FOODBORNE DISEASE INVESTIGATION MANUAL

WEST VIRGINIA Department of Health & Human Resources
BUREAU FOR PUBLIC HEALTH

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Introduction

Foodborne illness (sometimes called "foodborne disease," "foodborne infection," or "food poisoning) is a common, costly, yet preventable, public health problem. Each year 1 in 6, or 48 million, Americans gets sick after consuming contaminated foods or beverages. Most illnesses happen suddenly and last a short time, and most people get better without treatment. Foodborne illnesses can be more serious, especially for people at higher risk for complications. Many of these cases occur sporadically, but some illnesses are part of outbreaks.

Finding the source of an outbreak is important to prevent it from continuing to cause illness. Investigating outbreaks allows us to halt disease transmission, and can help us learn to prevent future outbreaks of the same or similar illness.

An outbreak is defined as a situation when the number of cases of an illness identified exceeds the expected number in a specific time and place. An outbreak of foodborne illness is defined as two or more persons experiencing a similar illness after ingestion of a common food or different food prepared or served in a common place. With certain illnesses, such as botulism or chemical poisoning, a single case justifies an investigation.

The investigation team (including regional epidemiologists, nurses, and sanitarians) at each local health department (LHD) should work together with Division of Infectious Disease Epidemiology (DIDE) to determine if reported foodborne related illnesses should be investigated as an outbreak. Health Officers and/or Administrators should be informed and updated about the outbreak and investigation as soon as possible.

This manual describes how to approach foodborne disease outbreak including detection, investigation, control, and prevention.

Legal Authority

In West Virginia, legislative rule (§64CSR7, Reportable Diseases, Events and Conditions) mandates the reporting of certain diseases and conditions, unusual health events and clusters or outbreaks of diseases to the State and local health department. It also establishes the responsibility of various individuals and facilities in controlling communicable diseases.

Under legislative rule §64CSR7, State and local health departments have the authority to obtain any and all information necessary from the implicated establishment, medical personnel, hospitals, laboratories, other agencies, etc., including personally identifiable information relative to reportable diseases. The HIPAA Privacy Rule (45 CFR Parts 160 and 164), guarantees certain privacy rights to individuals; however, the HIPAA Privacy Rule provides that personally identifiable health information may be used and disclosed to a public health authority without the authorization of the subject of that information for public health activities and purposes that are authorized by law. For additional information about the HIPPA Privacy Rule, see http://www.dhhr.wv.gov/oeps/disease/Reporting/documents/HIPAA-Letter.pdf.

For more information about the legislative rule (§64CSR7) and other state public health legislation, please refer to the West Virginia Secretary of State website at http://apps.sos.wv.gov/adlaw/csr/readfile.aspx?DocId=25071&Format=PDF.

Confidentiality of Data

West Virginia has very stringent confidentiality laws and it is important that investigators be familiar with them. Legislative rule (§64CSR7) states in general that identifiable health data shall not be disclosed except under certain circumstances to prevent the spread of disease. Information that cannot be disclosed includes the names of the implicated food establishment and people associated with an outbreak. All information related to an outbreak investigation should be considered confidential and not releasable to the media, public, or other parties except when absolutely necessary to protect public health after consultation with West Virginia Bureau for Public Health (see examples below).

Information regarding outbreak investigations can be shared with the investigators, other LHD, and other agencies involved in the investigation (e.g., DIDE, Office of Laboratory Services (OLS), Office of Environmental Health Services (OEHS), Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), other state health departments) as outlined in legislative rule (§64CSR7).

Examples of situations when confidential information may need to be released include:

- To notify the owner/manager/Person in Charge (PIC) of the names of food service workers with symptoms of diarrhea and/or vomiting so they can be excluded for the appropriate time period.
- To notify the owner/manager/PIC of the names of food workers with certain positive stool results so they can be excluded and retested, if necessary.
- To inform the public of a public health threat to reduce the risk of additional exposures (e.g. if the implicated food item is still in the homes of those who purchased the food item).
- To inform the public that they may have been exposed to a foodborne pathogen by identifying the implicated food item/meal and/or food establishment where an outbreak occurred.
- To inform the public of their risk for becoming ill, treatment recommendations (e.g. seek medical care), or methods for proper disposition of the suspect food item if it is likely that it may still be in circulation.
- To notify the public when a recall is instituted as a result of an outbreak investigation.

Each of the key players in outbreak investigations has the crucial responsibility of maintaining confidentiality of the individuals involved in the outbreak. Personally identifiable information should never be released unless needed to properly conduct the outbreak investigation and protect the public's health. Extreme consideration should be taken to ensure that information is released only on a "need-to-know" basis.

Purpose of Investigation:

Control and prevention
The primary reason to investigate an outbreak is to control the occurrence of disease and prevent further illnesses. Therefore, it is necessary to first determine whether the outbreak is ongoing or is over. If the outbreak is ongoing, the first goal should be to prevent new cases by identifying and removing the associated food product from commerce or eliminating the source of contamination. If the outbreak has already occurred, the goal should be to determine the factors or sources that contributed to the outbreak and prevent future outbreaks.

Surveillance
Outbreak investigations can add valuable information to ongoing public health surveillance activities. The goal of surveillance is not to compile numbers of cases of illness for administrative purposes, but to provide data that are important to guide public health policy and action. Continual surveillance adds to existing knowledge regarding the potential for and occurrence of a disease in a population.

Training opportunities
Outbreak investigations may offer the LHD an opportunity to work closely with more experienced epidemiologists, become familiar with investigative techniques or practices, develop thought processes used in designing questionnaires and interviewing, and gain valuable on-the-job training and experience for future outbreaks.

Political or legal concerns
Outbreaks are occasionally investigated in response to pressures placed on the LHD by families of affected individuals, the media, local politicians and others to determine the source of an outbreak and whether it may pose a continued or future threat to the community.

Steps of an Outbreak Investigation:
Once a foodborne related disease has been reported, the outbreak team should respond quickly and appropriately. A listing of the steps in an outbreak investigation is included in this section. While not all steps may follow in the order listed, all should be considered in an investigation.

1. Prepare for an outbreak investigation and field work
2. Confirm the existence of an epidemic or outbreak
3. Verify the diagnosis
4. Define a case and identify and count cases
5. Describe the data in terms of person, place and time
6. Develop hypotheses
7. Evaluate hypotheses (analyze and interpret the data)
8. Refine hypotheses and carry out additional studies

9. Implement control and prevention measures

10. Communicate findings, write a report, and enter information into the National Outbreak Reporting System (NORS)

Roles and Responsibilities:

Physicians, Health Care Providers

1. Collect specimens and order lab testing on suspected cases of foodborne illness.

2. Contact the LHD regarding any person with a communicable enteric disease who is employed in the food service industry.

3. Familiarize yourself with:
    a. The legislative rule (§64CSR7) and contacts at your LHD.
    b. Health Care Provider Guidelines for Reporting Suspected Foodborne Outbreak-related Illnesses (Appendix A1).
    c. The Infectious Disease Society of America's Practice Guidelines for the Management of Infectious Diarrhea. http://www.idsociety.org/uploadedFiles/IDSA/Guidelines-Patient_Care/PDF_Library/Diarrhea.pdf

When you suspect a foodborne outbreak:

1. Report to LHD by telephone immediately.

2. Cooperate with LHD in the investigation and control of an outbreak.

3. Collect specimens as requested and work with the LHD to facilitate submission to OLS (testing of specimens submitted to OLS for the purpose of an outbreak investigation are free of charge).

4. Encourage patients to adhere to the prevention and control recommendations of the LHD.

Local Health Departments (LHDs)

1. Maintain an ongoing foodborne disease complaint file or log.

2. Establish a schedule to review foodborne disease complaint log for commonalities (person, place, time).

3. Provide education to health care providers on detecting, reporting foodborne outbreaks and appropriate specimen collection.

4. Maintain unexpired Cary-Blair kits for collection of stool specimens (Appendix B1).

5. Ensure that LHD staff are routinely trained in foodborne outbreak investigation. Request assistance from regional epidemiologist or DIDE for training as needed.

6. Establish a schedule to routinely monitor enteric disease investigations West Virginia Electronic Disease Surveillance System (WVEDSS) to identify trends and detect increases in the number of cases which may indicate an outbreak or cluster.

When you suspect a foodborne outbreak:

1. Immediately notify DIDE of any suspected outbreak. Notify regional epidemiologist and district sanitarian as early as possible in the investigation.

2. Conduct interviews, compile line lists, and record onset dates and times and other important epidemiologic data. Request assistance as needed from regional epidemiologist and/or DIDE to complete in a timely manner.

3. Obtain clinical specimens from symptomatic individuals. Consult DIDE and OLS for appropriate collection, handling and shipping of specimens.

4. Conduct a complete environmental investigation (not routine inspection) of the facility or site of a suspected outbreak. Use epidemiologic data when available to focus the environmental investigation. Request assistance from district sanitarian and OEHS to complete in a timely manner. Do a Hazard Analysis and Critical Control Points (HACCP) investigation for implicated food(s) (Appendix C1).

5. Collect food, water, and other specimens as needed. Complete a Chain of Custody Form (Appendix B2).

6. Provide direction to food establishment operators regarding the implementation of food employee exclusions and restrictions (Appendix C2).

7. Provide education to food workers regarding proper food handling and personal hygiene.

8. Health Officers have the authority to take official action to close permitted facilities and establishments if necessary and direct or enforce the implementation of other control measures as needed.

9. Assist with or develop a final outbreak report to be shared with stakeholders and forward a copy along with all supporting documentation (sanitarian reports, etc.) to DIDE.

Regional Epidemiologist (RE)

1. Provide training to LHD staff on foodborne outbreak investigation in collaboration with DIDE as needed.

2. Assist LHDs with providing outreach to healthcare providers, laboratories, schools, food establishments and other entities on identification and reporting foodborne outbreaks.

3. Ensure LHDs maintain unexpired Cary-Blair test kits for stool specimen collection (Appendix B1).

4. Establish a schedule to routinely monitor enteric disease surveillance data to identify trends and detect increases in the number of cases which may indicate an outbreak or cluster.

When you suspect a foodborne outbreak:

1. Notify DIDE of all outbreak investigations.

2. Provide consultation and appropriate technical assistance to the LHD in epidemiologic investigation of disease outbreaks (i.e. initiating control measures, collecting specimen, interviewing cases, preparing outbreak report, etc.).

3. Ensure the involvement of all appropriate local agencies.

4. For outbreaks involving multiple counties, RE will take a leadership role in coordinating the investigations among counties in the region.

5. Assist LHDs with media communication, if needed, after consultation with DIDE.

District Public Health Sanitarian

1. Inspect establishment and enforce rules pertaining to the regulation of state managed facilities.

2. Maintain foodborne outbreak investigation kits and ensure all supplies are current and unexpired (Appendix C3).

When you suspect a foodborne outbreak:

1. Consult, participate and provide expertise in environmental investigations being conducted by LHDs when needed.

2. In a state permitted and inspected facility:

    a. Conduct a complete environmental investigation (not routine inspection) of the facility or site of a suspected outbreak. Use epidemiologic data when available to focus on the environmental investigation. Do a HACCP investigation for implicated food(s) (Appendix C1).

    b. Collect food, water, and other specimens as needed. Complete a Chain of Custody Form (Appendix B2).

c. Take official action to close permitted facilities and establishments if necessary and direct the implementation of other control measures as needed.

d. Ensure a copy of the environmental investigation report is shared with LHD, OEHS and DIDE.

Division of Infectious Disease Epidemiology (DIDE)

1. Provide training materials instructive in the methods of foodborne outbreak investigations and use of this manual.
2. Routinely monitor enteric disease surveillance data to establish a trend and detect increases in the number of cases which may indicate an outbreak or cluster.
3. Routinely monitor food illness complaint data, in collaboration with OEHS, (i.e. Environmental Health Electronic Reporting System (EHERS), consumer complaint log) to establish trends and identify outbreaks or clusters.
4. Maintain and routinely distribute surveillance information and summary reports relating to foodborne outbreaks to LHDs, regional epidemiologists, physicians and other agencies.
5. Routinely review pulse field gel electrophoresis (PFGE) data in collaboration with OLS to identify outbreaks or clusters.
6. Continue to improve foodborne outbreak recognition and response in the state.

<u>When you suspect a foodborne outbreak:</u>

1. Provide consultation and technical assistance to regional epidemiologists and LHD staff in the epidemiologic investigation of disease outbreaks.
2. Provide guidance on the epidemiologic investigation and control of a specific outbreak consistent with state and national objectives, current policy, and current medical and scientific literature, such as developing questionnaires, conducting data analysis, etc.
3. Determine whether a particular outbreak warrants further epidemiologic investigation (case-control or cohort study) and the nature and extent of additional epidemiologic or laboratory data required.
4. Report all foodborne outbreaks to the CDC using the National Outbreak Reporting System (NORS).
5. Identify and arrange for additional staff and material resources if an outbreak exceeds the resource capacity of the LHD. Coordinate response to multi-state outbreaks and lead multi-region outbreaks.

6. Contact OLS for submission of clinical, food and environmental samples and provide authorization for testing.

7. Provide advice on collection of clinical, food and environmental specimens in coordination with OLS and/or OEHS.

8. Recommend and request implementation of control measures.

9. Collaborate with federal, other states, and West Virginia agencies as needed. If warranted, request additional assistance from CDC in conducting further epidemiologic investigation of the outbreak (e.g., Epi-Aid).

Office of Environmental Health Services (OEHS)

1. Monitor and evaluate the inspection and enforcement procedures and practices of regional offices and LHD environmental sanitation programs to promote uniform interpretation and application of rules relating to permitted establishments.

2. Maintain and update the OEHS Procedures Manual concerning food illness complaints and suspected outbreaks.

3. Provide training to district offices and LHDs on investigation and follow up of foodborne outbreaks and routine surveillance of food illness complaints.

4. Work with DIDE to monitor food illness complaints at state level (i.e. Environmental Health Electronic Reporting System (EHERS), consumer complaint log).

<u>When you suspect a foodborne outbreak:</u>

1. Provide technical assistance and support to district offices and LHDs when requested, regarding the investigation and follow-up of foodborne outbreaks.

2. Coordinate with LHD staff to provide investigation services within their jurisdiction.

3. Contact the U.S. Department of Agriculture (USDA) Compliance Office if a meat or poultry product under federal-inspection is suspected.

4. Contact the U.S. Food and Drug Administration (FDA) if a food product under their regulatory authority is suspected.

5. Contact appropriate regulatory authorities in other states, as warranted.

6. Where warranted, conduct/coordinate recall effectiveness checks.

Office of Laboratory Services (OLS)

1. Provide specimen collection supplies to LHDs as requested.

2. Provide PFGE testing on bacterial isolates in collaboration with DIDE and CDC.
3. Routinely review PFGE data in collaboration with DIDE to identify outbreaks or clusters.
4. Maintain memorandum of understanding (MOU) with WVDA for food testing.
5. Prepare or order specialized media, reagents and materials needed to test for foodborne pathogens.
6. Provide training as needed regarding proper collection and handling of clinical or environmental specimens.

When you suspect a foodborne outbreak:

1. Provide consultation regarding proper collection and handling of clinical or environmental specimens.
2. Receive initial alert on the number, expected arrival time, and suspected pathogen(s) to be tested for food samples authorized to be collected and sent for testing.
3. Receive preauthorized food samples submitted for testing and maintain chain of custody documentation.
4. Provide timely testing of clinical or coordination of environmental specimens for evidence of microorganisms.
5. Report laboratory test results to LHD, DIDE, and submitter.
6. Forward specimens to CDC for more specific testing when indicated or requested by DIDE or CDC for surveillance purposes.

West Virginia Department of Agriculture

1. Maintain MOU with OLS to provide food specimen testing.
2. Maintain capacity for food specimen testing.
3. Be familiar with contacts at OLS, DIDE and OEHS regarding foodborne outbreak response.

When you suspect a foodborne outbreak:

1. Provide testing for food samples through MOU with OLS as part of foodborne outbreak investigations.
2. Cooperate in the process of the control and eradication of foreign animal disease that could impact the food supply.

3. Conduct investigations in WVDA regulated facilities that are implicated as a possible source of a foodborne outbreak.

4. Cooperate and provide communications with other agencies and organizations on the federal, state and local levels: veterinarians, producers, and animal owners in West Virginia.

West Virginia Rapid Response Team (RRT)

1. Develop and provide training opportunities.

2. Develop and coordinate a directed sampling plan for FDA regulated products and West Virginia firms deemed to produce high-risk products.

When you suspect a foodborne outbreak:

1. Work in conjunction with OEHS food program staff and DIDE.

2. Coordinate with other jurisdictions and RRT on a case by case basis.

Center for Threat Preparedness

1. If needed, facilitate or provide instruction on foodborne outbreak investigation trainings for local, regional, and state staff.

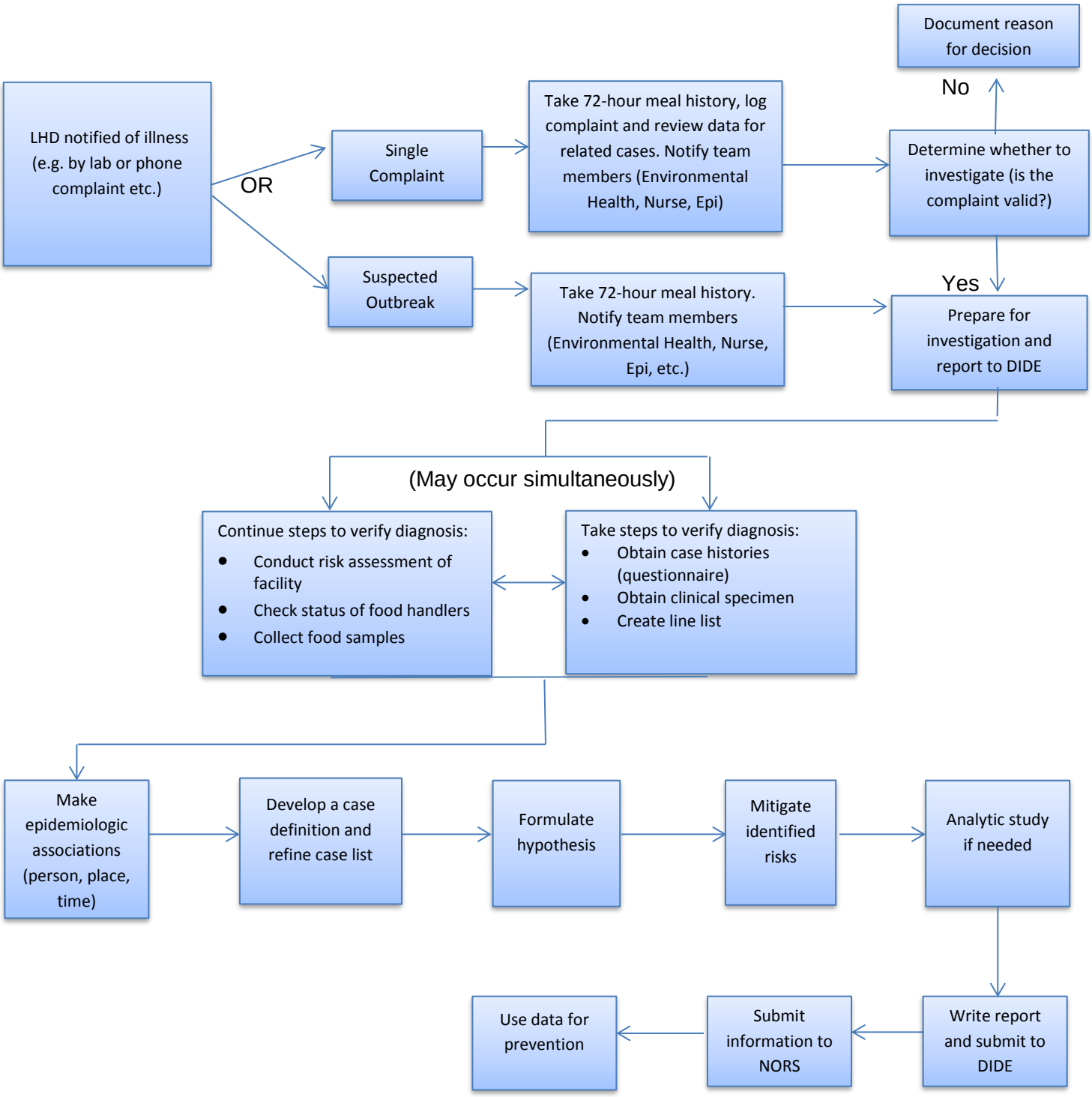
2. Maintain trained staff in the National Incident Management System (NIMS).

When you suspect a foodborne outbreak:

1. Stand up Incident Command System (ICS). Foodborne outbreaks that may require activation of ICS include:
    a. Foodborne outbreaks with suspected intentional contamination.
    b. Foodborne outbreaks that may include severe illness, multiple jurisdictions and affect large number of population.
    c. Foodborne outbreaks that require trace back and recall of a widely distributed contaminated food item.

2. Assure that a foodborne outbreak team, or work unit is placed within the ICS structure, under the direction of the operations chief.

Foodborne Investigation Flow Chart



"How do I know there's a problem?"

There are two important components to foodborne outbreak detection: pathogen-specific foodborne disease surveillance and food complaint investigation. Together, these two components are an integral part of identifying foodborne outbreaks.

Pathogen-specific foodborne disease surveillance is the routine monitoring of foodborne disease in the population. Continuous surveillance is useful for identifying unusual trends with a specific enteric disease. Identifying these trends may indicate further investigation is needed, and this may lead to the identification of an outbreak.

Pathogen-specific surveillance is comprised of four factors.

1. Case reporting: West Virginia has a mandatory reportable disease system. This system relies on healthcare providers and laboratories to report suspected foodborne diseases to the local and state health departments. Timely and accurate submission to the system is vital to outbreak detection. Delays in the submission process may interfere with the detection of an outbreak and prolong or interfere with investigation. For a list of reportable diseases, see legislative rule §64CSR7: http://apps.sos.wv.gov/adlaw/csr/readfile.aspx?DocId=25071&Format=PDF

2. Lab testing: Lab results for certain foodborne diseases are required to be submitted to the local and state health departments and specimens or isolates may need to be submitted to OLS for additional testing. OLS can perform lab testing to confirm pathogen and identify closely related organisms that may indicate a cluster or outbreak is occurring.

3. Disease-specific case investigation: During this step, crucial information is collected about demographics, exposure, and additional cases. This information is important for identifying patterns, associations, and/or common exposures between cases that may indicate an outbreak.

4. Monitoring of surveillance data: Routine monitoring of enteric disease cases by local, regional, and state staff is a very important factor when using surveillance as a method of outbreak identification. Data should be reviewed at regular intervals to identify trends such as an increase in the number of cases for a particular area or demographic.

Once you have identified a potential outbreak from the surveillance activities, please notify DIDE and the outbreak team.

Another way that outbreaks are reported is by direct notification from attendees of a gathering when it is known that there are multiple cases of illness. For example, the organizer of an event such as a party, conference, or other group function calls to report that several attendees have become ill. These reports of illnesses with a common exposure should immediately be reported and investigated as an outbreak.

Other times a single complaint about a restaurant or facility can indicate a problem and lead to identification of additional cases and an outbreak. Therefore, systematic follow up and monitoring of food illness complaints regularly is essential to foodborne outbreak detection.

"What do I do about a food complaint?"

The Food Complaint Form (Appendix C4) should be used to collect information when a complaint of a possible foodborne illness is received at a LHD. Once completed, the information should be entered into the Foodborne Illness Complaint module of Environmental Health Electronic Reporting System (EHERS).

Completing the Form:

The sanitarian is typically responsible for interviewing the complainant using the Food Complaint Form (Appendix C4). In some LHDs, the epidemiologist, public health nurse, or sanitarian is responsible for the form's completion. In an effort to ensure objectivity and accuracy, it should not be completed by the complainant or support staff. It is important to complete all sections of the form and obtain information about the symptoms, numbered by the order in which each symptom occurred. Since it is common for individuals to blame the last food they ate as the cause of their illness, it is critical to obtain a 72-hour food history. The history identifies other foods that the complainant consumed that may have caused the illness. To encourage the complainant's recall, it may be necessary to ask exploratory questions like: "Did you dine out anywhere?" "Meet anyone?" "Do anything special?" "Does the date have a special meaning?" Questions should be asked in a neutral manner to avoid interviewer bias or implication of suspected source that could influence the complainant's response.

It is important to fill out the complaint form as completely as possible. Incomplete complaint forms often require follow up calls as well as cause avoidable delays in the investigation process. This form is intended to use for interviewing the complainant during food complaint investigation. If an outbreak is detected, PLEASE DO NOT USE THE FORM TO INTERVIEW PATIENTS. If the food complaint investigation indicates an outbreak, DIDE should be notified immediately so that the appropriate investigation procedures can be instituted, including the creation of a situation specific questionnaire.

Responding to the Complaint:

Once the food complaint form has been completed, the sanitarian must assess the validity and significance of the complaint to determine the appropriate response. The response to the complaint will vary depending on the information received. It can range from making a phone call to the food establishment to conducting an in-depth site investigation. The response should begin promptly. If it is the beginning of an outbreak, the sooner an investigation can be started the more likely it is to be successful in limiting additional illnesses.

It is very important that all complaints are evaluated, and evaluations should be documented since any single case may be the beginning of an outbreak. Remember, the objective is to prevent foodborne illness.

The following are some examples of when onsite investigation should be made:

1. A case that has been hospitalized with a clear association with a food establishment.
2. A case with a confirmed foodborne pathogen and a clear association with a food establishment.
3. An alert involving a food establishment that has been cited for significant or repeat risk factor violations during inspections.
4. A case with a probable association with a food item of interest – e.g. raw shellfish, undercooked beef, fresh squeezed juice, etc.

If a site investigation is warranted, the sanitarian should visit the establishment immediately or as soon as possible. Do not perform a routine inspection. Conducting an onsite investigation immediately will allow the sanitarian to assess the conditions in the establishment, speak with food workers about illness and preparation practices, and find out about any complaints received by the owner/manager. An environmental investigation assessment form (C5), a master list of establishment staff template for tracking employee involvement (C6) and a food worker interview form (C7) are available in the appendix. If unsure of how to proceed, the LHD may consult with DIDE and OEHS to determine the appropriate response.

Note: As a rule, food, stool and environmental samples are not collected for a single complaint. Exceptions can only be made by DIDE.

If an onsite investigation is not feasible or warranted, the establishment must be, as a minimum:

1. Notified that a complaint was received regarding an alleged foodborne illness.
2. Asked if they have received other complaints of illness.
3. Asked if any food workers have been absent from work due to illness or recently experienced gastrointestinal symptoms.

The sanitarian should direct their inquiries to the person in charge (PIC), owner, operator, and other staff as appropriate. Review with the PIC, manager, or owner the West Virginia State Regulations pertaining to:

1. Reporting food worker illness to the local health department.
2. Ill food handler exclusion policies:
    a. Does the PIC ask food workers their symptoms if they call out or go home sick?
    b. Does the PIC know that ill food workers must be reported to the local health department?
3. Minimizing bare hand contact with ready-to-eat foods.
4. Hand washing policies and procedures.
5. Sanitization practices.

Note: If the establishment suspected by the complainant of being responsible for illness is located in another LHD's jurisdiction, the sanitarian will need to contact the LHD with jurisdiction (and

OEHS) to inform them of the complaint. The sanitarian must then forward all information from the complainant to the LHD with jurisdiction so that the investigation can be initiated. When the establishment involved is located in a different jurisdiction, the sanitarian receiving the initial call should try to collect as much information as possible. Often an opportunity to collect important information is missed if the call is referred but no one at the health department that has jurisdiction is available to take the call. If this occurs, OEHS should be notified. The sanitarian should also remind the caller that they will likely be contacted again for additional information.

Contact the OEHS at (304) 558-2981:

1. If you are not sure whether a single complaint warrants a follow up investigation.
2. If other health department personnel cannot be reached in a multi-jurisdictional complaint.

"Could the complaint be an outbreak?"

An outbreak of foodborne illness is defined as two or more persons experiencing a similar illness after ingestion of a common food or different foods in a common place. The following may be indicators that an outbreak is occurring:

1. Complainant reports multiple people have become ill.
2. Multiple complaints naming a single food establishment or event.
3. Multiple complaints report a single grocery store or food item.
4. Complainant reports consuming an item involved in a known recall or outbreak.

"So, I think I have an outbreak, what do I do next? Who do I tell?"

Once it has been determined that an outbreak is likely occurring, the investigative team is notified and assembled. Prompt notification is essential as a delay can hinder the investigation.

1. Upon notification or suspicion of an outbreak, the LHD will contact DIDE within 60 minutes. The LHD should also notify the regional epidemiologist, and/or the district sanitarian for assistance when necessary. If the initial identification of an outbreak is received by DIDE or OEHS, the LHD will be notified within 60 minutes.
2. DIDE will notify OLS and OEHS of all reported foodborne outbreaks.
3. Activation of the WV Rapid Response Team will be considered on a case-by-case basis by the Bureau for Public Health.
4. DIDE will provide guidance and direction on the next steps in the investigation.

Important questions to ask at this stage in an outbreak investigation are the following:

"What criteria should be used to determine if an ill person is part of an outbreak?"
"Who else is ill?"

Outbreaks and their corresponding investigations can quickly become complex. As a result, it is important to establish a clear understanding of the outbreak as early as possible. Organizing the preliminary information will help in the development of a case definition and may also provide clues about the pathogen and its transmission.

Case Finding:
Methods for case finding will vary according to the disease in question and the community setting. When an outbreak is first recognized, investigators should attempt to cast a wide net to determine the extent of the outbreak and identify additional cases.

Look for additional cases in those with time, place, or person association with the identified cases. Case finding methods might include the following:

- Reviewing complaint log.
- Asking affected persons to provide the names and contact information of other ill persons.
- Directly contacting physicians' clinics, hospitals, laboratories, schools, or nursing homes, as appropriate.
- Obtaining food establishment reservation list, computer records or credit card slips if necessary.
- Alerting the public directly through the media if needed to protect the public's health.

The data obtained during case finding can provide clues about the outbreak and potential risk factors associated with illness.

Line Listing

To initially assist in the organization of data, a good starting point can be the creation of a "line listing" table. Case names or alternate ID are listed down the left-hand column, and the heading row at the top of the table should contain pertinent information such as demographics, clinical information, and other epidemiologic information including risk factors related to illness.

Line Listing Example:

ID	Name	Age	Sex	Onset Date	Onset Time	D	N	V	F	Office Brunch	Sample?	Results?
1	S.A.	45	F	10/19/16	1:00a	Y	Y	Y	N	Y	Y	Pending
2	S.I.	57	F	10/18/16	11:00p	Y	Y	N	N	Y	Y	S Newport
3	C.W.	39	M	10/18/16	11:45p	Y	N	N	N	Y	Y	Pending
4	J.M.	32	M	Not ill						Y	N	
5	J.W.	27	F	Not ill						Y	Y	Pending
6	C.O.	25	F	Not Ill						N	N	
7	C.T.	16	F	10/19/16	6:00a	N	Y	N	Y	Y	N	

This line list shows that four ill individuals experienced similar symptoms around the same time

period. In addition, they all attended the same office party. Based on this information, it is highly likely that these individuals became ill after eating something served at an office brunch they attended 2 days earlier. Refer to Appendix D1 to learn more about creating a line listing.

The Questionnaire/Survey

A common method of finding cases, organizing and analyzing data is to conduct a questionnaire or survey among the population you believe to be at risk (e.g., attendees of an office brunch). A questionnaire that asks specific questions about foods eaten and symptoms experienced is a valuable epidemiologic tool. A questionnaire is administered to those ill and well and associated with the incident. The survey assists in developing better hypotheses about the etiologic agent's identity and source, including the means and time of transmission.

Key questions to consider when developing a questionnaire:

- What are the demographic characteristics of the individual? (name, age, sex, race, occupation, home and work addresses, phone numbers)
- Was the individual exposed to the suspected source and when?
- What are the symptoms, date of onset, order of occurrence and duration?
- What medical treatment has been sought and received? Hospitalized? Received any antibiotics?
- Is there a diagnosis or laboratory results?
- Who else has been exposed to a case during his or her infectious period (secondary contacts)?
- What foods were consumed in the last 72 hours (or other appropriate time frame) before the time of onset? It is also important to interview and obtain food histories from those who ate the same suspect food and did not get sick.
- Any other potential exposures, including specific activities/events.

When possible, a menu should be obtained, and specific food items, including drinks and ice, should be listed in the exposure or risk factor section. This will help with recall of food items eaten.

A questionnaire template should be created ahead of time and modified to fit the specifics of a given outbreak. These questions are intended to be used as a guide. They will require modification to fit the investigation. DIDE will assist with the creation of the questionnaire and examples of questionnaires used in the past are available upon request.

The question to be answered in the next step is the following:

"What is the organism that has caused illness?"

Determining what organism caused the illness is an important step in the outbreak investigation. Identifying the organism may indicate the food item involved and/or influence control measures needed to help stop the spread of illness. Clinical symptoms and time of onset may indicate the

causative or etiologic agent (Appendix A2); however, laboratory testing is needed to confirm the etiology. For most foodborne disease outbreaks, stool samples are collected from persons experiencing diarrhea to identify or confirm the pathogen. Blood cultures or serology testing are recommended for systemic infections, such as *Listeria monocytogenes* or hepatitis A virus. However, serology is less useful for most other foodborne illnesses.

Collection of Biological Specimens

It is important to start collection of stool specimens immediately after becoming aware of an outbreak. The optimum time of collection is during the acute onset of illness, preferably during the first 48 hours of illness. Encourage ill persons to submit specimens while they are still experiencing symptoms of illness. Aim to collect samples from 8-10 ill persons. In addition to collecting specimens from ill persons, it may be necessary to also collect specimens from well/asymptomatic persons. Specimen Kits can be requested from OLS using the "Microbiology Specimen Kit Request Form" (Appendix B1). Label all specimen containers with at least two patient identifiers. Identifying information can be provided by writing clearly on the vial. Information should match the information provided on the specimen submission form (Appendix B4). OLS will not test specimens that are not labeled appropriately.

Cary-Blair

OLS tests stool specimens from a foodborne outbreak using the BioFire Film Array Gastrointestinal Panel which tests for 23 different pathogens including bacteria, viruses and protozoa at no cost to the patient. Specimens should be collected in Cary-Blair transport vials. Specimen collection instructions are available in Appendix B3. Vomitus is not accepted for testing. Obtain specimens PRIOR to antibiotic treatment, if possible. Testing will only be performed after consultation with DIDE.

If laboratory testing has already been performed by the primary care provider or another laboratory, please request copies of the results of testing performed.

Shipping

Completely fill out the "Microbiology Laboratory Specimen Submission Form" (Appendix B4 or available at OLS website - www.wvdhhr.org/labservices/forms). Inform OLS of the shipment and expected arrival date. All stool specimens shipped to OLS for testing must be shipped as Category B, Biological Substances (UN3373). Consult OLS at 304-558-3530 for questions regarding shipping.

"What should be done at the suspected facility once an outbreak has been identified?"

It is important to not approach Environmental Assessments the same as a routine inspection. An environmental assessment is not about identifying regulatory violations; it is about attempting to identify the conditions under which the suspected foods were prepared. The investigation should

be guided by knowledge of food microbiology and the three main hazard categories. See Appendix C8 for information regarding the Fundamental Concepts of Food Microbiology.

Steps of an Environmental Assessment during an Outbreak Investigation include:

1. Prepare
2. Interview
3. Observe
4. Collect Samples
5. Record
6. Analyze
7. Correct
8. Summarize

Step 1: Prepare

Prior to going to the facility to conduct the environmental assessment, prepare by identifying either the paper forms or the sections of EHERS that will be used for the assessment. Forms used during an environmental assessment may include the Environmental Investigation Assessment Form (Appendix C5), Food Worker Interview Form (Appendix C7) and/or Food Specimen Tracking Form (Appendix C9).

Review the suspected facility's prior inspections and any complaints about the facility. Look for trends in violation history that could contribute to foodborne illness or repeat complaints. Review the epidemiological information and/or foodborne illness complaint to identify common foods and the possible type of foodborne illness. This will help guide some of the assessment by identifying the implicated food and areas of concern.

Identify what types of records to review at the facility, such as menus, cleaning records, or temperature logs. Gather equipment needed for investigation, including sampling materials if collecting samples.

Step 2: Interview

Upon arriving at the facility, introduction to the manager should be made and the reason for the visit should be explained. The manger should be asked about ill food workers and any complaints received by the facility. Use the Food Worker Form (Appendix C7) to interview any ill food workers.

All food handlers who were directly involved in producing, preparing or handling suspect foods should be interviewed. Gather information about their specific duties in the facility. Ask if there was anything different or special about the day the suspect food was prepared. If there is no specific day in question, asking questions about changes in preparation or how the operation usually occurs should be asked instead. Answers to these questions may reveal variations in how the food was prepared or held, which may provide an area of focus for the assessment.

Step 3: Observe

Observe operations and flow of food through the facility. Follow the suspect foods from receipt to storage or serving. If possible, have the food workers demonstrate how the suspect food is prepared and stored. Drawing a flow diagram for the food can help with keeping track of how the food travels through the facility. The assessment of the facility operation should focus on the risk factors and public health intervention measures.

Use the Environmental Investigation Assessment Form (Appendix C5) or the appropriate section of the environmental health electronic reporting system to conduct a HACCP investigation of suspect food or implicated foods (Appendix C1).

Step 4: Collect Samples

Food Samples

The sanitarian should collect samples of suspect food(s), if still available. Targeted sampling and laboratory testing of foods should be directed by epidemiological and environmental investigations. If an implicated food has not been identified at the time of sampling, various specimens may be collected and stored for future laboratory testing as additional information becomes available.

Food samples that may be appropriate for collection and testing include:

- Ingredients used to prepare implicated foods.
- Leftover foods from a suspect meal.
- Foods from a menu that has been implicated epidemiologically.
- Foods known to be associated with the pathogen in question.
- Foods in an environment that may have permitted the survival or growth of microorganisms.

If a packaged food item is suspected of being involved in an outbreak, it is particularly important to collect unopened packages of that food – ideally, from the same lot. This can help establish whether the food was contaminated before its receipt at the site of preparation. If no foods are left from a suspect meal, samples of items that were prepared subsequently but in a similar manner may be collected instead, although findings from these tests must be interpreted with care. Any ingredients and raw items that are still available should also be sampled.

Food sample testing will be conducted by the West Virginia Department of Agriculture (WVDA) laboratory; however, OLS will coordinate the collection and shipping of samples for testing. Do not send specimens directly to WVDA.

Collection Instructions

1. Collect the food samples using aseptic (sterile) techniques as much as possible. Use sterile jars, containers, or plastic bags in which to place samples. Use sterile pre-wrapped utensils for sampling.
2. Provide a large enough sample, approximately ½ lb. or 200ml (100-150 grams or 4-6 fluid ounces).
3. Do not fill containers to the brim.
4. Record temperature at which food is stored.

5. Collect frozen samples in pre-chilled containers and keep frozen.
6. If sample is hot, cool the container with ice or cold running water.
7. Make sure all caps are tight to avoid leakage.
8. Label each sample container with a unique identifier. Make sure the unique identifier from the container is also on the form.
9. Complete the following forms: "Food Laboratory Specimen Submission Form" (Appendix B5), "Food Specimen Tracking Form" (Appendix C9) and "Chain of Custody Record" (Appendix B2, or available at OLS website - www.wvdhhr.org/labservices/forms).
10. Transport food specimen at < 40° F (insulate with ice packs or dry ice see note below).
11. Record all samples sent
    - ID number
    - Date
    - Time
    - Type of sample
    - Type of test
12. Mail tightly sealed sample(s) and all forms in insulated container to OLS, priority status.

Note: Food specimens should be shipped refrigerated unless the specimen was originally frozen. If the specimen was originally frozen, the specimen should be shipped frozen on dry ice.

Inform OLS of shipment and expected arrival date. There are no specific labeling requirements for shipping of food specimens to OLS. Consult OLS at 304-558-3530 for questions regarding collection, shipping and test results of food specimens.

Environmental Samples

The purpose of collecting environmental samples is to trace the potential sources of, and evaluate the extent of contamination that may have led to, the outbreak. Samples may be taken from work surfaces, food contact surfaces of equipment, containers, and other surfaces such as refrigerators, door handles, etc. Swabs can also be taken from tables, cutting boards, grinders, slicing machines and other utensils that had contact with the suspect food. Environmental samples may also include water used for food processing.

Step 5: Record

Document all observations made during the assessment, including, but not limited to:

- Employee practices
- Processes observed
- Trace back information
- Temperatures
- Photos
- Manager/employee interview information
- Notes/copies of records reviewed

Step 6: Analyze

Review and compare epidemiologic data, laboratory data, environmental assessment findings, high-risk food preparation and handling practices and knowledge of food microbiology and food preparation risk factors to identify implicated foods and/or processes.

Step 7: Correct
Implement the appropriate corrective measures.

- Immediate measures include:
    - Hold order
    - Voluntary destruction of food
    - Seize
    - Suspend permit
- Long term measures include:
    - HACCP
    - Risk Control Plan
    - Training
    - Menu/supplier/recipe modification

Education and prevention measures should be discussed to ensure that the establishment serves food that is safe, unadulterated and honestly presented.

Step 8: Summarize and Report
Summarize and report findings in writing. Be sure to include:

- Accurate information
- Implicated food or process
- Flow of food
- Sources
- Kitchen diagram
- Time, temperature, solution measurements
- Photos
- Other key findings
- Corrective Actions

"What do we do with all this data we've collected?"

Using the questionnaires, line lists, laboratory findings, etc., characterize the cases and their illness using descriptive epidemiology techniques.

1. Develop a case definition: a case definition is a set of criteria that includes clinical and laboratory information and characteristics of person, place, and time. Developing a case definition is a critical step in the investigation as it classifies exposed individuals as cases or not cases. At the beginning of the outbreak a case definition can be broad (sensitive) to capture all potential cases. As more information becomes available, case definition can

be refined to be narrower (specific). It is crucial not to include the exposure in the case definition.

2. Refine case list and classify according to established case definition to exclude non-cases.
3. Organize information and summarize data collected in terms of person, place and time.
4. Review data to determine who is at risk (age, gender, occupation, grade, etc.) and where ill people live, work, etc.
5. Define the population at risk and the geographic extent of the outbreak.
6. Construct an epidemic curve, commonly known as an epi curve, which describes the course of the outbreak and helps to determine if the illness originated from a single source or is transmitted from person-to-person. An epi curve plots time on the x-axis and the number of ill persons or cases on the y-axis (Appendix D2)

See Appendix D3 for detailed instruction on performing descriptive epidemiology tasks.

"After looking at all this data, what do we think happened to cause the outbreak?"

Formulate hypothesis

A hypothesis is an educated guess about the cause of the outbreak and the factors that may have contributed to illness. Formulate a tentative hypothesis using the person, place and time associations. Hypotheses are usually formulated at the beginning of the outbreak and can be refined and modified as more information becomes available. It is very important not to be too restrictive in your focus, thereby excluding potentially important cases or events. By focusing too narrowly on one hypothesis you may miss pertinent cases. The sooner these hypotheses are developed, the sooner public health interventions may be implemented.

Occasionally, it may be useful to conduct analytic epidemiologic studies to test, evaluate, and/or refine the hypothesis. An experienced epidemiologist needs to be consulted to aid with such activities; DIDE will assist with these studies.

"What should we do now to mitigate risk and prevent additional illnesses?"

Implementing appropriate and effective control measures, in a timely manner, is a priority in each outbreak investigation. Control measures should be targeted to interrupt the transmission of disease, and should be determined and implemented based on available evidence and in consultation with epidemiologists, environmentalists and laboratory personnel. Important control and prevention measures related to foodborne outbreaks may include:

1. Emphasizing good handwashing.
2. Immediate removal of contaminated/suspected food.
3. Educating pertinent individuals (food service workers, mangers, patients or public if needed).
4. Excluding ill persons who are at high risk of spreading illness, including food handlers, day care attendees and providers, and persons involved with patient care.
5. Thorough cleaning of contaminated areas.
6. Closing the food establishment, if necessary.

7. Protection of close contacts and exposed individuals through immunization and/or antibiotic treatment, if indicated based upon the suspected disease-causing agent.

"Now that it's all over, what's left to do?"

Final Report

When an investigation is complete, it is imperative to provide written documentation of events. This is necessary not only for large outbreaks involving many people but also for complaints of possible foodborne illness.

The report documents what happened in a foodborne illness investigation. It is public record and must be objective, accurate, clear, and timely.

Detail in the document should reflect the complexity of the incident under investigation. A single complaint might result in a "complaint form" being completed with a list of action steps and any follow-up.

A more complicated occurrence (i.e., a large outbreak) might involve people outside your local jurisdiction and require a more comprehensive report. Guidelines for writing a final outbreak investigation report can be found in Appendix D4. It may be necessary to enlist all involved parties when preparing a final report.

Whether the report is being written in response to an outbreak or a single complaint, complete documentation is important for the following reasons:

- **A document for action**: In some cases, control and prevention measures will only be instituted in response to a written report. Until an outbreak is documented and summarized in a formal "outbreak report," it is easy for the implicated establishment operator to shift responsibility. The document contains the "official" findings. It should be used in refuting any rumors and/or speculation.
- **A record of performance**: A well-written report documents the magnitude of health problems and justifies program activities. A report clearly states events that occurred and the process that was followed. It should include all steps undertaken by everyone involved. The person writing the report will need to gather that information. The comprehensiveness of the outbreak report should reflect the complexity of the investigation. This accurately documents events and clearly illustrates staffing resources required to undertake the investigations.
- **A document for potential legal issues**: An investigative report written by health professionals must be written objectively, honestly and fairly. Information in these investigations is frequently used in legal actions. It is very important that a record exists that accurately documents events to aid in any legal investigations that might ensue.
- **An instrument to present control and preventive measures**: The primary reason to undertake an investigation is to control and prevent disease. The written report is an official medium to present control and preventive measures, and perform needs assessments. When

the report is presented to the owners and managers, encourage them to use it as a catalyst for change. This document is an educational tool and may help to prevent the same problems from reoccurring.

National Outbreak Reporting System (NORS)

When the outbreak is over, DIDE will enter the outbreak into NORS. NORS is the CDC developed web based outbreak data entry system for waterborne, foodborne, enteric person-to-person, animal contact, and environmental contact disease outbreaks.

After Action Review (AAR)

In some cases, it may be helpful to have a debriefing (after action report meeting or "hot wash") where those involved can meet to review the results of the investigation and discuss what went right and what could have been done differently. Such discussions can help improve future investigations.

Foodborne Outbreaks Resulting from Intentional Contamination

Intentional contamination of food should be considered if epidemiologic clues suggest that an outbreak may have been deliberately caused. When intentional contamination is suspected, it is imperative that law enforcement be contacted immediately. In these situations, law enforcement becomes the lead agency in the investigation.

From the perspective of the environmental assessment, unusual findings observed during the inspection may provide evidence that a pathogen or chemical was deliberately added.

Environmental Clues
• Reports of unusual color, odor, or appearance of food
• Evidence of tampering in food packaging
• Unusual agent or vehicle
• Chemicals that do not belong at the site
• Sick or dead animals in the vicinity of the food preparation facility
Source: International Association for Food Protection. *Procedures to Investigate Foodborne Illness*. 5th Edition. 1999. Reprinted 2007.

A strong and flexible public health infrastructure is the best defense against any disease outbreak – naturally or intentionally caused. As with all public health events, coordination and cooperation among all agencies are critical to the success of any response.

A1: HEALTH CARE PROVIDER GUIDELINES FOR REPORTING SUSPECTED FOODBORNE OUTBREAK-RELATED ILLNESSES

If two or more persons are suspected of having a foodborne illness, the health care provider should:

1. Inquire whether there are other ill persons.
2. Immediately contact the WV Division of Infectious Disease Epidemiology (DIDE) and/or your Local Health Department (LHD).*
3. Collect clinical samples for laboratory analysis.
4. The Office of Laboratory Services (OLS) offers testing at no cost during a suspected foodborne outbreak. Specimen should be collected in Cary-Blair medium. Questions regarding sample collecting/testing of clinical samples should be directed to DIDE at (304) 558-5358.
5. If suspected food items are available, instruct the individual not to ingest or discard food, but to keep it refrigerated. Arrangements should be made to collect and analyze the food samples pending further investigation. Arrangements must be made by the LHD to collect and hold the food items under refrigeration. Questions regarding sample collecting/testing of food samples should be directed to DIDE at (304) 558-5358.

Please provide the following information:

- Brief description of situation
- Names of ill persons
- Address, telephone number
- Age, sex
- Onset of symptoms (date, time)
- Description of symptoms
- Hospitalization status
- Other available information (other ill persons, possible food sources, etc.)
- Name of physician (if different than reporter), address, telephone number

General Definition of a Foodborne Outbreak:

2 or more persons who experience a similar illness after ingestion of a common food or different food in a common place.

* Division of Infectious Disease Epidemiology is available 24/7/365 at: (304) 558-5358 or Toll Free: (800) 423-1271 in WV

A2: CRITERIA FOR CONFIRMATION OF BACTERIAL AGENTS RESPONSIBLE FOR FOODBORNE AND WATERBORNE ILLNESS

Etiologic Agent	**Incubation Period** Average (Range)	**Clinical Syndrome**	**Characteristic Foods**
Bacillus cereus	**A. Vomiting type** 2-4 hours (1-6 hours) **B. Diarrheal type** 12 hours (4-16 hours)	A. Vomiting, nausea, occasional diarrhea (Heat-stable enterotoxin) B. Diarrhea (watery), abdominal cramps (Heat-labile enterotoxin)	A. Boiled or fried rice B. Custards, sauces, meat loaf, cereal products, refried beans, dried potatoes
Campylobacter jejuni	2-5 days (1-10 days)	Abdominal cramps (often severe), diarrhea, bloody diarrhea, fever, headache	Poultry, unpasteurized milk, water, raw clams
Clostridium botulinum	12-48 hours (2 hours -8 days)	Acute bilateral cranial nerve impairment and descending weakness or paralysis; usually preceded by blurred or double vision, difficulty swallowing, dry mouth, vomiting and constipation	Canned low-acid foods, smoked fish, cooked potatoes, marine mammals
Clostridium perfringens	10-12 hours (6-24 hours)	Diarrhea (watery), colic, nausea and gas (Vomiting and fever are uncommon and symptoms usually resolve within 24 hours)	Inadequately heated or reheated meats, meat pies, stews, gravy, sauces, refried beans
Escherichia coli (Enteroinvasive or Enterotoxigenic) *E. coli* 0157:H7 (Enterohemorrhagic)	10-12 hours (Heat-stable toxin) 10-12 hours (Heat-labile toxin) 48-96 hours (up to 10 days)	Profuse watery diarrhea without blood or mucus, abdominal cramping, vomiting, low-grade fever and dehydration Bloody or non-bloody diarrhea, severe abdominal cramps and occasional vomiting; fever infrequent	A. Uncooked vegetables, salads, water B. Undercooked ground beef and beef, raw milk, soft cheese, water
Salmonella spp. (Non-typhoid)	18-36 hours (12-72 hours)	Acute enterocolitis, diarrhea, fever, nausea, abdominal cramps, headache, occasional vomiting	Poultry, egg products, meat, unpasteurized milk
Salmonella Typhi	3 days - 3 months (1-3 weeks)	Insidious onset of fever, headache, malaise, constipation or diarrhea, anorexia	Fecally contaminated foods such as shellfish, raw fruits, and water
Shigella	24-72 hours (12-96 hours)	Diarrhea, fever, nausea, vomiting, tenesmus, severe abdominal cramping	Fecally contaminated foods such as salads, cut fruit and water
Staphylococcus aureus	2-4 hours (1-8 hours)	Sudden onset of severe abdominal cramps, nausea, vomiting, diarrhea, chills, headache, weakness, dizziness	Ham, meat & poultry, cream filled pastries, custard, high protein leftover foods
Vibrio cholerae 01 or 0139 *Vibrio cholerae* non-01	24-72 hours (few hours - 5 days)	Sudden onset of profuse watery diarrhea, rapid dehydration, vomiting Watery diarrhea, vomiting	Raw fish or shellfish, crustacea, water, fecally contaminated foods
Vibrio parahaemolyticus	12-24 hours (4-96 hours)	Watery diarrhea, abdominal cramps, nausea, vomiting, fever, headache	Marine fish, shellfish, crustacea (raw or contaminated)
Vibrio vulnificus	24-48 hours	Fever, nausea, abdominal cramps and muscle aches; often leads to septicemia in immunocompromised persons	Raw oysters

Criteria for confirmation of bacterial agents responsible for foodborne and waterborne illness.

Etiologic Agent	Laboratory and Epidemiologic Criteria for Confirmation	Specimen	Type of Container
Bacillus cereus	Isolation of 10^6 *B. cereus*/gm of implicated food, **OR** Isolation of *B. cereus* from stool of ill person.	5-50 g stool	Cary-Blair
Campylobacter jejuni	Isolation of *C. jejuni* from implicated food, **OR** Isolation of *C. jejuni* from stool or blood of ill person.	15 ml stool	Cary-Blair
Clostridium botulinum	Detection of *C. botulinum* toxin from implicated food, **OR** Detection of *C. botulinum* toxin from human sera, or feces, **OR** Isolation of *C. botulinum* from stool of persons with clinical syndrome, **OR** Consistent clinical syndrome in persons known to have eaten same food as persons with laboratory proven cases.	25-50 g stool	Sterile, leak-proof container
Clostridium perfringens	Isolation of $>10^5$ *C. perfringens/*gm of implicated food, **OR** Isolation of *C. perfringens* in stool of ill persons, **OR** Detection of enterotoxin by latex agglutination (from stool extracts of culture isolates).	5-50 g stool	Cary-Blair
Escherichia coli (Enteroinvasive or Enterotoxigenic) *E. coli* 0157:H7 (Enterohemorrhagic)	Demonstration of *E. coli* of same serotype in implicated food and stools in persons, **OR** Isolation of *E. coli* of the same serotype shown to be enteroinvasive or enterotoxigenic from stool of ill persons, **OR** Demonstration of *E. coli* isolates from stools that are enterotoxigenic or enterohemorrhagic.	15 ml stool	Cary-Blair
Salmonella spp. (Non-typhoid)	Isolation of *Salmonella* from implicated food or water, **OR** Isolation of *Salmonella* from stool from ill persons.	15 ml stool	Cary-Blair
Salmonella Typhi	Isolation of *S. typhi* from blood, stool or other clinical specimens.	15 ml stool	Cary-Blair
Shigella	Isolation of *Shigella* from implicated food, **OR** Isolation of *Shigella* from stool of ill persons.	15 ml stool	Cary-Blair
Staphylococcus aureus	Isolation of an enterotoxin producing strain of *S. aureus* in implicated food, **OR** Isolation of enterotoxin producing strain of *S. aureus* from stool of ill persons.	5-50 g stool	Cary-Blair
Vibrio cholerae 01 or 0139 *Vibrio cholerae* non-01	Isolation of toxigenic *V. cholerae* 01 or 0139 from implicated food, **OR** Isolation of *V. cholerae* 01 or 0139 from stool or vomitus of ill persons, **OR** Significant rise (fourfold) in vibriocidal antibodies. Isolation of *V. cholerae* non-01 from stool of ill person. Isolation of *V. cholerae* non-01 from implicated food is supportive evidence.	15 ml stool	Cary-Blair
Vibrio parahaemolyticus	Isolation of 10^5/g *V. parahaemolyticus* from implicated food (usually seafood), **OR** Isolation of V. *parahaemolyticus* from stool of ill persons.	15 ml stool	Cary-Blair
Vibrio vulnificus	Isolation of *V. vulnificus* from blood of ill persons.	Blood	Sterile Container

Criteria for confirmation of viral agents responsible for foodborne and waterborne illness.

Etiologic Agent	**Incubation Period** Average (Range)	**Clinical Syndrome**	**Characteristic Foods**
Hepatitis A virus	28-30 days (15-50 days)	Acute febrile illness with anorexia, fever, abdominal discomfort, nausea, jaundice	Fecally contaminated cold foods or water, raw shellfish
Norovirus	30-36 hours (10-96 hours)	Nausea, vomiting (often projectile), diarrhea, abdominal cramps, muscle aches, headaches, low-grade fever	Fecally contaminated cold foods or water, oysters or clams, frostings

Criteria for confirmation of parasitic agents responsible for foodborne and waterborne illness.

Etiologic Agent	**Incubation Period** Average (Range)	**Clinical Syndrome**	**Characteristic Foods**
Cyclospora cayetanensus	7 days (1-11 days)	Fatigue, protracted watery diarrhea, often relapsing	Fecally contaminated fruits, produce or water
Cryptosporidium parvum	7 days (2-12 days)	Profuse watery diarrhea, abdominal cramps, nausea, low-grade fever, anorexia, vomiting	Fecally contaminated fruits, produce or water
Entamoeba histolytica	2-4 weeks (few weeks - several months	Illness of varying severity ranging from mild chronic diarrhea to fulminant dysentery	Fecally contaminated fruits, produce or water
Giardia lamblia	7-10 days (2-25 days)	Diarrhea, abdominal cramps, bloating, weight loss, malabsorption; infected persons may be asymptomatic	Fecally contaminated fruits, produce or water
Trichinella spiralis	8-15 days (5-45 days)	Initially diarrhea, nausea, vomiting, abdominal discomfort, muscle aches, edema of the eyelids; variable symptoms depending on the number of larvae ingested	Undercooked pork or bear meat

Criteria for confirmation of viral agents responsible for foodborne and waterborne illness.

Etiologic Agent	Laboratory and Epidemiologic Criteria for Confirmation	Specimen	Type of Container
Hepatitis A virus	Positive anti-HAV IgM test, **OR** Liver function tests compatible with hepatitis in persons who ate the implicated food.	3 ml serum or 7ml vacutainer, no additives	Sterile container
Norovirus	Diagnosed is often based on symptoms, onset times, and ruling out other enteric pathogens, **OR** Identification of virus in stool by polymerase chain reaction (PCR).	15 ml stool	Sterile, leak-proof container

Criteria for confirmation of parasitic agents responsible for foodborne and waterborne illness.

Etiologic Agent	Laboratory and Epidemiologic Criteria for Confirmation	Specimen	Type of Container
Cyclospora cayetanensus	Demonstration of *C. cayetanensus* in stool of two or more ill persons.	10-15 ml stool	10% formalin
Cryptosporidium parvum	Isolation of *C. parvum* oocysts from implicated food, **OR** Isolation of *C. parvum* oocysts from stool of ill persons**, OR** Demonstration of *C. parvum* in intestinal fluid, or small bowel biopsy specimens, **OR** Demonstration of *C. parvum* antigen in stool by a specific immunodiagnostic test (e.g., enzyme-linked immunosorbent assay (ELISA).	10-15 ml stool	10% formalin
Entamoeba histolytica	Isolation of *E. histolytica* from stool of ill persons, **OR** Demonstration of *E. histolytica* trophozoites in tissue biopsy, culture or histopathology.	10-15 ml stool	10% formalin
Giardia lamblia	Isolation of *G. lamblia* cysts from implicated food or water, **OR** Isolation of *G. lamblia* from stool of ill persons, **OR** Demonstration of *G. lamblia* trophozoites in duodenal fluid or small bowel biopsy, **OR** Demonstration of *G. lamblia* antigen by specific immunodiagnostic test (e.g., direct fluorescent antigen (DFA)).	10-15 ml stool	10% formalin
Trichinella spiralis	Detection of *T. spiralis* from muscle biopsy from ill person, **OR** Fourfold change or positive serologic test, **OR** Demonstration of *T. spiralis* in implicated food, OR Associated cases are confirmed if patient ate epidemiologically linked meal and is clinically compatible.	Tissue or serum	Sterile container

Criteria for confirmation of other agents responsible for foodborne and waterborne illness.

Etiologic Agent	**Incubation Period** Average (Range)	**Clinical Syndrome**	**Characteristic Foods**
Heavy metals (antimony, cadmium, copper, iron, tin, zinc)	Usually < 1 hour (5 minutes - 8 hours)	Compatible clinical syndrome - usually gastroenteritis with metallic taste	High acid foods/beverages stored or prepared in containers coated, lined, or contaminated with the offending metal
Scombroid fish poisoning	Usually < 1 hour (1 minute - 3 hours)	Flushing, headache, dizziness, burning of mouth and throat, upper and lower gastrointestinal symptoms, urticaria and generalized pruritis	Temperature abused fish (especially tuna, mahi-mahi, mackerel, bluefish, escolar)
Ciguatoxin	2-8 hours (1-48 hours)	Gastrointestinal symptoms followed by neurologic manifestations, including pricking or burning sensation of lips, tongue or extremities, reversal of hot/cold sensations	Fish (especially snapper, grouper, amberjack)
Paralytic shellfish poisoning (PSP)	30 minutes - 3 hours	First symptoms include tingling and numbness of lips and mouth, spreading to adjoining parts of face; symptoms vary depending on type, amount and retention of toxins in the body	Shellfish
Mushroom poisoning	6-24 hours (1-24 hours)	Initially nausea, vomiting, watery diarrhea which may progress to liver failure and death	Mushrooms (usually of the genus *Amanita*)
Monosodium glutamate poisoning	Usually < 1 hour (3 minutes - 2 hours)	Burning sensation in chest, neck, abdomen or extremities, sensations of lightness and pressure over face, or heavy feeling in the chest	Food containing large amounts of MSG (usually >1.5g)

Criteria for confirmation of other agents responsible for foodborne and waterborne illness.

Etiologic Agent	Laboratory and Epidemiologic Criteria for Confirmation	Specimen	Type of Container
Heavy metals (antimony, cadmium, copper, iron, tin, zinc)	Demonstration of high concentrations of metallic ion in implicated food or beverage (e.g., >400 ppm for tin).	*	*
Scombroid fish poisoning	Demonstration of elevated histamine levels (>50mg/100g) in implicated fish, cheese, or other food, **OR** Clinical syndrome in persons known to have eaten fish of Order *Scombrodei* or types of fish previously associated with scombroid poisoning (e.g., mahi-mahi, tuna, bluefish).	*	*
Ciguatoxin	Demonstration of ciguatoxin in implicated fish, **OR** Clinical syndrome in persons who have eaten a type of fish previously associated with ciguatera poisoning (e.g., amberjack, snapper, grouper).	*	*
Paralytic shellfish poisoning (PSP)	Detection of toxin in implicated mollusks, **OR** Detection of large numbers of shellfish poisoning-associated species of dinoflagellates in water from which implicated mollusks were gathered.	*	*
Mushroom poisoning	Demonstration of toxic chemical in implicated mushrooms, **OR** Epidemiologically implicated mushrooms identified as toxic.	*	*
Monosodium glutamate poisoning	History of ingesting implicated foods containing large amounts of MSG (usually >1.5g).	*	*

*If an outbreak involves any of the agents listed on these tables, immediately contact the OLS and DIDE to receive instructions as to which specimens to collect, how to transport these specimens.

B1: MICROBIOLOGY SPECIMEN KIT REQUEST FORM

NAME OF FACILITY			DATE OF REQUEST
MAILING ADDRESS	CITY	STATE	ZIP
NAME OF PERSON REQUESTING KITS		TITLE	
PHONE NUMBER	EMAIL ADDRESS		

COMPLETE COLLECTION KIT	QUANTITY	
	REQUESTED	SENT
Stool Culture Kit (CARY BLAIR) USE: *For screening stool specimens for the presence of enteric bacteria.* EACH		
Parasitology Kit (10% FORMALIN) USE: *For screening stool for presence of parasites.* EACH		
Pinworm Kit USE: *For screening cellulose tape mounts for the presence of pinworms or pinworm eggs.* EACH		
Mycobacteriology (TB) Kit USE: *For screening clinical specimens for the presence of* Mycobacterium tuberculosis. EACH		
Pertussis Kit (AMIES liquid) USE: *For screening nasopharyngeal swabs for the presence of* Bordetella pertussis. EACH		

NOTE: Most kits contain specimen collection vial/tube, absorbent sheet, zippered plastic bag, inner and outer mailer, and test request form.

ADDITIONAL SUPPLIES		
Mycobacteriology (TB) Inner Bag Kits (clear zippered bag, Tyvek bag, and 50mL tube)		
Cary Blair		
10% Formalin		
Amies liquid (blister pack with swab)		

CONTACT INFORMATION	
Section/Unit	*Extension*
Microbiology Section	2602
TB Unit	2621
Containers Unit	2204

Order Filled By: _____

Order Shipped By: _____

Date: _____

Rev. 05/2015

B2: CHAIN OF CUSTODY RECORD

TO BE COMPLETED BY SUBMITTER		
Date Collected:	Time Collected:	Collected By: (name)
Submitting Agency Name:		
Description of Sample:		
Method of Sample Transportation: ❑ FedEx ❑ UPS ❑ USPS ❑ Hand delivered ❑ Other _____	Tracking number: (if applicable)	Seal Number:

REMAINDER OF FORM FOR OLS USE ONLY

OLS Lab #	Date Received at OLS:	Time Received at OLS:
Condition of Sample at Receipt:	Temperature of Sample at Receipt:	Seal Intact? ❑ Yes ❑ No
Person Receiving Sample at OLS:	Sample Being Submitted For:	Storage Condition at OLS: ❑ Refrigerated ❑Frozen ❑ Room temperature Refrigerator/Freezer # _____

INTERNAL TRANSFER RECORD:					
LOCATION TRANSFERRED FROM	BY	DATE/TIME	LOCATION TRANSFERRED TO	BY	DATE/TIME
	Signature: Print Name:	____ /____ /____		Signature: Print Name:	____ /____ /____
	Signature: Print Name:	____ /____ /____		Signature: Print Name:	____ /____ /____
	Signature: Print Name:	____ /____ /____		Signature: Print Name:	____ /____ /____

EXTERNAL TRANSFER RECORD:					
RELINQUISHED FROM	ORGANIZATION	DATE/TIME	RECEIVED BY	ORGANIZATION	DATE/TIME
Signature: Print Name:		____ /____ /____	Signature: Print Name:		____ /____ /____
Signature: Print Name:		____ /____ /____	Signature: Print Name:		____ /____ /____
Signature: Print Name:		____ /____ /____	Signature: Print Name:		____ /____ /____

SAMPLE DISPOSITION RECORD	
Was sample transferred or destroyed after testing was complete?	❑ Destroyed ❑ Transferred

COMPLETE IF TRANSFERRED			
Sample Transferred Via: ❑ FedEx ❑ UPS ❑ USPS ❑ Hand delivered ❑ Other _____	Sample Transferred To:	Name of Transferee:	Date Transferred:
OLS Staff Preparing Transfer:			

COMPLETE IF DESTROYED	
How was sample destroyed? (i.e., autoclave, incineration, etc.)	
Destroyed By:	
Date Destroyed:	Time Destroyed:

Comments:

B3: SPECIMEN COLLECTION INSTRUCTIONS

These laboratory instructions provide guidance on how to properly collect stool specimens and how to successfully ensure safe transport to the laboratory. It is absolutely critical that specimens be collected properly, labeled properly, stored appropriately, and submitted with a complete laboratory test request/submission form for Enteric Bacteriology testing.

WHAT IS COLLECTED: The preferred specimen is loose or semi-solid stool. OLS will also accept bloody and watery stool. Formed or hard stool specimens are not optimal, but will be accepted.

TIMING OF COLLECTION: Specimens for testing should only be collected from individuals who have been symptomatic for less than 72 hours and have not been placed on antimicrobial therapy.

HOW TO COLLECT: Once collected, the stool should be placed in Cary Blair as soon as possible (within two hours of collection). Make sure the lid is securely closed. It is recommended to use Parafilm or tape to seal the lid. Cary Blair is a red liquid. Do not remove the liquid inside the collection vial. Other enteric transport media such as C&S are also acceptable. Raw stool not in transport media will result in rejection of the specimen.

PERSONAL PROTECTIVE EQUIPMENT (PPE): Disposable gloves are recommended when collecting stool specimens. When collection is complete, dispose of all PPE and other contaminated materials in a trash receptacle. Wash hands thoroughly with soap and water or use an alcohol-based hand gel before and after the collection procedure.

STEPS TO STOOL SPECIMEN COLLECTION:

1. Label the Cary Blair vial with the patient's first and last name (or unique identifier) and the date of collection.
2. Obtain clean newspaper, plastic wrap (as shown below) or wide-mouthed container. Collect the stool specimen as shown below.

A. Lift the toilet seat. Cover the toilet bowl with a large sheet of newspaper or plastic wrap. Make a depression in the material with your hand to allow for collection. (If using wide-mouthed container, hold so that stool goes directly into container and does not come into contact with water or urine.)

B. Lower the toilet seat and sit to pass specimen onto newspaper or plastic wrap.

3. An appropriate (i.e. bloody, slimy, watery) area of stool should be selected and sampled with the collection spoon provided in the cap of the container. Sufficient stool is added to the container to bring the liquid level up to the "fill to here" line (approximately 1 gram). DO NOT REMOVE THE LIQUID INSIDE THE COLLECTION VIAL.
4. **DO NOT TAKE STOOL FROM TOILET BOWL.** Stool samples cannot be tested if mixed with water or urine.
5. After collecting stool specimen, dispose of newspaper or plastic wrap.
6. Agitate each specimen with the spoon along the sides of the container, tighten the cap. Gently invert vial to insure that the specimen is adequately mixed.

COMPLETION OF TEST REQUEST FORM: The test request form must contain the patient name (and/or unique identifier), patient date of birth, date of specimen collection, source of specimen, and submitting facility name and address at a minimum. The specimen tube must have the patient name or unique identifier that matches the test request form. **FAILURE TO COMPLETE THE REQUIRED INFORMATION ON THE TEST REQUEST FORM MAY RESULT IN THE REJECTION OF THE SAMPLE.**

If specimens are being submitted as part of an outbreak, the Outbreak Number must be written in the designated area on the form. To obtain an Outbreak Number, contact the Division of Infectious Disease Epidemiology at 304-558-5358.

STORAGE: After collection, place the vial containing the specimen into a zippered or sealable biohazard labeled bag. It is best to keep the specimen(s) refrigerated at 4°C (39.2°F) until shipping. If refrigeration is not available, specimen(s) can be kept at room temperature (19-25°C [66-77°F]).

PACKAGING AND SHIPPING: Specimens can be shipped at ambient temperature and do not require ice packs. DO NOT SHIP SPECIMENS IF THEY WILL ARRIVE AT OLS DURING WEEKENDS OR HOLIDAYS. OLS does not have the means to accept any packages during weekends or holidays. The package must be shipped according to the current DOT, IATA, and ICAO regulations. See our website - *www.wvdhhr.org/labservices* - for complete packaging and shipping guidelines.

OFFICE OF LABORATORY SERVICES
167 11th Avenue | South Charleston, WV 25303
PH: (304) 558-3530 | FX: (304) 558-2006

PLACE BARCODE HERE

OLS USE ONLY

B4: MICROBIOLOGY LABORATORY SPECIMEN SUBMISSION FORM

PATIENT INFORMATION

PATIENT ID (Chart #, etc.) *MAX. 17 CHARACTERS*		
LAST NAME	FIRST NAME	MI
DATE OF BIRTH	SS# *(last 4 only, optional)*	
COUNTY OF RESIDENCE	SEX ❑ Female ❑ Male	
STREET ADDRESS		
CITY	STATE	ZIP
PATIENT PHONE NO. *(optional)*		

SUBMITTER INFORMATION

FACILITY NAME		
MAILING ADDRESS		
CITY	STATE	ZIP
COUNTY		
ATTENTION TO		
PHONE NO.		
FAX NO.		

COMMENTS:

DATE OF COLLECTION:

SITE/SOURCE OF SPECIMEN:

❑ Blood	❑ Sputum
❑ Cellulose tape mount	❑ Sputum, induced
❑ CSF	❑ Stool
❑ Nasopharyngeal	❑ Stool, bloody
❑ Rectal	❑ Throat
❑ Serum	❑ Urethra
❑ Serum, acute	❑ Urine
❑ Serum, convalescent	
❑ Wound Location:	
❑ Bronchial Specify:	
❑ Tissue Specify:	
❑ Fluid Specify:	
❑ Other Specify:	

TEST(S) REQUESTED:

BACTERIOLOGY

- ❑ Referred Culture
- ❑ Pertussis culture / PCR
- ❑ Enteric (stool in Cary-Blair)
- ❑ Gonorrhea culture/smear
- ❑ Unknown bacteriology ID

Suspected Organism (s):

VIROLOGY

- ❑ Influenza RT-PCR
  - Submitted for:
  - ❑ Surveillance (Sentinel)
  - ❑ Other *(note in Comments)*
  - ❑ Outbreak
    - If outbreak . . .
    - ❑ School
    - ❑ Nursing Home/LTCF
    - ❑ Other
- ❑ Respiratory Pathogen Panel ***

Was specimen pre-screened for presence of Influenza? ❑ Yes ❑ No

- ❑ Norovirus RT-PCR ***
- ❑ GI Pathogen Panel ***

MYCOBACTERIOLOGY

- ❑ Culture/Smear C
- ❑ TB ID/Confirmation R
- ❑ MOTT Identification R

Suspected Organism:

Date growth appeared:

Patient taking TB drugs?
❑ Yes ❑ No
Date Started:

Skin Test
❑ POS (+) ❑ NEG (-)

Chest X-ray
❑ Abnormal ❑ Normal

Contact to TB patient?
❑ Yes ❑ No

Refrigerated? ❑ Yes ❑ No

PARASITOLOGY

- ❑ Fecal Parasite Exam (10% formalin)
- ❑ Pinworm Exam (cellulose tape mount)

SENDOUT

- ❑ Referred Culture/ID

OLS USE ONLY	
❑ UNSAT | Reason:	ACC:
❑ UNRELIABLE | Reason:	DE:
❑ SATISFACTORY	CKD:

OUTBREAK NUMBER
(REQUIRED FOR OUTBREAKS - OBTAIN FROM DIDE)

CONTACT NAME: _____

****** Testing performed on outbreak specimens ONLY.***

DIDE = Division of Infectious Disease Epi

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PH: (304) 558-3530 | FX: (304) 558-2006

PLACE BARCODE HERE

OLS USE ONLY

B5: FOOD LABORATORY SPECIMEN SUBMISSION FORM

PATIENT INFORMATION
(if applicable)

PATIENT #1

LAST NAME	FIRST NAME	MI

DATE OF BIRTH	SS# *(last 4 only, optional)*
COUNTY OF RESIDENCE	SEX ❑ Female ❑ Male
STREET ADDRESS	

CITY	STATE	ZIP

PATIENT #2

LAST NAME	FIRST NAME	MI

DATE OF BIRTH	SS# *(last 4 only, optional)*
COUNTY OF RESIDENCE	SEX ❑ Female ❑ Male
STREET ADDRESS	

CITY	STATE	ZIP

NOTE: PLEASE USE BACK OF THIS FORM FOR PATIENT INFORMATION IF MORE THAN 2 PERSONS ARE INVOLVED.

SUBMITTER INFORMATION

FACILITY NAME		
MAILING ADDRESS		
CITY	STATE	ZIP
COUNTY		
ATTENTION TO:		
PHONE NO.		
FAX NO.		

OLS USE ONLY	ACC:
❑ UNSAT	DE:
Reason/ID:	CKD:

DATE OF COLLECTION:

TEST REQUESTED:

❑ Routine Food Testing*	❑ Other ID Specify:

*Includes testing for: *Salmonella* spp., *Shigella* spp., *S. aureus, Escherichia coli* O157:H7, *C. jejuni*, and coliforms.

ROUTINE FOOD SAMPLE INFORMATION:

Name of Investigator	
Phone # of Investigator	
Specimen Description	
Manufacturer	
Lot Number	
Date & Time Served	
Date & Time of First Symptoms	
Number of persons consuming food	
Number of ill persons	
Suspected Organism(s)	

COMMENTS:

C1: HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP)

Overview

Hazard Analysis and Critical Control Point, or HACCP (pronounced HAS-SIP), is a systematic, science-based approach of identifying, evaluating, and controlling food safety hazards.† Initially developed to keep food safe for astronauts within the space program, this approach was adopted by the Food and Drug Administration and the U.S. Department of Agriculture as a means of ensuring a safe food supply from harvest to consumption. Currently, the seafood industry, juice industry, and meat and poultry processing plants are required to follow a HACCP plan, or a written documentation of all food processing and handling procedures. A number of food companies in the U. S. have also adopted a HACCP plan in their manufacturing processes.

The following table lists the seven fundamental HACCP principles.

HACCP Principles†	
1.	Conduct a hazard analysis
2.	Identify the critical control points (CCP)
3.	Establish critical limits for each CCP
4.	Establish monitoring procedures
5.	Establish corrective actions
6.	Establish recordkeeping procedures
7.	Establish verification procedures

PRINCIPLE #1: Conduct a hazard analysis

The purpose of this principle is to develop a list of hazards that likely to cause injury or illness if not effectively controlled. Common hazards include microorganisms naturally found in meat or poultry products (i.e. *Campylobacter*, *Salmonella*), chemicals that are unintentionally added to food (i.e. pesticides, cleaners), or foreign materials that are accidentally found in food (i.e. metal, plastic).

PRINCIPLE #2: Identify the critical control points (CCPs)

A CCP refers to a point, step, or procedure in the food process during which control measures may be applied to prevent, eliminate, or reduce hazards. An example of a CCP is the procedure of cooking poultry to 165º F to destroy microorganisms that may be present.

PRINCIPLE #3: Establish critical limits for each CCP

Critical limits are defined as the maximum or minimum value at which a biological, chemical, or physical hazard must be controlled at a given CCP to ensure food safety. An example of a critical limit includes holding temperatures, such as the minimum hot holding temperature of 140º F or the maximum cold holding temperature of 41º F.

PRINCIPLE #4: Establish monitoring procedures

Monitoring procedures are procedures that check, measure, and document the food process at a given CCP. An example of a monitoring procedure is the routine observation and recording of cooking times and temperatures.

PRINCIPLE #5: Establish corrective actions

When deviations or problems are identified through monitoring, corrective actions are initiated. An example of a corrective action is the disposing of food if the minimum cooking temperature is not met.

† FDA. *HACCP: A State-of-the-Art Approach to Food Safety*. http://www.cfsan.fda.gov/~lrd/bghaccp.html

PRINCIPLE #6: Establish recordkeeping procedures
Recordkeeping is essential for the documentation of monitoring procedures, hazards identified, and actions taken to correct potential problems. Moreover, recordkeeping ensures that regulatory requirements are met.

PRINCIPLE #7: Establish verification procedures
Verification procedures are necessary to evaluate a HACCP system and determine if the system is working properly. Verification often involves the testing and reviewing of specific steps, quality control and assurance of equipment and procedures, and annual assessments.

Application of HACCP Principles during an Environmental Investigation

When a foodborne disease outbreak is identified in a food service establishment, food inspectors conduct an inspection that is based on the HACCP principles. Food inspectors follow the food process in the establishment, paying close attention to the preparation of suspect foods or foods implicated in the foodborne disease outbreak.

The following paragraphs describe the general procedures of a HACCP inspection during a foodborne disease outbreak investigation.

Introduction and purpose
Upon arrival at the food service establishment, the inspector should introduce himself to the person in charge and explain the purpose of the inspection.

Identification of ingredients and steps
The inspector should review the menu and identify the ingredients and steps involved in the receiving, storage, preparation and service of suspect food(s). The inspector should obtain recipes for all suspect food(s), identify the ingredients, and collect information about the source. The inspector should also pay close attention to potentially hazardous foods and high-risk preparation factors.

Identify critical control points
Based on the observations made, the inspector should identify critical control points and corrective actions to reduce potential hazards. Microbiological hazards account for the majority of foodborne illness; therefore, emphasis should be placed on contamination, survival, and growth/toxin production risks at these points.

Observe suspect food(s) through establishment
The inspector should observe the suspect food(s) and record the procedures conducted through the operation — from receipt of food from the delivery truck to consumption by the consumer.

All risk factors should be observed, including the food source, cooking and holding procedures, potential contamination factors, and poor personal hygiene. Inspectors should have the proper equipment (e.g., thermometers) to assist with these observations. Written documentation on how food(s) were handled and what equipment was used should be completed. Observation and documentation of who handled the food(s) during each preparation step should also be done to help determine if a specific food handler or particular role may have contributed to illness. A flow chart should be developed as a visual tool of the process.

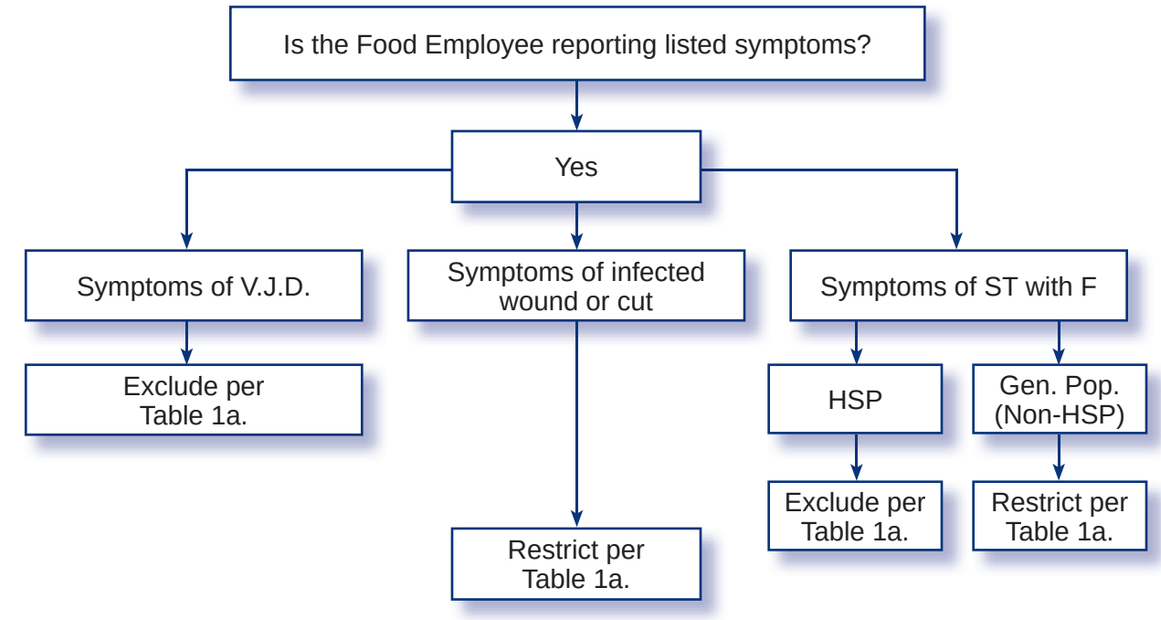
Monitoring and corrective action procedures

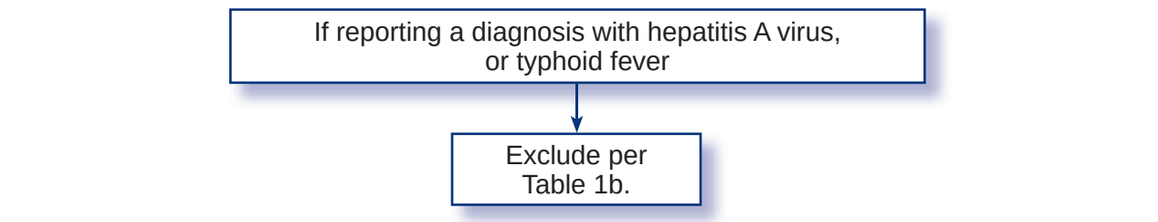
Monitoring procedures and corrective actions should be established. These should be discussed in a brief exit interview with the person in charge.

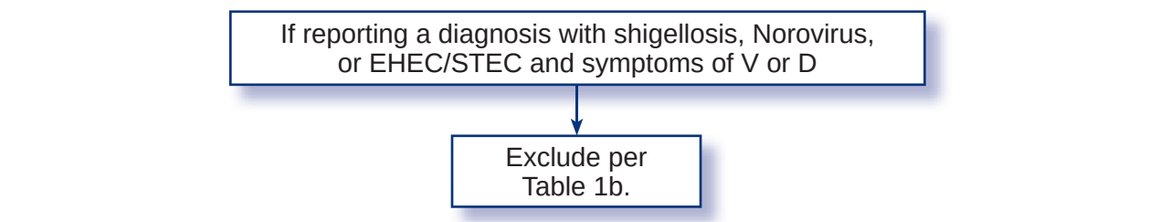
Submit paperwork

Inspectors should write and submit a HACCP inspection report, complete with flow charts, recommendations, and other appropriate paperwork to their supervisor and the epidemiology investigator. Following submission of the report, the inspector should return to the food service establishment to present the report and discuss recommendations with the person in charge.

2-201.11 / 2-201.12 Decision Tree 1. When to Exclude or Restrict a Food Employee Who Reports a Symptom and When to Exclude a Food Employee Who Reports a Diagnosis with Symptoms Under the Food Code



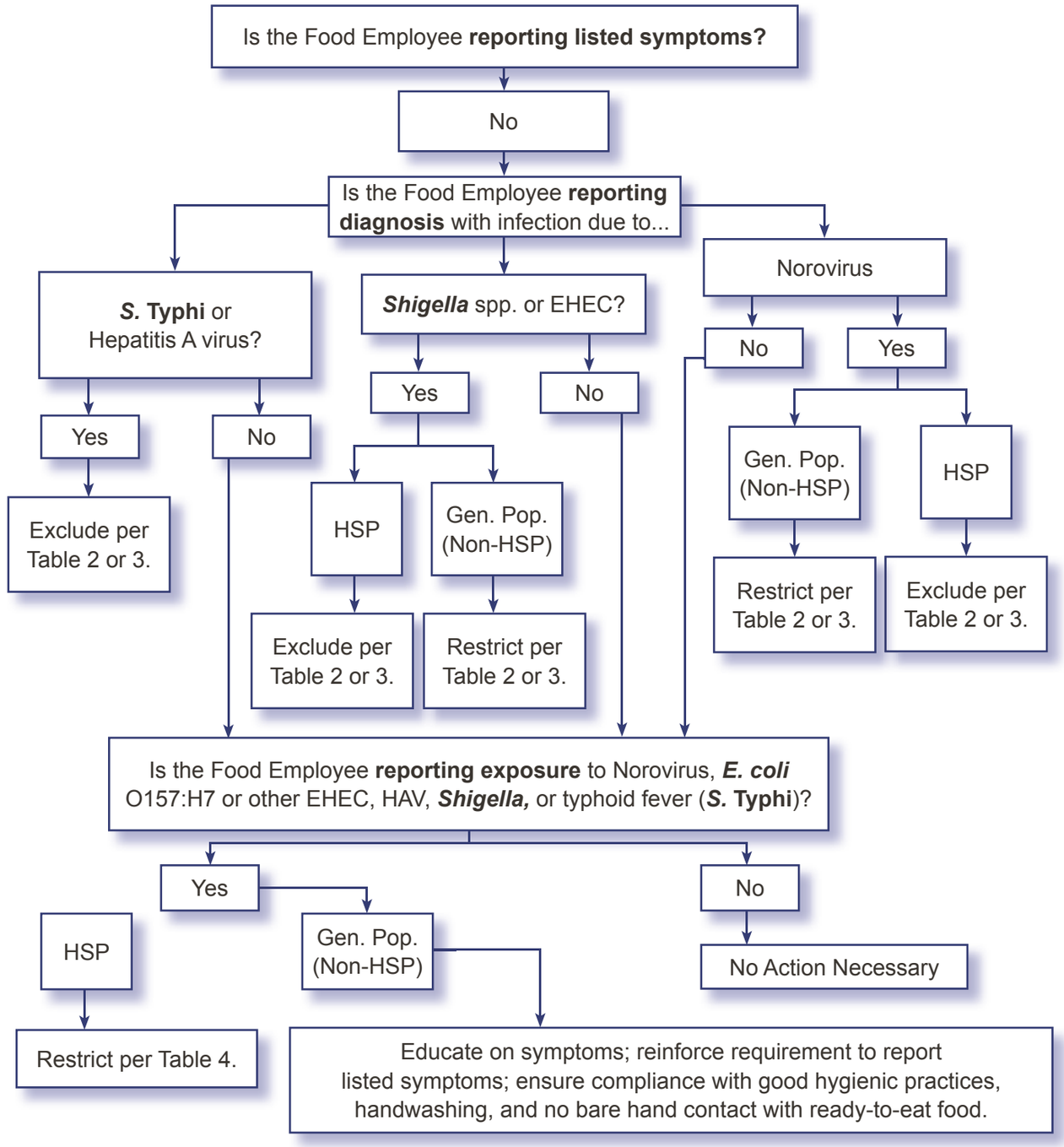




Key:

Listed Symptoms for Reporting: (V) Vomiting; (J) Jaundice; (D) Diarrhea; (ST with F) Sore Throat with Fever; (HSP) Highly Susceptible Population; and (Gen. Pop.) General Population

2-201.11 / 2-201.12 Decision Tree 2. When to Exclude or Restrict a Food Employee Who is Asymptomatic and Reports a Listed Diagnosis and When to Restrict a Food Employee Who Reports a Listed Exposure Under the Food Code



Key: (HSP) Highly Susceptible Population and (Gen. Pop.) General Population

2-201.12 Table 1a: Summary of Requirements for Symptomatic Food Employees

Food employees and conditional employees shall report symptoms immediately to the person in charge				
The person in charge shall prohibit a conditional employee who reports a listed symptom from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a symptomatic food employee.				
Symptom	**EXCLUSION OR RESTRICTION**		**Removing Symptomatic Food Employees from Exclusion or Restriction**	**RA Approval Needed to Return to Work?**
	Facilities Serving an HSP	**Facilities Not Serving an HSP**		
Vomiting	**EXCLUDE** 2-201.12(A)(1)	**EXCLUDE** 2-201.12(A)(1)	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation 2-201.13(A)(1). ***Exceptions:*** If diagnosed with Norovirus, ***Shigella*** spp., ***E. coli*** O157:H7 or other EHEC/STEC, HAV, or typhoid fever (***S.* Typhi**) (see Tables 1b & 2).	No if not diagnosed
Diarrhea	**EXCLUDE** 2-201.12(A)(1)	**EXCLUDE** 2-201.12(A)(1)	When the excluded food employee has been asymptomatic for at least 24 hours or provides medical documentation 2-201.13(A). ***Exceptions:*** If diagnosed with Norovirus, ***E. coli*** O157:H7 or other EHEC/STEC, HAV, or ***S.* Typhi** (see Tables 1b & 2).	No if not diagnosed
Jaundice	**EXCLUDE** 2-201.12(B)(1) if the onset occurred within the last 7 days	**EXCLUDE** 2-201.12(B)(1) if the onset occurred within the last 7 days	When approval is obtained from the RA 2-201.13(B), and: • Food employee has been jaundiced for more than 7 calendar days 2-201.13 (B)(1), or • Food employee provides medical documentation 2-201.13(B)(3).	Yes

(continued)

2-201.12 Table 1a: Summary of Requirements for Symptomatic Food Employees (continued)

Symptom	EXCLUSION OR RESTRICTION		Removing Symptomatic Food Employees from Exclusion or Restriction	RA Approval Needed to Return to Work?
	Facilities Serving an HSP	Facilities Not Serving an HSP		
Sore throat with fever	**EXCLUDE** 2-201.12(G)(1)	**RESTRICT** 2-201.12(G)(2)	When food employee provides written medical documentation 2-201.13(G)(1)-(3).	No
Infected wound or pustular boil	**RESTRICT** 2-201.12(H)	**RESTRICT** 2-201.12(H)	When the infected wound or boil is properly covered 2-201.13(H)(1)-(3).	No

Key for Table 1a:

HSP = Highly Susceptible Population

RA = Regulatory Authority

EHEC/STEC = Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*

HAV = Hepatitis A Virus

2-201.12 Table 1b: Summary of Requirements for Diagnosed, Symptomatic Food Employees

Food employees and conditional employees shall report a listed diagnosis with symptoms immediately to the person in charge			
The person in charge shall notify the RA when a food employee is jaundiced or reports a listed diagnosis			
The person in charge shall prohibit a conditional employee who reports a listed diagnosis with symptoms from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed, symptomatic food employee.			
Diagnosis	**EXCLUSION Facilities Serving an HSP or Not Serving an HSP**	**Removing Diagnosed, Symptomatic Food Employees from Exclusion**	**RA Approval Needed to Return to Work?**
Hepatitis A virus	**EXCLUDE** if within 14 days of any symptom, or within 7 days of jaundice 2-201.12(B)(2)	When approval is obtained from the RA 2-201.13(B), and: ● The food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or ● The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or ● The food employee provides medical documentation 2-201.13 (B)(3) (also see Table 2).	Yes
Typhoid fever (***S.* Typhi**)	**EXCLUDE** 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: ● Food employee provides medical documentation that states the food employee is free of an ***S.* Typhi** infection 2-201.13(C)(2) (also see Table 2).	Yes

(continued)

2-201.12 Table 1b: Summary of Requirements for Diagnosed, Symptomatic Food Employees (continued)

Diagnosis	EXCLUSION Facilities Serving an HSP or Not Serving an HSP	Removing Diagnosed, Symptomatic Food Employees from Exclusion	RA Approval Needed to Return to Work?
E. coli O157:H7 or other EHEC/ STEC	**EXCLUDE** Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	1. Serving a non-HSP facility: 2-201.13(A)(4)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed below: 2. Serving an HSP facility: 2-201.13(A)(4)(b): Remains excluded until meeting the requirements listed below: ● Approval is obtained from the RA 2-201.13(F), and ● Medically cleared 2-201.13(F)(1), or ● More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13 (F)(2) (also see Table 2).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
Norovirus	**EXCLUDE** Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	1. Serving a non-HSP facility: 2-201.13 (A)(2)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed below: 2. Serving an HSP facility: 2-201.13(A)(2)(b): Remains excluded until meeting the requirements listed below: ● Approval is obtained from the RA 2-201.13(D), and ● Medically cleared 2-201.13(D)(1), or ● More than 48 hours have passed since the food employee became asymptomatic 2-201.13(D)(2) (also see Table 2).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility

(continued)

2-201.12 Table 1b: Summary of Requirements for Diagnosed, Symptomatic Food Employees (continued)

Diagnosis	EXCLUSION Facilities Serving an HSP or Not Serving an HSP	Removing Diagnosed, Symptomatic Food Employees from Exclusion	RA Approval Needed to Return to Work?
Shigella spp.	**EXCLUDE** Based on vomiting or diarrhea symptoms, under 2-201.12(A)(2)	1. Serving a non-HSP facility: 2-201.13(A)(3)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed below: 2. Serving an HSP facility: 2-201.13(A)(3)(b): Remains excluded until meeting the requirements listed below: ● Approval is obtained from the RA 2-201.13(E), and ● Medically cleared 2-201.13(E)(1), or ● More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(E)(2) (also see Table 2).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility

Key for Table 1b:

RA = Regulatory Authority

HSP = Highly Susceptible Population

EHEC/STEC = Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*

2-201.12 Table 2: Summary of Requirements for Diagnosed Food Employees with Resolved Symptoms

Food employees and conditional employees shall report a listed diagnosis immediately to the person in charge				
The person in charge shall notify the RA when a food employee reports a listed diagnosis				
The person in charge shall prohibit a conditional employee who reports a listed diagnosis from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed food employee.				
Pathogen Diagnosis	**Facilities Serving an HSP**	**Facilities Not Serving an HSP**	**Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction**	**RA Approval Required to Return to Work?**
Typhoid fever (***S.* Typhi**) including previous illness with ***S.* Typhi** (see 2-201.11(A)(3))	**EXCLUDE** 2-201.12(C)	**EXCLUDE** 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: ● Food employee provides medical documentation that states the food employee is free of an ***S.* Typhi** infection 2-201.13)(C)(2) (also see Table 1b).	Yes
Shigella spp.	**EXCLUDE** 2-201.12(E)(1)	**RESTRICT** 2-201.12(E)(2)	1. Serving a non-HSP facility: 2-201.13(A)(3)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed below: 2. Serving an HSP facility: 2-201.13(A)(3)(b): Remains excluded until meeting the requirements listed below: ● Approval is obtained from the RA 2-201.13(E), and ● Medically cleared 2-201.13 (E)(1), or ● More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(E)(3)(a) (also see Table 1b).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility

(continued)

2-201.12 Table 2: Summary of Requirements for Diagnosed Food Employees with Resolved Symptoms (continued)

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
Norovirus	**EXCLUDE** 2-201.12(D)(1)	**RESTRICT** 2-201.12(D)(2)	1. Serving a non-HSP facility: 2-201.13(A)(2)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed below: 2. Serving an HSP facility: 2-201.13(A)(2)(b): Remains excluded until meeting the requirements listed below: ● Approval is obtained from the RA 2-201.13(D), and ● Medically cleared 2-201.13(D)(1), or ● More than 48 hours have passed since the food employee became asymptomatic 2-201.13(D)(2) (also see Table 1b).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility

(continued)

2-201.12 Table 2: Summary of Requirements for Diagnosed Food Employees with Resolved Symptoms (continued)

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	Removing Diagnosed Food Employees with Resolved Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
E. coli O157:H7 or other EHEC/ STEC	**EXCLUDE** 2-201.12(F)(1)	**RESTRICT** 2-201.12(F)(2)	1. Serving a non-HSP facility: 2-201.13(A)(4)(a): Shall only work on a restricted basis 24 hours after symptoms resolve and remains restricted until meeting the requirements listed below: 2. Serving an HSP facility: 2-201.13(A)(4)(b): Remains excluded until meeting the requirements listed below: ● Approval is obtained from the RA 2-201.13(F), and ● Medically cleared 2-201.13(F)(1), or ● More than 7 calendar days have passed since the food employee became asymptomatic 2-201.13(F)(2).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
Hepatitis A virus	**EXCLUDE** If within 14 days of any symptom, or within 7 days of jaundice 2-201.12(B)(2)	**EXCLUDE** If within 14 days of any symptom, or within 7 days of jaundice 2-201.12(B)(2)	When approval is obtained from the RA 2-201.13(B), and: ● The food employee has been jaundiced for more than 7 calendar days 2-201.13(B)(1), or ● The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or ● The food employee provides medical documentation 2-201.13(B)(3) (see also Table 1b).	Yes

Key for Table 2:

RA = Regulatory Authority

HSP = Highly Susceptible Population

EHEC/STEC = Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*

2-201.12 Table 3: Summary of Requirements for Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms

Food employees and conditional employees shall report a listed diagnosis immediately to the person in charge				
The person in charge shall notify the RA when a food employee reports a listed diagnosis				
The person in charge shall prohibit a conditional employee who reports a listed diagnosis from becoming a food employee until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of a diagnosed food employee.				
Pathogen Diagnosis	**Facilities Serving an HSP**	**Facilities Not Serving an HSP**	**Removing Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms from Exclusion or Restriction**	**RA Approval Required to Return to Work?**
Typhoid fever (***S.* Typhi**) including previous illness with ***S.* Typhi** (see 2-201.11(A)(3))	**EXCLUDE** 2-201.12(C)	**EXCLUDE** 2-201.12(C)	When approval is obtained from the RA 2-201.13(C)(1), and: ● Food employee provides medical documentation, specifying that the food employee is free of an ***S.* Typhi** infection 2-201.13(C)(2).	Yes
Shigella spp.	**EXCLUDE** 2-201.12(E)(1)	**RESTRICT** 2-201.12(E)(2)	Remains excluded or restricted until approval is obtained from the RA, and: ● Medically cleared 2-201.13(E)(1), or ● More than 7 calendar days have passed since the food employee was last diagnosed 2-201.13(E)(3).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
Norovirus	**EXCLUDE** 2-201.12(D)(1)	**RESTRICT** 2-201.12(D)(2)	Remains excluded or restricted until approval is obtained from the RA 2-201.13(D), and ● Medically cleared 2-201.13(D)(1), or ● More than 48 hours have passed since the food employee was diagnosed 2-201.13(D)(3).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility

(continued)

2-201.12 Table 3: Summary of Requirements for Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms (continued)

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	Removing Diagnosed Food Employees Who Never Develop Gastrointestinal Symptoms from Exclusion or Restriction	RA Approval Required to Return to Work?
E. coli O157:H7 or other EHEC/ STEC	**EXCLUDE** 2-201.12(F)(1)	**RESTRICT** 2-201.12(F)(2)	Remains excluded or restricted until approval is obtained from the RA 2-201.13(F), and: ● Medically cleared 2-201.13(F)(1), or ● More than 7 calendar days have passed since the food employee was diagnosed 2-201.13(F)(3).	Yes to return to an HSP or to return unrestricted; not required to work on a restricted basis in a non-HSP facility
Hepatitis A virus	**EXCLUDE** 2-201.12(B)(3)	**EXCLUDE** 2-201.12(B)(3)	When approval is obtained from the RA 2-201.13(B), and ● The anicteric food employee has had symptoms for more than 14 days 2-201.13(B)(2), or ● The food employee provides medical documentation 2-201.13(B)(3).	Yes

Key for Table 3:

RA = Regulatory Authority

HSP = Highly Susceptible Population

EHEC/STEC = Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*

2-201.12 Table 4: History of Exposure, and Absent Symptoms or Diagnosis

Food employees and conditional employees shall report a listed exposure to the person in charge				
The person in charge shall prohibit a conditional employee who reports a listed exposure from becoming a food employee in a facility serving an HSP until meeting the criteria listed in section 2-201.13 of the Food Code, for reinstatement of an exposed food employee				
The person in charge shall reinforce and ensure compliance with good hygienic practices, symptom reporting requirements, proper handwashing, and no BHC with RTE foods for all food employees that report a listed exposure.				
Pathogen Diagnosis	**Facilities Serving an HSP**	**Facilities Not Serving an HSP**	**When Can the Restricted Food Employee Return to Work?**	**RA Approval Needed?**
Typhoid fever (***S.* Typhi**)	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing, and no BHC with RTE foods.	2-201.13(I)(3) When 14 calendar days have passed since the last exposure, or more than 14 days have passed since the food employee's household contact became asymptomatic.	No
Shigella spp.	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing, and no BHC with RTE foods.	2-201.13(I)(2) When more than 3 calendar days have passed since the last exposure, or more than 3 days have passed since the food employee's household contact became asymptomatic.	No
Norovirus	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing, and no BHC with RTE foods.	2-201.13(I)(1) When more than 48 hours have passed since the last exposure, or more than 48 hours have passed since the food employee's household contact became asymptomatic.	No

(continued)

2-201.12 Table 4: History of Exposure, and Absent Symptoms or Diagnosis (continued)

Pathogen Diagnosis	Facilities Serving an HSP	Facilities Not Serving an HSP	When Can the Restricted Food Employee Return to Work?	RA Approval Needed?
E. coli O157:H7 or other EHEC/ STEC	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing, and no BHC with RTE foods.	2-201.13(I)(2) When more than 3 calendar days have passed since the last exposure, or more than 3 calendar days have passed since the food employee's household contact became asymptomatic.	No
Hepatitis A virus	**RESTRICT** 2-201.12(I)	Educate food employee on symptoms to watch for and ensure compliance with GHP, handwashing, and no BHC with RTE foods.	2-201.13(I)(4) When any of the following conditions is met: ● The food employee is immune to HAV infection because of a prior illness from HAV, vaccination against HAV, or IgG administration; or ● More than 30 calendar days have passed since the last exposure, or since the food employee's household contact became jaundiced; or ● The food employee does not use an alternative procedure that allows BHC with RTE food until at least 30 days after the potential exposure, and the employee receives additional training.	No

Key for Table 4:

HSP = Highly Susceptible Population; BHC = Bare Hand Contact; RTE = Ready-to-Eat; RA = Regulatory Authority; GHP = Good Hygienic Practices; and EHEC/STEC = Entero-hemorrhagic or Shiga Toxin-producing *Escherichia coli*

	West Virginia Department of Health and Human Resources						
Section	VNRFRPS Standard 5	Date	4/7/2015	Procedure #	5-2		
Subject	Foodborne Illness Investigation Kit Supplies			Page	1	of	

The following forms and supplies are made available for each District Office kit as well as one kit in the central office. Procedure 5-1 provides information on how each kit is to be kept current with supplies.

Forms and Reference Material:	Revision date
1. CD-7 Form A-Case History	12/05
2. CD-7 Form B- Summary of Case Histories	12/05
3. CD-7 Form C-Food Preparation and Sanitation Report	12/05
4. Control of Communicable Disease in Man	
5. Procedures to Investigate Foodborne Illness Book	
6. Diagnosis and Management of Foodborne Illness pack	
7. SF-39 Official Notice of Embargo-Seizure	12/05
8. SF-40 Report of Destruction of Foodstuffs or Material(s)	12/05
9. Attack Rate Work Sheet	
10. CDC/Foodborne Disease Outbreak Sample Collection-Report Form	06/2002

Supplies:

1. 4 oz./118 ml Plain Whirl Pak Bags-1 Box
2. Triflex Powder Free Sterile Vinyl Synthetic Exam Gloves-2 Boxes
3. BD Sterile Pack Swabs-3 Packs
4. Masking Tape
5. Waterproof Pen
6. Knife
7. Scissors
8. Water Sample Bottles with Forms-5 Bottles
9. Enteric Specimen Containers (Cary Blair Media)-6 Containers
10. Parasite Containers-16 Containers
11. Vacutainers and Needles-1 Box of each
12. Chemical Sample Containers (Cubitainer)-2
13. Kim Wipes- 1 Box
14. Alcohol Swabs- 1 Box
15. Insulated Shipment Container
16. BBL Culture Swab-1 Bag
17. Sterileware Scoops-12
18. Sterileware Knives-30
19. White Spoons-16
20. Pre-moistened Speci-Sponge Bags-9
21. Hand Sanitizer-1 Bottle
22. Softsoap-1 Bottle
23. White Lids-1 Box
24. Disposable Staccups 500cc-3 packs
25. Tongue Depressors-10
26. Sterile Cottontip Swabs in vial-1 Box
27. 10% Formalin Bottles-3 Bottles
28. 10% Formalin Fixative-3 Bottles

Other supplies as deemed necessary.

C4: FOOD COMPLAINT FORM

County/LHD_____
Complaint ID#. _____

Food Complaint Information (to be completed by LHD when complaint is received)

Date/Time Received: / / : AM/PM	Call Received By:	
Name:	DOB: / /	Gender: M F
Phone 1: H/W/C	Phone 2: H/W/C	
Address:		
City:	State:	ZIP Code:
Occupation(s):		
Food premises or event involved:	Location:	
Complaint:		
Complaint involves: Foodborne Illness: ☐Y ☐N (if **No**, do not continue on this form) Multiple ill persons: ☐Y ☐N #_____		

Complaint Investigation (to be completed by LHD nurse or sanitarian following up on complaint)

Investigated By:	Investigation Start Date: / /

Suspected Meal Data

Date/time of meal: / / : AM/PM	Suspected items:
List anything unusual about the meal (temperature, taste, odor, color etc.):	

Clinical Information

Clinical Information about: ☐ Complainant ☐ Someone else [Name: Relationship:]

Illness Onset Date/Time: / / : AM/PM	Illness End Date/Time: / / : AM/PM

Signs and Symptoms (mark all that apply):

☐ Diarrhea [frequency in 24 hours:_____ ☐ watery ☐ bloody] ☐ Nausea ☐ Jaundice ☐ Vomiting ☐ Rash

☐ Chills ☐ Fever [temp. °F] ☐ Abdominal pain ☐ Other :

Doctor or healthcare provider/ emergency visit: ☐ Y ☐ N Date: / /

Physician/provider/facility: Number:

Hospitalized due to illness: ☐ Y ☐ N Admission date: / / Hospital :

Clinical specimens taken: ☐ Blood ☐ Stool ☐ None (Patient willing to provide a stool/blood sample ?: ☐ Y ☐ N)

Diagnosis:

Other Ill Persons Associated with Meal/Location

Number of people in party:	Number of people ill:	Number of people not ill:
Earliest onset date/time: / / : AM/PM	Latest onset date/time: / / : AM/PM	
Predominant symptoms:		
Name:	Phone: H/W/C	
Name:	Phone: H/W/C	
Name:	Phone: H/W/C	
☐ Additional contact info. attached	☐ High risk occupation(s) involved (food worker, daycare staff, healthcare worker, etc.)	

Other Possible Non-Food Exposures in the Past 2 Weeks

☐ Travel outside the US Dates: / / to / / Location(s):

Drinking Water Sources (mark all that apply):

☐ Well Location(s): ☐ Surface/spring ☐ Tap (city/municipal) ☐ Bottled ☐ Other:

Recreational Water Exposure (mark all that apply):

☐ Swimming pool ☐ River/lake ☐Splash pad/spray park ☐ Other:_____

Location: Location: Location: Location:

Additional Exposures (mark all that apply):

☐ Ill persons in or outside home ☐ Daycare facility ☐ Nursing home ☐ Diapered kids or adults

☐ Mass gatherings ☐ Domestic animals/livestock ☐ Petting zoo ☐ Birds/reptiles ☐ Ill animals

☐ Other: Location(s) of exposures:

72-hour Food History (collect information about what was consumed within the 72-hours prior to illness)

Dates of 72-hour Food History: / / to / / (first day of illness plus 3 days prior)

Day of Illness Onset (include all food and drinks consumed)		Date: / /
Breakfast:	Location	Time: : AM/PM
Lunch:	Location	Time: : AM/PM
Dinner:	Location	Time: : AM/PM
Other Food/Drinks:	Location	Time: : AM/PM
1 Day Prior (include all food and drinks consumed)		Date: / /
Breakfast:	Location	Time: : AM/PM
Lunch:	Location	Time: : AM/PM
Dinner:	Location	Time: : AM/PM
Other Food/Drinks:	Location	Time: : AM/PM
2 Days Prior (include all food and drinks consumed)		Date: / /
Breakfast:	Location	Time: : AM/PM
Lunch:	Location	Time: : AM/PM
Dinner:	Location	Time: : AM/PM
Other Food/Drinks:	Location	Time: : AM/PM
3 Days Prior (include all food and drinks consumed)		Date: / /
Breakfast:	Location	Time: : AM/PM
Lunch:	Location	Time: : AM/PM
Dinner:	Location	Time: : AM/PM
Other Food/Drinks:	Location	Time: : AM/PM

Public Health Actions and Additional Information (to be completed after investigation is finished)

☐ Food complaint **NOT** an outbreak (state reason):_____

☐ Food complaint part of an outbreak Date/time reported to DIDE: / / : AM/PM Outbreak #_____

(**Fax form to DIDE when outbreak is reported**)

☐ Line list available ☐ Outbreak specific questionnaire used ☐ Outbreak specific food inspection performed

☐ Site visit/routine inspection performed ☐ Food samples taken ☐ Food worker interview form(s) completed

☐ Calls made to others who were ill/exposed ☐ LHD sent clinical specimens to lab ☐ Other:

C5: ENVIRONMENTAL INVESTIGATION AND ASSESSMENT FORM

NOTE: *This form is to be used by Local Health Departments that do not have access to the Environmental Health Electronic Reporting System. Local Health Departments with access to the electronic reporting system may use this form for guidance, but information is to be entered electronically.*

Completed By: **Title**: **Agency:**

A. Establishment Information

Establishment:	**Type of Operation(s) :** ☐ **Food Service** ☐ **Retail** ☐ **Mobile** ☐ **Temporary** ☐ **Other:**_____
Address:	
Date Complaint Received:	**Date(s) Environmental Investigation Completed:**
Implicated Food(s):	
Food Samples Collected: Y N	**From:** ☐ **Consumer** ☐ **Food Establishment** ☐ **Food Manufacturer/Distributor**
Food Worker Questionnaire(s) Completed: Y N	**Number Questionnaires Completed:** / **Number of Employees at Establishment:**

B. Recent Compliance History

☐ **Most recent inspection report prior to the complaint attached.**	**Date of prior inspection:**

C. Risk Assessment of Suspect Food *(Required)*

☐ ***HACCP based risk assessment* of the suspect food(s) or process(es) attached**. Include food source, volume prepared, preparation steps (who, how, where, when), monitoring procedures used, identification of critical control points and any corrective actions that were taken if necessary to correct inadequate monitoring procedures.

If you need assistance with your risk assessment, please call Food Program Staff at 304-558-2981.

D. Level of Compliance Noted During On-site Investigation(s)

IN (In Compliance) OUT (Out of Compliance) NA (Not Applicable) NO (Not Observed)

Observation *Indicates the observation number in the Environmental Health Electronic Reporting System In/Out section.	**Compliance Observation**				**Notes**
1. Person in charge, present, demonstrates knowledge, and performs duties.	**IN**	**OUT**			
2. Management awareness, policy present.	**IN**	**OUT**			
3. Proper use of reporting, restriction and exclusion.	**IN**	**OUT**			
4. Proper eating, tasting, drinking, or tobacco use.	**IN**	**OUT**			
5. No discharge from eyes, nose, and mouth.	**IN**	**OUT**	**NA**	**NO**	
6. Hands clean & properly washed.	**IN**	**OUT**	**NA**	**NO**	
7. No bare hand contact with ready to eat (RTE) foods or approved alternate method properly followed.	**IN**	**OUT**	**NA**	**NO**	
8. Adequate hand washing facilities supplied and accessible.	**IN**	**OUT**	**NA**	**NO**	
9. Food obtained from approved source.	**IN**	**OUT**			

10. Food received at proper temperature.	**IN**	**OUT**			
11. Food in good condition, safe and unadulterated.	**IN**	**OUT**			
12. (14)* Food-contact surfaces: cleaned and sanitized.	**IN**	**OUT**			
13. (16)* Proper cooking time and temperatures.	**IN**	**OUT**	**NA**	**NO**	
14. (17)* Proper reheating procedures for hot holding.	**IN**	**OUT**	**NA**	**NO**	
15. (18)* Proper cooling time and temperatures.	**IN**	**OUT**			
16. (19)* Proper hot holding temperatures.	**IN**	**OUT**	**NA**	**NO**	
17. (20)* Proper cold holding temperatures.	**IN**	**OUT**	**NA**	**NO**	
18. (21)* Proper date marking & disposition.	**IN**	**OUT**	**NA**	**NO**	
19. (22)* Time as a public health control: procedures and record.	**IN**	**OUT**	**NA**	**NO**	
20. (27)* Compliance with variance, specialized process and HACCP plan.	**IN**	**OUT**	**NA**	**NO**	
21. (44)* Gloves properly used.	**IN**	**OUT**	**NA**	**NO**	

E. Corrective and Enforcement Actions

Check corrective or enforcement actions that were taken in response to the complaint.

☐ **None**

☐ **Order for Correction Issued to correct violations relating to:**

☐ **Risk factors and major interventions** ☐ **Good retail practices**

☐ **Food Employee/Food Handling Procedures & Policies Modified**

☐ **Voluntary Disposal**

☐ **Emergency Suspension or Closure**

☐ **Food Employee/Food Handling Procedures & Policies Modified**

☐ **Food Employee Restriction/Exclusion**

☐ **Food Employee/PIC Training**

☐ **Press Release/News Alert**

☐ **Equipment/Physical & Sanitary Facilities Modified /Upgraded**

☐ **Other: (describe)**

REMINDER: ***Submit the following documents along with this form to the*** **Food Program Public Health Sanitation Division**

1. Copy of Most Recent Inspection Report Issued Prior to Complaint
2. HACCP Risk Assessment and Related Environmental Data
3. Related Enforcement Documents
4. **Mail or Fax To: Office of Environmental Health, Public Health Sanitation Division**
   350 Capitol Street, Room 313 Charleston, WV 25301-3713 Fax (304) 558-1071

Establishment:	Phone Number:

C6: MASTER LIST OF ESTABLISHMENT STAFF

Include:

All waitstaff, dishwashers, food preparation workers, cooks, bartenders, bussers, Supervisor, Owner/Manager, host/hostess, delivery/transport personnel, bakers, or any other staff.

Include all those who worked between: _____ and _____
Number of employees on-site date of event/suspect meal: _____
Manager in charge of the facility the date of the event/suspect meal: _____
Person in charge of the kitchen the date of event/suspect meal: _____

Name	Title	Phone Number

Name	Title	Phone Number

C7: FOOD WORKER INTERVIEW FORM

(All employees must be interviewed with this form)

Date(s) of suspect event (date of first onset) or date suspect meals eaten: _____

Name:
Title:
Address:
City/ State:
Phone:

Interview date:
Interview conducted by:
How long have you worked here?
Are you a food worker anywhere else? Y N
If yes, where:

WORK HISTORY

Time period of risk: ___ /___ /____ to ___ /___ /____

To be determined prior to interview(typically 2-4 weeks). Consult DIDE for assistance.

1. Use the calendar to determine the days worked during the time frame of risk: _____
2. List any day(s) you were sick during this period:_____
3. Did you work the day of the suspect event/meal? Y N
   If yes, what hours? _____
4. Did you work the day before the suspect event/meal? Y N
   If yes, what hours? _____
5. Did you handle/prepare any of the foods served? (see provided food list) Y N
6. Were any of these prepared 6 hours or more in advance of the event/meal? Y N
7. Did you eat any foods served on date of event or suspect meal? Y N
   If yes, date(s) and what foods? _____

Wednesday						
Sun	Mon	Tue	Wed	Thur	Fr	Sat
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
27	28	30	31			

Insert perpetual calendar here

Sa						
Sun	Mon	Tue		Thur	Fr	Sat
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

ILLNESS HISTORY

Have you or anyone in your household had any of the following symptoms during the time period of risk:

Food worker	**Household members**
Diarrhea/Loose Stool: Y N	Diarrhea/Loose Stool: Y N
Vomiting: Y N	Vomiting: Y N
Jaundice: Y N	Jaundice: Y N
Fever: Y N If yes, highest temp: _____	Fever: Y N If yes, highest temp: _____
Sore Throat: Y N	Sore Throat: Y N
Wounds or Sores: Y N	Wounds or Sores: Y N

If ill with any of the above symptoms, obtain the following:

Food worker	**Household members**
When did the symptoms first start? Date/time	When did symptoms first start?
When did the symptoms end?	When did the symptoms end?
What is the first day you worked after being ill?	Occupation:
Did you go to the doctor or hospital? Y N If yes, indicate health care provider:	If household member is a food worker, place of employment:
Diagnosis/Treatment:	

1. Are you required to tell your employer when you are sick with diarrhea or vomiting? Y N
2. What happens if to tell your employer when you are sick with diarrhea or vomiting? _____
3. Do you receive sick leave pay? Y N

STOOL SPECIMEN

Was the food worker provided with a stool kit: Y N Date kit(s) distributed: _____

- Instruct worker that submission of stool must be within 48 hours or the worker may be excluded from work

PERPETUAL CALENDARS FOR INSERTION ON FOODWORKER INTERVIEW FORM

A perpetual calendar is a calendar that shows the days of the month without designating the month. This way the calendar can be used for any month. Before using the interview form, choose the calendar that starts on the same day as the month of the event and copy and paste it into the interview form for reference. For example, if the 1st day of the event month is Monday, choose the calendar labeled Monday.

Sunday						
Sun	Mon	Tue	Wed	Thur	Fr	Sat
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Monday						
Sun	Mon	Tue	Wed	Thur	Fr	Sat
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

Tuesday						
Sun	Mon	Tue	Wed	Thur	Fr	Sat
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

Wednesday						
Sun	Mon	Tue	Wed	Thur	Fr	Sat
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	23	24	25	26
27	28	30	31			

Thursday						
	Mon	Tue	Wed	Thur	Fr	Sat
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Friday						
Sun	Mon	Tue	Wed	Thur	Fr	Sat
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

Saturday						
Sun	Mon	Tue	Wed	Thur	Fr	Sat
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

C8: FUNDAMENTAL CONCEPTS OF MICROBIOLOGY

Familiarity with certain fundamental concepts related to food microbiology is essential to understanding the steps of an environmental outbreak investigation. Such concepts include potentially hazardous foods and the three main hazard categories.

Potentially Hazardous Foods/Time Temperature Control for Safety Foods:
Certain conditions favor the growth of foodborne microorganisms within the environmental setting. Such conditions include the food, acidity, time, temperature, oxygen and moisture, collectively known as FAT TOM. (**NOTE**: Viruses and parasites cannot multiply in food or produce toxins.)

The following table describes the concepts of FAT TOM. **Condition**	**Explanation**
Food	Nutrient-rich foods provide a good environment for microorganisms to thrive
Acidity	Bacterial growth is best in neutral or slightly acidic environments – foods with a pH range between 6.6 and 7.5
Time	Microorganisms proliferate if placed in optimal temperatures for longer than two hours
Temperature	Microorganisms thrive in the "danger zone" (temperatures between 41°F and 135°F) and some thrive in refrigerated temperatures
Oxygen	The presence or absence of oxygen influences growth of microorganisms
Moisture	Moisture content in foods influences microbial growth – high water activity (>0.86) supports rapid growth

The optimum growth temperature range for most pathogens is between 60°F and 120°F. When bacterial spores are heat shocked into a vegetative state and the contaminated food is held at this temperature range, the bacteria can double in number every 15-20 minutes. Some pathogens, such as *Staphylococcus aureus* and *Bacillus cereus*, can also produce heat-stable toxins when the contaminated food is stored at optimum growth temperatures. These toxins, which cannot be destroyed by heating, can remain toxic even after reheating. Other pathogens, particularly *Listeria monocytogenes*, proliferate when placed under refrigeration temperature ranges. Most foodborne pathogens survive but do not grow at below freezing temperatures and are destroyed at temperatures above 135°F.

High-Risk Factors in Food Preparation:

Though some foods possess conditions that increase the likelihood of contamination, non-potentially hazardous foods (PHFs) can still become contaminated and cause foodborne illnesses. Certain risk factors or practices and procedures pose the greatest potential for foodborne illness. The following list provides the three hazard categories and highest risk factors as determined by the CDC and FDA.

Contamination hazard

- Food Source
    - Food from unapproved or uninspected source (e.g., unpasteurized milk)
    - Adulterated food
- Cross-Contamination
    - Raw meats not separated from ready-to-eat foods
    - Equipment not properly cleaned and sanitized
- Poor personal hygiene
    - Lack of appropriate hand washing
    - Bare hand contact with ready-to-eat food
    - Ill food workers
- Environmental contamination
    - Improper storage, labeling, or usage of chemicals
    - Presence of insects or rodents
    - Lack of potable water
    - Improper sewage disposal

Survival hazard

- Inadequate cooking
- Improper reheating temperatures

Growth/Toxin production hazard

- Improper holding
- Unsafe cooling or inadequate refrigeration
- Improper cold/hot holding temperatures
- Preparation several hours before serving

C9: FOOD SPECIMEN TRACKING FORM

Name _____
Phone _____
Affiliation_____
Outbreak #_____

DO NOT SEND THIS FORM TO OLS; use the **FOOD LABORATORY SPECIMEN SUBMISSION FORM**. This form is to be filled out when samples are taken and updated with lab results once OLS has completed specimen processing. For additional instructions, see the back of the form. A copy of the completed form is to be sent to DIDE. It is important to complete all information on this form as it contains additional information not collected on the OLS specimen form.

Suspected Agent: _____ **Collected By: _____**

Name of restaurant, company, event, etc. where samples were taken: _____

	Description of Sample						Lab Testing		
	Food Item	**Location collected from**	**Date prepared**	**Date consumed**	**Date collected**	**Temperature**	**Tested (Y/N)**	**Lab Result**	**Comments**
1.									
2.									
3.									
4.									
5.									
6.									
7.									
8.									
9.									
10.									

Before submitting specimens to the Office of Laboratory Services (OLS): Specimens must be labeled and submission form must be complete. OLS will not be able to process specimens if forms are not complete. Inform the lab that specimens will be coming in and the approximate number of submissions. For additional instructions or questions regarding specimen submission, contact OLS at (304) 558-3530**. Consult with DIDE before submitting any food specimens for testing.**

Explanation of Tracking Form Table Headings

- **Food Item:** List the name of the food item from which the sample is being taken. Example: gravy.
- **Location collected from:** Describe the location of the sample being collected. Examples: From food in kitchen, from customers saved leftovers, from "dead man's tray."
- **Date prepared:** List the date the food being sampled was prepared.
- **Date consumed:** Record the date the food was consumed if known.
- **Date collected:** List the date the sample is being collected.
- **Temperature:** Record the temperature of the food item when the sample was collected.
- **Lab Tested (Y/N):** Was the sample sent to the laboratory for testing? Select Yes or No.
- **Lab Result:** List the results of laboratory testing. Examples: not tested, negative, positive for *Bacillus cereus.*
- **Comments:** Record any additional information about the sample, collection process, or laboratory testing.

D1: CREATING A LINE LISTING

A line listing is a grid containing information about persons who are under study. Each row shows data on a single case. Each column represents a variable such as identifying information, clinical data, and epidemiologic information, such as risk and exposure factors. Line listings can be created by hand or on a computer using Microsoft Excel®. The advantage of using an electronic line listing is that frequency distributions and epidemic curves can be generated rapidly. The information that goes into a line listing is generally collected on a questionnaire. The important elements from the questionnaire are then used to create a line listing.

To set up a line listing, create a table in which each row represents a case and each column represents a variable of interest.

Typical variables include:

- Personal information
  - Name, address, phone number, city and county of residence
- Demographic information
  - Age or date of birth, gender, race and occupation
- Illness information
  - Date and time of onset, date and time of recovery, date of specimen collection, results of laboratory tests
  - Symptoms including diarrhea, bloody stools, vomiting, abdominal cramps, nausea, fever, and other symptoms
- Exposure information
  - Meal location, date and time of meal, foods eaten, drinks
- Comments/Notes

It is helpful to have a comment variable on your line listing so that important information that might not be captured in any of the variables can be included. This is not an exhaustive list of variables that can be included on a line listing. The number and type of variables will change depending on the type of outbreak and the specific needs of the investigation.

After the line listing is created, cases can be added and updated during the course of the investigation.

Example line listing:

ID	Name	Age	Sex	Ill?	Onset Date	Onset Time	D	N	V	F	Office Brunch	Sample?	Results?	Comments
1	S.A.	45	F	Yes	10/19/08	1:00a	Y	Y	Y	N	Y	Y	Pending	
2	S.I.	57	F	Yes	10/18/08	11:00p	Y	Y	N	N	Y	Y	S Newport	
3	C.W.	39	M	Yes	10/18/08	11:45p	Y	N	N	N	Y	Y	Pending	drank iced tea
4	J.M.	32	M	No							Y	N		
5	J.W.	27	F	No							Y	Y	Pending	
6	C.O.	25	F	No							N			
7	C.T.	16	F	Yes	10/19/08	6:00a	N	Y	N	Y	Y	N		

D2: CREATING AN EPIDEMIC CURVE[1]

Epidemic (Epi) curves can be easily made by hand or with a software package such as Microsoft Office Excel® or Epi Info. The structure of an epi curve is straight forward. Simply plot the number of cases reported during an outbreak on the y-axis and the onset date and/or time on the x-axis. One of the more difficult aspects of creating an epi curve is choosing the unit of time for the x-axis. The choice is usually based on the incubation period and the time interval of the outbreak. In general, a time unit that is ¼ of the incubation period is usually appropriate. For example, the mean incubation period for Shigellosis is 48 hours, so the unit of time for the x-axis would be 12 hours. If the incubation period for the outbreak is unknown, several time intervals for the x-axis can be plotted to see which one best represents the data. Because epi curves are histograms, there should be *no* spaces between the bars. The onset date and time that is shown on the x-axis should be prior to the start of the outbreak.

If Excel is used, the easiest way to set up the data is shown in Table 1. Then follow the following steps.

Table 1 An Outbreak of Shigellosis

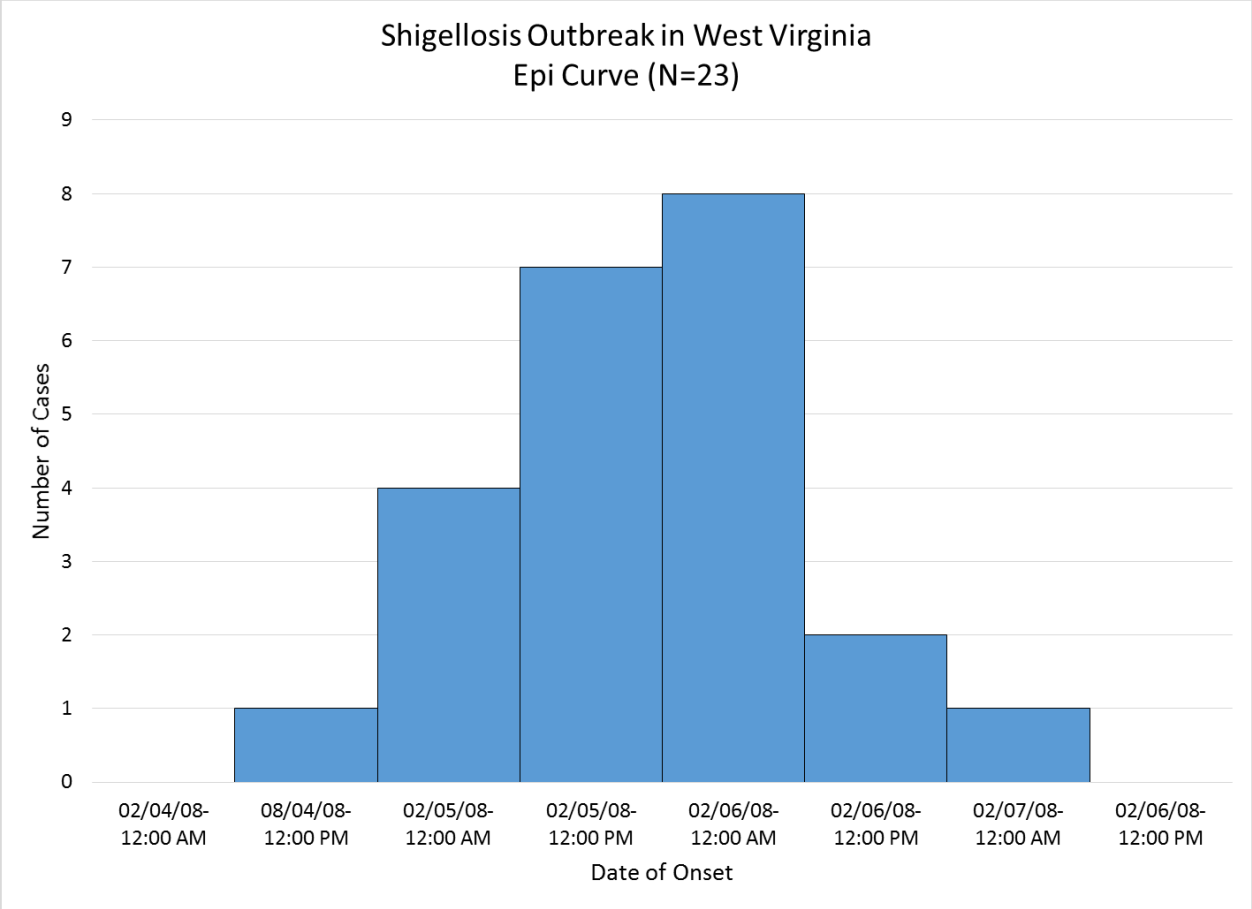
Onset Date and Time	Number of Cases
02/04/08- 12:00 AM	0
08/04/08- 12:00 PM	1
02/05/08- 12:00 AM	4
02/05/08- 12:00 PM	7
02/06/08- 12:00 AM	8
02/06/08- 12:00 PM	2
02/07/08- 12:00 AM	1
02/06/08- 12:00 PM	0

1. Highlight columns and rows containing data to be used for chart.
2. Click "Insert" on the tool bar.
3. Choose "Column" as the chart type.
4. Under "Chart Title" include a descriptive title for the epi curve.
5. Label the x-axis and the y-axis.
6. At this point the bars on the graph won't be touching as they should, so double click on one of the bars.
7. Under "Format Data Series" choose the "Options" tab and set the "Gap width" to 0.
8. If the y-axis scale is set to a number that is less than 1 (example: 0.5), double click on a number on the y-axis and under "Format Axis" select the "Scale" tab.
9. Beside the "Major unit" enter in 1 unless it is a large outbreak and then enter in an appropriate number. Example of an epi curve is shown in Figure 1.

[1] Adapted from Torok, M., Focus on Field Epidemiology, Volume, 1 Issue 5

Epidemic Curve Continued:

Figure 1



D3: DATA ANALYSES

ANALYZING THE DATA COLLECTED:

Data should be organized and collected from the interviews of ill and well persons who ate the suspect meal or food item, who attended a common event, or who were part of a family or group of which persons became ill. Data should be used to:

- Classify the illness
- Identify affected groups
- Test the hypothesis as to whether the outbreak was associated with a common source
- Determine a vehicle
- Measure disease association
- Calculate confidence interval and statistical significance
- Determine the necessity for further field or laboratory investigations

The following are some general steps in an analysis plan:

1. Generate hypotheses
2. Determine data needed to evaluate hypotheses
3. Design questionnaire and data collection forms to get needed data
4. Collect data
5. "Manage" data: enter and edit
6. Descriptive statistics/epidemiology: numbers, frequency distributions, percentages, rates
7. Simple cross-tabulation with appropriate measures of association, tests of significance and confidence intervals
8. Stratified analysis; evaluate for confounding and effect modification
9. Multivariate analysis as needed
10. Refine analysis as needed
11. Interpret appropriately; evaluate for causal relationship

The following should be calculated to understand the data collected: frequencies and percentages, the incubation period and recovery periods, the measures of association between exposure and disease, and appropriate tests of statistical significance.

CALCULATING FREQUENCIES:

COUNTS and **PERCENTAGES** should be calculated to define the outbreak:
The following is a list of common calculations:

- For all individuals (retrospective cohort or case-control study)
    - Number and percentage of persons by sex
    - Median age and age range
    - Number and percentage of ill and not ill, for retrospective cohort studies
    - Number and percentage of cases and controls for case-control studies
    - Other characteristics may be recommended depending upon the outbreak, including race/ethnicity, occupation, county, state, zip code, school name, school grade, nursing home name, room number

- Total number of persons exposed (cohort study)

- For ill persons or cases (cohort or case-control study)
    - Number and percentage of each symptom experienced
        - Diarrhea (3 or more loose stools in a 24-hour period), bloody diarrhea, vomiting, nausea, abdominal cramping, fever, malaise, headache are common symptoms
    - Number of samples collected and submitted for testing
        - Stool, blood, urine
    - Number and percentage of laboratory-confirmed results
    - Number and percentage of persons hospitalized
    - Number and percentage of medical visits

How to Calculate the MEDIAN:
The median is the midpoint of a series of ordered values. It divides a set of values into two equal parts. To identify the median from individual data:

- Arrange the observations in increasing or decreasing order
- Find the middle rank using the following formula: middle rank = (n+1)/2
    - If the number of values is odd, the middle rank falls on one observation
    - If the number of values is even, the middle rank falls between two observations
- Identify the value of the median
    - If the middle rank falls on a specific observation, the median is equal to the value of the middle rank
    - If the middle rank falls between two observations, the median is equal to the average of the values of those observations

Example 1
To calculate the median for the following observations: 1, 20, 5, 3 and 9:
- Arrange the observations (n = 5) by order of magnitude: 1, 3, 5, 9, 20
- Identify the middle rank: (5 + 1)/2 = 3
- The median is the third observation of the ordered series, namely 5

Example 2
To calculate the median for the following observations: 1, 20, 5, 3, 9, 21
- Arrange the observations (n = 6) by order of magnitude: 1, 3, 5, 9, 20, 21
- Identify the middle rank: (6 + 1)/2 = 3.5
- The median is the average of the value of the third and fourth observations, namely 5 and 9. Thus the median value = (5 + 9)/2 = 7

Median can also be calculated by entering values (in any order) into an excel spreadsheet column and then selecting Median from the autosum more functions menu.

Calculate the INCUBATION PERIOD and RECOVERY PERIOD:

The **INCUBATION PERIOD** is the interval from the time an individual is infected (exposed) to the time when symptoms first appear. The incubation period may differ from person to person and from organism to organism.

Incubation period = onset time – time of exposure

Example:

Time of exposure = 8:00 PM on Saturday evening
Onset of symptoms = 2:00 AM on Monday morning

1. Determine how many hours there were per day
   (*Hint:* Time and days listed in military time or 24-hour increments will make calculations much easier for most analytic software)

   Saturday: 8:00 PM is equivalent to 20:00 in military time. So, 24:00 - 20:00 = 4 hours
   Sunday: All hours were of interest = 24 hours
   Monday: 2:00 AM is equivalent to 02:00 in military time = 2 hours

2. Add all the hours together for the days of interest.

   4 + 24 + 2 = 30 hours

   30 hours/24 hours = 1.25 days

   Incubation period for ill persons = 30 hours or 1.3 days

3. Calculate the incubation period for each ill person. Determine the **median** incubation period and the **range** (the minimum and maximum numbers).

Person	Incubation Period
#1	14 hours ---------- Minimum
#2	18 hours
#3	23 hours
#4	30 hours ---------- Median
#5	36 hours
#6	45 hours
#7	47 hours ---------- Maximum

The **RECOVERY PERIOD** is the period when symptoms decline and illness improves.

Recovery period = recovery time – onset time

Example:

Onset of symptoms = 2:00 AM on Monday morning
Recovery from illness = 11:00 PM on Tuesday evening

1. Determine how many hours there were per day

(*Hint:* Time and days listed in military time or 24-hour increments will make calculations much easier for most analytic software)

Monday: 2:00 AM is equivalent to 02:00 in military time. So, 24:00 - 2:00 = 22 hours
Tuesday: 11:00 PM is equivalent to 23:00 in military time. So the hours of interest on Tuesday = 23 hours

2. Add all the hours together for the days of interest
   22 + 23 = 45 hours

   45 hours/ 24 hours = 1.88 days

   Recovery period for ill person = 45 hours or 1.9 days

3. Calculate the recovery period for each ill person. Determine the **median** recovery period and the **range**.

Person	Incubation Period
#1	28 hours ---------- Minimum
#2	29 hours
#3	33 hours
#4	37 hours ---------- Median
#5	40 hours
#6	45 hours
#7	51 hours ---------- Maximum

Calculate **MEASURES OF ASSOCIATION:**

A measure of association quantifies the strength or magnitude of the statistical association between the exposure and the health problem of interest. Measures of association are sometimes called measures of effect because – if the exposure is causally related to the disease – the measures quantify the effect of having the exposure on the incidence of disease.

In **COHORT** studies, the measure of association most commonly used is the **RELATIVE RISK.**

In **CASE-CONTROL** studies, the **ODDS RATIO** is the most commonly used measure of association.

Utilize a 2 x 2 table to calculate measures of association:

A 2 x 2 contingency table can be used to compare the association between illness and exposure.

	Ill	Not Ill	
Exposed	**a**	**b**	**(a + b)**
Not Exposed	**c**	**d**	**(c + d)**
	(a + c)	**(b + d)**	**a + b + c + d**

Interpretation of the elements in the 2 x 2 table:

a = the number of ill persons who were exposed to a specific risk factor
b = the number of persons who did not become ill, but were exposed to a specific risk factor
c = the number of ill persons who were not exposed to a specific risk factor
d = the number of persons who did not become ill and were not exposed to a specific risk factor

(a + b) = the total number of persons exposed
(c + d) = the total number of persons not exposed
(a + c) = The total number of ill persons
(b + d) = the total number of not-ill persons

a + b + c + d = the total number of persons

Statistical programs are available to assist in the calculation of these measures, including SAS, SPSS, EpiInfo and online programs such as *OpenEpi* and *MedCalc*.

CALCULATIONS FOR RETROSPECTIVE COHORT STUDIES:

Using a 2 x 2 table, attack rates, food-specific attack rates, and relative risk ratios may be calculated to describe the association between illness and exposure for retrospective cohort studies.

ATTACK RATES (includes food-specific attack rates):

An **attack rate** represents the occurrence of disease observed among a defined population over a limited period of time. Specifically, it is used to calculate (1) the percentage of illness among all individuals who were exposed to a specific risk factor and (2) the percentage of illness among all individuals who were not exposed to the specific risk factor.

Attack rate for ill persons who were exposed = $\frac{a}{\square}$ **X 100**

Attack rate for ill persons who were not exposed = $\frac{c}{\square}$ **X 100**

RELATIVE RISK:

A relative risk (RR) is the measure of association between exposure and illness used for cohort studies. The relative risk reflects the excess risk in the exposed group compared with the unexposed (background, expected) group.

In acute outbreak settings, risk is represented by the attack rate and thus the RR is the ratio of the attack rate for ill persons who were exposed and the attack rate for ill persons who were not exposed.

$$\textbf{Relative risk ratio} = \frac{\text{Attack rate for ill persons who were exposed}}{\text{Attack rate for ill persons who were not exposed}} = \frac{a/a+b}{c/c+d}$$

How to interpret the Relative Risk:

RR = 1: The risk of illness among exposed persons is the same as the risk of illness among those not exposed

RR > 1: Risk of illness is greater in the exposed group than in the unexposed group

RR < 1: Risk of illness in the exposed group is less than the risk in the unexposed group

Example 1: One hundred fifty individuals attended a wedding reception. Several persons became ill with diarrhea and vomiting between 12 and 48 hours after eating food served at the reception. Calculate the attack rate for (1) ill persons who ate the food served at the reception and (2) ill persons who did not eat the food served at the reception. Also calculate the relative risk (RR) ratio and interpret the results.

	Ill	Not Ill	
Ate food at reception	**72**	**63**	**135**
Did not eat food at reception	**2**	**13**	**15**
	74	**76**	**150**

$$\textbf{Attack rate for ill persons who ate food} = \frac{72}{} \times 100 = 53.3\%$$

$$\textbf{Attack rate for ill persons who did not eat food} = \frac{2}{} \times 100 = 13.3\%$$

$$\textbf{RR} = \frac{\text{AR for ill persons who ate at reception}}{\text{AR for ill persons who did not eat at reception}} = \frac{72/135}{2/15} = \frac{.533}{.133} = 4.0$$

Interpretation: About 53% of the persons who became ill had eaten the food served at the reception compared to 13% who became ill and had not eaten the food. The risk of illness among persons who ate food at the reception appears to be 4 time higher than the risk of illness among persons who did not eat food at the reception. In other words, persons who ate food at the reception were four times more likely to experience illness compared to persons who did not eat food at the reception.

Example 2: One hundred thirty-five individuals attended the wedding reception and ate the food served. Specific foods served included salad, dinner rolls, chicken, and cake. Calculate the food-specific attack rates for (1) ill persons who ate each of these items and (2) ill persons who did not eat each of these items. Also calculate the respective relative risk (RR) ratios and interpret the results.

EATING SALAD vs. BECOMING ILL

	Ill	Not Ill	
Ate salad	**62**	**53**	**115**
Did not eat salad	**10**	**10**	**20**
	72	**63**	**135**

Attack rate for ill persons who ate salad = $\frac{62}{\square}$ X 100 = 53.9%

Attack rate for ill persons who did not eat salad = $\frac{10}{\square}$ X 100 = 50.0%

$$\textbf{RR} = \frac{\textbf{AR for ill persons who ate salad}}{\textbf{AR for ill persons who did not eat salad}} = \frac{62/115}{10/20} = \frac{.539}{.50} = 1.1$$

Interpretation: About 54% of the persons who became ill had eaten the salad served at the reception compared to 50% who became ill and had not eaten the salad. The risk of illness among persons who ate salad served at the reception was almost the same as the risk of illness among persons who did not eat the salad. In other words, persons who ate salad served at the reception were as likely to experience illness as persons who did not eat the salad.

EATING DINNER ROLLS vs. BECOMING ILL

	Ill	Not Ill	
Ate dinner rolls	57	40	97
Did not eat dinner rolls	15	23	38
	72	63	135

AR for ill persons who ate dinner roll = $\frac{57}{\square}$ X 100 = 58.8%

AR for ill persons who did not eat dinner roll = $\frac{15}{\square}$ X 100 = 39.5%

$$\textbf{RR} = \frac{\text{AR for ill persons who ate dinner roll}}{\text{AR for ill persons who did not eat dinner roll}} = \frac{57/97}{15/38} = \frac{.588}{.395} = 1.49$$

Interpretation: About 59% of the persons who became ill had eaten the dinner rolls served at the reception compared to 40% who became ill and had not eaten the dinner rolls. The risk of illness among persons who ate the dinner rolls served at the reception was 1.5 times higher than the risk of illness among persons who did not eat the dinner rolls. In other words, persons who ate the dinner rolls served at the reception were 1.5 times more likely to experience illness compared to persons who did not eat the dinner rolls.

EATING CHICKEN vs. BECOMING ILL

	Ill	Not Ill	
Ate chicken	66	57	123
Did not eat chicken	6	6	12
	72	63	135

AR for ill persons who ate chicken = $\frac{66}{\square}$ X 100 = 53.7%

AR for ill persons who did not eat chicken = $\frac{6}{\square}$ X 100 = 50.0%

$$\textbf{RR} = \frac{\text{AR for ill persons who ate chicken}}{\text{AR for ill persons who did not eat chicken}} = \frac{66/123}{6/12} = \frac{.537}{.500} = 1.1$$

Interpretation: About 54% of the persons who became ill had eaten the chicken served at the reception compared to 50% who became ill and had not eaten the chicken. The risk of illness among persons who ate chicken served at the reception was almost the same as the risk of illness among persons who did not eat the chicken. In other words, persons who ate chicken served at the reception were as likely to experience illness compared to those persons who did not eat the chicken.

EATING CAKE vs. BECOMING ILL

	Ill	Not Ill	
Ate cake	66	28	94
Did not eat cake	6	35	41
	72	63	135

AR for ill persons who ate cake = $\frac{66}{\square}$ X 100 = 70.2%

AR for ill persons who did not eat cake = $\frac{6}{\square}$ X 100 = 14.6%

$$\textbf{RR} = \frac{\text{AR for ill persons who ate cake}}{\text{AR for ill persons who did not eat cake}} = \frac{66/94}{6/41} = \frac{.702}{.146} = 4.8$$

Interpretation: About 70% of the persons who became ill had eaten the cake served at the reception compared to 15% who became ill and had not eaten the cake. The risk of illness among persons who ate cake served at the reception was almost five times higher than the risk of illness among persons who did not eat cake. In other words, persons who ate cake served at the reception were almost five times more likely to experience illness compared to persons who did not eat cake.

SUMMARY EXPOSURE TABLES:
If the goal of the investigation is to identify one or more vehicles or risk factors for disease, it may be helpful to summarize the exposures of interest in a single table. For a foodborne outbreak, the table typically includes each food item served, numbers of ill and well persons by food consumption history, food-specific attack rates (if a cohort study was done), relative risk (or odds ratio), confidence intervals and chi-square and/or p-value. To identify a culprit, you should look for a food item with two features:

1. An elevated relative risk, odds ratio, or chi-square (small p-value), reflecting a substantial difference in attack rates among those exposed to the item and those not exposed.

2. Most of the ill persons had been exposed, so that the exposure could "explain" most if not all of the cases

Food-Specific Attack Rates for Persons Who Ate at Wedding Reception*

	ATE			DID NOT EAT					
Food	**# Cases**	**Total**	**AR %**	**# Cases**	**Total**	**AR %**	**RR**	**(95% CI)**	***P* Value**
Salad	62	115	55%	10	20	50%	1.1	0.67-1.76	0.75
Dinner Rolls	57	97	59%	15	38	40%	1.5	1.03-2.08	0.04
Chicken	66	123	54%	6	12	50%	1.1	0.59-1.96	0.81
Cake	66	94	70%	6	41	15%	4.8	2.26-10.17	<0.00

*AR=attack rate; RR=relative risk; and CI=confidence interval.

OVERALL INTERPRETATION: Based on the attack rates and relative risk ratios for each food item served at the reception, cake appears to be the most likely suspect food item as it has the highest relative risk (and smallest p-value) and can account for 66 of 72 cases.

CALCULATIONS FOR CASE-CONTROL STUDIES

The 2x2 table may also be used to calculate the odds ratio for case-control studies.

The **ODDS RATIO (OR)** measures whether a specific exposure is associated with a certain disease. In other words, it is the ratio of the odds that the cases were exposed to the odds that the controls were exposed. Odds ratios related to exposure to specific food items can also be calculated.

NOTE: The relative risk ratio cannot be used to measure the association between exposure and illness for case-control studies because the total population exposed in not well-defined.

	Ill	Not Ill	
Exposed	**a**	**b**	**(a + b)**
Not Exposed	**c**	**d**	**(c + d)**
	(a + c)	**(b + d)**	**a + b + c + d**

$$\text{Odds that the cases were exposed} = \frac{a}{b}$$

$$\text{Odds that the controls were exposed} = \frac{c}{d}$$

$$\text{OR} = \frac{\text{Odds that the cases were exposed}}{\text{Odds that the controls were exposed}} = \frac{a/b}{c/d} = \frac{ad}{bc}$$

Interpretations of Odds Ratio (OR):

OR = 1: The odds of exposure among cases is the same as the odds of exposure among controls

OR > 1: Odds of exposure among cases is *higher* than the odds of exposure among controls

OR < 1: Odds of exposure among cases is *lower* than the odds of exposure among controls

Example: Five persons reported eating at Restaurant X and becoming ill. After conducting a case-control study, the following numbers were obtained. Calculate the odds ratio and interpret the results. Also calculate the odds of becoming ill from eating a beef dish served at Restaurant X.

	Case	Control	
Ate at Restaurant X	**25**	**30**	**55**
Did not eat at Restaurant X	**10**	**40**	**50**
	35	**70**	**105**

$$\text{OR} = \frac{\text{Odds that the cases ate at Restaurant X}}{\text{Odds that the controls ate at Restaurant X}} = \frac{25/30}{10/40} = \frac{25(40)}{30(10)} = \frac{1000}{300}$$

= 3.3

Interpretation: The odds of being exposed to Restaurant X are 3 times higher among cases than among controls. It is also reasonable to say that the odds of developing illness are 3.3 times higher among those exposed to Restaurant X than among those not exposed. Thus, it can be concluded that eating at Restaurant X may have contributed to illness.

ODDS OF BECOMING A CASE FROM EATING BEEF AT RESTAURANT X

	Case	Control	
Ate beef at Restaurant X	**30**	**13**	**43**
Did not eat beef at Restaurant X	**3**	**9**	**12**
	33	**22**	**55**

$$\text{OR} = \frac{\text{Odds that the cases ate beef}}{} = \frac{30/13}{3/9} = \cdot\ \frac{30(9)}{3(13)} = \cdot\ \frac{270}{39}$$

= 6.9

Interpretation: The odds of being exposed to beef at Restaurant X are approximately 7 times higher among cases than among controls. From this it can be concluded that eating beef at Restaurant X may have contributed to illness.

CONFIDENCE TESTING OF THE RR AND THE OR

Tests of significance are calculated to determine if the association between exposure and illness occurred by chance alone. In other words, was the association observed between exposure and illness a random occurrence? The **95% confidence intervals** and the **p-values** may be calculated to determine the significance of the association between exposure and illness.

The 95% confidence intervals (CI) indicate how "confident" one can be that the RR or the OR observed actually lies within a range of numbers. In other words, the confidence interval is an estimated range of values within which the true RR or OR is likely to fall 95% of the time. Suppose that you conducted a study in which the relative risk for eating peanut butter and Salmonella was 4.0, and the 95% confidence interval was 3.0 to 5.3. Your single best guess of the association in the general population is 4.0, but your data are consistent with values anywhere from 3.0 to 5.3. The width of a CI (i.e., the values included) reflects the precision with which a study can pinpoint an association such as a relative risk. A wide confidence interval reflects a large amount of variability or imprecision. A narrow confidence interval reflects little variability and high precision. Usually, the larger the number of subjects or observations in a study, the greater the precision and the narrower the confidence interval. If a confidence interval includes 1.0 then the results can be interpreted to mean that risk of illness in those exposed is the same as the risk of illness in those not exposed.

In contrast, p-values represent the probability that the association observed between exposure and illness could have occurred by chance alone. Epidemiologists typically select the probability level (alpha) for determining the significance of the data at 0.05. If the p-value is smaller than this cutoff, the association is then said to be "statistically significant".

Many statistical programs, like EpiInfo™, SAS, SPSS and *OpenEpi* readily calculate these values. Refer to these statistical programs or statistical books for more information.

D4: GUIDELINES FOR WRITING A FINAL OUTBREAK INVESTIGATION REPORT

(This outline should be adapted as needed for the purpose of clear, concise communication)

Cover page should include the following:

Date Written:

Release Date:

To:

From:

Report Co-authors:

Peer Reviewers:

Date Reported:

Reported By:

Person Contacted:

Also Contacted:

1. **Introduction**
    a. Date and time notification was received by your agency
    b. Describe the context of the outbreak:
        - Who → population affected
        - Where → location / place / setting
        - When → Time of onset
        - What → describe clinical findings
        - Why→ suspected or known etiology or risk factors
    c. Date and time investigation was initiated by the agency
    d. Describe the primary objective(s) of the investigation
2. **Background**
    a. Brief scientific background on the disease and/or suspected etiologic agent
3. **Investigation Methods**
    a. Epidemiologic:
        - Initial investigation methods including interviews, site visits, conference calls, etc.
        - Case definition
        - Data collection (case-finding and line listing, medical record reviews)
        - Data analysis methods (e.g., descriptive epi, hypothesis generating interviews, cohort or case-control studies, other epidemiological data collection and analysis)
    b. Microbiological/toxicological
        - Laboratories involved
        - Type of clinical specimens and sources
        - Laboratory methods
    c. Environmental
        - Review reports developed by environmental responders
        - Describe any trace back investigations that were done (e.g. food products, etc.)
        - Describe any environmental specimens collected
4. **Results**
    a. Epidemiological - descriptive epidemiology results including:
        - Cases
            1. Demographic data
            2. Clinical data (symptoms, signs, duration of illness, incubation period
            3. Outcome of illness (hospitalization, death, chronic effects**)**
        - Location of cases (facility, county, city, etc.)
        - Epidemic curve and other graphs
        - Compare characteristics of cases and controls, if applicable
        - Describe exposed population, if applicable
        - Describe the results of analytical studies
    b. Microbiological/toxicological
        - Number and nature of specimens submitted for testing and results of laboratory testing
    c. Environmental
        - Describe observations and pertinent findings from environmental investigation(s)
        - Describe the results of trace-back investigations
        - Results of environmental testing (if any)

5. **Limitations of the study**
    a. Discuss any factors that limited the investigation such as (small number of cases, poor information, late reporting, limited resources to conduct investigation, etc.)

6. **Conclusion / Discussion:** Analysis and interpretation of the investigation results and any conclusions drawn as a result of this investigation
    a. Discuss the main hypothesis
    b. Describe the likely causative agent and mode of transmission
    c. Describe the risk factors
    d. Explain what was done to control the outbreak
    e. Describe the conclusions and actions taken
7. Discuss lessons learned and recommendations for controlling disease and/or preventing/mitigating exposure:
    a. Recommendations to improve investigation and management of such outbreaks in the future
    b. Measures to prevent similar outbreaks in the future
    c. Educational message to the public, public health professionals and policy makers

Additional instructions:

- Outbreak report should be completed within one month of outbreak closure.
- A final outbreak report is required for all outbreaks. Outbreak report templates may be used for most outbreaks. A more detailed report written following these guidelines should be used in the following situations:
    - Complex outbreaks for which the template cannot effectively describe the outbreak
    - Any outbreak in which an analytical study was done
    - Outbreaks that required a site visit
    - The decision to write a detailed outbreak report in any outbreak should be made on a case-by-case basis
- Please be careful not to mention any personal or entity identifying information
- Refrain from attributing any specific info to a specific individual
- Reports should be written objectively based on scientific data
- Cite references used