, consistent, required, or communicated in a reliable or timely manner. Reporting requirements for notifiable conditions vary across local and state jurisdictions. While there have been significant efforts made by CDC and CSTE in the area of identifying and reporting nationally notifiable diseases, there is still not a complete list of agreed upon nationally notifiable disease criteria, trigger data, and reporting requirements.
 - Without agreed upon criteria, trigger data, specifications, and methods of communication, information exchanges between providers and/or across jurisdictional public health departments may be limited.
 - Furthermore, without agreed upon criteria, trigger data, specifications, and procedures for criteria and standards development, the benefits of using capabilities associated with EHRs, LISs, decision support tools, etc will not be realized.

- **Information Interoperability and Exchange**

- Today, PH Case and AE reporting is typically accomplished via the submission of various paper reports which communicate the presence of a notifiable condition, PH Case, or AE. Transmission typically occurs by phone, fax, and in some cases information entry into specialized networked reporting tools operated by public health entities. In many cases feedback loops which inform the reporting entities of the status of their submitted reports do not exist today.
 - The use of inconsistent paper-based forms and non-electronic reporting processes does not encourage active surveillance and in some cases does not adequately support passive surveillance, particularly for mandated public health and safety requirements.
 - The inability to provide feedback may prevent providers and other entities from properly treating and identifying additional possible PH Cases and AEs.
- There is currently a lack of financial, network, technical, and policy infrastructures to enable information exchange that is secure, consistent, appropriate, reliable, and accurate.
 - Consequently, healthcare facilities' (i.e., hospitals, clinics, laboratories, ancillary clinical facilities) may not have the information or the capabilities to electronically collect, process, and transmit pertinent public health data in a



secure and timely manner. This significantly limits the effectiveness of an electronic reporting process.





5.0 Use Case Perspectives

The Public Health Case Reporting Detailed Use Case focuses on the exchange of health information from EHRs to support the reporting of PH Cases and AEs and the management of possible PH Cases. The use case describes aspects of these processes from viewpoints associated with four perspectives. The perspectives included in the use case are intended to indicate roles and functions, rather than organizations or physical locations. Each perspective is described below:

- **Provider**

The provider perspective includes clinicians who may be practicing in various settings, such as: health care delivery organizations, office practices, monitoring entities, research entities, manufacturers/distributors, correctional institutions, schools, veterinarian practices, and public health entities. Providers may utilize information associated with EHRs and other systems and may augment EHR information in order to report PH Cases and AEs. Information gained by providers may be initially reported by or later provided by patients, consumers, or other sources of information.

- **Laboratory**

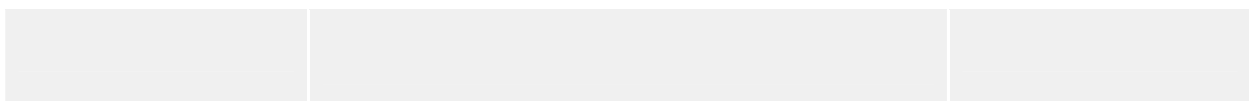
The laboratory perspective includes personnel from various private and public laboratories, such as: clinical, medical, service, anatomical pathology, research, environmental, and veterinarian laboratories, and those laboratories which perform specific public health laboratory functions. The personnel of these laboratories are responsible for receiving, testing, analyzing, resulting, and communicating results. Laboratories may communicate results to the ordering provider for incorporation into EHRs as described in the 2006 EHR-Lab Results Detailed Use Case.

- **Public Health**

The public health perspective includes individuals performing public health functions in various settings such as: infection control within facilities/organizations, independent monitoring entities including manufacturers and researchers, as well as local, state, territorial, tribal, and federal public health organizations. Public health determines reporting criteria, receives reports, performs investigations, determines case status, and performs additional functions in order to communicate appropriate public health information.

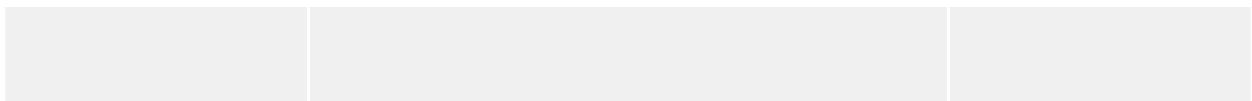
- **Information Exchange**

The information exchange perspective may include a variety of organizations including free-standing or geographic health information exchanges (e.g., Regional Health Information Organizations (RHIOs), integrated care delivery networks, provider organizations, health record banks, public health networks, specialty networks, etc.) These entities may support specific functional capabilities which assist in facilitating health information exchange activities.





These perspectives are the focus of the events detailed in the scenarios described in Section 6.0.





6.0 Use Case Scenarios

The Public Health Case Reporting Detailed Use Case focuses on the exchange of population health information to support the reporting of PH Cases and AEs, investigation, and varying levels of information sharing.

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

- **Reporting from EHRs**

This scenario is focused on identifying and incorporating reporting criteria such as case criteria, including trigger data and events into providers' EHRs for the reporting of possible PH Cases. To support the reporting of AEs, criteria, including available trigger data and reporting specifications could also be incorporated into EHRs. Managing standardized questions and forms within EHRs and the ability to pre-populate existing EHR information as well as augment existing EHR information will assist providers in reporting possible PH Cases and AEs. Specifics regarding criteria and reporting specifications are further addressed in the events and actions in sections 7.0 and 8.0.

- **Public Health Case Investigation and Information Sharing**

This scenario is focused on public health personnel, managing cases, determining the need for further action by requesting and accessing additional information to assist in their investigations, identifying additional at risk individuals or populations and supporting the information needs of appropriate response activities. The information exchanges and analysis conducted during investigations will assist Public Health in determining case status, refining reporting criteria, performing contact tracing, assessing impact, determining management plans, and communicating appropriate public health information.



7.0 Scenario 1: Reporting from EHRs

Figure 7-1. Reporting from EHRs

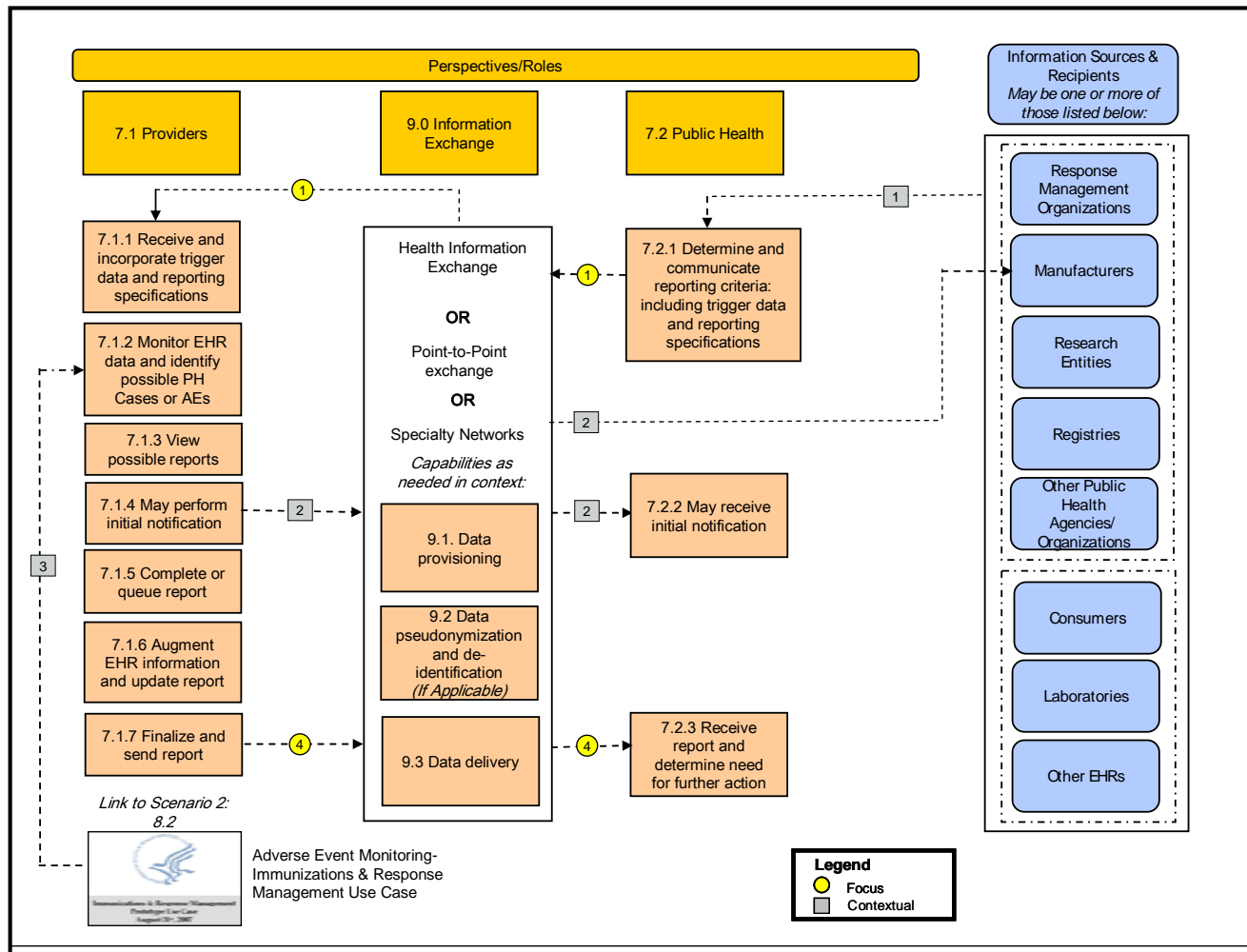




Figure 7-2. Reporting from EHRs – Scenario Flows

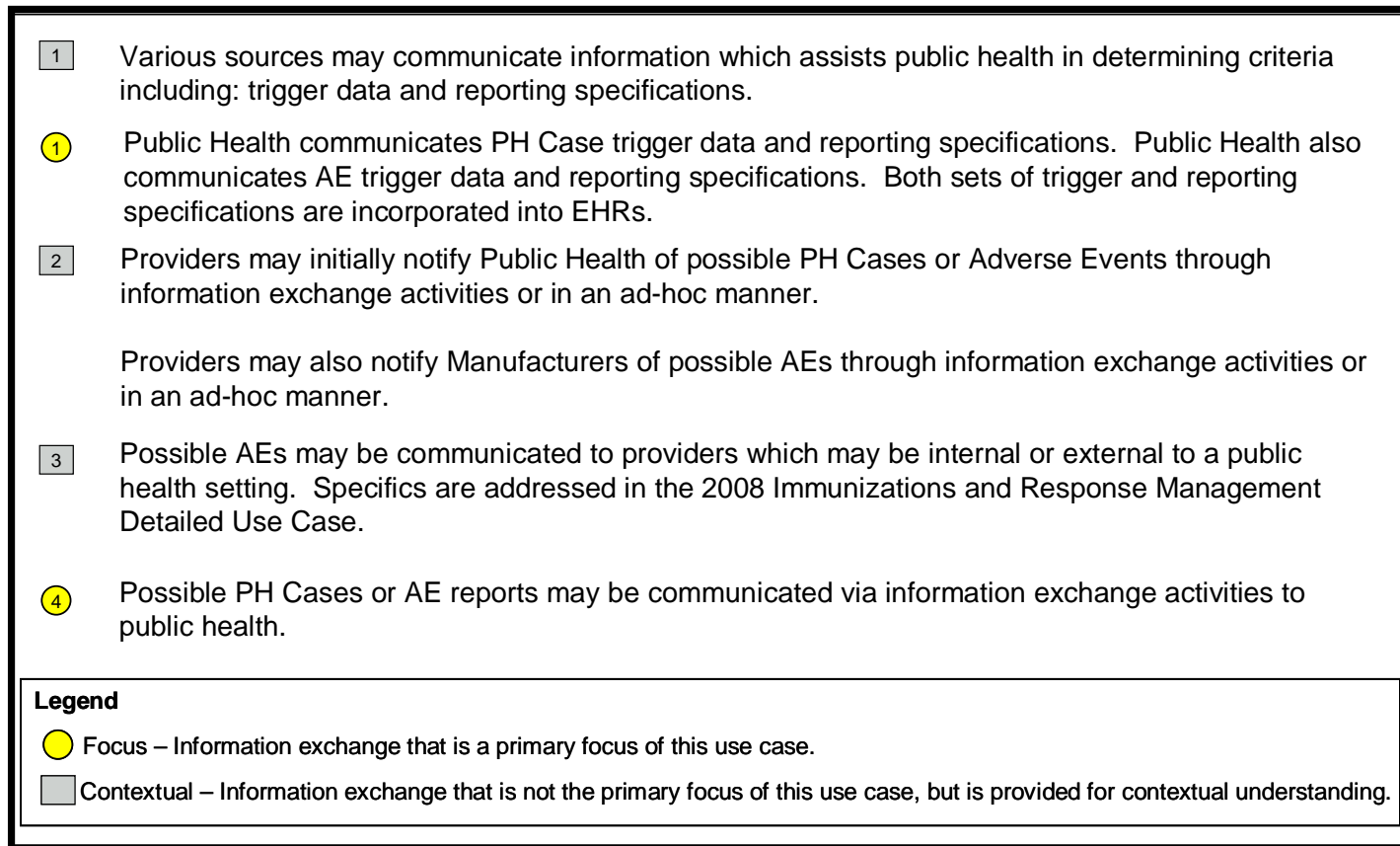
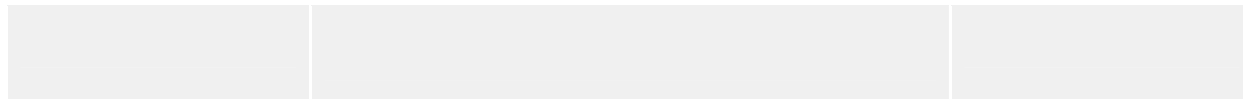




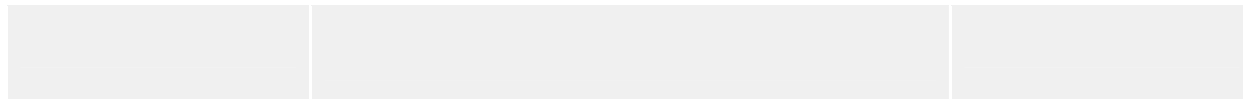
Figure 7.3. Reporting from EHRs – Provider Perspective

Code	Description	Comments
7.1.1	Event: Receive and incorporate trigger data and reporting specifications	Figure 7-1 Focus Flow 1
7.1.1.1	Action: Receive and incorporate reporting criteria for both PH Cases and AEs. Reporting criteria include: trigger data and reporting specifications.	Providers receive reporting criteria for both PH Cases and AEs. Reporting criteria include: trigger data and events and reporting specifications. The methods for incorporating reporting criteria for utilization by EHRs may vary.
7.1.1.2	Action: Incorporate PH trigger data and reporting specifications.	<p>Providers incorporate PH Case trigger data and reporting specifications into their EHRs. Trigger data may be specific information/combinations of information/data elements which may or may not be available via EHRs which may prompt that a possible PH Case may exist. Trigger data may need to be updatable and the frequency may be based on the public health situations. For certain public health conditions such as in the case of an emerging infectious disease, the update may need to be made in real-time. Reporting specifications may include electronic forms which may be processed by EHRs, which contain specific standardized questions and answers. Today, this information may be available in the form of published documents, web pages, etc.</p> <p>The incorporation and use of electronic forms will promote the use of standardized information/data elements which may already be available in EHRs. EHR data can also be augmented by clinicians or clinical support personnel using electronic forms. The use of electronic forms allows reports to be transmitted in their entirety, segments, or smaller pieces. In promoting interoperability, the format and methods of transmission may also include data sets, data elements, etc. Reporting specifications may also include routing requirements which assist in determining where information should be sent, how often, etc.</p>



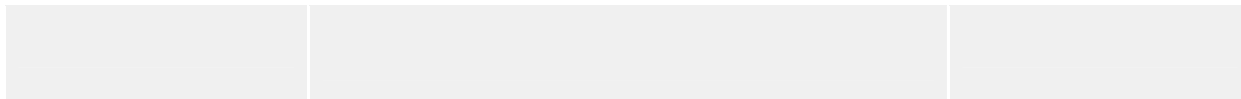


Code	Description	Comments
7.1.1.3	<p>Action: Incorporate AE trigger data and reporting specifications.</p>	<p>Providers incorporate AE trigger data and reporting specifications into their EHRs. Trigger data may be specific information/combinations of information/data elements which may or may not be available via EHRs that may prompt that a possible adverse event has occurred. Trigger data may be determined based upon criteria associated with previously reported AEs or criteria utilized when evaluating events of interest. Criteria may be highly objective but in many cases is highly subjective. Trigger data may include the combination of a confirmed medication administration, an abnormal test result, and an abnormal system assessment. Trigger data may need to be updatable and the frequency may be based on the need to more closely monitor for newly recognized AEs.</p> <p>In order to identify a possible AE, capabilities are needed to relate products to events, therefore; EHRs and or other systems would need to capture data about the administration of products as is specified in the 2008 Immunizations and Response Management Detailed Use Case. As per information from previously documented AEs related to vaccine products may also be trigger data and may be incorporated into EHRs.</p> <p>The incorporation and use of electronic forms may promote the use of standardized information/data elements which may be available in EHRs. EHR data can also be augmented using electronic forms. The use of electronic forms allows reports to be transmitted in their entirety, segments, or smaller pieces. In promoting interoperability, the format and methods of transmission may also include data sets, data elements, etc. Reporting specifications may also include routing requirements which assist in determining where information should be sent, how often, etc.</p>
7.1.2	<p>Event: Monitor EHR data and identify possible PH Cases or AEs</p>	<p>Figure 7-1, Contextual Flow 3</p>



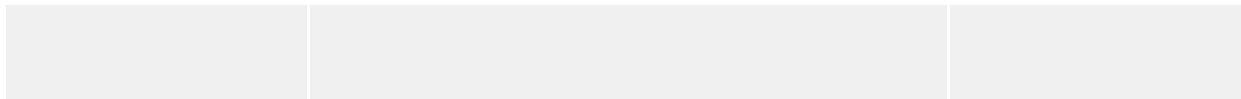


Code	Description	Comments
7.1.2.1	<p>Action: Monitor EHR data for information matching inclusion/exclusion factors.</p>	<p>Based on the incorporated reporting criteria which include: Trigger data and reporting specifications, EHRs may monitor for possible PH Cases or AEs. Data which may be monitored may include data associated with the following: chief complaint/reason for visit, medical history, medication history, assessment, orders, tests, results, diagnosis, etc. The inclusion of lab results in an EHR is addressed in the 2006 EHR – Lab Results Use Case.</p> <p>Continuous monitoring is also required for some public health conditions such as BT agents or other disease which require immediate reporting. Aspects of continuous monitoring are also specified in the 2006 Biosurveillance Use Case. EHR monitoring over a specified period of time is also useful in the case of a public health emergency involving a disease or specific medical product or products.</p>
7.1.2.2	<p>Action: Identify, view, evaluate, and triage possible PH Cases and AEs.</p>	<p>The provider may view and evaluate the possible PH Cases and AEs which have been identified. There may be various mechanisms which alert the provider to these possible PH Cases and AEs. Mechanisms may include alerts, reports, inbox entries, etc. There may be processes, personnel, and/or technologies in place which assist with triage and prioritization.</p> <p>Those possible PH Cases and AEs which are identified may be presented as inputs into an electronic reporting form. The form may be pre-populated with relevant demographic, clinical, and/or other information from EHRs. This information may assist the provider in determining whether or not the event requires notification to Public Health entities.</p>
7.1.3	<p>Event: View possible reports</p>	
7.1.3.1	<p>Action: Select possible PH Cases or AEs.</p>	<p>Conditions which require immediate reporting may bypass this action, however, the provider may opt to view additional information regarding a possible PH Case or AE which has been identified. The EHR may offer various mechanisms and processes, for selecting and viewing information which has been associated with a possible PH Case or AE.</p>



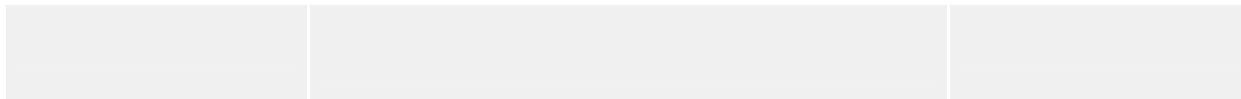


Code	Description	Comments
7.1.3.2	Action: View report for selected possible PH Cases or AEs.	The provider may view the details regarding a possible PH Case or AE utilizing a pre-populated form or report. The form may have capabilities to draw upon information/data elements associated with a possible PH Case or AE to pre-populate various fields. Depending on the previously incorporated reporting specifications (7.1.1), forms may be pre-populated with relevant demographic, clinical, and/or other information available within the EHR.
7.1.4	Event: May perform initial notification	Figure 7,1, Contextual Flow 2
7.1.4.1	Action: (If Applicable): Communicate initial notification to Public Health.	<p>The Provider may supply Public Health with an initial notification of a possible PH Case or AE. Performing an initial notification prior to the completion of PH Case or AE Report is not always necessary. The methods and procedures which govern the practice of initial notification may be defined by the receiving public health entity. These procedures may be included in the reporting specifications and may be supported by varying degrees through the use of decision support.</p> <p>Today these communications have a tendency to be very limited in information and can occur via fax, phone, and in some cases, electronic exchanges.</p>
7.1.4.2	Action: (If Applicable) Communicate initial notification to Manufacturers.	<p>The Provider may supply Manufacturers with an initial notification or inquiry based on a possible AE. During the notification/inquiry, Providers may request information regarding previously reported AEs, prevalence, drug/vaccine, specifics, etc.</p> <p>Today these communications have a tendency to be very limited in information and can occur via fax, phone, and in some cases, electronic exchanges.</p>
7.1.5	Event: Complete and/or queue report	





Code	Description	Comments
7.1.5.1	<p>Action: Automatically send PH Case Reports or AE Reports which meet all reporting criteria. Reporting criteria include: trigger data and reporting specifications.</p>	<p>The Provider may choose to have PH Case Reports and AE Reports which meet all reporting criteria sent automatically to Public Health. Since the identification of possible AEs normally requires clinical judgment, this action may not be appropriate for AEs. Therefore, 7.1.5.2 and 7.1.5.3 may be more suitable when addressing the reporting of AEs.</p> <p>The implementation of such an automated process may present various risks but might also be less disruptive to a provider's workflow. Specifics regarding implementation and policy will need to be addressed by the appropriate governing entities.</p>
7.1.5.2	<p>Action: Send PH Case Reports or AE Reports which meet all reporting criteria to a review or approval queue. Reporting criteria include: trigger data and reporting specifications.</p>	<p>The Provider may choose to queue reports. Reports may be queued for various reasons including the need to be completed by support personnel, reviewed, validated, or confirmed.</p>
7.1.5.3	<p>Action: Send PH Case Reports or AE Reports which do not meet all reporting criteria to a completion queue. Reporting criteria include: trigger data and reporting specifications.</p>	<p>The Provider may choose to queue reports. Reports may be queued for various reasons including the need to be completed by support personnel updated, completed, corrected, etc.</p>
7.1.6	<p>Event: Augment EHR Information and update report</p>	
7.1.6.1	<p>Action: Information related to possible PH Cases or AEs that is not available through an EHR is manually gathered.</p>	<p>Some information that is needed to meet public health reporting criteria may not be available in the EHR. Today, outstanding information required to complete PH Case reporting criteria and AE reporting criteria may be manually abstracted by the clinician and/or individuals supporting the provider from other non-electronic sources including: patient or consumer reports, paper-based records, information acquired during interviews, etc.</p>





Code	Description	Comments
7.1.6.2	Action: Information related to possible PH Cases or AEs that is not available through an EHR may be gained through electronic information exchanges.	Some information that is needed to meet Public Health reporting criteria may not be available in the EHR. Outstanding information needed to complete PH Case reporting criteria and AE reporting criteria may be gained through information exchange activities. Information availability may be dependent on permissions and processes established by governing entities and may be limited to public health reportable data.
7.1.6.3	Action: Update PH Case Report or AE Report.	Using data available in the EHR, as well as augmenting EHR data, the PH Case Report or AE Report is updated.
7.1.7	Event: Finalize and Send Report	Figure 7-1, Focus Flow 4
7.1.7.1	Action: Confirm PH Case Report or AE Report.	Based on the incorporated reporting criteria, which include trigger data and reporting specifications, the provider may confirm the PH Case Report or AE Report. Based on concepts discussed in the 2007 Consumer Empowerment: Consumer Access to Clinical Information Detailed Use Case, the provider may have the opportunity to identify the source of EHR data, as well as the source of the augmented EHR data.
7.1.7.2	Action: Transmit confirmed PH Case Reports or AE Reports to public health.	PH Case Reports and AE Reports are transmitted to public health. Based on reporting specifications, the information sent to Public Health may be transmitted in various formats.

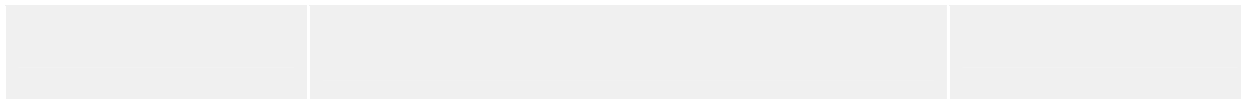
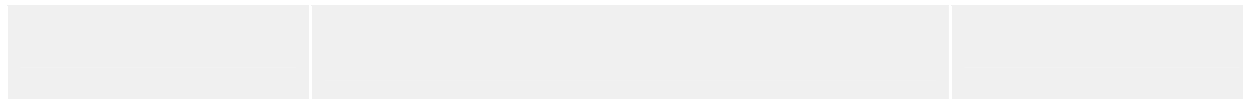




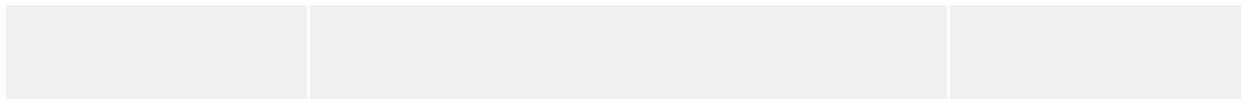
Figure 7.4. Reporting from EHRs – Public Health Perspective

Code	Description	Comments
7.2.1	Event: Determine and communicate reporting criteria including: trigger data and reporting specifications	Figure 7.1, Contextual Flow 1, Focus Flow 1
7.2.1.1	Action: Determine PH Case Criteria.	<p>Various entities including response management organizations, manufacturers, research entities, registries, and other public health agencies/organizations may provide information assisting public health in the refinement or development of pre-determined case criteria. The refinement or development of case criteria may be assisted by referencing formal case definitions.</p> <p>PH Case criteria may assist in identifying notifiable conditions/diseases and events which may be reported to Public Health. These diseases and events may be categorized as communicable/infectious or non-communicable, which can be identified by signs, symptoms, lab results, etc., and may be indicative of these reportable conditions or events. Public health case criteria may differ among public health entities. Therefore, reporting outside of the types of public health cases listed above may be considered in future efforts.</p>



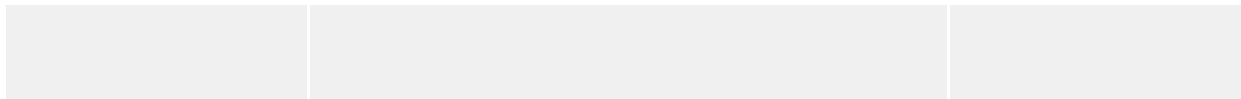


Code	Description	Comments
7.2.1.2	<p>Action: Determine PH trigger data and reporting specifications.</p>	<p>Through the use of case criteria, Public Health may work with other entities to determine PH trigger data. Trigger data may be specific information/combinations of information/data elements which may or may not be available via EHRs indicating that a possible PH Case may exist.</p> <p>Public Health also determines PH case reporting specifications. Reporting specifications may include electronic forms which contain specific standardized questions and answers. Today, this information may be available in the form of published documents, web pages, etc.</p> <p>The incorporation and use of electronic forms may promote the use of standardized information/data elements which may be available in EHRs. EHR data can also be augmented using electronic forms. The use of electronic forms allows reports to be transmitted in their entirety, segments, or smaller pieces. In promoting interoperability, the format and methods of transmission may also include data sets, data elements, etc. Reporting specifications may also include routing requirements which assist in determining where information should be sent, how often, etc.</p>



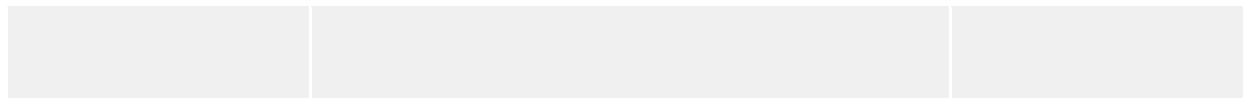


Code	Description	Comments
7.2.1.3	<p>Action: Determine AE trigger data and reporting specifications.</p>	<p>Public Health may work with other entities to determine AE trigger data. Trigger data may be specific information/events/data elements which may or may not be available via EHRs. Trigger data may be determined based upon criteria associated with previously reported AEs or criteria utilized when evaluating events of interest. Criteria may be highly objective but in many cases is highly subjective. Trigger data may include the combination of a confirmed medication administration, an abnormal test result, and an abnormal system assessment. Information from previously documented AEs related to vaccine products may also be trigger data and may be incorporated into EHRs.</p> <p>Public Health also determines AE reporting specifications. Reporting specifications may include electronic forms which contain specific standardized questions and answers.</p> <p>The incorporation and use of electronic forms may promote the use of standardized information/data elements which may be available in EHRs. EHR data can also be augmented using electronic forms. The use of electronic forms allows reports to be transmitted in their entirety, segments, or smaller pieces. In promoting interoperability, the format and methods of transmission may also include data sets, data elements, etc. Reporting specifications may also include routing requirements which assist in determining where information should be sent, how often, etc.</p>
7.2.1.4	<p>Action: Communicate reporting criteria for both PH Cases and AEs. Reporting criteria include: trigger data and reporting specifications.</p>	<p>Reporting criteria for both PH Cases and AEs is communicated to Providers. Reporting criteria include: trigger data and reporting specifications. The methods and formats used for communicating reporting criteria may vary and may include specific: data elements, messages, algorithms, electronic forms, etc.</p>
7.2.2	<p>Event: May receive initial notification</p>	<p>Figure 7-1, Contextual Flow 2</p>





Code	Description	Comments
7.2.2.1	<p>Action: (If Applicable): Receive initial notification from Providers.</p>	<p>Public Health may receive an initial notification of a possible PH Case or AE from providers. The methods and procedures which govern the practice of initial notification may be defined by the receiving public health entity. These procedures may be included in the reporting specifications which Public Health communicates to providers.</p> <p>Today, these communications have a tendency to be very limited in information and can occur via fax, phone, and in some cases electronic exchanges.</p>
7.2.2.2	<p>Action: (If Applicable): Respond to initial notifications requiring immediate attention.</p>	<p>In some cases, upon the initial notification of a possible PH Case or AE, Public Health may be required to respond immediately, prior to the receipt of a full report as described in 7.2.3.2. Thresholds and response procedures vary among public health entities and must be managed accordingly.</p>
7.2.3	<p>Event: Receive report and determine need for further action.</p>	<p>Figure 7-1, Focus Flow 4</p>
7.2.3.1	<p>Action: Public Health receives and evaluates reports.</p>	<p>Public Health receives reports and evaluates for compliance and completeness in relation to reporting criteria. Public Health may then triage and prioritize reports.</p>
7.2.3.2	<p>Action: Public Health determines need for further action.</p>	<p>Based upon the outcomes of the initial evaluation, Public Health may be required to respond immediately. Thresholds and response procedures vary amongst public health entities and must be managed accordingly.</p> <p>Based on current information, Public Health may determine the need for further action. Furthermore, Public Health may consider requesting additional information in order to assist in classifying the possible PH Case Reports or AE Reports in order to determine appropriate resources, attention, and specific next steps.</p>





8.0 Scenario 2: Public Health Case Investigation & Information Sharing

Figure 8-1. Public Health Case Investigation & Information Sharing

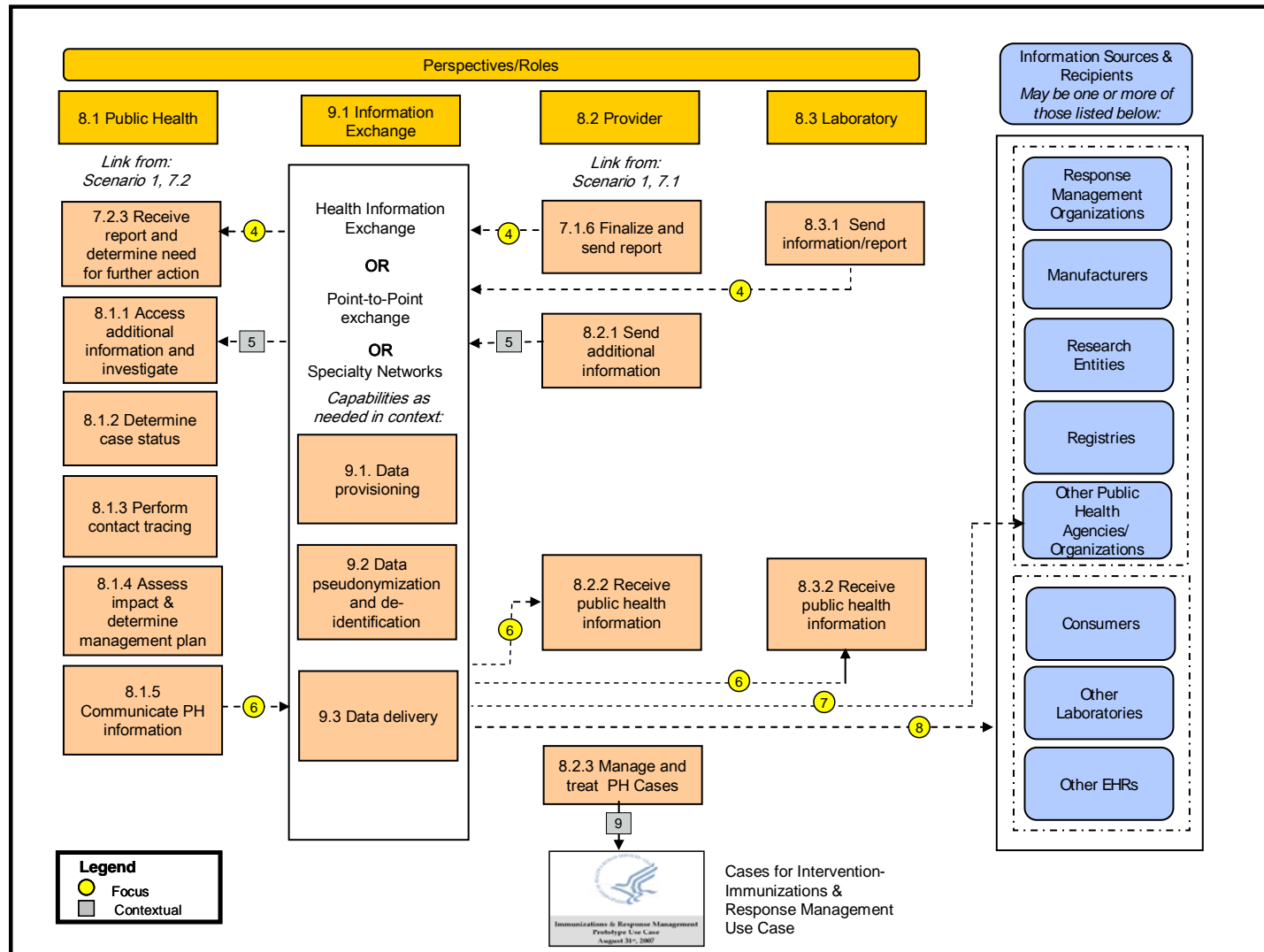




Figure 8-2. Public Health Case Investigation & Information Sharing

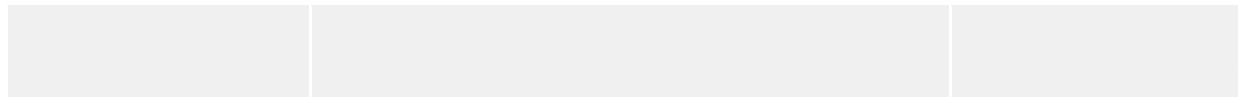
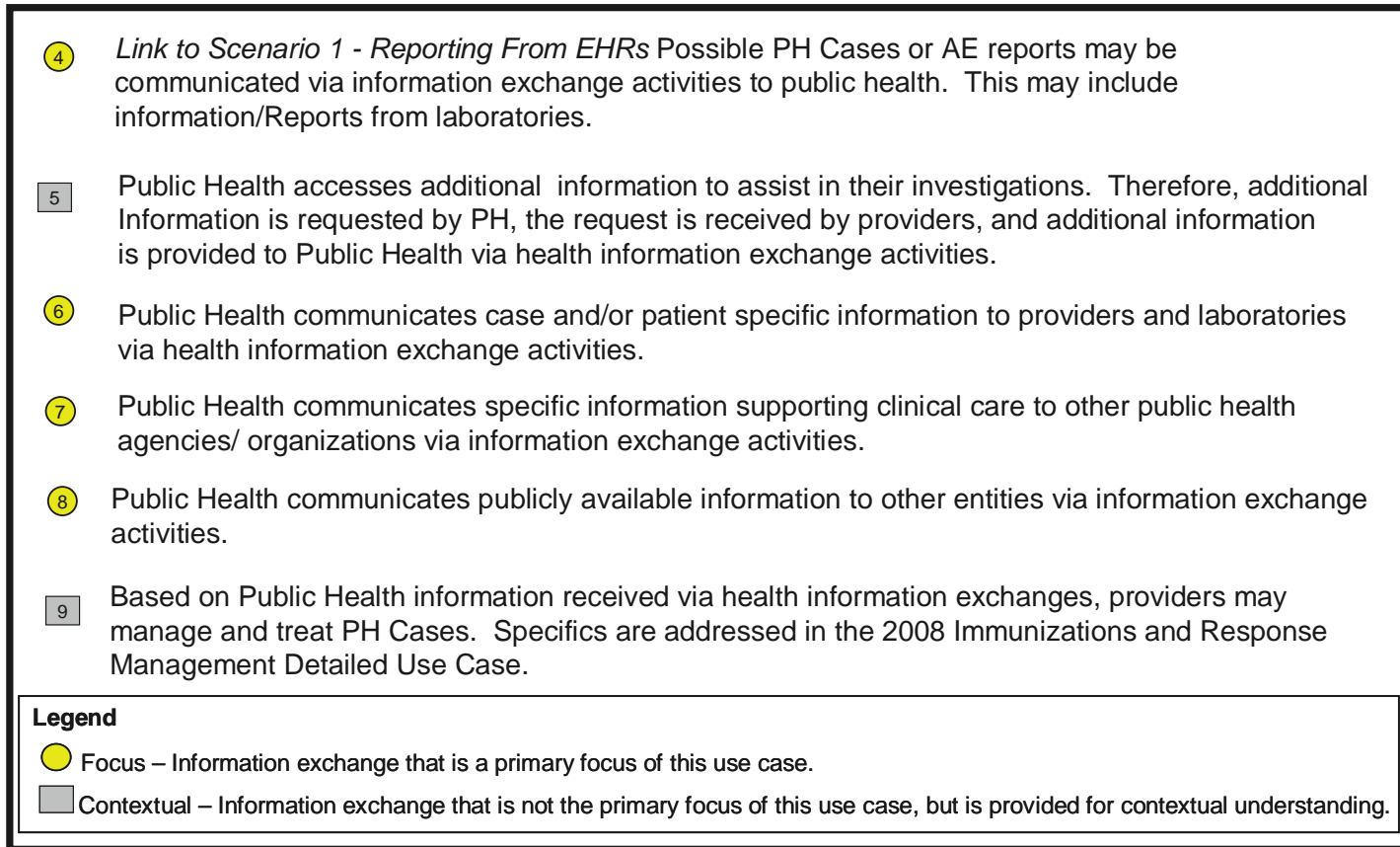
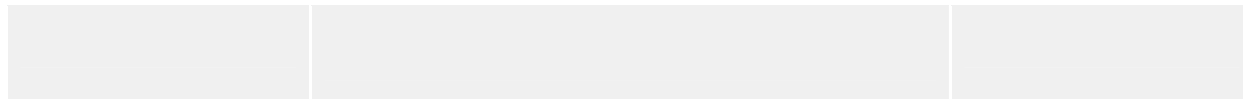




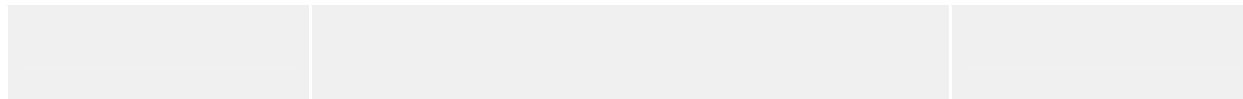
Figure 8.3 Public Health Case Investigation & Information Sharing – Public Health Perspective

Code	Description	Comments
7.2.3	Event: Receive report and determine need for further action	Link to Scenario 1, Figure 8-1, Flow 4
8.1.1	Event: Access additional information and investigate	Figure 8-1, Flow 5
8.1.1.1	Action: Request information from submitters of reports/information.	In order to perform investigations, public health may request additional information directly from the submitters of reports/information, including providers. Today, this request may be facilitated in an <u>ad hoc</u> manner by way of a phone call or fax.
8.1.1.1a	Alternate Action: Request information by utilizing information exchanges. Public Health may query for existing public health reportable data.	Public Health may also consider utilizing information exchange activities for the purposes of obtaining appropriately authorized additional information. The request may be for any type of information, however, there may be potential to standardize the electronic format in which any appropriate information is requested by Public Health. Information availability will be dependent on permissions and processes established for the identification of appropriate public health reportable data.
8.1.1.2	Action: Receive additional information to assist in investigation activities.	<p>In response to Public Health's requests, providers or other sources may make information accessible to Public Health. Although not the focus of this use case, assuming there are standing agreements, other sources of information may also include other public health agencies/organizations.</p> <p>For the purposes of investigation, additional information requested and received by Public Health may assist in classifying and prioritizing the possible PH Cases in order to determine appropriate resources, attention, etc.</p>



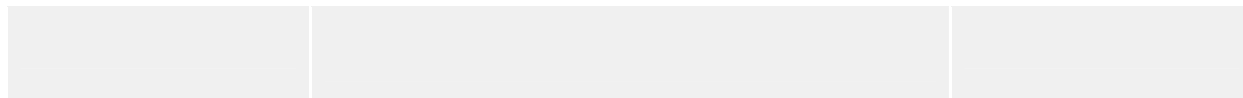


Code	Description	Comments
8.1.1.3	Action: Perform investigation activities.	<p>During the investigation, PH Case investigators utilize information such as: subject data, health event, clinical data, conveyance information, case/event investigation, exposure, initial monitoring, follow-up, and treatment information.</p> <p>For possible PH Cases onset, symptoms, risk factors, laboratory results, procedures, diagnosis, health status, counts, trends, patterns, etc. are investigated. Activities such as site visits, environmental testing, and other investigation techniques may also be utilized in accessing additional information.</p>
8.1.2	Event: Determine Case Status	
8.1.2.1	Action: Evaluate and classify PH Cases.	Through the investigation process, applicable information will be evaluated by Public Health investigators and PH Cases will be classified.
8.1.2.2	Action: Determine status of PH Case reports.	Through the classification process, the status of PH Case reports will be determined. Critical activities such as refining a pre-determined Case Definition, or developing a Case Definition and executing a testing hypothesis may occur during this process. Case criteria and reporting specifications may also be updated as a result of this process and therefore may be an input into 7.2.1.
8.1.3	Event: Perform Contact Tracing	
8.1.3.1	Action: Identify those who may have come in contact.	While performing PH Case management, determining case status and exposure source, activities associated with contact tracing may be performed. One aspect of contact tracing, is determining other individuals or populations who may have been exposed or are at risk.



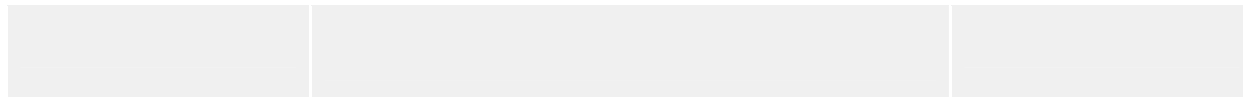


Code	Description	Comments
8.1.3.2	Action: Identify additional possible PH Cases.	<p>Through contact tracing, additional possible exposures or possible PH Cases may be identified and managed. Reporting of these possible PH Cases is addressed in 7.1.</p> <p>Confirming the status of reported PH Cases and identifying additional cases will assist Public Health in determining official case counts.</p>



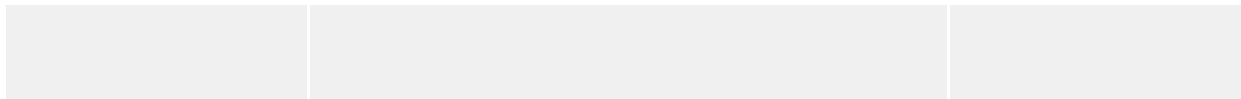


Code	Description	Comments
8.1.4	Event: Assess Impact and Determine Management Plan.	
8.1.4.1	Action: Assess and understand impact.	Understanding agents of urgent importance, case definitions, exposures, and spread will assist Public Health in assessing the impact and determining a management activities and plans.
8.1.4.2	Action: Determine management plan.	<p>The development of the management plan may be completed in collaboration with other entities including: response management organizations, manufacturers, research entities, laboratories, including environmental or animal testing facilities (depending on the nature of the event), other public health agencies, etc. The management plan may include: processes for monitoring and follow-up, the administration of countermeasures including prophylaxis and treatment, as well as communications.</p> <p>The processes for carrying out the appropriate clinical interventions are described separately in events 7.1.2 through 7.1.6 in the 2008 Immunizations and Response Management Detailed Use Case.</p>
8.1.5	Event: Communicate public health information	Figure 8-1, Flows 7, 8, 9





Code	Description	Comments
8.1.5.1	<p>Action: Communicate case or patient specific information.</p>	<p>Following Public Health’s investigation, specific information may be sent to reporting entities which relate to PH Cases which may have been previously reported. The information which Public Health communicates to these reporting entities may be: sensitive, identifiable, specific, need to be exchanged via secure methods, and candidate for standardization. Additional specifics regarding this communication can be found in Section 10.0 – Data Set Considerations and Appendix B.</p> <p>The intent of this process step and communication is to provide direct feedback to reporting entities which may assist them in identifying additional possible PH Cases and determining best methods for managing and treating their patients.</p>
8.1.5.2	<p>Action: Communicate specific clinically relevant Public Health information.</p>	<p>Following Public Health’s investigation, specific clinically relevant public health information may be made available to authorized entities. These entities include those who are granted access to situational awareness alerts, case counts, and information that would be considered sensitive because of “small cell sizes” – i.e. it is not directly identified data, but if not managed properly individuals might be identified via other publicly available information or the specific context. Communications may occur in a secure method. This information may be specific in nature and has the potential to be standardized. Additional specifics regarding this communication can be found in Section 10.0 – Data Set Considerations and Appendix B.</p> <p>Information which is communicated directly between various public health agencies/organizations would align with appropriate regulations and standing agreements.</p>

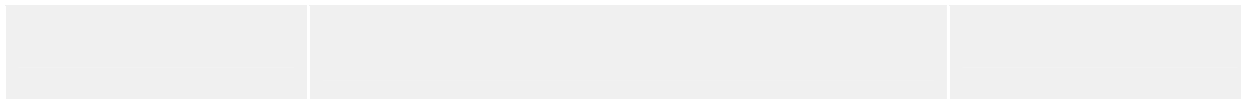




Code	Description	Comments
8.1.5.3	Action: Communicate publicly available information.	<p>Following Public Health’s investigation, general public health information may be made available which is, not identifiable and of value to clinicians and / or the public . This information is non-sensitive, de-identified, and may be web accessible. The security, specificity, and ability for this information to be standardized may be limited. Additional specifics regarding this communication can be found in Section 10.0 – Data Set Considerations and Appendix B.</p> <p>This information may be communicated in various forms, including through information exchange activities, web portals, etc. Access to this information may offer views into community trends.</p>

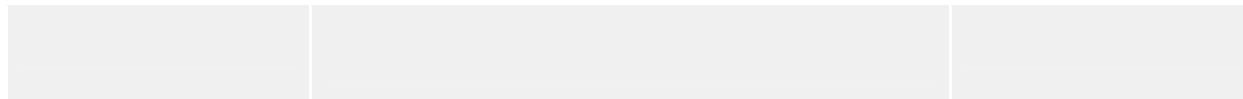
Figure 8.4. Public Health Case Investigation & Information Sharing – Provider Perspective

Code	Description	Comments
7.1.6	Event: Finalize and send report	Link to Scenario 1, Figure 8-1, Focus Flow 4
8.2.1	Event: Send Additional Information	Figure 8-1, Flow 5
8.2.1.1	Action: Receive request for additional information from Public Health.	Providers receive requests from Public Health for additional information. Providers may utilize their EHRs, other systems, or other mechanisms to obtain the information requested by Public Health.
8.2.1.2	Action: Send information to public health related to previously reported PH Cases and/or other information.	Based upon requests from Public Health for additional information, providers may supply appropriate information to Public Health related to the PH Cases that they have reported and/or other information which may assist public health in performing their investigations.
8.2.2	Event: Receive Public Health Information	Figure 8-1, Flows 6, 7, 8





Code	Description	Comments
8.2.2.1	Action: Receive case or patient specific information.	<p>Providers may receive specific information which relates to PH Cases which may have been previously reported. This information may be: sensitive, identifiable, specific, standardized and exchanged via secure methods.</p> <p>By receiving this information providers may gain case or patient specific information which may assist them in identifying additional possible PH Cases and determining best methods for managing and treating their patients.</p>
8.2.2.2	Action: Receive specific clinically relevant Public Health information	<p>Specific entities, including providers, may receive sensitive, de-identified, and/or partially de-identified clinically relevant Public Health information. These entities include those who are granted access to situational awareness alerts, case counts, and information that may be sensitive due to small numbers of possible individuals. Secure communication methods may be needed for this information. This information may be specific in nature and has some potential to be standardized.</p> <p>Information which is directly received by other public health agencies/organizations would conform to appropriate regulations and standing agreements.</p>
8.2.2.3	Action: Receive Publicly Available Information.	<p>Providers, as well as the general public, may have access to publicly available information. This information may be non-sensitive, de-identified, and web accessible. The security, specificity, and ability for the information to be standardized may be, at times, limited.</p> <p>The information may be communicated in various forms, including through health information exchange activities, web portals, etc. Access to this information may offer views into community trends.</p>
8.2.3	Event: Manage and treat PH Cases	Figure 8-1, Flow 9

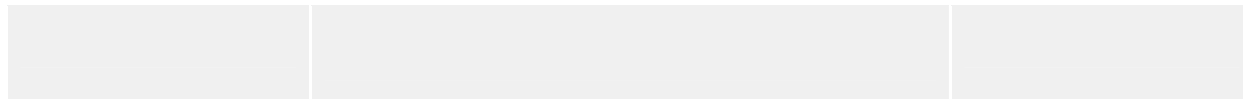




Code	Description	Comments
8.2.3.1	Action: Identify and manage additional possible PH Cases.	Using information communicated by Public Health, providers may have the ability to identify other possible PH Cases. The process for identifying possible PH Cases is discussed in 7.1.2. Information communicated by Public Health may also assist providers in managing PH Cases.
8.2.3.1	Action: Treat confirmed and additional possible PH Cases.	The processes for carrying out the appropriate clinical interventions are described separately in events 7.1.2 through 7.1.6 in the 2008 Immunizations and Response Management Detailed Use Case.

Figure 8.5. Public Health Case Investigation & Information Sharing – Laboratory Perspective

Code	Description	Comments
8.3.1	Event: Send information/report	Figure 8-1, Flow 4
8.3.1.1	Action: Incorporate and utilize Public Health reporting specifications.	Although not depicted in figure 7-1, similar to the events and actions discussed in 7.1.1, laboratories may receive and incorporate reporting criteria into their LISs or other systems. Reporting requirements/criteria may include: trigger data and reporting specifications. Laboratories may utilize this information to identify results which may be indicative of PH Cases.
8.3.1.2	Action: Identify and send information/report.	Depending on processes established by governing entities, Laboratories may send information/reports which may be indicative of PH Cases and meet reporting criteria to Public Health. As discussed in the 2006 EHR – Laboratory Resulting Detailed Use Case, results may also be sent to the ordering provider’s EHR.





Code	Description	Comments
8.3.1.2a	Alternate Action: Send information related to previously reported PH Cases and/or other information may be sent to Public Health.	There may be circumstances where Public Health requests additional information to support PH Case investigations. Based upon requests from Public Health for additional information, Laboratories may supply Public Health with information related to notifiable conditions/diseases that they have reported and/or other information which may assist Public Health in performing their investigations.
8.3.2	Event: Receive Public Health Information	Figure 8-1, Flows 7, 8, 9
8.3.2.1	Action: Receive specimen status information or patient specific information.	<p>There may be circumstances where laboratories may receive specific information which relates to notifiable conditions/diseases which may have been previously reported. This information may be: sensitive, identifiable, specific, and exchanged via secure methods.</p> <p>By receiving this information laboratories may gain specimen status information or patient specific information which may assist them analyzing their specimens and reporting results back to ordering providers.</p>
8.3.2.1a	Alternate Action: Receive specific clinically relevant public health information or publicly available information.	In some settings laboratories may receive additional relevant public health information. Laboratories that are granted access to situational awareness alerts, case counts, and information necessary to support their operations.

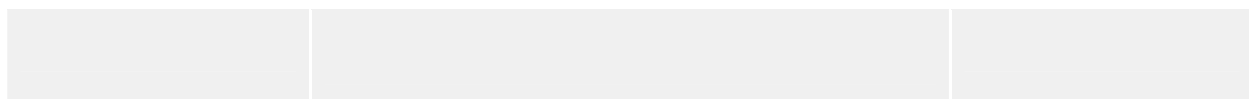


9.0 Information Exchange

This section highlights selected information exchange capabilities which enable the scenarios described in this use case. These are functional capabilities which may be provided by a variety of organizations including free-standing RHIOs, integrated care delivery organizations, provider organizations, health record banks, public health networks, specialty networks, and others providing these capabilities.

Figure 9-1. Public Health Case Reporting Information Exchange Capabilities

Code	Capability	Comments
9.1	Data provisioning – including support for secondary uses – data provisioning and distribution of data transmission parameters	Capability to distribute pre-determined data reporting requirements, logical algorithms, vocabularies, guidelines or similar information to target systems so that these systems can implement the associated capabilities. For purposes of this use case, target systems may include EHRs, LISs, and possibly those systems involved in information exchange. In some cases, the data transmission parameters include information reporting requirements (e.g. filtering criteria, data to report, vocabularies to use, reporting formats and destinations). For example, reporting requirements for notifiable diseases could be distributed electronically to systems capable of receiving and implementing them to evaluate data being processed through routine care activities.
9.2	Data pseudonymization and re-identification as well as HIPAA de-identification	Capability to pseudonymize and re-link data, as well as capability to de-identify data per HIPAA requirements, which may be a requirement for specific types of public health case reports.
9.3	Data delivery – including secure data delivery, data receipt and confirmation of delivery to EHRs, personally controlled health records, other systems and networks	Capability to securely deliver data to the intended recipient, confirm delivery, including the ability to route data based on message content if required. For example, routing or distributing public health case reports or adverse event reports may be based on information contained within the report or associated messages.



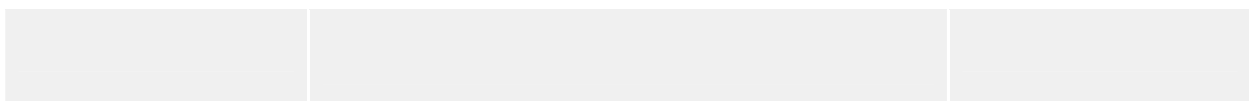


While not described in this section, other capabilities which support information exchange includes data integrity and non-repudiation checking; subject and user identity arbitration with like identities during information exchanges; access logging and error handling for data access and exchange; consumer review of disclosure and access logs; and routing consumer requests to correct data.

Geographic Health Information Exchange (HIE): The functional capability to exchange health information among systems within a defined network, as well as, between networks in order to facilitate the exchange of health information of individuals or populations. These functional capabilities may be provided fully or partially by a variety of organizations including free-standing or geographic health information exchanges (e.g. RHIOs), integrated care delivery networks, provider organizations, health record banks, public health networks, specialty networks, and others providing these capabilities.

Specialty Network: May provide all, or a portion of the capabilities needed to accomplish the activities involved in the exchange of health information. Specialty networks may focus on the exchange of specific types of health information, may focus on specific patient populations, may focus on the capabilities needed to support specific types of healthcare activities, or may perform a combination of information exchange activities and other services.

Point-to-Point Exchange: For the purposes of this use case, point-to-point exchange includes direct interactions between two systems which do not involve intermediary information exchange functions to route and deliver the data. Representative architectures could include point-to-point messaging, service-oriented-architectures, or information exchange among participants using a common application platform.





10.0 Public Health Case Reporting Dataset Considerations

This use case acknowledges the variations in requirements for reporting across local, state, tribal, and territorial boundaries as well as voluntary versus mandatory requirements. Although mandated requirements for PH Case reporting at the federal level do not currently exist, CSTE and CDC have made preliminary recommendations which are:

- Based upon a minimum set of common data elements for electronic messaging used to report a notifiable condition from a healthcare provider [and health information exchange entities] to (and across) health jurisdiction(s),
- May include disease-specific data elements. Initially, this is likely to be limited to four conditions (Anthrax, Hepatitis B, Tuberculosis, and Tularemia). Later, through the development of a process for the identification of disease-specific data elements for all conditions, the data elements may expand.

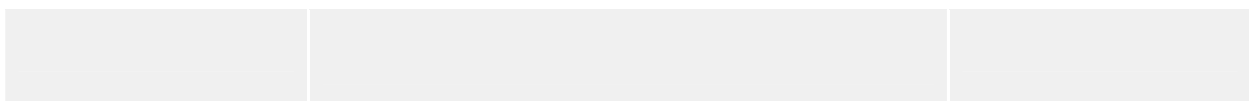
The federal government also currently receives PH Case information which has been voluntarily reported. For reporting of AEs, both mandatory, as designated by the statutes and regulations of the FDA, and voluntary reporting also exists.

This use case is focused on leveraging current processes and information in standardizing reporting criteria which includes trigger data and reporting specifications. Therefore, the following may be considered when identifying data sets and data requiring standardization: trigger events and data, EHR data and EHR augmented data which may be used to populate electronic reporting forms, questions and answers which compose electronic reporting forms, and PH Case reports and AE reports. Metadata which supports queuing functions may also be considered for standardization.

The evaluation of trigger data and reporting specifications is expected to be a complimentary process involving various efforts within the industry. The analysis is expected to address the incorporation of reporting criteria and the utilization of information from EHRs to assist in the reporting of PH Cases and AEs. This analysis may be demonstrated in future products offered by AHIC which compliment this use case.

In the interim, the following non-exhaustive information categories which may be present in EHRs or augmented, along with limited examples, which address the scenarios in this use case have been included:

- Information which may be utilized in both PH Case and AE reporting:
 - Demographic Information
 - Health History & Status Information
 - Clinical Information



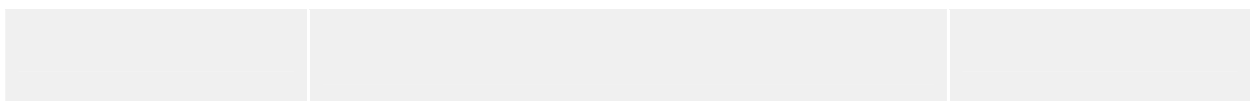


- Specimen/Laboratory Information
- Information which may be utilized in PH Case reporting:
 - Condition/Disease Information
 - Contact/Exposure Information
- Information which may be utilized in AE reporting:
 - Event Information
 - Product Information
 - Manufacturer Information

This use case offers another opportunity for standardization which is described initially in Scenario 2 and then later in Appendix B. Scenario 2: Public Health Investigation and Information Sharing describes various levels of bi-directional communication which may assist public health in communicating with clinicians. Appendix B describes three levels of bi-directional communication which are:

- Case or patient specific information
- Clinically relevant, specific public health information
- Publicly available information

In addition, Appendix B discusses characteristics of the information including: security, specificity, and, the potential to be standardized.





Appendix A: Glossary

These items are included to clarify the intent of this use case. They should not be interpreted as approved terms or definitions but considered as contextual descriptions. There are parallel activities underway to develop specific terminology based on consensus throughout the industry.

Adverse Event: An adverse event is a change in health or "side-effect" that occurs in a person during a clinical trial or other health-related circumstance. Adverse events may be related to and declared regarding drugs, vaccinations, devices, procedures, patient care, and other health events.

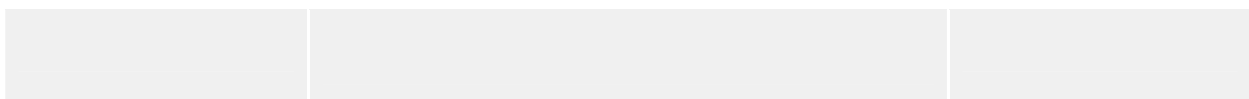
AHIC: American Health Information Community; a federal advisory body chartered in 2005, serving to make recommendations to the Secretary of the U.S. Department of Health and Human Services regarding the development and adoption of health information technology.

Case Criteria/Case Report Criteria: The criteria for detection and reporting are based on determinants of a recognizable event that may have a potential impact on the diagnosis of a possible public health case. Criteria may include but are not limited to: personal/genetic characteristics, reactions and medication intakes, general medical history of a patient [event/issue or case, tracing, results] or possible causes of possible public health cases.

Case Definition: The definition contains criteria for case classification (confirmed, probably, or suspect), which categorizes clinical, laboratory, and epidemiologic information of a (health group diagnosis) that can be reviewed and assessed by the PH perspective; recognized as being either a cluster or an individual focus bringing to attention specific criteria for various topics that may include disease outbreak, pharmaceuticals, biological, epidemiology, etc.

Case Investigation: Surveillance, prevention, or control taken on any potential infectious disease, outbreak, event, agent, or specimen dealing with a particular disease or threat that is present in order to gather relevant information about complications associated with a possible public health case.

CDC: Centers for Disease Control and Prevention; a federal agency within the Department of Health and Human Services that serves to enhance and promote the health and quality of life by preventing and controlling disease, injury and disability. Working with states and other partners, CDC provides a system of health surveillance to monitor and prevent disease outbreaks (including bioterrorism), implements disease prevention strategies, and maintains national health statistics. CDC also provides for immunization services, workplace safety, and environmental disease prevention. CDC also guards against international disease transmission.





Clinicians: Healthcare providers with patient care responsibilities, including physicians, advanced practice nurses, physician assistants, nurses, psychologists, pharmacists, and other licensed and credentialed personnel involved in treating patients.

CMS: Centers for Medicare & Medicaid Services; a federal agency within the Department of Health and Human Services that administers Medicare, Medicaid, and the State Children's Health Insurance Program through portability standards.

Consumers: Members of the public that include patients as well as caregivers, patient advocates, surrogates, family members, and other parties who may be acting for, or in support of, a patient receiving or potentially receiving healthcare services.

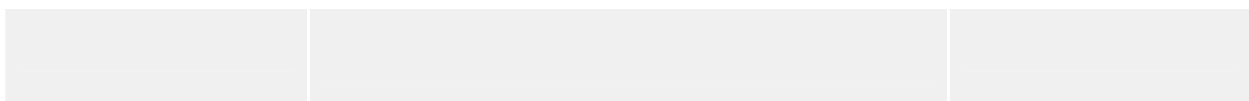
Contact Tracing: Identification, diagnosis, and monitoring of persons who may have come into contact with an infected subject or person as an attempt to interrupt transmissions of diseases, infections and/or outbreaks.

Decision Support: An activity that enables improved analysis and conclusions based on related information, recent research, algorithms, or other resources. In a clinical environment, decision support can help clinicians make more informed care decisions based on these resources. Clinical decision support is a related activity with specific components such as best practice guidelines, medication contraindication information, and access to recent research.

Department of Health and Human Services (HHS): The United States federal agency responsible for protecting the health of the nation and providing essential human services with the assistance of its operating divisions that include: Administration for Children and Families (ACF), Administration on Aging (AOA), Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Services (IHS), National Institutes of Health (NIH), Program Support Center (PSC), and Substance Abuse and Mental Health Services Administration (SAMHSA).

Electronic Health Record (EHR): An electronic, cumulative record of information on an individual across more than one health care setting that is collected, managed, and consulted by professionals involved in the individual's health and care. This EHR description encompasses similar information maintained on patients within a single care setting (a.k.a., Electronic Medical Record (EMR)).

Electronic Health Record (EHR) System Suppliers: Organizations which provide specific EHR solutions to clinicians and patients such as software applications and software services. These suppliers may include developers, providers, resellers, operators, and others who may provide these or similar capabilities.





FDA: Food and Drug Administration; a federal agency within the Department of Health and Human Services responsible for the safety regulation of foods, dietary supplements, vaccines, drugs, medical devices, veterinary products, biological medical products, blood products, and cosmetics.

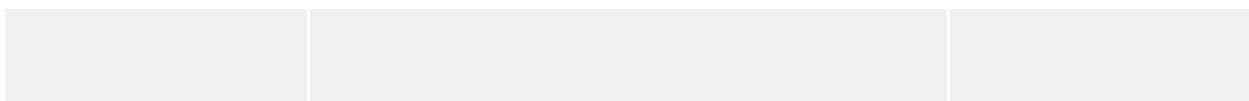
Geographic Health Information Exchange/ Regional Health Information

Organizations: A multi-stakeholder entity, which may be a free-standing organization (e.g., hospital, healthcare system, partnership organization) that supports health information exchange and enables the movement of health-related data within state, local, territorial, tribal, or jurisdictional participant groups. Activities supporting health information exchanges may also be provided by entities that are separate from geographic health information exchanges/Regional Health Information Organizations including integrated delivery networks, health record banks, and others.

Government Agencies: Federal, state, local, territorial, or tribal departments within the United States government responsible for the oversight and administration of a specific function; government agencies may include: Department of Health and Human Services (DHHS), Food & Drug Administration (FDA), Drug Enforcement Agency (DEA), Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), Department of Defense (DoD), Department of Veterans Affairs (VA), Indian Health Services (IHS), Department of Homeland Security (DHS), non-Federal public health departments/agencies, Agency for Healthcare Research and Quality (AHRQ), and Department of Agriculture (USDA).

Health Information Exchange (HIE): The electronic movement of health-related data and information among organizations according to specific standards, protocols, and other agreed criteria. These functional capabilities may be provided fully or partially by a variety of organizations including free-standing or geographic health information exchanges (e.g., Regional Health Information Organizations (RHIOs)), integrated care delivery networks, provider organizations, health record banks, public health networks, specialty networks, and others supporting these capabilities. This term may also be used to describe the specific organizations that provide these capabilities such as RHIOs and Health Information Exchange Organizations.

Healthcare Entities: Organizations that are engaged in or support the delivery of healthcare. These organizations could include hospitals, ambulatory clinics, long-term care facilities, community-based healthcare organizations, employers/occupational health programs, school health programs, dental clinics, psychology clinics, care delivery organizations, pharmacies, home health agencies, hospice care providers, and other healthcare facilities.





Healthcare Payors: Insurers, including health plans, self-insured employer plans, and third party administrators, providing healthcare benefits to enrolled members and reimbursing provider organizations.

HITSP: The American National Standards Institute (ANSI) Healthcare Information Technology Standards Panel; a body created in 2005 in an effort to promote interoperability and harmonization of healthcare information technology through standards that would serve as a cooperative partnership between the public and private sectors.

Infection Control: The discipline of preventing the spread of infections within a healthcare setting; a sub-discipline of epidemiology practiced within the confines of a health care delivery system.

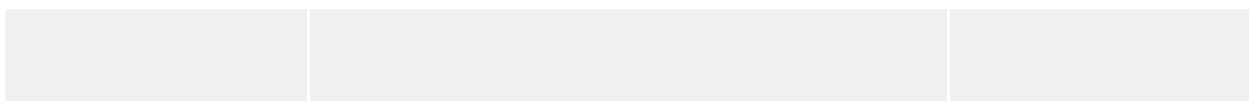
Laboratories: A laboratory (often abbreviated lab) is a setting where specimens are sent for testing and analysis, are resultated, and then results communicated back to the requestor. The types of laboratories may include anatomical pathology, clinical/medical, environmental, and veterinarian, and may be both private and/or public.

Laboratory Information System: A laboratory information system is a class of software which handles receiving, processing, transmitting, and storing information generated by medical laboratory processes. These systems often must interface with instruments and other information systems such as hospital information systems. An LIS is a highly configurable application which is customized to facilitate a wide variety of laboratory workflow models.

Laboratory Information System (LIS) Suppliers: Organizations which provide specific laboratory information system solutions. A laboratory information system is a class of software which handles receiving, processing, transmitting, and storing information generated by medical laboratory processes. These systems often must interface with instruments and other information systems such as hospital information systems. An LIS is a highly configurable application which is customized to facilitate a wide variety of laboratory workflow models.

Manufacturers/Distributors: Entities which may be involved in the following activities: research, development, testing, production, storage, distribution, surveillance, and communication regarding medical/healthcare products at the community, regional, and national level such as pharmaceutical manufacturers, drug wholesalers, medical device suppliers, etc.

Notifiable Condition: A disease or medical condition already recognized by the law that must be reported to the government for surveillance of potential threats and risks.





ONC: Office of the National Coordinator for Health Information Technology; serves as the Secretary's principal advisor on the development, application, and use of health information technology in an effort to improve the quality, safety, and efficiency of the nation's health through the development of an interoperable harmonized health information infrastructure.

Outbreak: A classification used in epidemiology to describe any group of people, region, country, or pandemic infected with a disease.

Patients: Members of the public who receive healthcare services.

Personal Health Record (PHR) System Suppliers: Organizations which provide specific PHR solutions to clinicians and patients such as software applications and software services. These suppliers may include developers, providers, resellers, operators, and others who may provide these or similar capabilities.

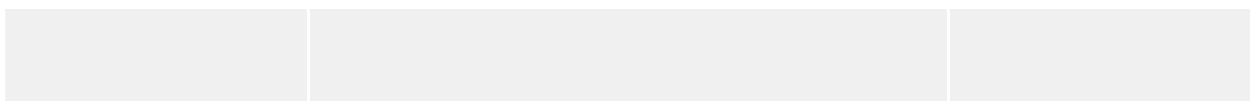
Point-to-Point Exchange: Point-to-point exchange includes direct interactions between two systems which do not involve intermediary information exchange functions to route and deliver the data. Representative architectures could include point-to-point messaging, service-oriented-architectures, or information exchange among participants using a common application platform.

Prophylaxis: Any medical or public health procedure, including vaccines, that aims to prevent, rather than treat or cure, disease; vaccines are an example used before the development of any illnesses to prevent infections.

Providers: The healthcare clinicians within healthcare delivery organizations with direct patient interaction in the delivery of care, including physicians, nurses, psychologists, and other clinicians. This can also refer to healthcare delivery organizations.

Public Health Agencies/Organizations (federal/state/local/territorial/tribal): Federal, state, local, territorial, and tribal government organizations and clinical care personnel that exist to help protect and improve the health of their respective constituents.

Public Health Case: A Public Health Case occurs when a possible or confirmed notifiable disease/condition has been detected. In some circumstances, the disease/condition may not be pre-determined and, therefore, may not initially fall into the notifiable category. Requirements for reporting diseases/conditions may vary in local, state, and federal jurisdictions based on applicable laws or regulations.





Public Health Knowledge Providers: Associations of public health individuals/organizations who provide technical advice and assistance to state and local health agencies in a broad range of areas including: occupational health, infectious diseases, immunization, environmental health, chronic diseases, injury control, and maternal and child health. These associations may include Council of State and Territorial Epidemiologists (CSTE), Association of Public Health Laboratories (APHL), and Association of State and Territorial Health Officials (ASTHO).

Registries: Organized systems for the collection, storage, retrieval, analysis and dissemination of information on individual persons to support health needs. This also includes government agencies and professional associations which define, develop, and support registries.

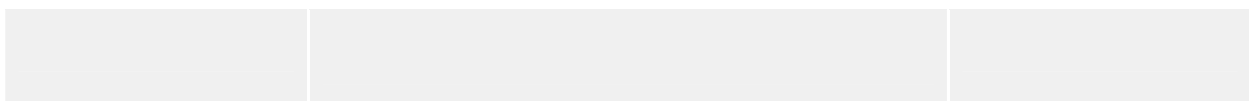
Reporting Entities: Organizations and/or individual clinicians that report possible and/or confirmed (within their organization) public health cases or adverse events to Public Health.

Reporting Criteria: *May include: trigger data and reporting specifications.* Specifics regarding PH Case reporting criteria are discussed further in 7.1.1.2., 7.2.1.1, and 7.2.1.2. Specifics regarding AE reporting criteria are discussed further in 7.1.1.3 and 7.2.1.3.

Research Entities: Organizations that are engaged in or support healthcare research including entities performing research, clinical trials, or other research activities (e.g., National Institutes of Health, academic centers).

Response Management Organizations: Organizations that are responsible for emergency evaluation and response to natural disasters (e.g., public health and emergency management organizations (Federal Emergency Management Agency, Red Cross, etc.)).

Vaccines: Substances or group of substances aimed at causing the immune system to break down a bacterium or virus in order to prevent a potential infection or disease.





Appendix B: Bi-Directional Communication: Information Sharing with Clinicians

Another dataset consideration addressed in the scenarios described in this use case concerns bi-directional information sharing between public health entities and clinicians as described below.

Figure B-1

Bi-Directional Communication: Sharing Public Health Information with Clinicians					
Sharing Categories	Data Characteristics	Security	Specificity	Ease of Standardizing	Scenario Flow Reference
Case or Patient Specific i.e - Status on a submitted PH Case Report/Patient is communicated	Sensitive Data	High	High	High	Data Exchanged During Scenario 2, Scenario Flow 6
	Identifiable Data				
Clinically Relevant Specific PH Information i.e. - Alerts, Situational Awareness, Case counts with small cell sizes	Sensitive Data	High/ Medium	Medium	Medium	Data Exchanged During Scenario 2, Scenario Flow 7
	De-Identified Data or Partially De-Identified Data				
Publicly Available i.e. - Trends across Communities (larger cell size)	Non Sensitive	Limited	Limited	Limited to Medium (Mostly Metada)	Data Exchanged During Scenario 2, Scenario Flow 8
	De-Identified Data				
	Web Accessible				

