What's been updated: Deleted content referring to OSHA ETS

Note: this guide is a resource for infection preventionists / employee health leaders to use. It is not intended to be used in place of other existing guides that address reports of possible exposure, exposure assessment tool, etc., involving pathogens other than SARS-CoV-2. Refer to these instead for specific instances to which they apply.

**Definition of Suspected Cluster or Outbreak of COVID-19 within a ministry:**

**NOTE:** the following are suggested definitions however ministries should follow definition/criteria issued by local, state or federal agencies that apply to their setting if different than those below.

- **In skilled nursing facility** a single new case of infection with SARS-CoV-2 among residents or colleagues is a trigger for beginning an investigation

- **In congregate setting or acute care ministry:** two or more patients with newly identified COVID-19 who are both being cared for on the same unit/area, having onset of infection/date of testing occurrence within 1 week and were not suspected of having COVID-19 at time of admission; or:
  
  - Identification of two or more colleagues with infection who work on the same unit or within the same department that are linked by possible occupational, close contact within the same 1-2 weeks
  - Suspected instance of one or more cases of transmission from colleague to patient/resident or other source of exposure, e.g. visitor, when the patient or resident was not suspected of infection on admission or prior, initial test was negative AND after 48-72 hours from time of admission to the facility.

**Additional, Related Definitions:**

- **Case definition for COVID-19:** detection of SARS-CoV-2 using molecular test/ or antigen detection method, AND:
Time, space and/or epidemiologic link in definition of cluster/outbreak above.

- Presumptive: detection of SARS-CoV-2 by molecular or antigen test in a respiratory specimen AND time, space, and/or epidemiologic link defined above

- **Close contact**: means being within 6 feet of any other person for a cumulative total of 15 minutes or more over a 24-hour period during that person’s potential period of transmission. The potential transmission period runs from 2 days before the person felt sick (or, for asymptomatic people, 2 days prior to test specimen collection) until the time the person is isolated. For colleagues and clinicians this type of exposure does not apply to instances where all PPE was worn as outlined in PPE Guidebook; [ppe-guide-booklet.pdf](trinity-health.org)

- **Contact tracing**: contact tracing follows case (newly identified person with COVID-19) investigation. It involves interviewing the case to identify everyone with whom they have had close contact during the timeframe while they may have been infectious. Ministry leaders in Employee Health and Infection Preventionists use contact tracing to notify these exposed individuals (contacts) of their potential exposure. Refer to the case investigation and contact tracing guide for additional details; [contact-tracing-for-th-colleagues.pdf](trinity-health.org)

- **Cluster**: an aggregation of cases grouped by time and place that may be greater than the expected number, whether the expected number is known or not; also referred to as a small outbreak.

- **Control measures**: various actions deployed in order to interrupt and reduce or eliminate the occurrence of a communicable disease or infection. Measures are tailored to the event and may include patient isolation and cohorting, enhanced cleaning and disinfection, enhanced hand hygiene, targeted staff education, and targeted or expanded surveillance and other modalities.

- **Line list**: a list established to assist and guide an outbreak investigation by documenting and organizing demographic data, clinical risk factors, and host or other contributing factors

- **Close contact**: Someone who was within 6 feet of an infected person for a cumulative total of 15 minutes or more over a 24-hour period starting from 2 days before illness onset (or, for asymptomatic patients, 2 days prior to test specimen collection) until the time the infected person is under isolation precautions.

**Priorities for Close Contact Evaluation and Monitoring:**

**EVALUATE/MONITOR CLOSE CONTACTS WHO ARE:**

- Individuals living, working or visiting acute care, skilled nursing, mental health, and long-term care facilities
- Hospitalized patients
- Healthcare personnel (HCP)
  - Non health care settings: Individuals living, working or visiting community congregate settings (e.g., correctional facilities, homeless shelters, educational institutions, mass gatherings, and workplaces including production plants)

**Risk Stratification by type of Setting:**

- **Skilled nursing facility**: outbreaks of SARS-CoV-2 have been reported by the CDC and others and residents in this setting are at high risk of severe disease if infected. Investigation of possible outbreak is of highest priority for SNF and similar types of congregate settings like assisted living facility because of high proportion of susceptible persons in a residential situation.
Risk is less in PACE program location as it is more of an ambulatory care setting with clients living independently but important to investigate a possible cluster involving the PACE clinic or ambulatory services / meeting location.

- Of the PACE settings:
  - Day Center – higher risk as colleagues and clients spend longer time in shared space.
  - Therapy – less risk but equivalent to episodic care common in ambulatory care setting.
  - Clinic – less risk as primarily involves PACE client and provider/colleague

- Acute care ministry: Risk is less than congregate setting however high proportion of patients have underlying conditions that place them at risk of more severe disease and HCP can transmit to colleagues, clinicians and patients. Risk factor for in-hospital transmission primarily relates to gaps in use of universal PPE, source control (masks) and physical distancing.

- MGPS; FURI clinics: Lower risk as all personnel will be wearing appropriate PPE and patients seeking care will have face covering. Investigation and notice to exposed therefore should be aimed at those with unprotected, close contact.

- Trinity Health at Home and PACE Home Services: Less risk as referral of patients to THAH include extensive clinical details that will provide colleague information on whether care plan is for support related to COVID-19. Only other likely situation would be colleague who’s cared for patient is found to be infected and the contact tracing guide would be applied.

- Trinity Health Medical Group (THMG) ; Well care: Lowest risk because all working or entering this setting are screened for symptoms and wearing face covering or mask. Personnel are also wearing eye protection for direct patient care. Focus investigation on exposure to unexpected instance of patient who may be a PUI but not identified at point of entry or close contacts of a colleague that is newly infected. There is no need to discontinue operations of the clinic during investigation unless there is evidence of sustained, prolonged transmission to several individuals.

Coordination of Cluster / Outbreak Response

Notification of infection and/or exposure among colleagues most often is initially received by Employee/Occupational Health Service (EHS) or other process (e.g. exposure support hotline) established at the ministry. Collaboration between Employee Health and or leader that receives this notice and Infection Prevention/Control therefore is important for prompt response to begin investigation and control.

Note: Follow System exposure assessment tool for classifying exposure after notification by the colleague available from this link: Colleague Exposure Assessment Tool

Medical removal from the workplace is required for colleagues who have COVID-19 based on the application of the exposure assessment tool above. Colleagues will continue removed until they meet the return to work criteria available here; guidance-for-colleagues-returning-to-work-post-covid-19.pdf (trinity-health.org)

Case investigation and contact tracing will most often lead to identification of a possible facility-onset (nosocomial and/or workplace) cluster of SARS-CoV-2 within the health ministry. (see also Contact Tracing guide)

Infection preventionists and Employee Health leaders at the health ministry will typically oversee coordination of response and mitigation of a possible cluster or outbreak in collaboration with ministry leadership – especially for the unit/area/department involved, and other relevant subject matter experts, e.g. local public health. Prevention of transmission within the facilities may also require complementary community case investigation and contact tracing efforts provided by public health. Planning and activation
of these activities therefore should be a joint endeavor involving ministry and applicable public health personnel.

Additional recommendations and tips for outbreak investigation:

- Details regarding employment, hours, working conditions, and workplace contacts should be obtained during the initial interview with the person identified as possible source of an outbreak or cluster. Enter these details in the COVID-19 Log.
- Employee/patient/resident lists are helpful for identifying contacts but be aware of changes and type of personnel to include as certain employees might have left the workplace and thus not appear in current rosters. Also consider contractual personnel who may not be on workplace rosters but could also be exposed (e.g., vendors supporting critical building operations, business associates, etc.)
- Assure HR and other leaders with expertise in legal, workers’ compensation, risk, etc. are aware of an ongoing investigation as they have expertise regarding liability, lost productivity, sick leave policies, responsibility for testing and screening, and media coverage.
- Assure protection of confidentiality of the source persons and any others with evidence of infection under existing regulations like Health Insurance Portability and Accountability Act of 1996 (HIPAA)
- Nursing homes and other long-term care facilities (LTCF) have been especially vulnerable to COVID-19 outbreaks. Refer to CDC and CMS guidance on how LTCF and nursing homes can be prepared to prevent COVID-19.
- Infection preventionists (IPs) are familiar with general aspects of exposure investigation, management of possible outbreaks but may or may not be familiar with COVID-19 case investigations and contact tracing. IPs are encouraged to collaborate with colleagues at the local health department and review reporting requirements, data sharing and division of responsibilities.
- In healthcare settings, there may be unique concerns about liability, confidentiality, media coverage, and occupational hazards. Occupational Safety & Health Administration (OSHA) has guidance to assist employers in understanding the agency’s requirements. These may include instructions on when and what to report related to occupational exposure.
- Refer to Colleague Work-Related Incident Reporting Frequently Asked Questions for additional details. Guidance is also available regarding how to report an incident.
  - Questions and support for colleagues reporting exposures should be referred to appropriate leaders at the ministry with expertise in applicable process and procedures.

Testing of Exposed Patient/Resident/Healthcare Personnel (HCP) as Part of Cluster/Outbreak Response:

After identification of suspected cluster or outbreak, expand scope of testing to include all HCP and any patients based on preliminary results of line listing and identification of the extent of the cluster or outbreak, even if there is no evidence of close, prolonged contact, e.g. all HCP working on the involved patient care unit.

- If preliminary investigation identifies transmission of infection beyond those in close contact and implicates a specific patient care unit or service area, expand testing more broadly, e.g. all HCP working on the same unit or service area, patients/residents who were possibly exposed to the index (source) person(s) with target for collecting specimen for testing at 5-7 days after possible exposure.
  - Important: To optimize effectiveness of control and prevention, it is strongly recommended colleagues identified as needing testing for possible infection agree to and participate in this testing. Questions they may have can be addressed by EHS/IPC and HR as needed.
- Continue surveillance testing of those who initially test negative every 5-7 days until 14 days since the most recent positive result has passed.
- See also CDC recommendations on use of antigen tests as this might be useful, especially for serial testing of exposed, asymptomatic persons for early detection of infection.

Steps Involved in Cluster Investigation and Control:
For outbreak testing, consider, document, and incorporate the following elements of an investigation [An Excel spreadsheet is available under contact tracing guide for developing a line listing or use the COVID-19 Log from the Total Rewards database tool]:

- Date the index (source) case infection was identified
  - Assure reports by colleagues of exposure are entered into appropriate systems like VOICE, Midas, and via calls to the Integrity Line.
- Date and results of initial test and re-testing of those with possible exposure, e.g. HCP, patients.
- Confirmation of cluster or outbreak
- Identifying investigation team and resources
- Establishing a preliminary case definition
- Alerting ministry leadership, incident command (if active) and other key stakeholders about the investigation
- Review applicable peer reviewed literature that is available
- Developing a methodology for case finding
- Preparing an initial line list and epidemic curve
- Observing and reviewing potentially implicated patient care activities
- Considering whether environmental sampling or HCP sampling should be performed
- Implementing initial control measures
- Defining and refining the case definition
- Continuing case finding and surveillance
- Reviewing regularly control measures
- Maintaining surveillance activities
- Considering whether an analytic study should be performed

Confirming Presence of an Outbreak

- When a possible outbreak is reported, the initial step in the investigation is to confirm and validate the information. For infectious disease outbreaks, this might be done by reviewing surveillance or microbiology records. Review of microbiological or historical surveillance data is an excellent starting point. In some instances, the decision to initiate an outbreak investigation might be based on the general perception of clinicians about whether the current occurrence of the event exceeds the baseline.

Identifying Investigation Team and Resources

- A disease outbreak is disruptive to normal operations within a healthcare facility and impacts patient safety. Assessing resources from a local, state, and federal level helps to define the scope of the investigative team and allocation of resources. Assembling the correct subject matter experts (SMEs) leads to swift corrective action and infection prevention and control measures and limits disease transmission.

Verifying the Diagnosis

- Verification of the clinical and laboratory diagnosis is vital in an investigation. Before an investigation can be formally launched, all presorted cases must be validated to be in existence. This action defines the problem in the outbreak and needed resources for appropriate interventions.

Establishing a Preliminary Case Definition

- Developing specific criteria for the case definition is essential. The initial case definition should be narrow enough to focus investigative efforts but broad enough to capture the majority of cases.

Alerting Ministry Leadership, Incident Command, & other Key HCP
At the outset of an outbreak investigation, it is critical to inform key partners, e.g. Employee Health, Unit leadership, and executive management, of the expanding situation. Ministry leadership should be notified so that resources can be made available and so that risk management, patient safety, and public affairs staff can prepare to assist. The microbiology laboratory should be notified if there is a decision to expand surveillance testing of HCP and other patients/residents.

Cluster / Outbreak Control and Response
Preparing an Initial Line List and Epidemic Curve

• The line list is perhaps the single most important tool in any outbreak investigation. In general, information that can be helpful on a line list includes details about patient signs or symptoms, dates of onset/detection of SARS-CoV-2, patient locations, contact with HCP, and host factors that might have predisposed the patients to the adverse event under investigation. Although line lists are powerful tools in guiding investigations, developing them is a resource-intensive activity because it involves a review of a variety of different sources of information, which might include medical records, patient location information (admission, discharge, and transfer data), and HCP interviews. Thus, it is critical to carefully weigh the benefits of any information to be included on the line list against the resources required to obtain it. One option is to create an initial simple line list with some very basic information on potential exposures.

• Data from the line list should also be used to create an epidemic curve (see Figure 1). In some instances, the shape of the epidemic curve will provide information that can help identify the mode of transmission. However, there are important caveats to interpreting epidemic curves in healthcare-associated outbreaks. First, patients may be asymptomatic or pre-symptomatic. Exposures in healthcare settings are often ongoing and infection may be transmitted from patient to patient.

Continuing Case Finding and Surveillance

• A methodology should be established to continue case-finding efforts. This will be critical in monitoring the progress of the outbreak and in ensuring that it has ended. This surveillance should continue for a predetermined period of time (e.g., 1-2 incubation periods) after the outbreak has terminated to ensure that it is truly over.

Regular Review of Control Measures

• All infection prevention and control measures that are implemented as part of an outbreak investigation should be appraised regularly. During the outbreak, compliance with the measures must be reviewed to ensure that recommended control measures are being carried out. In situations in which outbreaks persist and compliance with recommended measures is suboptimal, consideration must be given to how best to increase compliance. As the outbreak begins to subside, control measures should be critically assessed to determine if and when these activities can be discontinued. This is especially important for control measures that are very time consuming or resource intensive, such as patient-cohorting or dedicating staff to the care of case-patients.

Maintaining Surveillance Activities

• Ongoing surveillance evaluates the effectiveness of infection prevention and control measures and ensures the outbreak is ultimately over. Surveillance activities are recommended until the outbreak is declared over by the assembled investigative team. The surveillance activities are often dictated by the pathogen, the incubation period, and the patient population. Although active surveillance (e.g., contact by phone or electronic mail, or face-to-face interview to obtain follow-up data) is more labor-intensive than passive surveillance (e.g., screening records or laboratory reports), the data will yield valuable information for the investigation team. Generally, if active surveillance has been in place and no new cases have been identified during a period of twice as long as the incubation period, measures can be discontinued.
Communication

- Communication within the facility and with public health officials can be critical to the success of an outbreak investigation. In addition to working with public health experts, there are several important lines of communication within the facility that must be maintained over the course of an investigation. Clinicians working in the affected areas should be kept abreast of developments and findings and should be queried regularly on any additional thoughts or insights they might have. Not only will this provide important information to help guide the investigation, but these efforts will assure HCP that steps are being taken to end the outbreak.

- Decisions about whether to notify patients about an outbreak must be made on a case-by-case basis in close consultation with patients’ providers and ministry leadership. The case may also be referred to risk management and an ethics review board for additional review. In some instances, patients may hear about the outbreak or the investigation and have questions about their safety. All facilities should be proactive in preparing for patient inquiries and questions on outbreak investigations and should consider developing patient handouts, fact sheets, and frequently asked questions.

- The ministry public information officer and team should be kept informed during outbreak investigations. Outbreaks sometimes attract media attention, and the facility must be prepared to handle this should it occur. The press will want to know what the problem is, how it was detected, what the consequences are, and what is being done to investigate and control the problem. If there is no press or public relations officer at the facility, it is often best for the facility to designate one spokesperson to interact with the media. This provides reporters and the audience with a familiar voice for the duration of the outbreak and can help ensure consistent delivery of messages. The facility should also develop talking points about the outbreak and the investigation for media interviews.

Figure 1.
References & Resources:

- Campbell EA, Eichhorn CL. Outbreak Investigations. Chapter APIC Text Online,


- CDC. Identifying the source of the outbreak. Available at: https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/about-epidemiology/identifying-source-outbreak.html
