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

Public Health Case Reporting
Draft Detailed Use Case Disposition Report

Reading the Disposition Report

Column Name	You'll Find
Organization	The title of the organization associated with the feedback submission.
Feedback Reference	The Draft Detailed Use Case section to which the feedback text refers.
Feedback Text	The summation of the feedback submission.
Disposition Code	The disposition code assigned to the feedback by the Use Case team during the disposition process.
Rationale	The reasoning associated with the disposition code assigned to the feedback by the Use Case team during the disposition process.
Document Reference	The location of the changes in the Detailed Use Case, if applicable.

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
American Health Information Management Association	N/A	The American Health Information Management Association (AHIMA) welcomes the opportunity to comment on the Office of the National Coordinator's Public Health Case Reporting (PHCR) Draft Detailed Use Case.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	N/A
American Health Information Management Association	N/A	AHIMA is a not-for-profit professional association representing more than 51,000 health information management (HIM) professionals who work throughout the healthcare industry.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	N/A
American Health Information Management Association	N/A	AHIMA's HIM professionals are educated, trained, and certified to serve the healthcare industry and the public by managing, analyzing, reporting, and utilizing data vital for patient care, while making it accessible to healthcare providers and appropriate researchers when it is needed most.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	N/A
American Health Information Management Association	N/A	AHIMA and its members participate in a variety of projects with other industry groups and federal agencies related to the use of healthcare data for a variety of purposes including direct care, quality measurement, reimbursement, public health, patient safety, biosurveillance, and research.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	N/A
American Health Information Management Association	N/A	We recognize the industry's need for timely and accurate data for public health response and disease surveillance, but extracting data electronically from interfaced systems remains a challenging process because there are few broadly agreed-upon standards for data content. This climate of variation and confusion may well have a negative impact on the abilities of public health entities and providers to report and use accurate and timely data.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Challenges associated with the absence of consistent agreed upon standards is addressed in the issues and obstacles section of this use case.	4.0
American Health Information Management Association	N/A	Our comments focus on those areas of particular interest to our members. We believe the use case is a good foundation; however, we have outlined some recommendations as ONC continues to expand the document.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	N/A

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
American Health Information Management Association	N/A	Public health case (PH case) and adverse event (AE) reporting are two distinct reporting processes. The PHCR use case should more clearly depict the delineation between public health case and adverse event reporting.	Accepted	Feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions associated with public health cases and specific actions associated with adverse events.	7.0, 8.0 7.1.1.2, 7.2.1.1, 7.2.1.2, 7.1.1.3, 7.2.1.3
American Health Information Management Association	N/A	The PHCR use case should be divided into three separate scenarios: (1) reporting, (2) investigation, and (3) information sharing/intervention to more clearly delineate between the roles of each use case stakeholder and corresponding responsibilities.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address activities performed by other stakeholders.	7.0, 8.0, 7.1.4. 3.0
American Health Information Management Association	2.0	The first paragraph on page 3 states the PHCR use case applies to "some aspects of Adverse Event (AE) Reporting, including AEs associated with post-market medications and vaccines." There are other aspects of AE reporting besides post-market medications and vaccines. Is this use case only addressing these aspects or AE reporting? The word "some" is vague and should be further clarified for the reader.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. This use case focuses on using data in EHRs which may pertain to post-market medications and vaccines and in addition, augmenting EHR data in order to assist those individuals or entities performing provider roles in reporting to public health, manufacturers and other entities.	2.0
American Health Information Management Association	3.0	Decision support is a key function that enables improved analysis and informed care decisions, but it should not be described as an 'entity' within the stakeholder section of the use case. Decision support is an infrastructure requirement that impacts the public health case reporting data flow and related stakeholders described in the use case.	Accepted	Feedback has been incorporated into the document.	3.0

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American Health Information Management Association	3.0	Veterinary medicine plays an integral role in public health case reporting by monitoring illness and disease carried or spread by animals. AHIMA recommends incorporating veterinary providers into the "Provider" stakeholder category or adding a stakeholder category specific to veterinary medicine.	Accepted	Feedback has been incorporated into the document.	3.0, 5.0
American Health Information Management Association	4.0	Confidentiality, Privacy and Security: Issues and obstacles concerning confidentiality, privacy and security are dependent on the final PH case and AE reporting perspectives defined in the final detailed use case. Some of the issues and obstacles will need to be further defined after the use case is stabilized.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	4.0
American Health Information Management Association	4.0	Information Integrity, Interoperability, and Exchange: The collection and use of high quality data is critical to healthcare delivery both for clinical care and other secondary uses such as public health case reporting, quality measurement, research, and reimbursement.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	4.0
American Health Information Management Association	4.0	Information Integrity, Interoperability, and Exchange: The integrity of coded data and the ability to turn it into functional information require that all users consistently apply the same official coding rules, conventions, guidelines, and definitions (the basis of vocabulary, terminology or classification standards).	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Specifics regarding these processes address implementation considerations and may pertain to another working group and/or organization.	N/A
American Health Information Management Association	4.0	Information Integrity, Interoperability, and Exchange: Achieving interoperability requires terminology and classification systems that reflect current medical practice and are complementary, such as in the use of ICD-10. We recommend that this be reflected in the Issues and Obstacles section of the use case.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. While the use case acknowledges that achieving interoperability requires terminology and specification of standards, this subject is out of scope for this use case and may be addressed by other entities/organizations.	4.0
American Health Information Management Association	3.0	EHR and HIT Adoption: The use case focuses on provider adoption of information technology; however, adoption of information technology by public health entities is not addressed.	Accepted	Feedback has been incorporated into the document.	2.0

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American Health Information Management Association	3.0	EHR and HIT Adoption: The penetration and adoption of information technology in the public health sector is not consistent and AHIMA strongly recommends that this issue be addressed.	Accepted	Feedback has been incorporated into the document.	2.0
American Health Information Management Association	4.0	Public Health Reporting Criteria, Specifications, and Communications: The first bullet under this section on page 9 states "…PH Case and AE detection criteria and reporting specifications may not be defined, consistent, required, nor communicated in a reliable manner." We recommend adding the word "timely" so the sentence states "…nor communicated in a reliable or timely manner."	Accepted	Feedback has been incorporated into the document.	2.0
American Health Information Management Association	5.0	The consumer perspective is missing from the use case.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. This use case focuses on using data in EHRs and augmenting EHR data in order to assist providers in reporting to public health. Since direct consumer reporting to public health is not the focus of this use case, a separate perspective was not necessary, however, it is addressed within the information sources, recipients, and actions.	5.0, 7.0, 7.1.6.1, 8.0
American Health Information Management Association	5.0, 7.0	PH case reporting should include methods for communicating with consumers when public health investigation and intervention is important.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	8.1.5
American Health Information Management Association	5.0	Similarly, the exchange of information between electronic health record (EHR) and personal health record (PHR) systems is important whether for augmenting information in a report or directly communicating clinical care options.	Accepted	Feedback has been incorporated into the document.	5.0, 7.0, 7.1.6.1, 8.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
American Health Information Management Association	6.0	Reporting, investigation and information sharing are each unique operations with unique data flows and data content requirements. Dividing the use case into three separate scenarios will add significant clarity to the scenarios.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions and information exchanges which support unique data requirements.	7.0, 8.0, 10.0, Appendix B
American Health Information Management Association	7.0	As previously stated, we recommend the use case be divided into three separate scenarios: (1) reporting, (2) investigation, and (3) information sharing to more clearly delineate between the roles of each use case stakeholder, corresponding responsibilities and information flows.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address activities performed by other additional stakeholders.	7.0, 8.0, 7.1.4. 3.0
American Health Information Management Association	7.0	The use case diagram looks much different than diagrams depicted in other use case documents. There is a mixture of colored boxes, circles, numbers, and solid and dotted lines. We recommend including a legend in the diagram to make it easier to interpret.	Accepted	Feedback has been incorporated into the document.	7.0, 8.0
American Health Information Management Association	N/A	We recommend more consistent use of text across use cases where activities are similar. For example, the Quality Detailed Use Case uses the phrase "transmit information" and the PHCR use case states "disseminate reports." As standards for data exchange are developed and implemented for public health, report may not be the best term to use.	Partially Accepted	A portion of the feedback has been incorporated into the document. Language supporting events has been updated to reflect the needs of the Public Health Case Reporting Use Case.	7.0, 8.0
American Health Information Management Association	9.0	True interoperability will not occur until data definitions and codes are standardized and incorporated into technical standards.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. However, examples of this process may be addressed in specific actions within the use case.	4.0, 7.2.1.2, 7.2.1.3, 7.2.1.4

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American Health Information Management Association	9.0	AHIMA recommends including additional information describing how the data sets created for PH case and AE reporting will be aligned with other healthcare data sets (for example, the data set defined in the Quality Use Case Interoperability Specifications). Adding this guidance to the PHCR use case data set considerations will support a movement toward collecting data once so it can be repurposed multiple times.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. While there may be related data set considerations for similar purposes in the Quality and Public Health Case Reporting Use Cases, activities related to data set determination and harmonization are being addressed by other entities and organizations.	7.0, 8.0, 10.0 Appendix B
American Health Information Management Association	Appendix A	The terms pseudonymization and de-identification should be incorporated into Appendix A: Glossary to provide context for this use case and serve as a reference for the reader.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. These terms have been described in the information exchange section.	9.0
American Health Information Management Association	N/A	AHIMA agrees that capture and integration of data in EHRs is necessary to support multiple requests for data, including public health case reporting. As an active developer and promoter of EHR standards, we look forward to a day when all uses of data, whether produced for patient care, quality measurement, or public health reporting, accurately portray the diagnoses, severity, and services provided.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	N/A
Centers for Disease Control & Prevention	2.0	Combining Adverse Events (AE) into this Use Case is not advisable. An alternative Use Case would be more appropriate because AE represents different acts and actors.	Accepted	Feedback has been incorporated into the document.	7.0, 8.0 7.1.1.2, 7.2.1.1, 7.2.1.2, 7.1.1.3, 7.2.1.3
Centers for Disease Control & Prevention	N/A	This new version of the Public Health Case Reporting Use Case is much improved.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	N/A

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Centers for Disease Control & Prevention	2.0	There should be explicit recognition of the need to support rules-based case reporting from provider data systems to public health. That is, for some reportable conditions it is possible to establish algorithms or rules that permit the transmission of an automatic case report to public health. For many other conditions, it will be important to include human (e.g. physician, nurse, or ICP) input, prior to electronic case reporting to public health. Over time, increasing sophistication of algorithms and other informatics tools will permit increasing adoption of automated case reporting to public health.	Accepted	Feedback has been incorporated into the document.	2.0, 7.1.5, 7.2.2, 7.2.3
Centers for Disease Control & Prevention	7.0	Figure 7-1 could be revised to more simply reflect the scenario.	Accepted	Feedback has been incorporated into the document.	7.0, 8.0
Centers for Disease Control & Prevention	4.0	Little mention of the lack of standard vocabulary and surveillance variable definitions. The lack of standard vocabularies is a major hurdle, especially given the reticence to change vocabulary within a system because of disruption in the continuity of data. The lack of standard vocabulary is two sided: The same entity may be described, named, or coded differently in different systems and	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	2.0, 4.0, 10.0
Centers for Disease Control & Prevention	4.0	Little mention of the lack of standard vocabulary and surveillance variable definitions. The lack of standard vocabularies is a major hurdle, especially given the reticence to change vocabulary within a system because of disruption in the continuity of data. The lack of standard vocabulary is two sided: The same description, name, or code may be applied to different entities in different systems	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	2.0, 4.0, 10.0
Centers for Disease Control & Prevention	4.0	Even with in the more advanced medical vocabulary structures (i.e., SNOMED, and LOINC), there are many inconsistencies, errors, non-sense entries, duplicates and incomplete entities.	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	2.0, 4.0, 10.0
Centers for Disease Control & Prevention	4.0	There is no reference standard for many entities that constitute important public health information; for instance "exposure" has no reference standard whatsoever. Creating these standards will be difficult.	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	2.0, 4.0, 10.0, Appendix B

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Centers for Disease Control & Prevention	7.0	The information flow does not seem to include public health as a source of case report information. Cases may well be primarily identified by public health, and even for cases primarily identified by providers, much of the case information may be acquired by and added to electronic case information by public health. In addition, there are ongoing instances of reporting from one public health jurisdiction to another (i.e., reporting case information from one jurisdiction to the jurisdiction of residence for the case).	Accepted	Feedback has been incorporated into the document.	5.0, 8.1.1.2, 8.1.5.2, 8.2.2.2
Centers for Disease Control & Prevention	7.0	The capabilities need to emphasize the importance of data validation. This has been a problem in systems in which data is translated and exchanged multiple times- data can easily end up in the wrong data field in the end user database, given the complex mapping that must take place.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. While this use case acknowledges the need to have and determine whether or not data is valid, it is not the focus of this use case. Various aspects of this challenge (determining source) are discussed in the Consumer Access to Clinical Information Use Case and may also be addressed by other organizations/ entities.	4.0, 7.1.5.2
Centers for Disease Control & Prevention	7.0	In addition to data content and reports, it is imperative that data residing in datasets be available to the appropriate public health users (via established user policies) in flexible subsets and formats to allow for data management, exploration and analysis by professionals who may not have extensive IT skills.	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	7.1.1, 7.2.1, 10.0

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Centers for Disease Control & Prevention	4.0	Several very significant issues are listed, but no amelioration is suggested. Also, with constraints of this magnitude, perhaps a statement identifying the reality of limited near-term benefit from this use-case, etc should be included. For example: A.) Page 8. "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." This is an important constraint; in reality, a long time period of varied rates of adoption of EHRs will by definition impede the usefulness of the process.	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	4.0
Centers for Disease Control & Prevention	4.0	Several very significant issues are listed, but no amelioration is suggested. Also, with constraints of this magnitude, perhaps a statement identifying the reality of limited near-term benefit from this use-case, etc should be included. For example: B.) Page 10. "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." This is again an important constraint. (Also, at "healthcare facilities' … the apostrophe should be dropped.)	Accepted	Feedback has been incorporated into the document.	4.0
Centers for Disease Control & Prevention	7.0	2.) Page 16. Augment EHR Information. This section relates to the "manual" gathering of information that is not in EHR. An action and "alternate" action are listed. For the foreseeable future, both of these actions will be needed, so the second would not simply be an alternate to the first.	Accepted	Feedback has been incorporated into the document.	7.1.6.1
Centers for Disease Control & Prevention	5.0, 7.0	3.) Page 16-17. Section 7.1.4 and 7.1.5. (and parallel sections from the other "perspectives" …) Validate information and Send Additional Information. This assumes that the system has provided workable, validated information for which PH needs more information. However, wouldn't it be important to address the need to send more information to clarify situations where the original information seemed to not be valid?	Accepted	Feedback has been incorporated into the document.	7.1.6, 7.2.3, 8.2.1

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Centers for Disease Control & Prevention	7.0	4.) Page 23. 7.3.2.1. "Reports/information is received by public health. The reports may be received in a discrete format, as well as a summary/textual format." Isn't it likely that summary data could be something other than text? If so, these should be separated in the list. (Also, there is a subject-verb error …)	Accepted	Feedback has been incorporated into the document.	7.1.1, 7.2.1
Centers for Disease Control & Prevention	5.0, 7.0	5.) Page 24. 7.3.3.1. and 7.3.3.2a (Wouldn't the convention be to have a 7.3.3.2 before an "a?") These two sections stipulate that "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." I believe that within levels of PH requests for additional information can/do certainly include information exchanges, as given in the lab and provider "perspectives."	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Since the information may be ad-hoc in nature and be facilitated by way of a phone call or fax without specificity with little chance of being standardized; for the purposes of this use case this is not a focused information exchange.	7.1.6.1
Centers for Disease Control & Prevention	7.0	6.) Page 24. 7.3.4.1. Should be "additional" rather than addition. There are grammatical errors throughout this document.	Accepted	Feedback has been incorporated into the document.	7.2.1
Centers for Disease Control & Prevention	3.0	Stakeholder: Reporting Entities – Individual clinicians are also considered as Reporting Entities and should be listed here.	Accepted	Feedback has been incorporated into the document.	3.0
Centers for Disease Control & Prevention	9.0	Although the categories are "non-exhaustive," consider explicitly adding mention of work to the first example of Demographics, and 'and Work' to the second example, under the bullet 'Considerations for both PH Cases and AE's." Employment and work history need to be explicitly mentioned as part of both demographics and past medical history or it will be overlooked.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Demographic information is relevant to PH Case and AE reporting. While employment and work history may also be considered, they are not the focus of this use case.	2.0, 10.0
Centers for Disease Control & Prevention	Appendix A	Case Investigation – note that not all case investigations are of infectious disease and outbreaks can occur for non-infectious diseases/conditions	Accepted	Feedback has been incorporated into the document.	2.0

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Centers for Disease Control & Prevention	Appendix A	Electronic Health Record (EHR) – add the words "including work history," so the paragraph reads, "information my include patient demographics, including work history, progress notes,…"	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Demographic information is relevant to PH Case and AE reporting. While employment and work history may also be considered, they are not the focus of this use case.	2.0, 10.0
Centers for Disease Control & Prevention	Appendix A	Outbreak: remove the word "infected"	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	Appendix A
Centers for Disease Control & Prevention	Appendix A	Reporting Entities: Individual clinicians are also considered a Reporting Entity	Accepted	Feedback has been incorporated into the document.	3.0
Council of State and Territorial Epidemiologists	N/A	The whole document needs editing by someone with a better knowledge of English grammar, to fix problems such as use of etc. in conjunction with e.g. Also needs serious proofreading (e.g., Figure 3-1, pg 6 - missing / after tribal)	Accepted	Feedback has been incorporated into the document.	N/A
Council of State and Territorial Epidemiologists	N/A	"Information exchange" needs to be explicitly defined, in the document and in the glossary. Are information exchanges only electronic? The assumption seems to vary depending on the section of the document.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Depending on the context, information exchange activities may be electronic or completed via other mechanisms..	7.0, 8.0, 9.0
Council of State and Territorial Epidemiologists	N/A	Need to make explicit the relationship with animal health (including veterinarians, veterinary hospitals and veterinary labs). These are mandated reporters to PH in many jurisdictions. Animal health entity reporting to PH is inconsistently represented.	Accepted	Feedback has been incorporated into the document.	3.0, 5.0
Council of State and Territorial Epidemiologists	N/A	The document spends far too much time trying to describe processes internal to the actors (and doing it poorly), and far too little time and effort describing the information exchanges. Information exchange is why a REPORTING use case exists. This deficiency seems particularly problematic given that the next stop along the line is HITSP, which will try to determine applicable standards.	Acknowledged	Intent of the feedback has been acknowledged. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. The focus of this use case in on information exchanges between organizations/perspectives.	7.0, 8.0, 7.1.4

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Council of State and Territorial Epidemiologists	2.0	The second bullet in the middle of page 3 talks about using automated processes to prompt a provider of the need to report a possible and/or confirmed PH Case, based on the presence of clinical data.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	2.0, 7.1.5
Council of State and Territorial Epidemiologists	2.0	This document needs to also address the case where certain combinations of findings in electronic health records are passed automatically to public health, in the same manner as certain laboratory findings are.	Partially Accepted	A portion of the feedback has been incorporated into the document . The use case addresses various mechanisms for reporting. When reporting criteria are met, implementation decisions will need to be made to determine whether reporting can be automated or if clinical judgment is required.	2.0, 7.1.5, 7.2.2, 7.2.3
Council of State and Territorial Epidemiologists	2.0	If all case reporting has to await clinician review, we are missing opportunities for rapid reporting of high-priority findings, and reporting will still be slow, incomplete and inconsistent.	Partially Accepted	A portion of the feedback has been incorporated into the document . The use case addresses various mechanisms for reporting. When reporting criteria are met, implementation decisions will need to be made to determine whether reporting can be automated or if clinical judgment is required.	2.0, 7.1.5, 7.2.2, 7.2.3
Council of State and Territorial Epidemiologists	2.0	Automated case reports will still have to be reviewed by public health authorities and will often generate queries back to the reporting entity for more information.	Acknowledged	Intent of the feedback has been acknowledged and no content changes deemed necessary to the use case document. Automated reports and clinician validated reports sent to public health, may both require additional information to assist in public health investigations.	8.1.1
Council of State and Territorial Epidemiologists	2.0	On page 4, the second bullet is not clearly worded. It is not clear if "This information" at the beginning of the sentence refers to the information received, referred to in the previous bullet, or back to the text introducing these bullets, in which case it is more generally about information that is exchanged. Also, this sentence makes more sense to a public health epidemiologist if 'case definition' means 'criteria for identifying cases to be reported', rather than 'surveillance case definition'.	Accepted	Feedback has been incorporated into the document.	7.1.1, 7.2.1, 8.1.2.2, Appendix A

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Council of State and Territorial Epidemiologists	2.0	Page 4, last paragraph: reference is made to 'absence of requirements for reporting notifiable conditions to the federal level.' It needs to be clear to the reader that extensive reporting from states to the federal government on a voluntary basis, and also on a basis where funding for disease prevention and control programs is explicitly tied to compliance with reporting requirements (as it is in TB, STD, HIV/AIDS, and vaccine-preventable diseases).	Accepted	Feedback has been incorporated into the document.	2.0, 10.0
Council of State and Territorial Epidemiologists	2.0	There was discussion about coupling adverse event reporting along with traditional case reporting of notifiable diseases. [Comment: In UT, the department of health requires (law) AE reporting.] This may be confusing to two separate processes. Or are the processes the same? In the use case, providers include individual clinicians and also represent an entire healthcare delivery organization. However, AE reporting typically is reported from organizations (institution) and not an individual clinician. Request: Separate the roles for public health case reporting from AE reporting in the use case, or make an entirely separate use case for AE reporting.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address activities performed by other stakeholders.	3.0, 5.0, 7.0, 7.1.4, 8.0
Council of State and Territorial Epidemiologists	2.0	The use case should include another reporting entity: Organization or institution. This is further supported by the discussion above.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. The provider perspective may include individuals, organizations, or institutions. In addition, there are now specific actions which address activities performed by other stakeholders.	3.0, 5.0, 7.0, 7.1.4, 8.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Council of State and Territorial Epidemiologists	2.0	Error: Page 4 top paragraph. AHIC did not commission CSTE and CDC to identify a list of disease specific data elements for just these four listed diseases anthrax, hep B, TB, and tularemia (i.e., delete "including: (Anthrax, Hepatitis B, Tuberculosis, and Tularemia)"). AHIC simply asked CSTE-CDC to identify a list of disease specific data elements for initial conditions. Also, omitted from the document was any reference for CDC and CSTE to address the criteria for reporting. This should be included. Suggested language is "drawing upon the long-standing CSTE-CDC collaboration over development of case definitions for case classification, develop a parallel process for development of case definitions for public health case reporting ("criteria for reporting")".	Acknowledged	Intent of the feedback has been acknowledged and no content changes deemed necessary to the use case document.	10.0
Council of State and Territorial Epidemiologists	2.0	(pg 4, bullet 2) This needs to be clarified. There's some confusion about "to develop and refine case definitions or AE detection… "	Accepted	Feedback has been incorporated into the document.	7.1.1, 7.2.1, 8.1.2.2, Appendix A
Council of State and Territorial Epidemiologists	2.0	(pg 4, bullet 2) Maybe revise bullet 2 at the end of the sentence to include "and to estimate and manage the resulting impact on population health."	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. The intent of the feedback is included within the scenarios and events and actions.	6.0-8.0
Council of State and Territorial Epidemiologists	2.0	(pg 4, bullet 2) This should not be a bullet but rather a paragraph.	Accepted	Feedback has been incorporated into the document.	2.0
Council of State and Territorial Epidemiologists	2.0	"The absence of requirements for reporting notifiable conditions to the federal level" needs to be clarified. Is this in reference to case notifications (from state to CDC)? May include language to further clarify the variability in reporting criteria amongst the various levels (local, state, federal, tribe and territorial jurisdictions).	Accepted	Feedback has been incorporated into the document.	4.0, 10.0
Council of State and Territorial Epidemiologists	3.0	The stakeholder group 'Decision support' does not refer to an identifiable group of people, and should be deleted. The stakeholder group labeled as "Public health Knowledge Providers" seems to consist of public health associations like CSTE, APHL and ASTHO. Why not say so?	Accepted	Feedback has been incorporated into the document.	3.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Council of State and Territorial Epidemiologists	3.0	Add tribal. Also, line 3 should read "federal government agencies"	Accepted	Feedback has been incorporated into the document.	2.0-5.0, 10.0, Appendix A
Council of State and Territorial Epidemiologists	3.0	Delete "environmental".	Not Accepted	The feedback proposes a change which is not consistent with the design of the use case. While environmental testing and specimen results are not the focus of this use case, they are a source of information relevant to this use case.	3.0, 5.0, 8.1.1, 8.1.4
Council of State and Territorial Epidemiologists	3.0	Add EHR and LIS vendors.	Accepted	Feedback has been incorporated into the document.	3.0
Council of State and Territorial Epidemiologists	4.0	Page 9, the first sub bullet under Confidentiality, privacy and security suggests that there is not "the ability to ensure patient confidentiality". This is a libel on public health agencies, who all have strong legal protections for the confidentiality of health information they hold about individuals, and penalties for disclosure. It is true that these vary in detail from state to state but the data are not unprotected anywhere. The more relevant point here is that if those who have the responsibility to provide information to public health perceive that confidentiality is not protected, this is a potential barrier to health information exchange. This obstacle can be overcome through clear communication.	Accepted	Feedback has been incorporated into the document.	4.0
Council of State and Territorial Epidemiologists	N/A	There was a suggestion to reference HIPAA.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	9.0
Council of State and Territorial Epidemiologists	4.0	Under Information Interoperability and Exchange, the first bullet is not accurate. Suggested edit "The use of inconsistent paper-based forms and non-electronic reporting processes is not optimal for active surveillance…"	Accepted	Feedback has been incorporated into the document.	4.0
Council of State and Territorial Epidemiologists	4.0	Under Information Interoperability and Exchange, the second bullet is not accurate.	Not Understood	It was not possible to determine how the feedback could be incorporated into the use case.	4.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Council of State and Territorial Epidemiologists	5.0	An additional perspective is needed, that of the health care organization or institution. In many states, including the state of Florida, hospitals are required to report cases of notifiable diseases in their patients to PH, independent of the requirement placed on practitioners and on laboratories; and to report adverse events to the regulatory health agency in the state. Adding this perspective also facilitates the inclusion of automated reporting of records or combinations of records that indicate the likely presence of a case of a notifiable disease, using a mechanism similar to that for electronic laboratory reporting.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. The provider perspective may include individuals, organizations, or institutions. In addition, there are now specific actions which address activities performed by other stakeholders.	3.0, 5.0, 7.0, 7.1.4, 8.0
Council of State and Territorial Epidemiologists	5.0	The lab and providers may be a child (parent-child model) of the institution.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	5.0, 7.0, 8.0
Council of State and Territorial Epidemiologists	5.0	Under PH perspective, remove the words "or confirmed". PH receives possible cases and confirms cases.	Accepted	Feedback has been incorporated into the document.	8.1.2, 8.3.2, 10.0
Council of State and Territorial Epidemiologists	5.0	Under PH perspective, replace "completes a thorough investigation" with might complete a thorough investigation. Other suggested edit is "performs and investigates".	Accepted	Feedback has been incorporated into the document.	8.1
Council of State and Territorial Epidemiologists	5.0	Under PH perspective, add at the end of the bullet "… laboratories and/or other public health entities" new text "and carries out appropriate PH interventions."	Accepted	Feedback has been incorporated into the document.	8.2.3
Council of State and Territorial Epidemiologists	6.0	What are the associations with the other uses cases (e.g., Immunization and Response Management Draft Detailed Use Case)? Can AHIC enumerate and include in the appendix? This will help the reader better understand the association. This should be done for all use cases. In other words, for the Immunization use case an appendix enumerating the association with the PH case reporting use case should be included in that document as well.	Accepted	Feedback has been incorporated into the document and the Immunizations and Response Management Use Case.	7.1.1.3, 8.1.4, 8.2.3
Council of State and Territorial Epidemiologists	7.1	It's a little unclear where an organization like CSTE would fall under.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	2.0, 3.0, 10.0 Appendix A

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Council of State and Territorial Epidemiologists	7.1	What does the legend exactly mean, focus vs. conceptual? It is a little unclear.	Accepted	Feedback has been incorporated into the document and the Immunizations and Response Management Use Case.	7.0, 8.0
Council of State and Territorial Epidemiologists	7.1	Also, does this figure represent data flow diagram or functional/activity flow diagram? There are various dimensions that are not captured in a flat diagram. A request would be to breakdown the diagram in to various aspects that the use case is trying to accomplish.	Accepted	Feedback has been incorporated into the document and the Immunizations and Response Management Use Case.	7.0, 8.0
Council of State and Territorial Epidemiologists	7.1	Separate the reporting flows: 1. PH case reports, 2. lab reports, and 3. AE reports	Accepted	Feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions associated with public health cases and specific actions associated with adverse events.	7.0, 8.0 7.1.1.2, 7.2.1.1, 7.2.1.2, 7.1.1.3, 7.2.1.3
Council of State and Territorial Epidemiologists	N/A	If an "organization" entity were to be included, it would mimic the Laboratory entity flow.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. The provider perspective may include individuals, organizations, or institutions. In addition, there are now specific actions which address activities performed by other stakeholders.	3.0, 5.0, 7.0, 7.1.4, 8.0
Council of State and Territorial Epidemiologists	7.0	For this set of use cases, "Information Exchange" is the whole thing -- it should NOT be a role or a perspective. It is not specified as such in section 6. Its inclusion as a separate role confuses this diagram.	Accepted	Feedback has been incorporated into the document.	6.0 - 9.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Council of State and Territorial Epidemiologists	7.1.1.1	Action: receive the PH/AE criteria from public health Clinical info systems need to receive updated criteria in near-real time. This is critical for emerging infectious disease (e.g., SARS). A subscription of this information should be made available to physicians (and labs) by way of ontological tools hosted by a recognized national PH entity (e.g., CDC and CSTE jointly).	Accepted	Feedback has been incorporated into the document.	7.1.1, 7.1.1.2, 7.2.1
Council of State and Territorial Epidemiologists	7.1.1.2	Action: Incorporate the PH Case/AE Criteria into EHRs This information (reporting criteria and notifiable disease list) should be available for consumption, in human (physician, laboratorian) and/or machine-to-machine (clinical and lab system) in a consistent manner. Currently some of this information is made available on websites hosted by health jurisdiction. Edit "Criteria are incorporated in a consistent way into EHRs" to read "Criteria are incorporated in near-real-time and in a consistent way into EHRs".	Accepted	Feedback has been incorporated into the document.	7.1.1, 7.1.1.2, 7.2.1
Council of State and Territorial Epidemiologists	7.1.2	Action: Filter EHR data for information matching inclusion/exclusion factors. Does not specify the frequency this should be done. It should be on a continuous basis for suspect BT agents or other diseases which require immediate reporting. It can be done once a day for conditions where reporting timeframes are not immediate. Specific conditions that require immediate reporting (e.g., suspected anthrax) this may need to be recognized and reported in real time.	Partially Accepted	A portion of the feedback has been incorporated into the document. References to the need for real-time reporting and reporting criteria updates are addressed in this use case. Specifics regarding reporting frequencies are addressed in the 2006 Biosureveillance Use Case.	7.1.1.2, 7.1.2.1, 7.2.1
Council of State and Territorial Epidemiologists	7.1.2.1	Action: Filter EHR data for information matching inclusion/exclusion factors CSTE has passed a position statement which will include reporting criteria and data elements for each reportable diseases. CSTE expect the clinical info system to continuous apply for conditions identified as immediately reportable.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. The processes described in the feedback are included in this use case. Specifics regarding CSTE, addresses implementation considerations and may pertain to another working group and/or organization.	7.1.1, 7.2.1, 8.2.2, 8.3.2

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Council of State and Territorial Epidemiologists	7.1.2.2	Action: View and Evaluate PH Cases/AEs which have been identified Change 'potential' to 'possible' under description and comments	Accepted	Feedback has been incorporated into the document.	2.0-10.0
Council of State and Territorial Epidemiologists	7.1.2.2	Action: View and Evaluate PH Cases/AEs which have been identified This should not impede the reporting process. While it is important to improve completeness of reporting (sensitivity) this should not compromise the sensitivity of the surveillance. Routine review of the case passed by the filter is not appropriate for conditions where immediate reporting is required. In addition, this should not replace, but augment, when calling to report to a PH agency within their jurisdiction.	1	Feedback has been incorporated into the document.	2.0, 7.1.5, 7.2.2, 7.2.3
Council of State and Territorial Epidemiologists	7.1.2.2	Relocate the second paragraph into 7.1.3 Augment EHR information (which we propose to merge into 7.1.5).	1	Feedback has been incorporated into the document.	7.1, 7.2
Council of State and Territorial Epidemiologists	7.1.3	Event: Augment EHR Information This event should be omitted or incorporated in 7.1.5 this should not precede 7.1.4	1	Feedback has been incorporated into the document.	7.1, 7.2
Council of State and Territorial Epidemiologists	7.1.3.1	Action: Information related to a possible PH Case/AE that is not available through an HER is manually gathered This event should be omitted or incorporated in 7.1.5 this should not precede 7.1.4	Accepted	Feedback has been incorporated into the document.	7.1, 7.2
Council of State and Territorial Epidemiologists	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 This event should be omitted or incorporated in 7.1.5 this should not precede 7.1.4	Accepted	Feedback has been incorporated into the document.	7.1, 7.2
Council of State and Territorial Epidemiologists	7.1.4	Event: validate and disseminate report After a defined waiting period, case reports which require immediate reporting or routinely reported need to be reported to PH after a specific timeframe if the case has not been validated. This is related to the comment on 7.1.2.2. This appears to be a rate limiting step in the reporting process and does not necessarily encourage "automated case reporting".	Accepted	Feedback has been incorporated into the document.	2.0, 7.1.2.1, 7.1.5

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Council of State and Territorial Epidemiologists	7.1.4.1	Action: Validate information from the EHR, as well as augmented information This appears to be redundant with 7.1.2.2, and should be merged into that event. Omit 7.1.4.1 and re-title 7.1.4 to omit "validate and".	Accepted	Feedback has been incorporated into the document.	7.1, 7.2
Council of State and Territorial Epidemiologists	7.0	Add 'possible' before PH case under description and comments	Accepted	Feedback has been incorporated into the document.	2.0-10.0
Council of State and Territorial Epidemiologists	7.0	Prior to 7.1.5 there needs to be an event which specifies PH querying (7.3.3. in the Figure 7-1) the provider to addition information. Suggest "Receive request for additional information from Public Health".	Accepted	Feedback has been incorporated into the document.	7.2.2
Council of State and Territorial Epidemiologists	7.0	"Disseminated" is the wrong term here (and in all other references to this activity in which it or its variants are used). "Disseminate" means "to scatter widely", which is hardly what we are doing.	Accepted	Feedback has been incorporated into the document.	7.1.7
Council of State and Territorial Epidemiologists	7.1.5	Event: Send additional information Move 7.1.3 into event 7.1.5, this would incorporate the event "augment EHR information". Re-title 7.1.5 to "Augment EHR Information and Send additional information".	Accepted	Feedback has been incorporated into the document.	7.1, 7.2
Council of State and Territorial Epidemiologists	7.0	Action: Send information related to previously reported PH Cases/AEs and/or other information may be sent to public health Re-number 7.1.3.1 as 7.1.5.1, 7.1.3.1a as 7.1.5.2, current 7.1.5.1 as 7.1.5.3.	Accepted	Feedback has been incorporated into the document.	7.1, 7.2, 8.2.2, 8.3.2
Council of State and Territorial Epidemiologists	7.1.6.1	Action: Receive information from public health regarding PH Cases/AE reports which have been transmitted to public health This information will include also information about how to recognize, diagnose and manage additional cases, and how to identify and manage contacts who are at risk for the same disease. Delete "/refutation".	Accepted	Feedback has been incorporated into the document.	8.1.2
Council of State and Territorial Epidemiologists	7.1.7.1	Action: Identify confirmed and additional possible PH Cases/AEs The assumption is that the newly identified cases will be reported. This is step needs to be incorporated.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	8.2.2, 8.3.2, 7.1.2

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Council of State and Territorial Epidemiologists	7.1.7.2, 7.1.6.1	Action: Treat confirmed and additional possible PH Cases/AEs Include reporting the new "additional possible PH Cases" to PH.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	8.2.2, 8.3.2, 7.1.2
Council of State and Territorial Epidemiologists	7.2.1	Event: receive and incorporate Notifiable Condition/AE criteria The process is similar 7.1.1.1. Laboratory info systems need to receive updated criteria in near-real time. This is critical for emerging infectious disease (e.g., SARS). A subscription of this information should be made available to labs by way of ontological tools hosted by a recognized national PH entity (e.g., CDC and CSTE jointly).	Accepted	Feedback has been incorporated into the document.	7.1.1, 7.1.1.2, 7.2.1, 8.3.1.1
Council of State and Territorial Epidemiologists	7.2.1.2	Action: Incorporate the PH Case/AE Criteria into the LIS This should be done in real time. Edit "Criteria are incorporated in a consistent way into the LIS" to read "Criteria are incorporated in near-real-time and in a consistent way into the LIS".	Accepted	Feedback has been incorporated into the document.	7.1.1, 7.1.1.2, 7.2.1, 8.3.1.1
Council of State and Territorial Epidemiologists	7.2.2	Event: Identify potential Notifiable Condition/AE Change 'potential' to 'possible' under description	Accepted	Feedback has been incorporated into the document.	2.0-10.0
Council of State and Territorial Epidemiologists	7.2.2.1	Action: Filter LIS data for information matching inclusion / exclusion factors suggested edit… "laboratory test orders and results data are evaluated". For example in FL, labs are required to report if a specific lab test is ordered for a "immediately" notifiable condition. This is in addition to the provider prospective where criteria to report can include the request of a specific lab test (e.g., anthrax test order) which would serve as a trigger.	Accepted	Feedback has been incorporated into the document.	7.1.1, 7.1.1.2, 7.2.1, 8.3.1.1
Council of State and Territorial Epidemiologists	7.0	The second paragraph, the word ad hoc is inappropriately used. What's being communicated are test results (i.e., planned, regular, routine, not ad-hoc). Overall is this paragraph should be excluded.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	8.1.1.1
Council of State and Territorial Epidemiologists	7.2.3	Event: validate and disseminate results/information edit title for 7.2.3 to delete "validate and ".	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	7.1.5.2

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Council of State and Territorial Epidemiologists	7.2.3	Event: validate and disseminate results/information Does not specify the frequency this should be done. Is this on a continuous basis for suspect BT agents or other diseases which require immediate reporting? Or should this be done once a day for conditions. Specific conditions that require immediate reporting (e.g., suspected anthrax) this may need to be recognized and reported in real time.	Partially Accepted	A portion of the feedback has been incorporated into the document. References to the need for real-time reporting and reporting criteria updates are addressed in this use case. Specifics regarding reporting frequencies are addressed in the 2006 Biosureveillance Use Case.	7.1.1.2, 7.1.2.1, 7.2.1
Council of State and Territorial Epidemiologists	7.2.3	Event: validate and disseminate results/information AE in a laboratory setting will be challenging without combining with clinical information. Its unclear what public health needs to know about regarding adverse event in this setting. There's a lot of complexity that's not address. AE model does not fit in the lab model. this goes back to the discussion that AEs are typically reported at the organizational level.	Accepted	Feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions associated with public health cases and specific actions associated with adverse events.	7.0, 8.0 7.1.1.2, 7.2.1.1, 7.2.1.2, 7.1.1.3, 7.2.1.3
Council of State and Territorial Epidemiologists	7.2.3.1	Action: Validate information from the LIS This manual step is not implemented in most ELR systems, apart from the routine validation of all results for quality assurance purposes in the laboratory. It is not needed or appropriate as a separate function in ELR. Requiring such a step for ELR would kill most existing ELR systems. Merge this text into step 7.2.2.1 and delete 7.2.3.1.	Accepted	Feedback has been incorporated into the document.	8.3.1
Council of State and Territorial Epidemiologists	7.2.3.2	Action: Transmit validated PH Case/AE report is disseminated to public health Edit "results, along with specific information in regards to the reporting to public health may be communicated on an ad-hoc basis with the provider" to read "results, along with specific information in regards to the reporting to public health, are communicated to the provider"	Accepted	Feedback has been incorporated into the document.	8.3.1
Council of State and Territorial Epidemiologists	7.2.4	Event: Send additional information Again, missing a step in the request of additional information from public health. Prior to 7.2.4 there needs to be an event which specifies PH querying (7.3.3. in the Figure 7-1) the provider to addition information. Suggest "Receive request for additional information from Public Health".	Accepted	Feedback has been incorporated into the document.	7.2.2

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Council of State and Territorial Epidemiologists	7.2.5	Event: Receive public health information This information may include guidance on detecting agents of urgent importance, and on where to send specimens for confirmation or specialized testing.	Accepted	Feedback has been incorporated into the document.	7.1, 7.2, 9.1
Council of State and Territorial Epidemiologists	7.2.5.1	Action: Receive information from public health regarding Notifiable Condition/AE reports which have been transmitted to public health. please remove the word refutation.	Accepted	Feedback has been incorporated into the document.	8.1.2
Council of State and Territorial Epidemiologists	7.2.5.1a	Alternative Action: Receive information from public health regarding trends, groups, etc. Will labs utilize the public health information to identify additional Notifiable conditions/AE, since they only perform tests ordered by providers?	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	8.3.2
Council of State and Territorial Epidemiologists	7.3.1.1	Action: Determine PH Case/AE criteria Suggested edit to include parenthesis of the various entities.	Accepted	Feedback has been incorporated into the document.	3.0
Council of State and Territorial Epidemiologists	7.3.1.2	Action: Communicate PH Case/AE Criteria Suggested edit "In the future, by way of joint CSTE/CDC effort, there may be available through a PH knowledge-base (ontology tool) a means for providers to subscribe to jurisdiction-specific information making updates available in near-real-time"	Partially Accepted	A portion of the feedback has been incorporated into the document . References to the need for real-time reporting and reporting criteria updates are addressed in this use case. Specifics regarding providers of reporting criteria are not in scope for this use case.	7.1.1, 7.1.1.2, 7.2.1
Council of State and Territorial Epidemiologists	7.3.2.1	Action: Receive reports/information What does discrete mean? Does this mean a line listing format of information. Or does it mean a summary tabular information. Please clarify.	Accepted	Feedback has been incorporated into the document.	7.1.1.3
Council of State and Territorial Epidemiologists	7.3.3.2a	Alternative Action: Request information by utilizing the information exchange to send a call out for applicable information suggested edit, … for additional information "ought to be" specified… (i.e., change "additional information is not specified as an information exchange" to read "additional information is specified as an information exchange")	Accepted	Feedback has been incorporated into the document.	8.1.1, 8.2.1
Council of State and Territorial Epidemiologists	7.3.4	Event: Receive information and perform investigation Separate "receive information" and "perform investigation". Both should be separate events.	Accepted	Feedback has been incorporated into the document.	7.2.3, 8.1.1

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Council of State and Territorial Epidemiologists	7.3.4.1	Action: Receive addition information to assist in investigate activities suggested edit: Receive additional" information to assist in investigate activities	Accepted	Feedback has been incorporated into the document.	8.1.1
Council of State and Territorial Epidemiologists	7.3.4.2	Action: Perform investigation activities Investigation can include site visits, environmental testing, … and other additional information not found in the EHR.	Accepted	Feedback has been incorporated into the document.	7.1.6, 8.1.1.3
Council of State and Territorial Epidemiologists	7.3.5	Event: Confirm and/or refute PH case/AE reports Don't like 'determine whether reports are "real"'. How about determine whether reports meet criteria for further public health action, including investigation, intervention and inclusion in official case counts".	Accepted	Feedback has been incorporated into the document.	2.0-10.0, 8.1.3.2
Council of State and Territorial Epidemiologists	7.3.5.1	Action: Validate PH Cases and AEs Don't like "confirm or refute" - We aren't disagreeing that the person is ill or that it should have been reported. We are applying additional criteria to evaluate further.	Accepted	Feedback has been incorporated into the document.	2.0-10.0, 7.1.1.2, 8.1.2.2
Council of State and Territorial Epidemiologists	7.3.5.2	Action: Confirm and/or refute PH Case/AE Reports change title to read "Action: Determine the status of PH Case/AE reports". Comments: "Specific PH Cases/AEs will either be confirmed and/or refuted" should be changed to "Specific PH Cases/AEs will be classified." Many PH data systems use the three level classification of confirmed/probable/possible (though some use alternative terms "presumptive" instead of probable and "suspected" instead of possible), but there are exceptions: SARS and pesticide-related illness surveillance data systems use substantially different terminology. This use case may not be the place to explain all of the different terms in standard use.	Accepted	Feedback has been incorporated into the document.	2.0-10.0, 8.1.3.2
Council of State and Territorial Epidemiologists	7.3.5.2	Add a 7.3.5.3 as an Action: Determine uniqueness of record. Or possibly add in the comment section of the 7.3.5.1	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	9.0
Council of State and Territorial Epidemiologists	7.3.7.1	Action: Communicate information regarding specific Notifiable Condition, PH Case, and AE reports which have been transmitted to public health Add '…managing and treating their patients and contacts of those patients….'	Accepted	Feedback has been incorporated into the document.	8.1.3, 8.1.4, 8.2.3

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Council of State and Territorial Epidemiologists	9.0	Public Health Case Reporting Dataset Considerations Page 30, list of considerations for PH cases should include specific mention of pharmacy and radiology records, problem lists, and admitting and discharge diagnoses	Accepted	Feedback has been incorporated into the document.	7.1.2.1, 10.0
Federal Health Architecture	3.0	Please add tribal as a key participating group.	Accepted	Feedback has been incorporated into the document.	2.0-5.0, 10.0, Appendix A
Federal Health Architecture	3.0	Please add tribal as a part of the US Government description and include the following agencies where specific agencies are referenced: Department of Veteran's Affairs and Indian Health Service.	Accepted	Feedback has been incorporated into the document.	2.0-5.0, 10.0, Appendix A
Federal Health Architecture	N/A	The workflow for managing public health reporting versus adverse events is very different, yet the author seems to address these in similar ways. The author should consider writing these as two different workflows.	Accepted	Feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions associated with public health cases and specific actions associated with adverse events.	7.0, 8.0 7.1.1.2, 7.2.1.1, 7.2.1.2, 7.1.1.3, 7.2.1.3
Food & Drug Administration	N/A	We recognize that health information technology has great potential to improve identification and reporting of adverse events (AE) related to medical products. In particular, harmonization of terminologies and vocabularies that describe clinical events would dramatically improve the process and analysis of AE reports and the ability to develop active surveillance approaches.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	2.0
Food & Drug Administration	2.0	It appears that the original purpose of this particular Use Case was to describe workflows underlying the reporting of "notifiable conditions", not AE reporting.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	2.0
Food & Drug Administration	2.0	Many of the workflows described in this Use Case do not apply to medical product AE reporting. We therefore feel that this Use Case would be an inappropriate vehicle for standards harmonization relating to medical product AE reporting, and could cause confusion about the role and responsibility of the FDA in AE surveillance.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address activities and information needs specific to AE reporting from EHRs.	7.0, 8.0, 7.1.4. 3.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Food & Drug Administration	2.0	FDA therefore recommends removing AEs from the scope of this Use Case, to enable the Use Case to better provide detail relevant to notifiable conditions.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address activities and information needs specific to AE reporting (medications and vaccines) from EHRs.	7.0, 8.0, 7.1.4. 3.0
Food & Drug Administration	N/A	Thank you for the opportunity to comment on this Use Case, and for the recognition that AE reporting is an important component of public health surveillance. Further explanations and examples that support the exclusion of AE reporting from this Use Case are presented below.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	7.0, 8.0, 7.1.4. 3.0
Food & Drug Administration	2.0	Workflows in this Use Case presuppose and are built upon the existence of "AE reporting specifications" or "AE detection or reporting criteria" that are communicated to providers by a public health authority.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	7.2.1, 7.1.1
Food & Drug Administration	N/A	As noted in the Use Case: "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."	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	7.0
Food & Drug Administration	2.0	As explained below, neither this workflow, nor the underlying concept of AE reporting criteria, apply to medical product AE reporting .	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address activities and information needs specific to AE reporting (medications and vaccines) from EHRs.	7.0, 8.0, 7.1.1.3, 7.2.1.3, 7.1.4., 3.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Food & Drug Administration	2.0	Including AEs in these workflows could hinder HITSP's harmonization of standards for public health case reporting, by adding unnecessary complications to the identification of standards for true public health case reporting. The result could also suggest application of inapposite standards to AE reporting.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. The use case addresses common technologies and common information exchanges which may support both public health case and adverse event reporting. Actions and data set considerations specific to each are addressed in this use case.	7.1.1.3, 7.2.1.3, 7.1.4, 8.0, 10.0
Food & Drug Administration	2.0	Including AEs in these workflows may simply "muddy the waters" and cause confusion with respect to perspectives and actors (e.g., the laboratory perspective does not apply to AE reporting).	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address activities and information needs specific to AE reporting. The role of the laboratory in AE reporting has also been modified. .	7.1.1.3, 7.1.2.1, 7.2.1.3, 7.1.4., 8.3
Food & Drug Administration	7.0	There are no objective AE reporting specifications, as there are for PH Case Reporting. This invalidates the basic workflows in all three sections of this Use Case (see workflows described in 7.1.1, 7.1.2, 7.2.1, 7.2.2, and 7.3.1).	Partially Accepted	A portion of the feedback has been incorporated into the document. This use case acknowledges the challenges in developing and using AE reporting criteria. This use case recognizes that the use of criteria may be possible based upon previously reported or known AEs and may be more difficult in the case of newly recognized AEs.	7.1.1.3, 7.2.1.3
Food & Drug Administration	N/A	There is generally no direct equivalent to a "notifiable condition" or "detection criteria" for AEs.	Partially Accepted	A portion of the feedback has been incorporated into the document. This use case acknowledges the challenges in developing and using AE reporting criteria. This use case recognizes that the use of criteria may be possible based upon previously reported or known AEs and may be more difficult in the case of newly recognized AEs.	7.1.1.3, 7.2.1.3

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Food & Drug Administration	N/A	For AE reporting, the concept of what to report is often subjective. There are no current objective criteria such as a lab report or objective clinical presentations that would automatically trigger an AE report.	Partially Accepted	A portion of the feedback has been incorporated into the document. This use case acknowledges the challenges in developing and using AE reporting criteria. This use case recognizes that the use of criteria may be possible based upon previously reported or known AEs and may be more difficult in the case of newly recognized AEs. Furthermore, in many cases the detection and reporting of AEs requires clinical judgment.	2.0, 7.1.1.3, 7.1.5, 7.2.1.3
Food & Drug Administration	7.0	There are no inclusion/exclusion criteria for AE reporting; thus, workflows described in 7.1.2.1, and 7.2.2.1 is not valid with respect to AEs.	Partially Accepted	A portion of the feedback has been incorporated into the document. This use case acknowledges the challenges in determining and using AE inclusion/exclusion criteria. This use case recognizes that the use of criteria may be possible based upon previously reported or known AEs and may be more difficult in the case of newly recognized AEs.	7.1.1.3, 7.1.2.1, 7.2.1.3
Food & Drug Administration	7.0	For AEs, the public health authority -- the FDA -- does not develop or provide AE reporting specifications (either directly, or through information exchanges). This invalidates the basic workflows in all three sections of this Use Case (see workflows described in 7.1.1, 7.1.2, 7.2.1, 7.2.2, and 7.3.1, and those depicted in figures 7-1 and 7-2.).	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. This use case acknowledges the challenges in developing and using AE reporting criteria. This use case recognizes that the use of criteria may be possible based upon previously reported or known AEs and may be more difficult in the case of newly recognized AEs. This use case also acknowledges that the FDA does not provide or require AE reporting criteria.	7.1.1.3, 7.2.1.3, 10.0
Food & Drug Administration	N/A	AE reporting by healthcare providers is voluntary. The workflows in this Use Case support mandatory reporting by healthcare providers.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. This use case addresses both mandatory and voluntary reporting by providers.	2.0, 10.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Food & Drug Administration	N/A	The Use Case defines "notifiable condition" as a condition "already recognized by law that must be reported to the government …." This is inapplicable to the majority of medical product AEs3.	Partially Accepted	A portion of the feedback has been incorporated into the document. This use case acknowledges the challenges in developing and using AE reporting criteria. This use case recognizes that the use of criteria may be possible based upon previously reported or known AEs and may be more difficult in the case of newly recognized AEs.	7.1.1.3, 7.2.1.3
Food & Drug Administration	N/A	The Use Case defines "Public Health Case" as a possible or confirmed "notifiable condition," and thus is also inapplicable to AEs.	Accepted	Feedback has been incorporated into the document.	7.1.1.3, 7.2.1.3
Food & Drug Administration	5.0	The relevant actors and perspectives are different for AE reporting versus public health case reporting.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address activities performed by other stakeholders.	7.0, 8.0, 7.1.4. 3.0
Food & Drug Administration	7.0	Significantly, laboratories are not likely to report AEs to public health authorities (e.g., workflows described in 7.2.3, 7.2.4, and 7.2.5 are not valid with respect to AEs)	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address activities and information needs specific to AE reporting. The role of the laboratory in AE reporting has also been modified. .	7.1.1.3, 7.1.2.1, 7.2.1.3, 7.1.4., 8.3
Food & Drug Administration	7.0	The workflows outlined in this use case move from provider to the public health authority, and back. In 2006, roughly 5% of adverse drug event reports were submitted to FDA by individuals or providers; for devices the proportion is roughly 1%. The vast majority of adverse event reports are submitted to FDA by product sponsors, pursuant to regulatory requirements.	Accepted	Feedback has been incorporated into the document.	7.0, 7.1.4

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	N/A	Review the work of Infoway (Canada) Public Health Communicable Disease Surveillance and Management Project Requirements Definition (http://www.infoway-inforoute.ca/Admin/Upload/Dev/Document/PHSM_Requirements_EN.doc). The document covers public health reporting, follow up and case management and details the use case and required components (listed as appended documents). The overview also evaluated scope and eliminated complex policy issues and/or areas where standards were not mature.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	2.0-10.0
Health Information Technology Standards Panel	N/A	The use case supposes similarities between the management of surveillance and adverse event reporting. The workflows are sufficiently different that separate use cases are required. As justification, Adverse Event reporting is not mandatory from a hospital or clinician and does not have triggers identified by reporting agencies (e.g., FDA) whereas Public Health surveillance is based on mandatory reporting. The similarity is the need for timely data transmission and using similar infrastructure, but using variations in business logic. The greatest benefit is to focus on vocabularies for standardization. Triggering types are different. The use case also does not account for patients submitting their own Adverse Events.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address stakeholders, activities, and information needs specific to AE reporting (medications and vaccines) from EHRs. This use case acknowledges the challenges in determining and having providers use both voluntary and mandatory reporting criteria.	2.0, 5.0, 7.0, 7.1.1.3, 7.1.2.1, 7.1.6.1, 7.2.1.3, 8.0, 10.0
Health Information Technology Standards Panel	2.0	Recommend focusing on mandatory Public Health Reporting, voluntary reporting is out of scope.	Not Accepted	The feedback proposes a change which is not consistent with the design of the use case. This use case addresses both mandatory and voluntary reporting by providers.	2.0, 10.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	2.0	Adverse Events do not only use objective laboratory criteria as do Public Health surveillance. Adverse Event surveillance is often managed through individual clinician suspicion of individual patient cases or data mining of existing data. Therefore, vocabulary standardization has greater value. Additionally the subject matter experts are different for each Public Health Reporting and Adverse Event Reporting.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address stakeholders, activities, and information needs specific to AE reporting. The role of the laboratory in AE reporting has also been modified. .	7.1.1.3, 7.1.2.1, 7.2.1.3, 7.1.4., 8.3, 10.0
Health Information Technology Standards Panel	2.0	The use case creates expectations that may be out of scope based on expected flows. The use case requires some notification requesting additional testing that raises the question of logistical issues including who will pay for such testing and evaluations whether from the clinician or laboratory perspective.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. This use case discusses the identification and communication of additional possible public health cases and adverse events. This use case does not require additional testing and discusses the use of available lab results within EHRs.	4.0, 7.0, 8.0
Health Information Technology Standards Panel	2.0	Clarification is required regarding whether Adverse Event Reporting encompasses Patient Safety Event Reporting.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Regarding AE reporting, this use case focuses on post-market medications and vaccines.	2.0
Health Information Technology Standards Panel	2.0	2.0 Introduction and Scope (1) This use case should be broken into 3 scenarios: Reporting, Investigation, and Intervention. It is difficult to parse the responsibilities of various parties and intercommunications when combined into a single scenario. Each of the 3 scenarios should be separately displayed and discussed with respect to (a) Public Health case reporting for routine surveillance and (b) Adverse Events (a previous comment suggested creating a different use case for Adverse Event Reporting due to the inconsistencies).	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address stakeholders, activities, and information needs specific to AE reporting.	7.1.1.3, 7.1.2.1, 7.2.1.3, 7.1.4, 10.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	2.0	This use case should be broken into 3 scenarios: Reporting, Investigation, and Intervention.(2) Combining Public Health Case Reporting and Adverse Events causes confusion and often the documentation addresses one at the expense of the other. These are different concepts and would benefit significantly by displaying separate scenarios or by creating a separate use case. Note that, similar to Public Health Reporting, Adverse Event reporting also has 3 scenarios: Reporting, Investigation, and Intervention.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address stakeholders, activities, and information needs specific to AE reporting.	7.1.1.3, 7.1.2.1, 7.2.1.3, 7.1.4, 10.0
Health Information Technology Standards Panel	2.0	This use case should be broken into 3 scenarios: Reporting, Investigation, and Intervention. (3) It is assumed that Public Health Reporting is intended for routine surveillance rather than emergency or biosurveillance. The relationship to the Biosurveillance Use Case is not specified. Please clarify how this use case correlates with the Biosurveillance Use Case from 2006.	Accepted	Feedback has been incorporated into the document.	7.1.2.1
Health Information Technology Standards Panel	N/A	Other General Comments: (a) Reporting, Investigation, and Information Sharing: Intervention is a preferred term over Information Sharing. From the Public Health perspective the action is intervention	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	8.1.5, 8.2.3
Health Information Technology Standards Panel	N/A	Other General Comments: (b) There is reference in the document that some information would be sent from Public Health to providers expecting action. Such clinical decision support capability may be difficult to address in a relatively short time frame.	Acknowledged	Intent of the feedback has been acknowledged and is addressed in the document.	4.0
Health Information Technology Standards Panel	N/A	Other General Comments: (c) Routine surveillance supports Registries. There is some reference to interaction for immunization registries, but other disease registries (e.g., cancer registries) are managed under the auspices of Public Health.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. For the purposes of this use case, PH Case reporting may include the reporting of communicable /infectious and non-infectious diseases/ conditions. Additional reporting i.e. - cancer, tumor, occupational, may be addressed in future initiatives.	2.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	2.0	There is an established legislated (legal) system of reporting. The Use Case as identified will require review and modification of some state and local legislated requirements for full implementation as designed.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. This use case acknowledges that reporting requirements for public health cases and adverse events vary across local and state jurisdictions.	2.0, 4.0, 10.0
Health Information Technology Standards Panel	2.0	This use case seems to take a perspective of federal level reporting. There are additional requirements and variations on state, local and tribal levels. The presumption of reporting on a federal level is confusing since there is a state rights issue of control. Certainly state, local and tribal reporting needs must be accounted for in the use case.	Accepted	Feedback has been incorporated into the document.	2.0-10.0
Health Information Technology Standards Panel	2.0	Contractual reporting needs to be identified and discussed in the use case. One example is Biosense which introduces a contract between the provider and the CDC.	Accepted	Feedback has been incorporated into the document.	8.1.1.2
Health Information Technology Standards Panel	N/A	The use case does not seem limited to statutory reportable conditions. Is it constrained to legally notifiable conditions? If not, additional privacy and security safeguards will be necessary.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. This use case addresses both mandatory and voluntary reporting by providers.	2.0, 10.0
Health Information Technology Standards Panel	7.0	Combining reporting, investigation and bi-directional information sharing in one scenario creates an extremely broad scope that cannot be accomplished in a short time frame. Each has very specific constraints. We recommend improving clarity by splitting the scenario into three scenarios and clearly defining the scope of each - Reporting, Investigation and Intervention (the last instead of Information Sharing)	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address stakeholders, activities, and information needs specific to AE reporting.	7.1.1.3, 7.1.2.1, 7.2.1.3, 7.1.4, 10.0
Health Information Technology Standards Panel	3.0	Decision Support should not be a stakeholder. It is a basic infrastructure requirement that is used by all stakeholders. It is not, in itself, a stakeholder.	Accepted	Feedback has been incorporated into the document.	3.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	2.0	Manufacturers / distributors are not stakeholders for the public health reporting flow. They are, however, stakeholders for the Adverse Event reporting flow. The combination of adverse event reporting and public health reporting is problematic. These should be clearly separated into different scenarios or split into two use cases. Combination throughout causes confusion with respect to business and technical actors as well as data requirements.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address stakeholders, activities, and information needs specific to AE reporting.	7.1.1.3, 7.1.2.1, 7.2.1.3, 7.1.4, 10.0
Health Information Technology Standards Panel	3.0	Additional Governmental Stakeholders include AHRQ (medication and other injury detection and reporting) and Department of Agriculture. In the event of emergency management, Department of Homeland Security is also a stakeholder.	Accepted	Feedback has been incorporated into the document.	3.0
Health Information Technology Standards Panel	3.0	Correctional facilities are stakeholders with respect to adverse events and public health as reportable events may occur in these institutions.	Accepted	Feedback has been incorporated into the document.	5.0
Health Information Technology Standards Panel	7.0	The requirements for veterinary reporting are not specified. FDA and environmental organizations need to be incorporated into the flow with respect to public health reporting. There is a broader view of livestock illness, and the more narrow focus of domestic animal (pet) disease and communication to humans in near proximity. Example: leptospirosis and pet pigs, communication of respiratory viruses between pet birds and their owners, etc.	Accepted	Feedback has been incorporated into the document.	3.0, 5.0
Health Information Technology Standards Panel	3.0	What is the role of zoonotic testing with respect to the feedback loop and clinical decision support to the providers (and vice versa)? E.g., rates of West Nile Virus in local birds, rabies in local wildlife, etc.	Accepted	Feedback has been incorporated into the document.	3.0, 5.0, 7.0, 8.0
Health Information Technology Standards Panel	4.0	Confidentiality, Privacy and Security: There are issues of concern that need to be addressed after the use case is refined. Public Health laws are in play and vary by state.	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	2.0, 4.0
Health Information Technology Standards Panel	4.0	Confidentiality, Privacy and Security: From the consumer point of view, there is no consent for Public Health or Adverse Event reporting.	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	4.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	4.0	Confidentiality, Privacy and Security: The confidentiality and security issues remain significant, however, as data need to be protected within the reporting data flows. Public Health agencies and adverse event organizations receiving reports are not exempt from privacy and security concerns.	Accepted	Feedback has been incorporated into the document.	4.0
Health Information Technology Standards Panel	4.0	Issues and Obstacles: Information Integrity, Interoperability and Exchange Case definitions and criteria are fluid. A methodology is required for modifying case definition criteria in a standard manner.	Accepted	Feedback has been incorporated into the document.	8.1.2.2, 10.0
Health Information Technology Standards Panel	4.0	Issues and Obstacles: Information Integrity, Interoperability and Exchange The issue of EHR adoption is addressed. However, the penetration, adoption and interoperability of Public Health with respect to information technology is a significant issue.	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	2.0, 4.0
Health Information Technology Standards Panel	4.0	Issues and Obstacles: EHR and HIT Adoption Public Health legacy systems are highly customized and cannot easily be plugged in to health information exchanges.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	2.0, 4.0
Health Information Technology Standards Panel	4.0	Issues and Obstacles: EHR and HIT Adoption HIT optimization is required in the Public Health domain.	Accepted	Feedback has been incorporated into the document.	2.0
Health Information Technology Standards Panel	4.0	Issues and Obstacles: EHR and HIT Adoption Adoption is quite variable. Change management issues are significant to bring Public Health to the level of a full participant in this use case. Similarly, the adoption, semantic and technical interoperability of Adverse Event reporting systems is not discussed.	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	4.0
Health Information Technology Standards Panel	4.0	Issues and Obstacles: EHR and HIT Adoption Variability of integration approaches is complex (E.g., from laboratory information systems to Public Health).	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	4.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	4.0	Issues and Obstacles: Lack of Business Model and Infrastructure: There is a patchwork quilt of regulations of what gets reported to Public Health with variations by jurisdiction about what gets reported. Filters are important for required reporting, prohibited reporting, multiple- jurisdictions serviced by a provider.	Accepted	Feedback has been incorporated into the document.	2.0, 4.0, 7.1.1, 7.2.1
Health Information Technology Standards Panel	4.0	Issues and Obstacles: Policy Issues The potential number, frequency and overlapping Adverse Event reporting systems and requirements are not addressed. Similar to Public Health reporting there are varying requirements based on legislative mandates at local, regional, state and federal levels.	Accepted	Feedback has been incorporated into the document.	2.0, 7.1.1.3, 7.2.1.3
Health Information Technology Standards Panel	4.0	Issues and Obstacles: Policy Issues There is a policy issue in this area. IT rules cannot be used to make a decision on where to report because demographics do not provide enough information to determine reporting requirements. This applies to Public Health reporting criteria specifications and communications. Similarly, Adverse Event reporting must be reviewed to determine if similar issues are relevant.	Accepted	Feedback has been incorporated into the document.	7.1.1.2, 7.2.1.1, 7.2.1.2, 7.1.1.3, 7.2.1.3
Health Information Technology Standards Panel	5.0	Many communications are point-to-point, an issue that impacts security and privacy. Health exchange, to be architecturally neutral, can be point-to-point, query based, or reference a repository. Each has different aspects of confidentiality.	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	9.0
Health Information Technology Standards Panel	5.0	Security and Privacy: Need to account for disclosures of information.	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	9.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	5.0	The consumer perspective is missing. A method for communicating with the consumer for public health investigation and intervention is important. Similarly EHR and PHR communication has a role here whether for augmenting information in a report (public health or adverse event reporting) or directly communication clinical care options.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. This use case focuses on using data in EHRs and augmenting EHR data in order to assist providers in reporting to public health. While direct consumer reporting to public health is not the focus of this use case, it is addressed within the information sources, recipients, and actions.	5.0, 7.0, 7.1.6.1, 8.0
Health Information Technology Standards Panel	5.0	The Perspective section does not address requestors of or recipients of adverse event reporting (e.g., FDA, manufacturers, etc for medication-related adverse events). Non-medication related adverse events (e.g., implantable devices, prostheses, indwelling catheters, etc.) should also be covered in perspectives.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address stakeholders, activities, and information needs specific to AE reporting.	5.0, 7.1.1.3, 7.1.2.1, 7.2.1.3, 7.1.4, 10.0
Health Information Technology Standards Panel	2.0	The scope of adverse events and notifiable conditions needs to be clearly identified.	Accepted	Feedback has been incorporated into the document.	2.0
Health Information Technology Standards Panel	2.0	Healthcare associated adverse events include medication related, healthcare-related incidents (falls, pressure sores, injuries), and healthcare associated infections. Some of these have been categorized as Patient Safety Reports and some are reportable and some are not, depending on locations (state, local reporting requirements).	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. For the purposes of this use case, PH Case reporting may include the reporting of communicable /infectious and non-infectious diseases/ conditions. Additional reporting i.e. - cancer, tumor, occupational, may be addressed in future initiatives.	2.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	2.0	Public health also collects information on non-healthcare related injuries (falls in the home, firearm related injuries, automobile related injuries, etc) - is reporting on these events in scope for the use case, or is a similar method of reporting suggested for this type of injury?	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. For the purposes of this use case, PH Case reporting may include the reporting of communicable /infectious and non-infectious diseases/ conditions. Additional reporting i.e. - cancer, tumor, occupational, may be addressed in future initiatives.	2.0
Health Information Technology Standards Panel	5.0	Perspectives: Public Health Reporting Criteria, Specifications, and Communications Voluntary Public Health exchange should be explained. Public Health reporting criteria, specifications and communications need to address adverse event criteria, specifications and communications. The criteria need to be agreed upon by all parties.	Accepted	Feedback has been incorporated into the document.	7.1.1.2, 7.2.1.1, 7.2.1.2, 7.1.1.1, 7.2.1.3
Health Information Technology Standards Panel	5.0	Perspectives: Information Interoperability and Exchange There is a human factor causing resistance to adopting electronic systems as the primary communications means. Telephone based communications are currently in use a somewhat effective.	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	4.0
Health Information Technology Standards Panel	5.0, 7.0	Perspectives: Information Interoperability and Exchange Providers want the ability to validate and indicate it is appropriate send a report, whether Public Health reporting or Adverse Event reporting is considered. Providers often have more in depth knowledge of the patient's situation and can more accurately apply clinical judgment to determine if, in fact, a reportable event has occurred. Clarification is required as to whether a provider has the ability to approve transmission, or, conversely to disapprove of a transmission.	Partially Accepted	A portion of the feedback has been incorporated into the document . The use case addresses various mechanisms for reporting. When reporting criteria are met, implementation decisions will need to be made to determine whether reporting can be automated or if clinical judgment is required.	2.0, 7.1.5, 7.2.2, 7.2.3

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	5.0	Public Health providers need the ability to approve alerts to be sent to clinical care providers, rather than automating the process entirely based on thresholds exceeded. Similarly, Adverse Event monitoring agencies or organizations will need the same ability.	Partially Accepted	A portion of the feedback has been incorporated into the document . The use case addresses various mechanisms for reporting. When reporting criteria are met, implementation decisions will need to be made to determine whether reporting can be automated or if clinical judgment is required.	2.0, 7.1.5, 7.2.2, 7.2.3
Health Information Technology Standards Panel	2.0	Enforcement and potential penalties for providers who do not report either Public Health or Adverse Event incidents should be addressed.	Policy – Deferred - Policy/Regulatory Issue	The feedback relates to a policy or regulatory issue which cannot be addressed within this use case. The use case does address both voluntary and mandatory reporting activities but cannot dictate policy.	2.0, 4.0
Health Information Technology Standards Panel	5.0	Clarification of "active" vs. "passive" surveillance is required. Perceived definitions may be different depending on the edge of the NHIN. Is "active" and "passive" the same for Public Health and for Adverse Events? It is presumed that "active" refers to a trigger to initiate reporting at the time an event is noticed (at the occurrence). "Passive" is presumed to indicate retrospective reporting at some predetermined regular interval (e.g., monthly). Alternatively, "active" could refer to the interested agency actively querying for occurrences and "passive" referring to the interested agency receiving a steady stream of occurrences without specific action on the part of the agency.	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document. References to biosurveillance activities are also referenced in this use case.	4.0, 7.1.2.1

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	5.0	Triggers for reporting need to be identified for each reporting instance. Implementations will need to set triggers for when to report each type of Public Health occurrence and Adverse Event occurrence. Triggers may be different for each type of occurrence. E.g., triggers for Public Health reporting might be 'suspected' anthrax, 'presumptive' influenza, and 'confirmed' shigella. Thus, triggers and clear definitions would be expected in the case definitions provided by monitoring organizations. The use case presumes proactive case reporting. Note that there are two types of triggers: (a) triggers intended to determine the timing for capturing data in a concurrent model of data capture than may include clinical decision support components to request additional information or suggest specific actions, or (b) triggers intended to indicate the timing for transmission of reports to Public Health agencies. Both triggers require timing, data elements and expected actions to be specified.	Partially Accepted	A portion of the feedback has been incorporated into the document. References to the need for real-time reporting and reporting criteria (including case definition) updates are addressed in this use case. Specifics regarding reporting frequencies are addressed in the 2006 Biosureveillance Use Case.	7.1.1.2, 7.1.2.1, 7.2.1, 8.1.2.2
Health Information Technology Standards Panel	5.0	Adverse Events triggers are often locally derived or they are set by various organizations, not generally by federal monitoring agencies (e.g., FDA). Such triggers might be represented by 'suspected' rather than 'confirmed' medication reaction, and 'confirmed' healthcare associated infection. Adverse Event triggers, like Public Health triggers may take two forms: (a) triggers intended to determine the timing for capturing data in a concurrent model of data capture (e.g., all orders for Protamine to generate review for potential heparin related adverse events, or Vitamin K for warfarin related events) than may include clinical decision support components to evaluate additional information to determine if reporting or additional action is required, or (b) triggers intended to indicate the timing for transmission of reports to Adverse Event monitoring agencies.	Partially Accepted	A portion of the feedback has been incorporated into the document. References to the need for real-time reporting and reporting criteria (including case definition) updates are addressed in this use case. Specifics regarding reporting frequencies are addressed in the 2006 Biosureveillance Use Case.	7.1.1.2, 7.1.2.1, 7.2.1, 8.1.2.2

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	5.0	Is reporting always to local Public Health? Is reporting expected to occur simultaneously to multiple levels of infrastructure (e.g., State and CDC), or to follow traditional paths of Healthcare Organization to Local Public Health to State Public Health to CDC? Conversely, Adverse Event reporting and information exchange represents a different set of actors not necessarily addressed in the use case.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address stakeholders, activities, and information needs specific to AE reporting. In addition the public health perspective has been updated to reflect public feedback.	5.0, 7.1.1.3, 7.1.2.1, 7.2.1.3, 7.1.4, 10.0
Health Information Technology Standards Panel	5.0	Assuming reporting of Adverse Events, are events that occur but do not lead to harm included? If so the volume of events to be captured and transmitted increases considerably.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	N/A
Health Information Technology Standards Panel	5.0	Also, are near events to be captured and reported? If so, the methodology (triggers and evaluation logic) for identifying near events will need to be clearly and explicitly defined by monitoring agencies and criteria may significantly overburden the providers and clinical system implementations to enable capture of sufficient information to identify near events. The volume of events will increase dramatically.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	7.2.1, 10.0
Health Information Technology Standards Panel	5.0	Today, the Public Health system is organized to report only at the end point (confirmed occurrence). Adverse Event reporting is variable. The use case needs to address that multiple updated versions of each case report may be generated. E.g., a suspected medication reaction reported that, after further study is determined to be due to other causes, or conversely, shown to be highly likely related to the medication in question. Therefore, versioning of information about the same incident on the same patient is required.	Accepted	Feedback has been incorporated into the document.	7.0, 8.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	5.0	In an HIE (Health Information Exchange), which entity has the responsibility to report issues, since many are sharing the information? Although somewhat of a policy issue, the reporting entity identification impacts directly on security and privacy concerns.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	4.0, 7.1.1, 7.2.1, 9.0
Health Information Technology Standards Panel	5.0	When does a series of incidents become an issue of concern? E.g., when is an outbreak a true Public Health event, or when is a series of medication reactions a true medication event requiring modification of indications, usage recommendations or withdrawing availability? In an electronically interoperable environment the volume of information will change and therefore the criteria will also require scrutiny.	Accepted	Feedback has been incorporated into the document.	7.2.2.2, 7.2.3.2
Health Information Technology Standards Panel	5.0	Government agencies should be added as a perspective.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Government agencies function in a role associated with the perspectives identified in the use case.	3.0
Health Information Technology Standards Panel	5.0	Veterinarians need to be added to the provider perspective section. Whether related to individual case investigation and intervention or general disease reporting (or adverse event) surveillance, veterinarians are stakeholders and actors within the Public Health and Adverse Reporting infrastructure.	Accepted	Feedback has been incorporated into the document.	3.0, 5.0
Health Information Technology Standards Panel	7.0	Reporting, Investigation and Information Sharing are each unique operations with unique data flows and data content. The flow depicted is not representative of current activities.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing.	7.0, 8.0
Health Information Technology Standards Panel	7.0	Case investigation dataset harmonization will be a more long-term effort	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	10.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	7.0	Information sharing begins with the case investigation step with call-back to the provider to complete the data capture. The process is all part of case investigation. Again, splitting the current scenario into three components will add significantly to the clarity of the figure and the flow.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. Requests to the provider for additional information have also been addressed.	7.0, 8.0
Health Information Technology Standards Panel	7.0	Information sharing alerts suggests clinical decision support to send notification to the provider that something is changed (something new is happening)	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Clinical decision support capabilities may support processes described in the scenarios but are not the focus of this use case.	7.0, 8.0
Health Information Technology Standards Panel	7.0	Information sharing alerts about community status for import to the EHR is laudable but requires standardization and maturation of the clinical decision support capabilities within EHRs, and external to EHRs. That such information can be used to generate additional or altered care management for patients in the targeted population requires a semantically interoperable and actionable decision support component which is currently in the realm of research.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	8.1.5, 10.0
Health Information Technology Standards Panel	7.0	Recommend one scenario for Reporting, one for Investigation, one for Intervention. Also separate Public Health Reporting and Adverse Event Reporting for each scenario. Case identification (reporting) serves as input to the other scenarios.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address stakeholders, activities, and information needs specific to AE reporting.	7.1.1.3, 7.1.2.1, 7.2.1.3, 7.1.4, 10.0
Health Information Technology Standards Panel	5.0	Intervention is managed individually for specific patients as well as systematically to change processes for all patients. Therefore, interventions should be addressed from two perspectives - individual patient and system (e.g., modify isolation policies for MRSA) interventions.	Out of Scope	The feedback describes a need which is out of scope and cannot be addressed within this use case. Specifics regarding interventions are discussed in the 2008 Immunizations and Response Management Use Case.	8.2.3

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	7.0	The drawing implies there is a central HIE which implies an architecture. Public Health has not reached consensus on interaction with HIEs. Although the words are present to suggest point-to-point and other methods, the diagram should be more architecturally neutral and indicate data flows rather than human or system flows. That modification would enable various architectures. Additionally, what is the business case and requirement for changing from a point-to-point communication which can successfully transmit information today?	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.. Suggested modifications are applicable and are in the Patient - Provider Secure Messaging Use Case.	7.0-9.0
Health Information Technology Standards Panel	7.0	The drawing implies that the Immunization Response Management relationship may be that an immunization is required as an intervention for the PH event; and the other interaction is the Adverse Event due to an immunization would have input to the Adverse Event reporting. If there are many Adverse Events, a Public Health system intervention may be required.	Partially Accepted	A portion of the feedback has been incorporated into the document. The intent of the feedback is included within the scenarios and events and actions, including the links to the Immunizations and Response Management Use Case.	7.1.1.3, 8.1.4, 8.2.3
Health Information Technology Standards Panel	7.0	The provider / clinician will need to validate the report as a significant adverse event, or a public health report that, in fact, represents a reportable disease.	Partially Accepted	A portion of the feedback has been incorporated into the document . The use case addresses various mechanisms for reporting. When reporting criteria is met, implementation decisions will need to be made in determining whether reporting is automated or if clinical judgment is required.	2.0, 7.1.5, 7.2.2, 7.2.3
Health Information Technology Standards Panel	N/A	The mix of gray boxes and yellow circles in the diagram with similar numbers makes the drawing difficult to follow. Simplifying the diagram would be advantageous. Simplification could be accomplished by creating three scenarios (Reporting, Investigation, Intervention) as already noted.	Partially Accepted	A portion of the feedback has been incorporated into the document . The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing.	7.0, 8.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	7.0	Address the difference between national consolidators vs. local providers. The diagram shows local providers detecting local cases based on various means. In some cases this is a reference laboratory which can act as a national consolidator. It is difficult to determine the timing / triggers for reporting, e.g., at the end of each month from a central data store or the EHR.	Partially Accepted	A portion of the feedback has been incorporated into the document. References to the need for real-time reporting and reporting criteria updates are addressed in this use case. Specifics regarding reporting frequencies are addressed in the 2006 Biosureveillance Use Case.	7.1.1.2, 7.1.2.1, 7.2.1, 8.1.2.2
Health Information Technology Standards Panel	7.0	More attention to data flow will enable greater architecture neutrality. There are presumed architectures in the diagram that are confusing. The dataflow need to be sufficiently flexible to meet current and future evolving workflow requirements.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	7.0, 8.0
Health Information Technology Standards Panel	7.0	In cases of registries (e.g., a cancer registry) there is often no case investigation. Therefore, to maintain applicability, case investigation and intervention should be optional components depending on the local requirement.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Reporting which focuses on cancer or other registries may be addressed in future efforts and/or addressed by other entities. Some capabilities associated with registries areas are addressed in the Immunizations and Response Management Use Case.	2.0
Health Information Technology Standards Panel	7.0	Some Public Health reportable conditions may also require no specific investigation until there incidence reaches a locally or nationally established threshold. Presuming investigation and intervention as a requirement could overwhelm the system on the sending edge and the receiving edge.	Accepted	Feedback has been incorporated into the document.	7.2.2, 7.2.3
Health Information Technology Standards Panel	7.0	The diagram might be more easily understood by showing value stream mapping to show current state, value add components, and subsequently future state.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	2.0, 7.0, 8.0
Health Information Technology Standards Panel	7.0	From the future state, a data flow can be identified to manage the use case and enable various architectures to manage the appropriate data flow.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	2.0, 7.0, 8.0
Health Information Technology Standards Panel	7.0	In some cases of reporting (e.g., registries), local or organizational registry staff may collect and manage the information (rather than the clinician) and report to Public Health after analysis in the local registry.	Accepted	Feedback has been incorporated into the document.	7.1.1.2, 7.1.5

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	7.0	Data Provisioning is listed in 8.1 - 8.3, not in 9.1.1. There is a faulty reference in the diagram.	Accepted	Feedback has been incorporated into the document.	9.1
Health Information Technology Standards Panel	7.0	Investigation is generally the purview of Public Health and perhaps Adverse Event monitoring organizations.	Accepted	Feedback has been incorporated into the document.	2.0, 7.0, 8.0
Health Information Technology Standards Panel	7.0	Consolidating investigation in the scenario with reporting raises a presumption of additional reporting requirements for the clinical care provider to support case investigation. In most cases, the Public Health actor serves as an adjunct data collector (from the patient and contacts) to perform the investigation. While the initial clinical care provider can participate in this activity, it is unclear whether that is an expectation of the use case. Specialists may have additional information to support the investigation.	Accepted	Feedback has been incorporated into the document.	2.0, 7.0, 8.0
Health Information Technology Standards Panel	7.0	The use case does not include specialty care information which may be present in an HIE but is not necessarily included in the primary care EHR in the absence of an HIE. Similarly, adjunct care providers may be part of the reporting infrastructure. E.g., Infection Control Practitioners often assist with Public Health reporting data sets; hospital pharmacy staff may assist with medication Adverse Event reporting for Medwatch or VAERs. The use case should address how providers actually report data.	Accepted	Feedback has been incorporated into the document.	5.0, 7.0
Health Information Technology Standards Panel	7.0	Action: Augment EHR Information Retrieve / receive data boxes should be added to the drawing as separate events. Augmentation may occur locally by requesting additional data from alternate local data sharing or databases. It should not be assumed that augmentation will occur only through manual data entry or through the efforts of an HIE.	Accepted	Feedback has been incorporated into the document.	7.1.6, 7.2.3, 8.2.1

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	7.0	Action: Augment EHR Information Public Health may augment the information (e.g., with death certificate information) that is not desired for the EHR. Many times the augmentation may be population based and not individual patient information.	Accepted	Feedback has been incorporated into the document.	7.1.6.2
Health Information Technology Standards Panel	7.0	Action: Augment EHR Information The diagram should show a line into it from information sources and recipients	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	7.1.6
Health Information Technology Standards Panel	7.0, 2.0	Action: Receive Information and Manage and Treat The management and treatment may be accomplished by a provider referring the case to a public health clinic (e.g. a TB clinic). These situations represent Public Health as taking on the additional role of a clinical care provider for a specific problem. Coordination of care between the clinic and the primary care setting is out of the scope of this use case. It does correlate with other use cases (e.g. Consultation and Referral) for data sharing among clinical care providers.	Accepted	Feedback has been incorporated into the document.	8.2.3
Health Information Technology Standards Panel	7.0	Action: Receive and Incorporate Public Health Case / Adverse Event Criteria The action needs to include different timeframes for reporting. The trigger for receiving and incorporating the criteria should be specified (probably by the individual case or event criteria specification).	Partially Accepted	A portion of the feedback has been incorporated into the document. References to capabilities supporting reporting criteria updates are addressed in this use case. Specifics regarding reporting frequencies are addressed in the 2006 Biosureveillance Use Case.	7.1.1.2, 7.1.2.1, 7.2.1
Health Information Technology Standards Panel	7.0	Action: Receive and Incorporate Public Health Case / Adverse Event CriteriaEntry points (triggers) need to be carefully evaluated with respect to the impact on reporting, the value of the information, and the value of the interventions.	Accepted	Feedback has been incorporated into the document.	7.1.1, 7.2.1, 8.1.2.2, 10.0
Health Information Technology Standards Panel	7.0	Action: Filter EHR data for information matching inclusion/exclusion factors. What is the trigger that helps identify a Public Health reportable case? The Public Health entity needs to set the trigger timing and notification timeframe.	Partially Accepted	A portion of the feedback has been incorporated into the document. References to trigger data that might be indicative of a possible public health case are addressed in this use case. Specifics regarding reporting frequencies are addressed in the 2006 Biosureveillance Use Case.	7.1.1.2, 7.2.1.1, 7.2.1.2

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	7.0	Action: Filter EHR data for information matching inclusion/exclusion factors. For non-Adverse Events, what is the trigger? (e.g. registries may suffice with nightly, monthly triggers). There is considerable confusion in this step by mixing Adverse Events with Public Health Reporting.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. There are now specific actions which describe possible trigger data for AEs. Specifics regarding reporting frequencies are addressed in the 2006 Biosureveillance Use Case.	7.1.1.3, 7.1.4 7.2.1.3, 10.0
Health Information Technology Standards Panel	7.0	Action: Filter EHR data for information matching inclusion/exclusion factors. There is insufficient detail with respect to the requirements for Public Health case reporting. Does PH want suspected, presumptive, definitive case reporting, etc. The criteria for filtering will need to be provided by Public Health or the Adverse Event monitoring organization. Criteria may vary by illness of type of event. Criteria may also change depending on variation in incidence or prevalence. These issues should be addressed in the use case.	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	7.1.2, 7.2.1, 9.0, 10.0
Health Information Technology Standards Panel	7.0	Action: Filter EHR data for information matching inclusion/exclusion factors. In prior reviews of NHIN criteria, filters have been determined to be an edge system requirement, not a requirement of the NHIN itself. Therefore, filter requirements should be considered as logic required to manage the evaluation for filtering. The logic trigger needs to be created in a well thought-out fashion in a standard way taking into account the potential impact on sending and receiving organizations. E.g., fever is a common entry point. If this is a trigger, there will be a lot of unwarranted report submission, investigation and triage. Additionally, case definitions are constantly evolving. Therefore, logic representation and interchange must be sufficiently facile to enable ad hoc changes to the criteria.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Specifics regarding architecture and implementation considerations are not addressed in this use case and may pertain to another working group and/or organization.	7.2.1, 8.1.2.2, 9.0, 10.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	7.0	Action: View and Evaluate PH Cases/AEs which have been identified The comments are too prescriptive in architecture and should be neutral to architecture. Actors are implied but not identified. The source of information may not be an EHR and may be better worded 'all available information from the source or other available systems.'	Accepted	Feedback has been incorporated into the document.	7.0, 8.0, 9.0
Health Information Technology Standards Panel	7.0	Action: View and Evaluate PH Cases/AEs which have been identified The provider / clinician should have the opportunity to not report an event and criteria for non-reporting should be identified.	Accepted	Feedback has been incorporated into the document.	2.0, 7.1.5
Health Information Technology Standards Panel	7.0	Action: View and Evaluate PH Cases/AEs which have been identified The second paragraph in comments refers to augmentation of data and should be included under 7.1.3 rather than 7.1.2.2	Accepted	Feedback has been incorporated into the document.	7.1.6, 7.2.3, 8.2.1
Health Information Technology Standards Panel	7.0	Action: View and Evaluate PH Cases/AEs which have been identified Clarify the trigger classes for reporting, e.g., suspected, presumptive, confirmed, etc. A subscription rule from Public Health or the Adverse Reporting organization is required to filter on the these criteria.	Accepted	Feedback has been incorporated into the document.	7.1.1, 7.2.1, 8.1.2.2, 10.0
Health Information Technology Standards Panel	7.0	Action: Augment EHR Information Augmentation is required but the section is overly detailed. It is important to state that additional information must be captured through manual or electronic means.	Accepted	Feedback has been incorporated into the document.	7.1.6, 7.2.3, 8.2.1
Health Information Technology Standards Panel	7.0	Action: Validate information from the EHR, as well as augmented information Validation may be with a specialist and the actor may be a specialized care practitioner (e.g., Infection Control Practitioner, Clinical Pharmacist). The provider will want to validate what is submitted.	Accepted	Feedback has been incorporated into the document.	7.1.5.2, 7.2.3

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	7.0	Action: Validate information from the EHR, as well as augmented information For protection from liability, the provider may require pseudonymization. Privacy and security concerns for the provider need to be addressed in addition to patient privacy and security concerns.	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	9.0
Health Information Technology Standards Panel	7.0	Action: Validate information from the EHR, as well as augmented information Validate information - Is validating that the clinical information is correct, or validating if document is unaltered. What is the level of assurance required for the information? If it is the first, then the question is not applicable to Security and Privacy concerns. If both or the latter, then validation of source is dependent on level of assurance	Partially Accepted	A portion of the feedback has been incorporated into the document. Context associated with identifying the source and validity of data is further addressed in the Consumer Access to Clinical Information Use Case and/or may be addressed by other organizations/entities.	4.0, 7.1.5.2, 7.2.3
Health Information Technology Standards Panel	7.0	Action: Transmit validated PH Case/AE report is disseminated to public health. Does this have to be performed "securely?"	Out of Scope	The feedback describes a need which is out of scope and cannot be addressed within n this use case. The use case addresses the need for routing of information as well as the need for specifications and agreements which govern the exchange of information. Specifics regarding the implementation of these activities are not in scope for this use case.	7.1.7, 9.0
Health Information Technology Standards Panel	7.0	Action: Transmit validated PH Case/AE report is disseminated to public health. Clarify if the summary / textual report is a patient-level discrete report of all related data for one patient, or an organizational summary report of all patients for a defined period of time, or both.	Accepted	Feedback has been incorporated into the document.	7.1.1, 7.2.1
Health Information Technology Standards Panel	7.0	Action: Transmit validated PH Case/AE report is disseminated to public health. Public Health is not always the recipient, particularly for Adverse Events which may require reporting to FDA via Medwatch or VAERS. Reporting may also be required to a manufacturer, funder (e.g. NIH) or others. The use case should indicate 'appropriate group(s)'.	Accepted	Feedback has been incorporated into the document.	7.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	7.0	Action: Send information related to previously reported PH Cases/AEs and/or other information may be sent to public health. Clarification required. Is the requirement for a template for additional information? What is the expectation by which such additional information types would be identified (ad hoc by the provider or by the Public Health or Adverse Event monitoring organization)? The item presupposes a request from Public Health or an Adverse Event monitoring organization or a policy specifying the new information request. The Public Health or Adverse Event monitoring organization request for information is indicated in the Public Health / Adverse Event perspective. The interaction among the perspectives should be identified within each perspective table.	Accepted	Feedback has been incorporated into the document.	7.0, 8.1.1, 8.2.1
Health Information Technology Standards Panel	7.0	Action: Receive Public Health Information This section should start a second scenario for case investigation.	Accepted	Feedback has been incorporated into the document.	7.0, 8.0
Health Information Technology Standards Panel	7.0	Action: Receive information from public health regarding PH Cases/AE reports which have been transmitted to public health Privacy and Security issues include (a) zip codes, geographic codes, provider locations; (b) availability of trends and small number analysis that could enable individual patient identification; (c) provider privacy consideration	Accepted	Feedback has been incorporated into the document.	8.1.5, 10.0 Appendix B
Health Information Technology Standards Panel	7.0	Action: Receive information from public health regarding PH Cases/AE reports which have been transmitted to public health "Information communicated by public health and received by the providers may include…" There are several approaches to this statement and each context should be specified.	Accepted	Feedback has been incorporated into the document.	8.1.5, 10.0 Appendix B

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	7.0	Action: Receive information from public health regarding PH Cases/AE reports which have been transmitted to public health (1) Receipt of information from Public Health or an Adverse Event monitoring organization regarding an individual patient may be helpful in documentation of care and rationale, and may provide suggestions for additional care to be provided to the individual patient. Such triggers and logic require semantic and technical interoperability. Consumers are stakeholders in this situation as well. However, the impact of Public Health or Adverse Event monitoring organizations communicating directly with patients about their individual results requires careful evaluation and the provider needs to be part of the communication loop.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. There are now specific actions which describe public health information sharing. While not the focus of this use case, reporting by consumers is also referenced.	5.0, 7.0, 7.1.6.1, 8.1.5, 10.0 Appendix B
Health Information Technology Standards Panel	7.0	Action: Receive information from public health regarding PH Cases/AE reports which have been transmitted to public health (2) Receipt of information from Public Health or Adverse Event monitoring organizations suggesting modification of current treatment protocols for other patients (e.g., perform liver function tests at one month of therapy for all patients receiving a new anti-hypertensive patient) is another type of notification.	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	7.2.3
Health Information Technology Standards Panel	7.0	Action: Receive information from public health regarding PH Cases/AE reports which have been transmitted to public health (3) The third notification might be a link to trending and public health (or adverse event) displays. It is not clear what an EHR would do with that general information as it is not patient specific. Access to situational awareness is helpful also to the consumer, a perspective not addressed in the use case. If specific new triggers and logic is intended for incorporation into EHR clinical care workflow for individual patients, it needs to be so stated.	Accepted	Feedback has been incorporated into the document.	8.1.5, 10.0 Appendix B

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	7.0	Action: Receive alert/notification information from public health "Following public health's investigation…" implies the investigation is over and complete. The process is iterative.	Accepted	Feedback has been incorporated into the document.	8.1
Health Information Technology Standards Panel	7.0	Action: Manage and Treat PH Cases/AEs Treatment seems out of scope for the use case. It is not clear if the intent is to treat an individual patient (which would be out of scope unless monitoring of treatment is part of the required data flow.	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	7.2.3
Health Information Technology Standards Panel	2.0, 7.0	Action: Manage and Treat PH Cases/AEs The monitoring seems to be an action coordinated with the Quality use case to identify the denominator of patients and determine if appropriate interventions (numerator) actually occurred. Therefore, a connection to the Quality use case may be appropriate but the treatment and monitoring would be out of scope for the reporting use case. If, conversely, the treatment is for the event, the trigger and logic issues discussed above would apply. Treatment for the event related to environmental activities (e.g., treating a building with closure and appropriate cleaning) would be out of scope. Is treatment intended to address veterinarians regarding pets, livestock and wildlife and, if so, is that activity in scope?	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document. There are various capabilities described in this use case which are also applicable to the Quality Use Case. Aspects of treatment are addressed in the Immunizations and Response Management Use Case.	2.0, 5.0, 7.2.3, 9.0
Health Information Technology Standards Panel	2.0, 7.0	Action: Identify confirmed and additional possible PH Cases/AEs Treat confirmed and additional possible PH Cases / AEs - may be out of scope (see comments for 7.1.7). The diagram suggests interaction with the Immunization and Response use case. While immunizations may be one action for treatment, 'alternate actions' certainly apply as there are many other treatments other than immunizations. If treatment is to be part of the use case, efficacy monitoring and clinical decision support is an issue.	Accepted	Feedback has been incorporated into the document.	7.2.3

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	2.0, 7.0	Action: Identify confirmed and additional possible PH Cases/AEs In Adverse Events, the seriousness, severity of the outcome and what is used to treat the Adverse Event may be part of the initial evaluation. Adverse Event workflows do not necessarily include sharing of care plans with the monitoring agency.	Accepted	Feedback has been incorporated into the document.	7.0, 8.0
Health Information Technology Standards Panel		Action: Identify confirmed and additional possible PH Cases/AEs Sharing of care plans also is in the purview of clinical care provision between or among various clinical care providers (e.g., the primary care provider and the TB clinic acting as a treating consultant). In the TB example, there is correlation with the Consultation and Referral use case. Clarity is needed here.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. The sharing of information between providers for the purposes of treatment and care is discussed in the Consultations and Transfers of Care Use Case.	N/A
Health Information Technology Standards Panel	5.0	Reporting, Investigation and Information Sharing - Laboratory Perspective Laboratories are increasing their reporting capabilities for public health. If results are expected to be interfaced into EHRs and/or be signed off by providers before reporting, a significant delay will be added to the current system of reporting.	Partially Accepted	A portion of the feedback has been incorporated into the document. Specifics regarding reporting processes and criteria vary across, local, state, and federal jurisdictions and therefore are not in scope for this use case.	8.3.1
Health Information Technology Standards Panel	5.0	Reporting, Investigation and Information Sharing - Laboratory Perspective The laboratory perspective would not apply to Adverse Event reporting in that laboratory data alone are insufficient to define the Adverse Event.	Accepted	Feedback has been incorporated into the document.	7.0, 7.1.1.3, 8.0
Health Information Technology Standards Panel	5.0	Action: Receive the Notifiable Condition/AE Criteria from Public Health. The presumption is that reporting is from the Laboratory Information System (LIS). The laboratory may report before the data are entered into the LIS. Cultures, for example are resulted in a sub-system which has reportable results before the LIS. The fit with laboratory workflow is incomplete. Many reports are manual and immediate, others are routine reports.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Specific processes which may occur within a laboratory setting are not the focus of this use case. Additional references to laboratory resulting is addressed in the EHR Laboratory Resulting Use Case.	8.3.1

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	5.0	Action: Receive the Notifiable Condition/AE Criteria from Public Health. Criteria need to identify laboratory triggers and tests. There is inconsistency as to what constitutes a reportable condition in various locations (states, regions, federal) which causes significant work effort for national laboratories. The laboratory system may also have a different system than the LIS for reporting compliance management.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Specifics addressing implementation are not the focus of this use case.	2.0, 4.0
Health Information Technology Standards Panel	5.0	Action: Receive the Notifiable Condition/AE Criteria from Public Health. The Adverse Event reporting component would fit if there were sufficiently defined sentinel laboratory studies/results to indicate medication related concerns; the workflow should be separately defined. AE and PH reporting are similar but not sufficiently so to combine them. Also, provider labs may have different requirements or capabilities compared with reference laboratories.	Accepted	Feedback has been incorporated into the document.	4.0, 5.0, 7.1.1.3, 7.2.1.3
Health Information Technology Standards Panel	2.0	Action: Filter LIS data for information matching inclusion / exclusion factors. Filters require secondary data not necessarily available to laboratories. In hospitals there may be some availability of pharmacy data for the LIS to filter on inclusion / exclusion criteria. Reference laboratories most often do not have such additional information. Inclusion criteria may make sense but exclusion criteria are generally not available to reference laboratories. Decision support may be out of scope for this step.	Accepted	Feedback has been incorporated into the document.	7.1.2, 8.3.1
Health Information Technology Standards Panel	7.0	Action: Validate information from the LIS There is only one step, no second step for laboratories other than to confirm a rare organism. QC procedures involve a separate process in laboratories. Phone / fax or validation of the report to send generally enables sending if criteria are met.	Accepted	Feedback has been incorporated into the document.	8.3.1

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	2.0, 5.0, 7.0	Action: Validate information from the LIS For Adverse Events, there may be a system validation requirement. Obtaining additional information from providers adds a significant burden for laboratories and providers are not necessarily available to provide the information nor are they always willing to do so. This places a burden on the laboratory to submit incomplete data. AE reports do not necessarily go to Public Health however and the use case is vague on this point. HISPC - States should align their reporting requirements, including laboratory and provider responsibilities.	Accepted	Feedback has been incorporated into the document.	2.0, 4.0, 8.3.1
Health Information Technology Standards Panel	7.0	Action: Validate information from the LIS Is the validation process done by lab a clinical validation, i.e., validating the clinical information is correct, or is it validating if the document is unaltered? What is the level of assurance required for the information. If it is the first, then not applicable to Security and Privacy. If both, then validation of source is dependent on level of assurance.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	4.0, 7.1.5, 7.2.3, 8.3.1
Health Information Technology Standards Panel	5.0	Action: Receive information from public health regarding Notifiable Condition/AE reports which have been transmitted to public health. This laboratory perspective is relevant for private sector laboratories, not Public Health laboratories. Receipt of information from Public Health regarding previously submitted Notifiable conditions / AE reports is outside the laboratory workflow.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Specific processes which may occur within a laboratory setting are not the focus of this use case.	5.0, 8.3.1

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	2.0, 5.0	Action: Receive information from public health regarding Notifiable Condition/AE reports which have been transmitted to public health. Additionally, laboratories at present are not able to utilize Public Health information to identify additional cases. There is an implied requirement for reflex testing in the laboratory. E.g., if liver function test abnormalities are identified, additional testing for Hepatitis may be requested. This requirement has several issues. First, it places a significant burden on the laboratories which cannot currently legally perform a test without an order and subsequent payment. Additionally if abnormalities are identified the laboratory will be in an ethical quandary in that results would be sent to whoever ordered the test, not necessarily the clinician caring for the patient (i.e., Public Health may order the test). Additionally, the laboratory may not have sufficient specimen remaining to perform such additional reflex testing. The requirement may be out of scope for the use case.	Accepted	Feedback has been incorporated into the document.	8.3.1
Health Information Technology Standards Panel	5.0	Alternative Action: Receive information from public health regarding trends, groups, etc. Clarification is required. If specific new triggers and logic is intended for incorporation into the LIS workflow for individual patients, it needs to be so stated and such capability would be contrary to existing laboratory workflow. Information may be sent to laboratories regarding trends... It is likely that a link to trending and public health (or adverse event) displays will be more feasible. It is not clear what an LIS would do with the information as it is not patient specific. There is limited capability to act within an LIS even if the information were patient specific. An informational link would be more advantageous. This is modeling a new communication protocol and workflow that does not currently exist. See comments above regarding additional (reflex) testing.	Accepted	Feedback has been incorporated into the document.	8.1.5, 8.3.1

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	5.0	Reporting, Investigation, & Information Sharing – Public Health Perspective The use case provides this perspective with the presumption that Public Health is the receiving and requesting agency for Public Health reporting and Adverse Event reporting. That is not necessarily the case. The Adverse Event monitoring organization perspective is required and such organizations may include the Food and Drug Administration (FDA), Drug Enforcement Administration (DEA) and others. A more generic method for managing this perspective might, alternatively, be "Case Definition Specification Perspective".	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address stakeholders, activities, and information needs specific to AE reporting.	7.1.1.3, 7.1.2.1, 7.2.1.3, 7.1.4, 10.0
Health Information Technology Standards Panel	5.0	Reporting, Investigation, & Information Sharing – Public Health Perspective The underlying premise is that a Public Health authority provides inclusion and exclusion criteria. Medication and device reporting is not addressed in that manner.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address stakeholders, activities, and information needs specific to AE reporting.	7.1.1.3, 7.2.1.3,
Health Information Technology Standards Panel	5.0	Action: Communicate PH Case/AE Criteria. A case definition is sufficiently generic that there is no specific benefit to defining a transport protocol. Case definitions contain no personal health information to protect. However, security / privacy concerns might address protection again modification of criteria to insure integrity and avoid interception.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	7.2.1, 8.1.2.2
Health Information Technology Standards Panel		Action: Communicate PH Case/AE Criteria. Monitoring federal agencies generally do not create the Adverse Events criteria to be communicated.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	7.1.1.3, 7.2.1, 7.2.1.3

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	2.0	Action: Communicate PH Case/AE Criteria. There is also a requirement to define an "urgency" attribute as part of the triggers that are expected to generate the creation and transmission of submissions from clinical care providers. CSTE is expecting to make reportable disease criteria available through a central repository from which criteria can be pulled electronically. The use case should indicate that triggers are readable in human terms and computable terms using standards.	Accepted	Feedback has been incorporated into the document.	10.0
Health Information Technology Standards Panel	7.0	Action: Receive reports/information. Urgency should be built into the timing and triggers as expressed in the criteria for individual reports. Utilization of decision support for analysis of the data received is the responsibility of the edge (receiving system) and not a component of the NHIN interoperability. Decision support from received reports should be part of step 7.3.2.2, not 7.3.2.1.	Partially Accepted	A portion of the feedback has been incorporated into the document. Specifics regarding reporting specifications are addressed in this use case. Specifics regarding frequencies are addressed in the 2006 Biosureveillance Use Case. Implementation recommendations are not in scope for this use case.	7.1.1, 7.2.1
Health Information Technology Standards Panel	N/A	Action: Evaluate reports/information. Grammar comment: "...completeness in the reports, may determine additional information which is needed, etc." should read "completeness in the reports, may determine additional information that is needed, etc."	Accepted	Feedback has been incorporated into the document.	7.2.3
Health Information Technology Standards Panel	7.0	Action: Request information from submitters of reports/information. The receiving system may be able to reject information due to missing data and therefore additional information requests can be electronic. The comments need to express how this item is applicable for Adverse Event monitoring.	Accepted	Feedback has been incorporated into the document.	7.0, 8.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	7.0	Action: Request information from submitters of reports/information. Further, communication should be an automated communication. The current language is inconsistent with the Provider perspective which suggests an electronic communication for receipt of the request (7.1.6.1). The request may introduce a burden to the system if the organization receiving the request is not the primary source of the information.	Partially Accepted	A portion of the feedback has been incorporated into the document . Public Health may consider utilizing information exchange activities for the purposes of obtaining appropriately authorized additional information. Information availability will be dependent on processes and permissions.	8.1.1
Health Information Technology Standards Panel		Action: Request information from submitters of reports/information. The consumer may also provide benefit in providing the additional information desired as part of case investigation such that a consumer perspective is needed. The consumer issue raises a policy/workflow issue - should Public Health be required to work through the provider (or at least notify the provider with some lag time) to contact the patient? The latter is a policy issue but significant. If there is not some form of 'handshake' Public Health could access the patient for follow-up before the patient is aware of the result or issue generating the initial report.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. This use case discusses the methods in which public health might perform an investigation, however; processes may vary between local, state, and federal jurisdictions. Furthermore, while direct consumer reporting to public health is not the focus of this use case, it is addressed within the information sources, recipients, and actions.	5.0, 7.0, 7.1.6.1, 8.1.5
Health Information Technology Standards Panel	7.0	Action: Validate PH Cases and AEs. The use case suggests validation 'to determine whether the reports are "real".' What type of validation is this?	Accepted	Feedback has been incorporated into the document.	8.1.2, 8.3.2, 10.0
Health Information Technology Standards Panel	7.0	Action: Communicate information regarding specific Notifiable Condition, PH Case, and AE reports which have been transmitted to public health. "Information communicated by public health and received by the providers may include…" There are several approaches to this statement and each context should be specified.	Accepted	Feedback has been incorporated into the document.	8.1.5, 10.0, Appendix B

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	7.0	Action: Communicate information regarding specific Notifiable Condition, PH Case, and AE reports which have been transmitted to public health. (1) Communication of information from Public Health or an Adverse Event monitoring organization regarding an individual patient may be helpful in documentation of care and rationale, and may provide suggestions for additional care to be provided to the individual patient. Such triggers and logic require semantic and technical interoperability.	Accepted	Feedback has been incorporated into the document.	4.0, 8.1.5, 8.2.3, 10.0, Appendix B
Health Information Technology Standards Panel	3.0	Action: Communicate information regarding specific Notifiable Condition, PH Case, and AE reports which have been transmitted to public health. Consumers are stakeholders in this situation as well. However, the impact of Public Health or Adverse Event monitoring organizations communicating directly with patients about their individual results requires careful evaluation and the provider needs to be part of the communication loop.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Communicating results directly with patients is not the focus of this use case. The Consumer Access to Clinical Information Use Case does address the patient's/consumer's ability to view and incorporate their results.	2.0, 5.0, Appendix B
Health Information Technology Standards Panel	7.0	Action: Communicate information regarding specific Notifiable Condition, PH Case, and AE reports which have been transmitted to public health. (2) Communication of information from Public Health or Adverse Event monitoring organizations suggesting modification of current treatment protocols for other patients (e.g., perform liver function tests at one month of therapy for all patients receiving a new anti-hypertensive patient) is another type of notification.	Accepted	Feedback has been incorporated into the document.	7.0, 8.0
Health Information Technology Standards Panel	7.0	Alternative Action: Communicate information regarding trends, groups, etc. Communication might be a link to trending and public health (or adverse event) displays. It is not clear what an EHR would do with that general information as it is not patient specific.	Accepted	Feedback has been incorporated into the document.	8.1.5, 10.0, Appendix B

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	5.0, 7.0	Alternative Action: Communicate information regarding trends, groups, etc. Access to situational awareness is helpful also to the consumer, a perspective not addressed in the use case. If specific new triggers and logic is intended for incorporation into EHR clinical care workflow for individual patients, it needs to be so stated.	Accepted	Feedback has been incorporated into the document.	8.1.5, 10.0, Appendix B
Health Information Technology Standards Panel	2.0, 7.0	Data provisioning – including support for secondary uses – data provisioning and distribution of data transmission parameters Secondary use is a large and complex topic. Case reporting is for determining trends and does not necessarily represent secondary use. The requirement for requesting specific filtering criteria, data to report, vocabularies to use and formats is similar to requirements for the Quality Use Case for which standards have not been clearly identified.	Accepted	Feedback has been incorporated into the document.	9.0
Health Information Technology Standards Panel	7.0	Data pseudonymization and re-identification as well as HIPAA de-identification Depending on the anticipated use, provider or clinician pseudonymization may be required to protect the provider.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Policies and implementation considerations surrounding pseudonymization are not in the scope of this use case.	9.0
Health Information Technology Standards Panel	7.0	Public Health Case Reporting Dataset Considerations The list of disease specific data elements for four initial conditions is valuable. However, the diseases chosen are questioned (Anthrax, Hepatitis B, Tuberculosis, and Tularemia). Anthrax and Tularemia are two class A bioterrorism agents and Anthrax is also has a strong case for veterinary reporting. Adding a fifth common condition (or substituting for Tularemia) sexually transmitted diseases (STD) would be useful to address societal implications. If STDs are scoped out, the solution may not be complete. STD tests flow more robustly. MRSA is another significant disease with societal impact for consideration.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	10.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Health Information Technology Standards Panel	2.0	Public Health Case Reporting Dataset Considerations There are no exemplars or reporting dataset considerations for Adverse Events. This is a significant omission. Clarification on the scope of the use case is required if these reports are to be included, and reporting dataset considerations must be included. There are no specific nationally notifiable adverse events at the current time.	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document.	10.0
Healthcare Information &Management Systems Society	8.1	The interactions for this use case are of 2 types: 1) point-to-point where a given result is suspected or known to fit the parameters for reporting to a specific agency, and 2) broadcast of data to multiple agencies.	Acknowledged	Intent of the feedback has been acknowledged is addressed in the use case.	8.1.5, Appendix B
Healthcare Information &Management Systems Society	8.1	The HIE must be able to determine where such data is to be sent which implies either that the sender know and provide destination information, or that there is a registry of destinations by type of data, and that those destinations are capable of receiving authenticated unsolicited messages.	Accepted	Feedback has been incorporated into the document.	7.1.1, 7.2.1, 9.1
Healthcare Information &Management Systems Society	8.2	The ability to pseudonymize and re-link data, as well as de-identification of data per HIPAA requirements can be a function of the HIE, but triggering of that capability would have to be directed by the sender or by the registry providing information about the recipient.	Accepted	Feedback has been incorporated into the document.	7.1.1, 7.2.1, 9.1
Healthcare Information &Management Systems Society	8.3	Message routing would again be based as indicated above by instructions embedded within the message or in the PH location registry. It is also assumed that for such unsolicited messages, the HIE would have to retrieve all essential security AAA information from the PH location registry, or would have pre-arranged agreements with the applicable destinations.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. The use case addresses the need for routing of information as well as the need for specifications and agreements which govern the exchange of information. Specifics regarding the implementation of these activities are not in scope for this use case.	7.1.1, 7.2.1, 8.1.5, 8.2.2, 9.1
Healthcare Information &Management Systems Society	Appendix A	Glossary: Suggestion to include LIS -Laboratory Information Systems in the Glossary LIS-Laboratory Information Systems are databases oriented towards medical laboratories	Accepted	Feedback has been incorporated into the document.	3.0, Appendix A

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Healthcare Information &Management Systems Society	Appendix A	Glossary: Suggestion to include LIS -Laboratory Information Systems in the Glossary LIS-Laboratory Information Systems are databases oriented towards medical laboratories General comments: communication from public health regarding new outbreaks, risks, education, special programs, research studies etc should be included in either secure messaging or this use case	Accepted	Feedback has been incorporated into the document.	3.0, 8.1.5, Appendix A
Kaiser Permanente	2.0	We find it troublesome that Public Health Case Reporting and Adverse Events are lumped together into 1 scenario: Reporting, Investigation, and Information Sharing. The workflow and the persons engaged in these kinds of reporting can be very different. We suggest that this scenario be split into at least 2 scenarios.	Accepted	Feedback has been incorporated into the document.	7.0, 8.0
Kaiser Permanente	3.0	Please add Electronic Health Record (EHR) Service Providers as a stakeholder. The EHR is mentioned numerous times in the Events/Actions and comments section as either a source of information or as a recipient of information.	Accepted	Feedback has been incorporated into the document.	3.0
Kaiser Permanente	4.0	Another obstacle is that no registries exist for follow-up of conditions such as TB, Anthrax, Communicable Disease	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Registry functions are addressed in the Immunizations and Response Management Use Case. The development and utilization of registries may differ greatly across jurisdictions.	N/A
Kaiser Permanente	5.0	Please add a Consumer Perspective. There are important actions that the consumer can perform in an Adverse Event situation. One very important one is to access and file a report about an adverse immunization event in the Vaccine Adverse Event Reporting System (VAERS).	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. This use case focuses on using data in EHRs and augmenting EHR data in order to assist providers in reporting to public health. While direct consumer reporting to public health is not the focus of this use case, it is addressed within the information sources, recipients, and actions.	5.0, 7.0, 7.1.6.1, 8.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
Kaiser Permanente	7.1.4	7.1.4 Clinician Perspective: Validate and disseminate report	Accepted	Feedback has been incorporated into the document.	7.1.7
Kaiser Permanente	7.1.4.2	7.1.4.2. Lumping public health case reporting and adverse event reporting together creates confusion. Complications of communicable disease (e.g., encephalitis) would be captured in public health reporting; on the other hand an adverse event associated with an immunization is not a public health case reporting event.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address activities and information needs specific to AE reporting (medications and vaccines) from EHRs.	7.0, 8.0, 7.1.1.3, 7.2.1.3, 7.1.4., 3.0
Kaiser Permanente	7.1.4.2	7.1.4.2. Reporting of immunization adverse events can involve reporting back to manufacturers, whereas public health events do not. The reporting workflow is different.	Partially Accepted	A portion of the feedback has been incorporated into the document. The document now describes two separate scenarios: Reporting from EHRs and Public Health Case Investigation and Information Sharing. In addition, there are now specific actions which address stakeholders, activities, and information needs specific to AE reporting (medications and vaccines) from EHRs.	7.0, 8.0, 7.1.1.3, 7.2.1.3, 7.1.4., 3.0
Kaiser Permanente	7.1.4.2	7.1.4.2. There needs to be more emphasis on the documentation and reporting of notifiable diseases and complications. Perhaps some of the narrative from 7.1.2.2 could be moved here.	Accepted	Feedback has been incorporated into the document.	7.1
National Association of County & City Health Officials	4.0	Public health infrastructure (includes both technology and work force) to develop, operate, and exchange information is limited.	Accepted	Feedback has been incorporated into the document.	2.0
National Association of County & City Health Officials	4.0	Duplicative reporting – laboratories have limited information (demographics and results) which need to be supplemented by physicians.	Accepted	Feedback has been incorporated into the document.	8.3.1
National Association of County & City Health Officials	4.0	Also negative diagnostics – do not rule out illness – for example person can have tuberculosis based on a clinical response even with negative tuberculosis laboratory testing.	Accepted	Feedback has been incorporated into the document.	8.3.1

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
National Association of County & City Health Officials	4.0	Incomplete information is also related to behavioral factors (not relevant to clinical practice) and business processes of health care providers and organizations.	Accepted	Feedback has been incorporated into the document.	4.0
National Association of County & City Health Officials	7.0	Figure 7-1. Under public health, Box 7.3.3 (request additional information) – should there be an arrow to the information exchange.	Accepted	Feedback has been incorporated into the document.	8.1.1
National Association of County & City Health Officials	7.1.2.2	7.1.2.2. For critical events, having a report in the provider's inbox awaiting release could be problematic. System may need to consider time factors (5 days and then it is sent electronically or within 24 hours for priority public health events).	Accepted	Feedback has been incorporated into the document.	2.0, 7.1.5, 7.2.2, 7.2.3
National Association of County & City Health Officials	7.1.3.1	7.1.3.1. Need to consider the practical aspects of the providers collecting information from non-electronic sources (routinely) – i.e. additional interviews. How good is the information and what are the information sources even within the EHR?	Acknowledged	Intent of the feedback has been acknowledged and is included in the use case document. This use case addresses both aspects of current state processes, as well as discusses potential information exchanges. The specifics of identifying sources of information are addressed in the Consumer Access to Clinical Information Use Case.	4.0, 7.1.7.1, 8.1.1
National Association of County & City Health Officials	7.1.4.1	7.1.4.1. AE criteria: Complex and what information will be of value to public health? AE have a wide spectrum of presentations and some of which are unlikely to be related to the medication, procedure etc. The details may have significant impact on AE reporting and provider work flows. Decision analysis for AE will be complex and varied.	Accepted	Feedback has been incorporated into the document.	2.0, 7.0, 8.0
National Association of County & City Health Officials	7.1.4.2	7.1.4.2. Summary/Textual information: How will public health information systems and workflows handle this format? Will public health review this summary information to abstract the data elements to be entered into a public health information system? How will this impact the local/state work force needs?	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. This use case discusses potential methods in which information may be exchanged, however; this use case does not address policy or implementation concerns.	7.1.1, 7.2.1

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
National Association of County & City Health Officials	7.1.5.1	7.1.5.1 "Providers may provide" – keep in mind that public health has legal authority to request the information.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. This use case discusses activities where public health may request information. Specifics regarding regulations and legal matters are not the focus of this use case.	8.1.1
National Association of County & City Health Officials	7.2.1	7.2.1 Systems will need to rapidly incorporate changing case definitions and emerging conditions (i.e. SARS)	Accepted	Feedback has been incorporated into the document.	7.1.1.2, 7.2.1.1, 7.2.1.2, 8.1.2.2
National Association of County & City Health Officials	7.0	Additional information required by public health includes: Demographic information, risk factors when available, diagnostic tests (radiology, pathology etc – including both positive and negative findings), symptoms, and outcomes are required for case investigation and follow-up both routinely and during emergencies.	Accepted	Feedback has been incorporated into the document.	7.1.2.1, 10.0
National Association of County & City Health Officials	7.0	During emergencies, additional information may be required especially for emerging infections or exposures (i.e. Travel history as a risk factor for SARS).	Accepted	Feedback has been incorporated into the document.	7.1.6, 7.2.3, 8.2.1, 10.0
National Association of County & City Health Officials	7.3.5.1	7.3.5.1 "Real" – many reports that public health receives are updates for prior case reports especially for chronic conditions such as hepatitis B infection. All the reports are "real" not new to public health. How is "real" defined and what impact would there be for the use case?	Accepted	Feedback has been incorporated into the document.	8.1.2, 8.3.2, 10.0
National Association of County & City Health Officials	7.3.5.2	7.3.5.2 The use of "confirmed" is problematic. If this is taken as confirmed cases (culture positive), then suspect and probable cases would not be captured. How is confirmed being used in the use case?	Accepted	Feedback has been incorporated into the document.	8.1.2, 8.3.2, 10.0
National Association of County & City Health Officials	9.0	Consideration is needed to consider what is reasonable to obtain from an EHR and what are the other data sources that public health uses for investigation and response.	Partially Accepted	A portion of the feedback has been incorporated into the document . This use case cites several examples of trigger data which might be available in EHRs. Continued efforts in this area may be pursued by other groups/entities in the industry.	10.0

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
National Association of County & City Health Officials	9.0	Public health systems will also need to consider the validity of the information from the EHR and reconciliation of disparate data elements. For privacy issue, what can public health share with providers? For example, a case discloses information to public health that has been with held from a provider – should this be shared?	Policy - Deferred - Policy/Regulatory Issue	The feedback relates to a policy or regulatory issue which cannot be addressed within this use case. The use case acknowledges the need for information sharing and for compliance with all applicable state and federal regulations.	4.0, 8.1.1.2, 8.1.5.2, 8.2.2.2, Appendix B
National Institute for Occupational Safety& Health	9.0	It must be recognized that public health surveillance, investigation, and reporting extends to the occupational arena.	Out of Scope	The feedback describes a need which is out of scope and cannot be addressed within this use case . Reporting which focuses on occupational areas may be addressed in future efforts and/or addressed by other entities.	2.0
National Institute for Occupational Safety& Health	9.0	Occupational disease and injury accounts for a considerable fraction of total direct and indirect costs related to medical outcomes. For instance, occupationally-related chronic obstructive pulmonary disease and asthma account for $6.6 billion in direct and indirect costs per year.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document.	N/A
National Institute for Occupational Safety& Health	9.0	It follows that surveillance of work-related disease and injury is fundamentally important, providing the motivation and direction for public health interventions to prevent these adverse outcomes. Such surveillance depends critically on being able to identify the source of the exposures and the situations that led to the disease or outcomes. Conventionally this is obtained by acquiring information on jobs and industries worked from those adversely affected.	Partially Accepted	A portion of the feedback has been incorporated into the document. While reporting which focuses on occupational areas is out of scope for this use case, this use case does recognize the importance of determining the source of exposure.	8.1.3.1
National Institute for Occupational Safety& Health	9.0	It follows that for public health in the occupational arena to be at all successful, the electronic health record must have provision for recording and storing a current work history for each patient. Inclusion of this information in a standardized format would put easy retrieval and linkage with the adverse medical outcomes, not only leading to national figures on disease prevalence and incidence, permitting tracking by time and geography, but also permitting such advantageous strategies as sentinel event detection followed by intervention and other directed prevention activities.	Out of Scope	The feedback describes a need which is out of scope and cannot be addressed within this use case. The feedback describes a need which is out of scope for this use case. While this use case discusses utilizing information within EHRs to assist in public health case reporting, the feedback specifically addresses policy and implementation considerations which are out of scope for this use case.	7.1.1.2, 7.1.2

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
National Program of Cancer Registries	2.0	Introduction and Scope: Alerts for the reporting of cancers typically treated in physician offices could enhance cancer registry case finding.	Out of Scope	The feedback describes a need which is out of scope and cannot be addressed within this use case . Reporting which focuses on cancer registries may be addressed in future efforts and/or addressed by other entities.	2.0
National Program of Cancer Registries	2.0	Introduction and Scope: In case registration the identification of reportable conditions/tumors should be different depending on whether the EHR is within a healthcare facility or a physician's office. For a list of reportable data items, see the N/AACCR (North American Association of Central Cancer Registries) data dictionary: N/AACCR Standards for Cancer Registries, Volume II, Data Standards and Data Dictionary, http://www.naaccr.org/index.asp?Col_SectionKey=7&Col_ContentID=122.	Out of Scope	The feedback describes a need which is out of scope and cannot be addressed within this use case . Reporting which focuses on cancer registries may be addressed in future efforts and/or addressed by other entities.	2.0
National Program of Cancer Registries	3.0	Use Case Stakeholders: Add "anatomical pathology" to the list of types of laboratories.	Accepted	Feedback has been incorporated into the document.	3.0, 5.0, Appendix A
National Program of Cancer Registries	4.0	Issues and Obstacles: In cancer registration, there is a national definition of reportable cancers and tumors, but states often supplement this definition with additional cancers or tumors.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Reporting which focuses on cancer registries may be addressed in future efforts and/or addressed by other entities.	2.0, 4.0
National Program of Cancer Registries	4.0	Issues and Obstacles: In the existing cancer registration system, reports are typically transmitted electronically from the hospital to the central cancer registry.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Reporting which focuses on cancer registries may be addressed in future efforts and/or addressed by other entities.	N/A

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
National Program of Cancer Registries	4.0	Issues and Obstacles: Add an additional challenge related to patient identification where the hospital or central cancer registry need to determine if the new notifiable event relates to a patient already registered or represents a new patient.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Reporting which focuses on cancer registries may be addressed in future efforts and/or addressed by other entities. However the ability to identify patients and patient's related results is addressed in this and other previously published use cases.	9.0, Appendix B
National Program of Cancer Registries	4.0	Issues and Obstacles: Add an additional challenge related to inter-jurisdictional exchange. Patients who reside in one state may seek diagnosis and treatment in another state. The residence at the time of diagnosis determines the state jurisdiction of the cancer/tumor report.	Partially Accepted	A portion of the feedback has been incorporated into the document. Concepts relating to inter-jurisdictional requirements and exchange have been addressed in this use case. Specifics relating to cancer/tumor reporting requirements are not in scope for this use case.	2.0, 4.0
National Program of Cancer Registries	4.0	Issues and Obstacles: Add an additional challenge related to the address at diagnosis. To ascertain the address at cancer diagnosis, the EHR systems needs to have the capability of linking the admission of that diagnosis to associated address. GIS advocates note that using geo-coding software at the point of patient admission can reduce false address information.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. The ability to capture patient demographic information in EHRs, as well as the ability to determine and communicate source of exposure are addressed in this use case. Specifics regarding cancer/tumors and GIS locating is not in scope for this use case.	7.1.2.1, 8.1.1.3, 8.1.3.1
National Program of Cancer Registries	5.0	Use Case Perspectives: Add "anatomical pathology" to the list of laboratories.	Accepted	Feedback has been incorporated into the document.	3.0, 5.0, Appendix A
National Program of Cancer Registries	5.0	Laboratory Perspective: For quality control purposes in the cancer registry community, the identification of the reportable cancer/tumor among the multitude of reports in the anatomical pathology laboratory is typically done by trained cancer registry staff.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Reporting which focuses on cancer/tumors may be addressed in future efforts and/or addressed by other entities.	N/A

Organization	Feedback Reference	Feedback Text	Disposition Code	Rationale	Document Reference
National Program of Cancer Registries	5.0	Laboratory Perspective: In general, who performs quality control of the work conducted with the laboratory? Does public health have a role in this area?	Policy - Deferred - Policy/Regulatory Issue	The feedback relates to a policy or regulatory issue which cannot be addressed within this use case. . The use case acknowledges the need for compliance with all applicable state and federal regulations for, the regulation of laboratories may differ based on type, function, jurisdictional location, etc.	5.0, 8.3
National Program of Cancer Registries	5.0	Public Health Perspective: Cancer/tumor reports when received by the central cancer registry must be assessed in terms of basic quality by national standard data edits. In addition, reports on a cancer or tumor may be received from multiple healthcare entities. The central cancer registry must consolidate information from these multiple sources to create a single analyzable record.	Acknowledged	Intent of the feedback has been acknowledged and no changes deemed necessary to the use case document. Reporting which focuses on cancer/tumors may be addressed in future efforts and/or addressed by other entities. Registry functions are also addressed in the Immunizations and Response Management Use Case.	N/A