Joint Criminal and Epidemiological Investigations Handbook

2016 INTERNATIONAL EDITION

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INTRODUCTION

Key Highlights of Introduction Section

- 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.

Terrorists have demonstrated their willingness to employ non-traditional weapons to achieve their desired outcomes. One such class of these weapons is biological agents, which pose challenges to both law enforcement and public health due to their unique characteristics. 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 law enforcement and public health to conduct separate and independent investigations. Due to the challenges posed by a biological threat, an effective response calls for a high level of cooperation between 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. The effective use of all resources during a suspicious biological incident is critical to maximizing an efficient and appropriate response.

By working together, public health and law enforcement can achieve their shared objectives of identifying the biological agent, preventing the spread of the disease, preventing public panic, and apprehending those responsible.

Purpose

This handbook was developed to facilitate the use of resources and maximize communication and interaction among law enforcement and public health in an effort to minimize potential barriers during a 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 incident.

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.

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, public 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. Physicians may need 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. 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." In other words, epidemiologists 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:

- **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. Epidemiologists use interviews, surveys and data analysis to identify the causative agent and determine the source, mode of transmission, and the population at risk for the illness under investigation 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.

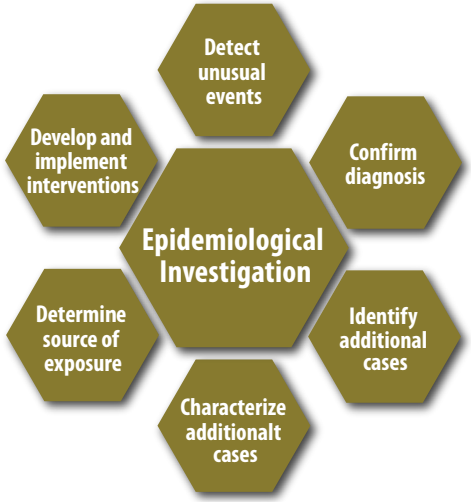


Figure 1. Elements of an epidemiological investigation.

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.

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 (*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

Generally, case reports of disease are submitted to public health by physicians, laboratories, or other healthcare practitioners. Depending on national or local statutes or authorities, it may be mandatory for case reports of disease to be reported to public health once a biological agent is identified. If reporting is not mandatory, healthcare providers should be encouraged to voluntarily submit case reports to public health.

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 2). However, 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.

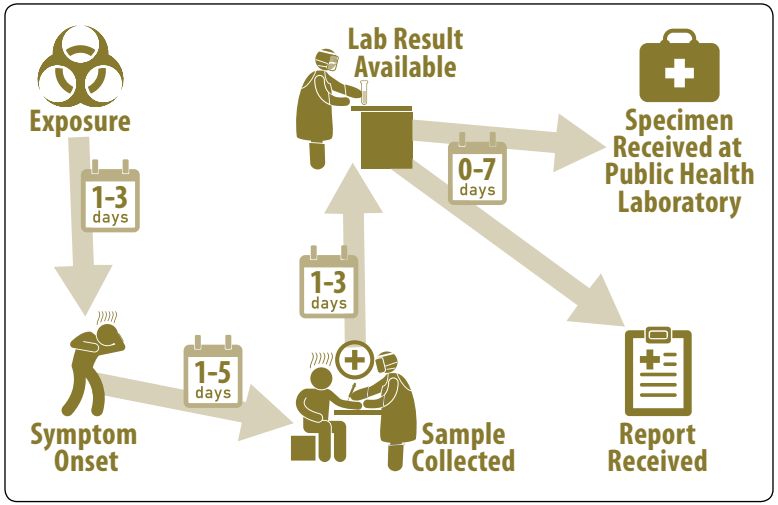


Figure 2.[1] **A depiction of the typical reporting time from initial exposure to receipt by public health.** Typically, a person is exposed to a pathogen and may experience symptoms within a few days. After a patient is seen by a physician, specimens are collected and sent to a clinical laboratory for 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.

[1] Courtesy of New Mexico Department of Health

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, 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 widespread impact on the public. For example, early detection of a contagious disease, like influenza, 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, public health may utilize a **syndromic surveillance system** that relies on existing health data to identify clusters of disease. 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 may 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 initial 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 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.

[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.

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 they initially present symptoms 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. Physicians may need 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**.

A **biological threat agent** is a biological pathogen or toxin that poses a severe threat to public, animal, and/or plant health through accidental or deliberate misuse. As part of a national Biological Laboratory Safety and Security Monitoring Program, officials might develop a country-specific "Agents of Concern" list to identify biological agents that may pose a threat to health and safety.

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. Other samples consist of living, intact materials, necessitating refrigerated or frozen transport of materials (i.e., cold chain) and/or extremely rapid delivery. Not all laboratories possess the capabilities to test for every biological threat agent; this may require specimens or samples to be transported to another laboratory with adequate expertise and capacities.

Laboratories vary in their ability to test for biological agents. For example, forensic laboratories that process criminal evidence may not be equipped to test for biological agents or know how to handle these specimens appropriately. Before testing specimens/samples for biological agents, laboratories should meet appropriate standards (*e.g.*, quality, biosafety, biosecurity). Additionally, these laboratories should continue to demonstrate their readiness through proficiency tests that validate their ability to correctly identify biological agents. Sending a specimen/sample to a laboratory that is not equipped to perform testing could dramatically delay the investigation and destroy material required to confirm the agent's identity and properly diagnose the causative agent of an illness.

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 relevant 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 skin rash and 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 bar graph 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 3, next page)

Multistate Outbreak of *E. coli* 0157:H7 Infection

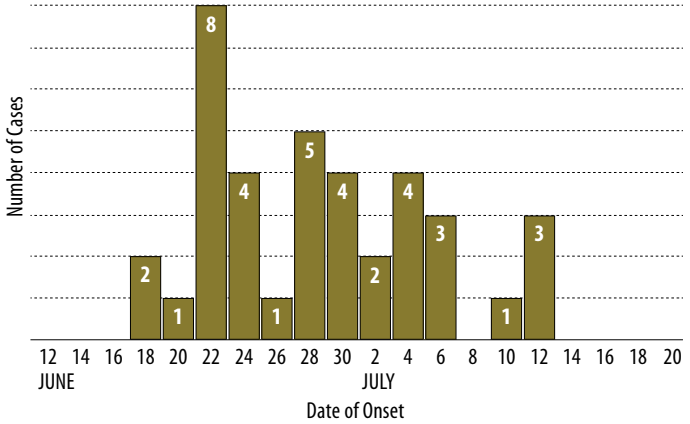


Figure 3. The Epi Curve.[4] This is a diagram of the number of cases of *E.coli* 0157:H7 infection that were associated with this outbreak and when they occurred. This graph, known as an epi curve, helps public health determine the source and spread of an outbreak.

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 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 recommend 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.

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

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.

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 agencies' primary goals are:

- **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 attack. Collection of evidence includes interviewing victims and witnesses as well as obtaining and preserving physical evidence. A criminal investigation of a biological attack is not complete until there is a successful prosecution and conviction of those responsible for the attack.
- **To protect law enforcement personnel**—Law enforcement personnel 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 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 occurred. Soft targets are often more appealing than solid or more stable targets, therefore, a country's strong response capability to a biological attack might result in a deterrent for terrorists choosing a pathogen as their method of attack.

Evaluating the Threat: Real or Hoax

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 biological threat 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 an intentional biological attack. If public health and law enforcement have established a working relationship prior to a biological threat 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.

All situations involving the suspected intentional misuse of a biological agent require a law enforcement-led threat credibility evaluation (see Figure 4), an assessment to determine how credible the threat is and what further action should be taken to mitigate the threat. 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?)

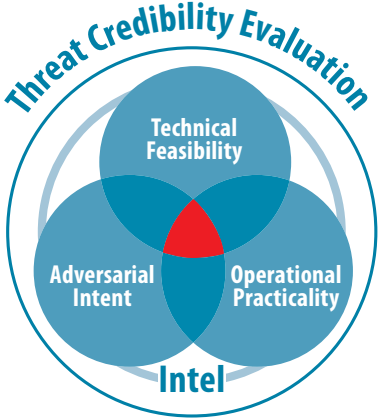


Figure 4. Threat Credibility Evaluation. When a threat is made, law enforcement should lead a threat credibility evaluation to determine how credible the threat is and what further action should be taken to mitigate the threat.

During the course of the threat credibility evaluation, law enforcement may contact various partners and subject matter experts, notably public health, to assist in determining the threat credibility. After the threat has been deemed credible, involved parties should consult to determine the next course of action, specifically regarding how to best collect and analyze the evidence, including biological environmental samples. If the threat is deemed non-credible, law enforcement may initiate an investigation to identify and prosecute those responsible for creating the perception of a threat (*i.e.*, a hoax). In the United States of America, a threat involving a disease-causing organism or toxin is a criminal act, whether or not the perpetrator actually possesses the agent or toxin.[5]

[5] 18 U.S.C. 2332a and 18 U.S.C. 175

Criminal Investigative Methods

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 5. 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. Similar to other criminal investigations, in the event a pathogen is intentionally released, investigators are unaware of what is and is not a critical piece of evidence needed to identify, arrest, and convict those responsible for the criminal act.

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

- **Chain of Custody**—It is important to ensure a methodology is used to track and maintain control and accountability of all evidentiary items during a criminal investigation. A strict methodology allows for accountability of evidence from the time of collection to the time of trial. 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. Both law enforcement and public health must provide accountability at each stage of collection, handling, testing, storing, transporting of the evidentiary items, and reporting any test results. Responders should implement formalized chain of custody procedures once there is suspicion that a crime has occurred.
- **Delivery of Biological Samples to Laboratory**—Laboratories vary in their ability to test for biological agents. For example, forensic laboratories that process criminal evidence may not be equipped to test for biological

agents or know how to handle these specimens appropriately. When submitting biological samples, it is important to ensure the laboratory receiving the sample is qualified and proficient in testing and familiar with the chain of custody procedures. Submitting evidentiary biological samples to unqualified laboratories may result in delays, improper analyses, or unintentional contamination of samples, which could ultimately create doubt surrounding the validity of test results in court.

- **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.[6] 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.

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

Evaluate Evidence

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 of the evidence 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. It is useful to have specially trained teams to handle the apprehension and collection of evidence in contaminated environments. Following the release of a pathogen, law enforcement will need to have the collected evidence analyzed in a laboratory to support and guide their investigation. As mentioned before, only laboratories qualified to handle and test biological evidence should 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.

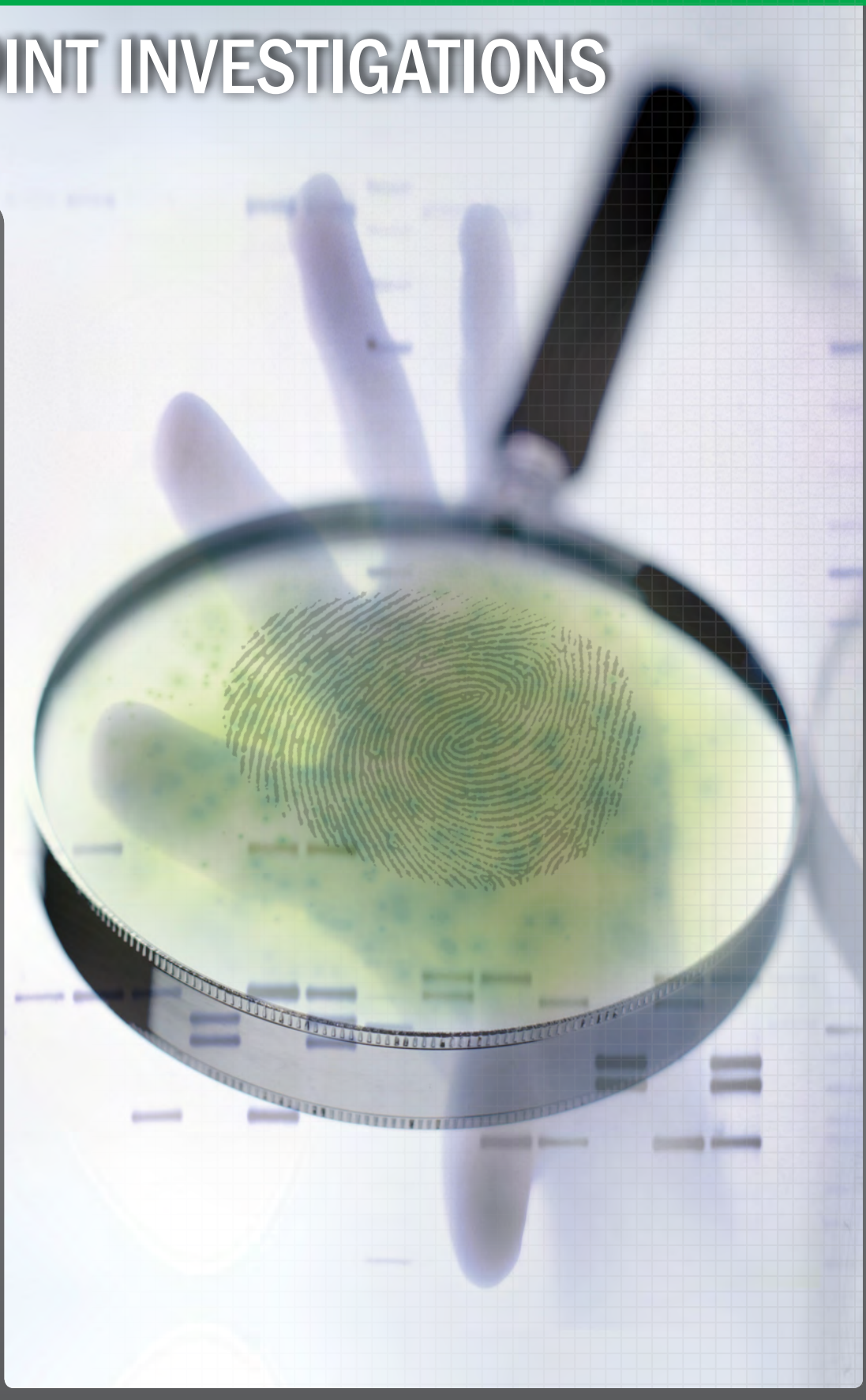
Apprehend Suspect(s)

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 any biological agent in the environment. 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. 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

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.

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. However, a mechanism for increasing cooperation and coordination between law enforcement and public health has since been developed, and is referred to as the **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:

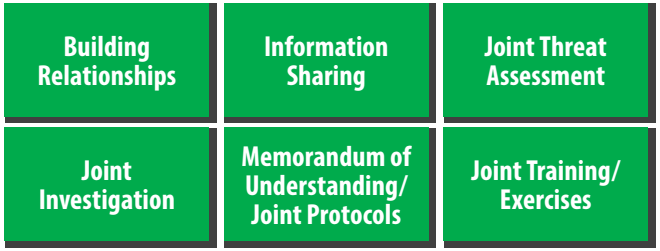


Figure 6. Elements of a Joint Criminal-Epidemiological Investigations Model.

Benefits of the Joint Criminal-Epidmiological Investigations Model

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

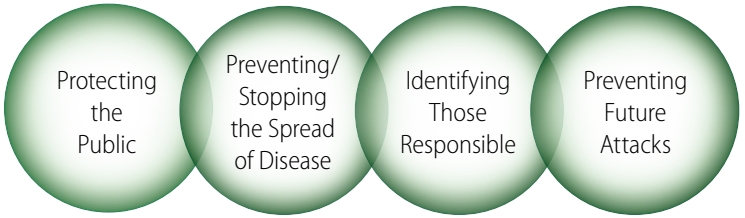


Figure 7. Common goals shared between public health and law enforcement during a response to a biological threat.

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) and
- 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 and
- 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

Building Relationships

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.

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. 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.

Figure 8. Information that is unique to law enforcement and public health that, if shared, could be beneficial to both a criminal and epidemiological investigation.

Law Enforcement	Public Health
• Terror Groups/Organizations	• Case Reports/Outbreaks
• Threats	• Laboratory Tests
• Intelligence	• Epidemiological Information
• Victim Information	• Patient Information

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. Public health and law enforcement 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.

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

A common potential challenge for public health is concern regarding legal liability for the release of patient information without the patient's consent. Individual countries may have specific laws indicating that a patient's medical information is confidential. Challenges arise when law enforcement requires access to patient clinical samples and/or sample results, as well as specific information from patient health records from physicians, hospitals, or public health. Due to the protected nature of the information, certain challenges are posed to public health when law enforcement requires this information as potential evidence of a crime.

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 the successful prosecution of the perpetrator(s).

Legal Issues Related to Information Sharing

Many countries have laws that protect patient confidentiality (sensitive medical information). However, patient privacy statutes and regulations can include exemptions (*e.g.*, threats to national security, or protecting the health and safety of the public) for the release of information to law enforcement. When

determining the process for sharing information between public health and law enforcement, legal counsel should be involved to ensure that the activity complies with all applicable statutes for the specific jurisdiction where they will be implemented. The legal basis for allowing patient medical information to be shared with law enforcement should be incorporated into a Memorandum of Understanding (MOU)/joint protocol so all entities are properly informed and can comply with the regulations surrounding the sharing of information.

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 are 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 mimic other diseases. Furthermore, many biological threat agents cause rare, non-endemic, or eradicated diseases, often with unknown or poorly characterized cause/source. 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 made.

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 or samples (clinical or 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., tularemia 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)
- Death or illness in humans preceded or accompanied by death or illness in animals that is unexplained or attributed to a zoonotic biological agent
- Unusual "typical patient" distribution (*i.e.*, several adults with an unexplained rash)

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

The identification of information or events, particularly when pre-determined triggers are met, should always lead to a joint threat 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 some countries, 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 Risk:** Highly likely the source of exposure occurred naturally (not intentional)
- **Possible Biological Threat Risk:** Information suggests possibility that exposure may be a result of an intentional exposure
- **Likely Biological Threat Risk:** 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 Risk:** Public health will continue to manage the incident
- **Possible Biological Threat Risk:** Parallel investigations or joint investigation
- **Likely Biological Threat Risk:** Joint Investigation

While the incident may be initially assessed at one of the described 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 event and included in an agreed upon protocol 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.

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 joint investigations, 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 a qualified 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 (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.

Public health may need to collect some additional information through use of a standardized survey instrument or questionnaire, either as part of the interview or afterwards. An epidemiological investigation involves statistical analysis of data obtained using a standardized survey instrument or questionnaire. The statistical analysis is essential in providing public health with mathematical evidence to confirm or reject a hypothesis, which is used to develop and implement an intervention to prevent people from becoming ill.

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 law enforcement and public health to coordinate their interaction with the media. Due to the nature of a biological threat, the media will aggressively seek information from public health and law enforcement. As a result, the media will have a substantial impact on the public reaction to a biological threat, which may affect the ability of investigators to respond to the incident. Therefore, 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/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 earlier in this chapter: information sharing triggers, joint threat assessments, and joint investigations. Additional information that could be helpful to incorporate into a MOU 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 protocols is a difficult task, requiring the input and agreement of many entities within law enforcement and public health. To assist public health and law enforcement with the creation of an MOU/joint protocols, a model MOU for joint investigations was developed. While the model MOU is based on statutes, regulations, and authorities in the United States of America, its principles and concepts can be generalized and utilized by other countries.

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 increase proficiency in joint investigations activities. It is important to already have MOU/joint protocols in place prior to conducting an exercise (and not using an 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

SUMMARY

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 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

- 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, public 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. Physicians may need 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. 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: Role of the U.S. Federal Bureau of Investigations and U.S. Centers for Disease Control and Prevention

Appendix 5: U.S. Bio-Related Laws to Prevent Bioterrorism

Appendix 6: U.S. 2014 Biological Select Agent and Toxin List

Appendix 7: U.S. National Response Framework

Appendix 8: International Obligations (BWC, UNSCR 1540, and IHR)

Appendix 9: 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, it is recommended that law enforcement and public health develop protocols to conduct a joint threat assessment between agencies. The following procedure is intended to serve as a guide; 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 law enforcement 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:

- Law enforcement (trained in WMD response)
- Public health (epidemiologist, clinician, laboratorian)
- Communications (law enforcement and public health)

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, religious affiliation, 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

- Law enforcement information/intelligence
  - » Information on existing threats in the jurisdiction (WMD or otherwise)
  - » WMD intelligence that may be connected to patient'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 patient'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 risk categories. While the incident may be initially assessed at one of the risk levels below (Table 6), it may be changed as the investigation begins and new information is collected.

Table 6. Three risk categories used to classify bioterrorism risk.

Risk Classification	Evidence Leading to Classification	Public Health Actions	Law Enforcement Actions
No Bioterrorism Threat: *Highly likely that source of exposure occurred naturally*	No evidence to suggest intentional release	Continue to manage the incident	No further action needed
Possible Bioterrorism Threat: *Possibility that exposure may be intentional*	Public health investigation has not revealed a likely exposure Unusual/unexplainable circumstances exist regarding patient's infection with biological threat 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; if applicable, share public health information with law enforcement partners	Query intelligence databases for relevant information/intelligence; if applicable, share law enforcement information with public health partners
Likely Bioterrorism Threat: *Reasonable belief that exposure was intentional*	Lab results are positive for a biological threat 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 Open case to investigate criminal intent and/or suspicious circumstances

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. A joint interview might include the following actions:

- Initial meeting between law enforcement and public health (prior to hospital visit)
- 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

It is recommended that law enforcement and public health exchange information as soon as possible in order to assess the possibility that a biological threat exists. Therefore, it is likely that joint interviews will occur as a part of the initial response activities to a suspected biological threat incident. 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:

- The public health investigator will:
  - » Provide an overview of the epidemiological investigation
  - » Provide a short briefing regarding the disease agent (*i.e.*, incubation period; how it is transmitted; cases per year in the immediate area, and the country)
  - » Recommend the appropriate level of Personal Protection Equipment (PPE) and prophylaxis, if necessary
- The law enforcement investigator will review all current WMD threats, intelligence, and reporting, which may be relevant to the situation
- The Joint Interview Team Leader will create 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 law enforcement and public health present during interviews. 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.

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 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, 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 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 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 should sit in chairs during the interview, rather than standing over the patient. 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, 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 law enforcement. They should try to collect this additional information as part of their interview. Once the interview is complete, law enforcement will meet with public health at a pre-designated area to discuss the interview results.

It is recommended that 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 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.

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 law enforcement may try several techniques to determine the credibility of the patient during their portion of the interview. Law enforcement may ask questions which seem repetitive or awkward to public health. It is recommended that public health allow law enforcement to proceed without interruption, unless there is an urgent need to meet outside the room to discuss the interview strategy.

Public health may need to collect some additional information through use of a standardized survey instrument or questionnaire, either as part of the interview or afterwards. An epidemiological investigation involves statistical analysis of data obtained using a standardized survey instrument or questionnaire. The statistical analysis is essential in providing public health with mathematical evidence to confirm or reject a hypothesis, which is used to develop and implement an intervention to prevent people from becoming ill.

As a general rule, the patient will not be physically examined in the presence of law enforcement, unless circumstances dictate that law enforcement be present in the room. Additionally, if the patient is a minor, the parents must be present during the law enforcement portion of the interview. If appropriate, the joint interview team may leave their personal business cards with the individual.

Post-Interview Review

Once the interview is complete, law enforcement and public health should meet to discuss their interview notes and ensure there are no discrepancies. If law enforcement requires copies of patient medical information, public health will provide this information to 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 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 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 the 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 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

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

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*

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: Role of the U.S. Federal Bureau of Investigation and U.S. Centers for Disease Control and Prevention

Introduction

Following the 2001 incident involving the intentional distribution of *Bacillus anthracis* through the mail system in the United States of America, the Federal Bureau of Investigation and Centers for Disease Control and Prevention worked together to develop the Joint Criminal-Epidemiological Investigations Model, increasing collaboration between the agencies. Many of the general public health, law enforcement, and joint investigation activities described in this handbook were initially developed and tested in the United States. This section provides additional details on Federal Bureau of Investigation and Centers for Disease Control and Prevention roles and responsibilities that support the implementation of the Joint Criminal-Epidemiological Investigations Model in the United States of America.

Federal Bureau of Investigation (FBI)

The FBI is 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. 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.

The FBI has multiple operational units to provide assistance in the event of a terrorist attack, including response teams trained in handling hazardous materials, evidence, and explosives. These teams provide expertise to the FBI field offices and other law enforcement agencies in both the United States and other countries. The FBI also has specially trained personnel, such as microbiologists and other scientists, qualified to collect contaminated evidence.

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, who then decides whether or not to bring the case to trial. 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 has 56 field offices located in major U.S. cities, as well as nearly 400 resident agencies in smaller towns (Figure 9). These offices allow the FBI to interact with local stakeholders and obtain unique geographic knowledge of

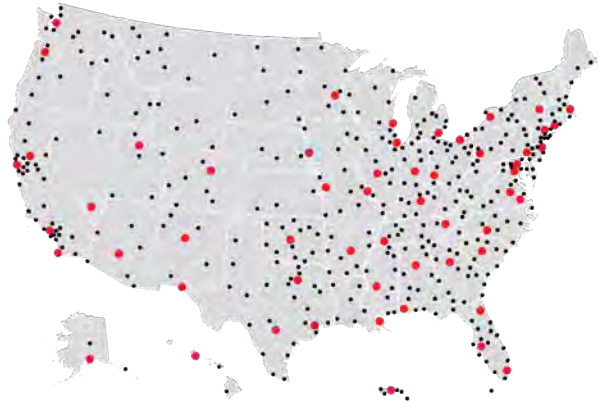


Figure 9. Map of FBI Field Offices and Resident Agencies

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.

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 Tblisi, 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

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).

Centers for Disease Control and Prevention (CDC)

The Department of Health and Human Services (DHHS) 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 DHHS, 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 U.S. against health threats and responds when these arise.

Public health response begins at the local level, since they will likely be the first to recognize cases of illness.

In the United States, 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, with CDC providing support to its state/local partners. 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.

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.

The Federal Select Agent Program is jointly comprised of the Centers for Disease Control and Prevention/Division of Select Agents and Toxins and the United States Department of Agriculture/Animal and Plant Health Inspection Service/Agriculture Select Agent Services. The Federal Select Agent Program oversees the possession, use, and transfer of biological agents and toxins identified in federal regulations (42 CFR part 73, 9 CFR part 121, 7 CFR part 331) as "select agents and toxins." 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. One of the fundamental elements of the federal regulations is to keep select agents and toxins out of the possession of individuals who might intend to misuse them, such as a criminal or terrorist. The Federal Select Agent Program works closely with the Federal Bureau of Investigation/Criminal Justice Information Services Division to identify those individuals who are prohibited from access to the select agents and toxins regulated by the Federal Select Agent Program based on the restrictions identified in the USA PATRIOT Act.

CDC International Efforts

The CDC has numerous international programs that provide support in identifying and containing events of public health concern. CDC provides resources and expertise to address global challenges and collaborate with other federal agencies and international partners to promote global health diplomacy and health security In addition, CDC's international programs help countries build sustainable capacity to rapidly detect, accurately identify, and promptly contain emerging infectious diseases and biological threats that occur internationally.

Appendix 5: U.S. 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.

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

18 USC 175—(Bio-specific Laws)	
§ 175(a)	• 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)	• 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	• 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 Select Agent Program • Part c: Crime to knowingly possess select agent, regardless of intent, if not registered with the Select Agent Program • Part d: Defines "select agent" and "restricted person" (see page 93)

18 USC 2332a—(Threatened Use of WMD)	
§ 2332a	• Crime to conspire, threaten, attempt, or use a WMD against person or property of United States (including mail or commerce)

18 USC 842(p)—(Distribution of WMD Information)	
§ 842(p)	• 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	• 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 the Federal Select Agent Program which provides regulatory oversight for 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 biosafety, incident response, and security plans, and personnel with access to select agents must undergo a 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 6: U.S. 2014 List of Select Agents and Toxins

In the United States, the possession, use, and transfer of select agents are subject to the requirements of the select agent regulations (42 CFR part 73, 9 CFR part 121, 7 CFR part 331).

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 provides regulatory oversight for the possession, use, and transfer of such agents to all entities within the U.S., regardless if they are public or private entities.

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.

The U.S. Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA) regulate the Select Agent List. Tier 1 agents are in **red bold font** and marked with an asterisk (*).

Note: This list is revised every two years. To find the current U.S. Select Agents and Toxins list, please visit: http://www.selectagents.gov/SelectAgentsandToxinsList.html

HHS-Regulated Select Agents

- Abrin
- **Botulinum neurotoxins***
- **Botulinum neurotoxin producing species of *Clostridium****
- Conotoxins[1]
- *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 virus[2]
- 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****

[1] Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$

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

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*

Appendix 7: U.S. National Response Framework

There are several departments and agencies within the United States that have roles and responsibilities during a disaster or emergency. In an effort to facilitate a coordinated and unified response, the United States implements its National Response Framework, which outlines guiding principles for all domestic response partners during any type of emergency or disaster (local, state, or national-level).

The National Response Framework:

- Describes specific authorities and best practices for managing disaster or emergency incidents for national, state, and local authorities, as well as industry, nongovernmental, and community partners.
- Allows governmental agencies to develop their own specific response plans, and those plans are exercised to identify and address conflicting roles and responsibilities.
- Is built upon scalable, flexible, and adaptable coordinating structures to align key roles and responsibilities.
- Covers capabilities necessary to save lives, protect property and the environment, and meet basic human needs after an incident has occurred.

It is noteworthy to underscore the importance of determining inter-governmental roles and responsibilities before a bioterrorism incident occurs to maximize the opportunity for a consistent, coordinated, and efficient nationwide response. Not all response plans are one-size-fits-all. An effective response plan should be tailored to fit the needs and capabilities of the country that is writing such a plan.

When drafting a national response plan, it may be helpful to:

- Methodically describe the "who, what, and how" of emergency preparedness and response.
- Describe not only federal roles, but also how state, local, industry, nongovernmental, and community partners would contribute to managing an emergency incident.
- Incorporate lessons learned from past federal, state, or local exercises that may be applied across the national spectrum.

The U.S. National Response Framework can be found at: http://www.fema.gov/pdf/emergency/nrf/nrf-core.pdf

Appendix 8: International Obligations

By proactively identifying how public health and law enforcement can work together to better prepare for and respond to a suspicious biological incident, these communities are working to uphold the fundamental goals of the Biological Weapons Convention, United Nations Security Council Resolution 1540, and the International Health Regulations. These three agreements, which mutually reinforce objectives of the Joint Criminal-Epidemiological Investigations Model, are briefly summarized below.

Biological Weapons Convention (BWC)

To supplement the 1925 Geneva Protocol, which bans the use (but not development) of chemical and biological weapons, the Biological Weapons Convention (BWC) was created to prohibit the development of bioweapons. Specifically, BWC members agree to never develop, produce, stockpile, retain, or transfer biological agents or toxins (and associated equipment or means of delivery) that have no justification for prophylactic, protective or other peaceful purposes. While the BWC prohibits the development of bioweapons, it also strives to protect and promote the advancement of science for peaceful purposes. Article IV of the BWC requires nations to take national measures to implement the BWC domestically. Such measures include laws, regulations, and biosecurity measures that prohibit individuals from misusing biological material for nefarious purposes. The Joint Criminal-Epidemiological Investigations Model engages international partners to optimize identification, assessment and response to a biological threat.

United Nations Security Council Resolution 1540 (UNSCR 1540)

In an effort to respond to the role non-state actors play in WMD proliferation, the United Nations Security Council passed Resolution 1540 (UNSCR 1540),

which imposes binding obligations on all States to adopt legislation to prevent the proliferation of nuclear, chemical, and biological weapons, and establish domestic controls to prevent illicit trafficking of such material. Resolution 1540 is unique in that it identifies WMD as a new dimension of proliferation, focuses on States preventing non-State actors from acquiring WMD, and fills the gap in other nonproliferation treaties such as the BWC, Chemical Weapons Convention, and Nonproliferation Treaty. Article 2 of Resolution 1540 requires nations to adopt and enforce laws which prohibit non-state actors from using WMD. Article 3 requires nations to maintain effective law enforcement efforts to detect, prevent, and combat the illicit trafficking and brokering of WMD, which might be detected during a joint investigation between public health and law enforcement.

International Health Regulations (IHR)

The International Health Regulations (IHR) obligates nations to detect, assess, report, and respond to public health emergencies of international concern, with the intent to mitigate the consequences of the event before it spreads across borders. The IHR provides guidance for Member States to assess and manage serious health threats, to include biological outbreaks, which can be natural or criminal in nature. Fundamental aspects of the IHR include developing, strengthening, and maintaining public health capacities for surveillance and response. The Joint Criminal-Epidemiological Investigations Model supports the IHR by bringing public health and law enforcement together to more effectively respond to a biological threat in real time. This, in turn, allows local stakeholders to implement control measures immediately, report essential information to appropriate authorities, and ultimately preserve public health and safety.

Appendix 9: 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.

Word	Description
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.
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, and ticks).
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, or 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).
Probative Value	Evidence which is sufficiently useful to prove something important in a trial.

Word	Description
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.

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Notes:

CDC

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