

# General Outbreak Investigation / Notification Protocol

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This protocol addresses outbreaks that are not linked to healthcare facilities such as hospitals, long-term care facilities, etc.). For healthcare-associated outbreaks please see <http://www.dhhr.wv.gov/oeps/disease/hai/documents/hai-protocol.pdf>.

## Definition of an 'Outbreak'

1. **Outbreaks** are defined as an increase in the number of cases of a disease over and above the expected number of cases.
2. **Definitions of common community-associated outbreaks**
  - An influenza or influenza-Like Illness (ILI) outbreak is defined as
    - Three or more cases of influenza-like illness in a congregate setting within a 3-day period (e.g., daycare, sports team, etc.), or
    - Two or more laboratory-confirmed cases of influenza within a 3-day period in a congregate setting (e.g., classroom, daycare), or
    - Increased absenteeism in association with ILI and/or laboratory confirmed influenza (e.g., schools, workplaces).
  - A foodborne disease outbreak is defined as two or more persons who experience a similar illness after ingestion of a common food. Please note two exceptions: one case of botulism or chemical poisoning constitutes an outbreak.
  - A waterborne disease outbreak is defined as two or more persons who experience a similar illness after consumption or use of water intended for drinking. Outbreaks in association with recreational water may include exposure to or unintentional ingestion of water. Please note that a single case of chemical poisoning also constitutes an outbreak.
  - Chickenpox: 5 or more cases in children of any age in a school or daycare facility.
  - Community-acquired methicillin resistant Staphylococcus aureus (CA-MRSA):
    - 2 or more epidemiologically-linked cases of CA-MRSA occurring in at least two distinct households
    - 2 or more cases clustered in time on a sports team; OR
    - An increase in the incidence of CA-MRSA over the expected incidence.
  - Hantavirus: 2 or more cases clustered in place and/or time
  - Leptospirosis: 2 or more cases clustered in place and time
  - Pertussis: 2 or more cases in 2 or more households clustered in place and time with at least one case culture or PCR-confirmed.

# General Outbreak Investigation / Notification Protocol

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3. A single case of any of the following constitutes an outbreak:
- a. Anthrax
  - b. Any agent of bioterrorism
  - c. Botulism
  - d. Diphtheria
  - e. Human rabies
  - f. Measles
  - g. Monkeypox
  - h. Novel influenza virus
  - i. Polio
  - j. *Salmonella typhi*
  - k. *Smallpox*
  - l. *Vibrio cholerae*.
  - m. VISA or VRSA (Vancomycin intermediate-resistant *Staphylococcus aureus* or vancomycin-resistant *Staphylococcus aureus*)
  - n. Suspect or confirmed illness due to intentional exposure
  - o. Viral hemorrhagic fever
  - p. Other novel or emerging infectious disease with an expected incidence of zero cases in West Virginia.

## Provider Responsibilities:

1. Report suspected **outbreaks**, including **foodborne and waterborne disease outbreaks** immediately by phone to the local health department in the jurisdiction where the outbreak is identified.
2. Collaborate with the local health department to obtain appropriate diagnostic laboratory evaluation. For public health investigation of outbreaks, and foodborne and waterborne disease outbreaks, the services of the Office of Laboratory Services (304-558-3530) are available free of charge. Consult the Division of Infectious Disease Epidemiology (DIDE) at (800-423-1271-ext 1 24/7) or your local health department for advice on confirmation. The local health department can assist with collection of specimens.
3. Collaborate with the local health department to institute appropriate control measures.
4. Collaborate with the local health department on the investigation. Local health departments may request, as needed:
  - a. A line listing of ill persons;

# General Outbreak Investigation / Notification Protocol

- b. Clinical and laboratory information on persons with a reportable condition.
- c. Other epidemiologically necessary information for investigation and control of the outbreak.

## Laboratory Responsibilities:

1. Report suspected **outbreaks**, including **foodborne and waterborne disease outbreaks** immediately by phone to the local health department in the jurisdiction where the outbreak is identified.
2. Collaborate with public health officials to obtain appropriate specimens for testing or confirmation.
3. Collaborate with local health officials on investigation of the outbreak. Local officials may request:
  - a. Isolates or specimens for further testing at WV Office of Laboratory Services, if necessary
  - b. A line listing of ill persons.
  - c. Copies of laboratory reports for persons meeting the outbreak case definition;
  - d. Other epidemiologically necessary information for investigation and control of the outbreak.

## Local Health Department Responsibilities:

NOTE: This investigation protocol is NOT a substitute for training and experience in outbreak investigation. Consult an experienced trained epidemiologist for complex outbreak investigations.

1. Educate laboratories and providers to report **outbreaks** including **foodborne and waterborne disease outbreaks** to the local health department immediately upon recognition of the outbreak.
2. Detect outbreaks: to detect outbreaks consider the following:
  - Regular systematic review of routine surveillance data
  - Investigate report(s) by one or more patients or member of the public
  - Investigate reports by astute, alert clinicians / infection preventionists who are concerned enough to call to LHD.

# General Outbreak Investigation / Notification Protocol

3. When an outbreak is reported:
  - Notify DIDE immediately (within 60 minutes)
  - Report the time of LHD notification
  - Expect an outbreak number to be assigned by DIDE staff to your outbreak
  - Use this assigned outbreak number in all correspondents related to this outbreak, such as laboratory slips, final reports, email communications, etc.
  - Negotiate responsibilities for the investigation at the time of reporting and indicate who will be the lead for the outbreak (LHD, regional epidemiologist, or DIDE). Please note that the outbreak lead investigator may change as the investigation unfolds. Indicate the outbreak lead in the final report.
  - Discuss your initial investigation steps and control measures with DIDE staff.
  - Expect DIDE staff to refer you to the appropriate outbreak toolkit if one is available
  - Agree on appropriate laboratory testing at OLS. Laboratory specimens should be collected, and shipped or transported as per OLS instructions in a timely manner. OLS will need an outbreak number to accept the specimens.
  - Agree on data to be collected on a line list, such as demographic clinical, laboratory, etc. and the timeframe to collect this data.
  - Agree on regular updates (DIDE will continue to follow the outbreak until the investigation is closed.)
  
4. When an outbreak is reported, refer to the appropriate outbreak toolkit and follow these steps of outbreak investigation. Outbreak toolkits can be found at <http://www.dhhr.wv.gov/oeps/disease/ob/Pages/OutbreakToolkits.aspx>  
Personnel who are learning to do outbreak investigation should be paired with a trained and experienced investigator. These steps may/should be adapted, according to the situation, and should be revisited as more information becomes available:
  - a. Step 1: Identify potential investigation team members and resources / prepare for fieldwork.
    - i. Investigation:
      1. Assemble information on the disease, including protocols, reference books, information sheets, outbreak toolkits and investigation forms. The

# General Outbreak Investigation / Notification Protocol

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- protocol for the disease will often have specific recommendations on outbreak investigation.
2. Consult with laboratory staff on the proper collection, storage and transportation of laboratory specimens.
  3. If personnel are learning how to do outbreak investigation, identify an experienced investigator to mentor inexperienced staff.
- ii. Administration:
    1. Make arrangements for your regular work to be covered.
    2. Make arrangements to cover personal matters, if needed.
  - iii. Identify a lead investigator:
    1. Clarify your role in the investigation with your supervisor if the outbreak is limited to your jurisdiction.
    2. If the outbreak is limited to one county and county resources are adequate, the appropriate lead investigator may be a member of the local health department staff.
    3. If the outbreak affects multiple jurisdictions or if local resources are inadequate, or if the disease is serious or requires clinical expertise for case ascertainment or control, DIDE involvement may be necessary. If the outbreak affects citizens in another state, DIDE will coordinate with the neighboring state and CDC.
    4. In multi-jurisdiction outbreaks, roles and responsibilities are usually negotiated respectfully between jurisdictions.
- d. Step 2: Establish the existence of an outbreak
- i. Determine the *expected* incidence of the disease by use of health department surveillance records or other sources of data. If the expected incidence of disease is unknown, consult DIDE.
  - ii. Evaluate the possibility of changes in reporting. Have there been changes in reporting procedures? Changes in laboratory testing? Changes in population? Have there been improvements in reporting? That is to say, are there alternative explanations for the observed increase in incidence?
  - iii. Sometimes, active surveillance (Step 5) is necessary to establish the existence of an outbreak.
  - iv. If you are uncertain whether you are dealing with an outbreak, consult DIDE.

# General Outbreak Investigation / Notification Protocol

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- e. Step 3: Verify the diagnosis
    - i. Review clinical findings and laboratory results. Compare the results with established case definitions
    - ii. Talk to patients with the disease. Ask them their symptoms and learn about the clinical features of the disease. Gather other information: What were their exposures prior to becoming ill? What do they think caused their illness? Do they know anyone else with the disease?
    - iii. Submit laboratory specimens for testing if not already done.
    - iv. Consult a physician or medical epidemiologist regarding possible diagnoses, especially if you are unfamiliar with the clinical syndrome.
  - f. Step 4: Construct a working case definition
    - i. Base your case definition on established case definitions. For example, if you are investigating an outbreak of shigellosis, begin with the CDC case definition for that disease. A good case definition:
      - 1. Uses a few simple clinical criteria
      - 2. May be restricted by person, place and/or time; and
      - 3. Does not include an exposure or risk factor you want to evaluate.
      - 4. Is 'loose' or 'sensitive' if used for case-finding; and 'specific' or 'tight' if used for hypothesis testing.
      - 5. Your case definition may and should change as you acquire more information.
  - g. Step 5: Find cases systematically and develop a line listing
    - i. As appropriate, identify additional cases through:
      - 1. Enhanced passive surveillance: send / fax a letter or memo to laboratories and/or providers asking them to report cases that meet the case definition.... OR
      - 2. Active surveillance: contact providers personally and request reporting of cases that meet the case definition.
    - ii. Collect the following information, as appropriate, on every case:
      - 1. identifying information (name, address, phone number)
      - 2. demographic information (date of birth, race, ethnicity, gender, occupation)
      - 3. clinical information (signs, symptoms, diagnostic tests)
      - 4. risk factor information
      - 5. names of other people who have a similar illness
      - 6. reporter information

# General Outbreak Investigation / Notification Protocol

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- iii. Organize the information in a line listing
  - h. Step 6: Perform descriptive epidemiology As appropriate, organize the data by:
    - i. Time. Construct an epidemic curve, using a unit of time one-eighth to one-third as long as the incubation period.
    - ii. Place. Map the cases.
    - iii. Person. Calculate the proportion of affected individuals by age and gender. Consider other factors, including occupation or risk behaviors. A school outbreak might be characterized by grade or classroom, teacher or student. An outbreak in a football team may be characterized by playing positions or listing of injuries, etc.
  - iv. Consult an experienced epidemiologist at this point. This is a critical point for deciding whether to proceed with more complex epidemiological studies. If it is necessary to proceed with case-control or cohort studies, consult an experienced epidemiologist.**
  - i. Step 7: Develop hypotheses.
    - i. Review the data collected thus far. What are the implications of your findings?
    - ii. Talk to about 8-10 case-patients in depth. Use open-ended interviewing techniques. In many cases a detailed hypothesis-generating questionnaire may be useful. Contact DIDE for suggestions.
    - iii. Summarize hypotheses.
  - j. Step 8: Evaluate hypotheses.
    - i. If the source of infection is obvious, e.g., in a situation where there is clear person-to-person transmission, no formal hypothesis testing is necessary.
    - ii. If the source of infection is not obvious, a cohort or case-control study is frequently necessary to test hypotheses. Contact DIDE for assistance.
  - k. Step 9: As necessary, reconsider and refine hypotheses and conduct additional studies. In some cases, analytical studies may reveal a source for the illness. In other cases, analytical studies may reveal only part of the answer or no answer at all. A second set of epidemiological, environmental or laboratory studies may be necessary to identify the source of illness. Consult DIDE for assistance.
  - l. Step 10: Implement control and prevention measures. In most outbreak investigations, your primary goal will be prevention and control, and these measures should be implemented at the earliest possible time. In the event of school outbreaks, closing the school

# General Outbreak Investigation / Notification Protocol

is rarely an effective measure to control the outbreak. School officials should consult with the LHD and DIDE before making decisions regarding school closing.

- m. Step 11: Communicate your findings. Communication should take two forms
- i. An oral report (Optional): Discuss your findings and recommendations with the appropriate individuals locally – the owner of the establishment involved in the outbreak, and/or other interested citizens. The oral report can help you build your confidence and credibility for outbreak investigation.
  - ii. Routine outbreaks: Complete the general outbreak report form, keep a copy for your record and share a copy with:
    1. Local Health Officer
    2. The notifying facility or establishment
    3. DIDE within 30 days
  - iii. None-Routine Outbreaks: Follow the usual scientific format of:
    1. Introduction
    2. Background
    3. Methods
    4. Results
    5. Limitations
    6. Discussion
    7. RecommendationsForward a copy of the report to DIDE ASAP. DIDE must report selected outbreaks to CDC within 60 days of the first disease onset.
- l. Step 12: Maintain surveillance to monitor trends and evaluate control/prevention measures.
- i. Continue surveillance to establish that your prevention and control measures are working.

## Division of Infectious Disease Epidemiology (DIDE) Responsibilities

1. Train local, regional public health personnel and other pertinent partners in outbreak investigation.
2. Track all West Virginia outbreaks using the outbreak intake form. Maintain the form on-file with the outbreak report and supporting information including interview forms, results of data analysis, etc. The information should be maintained and summarized on an annual basis.

# General Outbreak Investigation / Notification Protocol

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3. Report foodborne outbreaks to the CDC National Outbreak Reporting System (NORS) within 60 days of first disease onset.
4. Report chickenpox outbreaks to CDC using their outbreak line list (includes age, vaccination status and severity of illness, as well as outbreak setting).
5. Offer technical assistance and other resources, including epidemiologic and laboratory to the local health department routinely during outbreak investigation
6. DIDE will generally take a major leadership role in the investigation if
  - a. The local health department is unable to conduct the outbreak investigation due to lack of resources or experience.
  - b. The case-patients arise from multiple local jurisdictions;
  - c. The disease is an unusual or emerging disease;
  - d. The disease is unusually severe, i.e., resulting in hospitalization, death or disability;
  - e. The disease requires complicated medical or diagnostic evaluation;
  - f. The local health department is unable to adequately investigate the outbreak;
  - g. An analytical epidemiological study is required for full investigation; or
  - h. The disease is part of a multi-state or international outbreak.
7. For outbreaks of unusual diseases or diseases of unusual severity (e.g. pandemic or emerging infectious diseases) or outbreaks or cluster investigations that exceed the capacity of DIDE to investigate and manage DIDE will recommend that incident command and the All Hazard Emergency Operations Plan (AHEOP) be put into operation to address the disease outbreak or cluster. Examples of situations where activation of the AHEOP should be recommended include:
  - a. Sudden outbreak or cluster of severe respiratory, GI or neurological illness of unknown etiology, especially one affecting previously healthy individuals
  - b. Any situation where intentional infection is suspected or confirmed
  - c. Any large outbreak where the number of ill persons exceeds the capacity of DIDE to respond with available resources
  - d. Any outbreak related to a public water system
  - e. Serious outbreaks involving multiple outside agencies requiring management from leadership to resolve the course of action

# General Outbreak Investigation / Notification Protocol

8. Communicate the findings of investigations where DIDE takes a lead role as soon as possible. This may consist of a site visit report and/or an outbreak report. These reports will be completed by the investigation team and reviewed by a DIDE senior epidemiologist and the DIDE Director, as well as State Epidemiologist and State Health Officer if needed.
9. DIDE will arrange or request an After Action Review (AAR) for outbreaks or cluster investigations that presented unusual difficulties for the investigation team and the perspective of multiple stakeholders would be useful for evaluation within one month of closing the investigation. DIDE will conduct at least 2 AARs annually.
10. Summarize all outbreaks in the state on an annual basis, including lessons learned.

## Response to Bioterrorist Event

An unannounced bioterrorist event would likely present as an outbreak of unusual disease or disease of unusual severity.

In addition to the usual epidemiological investigation for an outbreak due to an agent of bioterrorism would proceed in much the same way. Investigators should expect a number of additional challenges:

- Documentation may become part of a law enforcement investigation and must be accurate, complete and up to date.
- Investigation may need to be done jointly with law enforcement
- Collaboration with multiple agencies and jurisdictions (federal, state and local) will be necessary.

The legal basis for investigation of outbreaks is found in 64CSR-7-7. The legal basis for investigation of bioterrorism is found in 64CSR-7-10. Per 64CSR 7-10.7, the local health officer is required to collaborate in “an epidemiological investigation of the bioterrorist event, usually to include a complete outbreak investigation as described in section seven (7) of this rule.”

## Surveillance Objectives:

1. Detect outbreaks at an early stage.
2. Detect and/or track emerging infectious diseases.
3. Track, characterize and summarize outbreaks in the state of West Virginia, including lessons learned on an annual basis.
4. Evaluate outbreak reporting, investigation, control and prevention efforts.

# General Outbreak Investigation / Notification Protocol

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## Disease Control Objective:

1. When an outbreak is reported, prevent additional cases through rapid and complete investigation so that control measures can be implemented quickly and additional cases prevented.

## Disease Prevention Objectives:

1. By thorough investigation of outbreaks,
  - a. Characterize risk factors so that disease can be prevented in the future.
  - b. Test / evaluate interventions to prevent and control disease to expand the scope of knowledge so that future outbreaks or cases of disease may be prevented effectively.
  - c. Remove, eliminate or mitigate ongoing sources of infection or disease.

## Public Health Significance:

Outbreak investigation is one of the major tools epidemiologists use to understand the epidemiology of a disease. Through outbreak investigation, epidemiologists learn why the outbreak occurred, and how further cases of disease can be prevented or controlled. Foodborne outbreak investigation has been compared with investigation of airplane crashes. The investigation – often after the fact – can be used to enhance knowledge and identify potential hazards in food processing and distribution. This information is then used to prevent future outbreaks.

Outbreak investigations often present opportunities to learn something new about disease prevention, diagnosis, treatment, etc. Investigation of outbreaks is also good training. The investigator who can handle a 'routine' pertussis, influenza, chickenpox or norovirus outbreak is better prepared to handle a more 'complex' investigation. In the event of a pandemic, unusually severe outbreak or bioterrorist attack, the epidemiological methods will be the same as for outbreak investigation. Thus, health departments that investigate a lot of outbreaks will be better prepared for more difficult challenges.

Public, political or legal concerns may also influence the decision to investigate an outbreak. Most health departments feel an obligation to be responsive to community concerns. Sometimes, an investigation may be initiated even if the concern has little scientific basis.

Finally, outbreak investigation may help identify weaknesses in public health programs, such as tuberculosis, food safety, immunization, infection control or

# General Outbreak Investigation / Notification Protocol

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sexually transmitted disease control. This information can then be used to strengthen the program and correct any problems identified.

The significance of outbreak investigation in learning about emerging infectious disease cannot be underestimated. Outbreak investigations have been used to characterize new diseases such as West Nile virus, intentionally disseminated *Bacillus anthracis*, SARS, monkeypox, avian influenza, and community acquired methicillin-resistant *Staphylococcus aureus*, Influenza (H3N2)v, etc.

## Surveillance Indicators:

1. Number of outbreaks reported by each county and region
2. Proportion of outbreaks with complete and appropriate laboratory confirmation.
3. Time lag between notification of the appropriate agencies:
  - a. Local health department (by DIDE)
  - b. Division of Infectious Disease Epidemiology (DIDE) by the local health department
4. Number of final outbreak reports generated by each county that contain the minimal requirements set by CDC.
5. (Statewide) Availability (yes/no) of an outbreak summary for the year, including lessons learned.