

Tips for Applying CDC's Infection Surveillance Guidance in Long-term Care Facilities (LTCF)

This summary of surveillance tips may be useful for infection preventionists (IPs) applying infection surveillance definitions to resident conditions. The Centers for Disease Control and Prevention (CDC), along with experts in long-term care, developed a national standard for infection surveillance in LTCF entitled, *Surveillance Definitions of Infections in Long-Term Care Facilities: Revisiting the McGeer Criteria* (Stone et al., 2012), which defines the resident symptoms and other clinical criteria that are used to meet infection surveillance definitions. Infection surveillance definitions are essential for consistently monitoring infections over time and to determine where infection prevention efforts are needed. A log or linelist can help organize information about resident infections).

Infection Linelist

The linelist should be monitored and updated regularly to identify clusters, outbreaks, and other unusual infection patterns. Infection cues that an IP can use to determine whether a resident may have an infection include:

- Antibiotic starts; while this can be a helpful trigger for tracking possible infections, it is not enough information to determine if an infection is present or the type of infection.
- Residents' signs and symptoms of infection: nursing personnel's recognition, assessment, documentation, and communication of resident symptoms impact the IP's ability to apply infection surveillance definitions, as they are based on specific symptom criteria.

Criteria needed to meet standardized infection definitions

Clinical information

Infection surveillance definitions require clear, descriptive symptom documentation. See the table below for examples.

Less descriptive symptom documentation	More descriptive symptom documentation
Fever	Specific temperature reading (e.g. 100.1°F)
Shortness of breath	Respiratory rate, oxygen saturation
Cough	Dry cough; productive cough

- If multiple symptoms are present, the onset date of each symptom should be noted.
- Many infection definitions require a change from baseline (e.g. symptom is new or increasing). Consider establishing a protocol for determining and documenting baseline values.
- If symptoms documented on the linelist suggest a potential infection, an IP should complete a worksheet to determine if infection surveillance criteria have been met (see Appendix X).
- Infection surveillance definitions should not be based on a single piece of evidence; clinical presentation and microbiologic/radiologic evidence must be considered if available.

Sources of resident data

- Sources of resident data are often documented in a variety of locations (e.g. electronic medical record progress notes, paper logs, 24-hour board). Ensure all relevant data sources are reviewed for evidence of resident infection.

Device use

- Clearly document the presence of urinary catheters. Note that CDC surveillance definitions for urinary tract infections (UTI) are different for residents with urinary catheters compared to those without.

Microbiology cultures

- The microorganism species and colony counts from urine cultures should be included on a UTI linelist, as CDC UTI definitions use different parameters based on the method of urine specimen collection:
 - At least 10^5 colony-forming units (cfu)/mL of no more than 2 species of microorganisms in a voided urine sample
 - At least 10^2 cfu/mL of any number of organisms in a urine sample collected by in-and-out catheter
 - At least 10^5 cfu/mL of any organism(s) in a urine sample collected by an indwelling urinary catheter

Criteria not used to meet standardized infection surveillance definitions

Some changes in resident status, including signs and symptoms, have historically been included on infection linelists, because they were thought to be indicative of a potential infection. The updated infection surveillance definitions are largely based on symptoms localizing to a specific body system (e.g. urinary tract, respiratory tract) or site (e.g. ear, skin). The examples below illustrate change in resident status documentation that should not be used to meet infection surveillance definitions.

- *Behavior and mental status changes.* While behavior and mental status changes can be important health indicators that require evaluation and follow-up, mental status changes without additional clinical symptoms will not meet infection surveillance definitions.
- *Falls.* A resident experiencing falls should be evaluated and interventions to promote safety implemented, but published studies indicate that a resident fall without additional signs or symptoms of infection is not included as a criterion that meets infection surveillance definitions (Stone et al. 2012).
- *Foul-smelling urine.* Malodorous urine can be caused by several factors, including dehydration, diet, medication, or the presence of specific bacteria. Foul-smelling urine alone does not indicate the presence of UTI as described in the CDC infection surveillance definition.
- *History of UTI.* Knowledge of a resident's UTI history may be helpful when making care decisions (e.g. teaching regarding perineal hygiene). However, a resident's *current* clinical signs and symptoms should be considered when assessing for a UTI.
- *Positive urinalysis (UA) or urine culture (UC).* Urine does not typically contain bacteria, yeast, or white blood cells (pus or pyuria) in younger, healthy people. However, bacteria and pus are frequently found in the urine of elderly and debilitated people due to increased age, chronic disease, functional impairment, invasive devices, dehydration, and other risk factors. A positive UA or UC in the absence of other clinical symptoms of UTI does not meet the CDC infection surveillance definitions.

Keep in mind that infection surveillance definitions are different than criteria used for clinical decision-making. According to CDC, "the criteria that define infections for surveillance purposes were selected to increase the likelihood that the events captured by application of the definitions are true infections. Presentations of infection in older residents of LTCFs may be atypical, so failure to meet surveillance definitions may not fully exclude the presence of infection."

For additional resources for infection surveillance in LTCF, visit the CDC website for long-term care facilities at:

<http://www.cdc.gov/longtermcare/staff.html>

Stone ND, Ashraf MS, Calder J, et al. Surveillance Definitions of Infections in Long-Term Care Facilities: Revisiting the McGeer Criteria. *Infection Control and Hospital Epidemiology*. 2012;33:965-77.

Available at: <http://www.jstor.org/stable/10.1086/667743>

An example of control techniques (by level). Each circumstance will vary. UNIT(s) affected _____

Outbreak Illness Control Plan: Date of Start of Control Plan: _____

RESIDENT/PATIENT

- Identify symptoms in resident/patient/personnel
- Take resident/patient temperatures twice a day to establish baseline and quickly identify fever.
- Residents/patients who show symptoms should be placed in Transmission-based Precautions. The healthcare personnel who discover symptoms may place patients in Precautions temporarily until order is received.
- Appropriate isolation precautions will be utilized. (**Droplet/Contact Precautions** will be considered). If there is more than one confirmed strain of virus circulating, or the cause of the outbreak is unknown, Droplet/Contact Precautions should be utilized.
- Supervisors will notify Infection Preventionist at: (email/phone) _____
- Ill residents/patients should stay in their room or apartment, unless transport is necessary, in which case they should wear a surgical/procedure mask.
- Contact Primary Healthcare Providers and work with department of public health.
- Antivirals and antibacterial agents should be used in a manner consistent with CDC recommendations and applicable law.
- Employee PPE use (Droplet/Contact Precautions) may be done without an order.

PERSONNEL

- All employees should promptly notify supervisor of any symptoms of respiratory illness in themselves, or individuals in their care. Employees who are ill will exclude themselves from work environments and will seek the advice of their healthcare providers.
- Staff may utilize extended use techniques with masks and goggles when caring for resident
- Do not wear PPE off affected units and areas unless directed as an enhanced control measure

UNIT/AREA CONTROL: Units and areas symptoms (fever, sore throat, headache, respiratory/gastrointestinal symptoms, aches and pains)

- Main unit entry doors should remain closed. Sign should be placed on area doors explaining that there is a respiratory/gastrointestinal illness, and traffic should be limited.
- Therapists to do in-room therapy
- Individual activities only. Work with Life Enrichment Department.
- Limit residents/clients to beauty shop. Limit transport of residents/clients to Beauty Shop. Wash hair in shower
- Limit residents/clients mingling with others.
- Limit Volunteer traffic and activity
- Limit/restrict intergenerational activities and those with community participants.

FACILITY CONTROL

- Infection Preventionist will contact department of public health
- Send letter out to all families (in consultation with Corporate Communications) describing control plan to prevent the spread of respiratory illness/gastroenteritis.
- Essential visitors only if there is sustained transmission of respiratory/gastrointestinal illness on a unit. Families are essential visitors, but will be screened before entry, and should be encouraged to wear a mask while on the unit.
- Nasal/pharyngeal swab for influenza, RSV, viral panel or prevailing respiratory consideration
- This action plan will cease when the infection rate has returned to a situation of no new targeted infections in 10 days.

Comments:

RESTRICTIONS LIFTED (Date) _____ SIGNED _____

An example of control techniques (by level). Each circumstance will vary. UNIT(s) affected _____

Outbreak Illness Control Plan: Date of Start of Control Plan: _____

RESIDENT/PATIENT

- Identify symptoms in resident/patient/personnel.
- Residents/patients who show symptoms should be placed in Transmission-based Precautions. The healthcare personnel who discover symptoms may place patients in Precautions temporarily until order is received.
- Appropriate isolation precautions will be utilized. (**Droplet/Contact Precautions** will be considered). If there is more than one confirmed strain of virus circulating, or the cause of the outbreak is unknown, Droplet/Contact Precautions should be utilized.
- Supervisors will notify Infection Preventionist at:(email/phone) _____
- Ill residents/patients should stay in their room or apartment, unless transport is necessary, in which case, they should wear a surgical/procedure mask.
- Document resident/patient education.
- Contact Primary Healthcare Providers and work with department of public health.
- Consider nasal/pharyngeal swab for influenza, RSV, viral panel or prevailing respiratory or gastrointestinal symptoms.
- Antivirals and antibacterial agents should be used in a manner consistent with CDC recommendations and applicable law.
- Take unit resident/patient temperatures twice a day to establish baseline and quickly identify fever.

PERSONNEL

- All personnel should promptly notify supervisor of any symptoms of respiratory illness in themselves, or individuals in their care. Personnel who are ill will exclude themselves from work environments and will seek the advice of their healthcare providers. Consider screening personnel with daily temperatures.
- Do not rotate or “float” staff off the affected unit.
- Personnel may utilize extended use techniques with masks and goggles when caring for residents.
- Personnel should not wear PPE off affected units and areas unless directed as an enhanced control measure.
- Start interdisciplinary cleaning/disinfecting (ensure competency of IDT with product) of all frequently touched surfaces every 1-2 hours and as needed with appropriate cleaner/disinfectant.

UNIT/AREA CONTROL: Units and areas symptoms (fever, sore throat, headache, respiratory/gastrointestinal symptoms, aches and pains)

- Main unit entry doors should remain closed. Sign should be placed on area doors explaining that there is a respiratory/gastrointestinal illness, and traffic should be limited.
- Ensure appropriate supplies of personal protective equipment (PPE) and cleaner/disinfectant.
- Actively look for other people with similar symptoms.
- In-room therapy and meals.
- Individual activities only. Work with Life Enrichment department. Limit/restrict intergenerational activities and volunteers and community participants.
- Limit/restrict transport of residents/clients to Beauty Shop. Wash hair in shower if appropriate.
- Limit Volunteer traffic.

FACILITY CONTROL

- Infection Preventionist will contact department of public health.
- Send letter out to all families (in consultation with Corporate Communications) describing control plan to prevent the spread of respiratory illness/gastroenteritis.
- Essential visitors only if there is sustained transmission of respiratory/gastrointestinal illness on a unit. Families are essential visitors, screen before entry, and encourage to wear a mask while on the unit.

This action plan will cease when the infection rate has returned to a situation of no new targeted infections in 10 days.

Comments:

RESTRICTIONS LIFTED (Date) _____ **SIGNED** _____

An example of control techniques (by level). Each circumstance will vary. UNIT(s) affected _____

Outbreak Illness Control Plan: Date of Start of Control Plan: _____

- Identify symptoms in resident/patient/personnel.
- Residents/patients who show symptoms should be placed in Transmission-based Precautions. The healthcare personnel who discover symptoms may place patients in Precautions temporarily until order is received.
- Appropriate isolation precautions will be utilized. (**Droplet/Contact Precautions** will be considered). If there is more than one confirmed strain of virus circulating, or the cause of the outbreak is unknown, Droplet/Contact Precautions should be utilized.
- Ensure appropriate supplies of personal protective equipment (PPE) and cleaner/disinfectant.
- Start interdisciplinary cleaning/disinfecting (ensure competency of IDT with product) of all frequently touched surfaces every 1-2 hours and as needed with appropriate cleaner/disinfectant.
- Document resident/patient education.
- All personnel should promptly notify supervisor of any symptoms of respiratory illness in themselves, or individuals in their care. Personnel who are ill will be sent home, and will exclude themselves from work environments and will seek the advice of their healthcare providers if requested.
- Actively look for other people with similar symptoms.
- Do not rotate or "float" staff off the affected unit.
- Supervisors will notify Infection Preventionist at:(email/phone) _____
- Infection Preventionist will contact department of public health.
- Ill residents/patients should stay in their room or apartment, unless transport is necessary, in which case, they should wear a surgical/procedure mask.
- Contact Primary Healthcare Providers for orders. and work with department of public health.
- Consider nasal/pharyngeal swab for influenza, RSV, viral panel or prevailing respiratory consideration, or stool cultures for gastroenteritis.
- Antivirals and antibacterial agents should be used in a manner consistent with CDC recommendations and applicable law.
- Main unit entry doors should remain closed. Sign should be placed on area doors explaining that there is a respiratory/gastrointestinal illness, and traffic should be limited.
- Send letter out to all resident, patients, families (in consultation with Corporate Communications) describing control plan to prevent the spread of respiratory illness/gastroenteritis.
- Essential visitors only if there is sustained transmission of respiratory/gastrointestinal illness on a unit. Families are essential visitors, but will be screened before entry, and should be encouraged to wear a mask while on the unit.
- Take resident/patient temperatures twice a day on entire unit to establish baseline and quickly identify fever. Consider screening personnel every shift.
- Staff may utilize extended use techniques with masks and goggles when caring for residents.
- Do not wear PPE off affected units and areas unless directed as an enhanced control measure.
- In-room therapy and meals.
- Individual activities only. Work with Life Enrichment Department.
- Limit/restrict transport of residents/clients to Beauty Shop. Wash hair in shower if appropriate.
- Limit/restrict Volunteer traffic and activity
- Limit/restrict intergenerational activities and those with community participants.

This action plan will cease when the infection rate has returned to a situation of no new targeted infections in 10 days.

Comments:

RESTRICTIONS LIFTED (Date) _____ **SIGNED** _____

Infection Criteria Checklist

Please check symptoms and lab results

Resident: _____

Room #: _____

Date: _____

Urinary Tract Infection WITHOUT indwelling catheter

AT Least ONE of the following must be present With a fever and/or leukocytosis. IF NO fever Or leukocytosis then two or more must be present: =

- Painful urination or acute pain
- Swelling of testes or prostate
- New or increase in frequency
- New or increase urgency
- New/Increase incontinence
- New flank pain or tenderness
- Supra-pubic pain
- Gross hematuria

If the above criteria are met, then ONE of the following microbiological must also be met.

- Clean catch sample 10^5 organisms/ml (100,000) of no more than 2 organisms
- Straight cath 10^2 organisms/ml (100) of any organism

Urinary Tract Infection WITH indwelling catheter

AT Least ONE of the following must be present with no other sign of infection

- Fever
- Rigors
- New onset hypotension
- Change in mental status or functional decline (with no alternate diagnosis and leucocytosis)
- New flank pain or tenderness
- Supra-pubic pain
- Purulent discharge from around the catheter
- Acute pain Swelling of testes or prostate

If the above criteria are met, then ONE of the following microbiological must also be met.

Any of the following:

If catheter removed within past 2 calendar days:

Clean catch (voided) urine culture with 100,000 or more colonies ($\geq 10^5$ CFU/ml) of no more than 2 species of microorganisms

In/Out catheter urine culture with 100 or more colonies ($\geq 10^2$ CFU/ml) of any number of microorganisms

If indwelling urinary catheter in place:

Positive urine culture with 100,000 colonies or more ($\geq 10^5$ CFU/ml) of any number of microorganisms

Respiratory /Common Cold Syndromes/Pharyngitis:

Resident must have TWO new signs or symptoms:

- Runny nose, sneezing, stuffy nose (congestion)
- Dry cough
- Swollen or tender glands in neck
- Sore throat, hoarseness, or difficulty swallowing

Respiratory Tract Infection /Influenza-Like Illness: Resident must have fever with a single oral or tympanic (37.8°C/100°F) OR repeated oral or tympanic of (37.2°C/99°F) OR (1.1 °C/2°F) above resident's baseline at any site and three of the following:

- Chills
- New headache or eye pain
- Malaise or loss of appetite
- Sore throat
- New or increased cough
- Dry cough
- Muscle pain or body ache

Pneumonia or lower respiratory.

MUST HAVE ONE of the following:

- Fever
- Leukocytosis
- New onset confusion
- New onset functional decline

If YES, then Chest X-ray with new infiltrate or pneumonia and with at least one of the following:

- New or increased cough
- New or increased O₂ sat < 94% on room air or > 3% of baseline
- New or changed lung sounds
- Pleuritic chest pain
- Respiratory rate >25

Infection Criteria Checklist

Please check symptoms and lab results

<p>Cellulitis/Soft Tissue/Wound Infection at least ONE criteria must be present:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Pus at wound, skin, or soft tissue site plus FOUR of the following: <input type="checkbox"/> Fever (>38°C/100°F) <input type="checkbox"/> New onset confusion <input type="checkbox"/> Leukocytosis <input type="checkbox"/> At the site of infection <input type="checkbox"/> Heat <input type="checkbox"/> Redness <input type="checkbox"/> Swelling <input type="checkbox"/> Tenderness or pain <input type="checkbox"/> Serous drainage <p>Conjunctivitis resident must have ONE criteria present:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Pus from one or both eyes for at least 24 hours <input type="checkbox"/> New or increased conjunctival redness, with or without <input type="checkbox"/> Itching new or increased pain, for at least 24 hours 	<p>Herpes Simplex and Zoster TWO criteria must be present</p> <ul style="list-style-type: none"> <input type="checkbox"/> A vesicular rash <input type="checkbox"/> Diagnosis by MD <input type="checkbox"/> Laboratory confirmation <p>Fungal Oral/Perioral and Skin Infections for all TWO criteria must be present:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Oral candidiasis <input type="checkbox"/> Presence of raised white patches on inflamed mucosa <input type="checkbox"/> Plaques on oral mucosa <input type="checkbox"/> Diagnosis by MD or DDS <input type="checkbox"/> Fungal skin infections <input type="checkbox"/> Characteristic rash or lesion <input type="checkbox"/> Diagnosis by MD <input type="checkbox"/> Laboratory confirmation <p>Scabies must have maculopapular and/or itching rash plus ONE of the following:</p> <ul style="list-style-type: none"> <input type="checkbox"/> MD diagnosis <input type="checkbox"/> Laboratory confirmation from scraping or biopsy <input type="checkbox"/> Epidemiological link to a case of scabies with laboratory confirmation
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Gastrointestinal Infections

<p>Gastroenteritis resident must have ONE criteria present:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Diarrhea: with three or more liquid/watery stools above resident baseline within a 24 hour period <input type="checkbox"/> Vomiting with two or more episodes in a 24 hour period <input type="checkbox"/> A stool culture positive for Salmonella, Shigella, shiga-toxin producing E-coli, or Campylobacter with 1 of nausea, vomiting, abdominal pain, tenderness or diarrhea <p>Norovirus resident must have ONE criteria present:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Diarrhea: with three or more liquid/watery stools above resident baseline within a 24 hour period. <input type="checkbox"/> Vomiting: with two or more episodes in a 24 hour period if ONE of the above then must also have: <input type="checkbox"/> Stool specimen for which norovirus is + by PCR, electron microscopy or enzyme immunoassay 	<p>Clostridium difficile resident must have one criteria present:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Diarrhea: with three or more liquid/watery stools above resident baseline within a 24 hour period <input type="checkbox"/> Presence of toxic megacolon (abnormal dilation of the large bowel, documented radiology) <p>AND ONE OF</p> <ul style="list-style-type: none"> <input type="checkbox"/> A C-diff positive stool specimen + by PCR, or toxin test <input type="checkbox"/> Pseudomembranous colitis is identified during endoscopic exam or surgery, or in histopathologic exam of a biopsy specimen
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Please write in ALL ANTIBIOTICS resident is taking

Organism _____ Fever? _____ Usual _____ Temp _____

Mental Status changes? _____ Labs _____

Care Plan Updated _____ Resident/Patient Teaching Done _____

Nurse Signature _____ Date _____

FACILITY NAME
Outbreak Investigation

Objectives of an Outbreak Investigation

The objectives at the beginning of an outbreak investigation are to define the problem and establish that the problem is real. The immediate goal is to prevent further cases if possible. There is always something to learn from an investigation.

Steps in an Outbreak Investigation*

1. Verify diagnosis
2. Research the disease
3. Confirm the existence of an outbreak; establish the background rate of the disease
4. If the existence of an outbreak is established, begin a binder or folder to contain all pertinent information related to the outbreak investigation
5. Define a case and conduct case finding
6. Relate outbreak to person, place, time; Prepare an epidemic curve
7. Formulate and evaluate a hypothesis
8. Implement control measures
9. Carry out additional studies
10. Analyze and interpret data
11. Formulate conclusions
12. Put additional control measures in place if necessary
13. Make a final report

These steps may occur simultaneously or be repeated as new information is received, especially Step 8--the implementing of control measures. This step may occur throughout the investigation until the outbreak ceases.

*The infection preventionist (IP) along with the Hospital Epidemiologist or designee should communicate as needed and at least weekly about the progress of the investigation.

Step 1: Verify the Diagnosis

1. Confirm the laboratory testing.

ALWAYS physically check the results. Never rely on “hearsay” or word of mouth to begin an outbreak investigation.

2. Rule out misdiagnosis or laboratory error.

Ensure that the problem has been properly diagnosed (i.e., that it really is what it is reported to be).

Make sure that the increase in diagnosed cases is not the result of a mistake in the laboratory (ex: linezolid-intermediate VRE isolates due to mistaken E-test results).

3. Review clinical findings to assess the symptoms and features of the illness.
4. Review the other laboratory findings for people who are affected to make sure that they fit.
5. If you expect a need for specialized laboratory testing such as special cultures or molecular analyses, you should begin obtaining the appropriate isolates, specimens, or other laboratory material from a sufficient number of patients/places as soon as possible.
6. With the Hospital Epidemiologist, generate a list of questions in preparation for conducting interviews of patients and staff. Conversations with patients and staff can be very helpful in generating hypotheses about the cause, source, and spread of disease.

Step 2: Research the Disease

1. Conduct a literature search to learn as much as you can about the disease or condition.
2. Specifically check the literature for details of other outbreaks of this disease.
3. Summarize the literature findings in one or two paragraphs.
4. File the literature and the summary in the binder/folder.

Step 3: Confirm the Existence of the Outbreak and Establish the Background Rate of the Disease

1. Verify that a suspected outbreak is indeed a real outbreak. Molecular epidemiologic studies may be necessary at this point to help determine the existence of an outbreak.

A first step is to determine if the observed number of cases exceeds the expected number. To determine the expected number:

- i. Compare the current number of cases with the number from the previous few weeks or months, or from a comparable period during the previous few years.

- ii. Sources of this data can be from local, in-hospital data; health department surveillance records if the disease is a reportable disease; national data; or telephone surveys of other institutions to see if they are also seeing more cases than usual.
2. Even if the current number exceeds the expected number, the excess may not indicate an outbreak. Other possibilities include:
 - A. Reasons you might see real increases
 - i. Increase in the size of the population
 - ii. Changes in population characteristics
 - iii. Random variation
 - B. Reasons you might see artificial increases:
 - i. Changes in reporting procedures—for instance, if 4 rather than 2 IPs are in a Department and are reporting, the incidence may increase just because of increased manpower
 - ii. Changes in case definitions
 - iii. Increased interest because of local or national awareness
 - iv. Improvements or changes in diagnostic procedures
 3. Whether or not you should investigate an apparent problem further is not strictly tied to verifying that an epidemic exists. Other factors may come into play, including the severity of the illness, the potential for spread, political considerations, public relations, and the availability of resources. This is a critical step. Proceeding before making sure that a real outbreak exists and that an investigation is warranted will utilize valuable time and resources that could have been used more effectively elsewhere. Therefore, before proceeding further, the Hospital Epidemiologist should be contacted.

Step 4: Begin a Binder

The binder will help to keep the investigation organized, will help your colleagues if they have to cover for you, and will be useful for final reports and/or manuscripts that may result from the investigation.

Step 5: Define a Case and Conduct Case Finding

Establish a case definition

1. The case definition is a standard set of criteria that are established and used to determine whether a person will be classified as having the disease that is under study. A case definition usually includes 4 components:
 - A. Clinical information about the disease. The clinical criteria should be based on simple, objective measures.
 - B. Characteristics about the people who are affected.
 - C. Information about the location or place.
 - D. A specification of time during which the outbreak occurred.
2. Ideally, the case definition should be broad enough to include most, if not all, of the actual cases, without capturing “false positives”. Cases might be classified as confirmed (usually

relies on laboratory confirmation), probable, or possible depending on the clinical situation due to the uncertainty of some diagnoses.

3. Early in an investigation, a loose case definition is often used to allow for the capture of as many cases as possible. Later, when hypotheses have come into sharper focus, the “possible” category might be dropped. This strategy is particularly helpful for large outbreak investigations, as it may prevent having to go back to collect more data later. It is important to get the data while you can.

Conduct Case Finding

1. The first cases to be recognized are usually only a small proportion of the total number. The true size and geographic extent of the problem must be identified.
2. Use as many sources as possible to help find cases. Surveillance of the entire exposed population is one approach.
3. Collect the following information from everyone who meets the case definition:
 - A. Identifying information such as name and medical record number.
 - B. Demographic information such as age, sex and race.
 - C. Clinical information.
 - D. Risk factor information
4. This information should be collected on a standardized data collection form.
5. The information from the data collection form should be entered into an electronic database (usually Microsoft Excel) in a line listing format for ease of viewing and comparing cases (Table 1).

Step 6: Relate the outbreak to person, place and time. Prepare an epidemic curve.

Characterizing the Outbreak

1. Characterizing by Person

This step determines the population at risk. This is usually defined by personal characteristics such as age, race, sex, or medical status or by exposures like occupation, leisure activities, or medication use. This is important because it relates to susceptibility to disease and to opportunities for exposure.

2. Characterizing by Place

Include the patient location or locations on the line listing. An assessment of an outbreak by place provides information on the extent of a problem and may also demonstrate clusters or patterns that provide clues to the identity and origins of a problem. A bar graph of cases by location that demonstrates clustering usually relates to either a focal source of an outbreak or person-to-person spread. Scattering of cases is more consistent with a common source.

3. Characterizing by Time

Construct an epidemiologic curve. An epidemic curve is essentially a histogram that shows the course of a disease outbreak or epidemic by plotting the number of cases by time of onset. The time course of an epidemic is usually best demonstrated by drawing a graph of the number of cases (y-axis) by their date of onset (x-axis). An epidemic curve provides a great deal of information such as:

- A. Where in the course the epidemic currently is.
- B. The probable time period of exposure if the disease and its usual incubation period are known. Allowing the investigation to focus on the identified time period.
- C. The epidemic pattern of common source, person-to person spread, or both.

Constructing an Epidemic Curve

1. Identify the time of onset of illness for each person. Day of onset is usually sufficient. For some rapidly incubating diseases, hour of onset may be necessary.
2. The number of cases is plotted on the y-axis and the unit of time on the x-axis.
3. Selecting the unit of time for the x-axis is based on the incubation period of the disease (if known) and the length of time over which cases are distributed. As a rule of thumb, select a unit that is one-fourth to one-third as long as the incubation period. Ex: *Clostridium perfringens* food poisoning has an incubation period of 10 to 12 hours with cases usually appearing over only a few days. Therefore use an x-axis unit of 2 or 3 hours.
4. When the incubation period and/or the disease are unknown, draw several epi curves using different time measures for the x-axis to find one that fits the data best.
5. Make sure you show both the pre- and post-epidemic period on the curve to illustrate the activity of the disease during those periods.

Interpreting an Epidemic Curve

1. When interpreting the epi curve, look at the overall shape, the period of time over which susceptible people are exposed, and the minimum, average, and maximum incubation periods for the disease.
2. An epi curve with a steep upslope and a gradual down slope indicates a single source or point source epidemic in which people are exposed to the same source over a relatively brief period. Classic examples are food poisoning at an event like a picnic or reunion. An extension of this is the sudden rise in the number of cases suggesting sudden exposure to a common source. In a point source epidemic, all the cases occur within one incubation period.
3. If the duration of the exposure is prolonged, the epi curve is called a continuous common source epidemic. The epidemic curve will have a plateau instead of a peak. Example: food handler with hepatitis A

4. Person-to-person spread is called a propagated epidemic. The pattern will demonstrate a series of progressively taller peaks. The time period between the peaks will represent one incubation period. Example: smallpox epidemic
5. Cases that stand apart (outliers) may be just as informative as the overall pattern. An early case may represent a background (unrelated) case, a source of the epidemic, or a person who was exposed earlier than most of the people affected (e.g., the cook who tasted her dish hours before bringing it to the picnic). Similarly, late cases may be unrelated, may have especially long incubation periods, may indicate exposure later than most of the people affected, or may be secondary cases. All outliers are worth examining carefully because if they are part of the outbreak, their unusual exposures may point directly to the source. For a disease such as hepatitis A, for instance, one of the early cases may be the food handler who is the source of the epidemic.
6. In a point-source epidemic of a known disease with a known incubation period, you can use the epi curve to identify a likely period of exposure. This is critical to asking the right questions to identify the source of the epidemic.

Step 7: Formulate and Evaluate a Hypothesis

1. Most often, hypotheses generating to explain why and how the outbreak occurred begins when the problem is first identified. Once people have been interviewed and the outbreak has been characterized by person, place, and time, the hypothesis will be more accurately focused.
2. The hypothesis should address the source of the agent, the mode of transmission, and the exposures that caused the disease (Example: water=source, spread through the dialysis apparatus=mode, during dialysis=exposure). The hypothesis should be proposed in a way that can be tested.
3. After the hypothesis is generated, evaluate its credibility. Compare the hypothesis with established facts and perform analytic epidemiology which allows statistical testing of the hypothesis.
4. The two types of analytic approaches are cohort studies and case-control studies.
 - i. A cohort study starts with exposure and follows to disease. This is the best method to use when analyzing an outbreak in a small, well-defined population. An example would be an outbreak of gastroenteritis in people who attended a wedding and a list of wedding guests is known. Ask each attendee the same set of questions (food exposures) and whether or not he/she became ill (disease). You would then calculate an attack rate for people who did and did not eat a particular food to narrow down the item. You can also calculate a relative risk (attack rate for people who were exposed to the item divided by attack rate for those who were not exposed to the item) to quantify the relationship between exposure and disease.
 - ii. A case-control study starts with a group with (cases) and a group without (controls) disease and back tracks to exposure. This is the methodology used for most outbreaks because often the entire exposed population is not known. Determine

exposures of both cases and controls and then calculate an odds ratio to quantify the relationship between exposure and disease.

Choosing controls is the trickiest part of this process. The controls must not have the disease in question (obviously—or they would be cases), but should come from the same population as the case patients. In other words, they should be similar to the case patients except that they do not have the disease.

In general, the more cases and controls there are, the easier it will be to find an association. Often, however, you are limited because the outbreak is small. In a hospital, 4 or 5 cases may constitute an outbreak. Fortunately, the number of potential controls will usually be more than you need. In an outbreak of 50 or more cases, 1 control per case is usually sufficient. In smaller outbreaks, two, three, or four controls per case might be used. More than four controls per case will rarely be worth your effort. Attack rates cannot be calculated in a case-control study and therefore relative risks cannot be calculated. The association used for a case-control study is the odds ratio.

To calculate an odds ratio, put the data in a 2x2 table as follows:

Exposure	Cases	Controls	Total
Yes	A	B	A+B
No	C	D	C+D
Total	A+C	B+D	A+B+C+D

The Odds Ratio= AD/BC

After this, conduct a test of statistical significance. This is done to determine how likely it is that your study results could have occurred by chance alone. The first step in testing for statistical significance is to assume that the exposure is not related to the disease.

This is the Null Hypothesis.

- After calculating a relative risk (cohort study) or odds ratio (case-control study), you use these to calculate a chi-square test (the statistical test most commonly used in studying an outbreak) or other statistical test. Once you have a chi-square value, you look up its corresponding p-value in a table of chi-squares. In interpreting a p-value, set the level of significance ahead of time. By convention, this is usually 0.05. When a p-value is below the predetermined cutoff point, the finding is considered statistically significant. Thus you reject the null hypothesis and conclude that the exposure is associated with the disease. The smaller the p-value, the stronger the evidence that your finding is statistically significant. For more information on the Chi-square test, refer to the following websites:

<http://www2.chass.ncsu.edu/garson/pa765/chisq.htm>

<http://www.mste.uiuc.edu/patel/chisquare/intro.html>

Step 8: Implement Control Measures

1. As with hypothesis generation, this step is probably happening before this point in the investigation; however, after the hypothesis has been tested, the control measures can be refined and focused.
2. Never forget that time is of the essence in an outbreak investigation. Implement common sense control measures at any point in the investigation.
3. Repeat steps 1 through 8 until the cases stop.

Step 9: Carry Out Additional Studies

1. Additional epidemiologic studies may be necessary when your original hypothesis is refuted. You may need to reconsider the hypothesis and look for new modes of transmission.
2. Even if the hypothesis is confirmed, it may need to be refined. You may need more specific information about your exposure source. For example, if you determine that CVVH machines are responsible for an outbreak, you may want to determine what exactly about the CVVH machine/procedure is responsible.
3. When an outbreak occurs, whether it is routine or unusual, you should consider what questions remain unanswered about the disease and what kind of study you might use to answer some of these questions. The circumstances may allow you to learn more about the disease, its modes of transmission, the characteristics of the agent, and host factors.
4. Laboratory studies: Although epidemiology studies can implicate certain modes of exposure, laboratory evidence can prove the findings. If molecular epidemiology needs to be employed or other laboratory tests (Example HCV PCR on a surgical container) need to be conducted, this is the time to make sure that all outstanding laboratory tests are followed up and that the results are obtained.
5. Traceback studies may be necessary to determine the exact source of the problem. For instance, if a certain GI scope is implicated, a traceback study might prove that a manufacturer's defect is responsible for an outbreak.
6. Applied research can result from the results of an outbreak investigation. This could be basic science research to explain a phenomenon, such as the exact mechanism of *E.coli*'s ability to survive on alfalfa sprouts.

Step 10: Analyze and Interpret Data

This is the step that is called “putting it all together”. This is in anticipation of the final control measures and conclusions. During this stage:

1. Review results of the epidemiologic studies
2. Review results of laboratory studies

3. Review results of any additional studies
4. Evaluate initial control measures
5. Evaluate status of the outbreak
6. Formulate plans for additional control measures

Step 11: Put Additional Control Measures in Place

Once the mode of exposure is known, evaluate control measures and decide if any additional measures are necessary for this outbreak. Also evaluate the need for additional measures to prevent recurrence of a similar situation.

Step 12: Formulate Conclusions and Communicate Findings

A summary of all findings should occur at this point. The final task in an investigation is to communicate your findings to others who need to know. The communications usually takes two forms (1) oral briefings and (2) written reports.

The oral briefing should include what you found, what you did, and what you think should be done about it now and in the future. Present the findings in a scientifically objective fashion and be able to defend your conclusions and recommendations.

The written report should follow the usual scientific format with an introduction, background, methods, results, discussion, and recommendations. This formal presentation provides a blueprint for action. It also serves as a record of performance, a document for potential legal issues, and a reference for similar situations in the future. Finally, if this report is published in the literature, it will serve the broader purpose of contributing to the scientific knowledge base of epidemiology and Infection Control and Prevention.

Checklist for an Outbreak Investigation

- 1. Verify diagnosis
- 2. Research the disease
- 3. Confirm the existence of outbreak; establish the background rate of the disease
- 4. If the existence of an outbreak is established, begin a binder or folder to contain all pertinent information related to the outbreak investigation
- 5. Define a case and conduct case finding
- 6. Relate outbreak to person, place, time; Prepare an epidemic curve
- 7. Formulate and evaluate a hypothesis
- 8. Implement control measures
- 9. Carry out additional studies
- 10. Analyze and interpret data
- 11. Formulate conclusions
- 12. Put additional control measures in place if necessary
- 13. Make a final report

Table 1. Example of a line listing for acute Hepatitis A*

Case #	Report Date	Onset	Physician Diagnosis	Signs/Symptoms						Labs		Demographics	
				N	V	A	F	D	J	HAIgM	Other	Sex	Age
1	10/12/02	10/5/02	Hepatitis A	1	1	1	1	1	1	1	Low SGOT	M	37
2	10/12/02	10/4/02	Hepatitis A	1	0	1	1	1	1	1	Low Alt	M	62
3	10/13/02	10/4/02	Hepatitis A	1	0	1	1	1	1	1	Low SGOT	M	38
4	10/13/02	10/9/02	NA	0	0	1	0	?	0	NA	NA	F	44
5	10/15/02		Hepatitis A	1	1	1	1	1	0	1	Hbs/Ag-	M	17
6	10/16/02	10/6/02	Hepatitis A	0	0	1	1	1	1	1	SGOT=24	F	43

N=nausea V=vomiting A=elevated aminotransferase F=fever D=discreet onset J=jaundice HAIgM=hepatitis AlgM antibody test SGOT=serum glutamic oxaloacetic transaminase ALT=alanine aminotransferase Hbs=hepatitis B surface antigen Ag-=antigen negative

1="yes", 0="no"

* This table illustrates a line listing that might be used during an outbreak of hepatitis A. It was adapted from the CDC's "Excellence in Curriculum Integration through Teaching Epidemiology" program. Additional variables that might be helpful to include are drug use, occupation, meal at restaurant X, neighborhood of residence and sexual orientation.

Wipes	YES- USE HERE!!!
<p>Advanced hydrogen peroxide 1 MINUTE CONTACT FOR BACTERIA AND VIRUSES _____ (Lid/Label/package color) <i>(Insert photo here)</i></p>	<p>WASHING MACHINES AND DRYERS CARTS and TABLES EQUIPMENT COMPUTER TOUCH SCREENS AND TERMINALS DIARRHEA, NAUSEA, VOMITING SAFE FOR SURFACES EXCEPT FOR MARBLE</p>
<p>BLEACH DETERGENT WIPES 1 MINUTE CONTACT TIME FOR BACTERIA AND VIRUSES _____ (Lid/Label/package color) <i>(Insert photo here)</i></p> <p>USE CAREFULLY WILL DAMAGE SURFACES USE GLOVES</p>	<p>WASHING MACHINES BLOOD TESTING EQUIPMENT ISOLATION ROOMS (INCLUDING C-DIFF) ROOMS WHERE INDIVIDUAL HAS HAD DIARRHEA, NAUSEA, VOMITING</p>
<p>Alcohol-based hand sanitizer wipes <i>(Insert photo here)</i> _____ (Lid/Label/package color)</p>	<p>HANDS OF RESIDENTS STAFF EMPLOYEES VISITORS CHILDREN WIPE 15- 30 SECONDS</p>
<p>PERSONAL CLEANSING CLOTHS THESE WIPES DO NOT KILL GERMS _____ (Lid/Label/package color) <i>(Insert photo here)</i></p>	<p>RESIDENT/PATIENT/CLIENT SKIN EVERY DAY CLEAN UP PERSONAL CARE INCONTINENCE CARE</p>