

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



**Public Health Case Reporting
Draft Detailed Use Case
January 18, 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) are now being developed into the 2008 Use Cases which will be processed in the national HIT agenda activities in 2008.

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

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

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



This Draft 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 draft 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 Provides 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 8.0, Information Exchange, describes the role of information exchange in the use case at a high level.
- Section 9.0, Dataset Considerations, identifies specific information opportunities relevant to this use case that may support future standardization and harmonization activities.
- Appendix A, the Glossary, provides draft descriptions of key concepts and terms contained in the draft detailed use case.

Following receipt of feedback from interested stakeholders, ONC will develop a final detailed use case.



2.0 Introduction and Scope

In January 2007, AHIC approved a recommendation to develop a use case addressing population health as it applies to Public Health Case (PH Case) Reporting and some aspects of Adverse Event (AE) Reporting, including AEs associated with post-market medications and vaccines. Specifically, the use case focuses on the utilization of Electronic Health Records (EHRs), Laboratory Information Systems (LISs), and other systems in the identification and reporting of possible PH Cases and AEs.

Population health can be enhanced through electronic public health case and adverse event reporting to local, state, tribal, territorial, and federal public health organizations, and other entities performing public health functions. Population health can be advanced by the integration of public health systems with EHRs, LISs and electronic communication between providers and public health entities as well as the advancement of capabilities for possible and confirmed case and adverse event management. Leveraging electronic clinical information to address public health data needs can also support providers in their decision making. Specifically, providers may benefit from having access to decision support that is informed by current population health data and having the capabilities to be alerted to the status in their communities of notifiable conditions, possible AEs and other population health concerns.

Providers and public health will benefit from having the ability to electronically exchange PH Case and AE information among clinical EHR systems and Public Health systems.

- Public Health will benefit from having the ability to integrate, pre-determined case criteria, and automated case reporting mechanisms into EHR systems and LISs.
- Providers and public health will benefit from having the ability to automate the process to prompt a provider of the need to report a possible and/or confirmed PH Case and/or AE, based on the presence of clinical data in the EHR, LIS, or potentially other sources of information. These capabilities support the automation of the reporting process from providers to the public health entities.
- Providers will benefit from population-level information being integrated with decision support.

One of the goals of AHIC is to establish a pathway, based on common data and technical standards, that facilitates and incorporates interoperable, predetermined case criteria and event reporting specifications into EHRs and/or other tools to support the defining, reporting and management of cases and adverse events of public health importance. This use case was developed to support the various stakeholders who are active in the development and implementation of EHRs and also those facilitating health information exchange activities, including those engaged in activities related to standards, interoperability, harmonization, architecture, policy development, and certification. These stakeholders include The Centers for Disease Control (CDC) and the Council of State and Territorial Epidemiologists (CSTE)



which were asked by AHIC to collaboratively : 1.) Identify 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), 2.) identify a list of disease specific data elements for initial conditions including: (Anthrax, Hepatitis B, Tuberculosis, and Tularemia), and 3.) develop and document the process for the future identification of disease specific data elements for all conditions.

This Draft Detailed Public Health Case Reporting Use Case focuses on the exchange of population health information between laboratories, providers, and public health and describes the following scenario:

- **Reporting, Investigation, and Information Sharing.** Pre-determined PH Case criteria and AE reporting specifications are utilized by providers and laboratories in the reporting of possible and/or confirmed PH Cases/AEs. As appropriate, Public Health may request and receive various types of information when performing their investigations including: PH Case/AE reports and information, additional information pertaining to i.e. – subject data, health event, clinical data, methods of conveyance, exposure information, initial monitoring, follow-up, and management/treatment information.
- This information is utilized by public health to confirm public health cases and adverse events, to develop and refine case definitions or AE detection or reporting criteria, and to estimate and manage the resulting impact. Information exchanges among public health entities as well as provider-to-provider communication may also occur, assisting public health and providers in better understanding the public health environment.

There are associations between the scenarios in this use case and the scenarios in the 2008 Draft Detailed Immunizations and Response Management 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 local, state, tribal, and territorial criteria and reporting requirements, as well as the absence of requirements for reporting notifiable conditions to the federal level. While acknowledging the issues and obstacles associated with these suppositions, this use case recognizes current efforts including those being focused on by CSTE, CDC, etc. and the advancement of these and other initiatives, which promote the development of longer-term efforts.



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.
Decision Support	An activity that enables improved analysis in 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.
Geographic Health Information Exchange/ Regional Health Information Organization	A multi-stakeholder entity, which may be a free-standing organization i.e. – hospitals, healthcare systems, partnership organizations, etc. that supports health information exchange which enable the movement of health-related data within state, local, territorial, or jurisdictional participant groups. Activities supporting health information exchanges may also be provided by entities which are separate from geographic health information exchanges/Regional Health Information Organizations and may include: integrated delivery networks, health data banks, etc.
Government Agencies	Local, state, territorial or federal departments within the United States government responsible for the oversight and administration of a specific function; government agencies that could participate in public health case reporting and management may include: Food & Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), Department of Defense (DoD), and Department of Homeland Security (DHS).
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, school health, dental clinics, psychology clinics, care delivery organizations, 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.



Stakeholder	Contextual Description
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 clinical/medical, environmental, veterinarian and may be both private and/or public.
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.
Patients	Members of the public who receive healthcare services that include medical attention, care, or treatment.
Providers	The healthcare clinicians within healthcare delivery organizations with direct patient interaction in the delivery of care, including physicians, nurses, and other clinicians. This can also refer to healthcare delivery organizations.
Public Health Agencies/Organizations (local/state/territorial/tribal federal)	Local, state, territorial, tribal and federal government organizations and clinical care personnel that exist to help protect and improve the health of their respective constituents.
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.
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 that report possible and/or confirmed (within their organization) cases/events to public health.
Research Entities	Organizations that are engaged in or support healthcare research that include those entities performing clinical trials (e.g., National Institutes of Health, , academic centers, etc.).



Stakeholder	Contextual Description
Response Management Organizations	Organizations that are responsible for the emergency evaluation and response to natural disasters. (e.g., Federal Emergency Management Agency (FEMA), Red Cross, etc.).



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 will be cross-cutting and therefore shown in all use cases, while others are unique to this specific use case.

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

- **Confidentiality, privacy, and security:**

Consumers may require privacy controls for personal health information that govern how patient data is accessed, viewed, and communicated. Privacy controls and the means of restricting data access, which are available for paper-based records, are not currently available for electronic records.

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 exchange 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 and implementation 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.

Electronic PH Case, AE reporting, and population health information exchange can provide valuable information to the public health and care providers. This information may be provided more readily than available today. Some of the issues raised and challenges regarding case reporting and population health information exchange include:

- **Confidentiality, privacy, and security:**

- There is currently no consistent approach for supporting patient confidentiality specifically in regards to the exchange of information related to public health case reporting and investigation.
 - Mandatory reporting is in place for many local, state, tribal, and territorial jurisdictions. However, without the ability to ensure patient confidentiality, 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, nor communicated in a reliable manner.



Reporting requirements for notifiable conditions, may be defined, but 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 no agreement upon the nationally notifiable disease criteria and reporting requirements.

- Without the agreed upon criteria, specifications, and methods of communication, information exchanges between providers and/or cross jurisdictional public health departments may be limited.
 - Furthermore, without the agreed upon criteria, specifications, and procedures for criteria and standards development; there will be little benefit in using capabilities associated with EHRs, LISs, decision support tools, etc.
- **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 specific networked reporting tools provided by public health entities. In many cases feedback loops which inform the reporting entities of the results 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 mandated public health and safety requirements.
 - The inability to provide feedback may prevent providers and other entities from properly treating and identifying additional possible public health cases and adverse events.
 - 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 Draft Detailed Use Case focuses on the exchange of population health information to support the reporting of possible and confirmed PH Cases and AEs. The use case will describe public health case reporting from the viewpoint associated with three 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, research entities, manufacturers/distributors, correctional institutions, schools, public health entities, etc. Providers may report possible PH Cases and/or AEs to public health entities as well as those cases which they have confirmed within their setting(s) to public health for investigation, conclusive confirmation, management, etc.

- **Laboratory**

The laboratory perspective may include personnel from various private and public laboratories, such as clinical, medical, service, research, environmental, veterinarian, and those laboratories which perform specific public health functions. The personnel of these laboratories are responsible for receiving, testing, analyzing, resulting, and communicating results. The appropriate laboratory personnel also report results that may be indicative of Notifiable Conditions or results which suggest possible AEs to providers and/or public health.

- **Public Health**

The public health perspective includes individuals at the facility/organization level as well as local, state, territorial, tribal and federal level public health organizations with responsibilities to maintain information control. Public health receives PH Cases and AEs which have been categorized as being a “possible” or “confirmed” threat/case by reporting entities (that includes providers and laboratories), completes a thorough investigation to gather and collect detailed information and then provides this information to the providers, laboratories and/or other public health entities.

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 Draft Detailed Use Case focuses on the exchange of population health information to support the reporting of possible and confirmed PH Cases and AEs, investigation, management and to a limited degree public health communication which is described in the following scenario.

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

- **Reporting, Investigation, and Information Sharing**

This scenario is focused on incorporating pre-determined PH Case, Notifiable Condition/Disease, and AE criteria, as well as applicable reporting specifications into EHRs, LISs, and other tools which are utilized by providers and laboratories in the reporting of possible and/or confirmed PH Cases/AEs to public health. Following the report to public health, an investigation is performed. This scenario includes public health requesting and receiving additional information to perform their investigation, confirm and/or refute PH Case/AE Reports, assess impact, determine a management plan, and communicate PH information.



7.0 Scenario 1: Reporting, Investigation, and Information Sharing

Figure 7-1. Reporting, Investigation, and Information Sharing

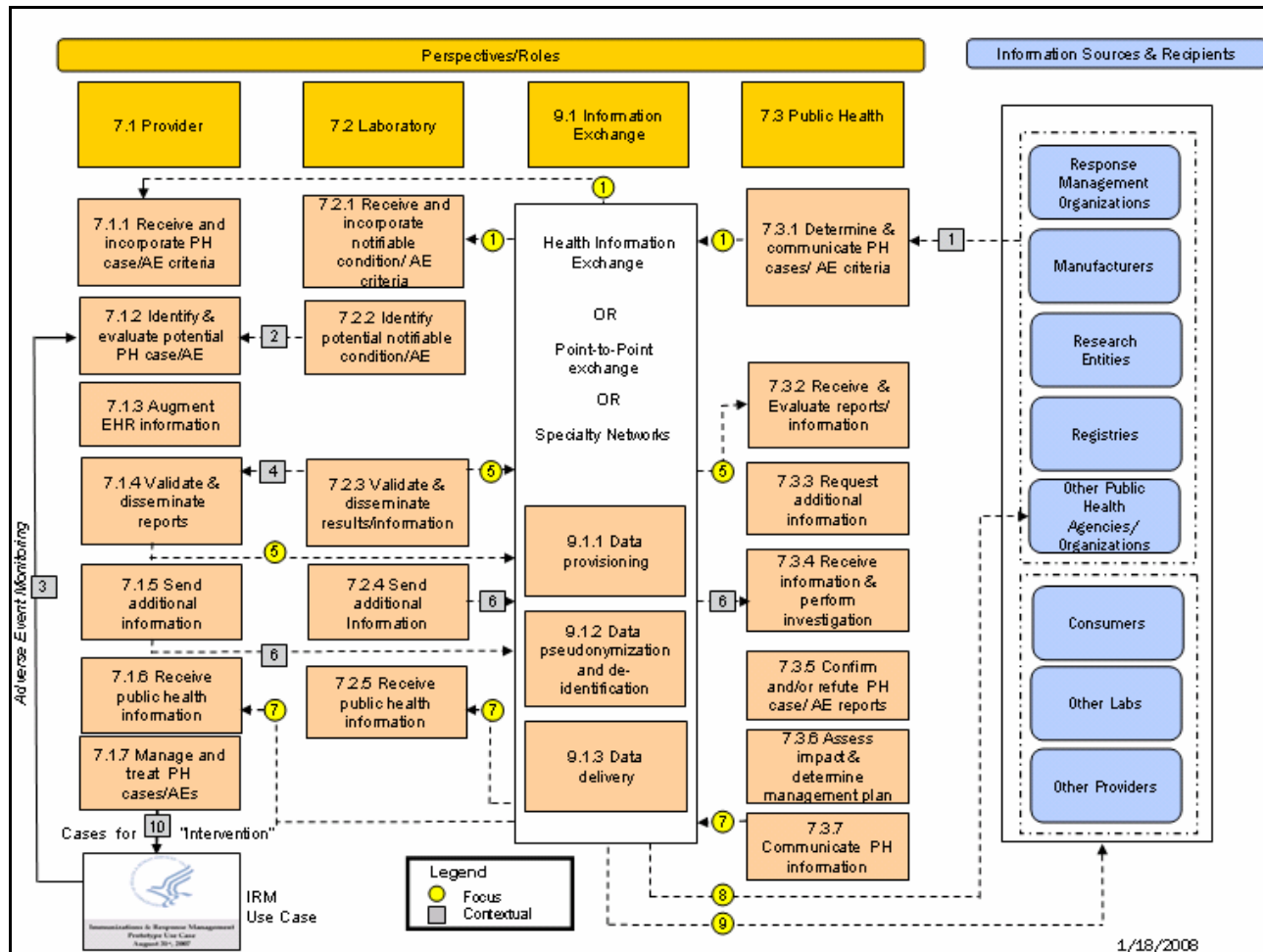




Figure 7-2. Reporting, Investigation, & Information Sharing – Scenario Flows

- 1 Various sources may communicate information which assists public health in determining criteria.
- 1 Public Health communicates PH Case and AE Criteria through information exchanges which are incorporated and utilized by Providers and Laboratories.
- 2 Laboratories may communicate preliminary results in an ad-hoc manner. This information may be indicative of possible notifiable conditions, PH Cases, and/or AEs.
- 3 Potential AEs may be communicated to providers which may be internal or external to a public health setting. Specifics are addressed in the 2008 Draft Detailed Immunization and Response Management Use Case.
- 4 Laboratories may communicate results/notifiable conditions which have been reported to public health on an ad-hoc manner with the ordering providers.
- 5 Possible PH Cases/AEs may be communicated via information exchanges to public health.
- 6 Responding to requests from public health, additional information may be transmitted through information exchanges to assist public health in their investigations.
- 7 Submitters of PH Case/AE reports may receive specific information from public health via information exchanges. Information may include: specifics or general information in regards to submitted reports, including counts, trends, locations, alerts and/or notifications.
- 8 Other Public Health Agencies/Organizations may receive focused information from public health via information exchanges. Information may include: focused information in regards to submitted reports, including counts, trends, locations, alerts and/or notifications. Other Public Health Agencies may also have the ability to request/view information which meets regulatory and other previous agreements.
- 9 Other recipients may receive general information from public health via information exchanges. Information may include: general information including alerts, notifications, etc.
- 10 Cases requiring the administration of treatment may be communicated to and addressed in the 2008 Draft Detailed Immunizations & Response Management Use Case.



Figure 7-3. Reporting, Investigation, & Information Sharing - Provider Perspective

Code	Description	Comments
7.1.1	Event: Receive and incorporate PH Case / AE Criteria	
7.1.1.1	Action: Receive the PH Case/AE Criteria from public health.	<p>Detailed PH Case/AE Criteria are communicated to the provider. The information which is provided by public health may also include: notifiable conditions/diseases, AE detection information, and reporting requirements/specifications. The information which public health provides may be based upon a pre-determined case definition and/or updated case definition.</p> <p>Today this information may be available in the form of published documents, web pages, or downloadable reference documents. For the purposes of electronic PH Case/AE reporting, criteria information may come in the form of: discrete information which may assist in triggering reporting alerts, standardized electronic forms with both questions/templates, and response data etc.</p>
7.1.1.2	Action: Incorporate the PH Case/AE Criteria into EHRs.	Electronic PH Case and AE Criteria are incorporated in a consistent way into EHRs, which may assist in determining possible PH Cases/AEs.
7.1.2	Event: Identify and evaluate potential PH Case/ AEs	
7.1.2.1	Action: Filter EHR data for information matching inclusion/exclusion factors.	Based on the defined PH Case/AE Criteria which have been incorporated into EHRs, clinical and other information is evaluated for possible occurrences of PH Cases/AEs. In the circumstance where there is a possibility that an AE may have occurred, varying levels and types of decision support may be utilized. For example, patient information regarding routine vaccinations and abnormal neurological assessments may be paired to assist in detecting possible AEs for provider consideration.



Code	Description	Comments
7.1.2.2	Action: View and evaluate potential PH Cases/AEs which have been identified.	<p>The provider may view and evaluate the possible PH Cases/AEs which have been identified. Those possible PH Cases/AEs which are identified may be presented as inputs into a template/form. The form may be pre-populated with relevant demographic, clinical, and/or other information from the EHR. This information may assist the provider in their evaluation and reporting.</p> <p>Furthermore, the provider may receive ad-hoc information from laboratories communicating that during the processing of specimens, a result indicative of a potential Notifiable Condition has been identified. This type of communication may occur through phone, fax, electronic exchange, etc.</p>
7.1.3	Event: Augment EHR Information	
7.1.3.1	Action: Information related to a possible PH Case/AE that is not available through an EHR is manually gathered.	Some information that is needed to complete a report to public health may not be available in the EHR. Today, outstanding information required to complete the reporting requirements for the PH Case/AE that is not present in the EHR, may be manually abstracted by the clinician and/or individuals supporting the provider from other non-electronic sources including: paper based records, acquired during interviews, etc.
7.1.3.1a	Alternate Action: Information related to a possible PH Case/AE that is not available through an EHR may be gained through electronic information exchanges.	<p>Some information that is needed to complete a report to public health may not be available in the EHR. Aligning with the provider's potential workflow, there may be an opportunity where a report needing additional information can be manually or automatically placed in a queue.</p> <p>In order to align with reporting requirements, outstanding information that is not present in the EHR, may be obtained through electronic information exchanges.</p>
7.1.4	Event: Validate and disseminate report	



Code	Description	Comments
7.1.4.1	Action: Validate information from the EHR, as well as augmented information.	<p>Based on the incorporated pre-determined PH Case/AE criteria and the various forms the information may come in discrete information for triggering alerts, and/or standardized forms/templates; the provider may validate the EHR and/or augmented information being used to populate the PH Case/AE reports.</p> <p>The provider may also have the opportunity to have completed reports which have been generated be queued, sent to others for confirmation, or automatically transmitted to public health.</p>
7.1.4.2	Action: Transmit validated PH Case/AE report is disseminated to public health.	PH Case/AE Reports are transmitted to public health. The information transmitted to public health may be discrete components which create a discrete report, a summary/textual report, etc.
7.1.5	Event: Send Additional Information	
7.1.5.1	Action: Send information related to previously reported PH Cases/AEs and/or other information may be sent to public health.	Based upon requests from public health for additional information, providers may provide public health with information related to the PH Cases/AEs that they have reported and/or other information which may assist public health in performing their investigations.
7.1.6	Event: Receive Public Health Information	
7.1.6.1	Action: Receive information from public health regarding PH Cases/AE reports which have been transmitted to public health.	<p>Following public health's investigation, specific information may be sent to providers regarding their previously submitted PH Cases/AE reports. Information communicated by public health and received by the providers may include the following: confirmation/refutation of a specific PH Case/AE Report, information regarding a specific PH Case/AE report, etc.</p> <p>Providers may utilize the public health information in identifying additional possible PH Cases/AEs, assisting public health in determining other individuals, groups, locations, who may be impacted, and managing and treating possible and confirmed PH Cases/AEs.</p>



Code	Description	Comments
7.1.6.1a	Alternate Action: Receive information from public health regarding trends, groups, etc.	Following public health's investigation, information may be sent to providers regarding trends and/or groups of PH Cases/AEs. Information communicated by public health and received by the providers may include: case counts, geographic trends, demographic trends, and/or other information that supports updated PH Case/AE criteria, etc.
7.1.6.1b	Alternate Action: Receive alert/notification information from public health.	Following public health's investigation, population health information may be sent to providers. Information communicated by public health and received by the providers may be include various alerts and notifications, which may assist providers in understanding the public health environment, which may assist them in their functions.
7.1.7	Event: Manage and Treat PH Cases/AEs	
7.1.7.1	Action: Identify confirmed and additional possible PH Cases/AEs.	Using information communicated by public health, providers may determine other possible PH Cases/AEs and may gain a better understanding of how they might further identify and manage these individuals within their provider settings.
7.1.7.2	Action: Treat confirmed and additional possible PH Cases/AEs.	The processes for carrying out the appropriate clinical interventions are described separately in events 7.1.2 through 7.1.6 in the 2008 Draft Detailed Immunizations and Response Management Use Case.



Figure 7-4. Reporting, Investigation, & Information Sharing – Laboratory Perspective

Code	Description	Comments
7.2.1	Event: Receive and incorporate Notifiable Condition/AE Criteria	
7.2.1.1	Action: Receive the Notifiable Condition/AE Criteria from public health.	<p>Detailed Notifiable Conditions/AE Criteria are communicated to laboratories. The information which is provided by public health may also include: notifiable conditions/diseases, AE detection information, and reporting requirements/specifications. The information which public health provides may be based upon a pre-determined and/or updated case definition which assists in defining criteria and reporting requirements for notifiable conditions/diseases.</p> <p>Today this information may be available in the form of published documents, web pages, or downloadable reference documents. For the purposes of reporting electronic notifiable conditions and results that may be indicative of adverse events, criteria information may come in the form of: discrete information which may assist in triggering reporting alerts, standardized electronic forms with both questions/templates, and response data etc.</p>
	Action: Incorporate the PH Case/AE Criteria into the LIS.	Electronic Notifiable Condition and AE Criteria are incorporated in a consistent way into the LIS, which may assist in determining possible Notifiable Conditions/AEs.
7.2.2	Event: Identify potential Notifiable Condition/AE	



Code	Description	Comments
7.2.2.1	<p>Action: Filter LIS data for information matching inclusion/exclusion factors.</p>	<p>Based on the defined Notifiable Condition/AE Criteria which have been incorporated into LISs, laboratory specimens are evaluated and results are identified as being Notifiable Conditions or indicative of possible PH Cases/AEs. In regards to the possibility that an AE may have occurred, varying levels and types of decision support may be utilized, for example preliminary laboratory information regarding abnormal liver enzymes abstracted from a specimen may be determined and communicated.</p> <p>Furthermore, the laboratory may communicate ad-hoc information to the provider of the specimen. Therefore, a laboratory may communicate the presence of a potential Notifiable Condition to the ordering provider. This type of communication may occur through phone, fax, electronic exchange, etc.</p> <p>In regards to AEs, laboratory communication to providers, for instance: abnormal liver enzymes, along with the use of decision support, may assist the provider in determining the potential cause and whether additional information should be evaluated in ruling out or reporting a possible AE.</p>
7.2.3	<p>Event: Validate and disseminate results/information</p>	
7.2.3.1	<p>Action: Validate information from the LIS.</p>	<p>Based on the incorporated pre-determined Notifiable Condition/AE criteria and the various forms the information may come in discrete information for triggering alerts, and/or standardized forms/templates; the laboratory will validate the Laboratory Results information being used to populate the Notifiable Condition and assist in the population of the AE report.</p>



Code	Description	Comments
7.2.3.2	<p>Action: Transmit validated Notifiable Condition Report /AE applicable information is disseminated to public health.</p>	<p>Notifiable Condition/AE Reports are transmitted to public health. The information transmitted to public health may be in discrete components which create a discrete report, or a summary/textual report, etc.</p> <p>The laboratory results, along with specific information in regards to the reporting to public health may be communicated on an ad-hoc basis with the provider of the specimen.</p>
7.2.4	<p>Event: Send Additional Information</p>	
7.2.4.1	<p>Action: Send information related to previously reported Notifiable Conditions/AEs and/or other information may be sent to public health.</p>	<p>Based upon requests from public health for additional information, laboratories may provide public health with information related to the Notifiable Conditions/AEs that they have reported and/or other information which may assist public health in performing their investigations.</p>
7.2.5	<p>Event: Receive Public Health Information</p>	
7.2.5.1	<p>Action: Receive information from public health regarding Notifiable Condition/AE reports which have been transmitted to public health.</p>	<p>Following public health's investigation, specific information may be sent to laboratories regarding previously submitted Notifiable Conditions/AE reports. Information communicated by public health and received by the laboratories may include the following: confirmation/refutation of a specific Notifiable Condition/AE Report, information regarding a specific Notifiable Condition/AE report, etc.</p> <p>Laboratories may utilize the public health information in identifying additional required Notifiable Conditions/AEs, assisting public health in determining other individuals, groups, and locations that may be impacted.</p>



Code	Description	Comments
7.2.5.1a	Alternative Action: Receive information from public health regarding trends, groups, etc.	Following public health's investigation, information may be sent to laboratories regarding trends and/or groups of Notifiable Conditions/AEs. Information communicated by public health and received by the laboratories may include: specimen counts, geographic trends, demographic trends, and/or other information that supports updated Notifiable Condition/AE criteria, etc.
7.2.5.1b	Alternative Action: Receive alert/notification information from public health.	Following public health's investigation, information may be sent to laboratories regarding trends and/or groups of Notifiable Conditions/AEs. Information communicated by public health and received by the laboratories may include various alerts and notifications, which may assist laboratories in understanding the public health environment, which may assist them in their functions.

Figure 7-5. Reporting, Investigation, & Information Sharing – Public Health Perspective

Code	Description	Comments
7.3.1	Event: Determine and communicate PH Case/AE Criteria	
7.3.1.1	Action: Determine PH Case/AE Criteria.	<p>Varying entities including: response management organizations, manufacturers, research entities, and other public health agencies/organizations may provide information assisting public health in the determination of PH Case/AE criteria and reporting requirements/ specifications.</p> <p>Information provided by these sources is addressed in a contextual manner for this use case and may possibly include: pre-determined and updated case definitions, surveillance information, etc.</p>



Code	Description	Comments
7.3.1.2	Action: Communicate PH Case/AE Criteria.	<p>Detailed PH Case/AE Criteria is communicated via public health to providers and laboratories. Today this information may be available in the form of published documents, web pages, or downloadable reference documents.</p> <p>The information which is provided by public health may also include: notifiable conditions/diseases, AE detection information, and reporting requirements/specifications. The information which public health provides may be based upon a pre-determined case definition and/or updated case definition.</p> <p>For the purposes of electronic PH Case/AE reporting, criteria information may come in the form of: discrete information which may assist in triggering reporting alerts, standardized electronic forms with both questions/templates, and response data etc.</p>
7.3.2	Event: Receive and Evaluate reports/information	
7.3.2.1	Action: Receive reports/information.	Reports/information is received by public health. The reports may be received in a discrete format, as well as a summary/textual format. The utilization of decision support may assist in identifying any reports which require immediate attention.
7.3.2.2	Action: Evaluate reports/information.	Public health evaluates the reports/information which they have received. During the evaluation, public health may prioritize the urgency of reports/information, may look for specific information, completeness in the reports, may determine additional information which is needed, etc.
7.3.3	Event: Request additional information	



Code	Description	Comments
7.3.3.1	Action: Request information from submitters of reports/information.	In order to perform investigations, public health may request information directly from the submitters of reports/information. The request may be ad-hoc in nature and be facilitated by way of a phone call, fax, etc. Therefore, for the purposes of this use case the request for additional information is not specified as an information exchange but is understood as being highly relevant to facilitating public health processes.
7.3.3.2a	Alternative Action: Request information by utilizing the information exchange to send a call out for applicable information.	Public health may also consider utilizing information exchanges for the purposes of obtaining additional information. The request may be ad-hoc in nature and may be in request for any type of information, from any number of sources. Therefore, for the purposes of this use case the request for additional information is not specified as an information exchange, but is understood as being highly relevant to facilitating public health processes and may be facilitated by information exchanges.
7.3.4	Event: Receive information and perform investigation	
7.3.4.1	Action: Receive addition information to assist in investigation activities.	<p>In response to public health's requests, provider, laboratories, and other sources send information to public health. For the purposes of this use case, these information exchanges are seen as contextual for the information which is sent by various sources and received by public health may be in regards to varying topics, specifications, etc.</p> <p>For the purposes of PH Cases and AE investigations, additional information requested and received by public health may assist in classifying the possible cases in order to determine appropriate resources, attention, etc.</p>



Code	Description	Comments
7.3.4.2	Action: Perform investigation activities.	<p>During the investigation, PH Case and AE 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 and AEs, onset, symptoms, risk factors, medication history, laboratory results, procedures, diagnosis, health status, counts, trends, patterns, etc. are investigated. In respect to possible PH Cases, additional epidemiological, contact tracing, and specimen/sample analysis activities may be performed.</p>
7.3.5	Event: Confirm and/or refute PH Case/AE Reports	
7.3.5.1	Action: Validate PH Cases and AEs.	Through the investigation process, the information within the reports will be validated by public health investigators. In validation of the reports a determination will need to be performed in order to determine whether the reports are “real”.
7.3.5.2	Action: Confirm and/or refute PH Case/AE Reports.	Specific PH Cases/AEs will either be confirmed and/or refuted. Critical activities such as establishing a case definition and a testing hypothesis will be addressed prior to or in alignment with the confirmation/refutation process.
7.3.6	Event: Assess impact and determine management plan	
7.3.6.1	Action: Assess and understand impact.	<p>In order to understand the impact for certain Notifiable Conditions, PH Cases, and AEs, the severity and need for immediate response may be identified upon or in some cases prior to the receipt of the report. For instance in most states, one reported incident of small pox is considered to be an outbreak and must be managed accordingly. There are also times that following the administration of a vaccination, possible adverse events are reported.</p> <p>This is described separately in the 2008 Draft Detailed Immunizations and Response Management Use Case.</p>



Code	Description	Comments
7.3.6.2	Action: Determine management plan.	<p>The development of the management plan may be completed in collaboration with other entities including: response management organizations, manufacturers, and research entities. The management plan may include: processes for monitoring and follow-up, the administration of prophylaxis and treatment, as well as communication.</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 Draft Detailed Immunizations and Response Management Use Case.</p>
7.3.7	Event: Communicate Public Health Information	
7.3.7.1	Action: Communicate information regarding specific Notifiable Condition, PH Case, and AE reports which have been transmitted to public health.	<p>Following public health's investigation, specific information may be sent to providers and laboratories regarding their previously submitted Notifiable Conditions/PH Case/AE reports.</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/AEs, determining the best methods for managing and treating their patients, and either actively informing submitters and/or giving them a mechanism to better understand their environment, as it relates to public health.</p>
7.3.7.1a	Alternative Action: Communicate information regarding trends, groups, etc.	<p>Following public health's investigation, focused information may be sent to providers and laboratories regarding trends and/or groups of Notifiable Conditions/PH Cases/AEs. Information communicated by public health and received by provider, laboratories, and other recipients may include: specimen counts, geographic trends, demographic trends, and/or other information that supports updated PH Case/AE criteria, etc.</p> <p>Information which is communicated via a transmission or a tool to other public health agencies/organizations may be more specific than communications to other sources and would align with appropriate regulations and standing agreements.</p>



Code	Description	Comments
7.3.7.1b	Alternate Action: Communicate alert/notification information.	Following public health's investigation, general population health information may be sent to providers and laboratories regarding trends and/or groups of Notifiable Conditions/AEs. Information communicated by public health and received by the providers, laboratories, and other recipients may include: various alerts and notifications which may assist entities in understanding the public health environment which may assist them in their functions.



8.0 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 8-1. Public Health Case Reporting Information Exchange Capabilities

Code	Capability	Comments
8.1	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.
8.2	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.
8.3	Data delivery – including secure data delivery, 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: A direct link or communication connection with defined endpoints.



9.0 Public Health Case Reporting Dataset Considerations

There are various information needs which are addressed by this use case.

Currently there are initiatives underway which are addressing consistent nationally notifiable conditions by focusing on:

- 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),
- A list of disease specific data elements for four initial conditions (Anthrax, Hepatitis B, Tuberculosis, and Tularemia), and
- The development of a process for the future identification of disease specific data elements for all conditions.

At this time, there is also discussion regarding what information might or could be available within EHRs, LISs, and other systems which could assist in the identification and reporting of possible PH Cases and AEs. For the purposes of PH Case and AE reporting, the following non-exhaustive information categories with limited examples may be considered:

- Considerations for both PH Cases and AEs:
 - Demographic Information
 - Health History & Status Information
 - Clinical Information
 - Specimen/Laboratory Information
- Specific considerations for PH Cases:
 - Condition/Disease Information
 - Contact/Exposure Information
- Specific considerations for AEs:
 - Event Information
 - Product Information
 - Manufacturer Information

In addition, there are needs for population health related information which might be incorporated into EHRs and LISs, as well as population health information that might be exchanged between providers, laboratories, public health, etc. Information exchanges among public health entities as well as provider-to-provider communication may also occur, assisting public health and providers in better understanding the public health environment.



For the purposes of population health information exchange, the following non-exhaustive information categories with limited examples may be considered:

- Status of Reports:
 - Acknowledgement of Report Information
 - Confirmation or Refutation Information
 - Summary Information
- Focused Population Health Communications:
 - Aggregate Information
 - Specimen Counts
 - Geographic Trends
 - Demographic Trends
- General Population Health Communications:
 - Alerts
 - Notifications



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.

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 in regards to 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 in regards to the development and adoption of health information technology.

Case Criteria: Determinants of a recognizable event (and/or issue) that may have a potential impact on the diagnosis (and/or result) of a suspected and/or confirmed public health case. Criteria may include but are not limited to: personal/genetic characteristics, reactions and medication intakes, general history of a patient/event/issue or case, tracing, results or possible causes of suspected and/or confirmed public case.

Case Definition: Defines and categorizes characteristics and traits 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.

Clinicians: Healthcare providers with patient care responsibilities, including physicians, advanced practice nurses, physician assistants, nurses, and other 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 person as an attempt to interrupt transmissions of diseases, infections and/or outbreaks.

Decision Support: An activity that enables improved analysis in conclusions based on related information, recent research, algorithms, or other resources.

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): A longitudinal electronic record of patient health information generated in one or more encounters in any care delivery setting; information may include patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory information and radiology reports.

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

Organization: A multi-stakeholder entity, which may be a free-standing organization i.e. – hospitals, healthcare systems, partnership organizations, etc. that supports health information exchange which enable the movement of health-related data within state, local, territorial, or jurisdictional participant groups. Activities supporting health information exchanges may also be provided by entities which are separate from geographic health information exchanges/Regional Health Information Organizations and may include: integrated delivery networks, health data banks, etc.

Government Agencies: Local, state, territorial, or federal departments within the United States government responsible for the oversight and administration of a specific function; government agencies that could participate in public health case reporting and management may include: Food & Drug Administration (FDA), Centers for Disease Control and Prevention



(CDC), Centers for Medicare & Medicaid Services (CMS), Department of Defense (DoD), and Department of Homeland Security (DHS).

Health information exchange (HIE): The functional capability to exchange health information between networks in order to exchange the 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 supporting these capabilities.

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, school health, dental clinics, psychology clinics, care delivery organizations, 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 resulted and then results communicated back to the requestor. The types of laboratories may include clinical/medical, environmental, veterinarian and may be both private and/or public.

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 nations 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 that include medical attention, care, or treatment.

Point-to-Point Exchange: A direct link or communication connection with defined endpoints.

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, and other clinicians. This can also refer to healthcare delivery organizations.

Public Health Agencies/Organizations (local/state/territorial, tribal/federal): Local, state, territorial, tribal and federal government organizations and clinical care personnel that exist to help protect and improve the health of their respective constituents. These organizations are also involved in the coordination of ordering and distributing resources such as vaccines.

Public Health Case: A possible or confirmed notifiable disease/condition that has been detected; the disease/condition may not be pre-determined and therefore, may not initially fall into the notifiable category; requirements for reporting disease/conditions may be different and may be mandated by local, state, federal 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.

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 that report possible and/or confirmed (within their organization) cases/events to public health.



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

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

Vaccine: A substance or group of substances aimed at causing the immune system to breakdown a bacterium or virus in order to prevent a potential infection or disease.