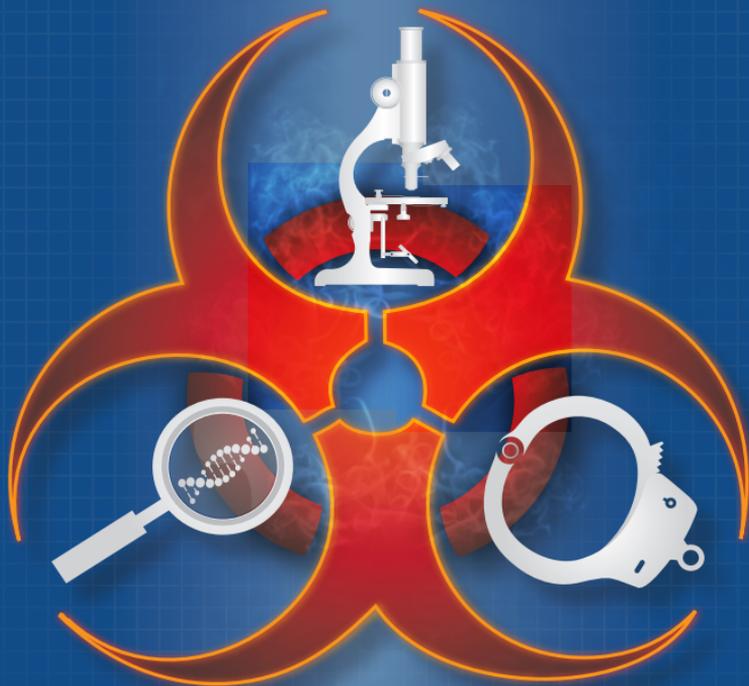




Joint Criminal and Epidemiological Investigations Handbook



2015 DOMESTIC EDITION

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INTRODUCTION



Purpose

This handbook was developed to facilitate the use of resources and maximize communication and interaction between law enforcement and public health. This combined effort can minimize potential barriers prior to and during the response to a biological threat.

Specifically, this handbook aims to:

- Provide an overview of both law enforcement and public health to enhance the appreciation and understanding of each discipline's expertise
- Discuss criminal and epidemiological investigational procedures and methodologies for a response to a biological threat
- Identify challenges to sharing information and provide potential solutions that may be adapted to meet the needs of the various agencies and jurisdictions
- Demonstrate effective law enforcement and public health collaboration

Law enforcement and public health are encouraged to read the entire handbook and not limit their review to just their respective sections.

It is important to take the time to understand the different goals and needs of each other's organization before a suspicious biological event occurs. Doing so, will enable law enforcement and public health personnel to more effectively respond in a coordinated manner during a biological threat.

While both disciplines have varying objectives and protocols, both public health and law enforcement ultimately share three common concerns:

- Early identification of an outbreak
- Determining whether the outbreak is intentional or naturally occurring
- Protecting public health and public safety

Even with these common concerns, each discipline may be hesitant to share information because of actual or perceived limitations or barriers. Identifying and resolving these issues in advance of a biological threat will help facilitate more effective dialogue and information exchange, thereby increasing the likelihood of identifying an incident and protecting public health and safety in a more efficient manner. Simply put, working together helps both law enforcement and public health achieve their separate but often overlapping goals and ultimately allows for a more effective and efficient response to a biological threat.

The 2015 edition of the Criminal and Epidemiological Investigation Handbook has been updated to reflect current Federal policies and includes modifications based upon experiences gained since the previous version was published.

Key Highlights of Introduction Section

- There has been a demonstrated interest and willingness by terrorist groups and individuals to acquire and employ biological agents as weapons against the American population.
- The intentional release of a biological agent may initially be difficult to discern from a natural incident, which can result in separate law enforcement and public health investigations.
- It is in public health and law enforcement's best interest to work together when first investigating a suspicious biological outbreak, which includes fostering mutual awareness and establishing joint communication procedures.
- By working together, public health and law enforcement can achieve their separate but often overlapping objectives of identifying the biological agent, preventing the spread of the disease, preventing public panic, and apprehending those responsible.

The Biological Threat

There has been a demonstrated interest and willingness by terrorist groups and individuals to acquire and employ biological agents as weapons against the American population.

Weapons of mass destruction (WMD) terrorism is an evolving threat to U.S. national security. In his 2010 testimony before the Senate and the House of Representatives, the Director of National Intelligence stated that terrorist groups have expressed an interest in obtaining WMD for use in future acts of terrorism. Indicators of this threat include the 2001 Amerithrax letters, the possession of WMD-related materials by Aafia Siddiqui in 2008, and multiple attempts by terrorists at home and abroad to use explosives improvised from basic chemical precursors.

Over the past few years, there has been an increased interest in extracting ricin from castor beans, which are readily available to the public, to intentionally harm others. Ricin is one of the most discussed toxins online, which includes discussions of criminal plots. In 2011, federal authorities disrupted a plot by a militia group in Georgia to deploy 10 pounds of ricin against various federal employee and facility targets. Since 2013, there have been several incidents involving individuals creating ricin and utilizing the U.S. Postal System as a delivery system for ricin-laced letters.

Most recently, the 'Dark Web'—the virtual black market for drugs, guns, explosives, and other illicit materials—has shown a growing number of sellers and buyers of biological material. The FBI has opened investigations on individuals who have attempted to sell or purchase illicit biological material, such as ricin and abrin, through the Internet.

Concern that nefarious actors might use biological material as a weapon will likely remain a persistent threat for years to come, especially as scientific advancements in technical capability, knowledge, and accessibility continue to grow. Despite

continued efforts in bioterrorism preparedness, the intentional use of biological agents as a weapon still poses challenges to both law enforcement and public health due to the unique circumstances of a biological incident. Since biological agents are often endemic or naturally occurring in the environment, an intentional release of a pathogen may be initially difficult to discern from a natural event, and efforts to respond to the attack and apprehend those responsible may be delayed.

In the past, it was common for public health (which conducts epidemiological investigations to natural incidents) and law enforcement (which conducts criminal investigations to intentional incidents) to conduct independent investigations. Due to the challenges posed by a biological threat, an effective response calls for a high level of cooperation between both these two disciplines. The lack of mutual awareness and understanding, as well as the absence of established communication procedures, could limit the effectiveness of these disciplines' separate, but often overlapping, investigations.

During a suspicious biological incident, it is mutually beneficial for public health and law enforcement to work in partnership. By working together, public health and law enforcement can more effectively achieve their shared objectives of identifying the biological agent, preventing the spread of the disease, preventing public panic, and apprehending those responsible.

Federal Bureau of Investigation (FBI)

The FBI is an intelligence-driven and threat-focused national security organization with both intelligence and law enforcement responsibilities—the principal investigative arm of the U.S. Department of Justice and a full member of the U.S. Intelligence Community. The FBI is vested by law and Presidential directives as the primary agency of the U.S. Federal Government with the authority and responsibility to investigate threats to national security, including biological threats, within the United States and relating to U.S. citizens and

interests overseas. Activities of “threat to the national security” commonly involve violations (or potential violations) of federal criminal laws, such as Title 18, U.S. Code, Section 175 (biological weapons). Hence, investigations of such threats may exercise both of the FBI’s criminal investigation authority and of the FBI’s authority to investigate threats to the national security.

Generally acting through the FBI, the Attorney General, in cooperation with other federal agencies engaged in activities to protect national security, coordinates the activities of other members of the law enforcement community to detect, prevent, preempt, and disrupt terrorist attacks against the United States. The FBI has multiple operational units to provide assistance in the event of a terrorist attack, including response teams trained to collect and handle hazardous materials and contaminated evidence. Along with the FBI Headquarters in Washington, D.C., there are numerous FBI field offices located in major cities throughout the United States. These field offices implement national level policy at the local level, where they are able to tailor their outreach to reflect the particular geographic threats and vulnerabilities unique to their specific jurisdiction.

There is a common misconception that the FBI prosecutes cases; however, this is incorrect. The FBI gathers facts and evidence and then presents the results to the Department of Justice, which is responsible for deciding if an individual will be brought to trial and if so, conducts the prosecution of the case. Therefore, during a suspicious biological incident, the FBI would work closely with public health to investigate whether the outbreak is criminal in nature and if so, gather evidence to build a case for prosecution of those responsible.

FBI WMD Coordinator

The FBI is headquartered in Washington D.C. The offices and divisions at FBI Headquarters provide direction and support to 56 field offices in big cities, approximately 360 smaller offices known as resident agencies, several

specialized field installations, and more than 60 liaison offices in other countries known as legal attachés (Figure 1). These offices allow the FBI to interact with

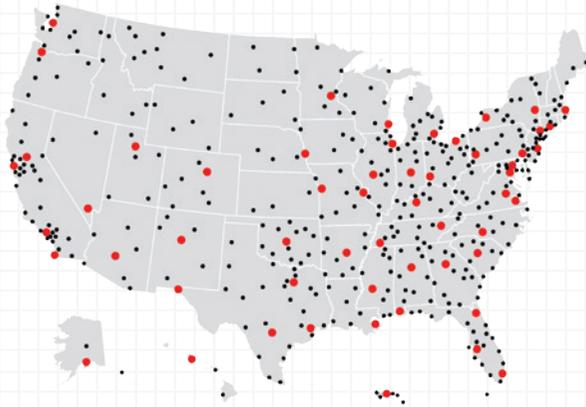


Figure 1. Map of FBI Field Offices and Resident Agencies

local stakeholders and obtain unique geographic knowledge of their area of responsibility. Each field office has a designated Special Agent, called a WMD Coordinator, who serves as a WMD subject matter expert and point of contact for local and state emergency responders and public health. In the event of a bioterrorism event, the WMD Coordinator would act as a conduit for obtaining federal assistance (*e.g.*, threat credibility evaluation and operational response) for local law enforcement. See Appendix 8 for additional information on WMD Coordinators.

Joint Terrorism Task Force

In an effort to promote communication and collaboration across the various law enforcement entities, the United States implements a partnership called the Joint Terrorism Task Force. These task forces combine the resources

and knowledge of various federal, state, and local law enforcement agencies to maximize the United States' collective ability to combat terrorism. Often memoranda of understanding (MOUs) are developed between participating law enforcement agencies to assist in determining in advance how law enforcement agencies can best prevent and respond to a terrorist event. The National Joint Terrorism Task Force is headquartered in Washington, D.C., and there are over one hundred area-specific Joint Terrorism Task Forces nationwide (many located at FBI field offices).

FBI International Efforts

The resources of the FBI are available to assist all law enforcement agencies throughout the world. FBI resources can be requested through the FBI Legal Attaché Office. The FBI has Legal Attaché personnel located in almost 70 countries throughout the world. The mission of these Legal Attaché offices is to foster strategic partnerships with foreign law enforcement, intelligence, and security services by sharing knowledge, experience, capabilities, and exploring joint operational opportunities. FBI Special Agents with specific expertise in WMD matters are located in Tbilisi, Georgia, and Singapore, Singapore. The FBI also coordinates extensively with INTERPOL and has a Special Agent with expertise in WMD stationed at the INTERPOL Headquarters in Lyon, France.

FBI Legal Attaché contact information may be found at:
<http://www.fbi.gov/contact-us/legat>

Centers for Disease Control and Prevention (CDC)

The Department of Health and Human Services (HHS) is the United States government's principal agency for protecting the health of all Americans and a leader in promoting activities associated with the medical and public health response to a biological incident. As an entity of HHS, CDC plays a critical role in leading the nation's public health efforts in strengthening capacity to detect and respond to a biological incident. To carry out these efforts, CDC conducts critical science and provides health information that protects the United States against health threats and responds when these arise.

For public health,
all response is
LOCAL!

The response to a public health emergency, including an intentional release of a pathogen, is the responsibility of public health at the state and/or local level. Public health agencies at the state and local level will likely be the first agencies to recognize cases of illness associated with a biological threat. Upon recognition of an incident, public health will initiate an investigation and respond to determine the source and implement interventions to prevent additional illness. If the state and local public health agencies need additional resources then they will request federal assistance.

Since a biological incident can occur in a variety of locations and populations, the FBI, CDC, and the Association of Public Health Laboratories (APHL) established the Laboratory Response Network (LRN). The mission of the LRN is to develop, maintain, and strengthen an integrated national and international network of laboratories that can respond quickly to needs for rapid testing, timely notification, and secure reporting of results that are associated with acts of biological terrorism or other high-consequence public health emergencies. All LRN member laboratories work under a single operational plan and adhere to strict policies of safety and security.

CDC Global Health Efforts

CDC's global health programs, research, and training activities improve health and save lives around the world and protect Americans from diseases and other health threats that begin overseas. Collaborating with other federal agencies and with international partners CDC helps other countries build capacity to prevent, rapidly detect and effectively respond to emerging infectious diseases and biological threats, whether they occur naturally, are intentionally produced, or are the result of laboratory accidents.

PUBLIC HEALTH



Key Highlights of Public Health Section

- The ultimate aim of an epidemiological investigation is to identify the source of the disease and implement efforts to control the outbreak and protect the public's health.
- An epidemiological investigation primarily involves the meticulous accumulation of information from patient interviews and surveys as well as data collected from surveillance systems.
- Goals of an epidemiological investigation include:
 - » Stopping the spread of disease (identify causative agent, determine source, mode of transmission and population at risk)
 - » Protecting the public's health (surveillance, medical countermeasures, health education)
 - » Protecting public health and other response personnel (protective equipment and preventive vaccines/medications)

- Important elements of an epidemiological investigation are:
 - » Detect unusual events
 - » Confirm diagnosis
 - » Identify and characterize additional cases
 - » Determine source of exposure
 - » Develop and implement interventions
- Laboratory analysis of clinical specimens is used to assist the physician in making a definitive diagnosis. While most physicians will wait for definitive laboratory results to confirm a biological threat agent diagnosis, physicians are likely to begin treatment before laboratory test results are confirmed since early treatment of disease increases the probability the patient will recover from the illness.
- A laboratory that tests for biological agents should meet applicable standards (*e.g.*, quality control measures, biosafety, and biosecurity) and participate in relevant proficiency testing.

Epidemiological Investigation Goals

Epidemiology is the fundamental science of public health. It is used by epidemiologists to study diseases or events that impact human health in order to reduce disease or disability in a population. Whether it is in response to a naturally occurring outbreak or a biological threat, public health will conduct an epidemiological investigation to gather information that will move investigators toward determining the source of the disease and the extent of the outbreak. When conducting an epidemiological investigation for a naturally occurring outbreak or biological threat, public health has the following basic goals:

According to the World Health Organization (WHO), "Epidemiology is the study of the distribution and determinants of health-related states or events (including disease), and the application of this study to the control of diseases and other health problems."

- **To stop the spread of disease:** One of the most basic missions of public health is the prevention of illness in the population. While physicians focus on curing the sick and promoting health in the individual, public health strives for health promotion and disease prevention in the entire population. For the illness under investigation, epidemiologists use interviews, surveys and data analysis to identify the causative agent, mode of transmission, source of exposure, and population at risk to limit the spread of the outbreak.
- **To protect the public:** Public health utilizes surveillance of health trends, medical information, and a variety of analytical tools to establish methods and implement interventions that protect the public from health threats. Vaccine campaigns, medical countermeasure distribution programs, disease surveillance, and health education all play a role in preventing and responding to serious health emergencies.

- **To protect public health and other response personnel:** A major consideration during an investigation is the protection of responders. Since epidemiologists and other responders may come in contact with potentially infectious individuals, provision of proper protective equipment and preventive medications or vaccines for investigative personnel is essential.

Epidemiological Investigative Methods

Public health uses investigative techniques to identify the causative agent and determine the source and extent of disease outbreaks. An epidemiological investigation primarily involves the meticulous accumulation of information from patient interviews and surveys, as well as data collected from surveillance systems. Since interview or disease surveillance information may be relevant to a criminal investigation, law enforcement should become familiar with the elements of an epidemiological investigation.

The following section provides a brief synopsis of the elements of an epidemiological investigation.

In an epidemiological investigation, the nature of each outbreak and the availability of personnel and resources will determine the sequence and scope of the actions that will be performed during the investigation.

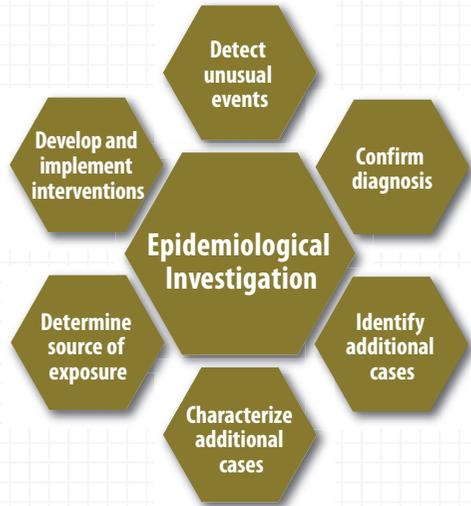


Figure 2. Elements of an epidemiological investigation.

Detect Unusual Events

The first indication of an unusual event is often an unexpected increase in the number of people with similar symptoms, referred to as *cases*. This increase in cases is detected either by monitoring surveillance systems or receiving notifiable disease reports from healthcare providers. If an unexpected increase occurs, public health will begin to collect additional patient information, as well as further characterize the illness to determine the nature of the incident.

Based on the information collected, the incident may be classified as an infectious disease outbreak and public health would begin an epidemiological investigation to determine the extent and source of the outbreak.

An *outbreak* is defined as an occurrence of cases associated with a specific place or group of people over a given period of time. For example, public health may determine that 15 cases of *E. coli* O157:H7 infection were due to victims having recently consumed unpasteurized apple cider from a local orchard in the last month. Since all of the cases have an association with the orchard over a similar period, public health may consider this an outbreak. For rare or uncommon diseases in the United States (e.g., botulism, SARS), public health may determine that a single case of the disease constitutes an outbreak since cases are not normally observed in their jurisdiction.

Case Reporting

All states and territories possess laws that require reporting of specific infectious diseases by healthcare providers. It is mandatory that reportable disease cases be reported to state and territorial jurisdictions when identified by a health provider, hospital, or laboratory. Each state has its own laws and regulations defining what diseases are reportable and the list varies among states and over time. In addition, notifiable disease cases are voluntarily reported to CDC by state and territorial jurisdictions (without direct personal identifiers) for nationwide aggregation and monitoring of disease data. The Council of State and Territorial Epidemiologists (CSTE) maintains a list of diseases that are reportable to the CDC (Appendix 6). States use the CSTE list of notifiable conditions to create their own reporting laws and may choose to add other diseases. For additional information on reporting requirements for a jurisdiction, contact the city, county or state health department.

While disease case reporting is standard practice for identifying unusual events, it is a time and resource intensive process that can be adversely impacted by delays in symptom onset, clinical diagnosis, laboratory testing and results reporting. Depending on the illness, it may be days or weeks before public health is notified by a healthcare provider or laboratory of a case report. (See Figure 3)

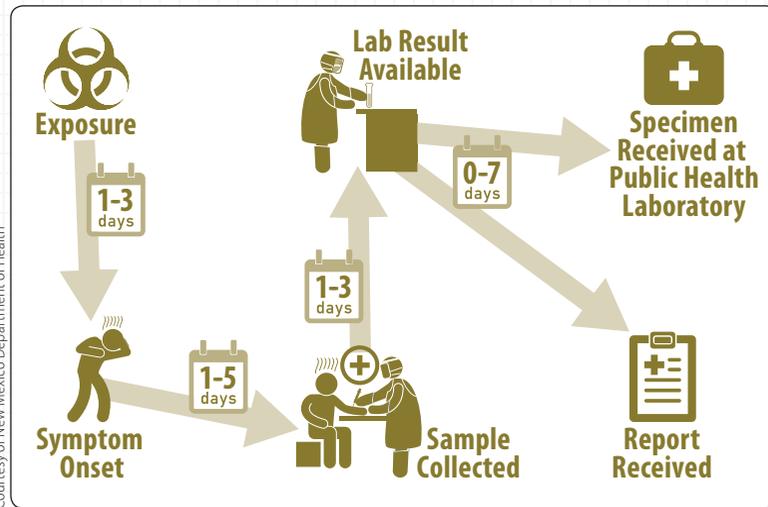


Figure 3. A depiction of the typical reporting time from initial exposure to receipt by public health. Typically, a person is exposed to a pathogen and may experience symptoms within a few days. After a patient is seen by a physician, specimens are collected and sent to a clinical laboratory for initial diagnostic testing, results are provided within a few days. If specimens are positive for a reportable disease, public health is notified of the case and specimens may be sent to a public health laboratory for additional testing.

Frequent and timely disease reports are critical for detecting outbreaks; identifying populations or geographic areas at high risk; developing, implementing, and evaluating prevention strategies; and improving public health policies.

Surveillance Systems

Public health surveillance is defined as the ongoing collection, analysis, and interpretation of health data for use in the planning, implementation, and evaluation of public health practices. Generally, public health tends to rely on passive methods of disease detection. This may include receiving case reports from physicians, laboratories, or other individuals or institutions as mandated by law. However, in the event of an outbreak or other event of public health concern, more active surveillance techniques may be used, in which public health will regularly contact reporting sources to obtain information. Any surveillance system must include the capacity for collecting and analyzing data, as well as the means to disseminate the data to individuals or groups involved in disease prevention and control activities.

Ideally, a surveillance system will detect the occurrence of disease within a sufficient time frame that allows public health to initiate an investigation and implement timely prevention and control programs, thereby limiting any impact on the public. For example, early detection of a contagious disease (e.g., influenza, measles, and smallpox) allows for implementation of a vaccination program that would greatly reduce the spread of disease and the number of people affected.

For incidents involving biological threats, public health will want to decrease the length of time between exposure and traditional disease reporting. To assist with this process, some cities and states may utilize a *syndromic surveillance* system to track pre-clinical healthcare indicators. Syndromic surveillance is a

system that relies on existing health data to identify clusters of disease, prior to clinical diagnosis or laboratory testing, or to look for disease symptoms that indicate patients are being misdiagnosed. The advantage of syndromic surveillance is that it may provide initial indication of an outbreak; track the size, spread, and tempo of an outbreak; monitor disease trends; or provide evidence that an outbreak has not occurred.^{2,3} Some healthcare indicators found in syndromic surveillance systems include:

- Number of upper respiratory disease cases seen in emergency departments
- Number of ambulance runs within an allotted period of time
- Number of antibiotics or over-the-counter drugs sold at pharmacies

It should be noted that syndromic surveillance is not guaranteed to detect the occurrence of an outbreak and does not replace other surveillance methods or direct case reporting to public health. However, it is a useful tool that enhances collaboration among public health, healthcare providers, information system professionals, academic investigators, and industry.³ Since many biological threat agents cause illness with symptoms similar to common ailments, supporters of syndromic surveillance believe that monitoring and analyzing healthcare indicator data will allow for rapid detection of covert biological threats.

Confirm the Diagnosis

Diagnosing the potential disease agent often begins with healthcare providers obtaining medical histories and conducting physical examinations of affected individuals. A medical history is the record of medical information gained by

² CDC. PHIN Messaging guide for syndromic surveillance: Emergency department, urgent care, and inpatient settings. HL7 Version 2.5.1. April. 2013

³ Henning, K. Overview of Syndromic Surveillance What is Syndromic Surveillance. MMWR. September 24, 2004 (Suppl); 5-11.

a physician during an exam and usually includes information on symptoms, recent events, travel, or any unusual circumstances that may contribute to an illness. Based on this information, physicians or public health may request laboratory tests to confirm the clinical diagnosis. However, physicians are likely to begin treatment before laboratory test results are available since early treatment of disease increases the probability the patient will recover from the illness, especially for biological threat agents.

Laboratory Analysis of Specimens and Samples

Diagnosing an illness by clinical signs and symptoms can be imprecise due to the nature and progression of the disease, especially for many biological threat agents, since the initial symptoms are similar to common infectious diseases (e.g., influenza). Therefore, laboratory analysis of clinical specimens is used to assist the physician in making a definitive diagnosis. Most physicians will wait for definitive laboratory results prior to confirming the diagnosis if a biological threat agent is suspected.

The materials that are typically collected to support a diagnosis or assist with a public health investigation may be clinical specimens (e.g., tissues, blood, and sputum) or environmental samples (e.g., food, water, air, dusts, powders, surface swabs). Some environmental samples may be considered hazardous materials and require specialized training and equipment for collection.

Field Testing:

A field assay test combined with clinical symptoms might suggest that a particular biological agent is present, but the field assay test alone cannot determine with absolute certainty that a particular biological agent is or is not present. The lack of specificity and comparably higher detection limits of these field assay tests make the use of an approved laboratory test critical.

Laboratories also vary in their ability to test for biological agents. For example, forensic laboratories that process criminal evidence may not be equipped to handle or test specimens containing a biological or chemical threat agent. Until the public health officials obtain the results from the confirmatory diagnostic test in an approved laboratory, such as the Laboratory Response Network, the diagnosis is considered unconfirmed or presumptive.

Laboratory Response Network

The FBI, CDC, and the Association of Public Health Laboratories (APHL) established the Laboratory Response Network (LRN) in 1999. The LRN is a network of laboratories located across the country that possess the expertise to conduct appropriate analyses with approved equipment, qualified personnel, validated assays, and accepted practices. LRN laboratories meet certain standards and continue to demonstrate their readiness through proficiency tests that validate their ability to correctly identify biological and chemical threat agents. Sending a specimen to a non-LRN laboratory could dramatically delay the investigation and may destroy material required to confirm the agent's identity and properly diagnose the causative agent of an illness. Additional information on the Laboratory Response Network is located in Appendix 5.

Due to their expertise and proficiency, only LRN facilities should be used to test clinical specimens or environmental samples for the presence of biological or chemical threat agents. Law enforcement agents should contact their local FBI WMD Coordinator to determine the location and procedures for submitting samples to the nearest LRN facility.

Identify and Characterize Additional Cases

The process of identifying and characterizing additional cases in an epidemiological investigation is very similar to that of a law enforcement investigation. In both disciplines, a generous amount of time and resources is required to obtain additional investigative information through interviews with cases and other contacts.

The first confirmed case of an outbreak is referred to as the *index case*. To prevent further impact and to try and find the source of the disease, there is a need to identify new, unreported or unrecognized cases and their contacts. In the search for additional cases, public health will interview family members, associates, co-workers, and other possible contacts of the index case. These interviews require extensive time and personnel commitments. Interviewees may be contacted multiple times as the investigation proceeds if there is a need to obtain additional information. Information collected by public health can include the following:

- Demographic data (name, address, age, race, ethnicity, gender)
- Clinical data (signs and symptoms, duration, onset)
- Exposure history (travel, meals, and significant events; all based on the type of illness suspected)
- Case contacts and knowledge of other cases

In addition to interviewing the index case and contacts, public health will attempt to identify additional cases by using a set of uniformed criteria, called a case definition. Public health provides the case definition to physicians, hospitals, and other health officials to identify any additional cases that may be related to the outbreak, both within and outside their jurisdiction.

Public health may also solicit assistance from the media in trying to identify additional cases. For example, public health may work with the media to inform the public that anyone with a certain type of symptom (e.g., skin rash, fever) may have been exposed to a biological agent and should report to a physician for an examination. Once additional cases have been identified, public health will collect information on each one to determine whether their illness could be associated with the outbreak.

Determine the Source of Exposure

Once the case/contact interview information has been collected, it is analyzed to identify common exposures and, ultimately, to suggest the source of illness. This process is known as *descriptive epidemiology*.

An example of descriptive epidemiology is the creation of a histogram (a bar graph that estimates a probability distribution) in which the number of disease cases are plotted by date or time of onset in order to visualize the progression of the outbreak. This bar graph, called an *epidemic curve* or *epi curve*, provides a visual representation of an outbreak's magnitude over a specific time period and can provide critical clues regarding the outbreak's onset and duration. (See Figure 4)

Multi-State Outreach of *E. coli* 0157:H7 Infection

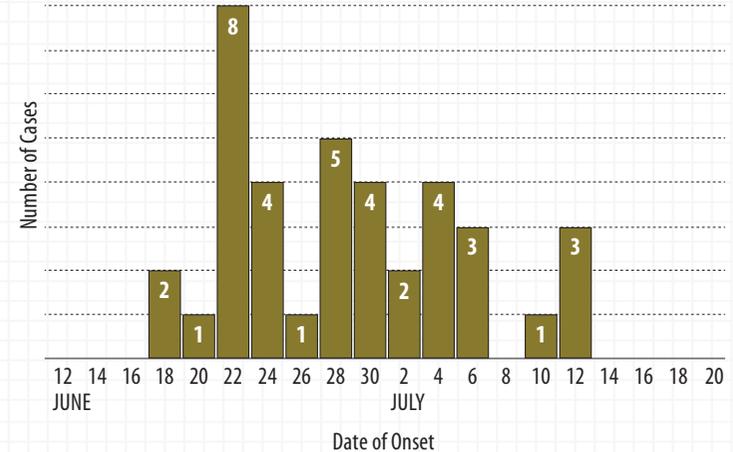


Figure 4. The Epi Curve.⁴ This is a diagram of the number of cases of *E. coli* 0157:H7 infection that were associated with this outbreak and date of occurrence. This graph, known as an epi curve, helps public health determine the source and spread of an outbreak.

Once the descriptive epidemiology has been reviewed, public health will try to develop a “best guess” for the source(s) of illness. This best, or informed, guess is known as a hypothesis. For example, if multiple cases shared an exposure, such as attending the same organized event, then public health may develop a hypothesis that the common event is the source of disease.

During an epidemiological investigation, public health may develop several hypotheses about the cause of the outbreak as they accumulate additional clinical, laboratory, and investigative information. To determine whether a

⁴ Stehr-Green J. (2002) Multistate Outbreak of *E. coli* 0157:H7 Infection. Instructor's Version. Retrieved from <http://www.cdc.gov/epicasestudies/downloads/ecoli.pdf>

hypothesis is correct, public health conducts a statistical analysis or study of data obtained using a standardized survey instrument or questionnaire. This process is known as *analytical epidemiology*. The statistical analysis provides public health with mathematical evidence to confirm or reject a hypothesis. If the analysis confirms a hypothesis then public health will develop and implement an intervention to prevent people from becoming ill. If a hypothesis is rejected by the analysis, then public health will develop a new hypothesis and continue to search for more cases in order to obtain additional information.

Develop and Implement Interventions

The ultimate aim of an epidemiological investigation is to identify the source of the disease and implement a plan to control the outbreak and protect the public's health. Often there is a need to develop and implement an intervention before the disease agent has been confirmed in order to ensure a successful intervention. Many illnesses, including those caused by biological threat agents, can be treated successfully if antibiotics or antivirals are provided early in the course of the illness. Also, *quarantine* (restricting movement of healthy people who may have been exposed to a contagious disease) or *isolation* (separating ill persons who have a contagious disease from those who are healthy) measures may be used to control spread of a contagious disease; however, these measures must be implemented early in an outbreak to be effective. Some control measures may be directed at the environment to remove the source (e.g., insects, contaminated food) of transmission.

Therefore, in the case of bioterrorism, interventions are often initiated based on the suspicion of disease rather than waiting for confirmation. Early suspicion, coordinated with law enforcement intelligence, can help public health intervene as quickly as possible and save lives.

LAW ENFORCEMENT



Key Highlights of Law Enforcement Section

- Primary goals of a criminal investigation for a biological threat are:
 - » To protect the health and safety of the public
 - » To prevent subsequent attacks
 - » To identify, apprehend, and prosecute the perpetrators
 - » To protect law enforcement personnel
- If public health and law enforcement have established a working relationship prior to a biological threat incident, public health may feel more comfortable contacting law enforcement early in their investigation.
- Law enforcement should include various subject matter experts, such as public health, to assist in determining the credibility of a biological threat.

- Once there is suspicion that a crime has occurred, chain of custody procedures should be implemented by both law enforcement and public health to ensure accountability of evidence. Failure to properly maintain the chain of custody may render evidence unusable at trial.
- In certain situations the environment might be contaminated; therefore, it is useful to have specially trained law enforcement teams to handle apprehension of the suspect and collection of evidence in contaminated environments.
- The need for rapid collection and testing to save lives outweighs normal evidence collection procedures.

Criminal Investigation Goals

During a biological threat incident, law enforcement has the following basic goals:

- **To prevent a criminal act and subsequent attacks:** Through ongoing surveillance, investigation, and intelligence-gathering techniques, law enforcement personnel work to gather information to identify potential terrorists, their targets, and methods of attack before an attack takes place, or to prevent subsequent attacks from being carried out.
- **To identify, apprehend, and prosecute the perpetrators:** Once a biological attack occurs, law enforcement gathers evidence and information to identify and apprehend the individual(s) responsible for the crime. Collection of evidence includes interviewing victims and witnesses as well as obtaining and preserving physical evidence. A criminal investigation is not complete until there is a successful prosecution and conviction of those responsible for the biological attack.
- **To protect law enforcement personnel:** Law enforcement personnel, including FBI agents, are likely to encounter situations where they may be at risk for exposure to a biological agent. Since some biological agents can be both infectious (can infect a person) and contagious (can spread from person to person), provision of proper personal protective equipment (PPE) and other preventive medications or vaccines for law enforcement personnel is essential.

Preventing Biological Attacks

The first step in preventing a biological attack is to attempt to identify potential terrorists or terrorist organizations that are both capable of and have intent to execute a biological attack. This process allows FBI and other law enforcement officials to identify potential targets and possible modes of attack. Despite all efforts, a biological attack may not be prevented. Therefore, appropriate law enforcement agencies must be prepared to respond to an incident either while it is occurring or after it has perpetrated. Since soft targets are often more appealing than solid or more stable targets, a country's strong response capability to a biological attack might be a deterrent for terrorists choosing a pathogen as their method of attack.

FBI WMD Threat Credibility Evaluation—Real or Hoax

FBI/law enforcement personnel may be confronted with a number of situations involving the actual or threatened use of a biological agent as a weapon. These situations may include non-credible threats (hoaxes), announcements or indications that a release of a biological agent has occurred (overt), or unannounced releases of a biological agent (covert).

During a covert event, the public health and medical community will likely be first to identify an occurrence of a bioterrorism incident as patients seeking treatment for an unexplained illness can often be a first indication of an attack. As soon as public health suspects an intentional event or is confronted with a case of illness caused by an agent or toxin of concern, they should notify law enforcement to determine the likelihood of a biological attack. If public health and law enforcement have established a working relationship prior to the occurrence of a bioterrorism incident, public health may feel more comfortable contacting their law enforcement counterparts early in the investigation, allowing for a more rapid initiation of the threat evaluation process.

During an overt biological threat, such as a “threat letter” or another announcement indicating the release of a biological agent, law enforcement will likely be the first to identify the incident since the threat would be reported to law enforcement before illness occurred. Even without the presences of a biological agent, hoaxes, can be a very effective way for perpetrators to cause fear since biological agents require an incubation time before symptoms develop, essentially causing the public to fear the unknown.

All situations involving the intentional use of a biological agent require an FBI-led threat credibility evaluation. In some jurisdictions, a local threat assessment may support the FBI threat credibility evaluation. Upon notification of a WMD threat or incident (e.g., an overt release such as a white powder letter accompanied by a threat), state and local law enforcement or emergency responders will contact their FBI WMD Coordinator to initiate the threat credibility evaluation process. The WMD Coordinator will then contact FBI Headquarters Weapons of Mass Destruction Directorate, which is responsible for convening a conference call to support the evaluation. A threat credibility evaluation should consist of three factors, plus an assessment of available intelligence and/or case information to determine the credibility of a threat:

- **Technical Feasibility:** Does the threat require technical expertise; if so, are those involved technically competent? (Will it work?)
- **Operational Practicality:** Does the operation that is used to carry out the threat seem practical? (Can it be done?)
- **Adversarial Intent:** Does the person display the behavioral resolve to carry out the operation? (Would the person do it?)



Figure 5. Threat Credibility Evaluation. When a threat is made, FBI may conduct a threat credibility evaluation to determine how credible the threat is and what further action should be taken to mitigate the threat.

During the course of the threat credibility evaluation, the FBI WMD Directorate may contact various partners and subject matter experts (e.g., CDC or United States Department of Agriculture) to assist in determining the threat credibility. If the threat is deemed credible, the FBI WMD Coordinator, along with state and local responders, will consult with FBI Headquarter assets to determine the next course of action, specifically regarding how to best collect and analyze the evidence, including environmental samples and other evidence. Additionally, the FBI Strategic Information and Operations Center (SIOC) will notify the DHS National Operations Center (NOC) immediately.

If the threat is deemed non-credible, FBI may initiate an investigation to identify and prosecute those responsible for creating the perception that there was a threat (i.e., a hoax). Under federal law (18 U.S.C. 2332a and 18 U.S.C. 175), a threat involving a disease-causing organism is a criminal act, whether or not the perpetrator actually possesses the biological agent.

Criminal Investigative Methods

FBI/law enforcement personnel conducting criminal investigations must operate within the applicable laws governing the investigations and the ensuing prosecution. As information is collected, it is necessary for law enforcement to develop a thorough understanding of the investigation and the unique circumstances of the case. This will help law enforcement to identify any missing or weak evidence, which may impact the ability to apprehend, prosecute, and convict the individual(s) responsible for committing the crime. A brief summary of criminal investigative methods is provided below. While some aspects of a criminal investigation may occur sequentially, they can also take place simultaneously.



Figure 6. Elements of a criminal investigation.

Gather Evidence

The process of gathering evidence during the criminal investigation of a potential biological threat will involve collection of physical evidence (e.g., dissemination devices, clothing of victims and suspects), clinical specimens (e.g., blood or other bodily secretions), documents, photographs, and witness statements. Law enforcement must consider a variety of issues to ensure that any evidence they gather can ultimately be used in a criminal prosecution.

The list below provides a summary of some of the key issues law enforcement must consider when gathering evidence.

- **Chain of Custody:** Chain of custody is an issue of significant concern during a criminal investigation. Both law enforcement and public health personnel must provide accountability at each stage of collection, handling, testing, storing, transporting the evidentiary items, and reporting any test results. Failure to properly maintain the chain of custody may render the evidence unusable at trial if law enforcement is not able to unequivocally state where the evidence was located and who had access during the time the evidence was in custody. Responders should implement formalized chain of custody procedures once there is suspicion that a crime has occurred.
- **Delivery of Biological Samples to the LRN:** Only laboratories within the Laboratory Response Network (LRN) should be used to test for biological agents. Submitting evidentiary biological samples to a non-approved laboratory will not only delay proper analyses, but may result in unintentional contamination of the samples and may be used to create doubt about the validity of test results in court. The FBI WMD Coordinators maintain a list of LRN laboratories within their field office's area of responsibility. See Appendix 5 for further information about the LRN.

- **Documents:** Original documents should be obtained by law enforcement when possible. Issues of authenticity and admissibility as evidence arise if copies are relied upon when original documents are available given that a copy could have been modified from the original.⁵ Example documents that law enforcement might gather as evidence include laboratory results or financial statements.
- **Witness Statements:** Witness descriptions of dissemination devices, vehicles, suspects, odors, tastes, sounds, and other specific information must be obtained as soon as possible following a potential pathogen release. Witness information is time sensitive and the sooner the information can be obtained, evaluated, and disseminated to other investigators, the more value it adds to the investigation. As time passes, a witness's memory can fade or become influenced by the opinion of other individuals.

During an investigation of a biological threat, law enforcement may need to decide between collecting evidence for public safety or for criminal prosecution. There may be an overriding need by authorities to identify the agents or materials as soon as possible to ensure that the proper response is implemented and steps are taken to protect the responders and the public. In this instance, the need for rapid collection and testing to save lives outweighs normal evidence collection procedures.

Evaluate Evidence

Similar to other criminal investigations, in the event a pathogen is intentionally released, an investigator may be unaware of what is and is not a critical piece of evidence that will be needed to identify, arrest, and convict those

⁵ Potentially contaminated documents should be stored and examined utilizing procedures which protect both the individuals handling the evidence and the evidence itself.

responsible for the criminal act. As evidence is collected, an ongoing evaluation of the evidence must be part of the investigative process. An understanding of evidence types and the rules governing its admissibility will lead to better evaluation as the criminal investigation progresses. While not intended to be all-inclusive, Table 1 identifies and provides a brief explanation of some types of evidence collected during a criminal investigation.

Table 1. Types of Evidence Collected During an Investigative Process

| Type Of Evidence | Explanation | Example |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| Direct | Documents, records, physical evidence, notes, computer data, videotapes, or other types of information that directly relate to the case. | Vehicle rental agreements, purchase receipts, phone records, eyewitness statements, dissemination devices. |
| Circumstantial | Facts, if proven, that allow the investigator to draw conclusions. Circumstantial evidence often has the same probative or substantiating value as direct evidence. | Suspect was treated for cutaneous anthrax at or about the same time a release of anthrax was attempted. |
| Trace | Very small particles of matter that can be examined microscopically, physically, and/or chemically. | Biological agent residue, fingerprints, DNA, biological properties of the agent. |
| Hearsay | Statements offered to prove the truth of the matter asserted; the person who made the statement is unavailable for cross-examination. | A statement taken from a third party who heard another person describe seeing the suspect spray a substance during the time in question. |
| Eyewitness Testimony | Observation or sensation personally seen, smelled, heard, felt, or tasted. | Witness reported smelling a particular odor, hearing a specific sound, or seeing someone. |

Generally, law enforcement should be accustomed to receiving results quickly when the event is significant, such as a death or high profile crime. Since evidence collected in a potentially contaminated environment must be assumed to be contaminated, this significantly complicates the evidence review and evaluation process. The FBI has specially trained teams to handle the collection of evidence in contaminated WMD environments. There are 24 fully operational Hazardous Evidence Response Teams that provide coverage of the FBI field offices, as well as specially trained FBI personnel, such as microbiologists and other scientists, trained to collect contaminated evidence. Following a biological attack, the FBI will have the collected evidence analyzed in a laboratory to support and guide their investigation. As mentioned before, only laboratories approved to handle biological evidence, such as those in the Laboratory Response Network, may accept samples.

From the beginning of a criminal investigation for a biological threat and until the case is submitted to a jury for a verdict, all facts collected during the investigation must be verified and inconsistencies resolved. Documents must be carefully reviewed to ensure they have been thoroughly analyzed and interpreted correctly. Sometimes information contained in statements or reports is subject to differing interpretations. Law enforcement investigators must examine the evidence for conflicting interpretations and resolve these issues, or be prepared to explain the contradictions to the prosecutor.

Once evidence has been collected and analyzed, it is important to submit all materials (*e.g.*, statements, laboratory reports, documents, photographs) to the prosecutor in an organized manner to ensure all the facts are identified before the trial. Sufficient time should be allowed to permit the prosecutor to meet with the investigators and witnesses to review all reports, evidence, and anticipated testimony.

Apprehend Suspect(s)

Once the threat to public health and safety has been eliminated, the top priority for law enforcement is the apprehension and prosecution of those responsible for the attack. During the apprehension of a suspect or group of suspects, law enforcement involved in the arrest must take precaution against possible injury from the perpetrator(s). It is also possible that the arresting officers will be confronted with either a contaminated environment or contaminated evidence. Therefore, appropriate PPE and a decontamination process must be utilized to prevent contamination by a biological agent. While apprehending the suspects is a goal of the criminal investigation, the safety of the arrest team and the general public is paramount.

Provide Testimony

Each law enforcement investigator involved in the case and potential witness should be available to meet with the prosecutor before he or she testifies at trial. It is important for the prosecutor to have the opportunity to evaluate each investigator and witness and his or her statements before appearing in front of a jury. During this time, any issues, problems, discrepancies, or gaps in evidence or testimony can be discussed and resolved.

JOINT INVESTIGATIONS



Key Highlights of Joint Criminal and Epidemiological Investigations Model Section

- The Joint Criminal-Epidemiological Investigations Model is made up of six strategic elements.
 - » Building Relationships
 - » Information Sharing
 - » Joint Threat Assessment
 - » Joint Investigation
 - » Memorandum of Understanding/Joint Protocols
 - » Joint Training/Exercises
- Benefits to conducting joint investigations:
 - » Law enforcement has access to public health experts who understand disease epidemiology and can provide relevant medical information.
 - » Public health has access to law enforcement case information which could assist in identifying the source of exposure and containing an outbreak.
- The timely exchange of information in the early stages of a response is critical. Both disciplines have access to unique information that could help to prevent or detect a biological threat.

- A joint threat assessment, which utilizes the unique expertise of both disciplines, can help determine more quickly the nature of the incident (intentional or natural) and lead to a more appropriate response to the threat.
- A joint investigation can maximize the efficiency for both law enforcement and public health in the event of a biological threat through the exchange of real-time investigative information.
- MOU/joint protocols between law enforcement and public health are critical in determining roles and responsibilities prior to an event occurring and help ensure consistent practices between the disciplines during a response. Important information to include in MOU/joint protocols include: information sharing triggers, joint threat assessments, joint investigations, joint interviews, and methods for sharing investigative results.
- Joint training and exercises are important elements of the Joint Criminal-Epidemiological Investigations Model since they allow public health and law enforcement to test, evaluate and refine their protocols. Amending protocols to reflect lessons learned from an exercise is particularly important to ensure best practices evolve and are strengthened over time.

Introduction

Collaboration between law enforcement and public health has not always been recognized as beneficial. In the past, it was common for law enforcement and public health to conduct separate and independent investigations during the response to a suspicious biological incident.

The Joint Criminal-Epidemiological Investigations Model highlights several practices and procedures that can be used by public health and law enforcement to increase collaboration and partnership.

However, following the 2001 anthrax mailings, a mechanism for increasing cooperation and coordination between law enforcement and public health was developed: *Joint Criminal-Epidemiological Investigations Model*. This model is not solely limited to the investigative process; rather, it incorporates a number of procedures and methodologies that require interaction between law enforcement and public health prior to the detection of a biological threat and through its resulting investigation.

The *Joint Criminal-Epidemiological Investigations Model* is composed of six elements:

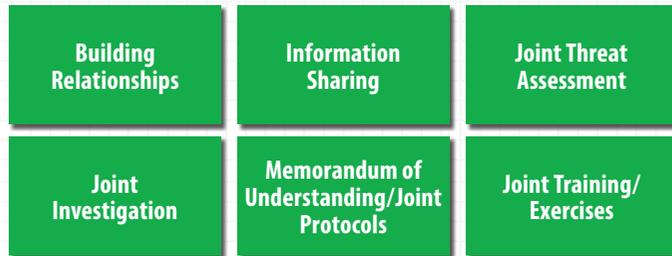


Figure 7. Elements of a *Joint Criminal-Epidemiological Investigations Model*.

Benefits of the Joint Criminal-Epidemiological Investigations Model

Public health and law enforcement share a set of common goals during the response to a biological threat, including:

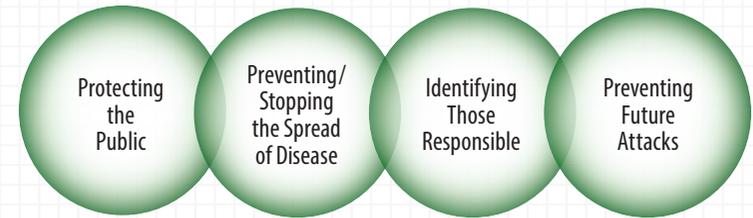


Figure 8. Common goals shared between public health and law enforcement during a response to a biological threat.

The Joint Criminal-Epidemiological Investigations Model allows law enforcement and public health to achieve their common goals by enabling a more efficient response to a biological threat, resulting in earlier detection of an attack, identification of a source, and implementation of interventions, thereby mitigating the effects of the outbreak. Additionally, this model highlights the need to combine the investigative efforts of law enforcement and public health, which minimizes potential discrepancies between investigators and maximizes the opportunities to identify, apprehend, prosecute and convict the perpetrator of the attack.

Law Enforcement Benefits

When operating under the Joint Criminal-Epidemiological Investigations Model, law enforcement personnel have:

- Access to experts who understand disease epidemiology (e.g., symptoms, diagnosis, possible causes)
- Access to relevant public health/medical information (e.g., results of the epidemiological investigation that may inform the criminal investigation)

Public Health Benefits

When operating under the Joint Criminal-Epidemiological Investigations Model, public health officials have:

- Access to law enforcement case information that may help to determine the source of the illness
- Assistance in containing the outbreak from law enforcement (who can help identify information that may lead to apprehending the perpetrator, thus preventing future releases, exposure and illness)

The Joint Criminal-Epidemiological Investigations Model: An Overview

Generally, law enforcement and public health may exchange information once they confirm the existence of a criminal act or an outbreak. However, waiting until a crime or outbreak has been confirmed is too late. For an effective response to biological threats, public health and law enforcement need to share information prior to the confirmation that an intentional incident has occurred. The timely exchange of information in the early stages of a response is critical to containing the outbreak and apprehending the perpetrators. Therefore, the Joint Criminal-Epidemiological Investigations

Model begins with the identification of public health and law enforcement contacts prior to an incident.

Building Relationships

The purpose of identifying contacts prior to an incident is to initiate dialogue between the disciplines in order to build a working relationship. Strong personal ties between law enforcement and public health tend to foster increased information exchange. Many of the barriers believed to prevent collaboration between public health and law enforcement can be overcome by developing an understanding of each other's roles/responsibilities and information needs and sensitivities. Over time, public health and law enforcement contacts become more familiar with each other and trust is gained, ensuring that information can be shared and properly protected.

Information Sharing

Both disciplines have access to unique information that may be important to share in order to prevent or detect a biological threat. Since neither agency will likely possess all the necessary data for a response, information sharing is an essential part of public health and law enforcement collaboration.

| Law Enforcement | Public Health |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none">• Terror Groups/Organizations• Threats• Intelligence• Victim Information | <ul style="list-style-type: none">• Case Reports/Outbreaks• Laboratory Tests• Epidemiological Information• Patient Information |

Figure 9. Information that is unique to law enforcement and public health that, if shared, could be beneficial to both a criminal and epidemiological investigation.

Public health and law enforcement officials are encouraged to notify and involve each other early in a potential investigation of a biological threat, even if it turns out to be a non-criminal event. The establishment of pre-incident communication mechanisms is essential for the expeditious exchange of information during an actual incident. This exchange of information requires law enforcement and public health personnel to be familiar with one another, and to know who should receive the information.

Information Sharing Challenges

There are challenges to sharing information between public health and law enforcement. The challenges are both perceived and real, and should be addressed before both disciplines can legally and safely share information and conduct joint investigations.

Public Health Challenges

Due to the Health Insurance Portability and Accountability Act (HIPAA) and applicable state privacy laws, a common potential challenge for public health is concern regarding legal liability for the release of patient health information without the patient's consent. Challenges arise when law enforcement requires access to "protected health information" as potential evidence of a crime from patient health records, which are maintained by public health, healthcare providers, health plans (health maintenance organizations, Medicare), or health care clearinghouses. However, as covered below, there are exceptions that allow law enforcement access to protected health information.

Another potential challenge regarding the exchange of patient information is issues of ethics and trust. Patients often provide detailed personal information to physicians and public health with the tacit understanding that their information will not be disclosed. Public health may be concerned

that providing confidential patient information to the law enforcement community, regardless of reason or intent, jeopardizes their future ability to obtain data critical to identifying an outbreak source and implementing effective control measures.

Law Enforcement Challenges

Law enforcement may also have concerns regarding the exchange of investigative information. For any criminal investigation, the more people with access to sensitive information, the more opportunities exist for inadvertent disclosure. Furthermore, the inadvertent release of sensitive information could jeopardize the safety of confidential informants or classified sources by allowing the suspects to directly identify law enforcement's source. As a result, suspected perpetrators may receive the advanced warning needed to facilitate the destruction of evidence, possibly avoid detection, and potentially affect a successful prosecution of the perpetrator(s).

Legal Issues Related to Information Sharing

Each agency's legal counsel is encouraged to evaluate federal, state, and local laws and regulations to determine ways to share information. A review of the applicable federal and state statutes should be conducted to determine the actual limitations and the exceptions that may exist, which allow the exchange of information between public health and law enforcement. For example, HIPAA prevents an individual's health information from being released without that individual's consent; however, there are specific exemptions in HIPAA that allow for the release of patient medical information to public health officials and law enforcement. One exemption relevant to a law enforcement investigation is often identified as the "imminent threat exemption." According to this exemption:

“A covered entity may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the covered entity, in good faith, believes the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public and the disclosure is made to a person reasonably able to prevent or lessen the threat (See 45 CFR 164.512 (j)(1)(i)).

Additionally, HIPAA requirements may be waived in certain circumstances. For example, in the event of 1) an emergency declared by the President and 2) a Public Health Emergency declaration by the Secretary of the HHS, the Secretary of HHS may waive certain HIPAA requirements under Section 1135 of the Social Security Act (42 U.S.C. § 1320b–5). Once both declarations are issued, covered entities may then request an 1135 waiver from the Secretary, which may allow for the disclosure of protected health information.

The legal basis for allowing patient medical information to be shared with law enforcement should be researched and incorporated into a MOU/joint protocol so all entities are properly informed and can comply with the legal requirements for sharing information. See Appendix 7 for additional information on the HIPAA law enforcement exemption.

Information Sharing Triggers

During a biological threat, certain information or a specific event should trigger the exchange of information between law enforcement and public health. For example, law enforcement conducts criminal investigations every day, and in recent years, there have been numerous hoaxes involving biological incidents. Therefore, what should prompt the law enforcement community to contact public health and involve them in the investigation of such an incident? Similarly, epidemiological investigations routinely take place; most outbreaks

not caused by an intentional act. At what point during an epidemiological investigation should public health be prompted to contact law enforcement?

Many factors could provide clues to potential biological threats. The difficulty of trying to use definitive criteria is that almost all infections produce initial symptoms that are non-descript and may be misdiagnosed as another disease. Furthermore, many biological threat agents cause rare or non-endemic diseases, often with unknown or poorly characterized etiology. As a result, physicians may not recognize the disease until it has progressed to its more serious and unique symptoms. In these cases, there may be a reluctance to report this “unknown” illness until a definitive diagnosis is determined.

The following tables provide a preliminary list of factors that could trigger public health (Table 2) or law enforcement (Table 3) to share information. These tables are not intended to be all-inclusive. Law enforcement and public health may want to add or remove triggers to suit their individual needs.

Table 2. Public Health Triggers

- Any specimens (clinical) or samples (environmental) submitted to public health for analysis that test positive for a potential biological threat-related agent
- Large numbers of patients with similar symptoms or disease
- Large numbers of unexplained symptoms, diseases, or deaths
- Disease with an unusual geographic or seasonal distribution (*e.g.*, plague in a non-endemic area)
- Unusual disease presentation (*e.g.*, inhalational vs. cutaneous anthrax)
- Endemic disease with unexplained increase in incidence (*e.g.*, tularemia, plague)
- Higher than expected morbidity and mortality associated with a common disease and/or failure of patients to respond to traditional therapy
- Unusual “typical patient” distribution (*i.e.*, several adults with an unexplained rash)
- Death or illness in humans preceded or accompanied by death or illness in animals that is unexplained or attributed to a zoonotic biological agent

Table 3. Law Enforcement Triggers

- Any intelligence or indication that any individual or group is unlawfully in possession of any biological agent
- Seizure of bio-processing equipment from any individual, group, or organization
- Seizure of potential dissemination devices from any individual, group, or organization
- Identification or seizure of literature pertaining to the development or dissemination of biological agents
- Any assessments that indicate a credible biological threat exists in an area
- A HAZMAT response that involves the presence of biological agents

The identification of law enforcement and public health triggers is intended to be a starting point to improve information sharing between agencies or jurisdictions. The most important aspect of this process is to overcome the hesitation or reluctance to share information before all of the facts are known. Early notification provides an early warning and should not be viewed negatively.

Joint Threat Assessment

To complement and support the threat credibility evaluation process coordinated by the FBI WMD Directorate, it is recommended that local FBI field offices, local law enforcement, and public health establish protocols for conducting a local joint threat assessment. Determining the nature of a reported incident (*i.e.*, natural or intentional) and implementing appropriate response activities requires a joint assessment by law enforcement and public health.

A joint threat assessment can be conducted in person (on the scene of an event) or over the phone (conference call). The outcome of the joint threat assessment is to determine the nature of the threat (*i.e.*, credible or not credible). A threat is deemed a “credible threat” if it is determined that potential for a real threat does exist. In the U.S., a threat may also be deemed credible

if there is intent to cause terror even though no pathogen is used (*e.g.*, an articulated threat in a mailed letter, which contains an unknown substance).

To complement and support the information sharing process, law enforcement and public health should establish protocols for conducting a joint threat assessment prior to an event. Determining the nature of a reported incident (*i.e.*, natural or intentional) and implementing appropriate response activities requires a joint assessment by law enforcement and public health.

A joint threat assessment can be conducted when either discipline identifies a defined trigger. During the threat assessment, public health and law enforcement will possess critical information that should be shared so that the participants can make an informed decision regarding the nature of the incident and appropriate follow-up activities. Once all available information has been shared, law enforcement and public health should classify the incident into one of three risk categories:

- **No Threat:** Highly likely the source of exposure occurred naturally (not intentional)
- **Possible Biological Threat:** Information suggests possibility that exposure may be a result of an intentional exposure
- **Likely Biological Threat:** There is a reasonable belief the exposure was caused intentionally

Based on the risk category, public health and law enforcement perform the next steps:

- **No Threat:** Public health will continue to manage the incident
- **Possible Biological Threat:** Separate investigations or joint investigation
- **Likely Biological Threat:** Joint Investigation

While the incident may be initially assessed at one of the above risk levels, it may be changed as the investigation begins and new information is collected.

Procedures for conducting joint threat assessments should be decided on prior to a potential biological threat and included in an agreed upon protocol or MOU between the two disciplines. For reference, a sample procedure for conducting a joint threat assessment can be found in Appendix 1.

Joint Investigations

The objective of a joint investigation is to maximize the efficiency of both law enforcement and public health through the exchange of real-time investigative information. When a joint investigation is initiated, law enforcement and public health are empowered to share information throughout the course of the joint operations.

The goals of joint investigations are to:

- Identify the disease causing agent
- Identify the source and perpetrators of the attack
- Determine the mode(s) of spread or transmission of the biological agent
- Determine where and when exposure to the biological agent may have occurred
- Identify who may have been exposed.

Joint Investigation Criteria

The following criteria may be used to establish a threshold for determining whether to conduct a joint investigation of a suspect bioterrorism incident:

- Case-patient(s) positive for a select agent,
- No known natural source to explain infection,
- No known risk factors for disease occurrence, **and/or**
- FBI intelligence suggests that the incident is criminal/intentional

These criteria are not all-inclusive and may not cover every possible biological threat. Once a decision has been made to work jointly, law enforcement and public health should follow previously developed procedures for conducting a joint investigation. These procedures should be located in a MOU/joint protocol.

Joint Investigations—Sharing of Investigative Information

During a joint investigation it may be difficult for law enforcement and public health to know the type of information that can be freely exchanged. As a general rule, when conducting a joint investigation, law enforcement should share relevant criminal investigative information that will be helpful to public health in mitigating the effects of the outbreak. Likewise, public health should share any epidemiological investigative information that may assist law enforcement to identify, apprehend, prosecute, and convict the perpetrator(s).

The following tables (Table 4 and Table 5) were developed to assist law enforcement and public health in determining the type of information needed by the other discipline.

Table 4. Public Health Information for Law Enforcement

- Time and locations where exposures may have occurred (may be based on agent-specific characteristics or other investigational findings)
- Names (including date of birth) for all confirmed, probable, and exposed case-patients
- Positive laboratory results for a biological threat agent from an approved laboratory
- Case definition (epidemiological picture of the outbreak)
- Risk factors that may be associated with exposure (*e.g.*, demographics, occupation, or other activities)
- Hypotheses generated by the epidemiological investigation
- Notification about when public health is planning to conduct interviews with case-patients or contacts
- National or international health alerts that may be related to the current biological threat
- Laboratory results used to characterize the specific biological agent (*e.g.*, strain, genetic sequencing, antimicrobial resistance)
- Identification of any unusual cases (*e.g.*, past case-patients, coroners' reports)
- Any other investigative information that may be relevant to the biological threat (*e.g.*, requests or theft of antibiotics, identification of a laboratory in someone's home)

Table 5. Law Enforcement Information for Public Health

- Law enforcement investigative information (*e.g.*, interviews scheduled and planned search warrants) that may assist public health with the identification of the agent and determination of the source of the outbreak
- Information regarding any known group or sector that may be targeted (*e.g.*, government or financial, entertainment, religious/ethnic groups) for an attack
- Other law enforcement cases which may have ties to the existing biological threat investigation
- Pre-incident indicators (*e.g.*, videotaping, sketching maps, break-ins, perimeter breaches at facilities) that may be related to the biological threat incident
- Information developed by law enforcement regarding the biological agent used, mechanism for delivery/dissemination, date, time and locations of exposures
- Information regarding any medical equipment, chemicals, toxins, biological agents or laboratory supplies stolen, developed, or uncovered that may be related to the biological threat
- Intelligence information regarding the characteristics of the biological agent (*e.g.*, strain, antimicrobial resistance, or weaponized nature)

Joint Interviews of Cases and Contacts

Much of the joint investigation will initially focus on interviews with patients and potential contacts that will primarily address where and when exposures to biological threat agents may have occurred. While many public health and law enforcement investigators may be familiar with conducting interviews, many have not practiced or conducted a joint interview with the other discipline present.

Although a joint interview with law enforcement can provoke anxiety in the patient, one interview with both agencies present may be less disruptive to the patient than two or more separate interviews repeating similar information. Additionally, separate questioning by law enforcement and public health may lead to conflicting statements, which can jeopardize the outcome of the criminal investigation. Therefore, a joint interview affords public health and law enforcement the opportunity to examine relevant facts based on the unique perspectives of both investigators. For reference, a sample procedure for conducting a joint law enforcement and public health interview can be found in Appendix 2.

For public health there are concerns that the presence of law enforcement could compromise the collection of sensitive medical information (*e.g.*, illegal drug use) by public health. However, a criminal investigation requires interviewing all potential witnesses and victims. In order to mitigate patient concerns, a provision should be established for confidential communications between public health and the interviewee in order to share specific health-related information during a joint interview. Special consideration should be made to protect the identifying information of the interviewees, due to privacy as well as the integrity of a criminal investigation.

In some instances, joint interviews may not be possible (e.g., the interviewee requests that law enforcement not be present) so each discipline should be aware of the types of information their counterpart is seeking. For reference, sample questions that may be asked by law enforcement and public health can be found in Appendix 3.

Joint Investigations and the Media

It is important for FBI, law enforcement and public health to coordinate their interaction with the media. The media will have a significant impact on the response and the public reaction to a biological threat. With public fear and the psychological impact of a bioterrorism incident, the media will aggressively seek information from the investigators. Therefore, FBI, law enforcement and public health must develop a working relationship with the media to help ensure that timely, useful information is shared with the media to keep the public accurately informed, but not overly alarmed.

Memorandum of Understanding/Joint Protocols

The creation of a Memorandum of Understanding (MOU) and/or joint protocols helps to establish joint investigative guidelines between law enforcement and public health, thus determining roles and responsibilities prior to an event actually occurring. These guidelines help to address many of the actual or perceived challenges and barriers to collaboration by outlining investigational procedures for the response to a biological threat or other naturally occurring incidents. In addition, MOU/joint protocols help establish consistent procedures among law enforcement and public health regardless of personnel rotation over time.

In general, the MOU/joint protocols outline some of the components discussed above: information sharing triggers, joint threat assessments, and joint investigations. Additional information that could be helpful to incorporate into

a MOU/joint protocol includes sharing of investigative results and the analysis of information (e.g., agreement on appropriate methods for handling clinical specimens and environmental samples and how information obtained from these sources will be shared).

The development of a MOU/joint protocol is a difficult task, requiring the input and agreement of many entities within law enforcement and public health. To assist agencies and jurisdictions with the creation of an MOU/joint protocol, the CDC and the Bureau of Justice Assistance (U.S. Department of Justice) convened a Public Health and Law Enforcement Emergency Preparedness Workgroup that developed a model MOU for joint public health and law enforcement investigations.

To obtain a copy of the model MOU, send an email request to:

phlawprogram@cdc.gov.

Joint Training/Exercises

Once relationships are established and MOU/joint protocols are developed, public health and law enforcement need to be trained in order to be proficient in joint investigations activities. It is important to already have MOU/joint protocols in place prior to conducting an exercise (and not use the exercise to create the joint protocol). Creating a joint training/exercise program will enable public health and law enforcement to test, evaluate and refine their protocols. Amending protocols to reflect lessons learned from an exercise is particularly important to ensure best practices evolve and are strengthened over time. Additionally, as new individuals are trained, it allows public health and law enforcement to continually build relationships with their counterparts and gain familiarity and expertise with joint investigations principles and methods prior to an actual incident.

SUMMARY

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This handbook provides an overview of law enforcement and public health roles and responsibilities and identifies the Joint Criminal-Epidemiological Investigations Model as a best practice to more effectively prepare for and respond to a biological threat. By implementing elements (*e.g.*, increasing information sharing, conducting joint threat assessments and conducting joint investigations/joint interviews) of the Joint Criminal-Epidemiological Investigations Model, law enforcement and public health can maximize their resources and achieve their individual and common goals during the response to a biological threat.

The procedures and methodologies described in the handbook are intended to serve as a guide. Law enforcement and public health should modify this guidance to accommodate the specific needs, statutes and authorities of their agency, jurisdiction, or country.

Key Highlights of Introduction Section

- There has been a demonstrated interest and willingness by terrorist groups and individuals to acquire and employ biological agents at weapons against the American population.
- The intentional release of a biological agent may initially be difficult to discern from a natural incident, which can result in separate law enforcement and public health investigations.
- It is in public health and law enforcement's best interest to work together when first investigating a suspicious biological outbreak, which includes fostering mutual awareness and establishing joint communication procedures.
- By working together, public health and law enforcement can achieve their separate but often overlapping objectives of identifying the biological agent, preventing the spread of the disease, preventing public panic, and apprehending those responsible.
- Law enforcement and public health are encouraged to read the entire handbook and not limit their review to just their respective sections, so each community can understand the different goals and needs of the other organization.

Key Highlights of Public Health Section

- The ultimate aim of an epidemiological investigation is to identify the source of the disease and implement efforts to control the outbreak and protect the public's health.
- An epidemiological investigation primarily involves the meticulous accumulation of information from patient interviews and surveys as well as data collected from surveillance systems.
- Goals of an epidemiological investigation include:
 - » Stopping the spread of disease (identify causative agent, determine source, mode of transmission and population at risk)
 - » Protecting the public's health (surveillance, medical countermeasures, health education)
 - » Protecting public health and other response personnel (protective equipment and preventive vaccines/medications)

- Important elements of an epidemiological investigation are:
 - » Detect unusual events
 - » Confirm diagnosis
 - » Identify and characterize additional cases
 - » Determine source of exposure
 - » Develop and implement interventions
- Laboratory analysis of clinical specimens is used to assist the physician in making a definitive diagnosis. While most physicians will wait for definitive laboratory results to confirm a biological threat agent diagnosis, physicians are likely to begin treatment before laboratory test results are confirmed since early treatment of disease increases the probability the patient will recover from the illness.
- A laboratory that tests for biological agents should meet applicable standards (*e.g.*, quality control measures, biosafety, and biosecurity) and participate in relevant proficiency testing.

Key Highlights of Law Enforcement Section

- Primary goals of a criminal investigation for a biological threat are:
 - » To protect the health and safety of the public
 - » To prevent subsequent attacks
 - » To identify, apprehend, and prosecute the perpetrators
 - » To protect law enforcement personnel
- If public health and law enforcement have established a working relationship prior to a biological threat incident, public health may feel more comfortable contacting law enforcement early in their investigation.
- Law enforcement should include various subject matter experts, such as public health, to assist in determining the credibility of a biological threat.

- Once there is suspicion that a crime has occurred, chain of custody procedures should be implemented by both law enforcement and public health to ensure accountability of evidence. Failure to properly maintain the chain of custody may render evidence unusable at trial.
- In certain situations the environment might be contaminated; therefore, it is useful to have specially trained law enforcement teams to handle apprehension of the suspect and collection of evidence in contaminated environments.
- The need for rapid collection and testing to save lives outweighs normal evidence collection procedures.

Key Highlights of Joint Criminal and Epidemiological Investigations Model Section

- The Joint Criminal-Epidemiological Investigations Model is made up of six strategic elements.
 - » Building Relationships
 - » Information Sharing
 - » Joint Threat Assessment
 - » Joint Investigation
 - » Memorandum of Understanding/Joint Protocols
 - » Joint Training/Exercises
- Benefits to conducting joint investigations:
 - » Law enforcement has access to public health experts who understand disease epidemiology and can provide relevant medical information.
 - » Public health has access to law enforcement case information which could assist in identifying the source of exposure and containing an outbreak.
- The timely exchange of information in the early stages of a response is critical. Both disciplines have access to unique information that could help to prevent or detect a biological threat.

- A joint threat assessment, which utilizes the unique expertise of both disciplines, can help determine more quickly the nature of the incident (intentional or natural) and lead to a more appropriate response to the threat.
- A joint investigation can maximize the efficiency for both law enforcement and public health in the event of a biological threat through the exchange of real-time investigative information.
- MOU/joint protocols between law enforcement and public health are critical in determining roles and responsibilities prior to an event occurring and help ensure consistent practices between the disciplines during a response. Important information to include in MOU/joint protocols include: information sharing triggers, joint threat assessments, joint investigations, joint interviews, and methods for sharing investigative results.
- Joint training and exercises are important elements of the Joint Criminal-Epidemiological Investigations Model since they allow public health and law enforcement to test, evaluate and refine their protocols. Amending protocols to reflect lessons learned from an exercise is particularly important to ensure best practices evolve and are strengthened over time.

APPENDICES



Appendices to Joint Criminal-Epidemiological Investigations Handbook

Sample Joint Criminal-Epidemiological Investigations Material

Appendix 1: Sample Procedure for a Joint Threat Assessment

Appendix 2: Sample Procedure for Joint Interviews

Appendix 3: Sample Joint Interview Questions

Reference Material

Appendix 4: List of Biological Select Agent and Toxins (2014)

Appendix 5: Laboratory Response Network (LRN)

Appendix 6: CSTE List of Nationally Notifiable Conditions (2013)

Appendix 7: HIPAA Privacy Rule & Permitted Disclosures

Appendix 8: Overview of the FBI's WMD Coordinators

Appendix 9: Bio-Related Laws to Prevent Bioterrorism

Appendix 10: Common Public Health and Law Enforcement Terminology

Appendix 1: Sample Procedure for a Joint Threat Assessment

To assist in the response to a biological threat at the local level, it is recommended that law enforcement and public health develop protocols to conduct a joint threat assessment between agencies and jurisdictions. The following procedure is intended to serve as a guide for conducting a joint threat assessment; law enforcement and public health may wish to adapt the procedures below to better suit the needs of their agencies.

Upon receiving a report indicating a potential biological threat, public health should immediately notify the local FBI WMD Coordinator to conduct a joint threat assessment. The purpose of the joint threat assessment is to determine the likelihood of an intentional incident and identify response actions that should be performed by law enforcement and public health.

It is recommended that the joint threat assessment be conducted by a conference call and, at a minimum, include the following representatives:

- Local FBI WMD Coordinator
- Local law enforcement representative (trained in WMD response)
- WMD representative from the jurisdiction's fusion center
- State Epidemiologist
- LRN Laboratory Director or Bioterrorism Coordinator
- Health Communications/Media
- Public Health Emergency Preparedness Director

The agenda of the conference call may include:

- Incident briefing by public health
 - » Explanation of concern by public health
 - » Update on confirmed or suspected cases

- ◊ Demographic information: gender, age, race, ethnicity, occupation, membership in any groups or associations.
- ◊ Description of where patient lives (e.g., urban, rural)
- ◊ Patient’s recent travel history (e.g., domestic or international)
- ◊ Recent activities that may be related to exposure and illness
- » Current laboratory test results
- » Hypotheses regarding source of exposure
- » Syndromic surveillance: any unusual patterns of disease presentation or geographical clustering of disease
- FBI/law enforcement information/intelligence
 - » Information on existing threats in the jurisdiction (WMD or otherwise)
 - » WMD intelligence that may be connected to case’s exposure (e.g., religious affiliation, group, association)
 - » Intelligence regarding acquisition or intended use of any biological threat agent, which may be related to the case’s symptoms

The joint threat assessment members will then assess the possibility that the incident may be intentional. If information needed to conduct an initial assessment is unavailable, judgment may be temporarily suspended until such information is obtained. If there is enough information to make a determination, the incident may be classified into one of three threat categories (Table 6), with corresponding FBI/law enforcement and public health actions. While the incident may be initially assessed at one of the threat levels below it may be changed as the investigation begins and new information is collected.

Table 6. Threat Assessment Categories and Corresponding FBI/Law Enforcement and Public Health Actions

| Threat Classification | Evidence Leading to Classification | Public Health Actions | FBI/Law Enforcement Actions |
|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| No Biological Threat: <i>Highly likely that source of exposure occurred naturally</i> | No evidence to suggest intentional release | Continue to manage the incident | No further action needed |
| Possible Biological Threat: <i>Possibility that exposure may be intentional</i> | Public health investigation has not revealed a likely exposure Unusual/unexplainable circumstances exist regarding patient’s infection with the biological agent (e.g., agent is not common or endemic to area) The event itself, while appearing to be non-credible, may draw media or law enforcement attention, which implies an intentional act | Conduct an epidemiological investigation to determine source of exposure; where applicable, share public health information with law enforcement partners | Query intelligence databases for relevant information/ intelligence; where applicable, share law enforcement information with public health partners |
| Likely Biological Threat: <i>Reasonable belief that exposure was intentional</i> | Lab results are positive for a biological agent No known natural source to explain infection No known risk factors for disease occurrence Intelligence and/or law enforcement suggest event is criminal/ intentional | Initiate a joint investigation | Initiate a joint investigation FBI opens case to investigate criminal intent and/or suspicious circumstances FBI Joint Operations Center is established, if required |

Appendix 2: Sample Procedure for Joint Interviews

An initial component of the joint investigation will focus on interviews with patients, relatives and potential contacts to determine the source of exposure to the biological threat agent. Therefore, it is likely that joint interviews will occur as a part of the initial response activities. A joint interview might include the following actions:

- Initial meeting between law enforcement and public health (prior to interview)
- Determination of staging area to review the interview strategy
- Introduction to the hospital administrator and interview of physician
- Joint public health/law enforcement interview of patient
- Post-interview review

The following sample joint interview procedures are intended to serve as a guide and may not be applicable in all circumstances. Law enforcement and public health may wish to adapt the procedures below to better suit the needs of their agencies.

Initial Meeting

Prior to conducting an interview, it is recommended that law enforcement and public health meet in-person to discuss the current investigative information and review procedures for the joint interview. If an in-person meeting is not feasible due to time constraints, a conference call between joint interview participants is an alternative. If multiple joint interviews are going to be conducted at one location, it is recommended that a Joint Interview Team Lead be assigned to coordinate interview teams and arrange follow-up meetings or conference calls.

An agenda for the initial meeting/conference call might include the following elements:

- Public health will:
 - » Provide an overview of the epidemiological investigation
 - » Provide a short briefing regarding the disease agent (i.e., incubation period; mode of transmission; cases per year in jurisdiction/country)
 - » Recommend the appropriate level of Personal Protection Equipment (PPE) and prophylaxis, if necessary
- FBI/law enforcement will review all current WMD threats, intelligence, and reporting, which may be relevant to the situation
- Joint Interview Team Leader will create FBI/law enforcement/public health interview teams and address any specific logistical requirements (e.g., translators)

Once the decision to conduct joint interviews has been made, agencies and jurisdictions should continue to re-evaluate the needs and the benefits gained by having both FBI/law enforcement and public health present during interviews.

Although a joint interview with FBI/law enforcement can provoke anxiety in the patient, one interview with both agencies present may be less disruptive to the patient than two or more separate interviews repeating similar information. Additionally, separate questioning by law enforcement and public health may lead to conflicting statements, which can jeopardize the outcome of the criminal investigation.

Staging Operations

Prior to arrival at the interview location (e.g., hospital, clinic or home), each joint interview team should meet at a staging area to review the interview strategy, determine how introductions to the subject of the interview will occur, and identify any other miscellaneous items that need to be considered. According to standard FBI/law enforcement procedures, background checks (i.e., criminal history) will be conducted on patients/contacts who are interviewed. Any relevant law enforcement data, including related intelligence or threat information, will be shared with public health at this staging area, prior to the interview. If appropriate, modifications to the interview questions should be made based upon information provided by law enforcement. Following the interview, FBI/law enforcement and public health should utilize the same or alternate staging area to discuss and review the interview notes.

Introduction to Hospital Administrator and Interview of Attending Physician (or Infection Control Practitioner)

If the interview is being conducted in a hospital or other medical facility, the interview team will likely need to brief the hospital or facility administration on the biological threat incident and provide them with an update on the activities that will be performed at the location. Public health should initiate contact with the administration since they may have a prior working relationship. The interview team will explain that public health and law enforcement personnel will be interviewing a patient(s) at their facility. Whenever possible, the interview will be conducted in a manner that minimizes disruption to normal hospital operations and patient care. It should be determined if the patient is in a private room, and if not, a request should be made to move the patient to a private area, if feasible, where the interview can be conducted.

Upon arrival at the hospital or medical facility, public health will ask to speak first with the patient's attending physician. Public health will explain

the purpose of the patient interview and the reason for the presence of law enforcement. The following information should be collected from the attending physician:

- Reason for patient admission to the hospital
- Physician initial contact and involvement with the case (i.e., How did the physician become involved?)
- Overview of patient medical history
- Opinion as to the level of cooperation that can be expected by the patient and any suggestions that may facilitate the interview process
- Consent to make introductions between patient and interviewers (Note: the physician would not normally be present during the interview)

Interview

During the interview of a patient in a hospital or other medical facility, the joint interview team should make every effort to be sensitive to the patient's concerns and needs. During the interview, the patient's medical needs take priority over conducting the interview. There may be numerous interruptions by medical staff to attend to the needs of the patient. During this time any discussion of sensitive information should be temporarily discontinued. Prior to entering the patient's room, the interview team should apply the appropriate level of personal protective equipment (PPE), as instructed by medical personnel or public health. Generally, the first part of the interview is conducted by public health and the second part by FBI/law enforcement.

If not already introduced by the attending physician, public health will introduce herself/himself, identify the law enforcement investigator, and explain the purpose of the joint interview and the reason for FBI/law enforcement's

presence, which is to determine if the patient may have been a victim of a crime. An example of what public health may say to the patient is as follows:

- “Due to the nature of your illness, we need to ensure that you have not been a victim of a crime. In order to do that, we will be asking standard questions to determine the nature of your exposure. Since much of this information is relevant to ensuring you have not been a victim of a crime, our standard procedure for [disease/agent] is to ask law enforcement to be present during this interview,” or
- “Our public health protocol for cases of [disease/agent] is to involve law enforcement in order to rule out the possibility that a crime has occurred.”

In some situations the patient may feel vulnerable due to their condition, and the presence of law enforcement, while not in uniform, can create additional anxiety. Therefore, the interview team should try to minimize the patient’s stress during the interview. For example, the interviewers could sit in chairs during the interview, rather than standing over the patient, to minimize the patient’s stress/anxiety. In other instances, the patient may refuse to have law enforcement present during the interview (*e.g.*, he/she may be worried about crimes that he/she may have committed or immigration status in the country). If the patient states he/she is unwilling to answer any questions with law enforcement present, but will answer questions from public health, FBI/law enforcement should leave the room so that public health can continue with the standard public health interview. If this occurs, public health needs to be mindful of the types of information that may be relevant to FBI/law enforcement. Once the interview is complete, FBI/law enforcement will meet with public health at a pre-designated area to discuss the interview results.

Initially, public health may collect information through use of a standardized survey instrument or questionnaire. This information will be used for a statistical analysis that will assist public health in determining the source of

exposure and implementing interventions which will prevent additional people from becoming ill. Following the public health portion of the interview, FBI/law enforcement may ask a series of law enforcement focused questions. Since a possibility exists that one of the individuals interviewed may be the subject (or related to the subject) responsible for the biological threat incident, public health should be aware that FBI/law enforcement may try several techniques to determine the credibility of the patient during their portion of the interview. FBI/Law enforcement may ask questions which seem repetitive or awkward to public health. It is recommended that public health allow FBI/law enforcement to proceed without interruption, unless there is an urgent need to meet outside the room to discuss the interview strategy.

It is recommended that FBI/law enforcement not pursue prosecutorial efforts related to minor or petty crimes that the patient discloses during the interview since they may be unrelated to the biological threat investigation. Additionally, pursuing these minor or petty crimes may compromise the epidemiological investigation, which can delay or prevent the identification of the exposure. While FBI/law enforcement should prioritize investigative efforts related to the biological threat, they may have a need to seek prosecution of those minor crimes at a later date. This issue should be openly discussed with public health. As a general rule, the patient will not be physically examined in the presence of FBI/law enforcement, unless circumstances dictate that FBI/law enforcement be present in the room. Additionally, if the patient is a minor, the parents must be present during the FBI/law enforcement portion of the interview. If appropriate, the joint interview team may leave their personal business cards with the individual. FBI/law enforcement should advise the patient that if it is determined the patient has been a victim of a crime the FBI Victim Assistance Coordinator will contact him/her.

Post-Interview Review

Once the interview is complete, FBI/law enforcement and public health should meet to discuss their interview notes and ensure there are no discrepancies. If FBI/law enforcement requires copies of patient medical information, public health will provide this information to FBI/law enforcement once they have checked to determine applicability under relevant privacy statutes. It is also recommended that public health remove any sensitive patient medical information that is not pertinent to the criminal investigation. Further questioning of the individual should be coordinated between the agencies and jurisdictions to ensure that law enforcement and public health both have an opportunity to participate.

Information Sharing Considerations Following the Interview

- Information provided to FBI/law enforcement from public health is considered “Public Health Sensitive” and should be marked as such; prior to releasing such information to other agencies, public health must authorize such a release.
- Information provided to public health from FBI/law enforcement is considered “Law Enforcement Sensitive” and should be marked as such; this information should not be disseminated unless law enforcement approves the release.
- Information such as immigration status is particularly sensitive information and release of such information could jeopardize patient’s willingness to cooperate with public health.
- Information that indicates a patient has a history of violent crime must be passed immediately back to public health due to safety considerations.

- If the criminal database check reveals a non-terrorism criminal history (e.g., warrant for arrest; location of fugitive in local, state or federal warrant), law enforcement may need to pursue its own separate investigation, but only after first consulting with public health to minimize any impact on the epidemiological investigation.
- Information obtained or developed by FBI/law enforcement may be sensitive in nature or classified, but may relate to the epidemiological investigation. Should this situation arise, this information will be provided to public health by law enforcement through an authorized procedure.

Appendix 3: Sample Joint Interview Questions

Personal Information

1. Patient's name*
2. Patient's date of birth*
3. Sex*
4. Patient's address*
5. Patient's occupation or employment (describe job and where patient works or goes to school)*
6. Patient's race/ethnicity/nationality*
7. Patient's level of education
8. Personal information above may also be needed for family members*

* Refers to information that public health may normally collect using a standard questionnaire.

Travel information

1. Has the patient traveled outside of the country (during the incubation period)? If yes, where?
2. Has the patient traveled away from home (during the incubation period)? If yes, where?
3. What is the patient's normal mode of transportation and route to/from work (during incubation period)?
4. Has the patient been to new or unique locations (e.g., a park, farm, wilderness area or body of water)?

Patient's address (or location where exposure may have taken place)

1. In what type of community does the patient live (rural vs. urban, heavy crime area)?
2. If the patient rents his/home, what is his/her landlord's name?

3. Who has access (keys) to the patient's residence (e.g., roommates, parents, and landlord)?

Incident Information

1. Has the patient received or heard any threats or unusual statements? Does the patient know if he/she is the subject of a threat (future or past)? Does the patient know anyone who has been the recipient of a threat? Has the patient's employer been the subject of a threat?
2. Did the patient see an unusual device or anyone spraying something or anything else (envelope with unknown substance) that could disperse a biological threat agent?
3. If patient attended a large event in the last 30 days, was there anything suspicious that occurred during the event? Any threats received at the event (or prior)?
4. Did the patient visit a laboratory or come in contact with any laboratory equipment? Does the patient know of anyone who works in a laboratory with biological or chemical agents?
5. Does the patient know why he/she feels they may have gotten sick?
6. Does the patient know anyone else who is sick? For example, someone with a fever and cough or unusual looking sores or rashes?
7. Has the patient seen or touched any dead animals? Does the patient have pets that may be sick?
8. Does the patient have any affiliations with high profile people (e.g., actors, politicians)?
9. Has the patient received anything unusual from a foreign country?
10. Has the patient consumed anything unusual?
11. Has the patient reported being bitten by insects or arthropods?

Appendix 4: List of Select Agents and Toxins (2014)

A *select agent* is a biological agent or toxin that has been determined by the United States to have potential to pose a severe threat to public, animal, or plant health. The United States implements the Federal Select Agent Program, which restricts the possession, use, and transfer of such agents to all entities within the United States, regardless if they are public or private entities.

The Federal Select Agent Program is jointly comprised of the Centers for Disease Control and Prevention/Division of Select Agents and Toxins and the Animal and Plant Health Inspection Services/ Agriculture Select Agent Services. The Federal Select Agent Program oversees the possession, use and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal or plant health or to animal or plant products. Additional information on the Federal Select Agent Program can be found at: www.selectagents.gov

Of the current 65 select agents and toxins, 13 agents were designated as Tier 1. Tier 1 select agents are determined to have the greatest ability to produce a mass casualty event or devastating effects to the economy, high communicability, low infectious dose, and a history of weaponization. The Tier 1 designation allows for targeted enhancement of security measures to Tier 1 laboratories, while avoiding burdening other facilities that do not possess, use, or transfer Tier 1 select agents. **Tier 1 agents are in red bold font and marked with an asterisk (*).**

⁶ Short, paralytic alpha conotoxins containing the following amino acid sequence
X₁CCX₂PACGX₃X₄X₅X₆CX₇

⁷ Reconstructed replication competent forms of 1918 pandemic influenza virus containing any portion of coding regions of all eight gene segments

HHS-Regulated Select Agents

- Abrin
- **Botulinum neurotoxins ***
- **Botulinum neurotoxin producing species of *Clostridium* ***
- Conotoxins⁶
- Coxiella burnetii
- Crimean-Congo haemorrhagic fever virus
- Diacetoxyscirpenol
- Eastern Equine Encephalitis virus
- **Ebola virus ***
- **Francisella tularensis ***
- Lassa fever virus
- Lujo virus
- **Marburg virus ***
- Monkeypox virus
- Reconstructed 1918 Influenza virus⁷
- Ricin
- *Rickettsia prowazekii*
- SARS-associated coronavirus
- Saxitoxin
- South American Hemorrhagic Fever viruses:
 - Chapare
 - Guanarito
 - Junin
 - Machupo
 - Sabia
- Staphylococcal enterotoxins A,B,C,D,E subtypes
- T-2 toxin
- Tetrodotoxin
- Tick-borne encephalitis complex (flavi) viruses:
 - Far Eastern subtype
 - Siberian subtype
 - Kyasanur Forest disease virus
 - Omsk hemorrhagic fever virus
 - **Variola major virus (Smallpox virus) ***
 - **Variola minor virus (Alastrim) ***
 - **Yersinia pestis ***

Joint HHS and USDA-Regulated Select Agents

- **Bacillus anthracis ***
- *Bacillus anthracis*
- Pasteur strain
- *Brucella abortus*
- *Brucella melitensis*
- *Brucella suis*
- **Burkholderia mallei ***
- **Burkholderia pseudomallei ***
- Hendra virus
- Nipah virus
- Rift Valley fever virus
- Venezuelan equine encephalitis virus

USDA-Regulated Select Agents

Animals

- African horse sickness virus
- African swine fever virus
- Avian influenza virus
- Classical swine fever virus
- **Foot-and-mouth disease virus ***
- Goat pox virus
- Lumpy skin disease virus
- *Mycoplasma capricolum*
- *Mycoplasma mycoides*
- Newcastle disease virus
- Peste des petits ruminants virus
- **Rinderpest virus ***
- Sheep pox virus
- Swine vesicular disease virus

Plants

- *Peronosclerospora philippinensis*
- *Phoma glycinicola*
- *Ralstonia solanacearum*
- *Rathayibacter toxicus*
- *Sclerophthora rayssiae*
- *Synchytrium endobioticum*
- *Xanthomonas oryzae*

Note: This list is revised every two years. To find the current Select Agents and Toxins list, please visit:

<http://www.selectagents.gov/SelectAgentsandToxinsList.html>

Appendix 5: Laboratory Response Network

History

The Laboratory Response Network (LRN) became operational in 1999, initially as a counter-terrorism asset used in rapid detection of bio threat agents. Since 1999, the LRN has evolved to include preparedness and response activities for emerging infectious diseases, such as SARS and avian influenza, as well as other public health emergencies.



Mission

The LRN is a national security asset that, with its partners, will develop, maintain and strengthen an integrated domestic and international network of laboratories to respond quickly to biological, chemical and radiological threats and other high priority public health emergencies through training, rapid testing, timely notification and secure electronic messaging of laboratory results.

Note: The LRN's chemical threat testing capabilities are not covered here since this section is dedicated to biological threat testing capabilities.

Membership and Function—Biological

The LRN is a national network of approximately 141 laboratories. Participation in the LRN is voluntary and all member laboratories work under a single operational plan and adhere to strict policies of safety and security. Because an event can occur in a variety of locations and populations, the LRN has created a diverse network of laboratories that can detect top tier bio threat agents and

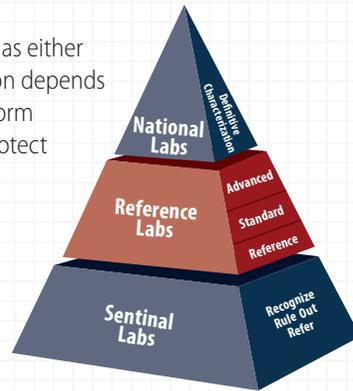
emerging infections in human and animal clinical specimens, environmental samples (e.g., powders, soil, water), and food. The network includes the following types of labs:

- State and local public health
- U.S. Military
- Food Testing
- Environmental
- Veterinary
- International: Canada, United Kingdom, Australia, Mexico, Republic of Korea, and select U.S. military bases abroad

The LRN Structure for Bioterrorism

LRN biological laboratories are designated as either National, Reference, or Sentinel. Designation depends on the types of tests a laboratory can perform and how it handles infectious agents to protect workers and the public.

- **National Laboratories** have unique resources to handle highly infectious agents and the ability to identify specific and complex agent strains.
- **Reference Laboratories** can rapidly perform tests to detect and confirm the presence of a threat agent or emerging infectious disease. Since testing occurs at the local level, this allows for a more rapid public health response. Reference Laboratories are broken into 3 levels from Reference to Standard to Advanced, based on complexity and number of tests performed.
- **Sentinel Laboratories** represent the thousands of hospital-based facilities that are on the front lines. Sentinel laboratories have direct



contact with patients. In an unannounced or covert terrorist attack Sentinel laboratories could be the first to identify a suspicious sample. A sentinel laboratory's responsibility is to refer samples to an LRN Reference Laboratory if they are unable to rule out suspicion of a bioterror agent while performing routine diagnostic tests.

Partnerships

The LRN has multiple partnerships with other government agencies and private organizations that have a stake in bioterrorism and chemical preparedness that include but is not limited to the following:

- Federal Bureau of Investigation (Founding Partner)
- Association of Public Health Laboratories (Founding Partner)
- Army Medical Research Institute (Founding Partner)
- American Association of Veterinary Laboratory Diagnosticians
- American Society for Microbiology
- U.S. Environmental Protection Agency
- U.S. Department of Agriculture
- U.S. Department of Defense
- U.S. Food and Drug Administration
- U.S. Department of Homeland Security

Appendix 6: CSTE List of Nationally Notifiable Conditions (2013)

This list indicates the nationally notifiable conditions for which health departments provide information to CDC. It specifies the manner and time frame in which the health department notifies CDC. Local requirements for reporting to public health by healthcare providers, laboratorians and others generally include these conditions but may require reporting of additional diseases, syndromes or findings and may specify different time frames. For information on local reporting requirements, contact the city, county or state health department.

Note: This list is revised every two years. To find the current CSTE list of notifiable conditions, please visit: <http://cymcdn.com/sites/www.cste.org/resource/resmgr/CSTENotifiableConditionListA.pdf>

IMMEDIATE, EXTREMELY URGENT—Notification within 4 hours
Call CDC EOC at 770-488-7100 within 4 hours; follow-up with electronic transmission of report by the next business day

| CONDITION | CASES REQUIRING NOTIFICATION |
|----------------------------------------------------------------------|-----------------------------------|
| Anthrax | |
| Source of infection not recognized | Confirmed and probable cases |
| Recognized BT exposure/potential mass exposure | Confirmed and probable cases |
| Serious illness of naturally-occurring anthrax | Confirmed and probable cases |
| Botulism | |
| Foodborne (except endemic to Alaska) | All cases prior to classification |
| Intentional or suspected intentional release | All cases prior to classification |
| Infant botulism (clusters or outbreaks) | All cases prior to classification |
| Cases of unknown etiology/not meeting standard notification criteria | All cases prior to classification |
| Plague | |
| Suspected intentional release | All cases prior to classification |
| Paralytic poliomyelitis | |
| | Confirmed cases |
| SARS - associated coronavirus | |
| | All cases prior to classification |
| Smallpox | |
| | Confirmed and probable cases |
| Tularemia | |
| Suspected intentional release | All cases prior to classification |
| Viral Hemorrhagic Fevers | |
| Suspected intentional | Confirmed and suspected cases |

⁸ Notifiable viral hemorrhagic fevers include those caused by Ebola or Marburg viruses, Lassa virus, Lujo virus, or new world Arenaviruses (Guanarito, Machupo, Junin, Sabia), and Crimean-Congo hemorrhagic fever

IMMEDIATE, URGENT—Notification within 4 hours

Call CDC EOC at 770-488-7100 within 24 hours; follow-up with report in next regularly scheduled electronic transmission

| CONDITION | CASES REQUIRING NOTIFICATION |
|-----------------------------------------------------------------|-----------------------------------|
| Anthrax | |
| Naturally-occurring or occupational, responding to treatment | Confirmed and probable cases |
| Brucellosis | |
| Multiple cases, temporally/spatially clustered | Confirmed and probable cases |
| Diphtheria | All cases prior to classification |
| Novel influenza A virus infection, initial detections of | Confirmed cases |
| Poliovirus infection, nonparalytic | Confirmed cases |
| Rabies in a human | Confirmed cases |
| Rabies in an animal | |
| Imported from outside continental US within past 60 days | Confirmed cases |
| Rubella | Confirmed cases |
| Viral hemorrhagic fevers* | |
| All cases other than suspected intentional | Confirmed and suspected cases |
| Yellow Fever | Confirmed and probable cases |

* Notifiable viral hemorrhagic fevers include those caused by Ebola or Marburg viruses, Lassa virus, Lujo virus, or new world Arenaviruses (Guanarito, Machupo, Junin, Sabia), and Crimean-Congo hemorrhagic fever

STANDARD—Notification by electronic transmission

Submit within the next normal reporting cycle (i.e., within 7 days for NNDSS conditions)

| CONDITION | CASES REQUIRING NOTIFICATION |
|-------------------------------------------------------|---------------------------------------|
| Anaplasmosis | Confirmed and probable cases |
| Arboviral disease | |
| Calif. serogroup, EEE, Powassan, SLE, WNV, WEE | Confirmed and probable cases |
| Babesiosis | Confirmed and probable cases |
| Botulism | |
| Infant, sporadic cases | All cases prior to classification |
| Wound, sporadic cases | All cases prior to classification |
| Brucellosis | |
| Cases not temporally/spatially clustered | Confirmed and probable cases |
| Cancer | Confirmed cases ⁹ |
| Carbon monoxide poisoning | Confirmed and probable cases |
| Chancroid | Confirmed and probable cases |
| Chlamydia trachomatis infection | Confirmed cases |
| Coccidioidomycosis | Confirmed cases |
| Cryptosporidiosis | Confirmed and probable cases |
| Cyclosporiasis | Confirmed and probable cases |
| Dengue virus infections | Confirmed, probable and suspect cases |
| Ehrlichiosis | Confirmed and probable cases |
| Escherichia coli, Shiga toxin-producing (STEC) | Confirmed and probable cases |
| Foodborne disease outbreaks | Confirmed outbreaks [‡] |

⁹ Notification for all confirmed cases of cancer should be made at least annually

STANDARD—Notification by electronic transmission

Submit within the next normal reporting cycle (i.e., within 7 days for NNDSS conditions)

| CONDITION | CASES REQUIRING NOTIFICATION |
|-------------------------------------------|---------------------------------------------------------------------------------------|
| Giardiasis | Confirmed and probable cases |
| Gonorrhea | Confirmed and probable cases |
| Haemophilus influenzae, invasive disease | All cases prior to classification |
| Hansen's disease | Confirmed cases |
| Hantavirus pulmonary syndrome | Confirmed cases |
| Hemolytic uremic syndrome, post-diarrheal | Confirmed and probable cases |
| Hepatitis A, acute | Confirmed cases |
| Hepatitis B, acute | Confirmed cases |
| Hepatitis B, chronic | Confirmed and probable cases |
| Hepatitis B, perinatal infection | Confirmed cases |
| Hepatitis C, acute | Confirmed cases |
| Hepatitis C infection, past or present | Confirmed and probable cases |
| HIV Infection | Confirmed cases of HIV infection; perinatally exposed infants prior to classification |
| Influenza-associated mortality, pediatric | Confirmed cases |
| Lead, exposure screening test result | All test results ¹⁰ |
| Legionellosis | Confirmed and suspected cases |
| Leptospirosis | Confirmed and probable cases |
| Listeriosis | Confirmed cases |

¹⁰ Notification for lead exposure screening results should be submitted quarterly for children and twice a year for adults

STANDARD—Notification by electronic transmission

Submit within the next normal reporting cycle (i.e., within 7 days for NNDSS conditions)

| CONDITION | CASES REQUIRING NOTIFICATION |
|---------------------------------------------------|--------------------------------------------------------------------------------|
| Lyme disease | Confirmed, probable and suspect cases |
| Malaria | Confirmed and suspected cases |
| Meningococcal disease (Neisseria meningitidis) | Confirmed and probable cases |
| Mumps | Confirmed and probable cases |
| Pertussis | All cases prior to classification |
| Pesticide-related illness, acute | Definite, probable, possible and suspicious cases |
| Plague | All cases not suspected to be intentional All cases prior to classification |
| Psittacosis | Confirmed and probable cases |
| Q Fever | Confirmed and probable cases |
| Rabies in an animal | Animal not imported within past 60 days |
| Rickettsiosis, Spotted Fever | Confirmed cases |
| Rubella, congenital syndrome | Confirmed and probable cases |
| Salmonellosis | Confirmed cases |
| Shigellosis | Confirmed and probable cases |
| Silicosis | Confirmed and probable cases |
| Staphylococcus aureus infection | |
| Vancomycin-intermediate (VISA) | Confirmed cases |
| Vancomycin-resistant (VRSA) | Confirmed cases |
| Streptococcus pneumoniae , invasive disease (IPD) | Confirmed cases |

STANDARD—Notification by electronic transmission

Submit within the next normal reporting cycle (i.e., within 7 days for NNDSS conditions)

| CONDITION | CASES REQUIRING NOTIFICATION |
|----------------------------------------------------|-----------------------------------|
| Streptococcal toxic shock syndrome (STSS) | Confirmed and probable cases |
| Syphilis | Confirmed and probable cases |
| Tetanus | All cases prior to classification |
| Toxic shock syndrome (non-Strep) | Confirmed and probable cases |
| Trichinellosis (Trichinosis) | All cases prior to classification |
| Tuberculosis | Confirmed cases |
| Tularemia | |
| All cases other than suspected intentional release | Confirmed and probable cases |
| Typhoid Fever | Confirmed and probable cases |
| Varicella | Confirmed and probable cases |
| Vibrio cholerae infection (Cholera) | Confirmed cases |
| Vibriosis | Confirmed and probable cases |
| Waterborne disease outbreaks | All outbreaks ¹¹ |

¹¹ Outbreaks are defined by state and local health departments, all situations deemed by a local or state health department to be an outbreak are notifiable

Appendix 7: HIPAA Privacy Rule & Permitted Disclosures

The U.S. Department of Health and Human Services issued the *Standards for Privacy of Individually Identifiable Health Information* (“Privacy Rule”) to implement the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996. The Privacy Rule set standards that address the use and disclosure of protected health information.

The goal of the Privacy Rule is to assure that an individual’s health information is properly protected, but also allows disclosure to enable high quality health care and to protect the public’s health and well-being. As such, the Privacy Rule permits the use and disclosure of protected health information, without an individual’s authorization of permission, for national priority purposes. Use and disclosure of information to law enforcement is one of the identified national priority purposes.¹²

Imminent Threat Exception

During a suspicious biological incident, a likely exemption that law enforcement may use to request patient information from a healthcare entity is the “imminent threat exemption.” According to this exemption: “A covered entity may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the covered entity, in good faith, believes the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public and the disclosure is made to a person reasonably able to prevent or lessen the threat.” (See 45 CFR 164.512 (j)(1)(i))

¹² <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf>

Below are the circumstances, identified by the Privacy Rule, that permit covered entities to disclose patient medical information to law enforcement (45 C.F.R. 164.512).

- 1. REQUIRED BY LAW**—mandatory reporting laws (164.512(f)(1)(i))
- 2. COURT ORDER**, or warrant, subpoena or summons issued by a judicial officer (164.512(f)(1)(ii)(A))
- 3. GRAND JURY SUBPOENA** (164.512(f)(1)(ii)(B))
- 4. ADMINISTRATIVE SUBPOENA** if it complies with all 3 specific requirements (164.512(f)(1)(ii)(C)):
 - a. Information sought is relevant and material to a legitimate law enforcement inquiry. [i.e., Only ask for information that you need for a real investigation.] AND
 - b. The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought. [i.e., Do not ask for the kitchen sink.] AND
 - c. De-identified information could not reasonably be used. [i.e., If person's name, SSN was removed from record, would be useless to the investigation.]
- 5. LOCATE AND IDENTIFY** (Suspect, fugitive, material witness or missing person): You can only request and obtain 8 types of information: name/address; date/place of birth; SSN; blood type/Rh factor; type of injury; date/time of treatment; date/time of death; observable physical characteristics such as eye and hair color, tattoos, gender, race, height, weight, facial hair. (164.512(f)(2))
- 6. CRIME ON PREMISES** (164.512(f)(5))
- 7. INFORMATION ABOUT VICTIM OF A CRIME** when information will *not* be used against the victim; law enforcement activity will be adversely and

materially affected by delay until the victim able to agree . . . AND giving law enforcement the information is in the best interest of the victim (victim is incapacitated or other emergency circumstances exist). (164.512(f)(3))

8. EMERGENCY HEALTH CARE WORKER CAN REPORT CRIMES/VICTIMS/ PERPETRATORS (164.512(f)(6))

9. VICTIM OF ABUSE, NEGLECT OR DOMESTIC VIOLENCE if:

- a. disclosure is required by law, or
- b. the individual has agreed to the disclosure or
- c. expressly authorized by law & disclosure is necessary to prevent serious harm, or
- d. authorized by law and the law enforcement agency represents that the information will not be used against the individual and law enforcement activity depends on the disclosure and would be materially and adversely affected by waiting until the individual is able to agree. (164.512(c))

10. DISCLOSURE TO CORONER OR MEDICAL EXAMINER (164.512(g))

11. TO AVERT SERIOUS THREAT TO HEALTH/SAFETY (164.512(j))

12. NATIONAL SECURITY AND INTELLIGENCE (164.512(k)(2))

13. PROTECTIVE SERVICES FOR THE PRESIDENT AND OTHERS (164.512(k)(3))

14. JAILS, PRISONS, LAW ENFORCEMENT CUSTODY (164.512(k)(5))

Protect the confidentiality of your investigation: In all cases, health oversight or otherwise, when it is necessary to stop a medical provider from telling patients that you have requested their medical information (164.528(a)(2)):

- 1) Make an oral request that the provider not disclose, and
- 2) Follow-up with a written request within 30 days on official letterhead

Substance abuse patient records: Stricter protections are afforded to the records of bona fide providers of substance abuse treatment. See 42 C.F.R. Part 2.

Health oversight: Disclosure permitted even when conducted by law enforcement agency (164.512 (d))

U.S. Department of Justice, Criminal Division (revised January 2013)

Appendix 8: Overview of the FBI's WMD Coordinators

What is a WMD Coordinator?

The FBI primarily relies on a designated Special Agent in each field office, referred to as the Weapons of Mass Destruction (WMD) Coordinator, to handle WMD-related events. Each field office is headed by a Special Agent in Charge (SAC) or Assistant Director in Charge, who is responsible for selecting Special Agents to be WMD Coordinators. In larger field offices, some WMD Coordinators may have Assistant WMD Coordinators.

Because WMD Coordinators serve as the field office's WMD subject matter expert, there are written qualifications for specific knowledge, skills, and abilities related to WMD areas of focus. The FBI implements a WMD Coordinator Certification Program to aid in the development of WMD expertise. The two-day Joint FBI/CDC Criminal-Epidemiological Investigations Workshop serves as an elective towards WMD Coordinator certification.

Why do WMD Coordinators exist?

In July 2006, the FBI consolidated its WMD investigation and prevention efforts into a WMD Directorate, located at FBI Headquarters. At the national level, the WMD Directorate develops WMD policy, guidance, and countermeasures efforts and provides headquarters oversight of field office investigations. At the local level, the FBI field offices implement these efforts. The WMD Coordinator works with their field office to obtain a strategic understanding of their unique geographical threats and vulnerabilities. This knowledge is then reported back to FBI Headquarters, which helps shape WMD Directorate policy, guidance, and countermeasures.

By having a WMD Coordinator at the local level, it allows the FBI to more effectively prevent, detect, and investigate WMD-related events since WMD Coordinators have a more detailed understanding of their area of responsibility. This detailed understanding is achieved by conducting core responsibilities of a WMD Coordinator, which include:

- Conduct outreach with federal, state, and local stakeholders (including industry, academia, and scientific communities)
 - » Develop partnerships with industry leaders
 - » Conduct biosecurity outreach to universities to promote safe and secure research
- Implement countermeasures, developed by FBI Headquarters (WMD Directorate), to detect and deter specific WMD threats and vulnerabilities
 - » Conduct assessments within area of responsibility to identify risks and vulnerabilities
 - » Promote biosecurity guidelines (ex. Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA)
- Investigate WMD crimes and acts of terrorism
 - » Identify individuals or groups expressing interest in acquiring WMD
 - » Coordinate with public health Laboratory Response Network
- Provide WMD training to both FBI and public community
 - » Conduct Joint Criminal-Epidemiological Investigation Training
 - » Conduct exercises with federal, state, local law enforcement and first responders

What benefits can a WMD Coordinator offer to public health?

Generally, law enforcement and public health may exchange information once they confirm the existence of a criminal act or an outbreak. However, waiting until a crime or outbreak has been confirmed is often too late and disadvantageous to both law enforcement and public health officials in determining cause or attribution of a biological event. For an effective response to biological threats, public health and law enforcement need to share information prior to the confirmation that an intentional incident has occurred. The timely exchange of information in the early stages of a response is critical to containing the outbreak and apprehending the perpetrators.

WMD Coordinators have a direct relationship with the WMD Directorate at FBI Headquarters, which can conduct robust analysis in a short amount of time. WMD Coordinators can provide public health officials timely information regarding whether an individual has a criminal history and/or suspicious ties to a national security threat. In addition, the FBI can quickly determine if an individual may be the victim of a crime, which might assist an epidemiologist during their investigation. Other areas where a WMD Coordinator may be able to assist public health during a joint investigation include:

- Law enforcement investigative information (*e.g.*, interviews scheduled and planned search warrants) that may assist public health with the identification of the agent and determination of the source of the outbreak
- Information regarding any known group or sector that may be targeted (*e.g.*, government or financial, entertainment, religious/ethnic groups) for an attack
- Other law enforcement cases which may have ties to the existing biological threat investigation

- Pre-incident indicators (*e.g.*, videotaping, sketching maps, break-ins, perimeter breaches at facilities) that may be related to the biological threat or incident
- Information developed by law enforcement regarding the biological agent used, mechanism for delivery/dissemination, date, time and locations of exposures
- Information regarding any medical equipment, chemicals, toxins, biological agents or laboratory supplies stolen, developed, or uncovered that may be related to the biological threat
- Intelligence information regarding the characteristics of the biological agent (*e.g.*, strain, antimicrobial resistance, or weaponized nature)

Appendix 9: Bio-Related Laws to Prevent Bioterrorism

The United States has implemented Federal laws criminalizing the deliberate misuse of biological material, as required under Article IV of the Biological Weapons Convention (BWC). The FBI and law enforcement community as a whole enforce these laws and hold U.S. citizens responsible for violations.

According to the U.S. Weapons of Mass Destruction (WMD) Statute, it is a crime to use (or conspire, threaten, or attempt to use) a WMD, which includes “any weapons involving a disease organism.” It is also a crime to teach or demonstrate the use of or making of WMD material. Note that actual use of a biological agent is not required in order to be charged with the crime, and that the biological agent does not have to be a select agent, only that that agent is capable of causing biological malfunction, disease, or death in a living organism. The United States has developed and enforces laws which criminalize the possession of *any* biological agent or toxin for use as a weapon or if not reasonably justified for peaceful purposes (*i.e.*, prophylactic or research purposes). In addition, it is a crime in the United States to possess a select agent, regardless of intent, if not registered with the Federal Select Agent Program (Appendix 4).

These laws, which can be found in the U.S. Federal Criminal Code, include:

| 18 USC 175 – (Bio-specific Laws) | |
|---------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| § 175(a) | <ul style="list-style-type: none"> • Crime to knowingly develop, produce, stockpile, transfer, acquire, retain, or possess any bio agent, toxin, or delivery system for use as weapon, or assists foreign state or organization to do so, or attempt, threaten or conspire to do so. • Note: “for use as a weapon” means to attempt to produce with intent to harm; actual use or attempted use does not have to occur to be charged with the crime |
| § 175(b) | <ul style="list-style-type: none"> • Crime to knowingly possess a biological agent, toxin, or delivery system if not reasonably justified by a prophylactic, protective, bona fide research or other peaceful purpose. Note: this applies to any biological agent, not just select agents. • Defines bio agent, toxin, and “for use as weapon” to protect justified research and bio industry. |
| § 175b | <ul style="list-style-type: none"> • Part a: No restricted person may transport or possess any select agent or toxin • Part b: Crime to transfer select agent to person who is not registered with Federal Select Agent Program • Part c: Crime to knowingly possess select agent, regardless of intent, if not registered with the Federal Select Agent Program • Part d: Defines “select agent” and “restricted person” |
| 18 USC 2332a – (Threatened Use of WMD) | |
| § 2332a | <ul style="list-style-type: none"> • Crime to conspire, threaten, attempt, or use a WMD against person or property of United States (including mail or commerce) • Term WMD includes “any weapon involving a disease organism” |
| 18 USC 842(p) – (Distribution of WMD Information) | |
| § 842(p) | <ul style="list-style-type: none"> • Crime to teach or demonstrate use of or making of explosive, destructive device, or WMD, or to distribute any information pertaining to the manufacture or use of an explosive, destructive device, or WMD, knowing that person intends to use such information for criminal activity. |
| 18 USC 1038 – (False Information and Hoaxes) | |
| § 1038 | <ul style="list-style-type: none"> • Crime to engage in conduct with intent to convey false or misleading information under circumstances where such information may reasonably be believed and concerning an activity that is a violation of a predicate offense. |

In the United States, a *select agent* is a biological agent or toxin that has been determined by the United States to have potential to pose a severe threat to public, animal, or plant health. The U.S. government manages a Federal Select Agent Program which restricts the possession, use, and transfer of such agents to all entities within the United States, regardless of whether they are public or private entities.

U.S. law requires that all entities possessing select agents must be registered, have security plans, and personnel with access to select agents receive an FBI Security Risk Assessment (SRA). The SRA is a series of database checks that aim to identify individuals who are legally restricted from accessing select agents based upon specific federal prohibitors (*e.g.*, a fugitive from justice) that are listed in the USA PATRIOT Act and the Bioterrorism Response Act.

Appendix 10: Common Public Health and Law Enforcement Terminology

Overlapping words used by both public health and law enforcement but have different meanings:

| Word | Description |
|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Agent | Public Health: A pathogen |
| | Law Enforcement: A law enforcement officer |
| Case | Public Health: An infected patient |
| | Law Enforcement: An investigation |
| Evidence | Public Health: Scientific data used to establish truth or falsehood |
| | Law Enforcement: Data presented to a court or jury to support a claim or belief; examples may include the testimony of witnesses, records, documents, or objects |
| Source | Public Health: The person, animal, or substance from which an infectious agent passed |
| | Law Enforcement: A person (usually confidential) that provides law enforcement with information |
| Surveillance | Public Health: Continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice |
| | Law Enforcement: Observations collected on a person, group, etc. |
| Suspect | Public Health: A person who may be a case (infected patient) |
| | Law Enforcement: A person under suspicion |

Common words used by **public health** officials:

| Word | Description |
|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Carrier | A person or animal that harbors an infectious agent for a disease that can transmit it to others, but does not demonstrate symptoms of the disease |
| Cluster | A group of disease cases or other health-related conditions, which are closely grouped in time and place. |
| Communicable | An illness caused by an infectious agent or its toxins that occurs through direct or indirect transmission from an infected individual, animal, vector or the environment to a susceptible host. |
| Contagious | Capable of being transmitted from one person to another by contact or close proximity. |
| Determinants of health | Factors which influence the health status of an individual and/or population. |
| Endemic | The constant presence of a disease or infectious agent within a given geographic area or population group. |
| Epidemic | The occurrence of more cases of disease than expected in a given area or among a specific group of people over a particular period of time. |
| Epidemiology | The study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to control of health problems. |
| Etiological agent | The infectious agent that causes an infection or disease |
| Exposure | Any factor that may be associated with the infection or disease |
| Immunity | Resistance developed in response to an antigen (infecting agent or vaccine), usually characterized by the presence of antibody produced by the host. |
| Incubation period | The time interval from exposure to an infectious agent to the onset of symptoms of an infectious disease. |
| Index case | The first case or instance of a patient coming to the attention of health authorities |
| Infectious | Capable of causing infection or disease by entrance of the infectious agent in to the body, which then grows and multiplies. |
| Infectivity | The ability of a disease agent to enter, survive, and multiply in a host. |
| Isolation | The physical separation of individuals with a contagious infectious illness from healthy individuals that have not been exposed to the biological agent. |

| Word | Description |
|--------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Morbidity | The number of people with illness in a defined population, location or other grouping of interest. |
| Mortality | The number of deaths in a defined population, location, or other grouping of interest. |
| Outbreak | The occurrence of more cases of disease (typically related or with a common cause) than expected in a given area or among a specific group of persons during a specific period of time. |
| Pandemic | An epidemic occurring over a very wide area (several countries or continents) and usually affecting a large proportion of the population. |
| Pathogenicity | The ability of an organism to cause disease after infection. |
| Personal Protective Equipment (PPE) | Equipment worn to minimize exposure to hazards, including contact with biological, chemical, radiological, physical, electrical, mechanical, or other hazards. Examples include gloves, foot and eye protection, protective hearing devices, hard hats, respirators, and full body suits |
| Quarantine | The segregation of individuals, families, groups and communities that have been exposed to a contagious disease, but are not ill. |
| Reservoir | The habitat where an infectious agent normally lives, grows, and multiplies, which can include humans, animals, or the environment. |
| Transmission | Any mode or mechanism by which an infectious agent is spread to a susceptible host. |
| Vector | A living intermediary that carries an agent from a reservoir to a susceptible host (e.g., mosquitoes, fleas, ticks, etc.) |
| Virulence | The proportion of people with clinical disease, who after becoming infected, become severely ill or die. |
| Zoonotic diseases | Contagious diseases that are spread between animals and humans. |

Common words used by **law enforcement** officials :

| Word | Description |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Accomplice | A person who helps another commit a crime. |
| Adversary | An enemy or opponent |
| Allegation | A claim that someone has done something wrong, typically without proof |
| Affidavit | A written declaration made under oath |
| Arrest | The deprivation of a person's liberty by legal authority in response to a criminal charge |
| Circumstantial Evidence | Indirect evidence that tends to establish a conclusion by inference |
| Credible Threat | A threat that has good grounds for being true (i.e., information is from a reliable source) |
| Custody | Under the care or control of a legal authority; usually related to a person or item (i.e., evidence) |
| Direct Evidence | Evidence directly relating to the fact in dispute |
| Elicitation | Attempt to get an otherwise unwilling participant to reveal valuable information; usually done by strategic conversation |
| Felony | A significant wrongdoing; usually results in 1+ years in prison |
| HazMat | Hazardous Material (e.g., flammable, radioactive, poisonous.) |
| Insider Threat | An employee within an organization with intent to do harm (usually has ability to bypass many internal security measures). |
| Intelligence | The product produced through the process of collecting, analyzing, and developing raw information into useful data. |
| Manipulation | Exerting influence over someone for one's own advantage |
| Misdemeanor | A minor wrongdoing; usually results in less than one year in prison |
| Outside Threat | Someone outside an organization/entity with intent to do harm. |
| Physical Evidence | Tangible items that contain information related to facts of a case |
| Probable Cause | A reasonable basis for believing that a crime may have been committed (for arrest) and that evidence of the crime is present in the place to be searched (for search) |

| Word | Description |
|--------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Probative Value | Evidence which is sufficiently useful to prove something important in a trial |
| Seizure | The taking by legal authority of evidence in a criminal case. |
| Threat Assessment | Analysis of threatening behavior or action; used to evaluate potential of violent actions |
| Threat Credibility Evaluation | An assessment to determine how credible the threat is and what further action should be taken. Includes analyzing the threat's technical feasibility, operational practicality, and intent. |
| Warrant | A document issued by a legal official authorizing police to make an arrest, search premises, or carry out other related actions |

A large, stylized graphic in shades of blue and white, centered on the page. It features a biohazard symbol with a microscope in the upper center, a DNA double helix on the left, and a petri dish on the right. The background has a subtle grid pattern.

For additional information, please contact the
FBI, WMD Directorate, Biological Countermeasures Unit at:
BiologicalCountermeasuresUnit_BCU@ic.fbi.gov