

# Healthcare Associated Infections (HAI) Outbreak Investigation / Notification Protocol

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## Definitions:

- **HAI Outbreaks** are defined as an increase in the number of hospital-acquired or healthcare facility-acquired cases of disease among patients or staff *over and above the expected number of cases*\*.
  - \* The expected number of cases can be determined through ongoing disease surveillance. This involves systematic collection of numerator and denominator data using standardized case definitions and surveillance methods.
- **Healthcare facilities** where HAI outbreaks can occur comprise both in-patient and out-patient settings included, but not limited to hospitals, nursing homes, rehabilitation centers, clinics, dialysis or cancer treatment centers, ambulatory surgery centers, physician offices, dental clinics, laboratories and any other facility which provides health care or diagnostic services to individuals, whether public or privately owned.
- Definitions of common healthcare associated infection (HAI) outbreaks
  - **An influenza or influenza-like illness (ILI) outbreak** is defined as
    - Three or more cases of influenza-like illness in a defined setting within a 3-day period (e.g., hospital unit, long term care facility, etc.),**OR**
    - One or more laboratory-confirmed cases of influenza within a 3-day period in a long term care facility**OR**
    - An increased absenteeism in association with ILI and/or laboratory confirmed influenza in healthcare workers.
  - **A Norovirus outbreak** is defined as onset of two or more epidemiologically linked cases within a three day period, where a case is defined as someone with 2 or more episodes of vomiting or three or more episodes of diarrhea within 24 hours.
  - **A *Clostridium difficile* infection (CDI) outbreak** is defined as three or more epidemiologically linked CDI cases within a period of  $\leq$  seven days.
  - **A Multi-drug Resistant Organism (MDRO) outbreak** is defined as an increase in the number of facility-acquired MDRO cases above and beyond the endemic (baseline) level in a certain facility/unit during a specific time period, and may include an increase in cases of methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococcus (VRE), carbapenem-resistant *Klebsiella pneumonia* (CRKP) or other carbapenem-resistant *Enterobacteriaceae* (CRE), multi-drug resistant *Acinetobacter* or *Pseudomonas*, or any other multi-drug resistant organisms.

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- Two or more infections with the same organism in patients receiving the same procedure within a short period of time (e.g. invasive staphylococcal infection in patients undergoing epidural or intraarticular injection, postoperative infection such as bacterial or fungal endophthalmitis in patients undergoing extracapsular cataract extraction and intraocular lens implantation, etc.)
  
- **A single case may constitute an outbreak, for example:**
  - a. Vancomycin-intermediate *Staphylococcus aureus* (VISA) or vancomycin-resistant *Staphylococcus aureus* (VRSA)
  - b. Any unusual multidrug-resistant organism (MDRO) or MDRO with an unusual resistance pattern conferring resistance to critical antibiotic(s)
  - c. Legionellosis if the patient has been in the healthcare facility for the entire incubation period (10 days)
  - d. Acute hepatitis B or C in a patient who had an invasive procedure during the incubation period and no other risk factors for hepatitis
  - e. Botulism in a patient who recently received botox injections
  - f. Exotic infection in a transplant or transfusions recipient with no additional risk factors for the disease (e.g. rabies, West Nile virus, etc.)
  - g. Post-procedure infection with an unusual organism (e.g. invasive fungal infection after an epidural procedure in an immunocompetent patient.)
  
- **Other outbreak definitions:**
  - a. **A chickenpox outbreak** is defined as 3 or more cases in a long-term care facility within 1 incubation period.
  - b. **A pertussis outbreak** is defined as two or more cases clustered in time (e.g., cases occurring within 42 days of each other) and space (e.g., in one building) where transmission is suspected to have occurred in that setting (e.g., nosocomial transmission in a hospital) with at least one case culture or PCR-confirmed.
  - c. **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.
  - d. **A waterborne disease outbreak** is defined as two or more persons who experience a similar illness after consumption or use of a common water source.

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## Healthcare Facility Infection Preventionist/Hospital Epidemiologist/Director of Nursing/Physician Responsibilities:

1. Report suspected **HAI outbreaks**, as well as all other 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, 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 submission of specimens if needed.
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;
  - b. Clinical and/or laboratory information for persons meeting the outbreak case definition;
  - c. Other epidemiologically necessary information for investigation and control of the outbreak;
  - d. If a case-control or cohort study is needed for the investigation, the local health department may also request information on well persons from the same setting.

## Laboratory Responsibilities:

1. Report suspected **HAI outbreaks**, as well as all other 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, including retrospective data on particular pathogens related to an outbreak

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## 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 **HAI outbreaks**, as well as all other outbreaks, to the local health department immediately upon recognition of the outbreak.
2. Detect outbreaks: to detect outbreaks, consider the following:
  - a. Regular systematic review of routine surveillance data
  - b. Review reports by one or more patients
  - c. Review reports by astute, alert clinicians and/or infection preventionists who are concerned enough to call the LHD
3. When an outbreak is reported:
  - a. Notify DIDE immediately (within 60 minutes)
  - b. Report the time of LHD notification
  - c. Expect an outbreak number to be assigned by DIDE staff to your outbreak
  - d. Use this assigned outbreak number in all correspondence related to this outbreak such as laboratory slips, final reports, email communications, etc.
  - e. Negotiate responsibilities of 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
  - f. Discuss your initial investigation steps and control measures with DIDE staff
  - g. Expect DIDE staff to refer you to the appropriate outbreak toolkit, if available
  - h. Agree on appropriate laboratory testing at OLS or other appropriate laboratory. 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.
  - i. Agree on data to be collected on a line list, such as demographics, clinical, laboratory, etc. and the timeframe to collect this data
  - j. Agree on regular update frequency (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:

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1. Assemble information on the disease, including protocols, reference books, information sheets, outbreak toolkits and investigation forms. The 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 necessary.
  - 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, state 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.
- b. Step 2: Establish the existence of an outbreak
- i. Determine the *expected* incidence of the disease by use of healthcare facility 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.
- c. Step 3: Verify the diagnosis
- i. Review clinical findings, laboratory results, and medical records if necessary. Compare the results with established case definitions.

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- ii. Talk to healthcare facility staff, including the infection preventionist, nurses and physicians caring for patients. Gather other information, including: What do they think caused the illness? What were the patient exposures prior to becoming ill?
- iii. Submit laboratory tests if not already done.
- iv. Consult a medical epidemiologist regarding diagnosis, especially if you are unfamiliar with the clinical syndrome.
- d. Step 4: Construct a working case definition
  - i. Base your case definition on established case definitions used for surveillance in health care settings, including National Healthcare Safety Network (NHSN) or McGeer's criteria. A good case definition:
    1. Uses a few simple clinical criteria
    2. May be restricted by person, place and/or time
    3. Does not include an exposure or risk factor you want to evaluate
    4. May be 'loose' and/or 'sensitive' if used for case-finding or 'specific' and/or 'tight' if used for hypothesis testing
    5. Your case definition may and should change as you acquire more information
- e. 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 patients that meet the case definition **OR**
    2. Active surveillance: review laboratory results and/or facility records for patients that meet the case definition.
  - ii. Collect the following information, as appropriate, on every case:
    1. identifying information (name of patient, name of healthcare facility, unit information, and room number)
    2. demographic information (date of birth, gender)
    3. clinical information (signs, symptoms, diagnostic tests)
    4. risk factor information
    5. names of and details for other people with a similar illness
    6. reporter information
  - iii. Organize the information in a line listing
- f. 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 within the healthcare facility
  - iii. Person: Calculate the proportion of affected individuals. A nursing home outbreak might be characterized by nursing unit, room number, those attending specific functions, or resident versus staff. Consider

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other factors, such as exposure to shared equipment, invasive procedures, medication, etc. when looking at proportion of affected individuals.

***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.***

g. Step 7: Develop hypotheses.

- i. Review the data collected thus far. What are the implications of your findings?
- ii. Talk to facility staff about risk factors and the proportion exposed to suspected risk factors who may not have become ill. Contact DIDE for suggestions if you have difficulty pinpointing likely risk factors.
- iii. Summarize hypotheses.

h. 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 may be necessary to test hypotheses. Contact DIDE for assistance.

i. 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.

j. 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. Work closely with staff at the healthcare facility to develop control measures that are appropriate to the situation and feasible to implement. Education of staff, patients and visitors about control measures is also important and should be included as an aspect of control measure implementation.

k. 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 medical director or Director of Nursing for a long term care facility or the head of the infection prevention department of a hospital. An oral report can help build your confidence and credibility related to outbreak investigations.
- ii. A written report:

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1. Routine Outbreaks: Complete the general outbreak report form, keep a copy for your records and share a copy with:
    - a. Local Health Officer
    - b. The involved healthcare facility
    - c. DIDE within 30 days of closing the outbreak
  2. Non-routine Outbreaks: Follow the usual scientific format of Introduction, Background, Methods, Results, Limitations, Discussion and Recommendations. Keep a copy of the report for your records and share a copy with:
    - a. Local Health Officer
    - b. The involved healthcare facility
    - c. **DIDE as soon as possible**. DIDE must report selected outbreaks to CDC within 60 days of the first disease onset.
- I. 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.

## State Health Department Responsibilities:

1. Train local and 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 compiled and summarized in aggregate on an annual basis.
3. Report foodborne outbreaks to the CDC National Outbreak Reporting System (NORS) within 60 days of first disease onset.
4. Offer technical assistance, including supplemental clinical knowledge, outbreak toolkits, line lists, support for control measures, and additional resources as needed to the local health department or facility during outbreak investigation.
5. Assist with publicizing outbreaks that require more extensive investigation and/or intervention.
6. DIDE will generally take a major leadership role in the investigation if:
  - a. The local health department is unable to adequately investigate the outbreak investigation due to lack of resources or experience
  - b. The disease is an unusual or emerging infection
  - c. The disease is unusually severe, i.e., resulting in hospitalization, death or disability
  - d. The disease requires complicated medical or diagnostic evaluation
  - e. An analytical epidemiological study is required for full investigation

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- f. The case-patients arise from multiple local jurisdictions, or are part of a multi-state or international outbreak.
7. Serve as a liaison with CDC when outbreaks are complex, involve multiple states and/or countries, and when additional laboratory testing is needed.
8. 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
9. 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.
10. 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.
11. Summarize all outbreaks in the state on an annual basis, including lessons learned.

## **Surveillance Objectives:**

1. Detect outbreaks at an early stage.
2. Detect and/or track emerging healthcare-associated infectious diseases and/or healthcare practices that put patients at risk for infection.
3. Track, characterize and summarize HAI outbreaks in the state of West Virginia, including lessons learned on an annual basis.
4. Evaluate HAI outbreak reporting, investigation, control and prevention efforts.

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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 and document lessons learned so that outbreaks 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 causes, distribution, and control of disease in a population. Investigation of healthcare-associated infection (HAI) outbreaks plays a critical role in both identifying and correcting infection control problems in health facilities.

Numerous recent outbreaks of hepatitis B and C resulted from unsafe injection practices. Outbreaks have been attributed to narcotic diversion by a healthcare worker<sup>1</sup>, common use of saline bags and reuse of single-dose vials<sup>2</sup>, and improper use of blood glucose monitoring equipment<sup>3</sup>. Investigation of these outbreaks and publication of the findings led to the national injection safety campaign.

Other HAI outbreaks have highlighted infection control issues in outpatient facilities. An outbreak of Hepatitis B in a mobile dental clinic was associated with multiple potential breaches and lack of dedicated personnel to plan and oversee infection prevention and control<sup>4</sup>. An outbreak of central line-associated blood stream infections (CLABSI) caused by *Tsukamurella* in an outpatient clinic was associated with improper environmental cleaning procedures and improper disinfection of central lines before access<sup>5</sup>. Central lines were disinfected non-sterile cotton balls soaked in alcohol from a common dispenser. In addition, the clinic used a common saline bag to prepare all the saline flushes needed during the day, disinfecting the port with non-sterile cotton balls and alcohol from a common dispenser. These outbreaks illustrate problems with infection control in outpatient clinics, where infection control expertise is not readily available.

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Two recent outbreaks involving contaminated preservative-free methylprednisolone (MPA) have called attention to infection control practices in free-standing compounding pharmacies. A large multi-state outbreak of invasive fungal infections, including meningitis was reported in October 2012, and has resulted in 749 cases and 63 deaths as of August 2013<sup>6, 7</sup>. A second recent outbreak from the spring of 2013 was associated with local skin and soft tissue inflammation at the site of injection<sup>8</sup>. These outbreaks have led to calls for regulation of compounding pharmacies.

MDRO outbreaks have drawn attention to the interconnections between different types of healthcare facilities. An outbreak of carbapenem-resistant *Klebsiella pneumonia* (CRKP) in West Virginia was reported by a local hospital noticed an increase of CRKP infections in patients associated with a nearby long term care facility (LTCF)<sup>9</sup>. This outbreak was associated with multiple infection control breaches and a vacant infection prevention position in the LTCF. Control of a country-wide outbreak of CRKP in Israeli hospitals<sup>10</sup>, has been addressed through a national intervention. This suggests that regional interventions may be most effective for control of CRE<sup>11</sup>.

Several relatively recent outbreaks have occurred in association with organ and tissue transplants. These include *Clostridium* infections caused by contaminated human allograft tissues<sup>12</sup>, West Nile virus<sup>13</sup>, rabies<sup>14,15</sup>, and lymphocytic choriomeningitis virus<sup>16</sup> transmission through organ transplants. These reports identified important safety gaps associated with transplantation of human tissues and organs that have been or are currently being addressed.

As highlighted above, outbreak investigation can help identify weaknesses in infection control programs and practices. This information can then be used to strengthen the program and correct any problems identified. These actions may be applied on a local, statewide, or even national level. The significance of outbreak investigation in learning about emerging healthcare-associated infections cannot be underestimated. The procedures and techniques employed in the healthcare setting are constantly evolving, and our understanding of how to prevent infections associated with these practices is vitally important for patient safety.

## **Surveillance Indicators:**

1. Number of HAI outbreaks reported by each county and region
2. Proportion of HAI outbreaks with complete and appropriate laboratory confirmation
3. Time lag between notification of the local health department and Division of Infectious Disease Epidemiology (DIDE)
4. Number of final outbreak reports generated by each county that contain the minimal requirements set by CDC and being shared with pertinent partners

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5. (Statewide) Availability (yes/no) of an outbreak summary for the year, including lessons learned and evaluation measures

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