Outbreak Investigations
The purpose of this chapter is to provide general guidance for outbreak investigations. For disease-specific guidance, consult disease-specific guide to surveillance and investigations (GSI) chapters, subject matter experts, and/or regional support staff.

PROTOCOL CHECKLIST

☐ Prepare for the outbreak investigation (including communication strategies) (see page 2)
☐ Verify the diagnosis (see page 2)
☐ Establish the existence of an outbreak (see page 3)
☐ Define and identify cases (see page 4)
  ☐ Prepare a working case definition
  ☐ Establish a data management system and common terminology
  ☐ Identify additional cases
☐ Implement control and prevention measures (see page 6)
☐ Describe the outbreak (see page 7)
  ☐ Prepare an EpiCom
☐ Develop hypotheses (see page 7)
☐ Evaluate and refine hypotheses (see page 8)
☐ Evaluate and refine control and prevention measures (see page 8)
☐ Communicate findings throughout (see page 9)

TECHNICAL APPENDIX

A. Investigation of Seasonal Influenza or Influenza-Like Illness Outbreaks in Long-Term Care Facilities and Health Care Facilities (see pages 11-16)
Outbreak Investigations

1. PREPARE FOR THE OUTBREAK INVESTIGATION

A. Identify staff resources
   - Know your local staff resources:
     - Primary epidemiologic contact
     - Medical staff available for consultation
     - Staff members capable of performing clinical testing and/or specimen collection
     - Staff member capable of conducting field interviews
     - Staff members capable of data management/analysis
     - IT staff for technological support
     - Environmental health staff to conduct environmental assessments
     - Staff member(s) responsible for communication
   - Know your support staff resources:
     - Subject matter expert for the diseases
     - Your Regional Epidemiologist–Laboratory Liaison
     - Your Regional Environmental Epidemiologist
     - Other
       - These may include consortium epidemiologist, epidemiology strike teams, and any other work-related organizations or any memorandum of understanding (MOU) for your region. Outbreaks may require assistance from outside organizations and agencies, such as Florida Department of Agriculture and Consumer Services, Centers for Disease Control and Prevention (CDC), health care providers, infection control prevention practitioners or Florida Poison Information Center Network.

B. Familiarize yourself with outbreak resources
   - Read disease-specific GSI chapters.
   - Train and practice with outbreak data management software (e.g., Epi Info™).
   - Read Field Epidemiology by Michael B. Gregg.
   - Have the Control of Communicable Diseases Manual (CCDM) and Red Book available for reference.

2. VERIFY THE DIAGNOSIS

A. Contact the reporting provider
   - Obtain clinical information.
   - Ensure the reported condition is clinically compatible.
   - If you are unsure about the diagnosis, contact your support staff.

B. Review any laboratory results
   - Make sure the results are appropriate for reported condition.
   - Ensure that the result is not due to a laboratory or interpretation error.
   - Forward the specimen to the Bureau of Public Health Laboratories (BPHL) for confirmation when appropriate.
• Contact your support staff if you are unsure about the laboratory results, or whether to submit specimens.

3. ESTABLISH THE EXISTENCE OF AN OUTBREAK

A. Determine if observed number of cases exceeds the expected baseline
   • Establish an expected baseline. This can be done through numerous methods depending on the type of the disease. Some examples include:
     o Data analysis in Merlin; look for geographic or seasonal patterns.
     o Review the number of cases reported in the Florida annual Morbidity Statistics Report over a similar timeframe.
     o Use ESSENCE-FL to identify similar discharge diagnoses.
     o Query the health care system’s health record for similar cases.
     o Review facility infection control records.
     o Review scientific literature.
     o Conduct a survey of people in the targeted community.
   • For certain reportable conditions, an outbreak can consist of two or more individuals (or households) with reported similar signs, symptoms, and exposure settings. Single cases of certain diseases or conditions are investigated similarly to outbreaks.
   • Collect additional specimens from those who are symptomatic to verify the existence of an outbreak and submit to BPHL for confirmation.
   • If you are unsure if the number of cases exceeds the baseline, contact your support staff and they can assist in developing methods for verifying the existence of an outbreak.

B. If the existence of an outbreak is established:
   • Notify your supervisor.
   • Determine with your supervisor and potentially your support staff if an incident management team (IMT) is needed, possibly including an incident commander.
   • Determine if personnel must function outside of normal duties. Personnel should request permission from their supervisor to participate in outbreak activities outside of their daily responsibilities.
   • Notify your appropriate support staff.
   • Prepare an EpiCom as early as possible with preliminary information, which should be updated as the investigation progresses.
4. DEFINE AND IDENTIFY CASES

A. Create a working case definition

- Case definitions can be modified as the outbreak investigation evolves.
  - Early in investigations, a loose case definition can be beneficial in understanding the scope of the outbreak and can subsequently be tightened to be more specific.
- All case definitions should include person, place and time.
  - Defining a person:
    - This should include clinical information about the disease, laboratory results, or characteristics about the people who are affected.
    - Examples may include: pregnant women diagnosed with influenza, children with a positive polymerase chain reaction (PCR) laboratory result for pertussis, or individuals with diarrhea, vomiting, or abdominal cramps in the preceding 72 hours.
  - Defining a place or setting:
    - This should be broad enough to include most cases that have a setting in common, but specific enough to minimize the number of individuals who may “falsely” meet the case definition.
    - Examples may include: at hospital A, at local elementary school B, in County C, or who ate at the Doe’s wedding rehearsal dinner.
  - Defining time:
    - This should give an idea as to when the outbreak occurred and be specific enough to replicate any search queries or investigation, including dates and years, when possible.
    - Examples may include: in 2014, from March 26 through May 19 2014, after June 29, 2013.
  - Examples:
    - Students with pertussis-like symptoms for greater than two weeks who attended School A in XXX County between January 1, 2014 and February 1, 2014.
    - Individuals with eye pain, corneal abrasions, or conjunctivitis following attendance at a foam party at Club A on March 26, 2014.
- Once a basic working case definition has been developed, different levels of the outbreak case definition can be established based on the certainty of a case being a “true case”. For reportable conditions, these criteria are in the reportable disease case definitions.
  - For example: confirmed cases (usually meet clinical case definition with laboratory confirmation or epidemiological links), probable cases (meeting the clinical case definition but lacking laboratory confirmation), and possible/suspect cases (individuals who need more investigation to determine if they meet the case definition but cannot at the time be ruled out as cases).

B. Establish a data management system

- Identify what data to collect and its purpose prior to conducting an outbreak investigation. These steps improve data quality and save time on analysis.
- Determine which software to use and its limitations prior to collecting data.
  - Review existing case report forms and any extended data screens in Merlin.
o Consider the need to create an incident-specific questionnaire or case report form.
o Determine if multiple data entry staff will be needed.
o Consider if data can be entered/collected remotely.
o Minimize redundancy in reporting into multiple data systems.
• Contact your support staff to assist in developing a data management system for the outbreak investigation.
• If investigating a reportable condition/disease, ensure that all persons meeting the Florida case definition are entered into Merlin.
o Merlin is the official tool for all reported cases during the investigation; however, other data management tools may be more useful in contact tracking, form design, epidemiologic studies, data analysis, etc.

C. Establish common terminology
• All individuals working together in the investigation should be utilizing common terminology for the investigation, and this is especially critical when multiple jurisdictions/agencies are involved in the investigation.
• Previous large-scale investigations have identified this need and some common terms identified are:
o Number of persons exposed: The identified number of persons in the investigation that had contact/exposure to/with a person/vector/product that could have resulted in an illness.
o Number of persons contacted: This is the number of exposed persons that public health resources have attempted to notify of the risk to their health from their contact/exposure during the course of the investigation.
o Number of persons reached: The total number of persons that were contacted and were successfully given a public health notification as a result of the investigation.

D. Communication during an investigation
• Communication between public health agencies during the investigation:
o An official point of contact should be designated at the county and state level.
  ▪ All contact between agencies should be through the official points of contact.
  ▪ Direct contact outside of the established outbreak chain of command with deployed staff is discouraged.
  ▪ All media inquiries should be handled by a specified point of contact designated by the Incident Commander or lead investigator in accordance with the communication strategy for the outbreak.
• Updates of findings should be communicated to the Incident Commander or official point of contact regularly.
o Updates should occur no more frequently than once per day.
o As the investigation progresses the frequency of regular updates with leadership should become less frequent.
o For a non-communicable disease, consider a weekly reporting schedule, as this will allow for the validation of cases prior to reporting.
• Communication to exposed individuals during the investigation (if warranted):
o Health care providers can be a valuable resource in contacting and notifying patients, especially during investigations involving exposures in a health care setting.
o When health care providers are unable or refuse to contact patients about exposures involving a health care setting, DOH is responsible for ensuring contact to exposed individuals.

E. Identify additional cases

- Determine which persons are at risk of becoming ill.
- Develop a surveillance strategy to identify additional cases.
- If applicable, collect additional laboratory samples/specimens.
- Exposed individuals determined to be at greatest risk of becoming ill or having the most adverse health outcomes should be prioritized for follow up.
  - Strategies for determining prioritization varies depending on the incident, but may include:
    - Amount of time individual was exposed
    - Number of exposures
    - Exposures to a specific lot/product/individual where previous transmission has occurred
    - When the exposure occurred
    - The presence of risk factors (i.e., pregnant women)
- Consider methods to identify additional cases based on the specific incident. Examples of methods to identify additional cases may include:
  - ESSENCE-FL search queries for chief complaints or discharge diagnoses
  - Medical record abstraction (remotely or in person)
  - Interviews of exposed individuals may include contact tracing, public outreach, and active surveillance
  - Randomized serosurveillance

5. IMPLEMENT CONTROL AND PREVENTION MEASURES

A. NOTE: THIS SHOULD BE DONE AS SOON AS POSSIBLE

- During most outbreaks, control measures can be identified early, prior to laboratory result confirmation or completion of epidemiologic data analysis.

B. Ideally, use data driven measures aimed at limiting transmission or exposure in the:

- Host
  - Cohorting
  - Isolating/quarantining
  - Vaccinations
  - Chemoprophylaxis
  - Behavioral modifications
- Agent
  - Antimicrobials
  - Vector reduction/removal
- Environment
  - Modifying air flow or limiting contact
  - Disinfection/sterilization of environment
  - Destruction of breeding sites or of contaminated foods/products
  - Vector reduction/removal
6. DESCRIBE THE OUTBREAK

A. Orient the data in terms of person, place and time

- Person descriptive epidemiology (minimum):
  - Number ill
  - Number exposed
  - Attack rates
  - Descriptive characteristics of ill and exposed
    - Age
    - Race/Ethnicity
    - Gender
    - Other demographic risk factors
  - Severity of incident (number hospitalized, mortality)
  - Incident specific risk factors (i.e., vaccinated, foods eaten, lot number)
  - Symptomology

- Place descriptive epidemiology (minimum):
  - Number ill per setting
  - Number exposed per setting
  - Attack rate per setting
  - Incident specific settings (i.e., grade level, daycare, hospital floor, ZIP codes)

- Time descriptive epidemiology (minimum):
  - Epi curve of symptom onset
    - Plot the frequency of cases with onset on the y-axis and by the date (or other time period) their symptoms began on the x-axis
  - Epi curve of exposure to causative agent
    - Plot the frequency of cases with exposure on the y-axis and by the date their exposure occurred on the x-axis
  - Duration of illness

- If you have any questions on how or what to include in orienting the data, contact your support staff.

B. Prepare an EpiCom for the outbreak (see guidance at:
https://floridahealth.sharepoint.com/sites/DISEASECONTROL/EPI/Shared%20Documents/epidemiology/surveillance-systems/epicom/epicom-user-guide-v2-1.pdf?e=4%3Afbd6721d79b34e41a5232b2657bbf6ea)

- Items to include:
  - Person
  - Place
  - Time
  - Relevant exposures
  - Status of the investigation
  - Control measures

7. DEVELOP HYPOTHESES

A. Generate examinable hypotheses that could explain how and why the outbreak occurred.

- Generating hypotheses should be performed at various steps throughout the process to ensure testable hypothesis data is captured in steps 2-5 above.
• Consider what you already know about the disease and its transmission.
• Identify any previously known risk factors by consulting the following resources:
  o Red Book, CCDM
  o Literature review
  o Subject matter experts or regional support staff
  o CDC, FDA, NIH websites
• Utilize open-ended and wide-ranging questions early on while verifying the diagnosis for common exposures or individual traits.
• Use descriptive epidemiology to generate hypotheses:
  o What is the epi curve suggesting and what events occurred around the exposure period?
  o Does a particular area, grade, or school have a higher attack rate?
  o Are persons of a different age, vaccine status, or sex at greater risk of illness?
• If you need assistance in generating hypotheses throughout the entire process of the investigation, contact your support staff.

8. EVALUATE AND REFINE HYPOTHESES

A. Use analytic epidemiology to test your hypotheses
   • Determine which type of study your outbreak investigation fits (e.g., cohort, prevalence, case-control).
   • Select appropriate statistical test methods for type of study.
   • Contact your support staff if you are having challenges in analyzing your hypotheses.

B. Determine if your results are confounded by additional factors
   • Utilize analytical methods to control for confounding factors where appropriate.

C. Continue to develop and evaluate hypotheses
   • Compare and control for risk factors affecting outcomes of interest.
   • Incorporate clinical and environmental samples as dictated by investigation.
   • Modify questionnaire or survey instruments as needed.
   • If previous hypotheses fail to yield results, the need to re-interview those infected or ask additional open-ended questions may be necessary.

9. EVALUATE CONTROL AND PREVENTION MEASURES

A. Use results from hypotheses testing to initiate any additional control and prevention measures
   • If more infected persons continue to be identified following implementation of control and prevention measures:
     o Determine if additional control and prevention measures need to be implemented as driven by data analysis.
     o Determine if currently implemented control measures are having the desired impact in control and prevention of the disease/condition.

B. As investigation progresses, continue to assess if control and prevention measures are sufficient
10. COMMUNICATE FINDINGS

A. Report investigation findings to stakeholders
   - Can be oral
     o Stakeholder meeting
     o Epidemiology Biweekly Conference Call
     o Bureau of Epidemiology Grand Rounds
   - Can be written
     o EpiCom post
     o Stakeholder reports
     o Epi Update article
     o Peer-reviewed published manuscript

B. Written reports should follow the scientific method including:
   - Background/Introduction (What is already known? What started the Investigation?)
   - Methods (What was done?)
   - Results (What was the outcome? What was found?)
   - Discussion and Recommendations (What was learned? What could be improved? What could prevent future incidents?)
   - References (Where can others find useful information on this topic?)

C. If assistance is needed in communicating findings, contact your support staff

11. IMPORTANT LINKS

A. Surveillance and Investigation Guidance:

B. FOCUS on Field Epidemiology:
   http://sph.unc.edu/nciph/focus/

C. Centers for Disease Control and Prevention Principles of Epidemiology in Public Health Practice, Third Edition, Lesson Six:

12. REFERENCES


13. TECHNICAL APPENDIX

A. Investigation of Seasonal Influenza or Influenza-Like Illness Outbreaks in Long-Term Care Facilities and Health Care Facilities (see pages 11-16)
Technical Appendix A: Investigation of Seasonal Influenza or Influenza-Like Illness Outbreaks in Long-Term Care Facilities and Health Care Facilities

This document expands upon the steps detailed in the outbreak investigations chapter of the Guide to Surveillance and Investigations in the context of respiratory disease or influenza-like illness outbreaks in long-term care facilities and health care facilities with an inpatient population.

Report of an Outbreak Received

Reports may be received from anyone (facility staff, patients, families, ombudsman, anonymous, other health care providers, etc.). Although some discretion and prioritization is expected, generally all reports of suspected outbreaks should be investigated to verify the diagnosis and the existence of an outbreak.

Verify the Diagnosis

- Contact the staff member responsible for infection prevention and control, director of nursing, or administrator of the facility.
- Request a brief (usually verbal) summary of the available clinical information of ill patients/staff to determine the general signs/symptoms/syndrome and any available laboratory test information. This should be obtained upon first contact, or same day.
- One positive laboratory result for influenza should be considered suspicion of an outbreak and result in enhanced surveillance within the facility.
- If a facility calls to report any ILI illness in a patient(s) or concerns that an ILI outbreak may be occurring, regardless of whether the outbreak case definition is met, the CHD should provide enhanced surveillance and disease control recommendations.
- Request records for patients that have been seen at emergency departments (ED), hospitalized, or died with a respiratory illness. This may include notes from: ED, admission history and physical, infectious disease consult, laboratory/microbiology records, death certificates, and discharge summary. These are typically obtained directly from the hospital.
- Notify supervisors and regional epidemiologists according to county health department (CHD) guidelines.
- Document the outbreak information within Merlin Outbreak Module with 48 hours of initial report and update as new information becomes available.

Establish the Existence of an Outbreak

- To define the population at risk, request the count of all staff and residents/patients.
- Health care facilities routinely include populations at high risk of severe infection from influenza, therefore a low threshold for detecting and defining outbreaks should be established.
- In long-term care facilities, an outbreak is defined as ≥2 patients experiencing influenza-like illness within 72 hours.
  - A single influenza positive laboratory result confirms that an influenza outbreak is occurring.
- In other health care facilities with an inpatient population:
An outbreak may be defined as ≥ 2 patients that develop infection >24 hours after admission with an epidemiologic linkage (e.g. in the same unit, shared health care workers, etc.), with the illness onsets within 72 hours.

If the facility has historical data to establish a baseline of influenza-like illness among their inpatient population, this information can be used to determine if they are exceeding the expected count, or rate, of infection.

Immediately Implement Control and Prevention Measures

- During the initial conversation with the facility staff, discuss recommended prevention and control measures.
- Provide recommendations and requests verbally and in writing by fax, email, or in-person.
- The facility should implement the existing CDC Guidelines for long-term care facilities. The Florida checklist summary document may be used to track the implementation of control measures.
- For health care facilities for which guidelines do not exist, the above guideline can be referenced, considering differences in the scope and intensity of the recommendation based on the impacted patient population. The recommendations are established in consultation with the facility medical director, medical epidemiologist (for hospitals), or infection prevention staff.
- Recommendations should focus on all reasonable measures to protect populations at high risk of complications from influenza.
- In some circumstances, antiviral medications may be provided by DOH central pharmacy for treatment and prevention of influenza during outbreaks. Refer to the documents for guidance: Considerations for Requesting Antivirals for the Treatment and Prevention of Influenza from the DOH Central Pharmacy Stockpile for Outbreak Response and the Public Antiviral Conops 2018 (Influenza SharePoint)
- County epidemiology staff should consider notifying the regulatory agencies (e.g. Agency for Health Care Administration [AHCA]) of influenza or IILI outbreak investigations in long-term care facilities, for which the facility is not communicating in a timely manner or not cooperating with recommendations. Key areas of concern include: lack of outbreak reporting, delayed communication, and delayed use (or lack of use) of antiviral treatment and chemoprophylaxis. Regional AHCA field offices contact information.
- While the Department’s role is to provide informed, clear and confident outbreak control recommendations, County Health Officers have broad authority to investigate and require control measures for reportable diseases, including outbreaks, as described in Chapter 64D-3, Florida Administrative Code. In certain circumstances, a County Health Officer, in consultation with legal counsel, may take steps to require compliance with epidemiologic investigation and control measures.

Submit Specimens to the Bureau of Public Health Laboratory (BPHL)

- Coordinate the collection and submission of specimens to the BPHL.
- Provide viral transport media specimen collection kits (≤5) to the facility.
Submit 3-5 nasopharyngeal (preferred) or oropharyngeal (throat) specimens from acutely ill patients (preferably for those who have been symptomatic for less than three days) for influenza and respiratory virus panel PCR. Swabs MUST be placed in 2-3 ml of viral transport media immediately after collection. Keep specimens refrigerated at 4ºC (NOT frozen) and ship on gel ice no later than 48 hours after collection. Pick up specimens, ensure proper labeling, and arrange shipping to your servicing BPHL location for arrival on a business day. Complete the DH1847 lab submission form for each specimen, including details regarding symptoms, vaccine status, and antiviral administration. See example below. Notify the laboratory and/or regional epidemiologist and laboratory liaison when specimens are being sent. Update the “people roster” within the Merlin Outbreak Module for each person who had a specimen collected for submission to BPHL for testing according to existing guidelines. Provide laboratory results to submitting facilities when received from BPHL.

Define and Count Cases

A simple ILI case definition: A resident/patient/staff member of [facility/unit/building] that has fever with cough or sore throat with onset after [insert date].
- May want to include persons diagnosed with pneumonia
- Elderly and immune compromised persons may not develop fever, therefore consider the presence of other respiratory symptoms to determine case status.
- Sometimes the clinical spectrum is wide and all acute respiratory illnesses are included.

It is routine that CHD staff will ask for information on all persons experiencing symptoms and then refine the case definition and classify cases. It is not recommended to rely on facility staff to classify cases; this may result in underreporting due to misunderstanding of clinical vs. epidemiologic case definitions. Provide a line list for the facility to complete for ill staff and residents/patients. One example is provided below, although CHDs can create other versions. Request that the completed line list is returned the next business day. Collect information on variables that include: the individual’s demographics, location in the facility, symptoms, pneumonia diagnosis, hospitalization, death, microbiology test results, vaccination, etc. Simple data management and analysis can be conducted in Microsoft Excel or Epi Info. Request daily updates to the line list.

Describe the Outbreak and Monitor the Effectiveness of Control Measures

Routinely quantify the count and proportion of case demographics, symptoms, pneumonia diagnoses, hospitalization, death, microbiology test results, etc. Summarize data obtained from hospitalization records to add to the available information. Create an epidemic curve by plotting the number of cases in residents and staff by onset day to visualize the pattern of cases.
- Request and document the number of staff and residents that have received the current season’s influenza vaccine.
- Request regular updates and document the implementation of control measures.
- Request and document antiviral treatment and antiviral chemoprophylaxis.
- Case information should be analyzed frequently to monitor the effectiveness of the interventions.
- Discuss interpretations of the findings with the facility to impact control measure implementation.

Develop Hypotheses/Evaluate and Refine (OPTIONAL - NOT GENERALLY APPLICABLE)

Evaluate and Refine Control and Prevention Measures (OPTIONAL - NOT GENERALLY APPLICABLE)

Communicate findings

- Create informal summaries of the analysis to share with peers, supervisors, and stakeholders as needed.
- Follow local guidelines for sharing information with CHD administration, especially for high severity or high publicity outbreaks.
- Document the outbreak information within Merlin Outbreak Module with 48 hours of initial report and update as new information becomes available. Complete all fields in the ILI survey, even if the fields are unknown.
- EpiCom posting is recommended, particularly for outbreaks that are notable (e.g. first outbreaks of the season, unusual disease patterns/severity/populations affected, effective use of control measures, multijurisdictional, etc.).
- Create a final report and share with stakeholders according to CHD guidelines.

For investigation and response consultations or assistance contact your regional epidemiologist and laboratory liaison.
Example Respiratory Illness Outbreak Line List

<table>
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<tr>
<th>Name</th>
<th>DOB</th>
<th>Sex</th>
<th>Room # (NA for staff)</th>
<th>Date of onset</th>
<th>Fever (highest temp.)</th>
<th>Cough</th>
<th>Sore throat</th>
<th>Congestion</th>
<th>Runny Nose</th>
<th>Muscle aches</th>
<th>Vomiting or diarrhea</th>
<th>Pneumonia</th>
<th>X-ray results</th>
<th>Influenza Lab Result</th>
<th>Influenza vaccine Y/N (+ date)</th>
<th>Hospitalized</th>
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<th>Comments</th>
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