

Foodborne Outbreak Investigation Manual

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Introduction to Foodborne Illness

The Problem

Foodborne illnesses are a major public health problem. The Centers for Disease Control and Prevention (CDC) estimate that each year one in six Americans get sick, 128,000; are hospitalized; and 3,000 die of foodborne diseases. Foodborne illnesses have the greatest impact on the young, elderly and people who may be immunocompromised or have other existing health conditions.

Causes

There are 31 known pathogens known to cause foodborne illness*. Primary causes of foodborne illnesses include bacteria, viruses, parasites and chemicals (Appendix A). According to CDC, from 1998 to 2008, 13,405 outbreaks were reported in the U.S. The etiology was determined for 8,366 (62%) of these outbreaks. Of those outbreaks where a single etiology was determined (7,998), bacterial pathogens caused 27 percent of the outbreaks; viruses caused 27 percent of outbreaks; chemical agents caused 5 percent of outbreaks; and parasites caused 1 percent of outbreaks. Of the outbreaks where a single bacterial pathogen was implicated, *Salmonella* was reported in 40 percent. *Salmonella* Enteritidis was the most frequently reported serotype, causing 31 percent of reported *Salmonella* outbreaks. Norovirus outbreaks have increased five-fold over time, from six percent of outbreaks in 1998 to 35 percent of outbreaks in 2008. The majority (67%) of foodborne outbreaks occurred in a restaurant or deli. The most commonly reported contamination factor that contributed to foodborne illness was contact by a food handler with bare hands.

Foodborne Illness in North Dakota

From 1988 through 2010, the North Dakota Department of Health has investigated 82 outbreaks. These outbreaks were responsible for more than 3,300 illnesses with the median number of illnesses per outbreak being 42. An etiology was determined for 48 (37%) of these outbreaks. Twenty-four (50%) of the outbreaks were attributed to viral causes, 17 (35%) were attributed to bacterial causes and 7 (15%) were attributed to toxins. The majority of outbreaks were due to norovirus, which caused 50 percent of all outbreaks with a known etiology. The outbreaks of known bacterial etiology were due to *Salmonella* sp. (9 outbreaks), shiga toxin producing *E.coli* (6 outbreaks) and *Campylobacter jejuni* (2 outbreaks). Ill food handlers were identified as the major contributing factor in 10 (12%) outbreaks. Inadequate cooking and improper reheating was identified as the major contributing factor in 9 (11%) outbreaks. Commercial restaurants were involved in 21 (26%) of the outbreaks and private homes in eight (10%) outbreaks. Additional information on the history of foodborne outbreaks reported in North Dakota since 1988 can be found at www.ndhealth.gov/disease/GI.

*Centers for Disease Control and Prevention. (2011, April 19). *CDC Estimates of Foodborne Illness in the United States*. Retrieved January 17, 2012, from Centers for Disease Control and Prevention: <http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>.

Definition of a Foodborne Outbreak

In North Dakota, a foodborne disease outbreak is defined in the following ways:

- 1. An incident in which two or more people experience a similar illness after ingestion of a common food and epidemiologic analysis implicates the food as the source of the illness (Council of State and Territorial Epidemiologists Case Definition: www.cdc.gov/osels/ph_surveillance/nndss/casedef/foodbornecurrent.htm).**
Household members generally share many meals together and experience close personal contact with one another. Therefore, similar illness among members of a single household may or may not be considered to be an outbreak. Investigations will be considered on a case-by-case basis.
- 2. An unexplained, unexpected increase of a similar illness and food is a likely source.** Further investigation to identify the source of illness should be done. For example, an increased number of *Campylobacter jejuni* identified at the state laboratory may suggest that a foodborne disease outbreak has occurred.

NOTE: Confirmed laboratory identification of the disease-causing organism is not necessary to determine that a foodborne disease outbreak has occurred. Furthermore, confirmed laboratory identification is not needed to begin an investigation, and outcomes of an investigation may be based solely on epidemiologic evidence. Nonetheless, laboratory testing of clinical specimens and food samples to confirm the pathogen of a foodborne disease outbreak should always be a priority.

Identifying Foodborne Disease Outbreaks

Foodborne disease outbreaks may be identified from the following:

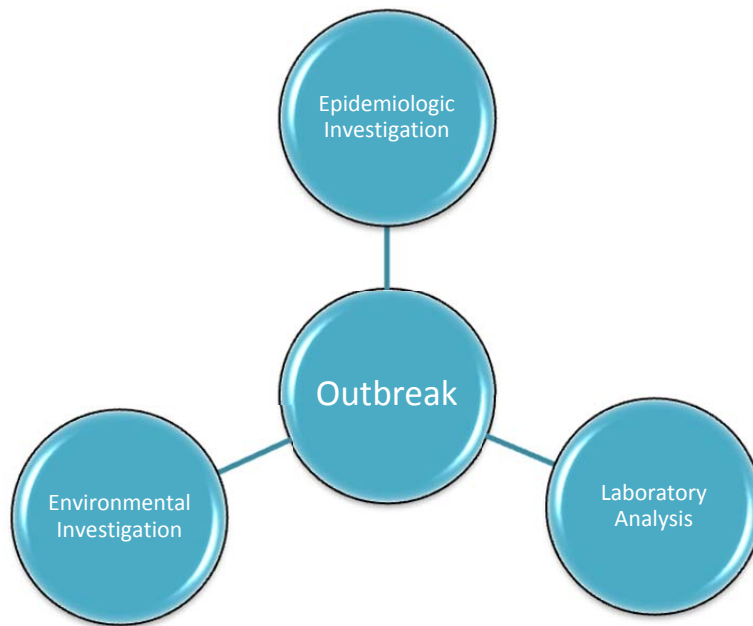
- Foodborne-illness complaints from private citizens.
- Medical evaluations of ill individuals from health-care professionals at hospitals, clinics or physician offices.
- Routine surveillance and case investigation of reportable diarrheal illnesses by epidemiologists and public health nurses at state and local public health units (LPHUs).
- Routine laboratory testing and techniques, including pulsed field gel electrophoresis (PFGE) conducted by microbiologists.
- Information received through the media and public information officers.
- Reports from state and federal food safety regulators and environmental health practitioners (EHPs).

How to Report Foodborne Outbreaks

The North Dakota Department of Health (NDDoH) Division of Disease Control should be notified if an outbreak has occurred or if assistance is needed in determining if an outbreak has occurred. Contact the Division of Disease Control by calling 800.472.2180 or 701.328.2378, or e-mail disease@nd.gov.

Three Components of a Foodborne Disease Outbreak Investigation

Foodborne disease outbreak investigations are conducted to determine what factors are associated with illness and what measures can be done to prevent further illness. This is achieved through (1) an epidemiologic investigation, (2) laboratory analysis, and (3) an environmental assessment. A thorough outbreak investigation cannot be conducted without these three components, which are often performed simultaneously. These three components of an investigation work together to complete goals and objectives. The Roles and Responsibilities section in the foodborne disease outbreak section beginning on page 6 of this manual highlights which agency is responsible for completing specific activities related to the goals and objectives of a foodborne disease outbreak investigation.



Foodborne Outbreak Investigation Goals

- Implement specific interventions that will stop the outbreak.
- Prevent a similar outbreak from occurring in the future.
- Increase knowledge of the epidemiology and control of foodborne diseases. Unanswered questions about the etiologic agent, the mode of transmission or contributing factors should be identified.

Foodborne Outbreak Investigation Objectives

- Identify the etiologic agent.
- Identify people at risk.
- Identify mode of transmission and vehicle.
- Identify source of contamination.
- Identify contributing factors.
- Determine potential for ongoing transmission and need for abatement procedure.

Roles and Responsibilities in a Foodborne Disease Outbreak Investigation

Roles and Responsibilities: Epidemiology

➤ Division of Disease Control

Scope: The Division of Disease Control is responsible as the lead agency for overall coordination and technical assistance/consultation for local public health units (LPHUs), city environmental health agencies, other health department divisions/sections and federal agencies during foodborne outbreak investigations.

Responsibilities:

- Upon notification of a food complaint and/or possible foodborne disease outbreak, coordinate with the city or local environmental health agency and/or state agency that has jurisdiction to ascertain whether or not an outbreak may be occurring.
- If sufficient information indicates a foodborne disease outbreak, the Division of Disease Control will notify:
 - The LPHU that has jurisdiction.
 - The Division of Food and Lodging and/or environmental health agency with licensing or regulatory authority.
 - The Division of Laboratory Services.
 - The Department Operations Center if additional resources are needed.
- Coordinate surveillance, develop the questionnaire tool, perform case/control interviews, data analysis and complete the final report.
- Assist environmental health staff to coordinate and initiate the environmental outbreak investigation, interview food workers and collect food/environmental samples and initiation of chain of custody when appropriate.
- Coordinate with the Division of Laboratory Services for distribution and testing of self-collected stool specimen kits and reporting of test results.
- Coordinate with the local health department to notify area health-care providers and/or institutional settings (e.g., nursing homes, hospitals, schools, etc.) and conduct surveillance activities to identify additional cases.
- Coordinate procurement and distribution of necessary biologics if the outbreak involves a disease that is preventable through prophylaxis or vaccination.
- Coordinate as necessary with:
 - State and local public information officers to coordinate the distribution of news releases, health alerts, conference calls and memos.
 - Centers for Disease Control and Prevention (CDC) and other federal agencies.
 - Out-of-state health departments.
- Prepare final outbreak investigation report and disseminate to appropriate parties involved in the outbreak investigation and upon request of public record.
- Report the outbreak via the CDC National Outbreak Reporting System (NORS) within 60 days of outbreak.

Roles and Responsibilities: Environmental Health

➤ City or Local Environmental Health Agency

Scope: The city or local environmental health agency is responsible for overall coordination of the environmental inspections within its jurisdictions during foodborne outbreak investigations.

Responsibilities:

- Initiate the environmental investigation which will include, but is not limited to, inspection and/or overview of possible outbreak food preparation, handling and storage, outbreak food sample collection and employee interviews, when applicable.
- Coordinate with the Division of Laboratory Services and the Division of Disease Control regarding shipping and handling of specimens.
- Assist Division of Disease Control staff to coordinate the human sample collection, food sample collection and shipping and handling guidelines.
- Upon completion of the environmental investigation, compile the employee questionnaires, review and submit to Division of Disease Control.
- Write up environmental health investigation report and submit to the Division of Disease Control when completed.
- Participate in all necessary conference calls with responding agencies.
- If the city or local environmental health agency is first to receive notification of the occurrence of a possible foodborne outbreak, notify the Division of Disease Control of:
 - The name and contact information of the party reporting, estimated number involved in outbreak, type of outbreak (restaurant, large gathering, etc.) and estimated time frame of outbreak.

➤ Division of Food and Lodging

Scope: The Division of Food and Lodging is responsible for environmental health inspections in food service establishments located in areas where no local environmental health practitioner is available. The division also will provide any needed coordination and technical assistance/consultation for city or local environmental health agencies and other health department divisions/sections with licensing or regulatory authority during foodborne outbreak investigations.

Responsibilities:

- Upon notification of the occurrence of a possible foodborne outbreak, the Division of Food and Lodging will notify:
 - The Division of Disease Control.
 - The city or local environmental health agency who has jurisdiction.
 - Any necessary federal agencies.
- If no local jurisdiction, initiate the environmental investigation which will include, but is not limited to, inspection and/or overview of food preparation, handling and storage, food sample collection and assisting in interviewing food workers using a standard questionnaire, when applicable.

- Coordinate with the Division of Laboratory Services and the Division of Disease Control regarding shipping and handling of food and environmental specimens.
- Assist Division of Disease Control staff to coordinate stool sample collection from food workers.
- Upon completion of the environmental investigation, compile the completed food worker questionnaires, review and submit to the Division of Disease Control.
- Prepare environmental health outbreak investigation report and submit to the Division of Disease Control.
- Participate in all necessary conference calls with responding agencies.
- Coordinate with the appropriate county States Attorney's Office to determine if legal action is necessary.
- Coordinate and cooperate as necessary with:
 - State Meat and Poultry Inspection Program, Division of Health Facilities, other state agencies, U.S. Department of Agriculture (USDA), U.S. Food and Drug Administration (FDA) and other federal agencies.
 - Out-of-state health departments and other U.S. state food regulatory agencies.

➤ **Division of Health Facilities**

Scope: The Division of Health Facilities is responsible for the environmental health inspections of licensed and/or certified health-care facilities in the state. Specifically, hospitals, nursing homes, and basic care facilities across the state where vulnerable individuals receive healthcare and services. Trained and experienced survey staff from the division will coordinate and collaborate with the Division of Food and Lodging to conduct foodborne outbreak environmental health inspections. The Division of Health Facilities will coordinate with state and local public health agencies to expedite the investigative process and take the appropriate licensing and certification actions as deemed necessary.

Responsibilities:

- Upon notification of the occurrence of a possible foodborne outbreak, the Division of Health Facilities will notify:
 - The Division of Disease Control.
 - The city or local environmental health agency that has jurisdiction.
- Initiate the environmental investigation which will include, but is not limited to, inspection and/or overview of food preparation, handling and storage, food sample collection and assisting in interviewing food and health-care workers using a standard questionnaire, when applicable.
- Coordinate with the Division of Laboratory Services and the Division of Disease Control regarding shipping and handling of food and environmental specimens.
- Assist Division of Disease Control staff to coordinate stool sample collection from food workers.
- Upon completion of the environmental investigation, compile the completed food worker questionnaires, review and submit to the Division of Disease Control.

- Prepare environmental health outbreak investigation report and submit to the Division of Disease Control.
- Participate in all necessary conference calls with responding agencies.
- Coordinate with the appropriate county State's Attorney Office to determine if legal action is necessary.
- Coordinate as necessary with:
 - Division of Food and Lodging, Division of Disease Control or local or city environmental health agencies.

➤ **State Meat/Poultry/Dairy Inspection Programs**

Scope: The State Meat/Poultry/Dairy Inspection Programs within the North Dakota Department of Agriculture are responsible for environmental health inspections of meat, livestock, dairy and egg producers and processors in North Dakota. The programs also will provide any needed coordination and technical assistance/consultation for local public health units and other health department divisions/sections during foodborne outbreak investigations.

Responsibilities:

- Upon notification
- in interviewing food workers using a standard questionnaire, when applicable.
- Coordinate with the Division of Laboratory Services and the Division of Disease Control regarding shipping and handling of food and environmental specimens.
- Assist Division of Disease Control staff to coordinate stool sample collection from food workers.
- Upon completion of the occurrence of a possible foodborne outbreak, the State Meat/Poultry/Dairy Inspection Programs will notify:
 - The Division of Disease Control.
 - The Division of Food and Lodging.
 - The city or local environmental health agency that has jurisdiction.
 - Any necessary federal agencies.
- Initiate the environmental investigation which will include, but is not limited to, inspection and/or overview of food preparation, handling and storage, food sample collection and assisting of the environmental investigation, compile the completed food worker questionnaires, review and submit to the Division of Disease Control.
- Prepare environmental health outbreak investigation report and submit to the Division of Disease Control.
- Participate in all necessary conference calls with responding agencies.
- Coordinate with the appropriate county State's Attorney Office to determine if legal action is necessary.
- Coordinate as necessary with:
 - Division of Food and Lodging, USDA, FDA and other federal agencies.
 - Out-of-state agriculture departments.

Roles and Responsibilities: Laboratory

➤ Division of Laboratory Services

Scope: The Division of Laboratory Services is responsible for testing human and environmental samples collected during the foodborne outbreak. The Division of Laboratory Services also will provide any needed coordination and technical assistance/consultation for city or local environmental health agencies and other health department divisions/sections during foodborne outbreak investigations.

Responsibilities:

- Coordinate with the Division of Disease Control regarding testing capabilities and priorities, capacity for samples, ordering of any additional reagents, etc.
- Provide sample collection kits to field epidemiologists and responding environmental health practitioners as needed.
- Provide guidance on sample collection (e.g., amount of sample needed, method of collection, etc.) to responding epidemiologists and EHPs.
- Coordinate shipping and handling of specimens.
- Organize and gather all necessary materials and methods to perform the testing for enteric bacteria, viruses or toxins in the laboratory.
- Coordinate any laboratory response activities as necessary with CDC and other federal agencies, along with other state health departments.
- Participate in all necessary conference calls with responding agencies.

Upon receipt of samples, the Division of Laboratory Services will:

- Inform the Division of Disease Control that samples have been received and report necessary information (e.g., patient name, number of samples, number of environmental swabs, etc.).
- Perform appropriate laboratory analysis of samples to identify any enteric bacterial pathogens, norovirus or other foodborne disease-causing organisms or toxins.
- Complete the chain of custody for all food and environmental samples.

Upon identification of positive samples, the Division of Laboratory Services will:

- Contact the Division of Disease Control with all necessary information (e.g., patient name, number of samples, number of environmental swabs, etc.) regarding positive samples.
- When appropriate, perform PFGE subtyping and post results on PulseNet.
- Communicate any relevant laboratory results or coordinate further testing with CDC and other agencies.

Conducting an Epidemiologic Outbreak Investigation

The main objectives of an epidemiologic outbreak investigation are (1) to identify an outbreak, (2) to collect information related to the outbreak, and (3) to develop conclusions and recommendations for prevention and control. In North Dakota, the Division of Disease Control is responsible for conducting activities related to the epidemiologic investigation. Illness and exposure histories are collected using questionnaires, and comparisons are made between people who became ill and those who did not. Conclusions about the outbreak are then formulated from the epidemiologic data, in conjunction with the results of the laboratory analysis and environmental assessment.

This checklist identifies the essential activities and objectives of an epidemiologic outbreak investigation:

- Determine that an outbreak has occurred.
- Obtain a list of individuals that were exposed during the outbreak to identify cases.
- Interview cases to characterize symptoms, incubation period and duration of illness.
- Identify cases that are willing to submit stool specimens using self-collection stool kits and coordinate testing of clinical specimens and environmental samples, including food samples.
- Establish case definition based on confirmed diagnosis or clinical profile of cases and determine attack rates.
- Identify mode of transmission and vehicle by interviewing cases and controls about all common exposure sources.
- Calculate statistical evidence of specific exposures during the outbreak.
- Combine descriptive and analytical epidemiology results to develop a conclusion for the outbreak.
- Prepare a final report using epidemiological, environmental and laboratory data and distribute results to agencies involved in foodborne outbreak response.

Each outbreak is unique, and the investigation should be conducted in a way that ensures that all activities and objectives are completed. Several activities and objectives may be, and sometimes should be, conducted simultaneously. For instance, control and prevention measures should be implemented as soon as the source of the foodborne outbreak is identified.

Foodborne-Illness Complaints

Foodborne-illness complaints are often sporadic and may not meet the definition of a foodborne outbreak. In general, single person complaints regarding single exposures do not initiate an investigation until further reports of illness are received. All complaints should be documented using a form similar to the Foodborne-Illness Complaint form (See Appendix B). Information collected on all foodborne-illness complaints should include:

- Basic demographic information (name, age, phone number, address).
- A three-day food history.
- Symptoms, hospitalization, treatment and test(s) ordered and/or results.
- Large gatherings attended (e.g., common meals, social events, weddings, potlucks, etc.).
- Information on any contacts, including those who also are ill.

Foodborne-illness complaints can be reported by:

1. An individual(s) who observes a pattern of illnesses;
2. An affected group of people, usually following a common exposure; or
3. Multiple independent complaints about illness in individuals with a common exposure.

Identifying foodborne disease outbreaks through illness complaints does not require the specific pathogen to be known. The role of the epidemiologist is to determine whether an illness complaint is a foodborne disease outbreak and then initiate an outbreak investigation.

Data Collection

Data collected during the outbreak investigation comes from case and control interviews, laboratory evidence and the environmental investigation. Data collection for the epidemiological investigation begins with a standardized questionnaire. The questionnaire is designed specifically for the common exposure and is used for hypothesis generation and both case and control interviews. Data analysis occurs at various points during the investigation and is a continuous process during the investigation as more information is collected. Initial data, such as incubation period, symptoms and duration of symptoms, are used to assist EHPs and laboratorians to identify probable etiologic agents and food vehicles. After interviews are complete, statistical analysis is used to determine an association between an exposure, such as a particular food item, and illness. Data analyses from studies are integrated with information from food worker interviews, environmental investigations and laboratory evidence to support conclusions regarding the outbreak.

Study Design and Data Analysis

Types of Epidemiologic Studies

Case series, cohort and case-control are examples of study designs used in epidemiologic investigations. The study design that is utilized during an investigation is going to depend on the number of individuals exposed, availability of controls and available resources.

Case Series

Case series studies are utilized when the number of exposed individuals is relatively small. Outbreaks that are analyzed using this study design occur when all exposed individuals became symptomatic; no exposed individuals are well. The study design can provide person, place and time associations. Statistical analysis revealing an association between an exposure and illness cannot be determined.

Cohort

In a cohort study design, groups of exposed and unexposed individuals can be easily identified. The outbreaks analyzed using cohort studies are usually not large outbreaks that require significant resources since all exposed and unexposed individuals are interviewed. In this study, risk of illness is compared by what was eaten and what was not eaten. An example of an outbreak that would use a cohort study design would be a church supper. After interviewing the attendees, one could determine the number of cases and controls that were exposed to each particular food item served at the dinner.

Case-Control

Case-controls studies are used in outbreak investigations when the exposed group is very large or not easily identified. In this study design, ill and non-ill individuals are compared to determine the likelihood of having eaten specific foods. An example of an outbreak that would require a case-control study is a large national convention attended from multiple states or when a widely distributed, brand name food commodity is implicated in a nationwide outbreak investigation. Identifying and interviewing all exposed individuals in these instances would most likely not be practical.

Measures of Association and Occurrence

There are different measures of association that can be utilized to determine the association between an exposure and illness. These measures include relative risk and odds ratio. The study design being used in the investigation determines which measure of association is going to be used. Relative risk is used in cohort studies and odds ratio is used during case-control studies.

Relative Risk (RR): Risk of developing disease given the exposure

Odds Ratio (OR): Odds of having the exposure given the disease

The attack rate is a measure of occurrence that is calculated to express the occurrence of a disease among a particular at-risk population for a limited period of time, often due to a very specific exposure. Attack rates can be event or food specific. Attack rates are used in calculating relative risk.

$$\text{Attack Rate} = \frac{\text{Number of Ill People Who Consumed Item}}{\text{Total Number of People Consuming Item}}$$

Table 1 is a 2 x 2 table that illustrates the calculation of relative risk. A 2 x 2 table is often utilized to estimate the magnitude of association between exposure and illness.

Table 1. 2 X 2 Table to Calculate Relative Risk

		Disease		
		Yes	No	Total
Exposure	Yes	a	b	a + b
	No	c	d	c + d
Total		a + c	b + d	a+b+c+d

$$\text{Relative Risk} = \frac{a / (a + b)}{c / (c + d)}$$

- RR = 1: No Association
- RR < 1: Negative Association
- RR > 1: Positive Association

Interpretation of the elements in the 2 x 2 table

a = the number of ill people who were exposed to a specific risk factor

b = the number of people who did not become ill, but were exposed to a specific risk factor

c = the number of ill people who were not exposed to a specific risk factor

d = the number of people who did not become ill and were not exposed to a specific risk factor

(**a + b**) = the total number of people exposed

(**c + d**) = the total number of people not exposed

(**a + c**) = the total number of ill people

(**b + d**) = the total number of people not ill

(**a + b + c + d**) = the total number of people

EXAMPLE: One hundred fifty individuals attended a wedding reception. Several people became ill with diarrhea and vomiting between 12 and 48 hours after eating food served at the reception. Calculate the attack rates for (1) ill people who ate the food served at the reception and (2) ill people 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

$$\text{Attack rate for ill people who ate food} = \frac{72}{135} \times 100 = 53.3\%$$

$$\text{Attack rate for ill people who did not eat food} = \frac{2}{15} \times 100 = 13.3\%$$

$$RR = \frac{\text{Attack rate for ill people who ate at the reception}}{\text{Attack rate for ill people who did not eat at the reception}} = \frac{72/135}{2/15} = \frac{.533}{.133} = 4$$

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

Table 2 is a 2 x 2 table that illustrates the calculation of odds ratio.

Table 2. 2 X 2 Table to Calculate Odds Ratio

		Disease		
		Yes	No	Total
Exposure	Yes	a	b	a + b
	No	c	d	c + d
	Total	a + c	b + d	a+b+c+d

$$\text{Odds Ratio} = \frac{\text{Odds of exposure among cases}}{\text{Odds of exposure among controls}} = \frac{a/c}{b/d} = \frac{ad}{bc}$$

- OR = 1: No Association
- OR < 1: Negative Association
- OR > 1: Positive Association

Example. Five people 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.

Odds of becoming a case from eating at restaurant X			
	Case	Control	
Ate at restaurant X	25	30	55
Did not eat at restaurant X	10	40	50
	35	70	105

$$OR = \frac{\text{Odds that the cases ate at restaurant}}{\text{Odds that the controls ate at restaurant}} = \frac{25/30}{10/40} = \frac{25(40)}{30(10)} = \frac{1000}{300} = 3.3$$

Interpretation: The odds of exposure to restaurant X was three times higher among cases than among controls. It can be concluded that eating at restaurant X may have contributed to illness.

Significance 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 percent confidence intervals** and the ***p*-values** may be calculated to determine the significance of the association between exposure and illness. The 95 percent confidence intervals 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 percent of the time. In contrast, *p*-values represent the probability that the association observed between exposure and illness could have occurred by chance alone. Many statistical programs, like EpiInfo™, readily calculate these values.

- A statistically significant value is defined as a **$p \leq 0.05$** .
- For a confidence interval to be considered significant, the interval cannot include the value 1.0.

Self-Collection Stool Kits

The Division of Disease Control can ship self-collection stool kits to symptomatic individuals during an outbreak investigation. The self-collection kits include: 1) category B shipper, 2) collection media vial, 3) toilet hat, 4) gloves, 5) laboratory test request form and 6) biohazard bag. To request stool kits, contact the Division of Disease Control at 800.472.2180 or 701.328.2378.

INSTRUCTIONS FOR SUBMITTING A STOOL SAMPLE TO NDDoH



1. Fill out the top portion of lab slip (circled area).



2. Legibly write first and last name on the vial.



3. Place collection container on toilet seat as shown.
Deposit stool in tissue portion of collection container.



4. Unscrew orange lid on vial.
Use attached scoop to fill vial with stool until fluid reaches the red line.
Replace the lid on the orange vial.



5. Remove tissue portion of collection container from cardboard portion.
Flush tissue portion and dispose of cardboard in trash.



6. Place vial into clear plastic biohazard bag along with the absorbent cloth.
Seal clear plastic biohazard bag.
Wash hands thoroughly with soap and water.



7. Place sealed clear plastic biohazard bag in to the white biohazard envelope.
Also place the completed lab slip in the white biohazard envelope. Seal the envelope.

8. Place white biohazard envelope(s) in the box. Close the box according to the instructions on the box. Place the box in the mailbox.

Please call _____ at _____ if you have any questions. Thank You.

Conducting an Environmental Outbreak Investigation

An environmental health investigation is a systematic, detailed, science-based evaluation of environmental factors that contributed to transmission of a particular disease in an outbreak. The environmental health investigation focuses on the problem at hand and considers how the causative agent, host factors and environmental conditions interacted to result in the problem. The primary goals of an environmental investigation are to identify (1) possible points of contamination, (2) how the causative agent could have survived, (3) whether conditions were conducive for subsequent growth or toxin production by the disease agent and (4) circumstances that resulted in the conditions allowing the outbreak to occur.

This checklist identifies the essential steps of an environmental investigation:

- Review previous inspection history.
- Interview management to determine whether there were any ill employees or any circumstances that could be the cause of a foodborne illness.
- Review employee absenteeism records.
- Interview food workers to determine illness and food-preparation responsibilities.
- Coordinate with the Division of Disease Control and the Division of Laboratory Services for stool, food and environmental sample collection.
- Look for skin inflammation, boils, cuts and bruises.
- Determine whether the setting or a food item suggests a likely pathogen.
- Review records of recent complaints.
- Obtain a menu from establishment or event.
- Review recent changes in recipes or new menu items.
- Identify mode of transmission and vehicle by reconstructing food flow for implicated meal or food item and identifying contributing factors.
- Evaluate food flow for implicated meal or food item to identify contamination event at point of preparation or service.
- Obtain time/temperature logs if available.
- Trace source of ingredients of implicated food item back through distribution to point where a contamination event can be identified or, if no contamination events can be identified during distribution, to source of production.
- Place special emphasis on food prepared in advance.
- Inquire about recent changes in suppliers/distributors.
- Inquire about security of premises.

- Evaluate results of environmental investigation, given the identification of agent and results of epidemiologic investigation, to identify factors most likely to have contributed to the outbreak. Provide report of results to epidemiologist for inclusion in the final outbreak report (Appendix D).
- Implement control measures and corrective actions to prevent further exposures.

Local/State/Federal Jurisdiction

Environmental investigations are conducted by city, local, state and federal environmental health practitioners. To determine if the city, local public health or state health agency has jurisdiction over the establishment involved in the investigation, please contact the Division of Food and Lodging at 701.328.1292 or the local public health unit where the establishment is located. Local public health unit contact information can be found at www.ndhealth.gov/localhd/. If a recalled product is part of interstate commerce, USDA and FDA should be notified of the outbreak and recalled product. In the event of a local jurisdiction needing assistance during an outbreak investigation, the Division of Food and Lodging will provide any needed assistance.

Foodborne-Illness Complaints

Initial illness complaints may be received by epidemiologists or EHPs. Tools for documenting illness and food complaints are available in Appendix B and C. Information collected on all foodborne-illness complaints should include:

- Basic demographic information (name, age, phone number, address).
- A three-day food history.
- Symptoms, hospitalization, treatment and test(s) ordered and/or results.
- Large gatherings attended (e.g., common meals, social events, weddings, potlucks, etc.).
- Information on any contacts, including those who also are ill.

Initial complaints can be forwarded to the Division of Disease Control or the local field epidemiologist (www.ndhealth.gov/Disease/Contacts/AreaCall.htm) to obtain all necessary information. Complaints should be forwarded to epidemiologists if it is determined that the complaint could possibly represent a foodborne outbreak. EHPs can consult with the lead foodborne outbreak investigator with the Division of Disease Control or their local field epidemiologist to aid in determining if the complaint is a possible outbreak.

Conducting a Laboratory Investigation

In North Dakota, the Division of Laboratory Services is responsible for conducting activities related to the laboratory investigation. The main objective of the laboratory outbreak investigation is to perform laboratory testing on clinical, food and environmental specimens in order to identify and confirm the causative agent of the outbreak.

This checklist identifies the essential activities and objectives of a laboratory investigation:

- Contact clinical laboratories that may have performed laboratory testing on cases and obtained specimens.
- Test clinical specimens to identify the causative agent.
- Test samples of implicated food or environmental items to identify the causative agent.
- Subtype isolates when appropriate.
- Evaluate results of all outbreak-associated cultures to highlight possible relations among isolates from clinical, food and environmental samples.
- Assess status of completed and pending cultures to identify gaps that suggest a potential for ongoing transmission.

Sample Collection and Testing During an Outbreak Investigation

General Guidelines for Food Sample Collection During an Outbreak Investigation

Microbiological analysis of food supports the epidemiologic investigation of a foodborne disease outbreak. The purpose of testing is to isolate and identify pathogenic microorganisms in food samples that have been implicated in the outbreak. Samples collected as part of the investigation should be treated as official samples and should be collected in a manner that reflects the food as it was prepared, served, or used in preparation of the suspected meal.

Submission of Food Samples for Analysis at the Division of Laboratory Services

Food sample collection is most often conducted by an environmental health practitioner. However, occasionally ill individuals will have food samples that can be brought to the local public health unit. However, all requests for laboratory examination of food or food-related samples must be made through the Division of Disease Control. Laboratory examination of food will be performed only when preapproved. In most cases, it is preferred that a foodborne pathogen has been detected in clinical specimens before food items are considered for testing. However, decisions are made on a case-by-case basis. Results of food analysis will be reported to the Division of Disease Control and the local public health unit responsible for submission. Samples can be delivered to the Division of Laboratory Services or shipped via courier or postal service.

Chain of Custody

Chain of custody establishes how environmental samples are collected, shipped and received by the Division of Laboratory Services. These procedures ensure that samples collected during an epidemiological investigation are valid, maintained under proper control and their handling is documented so that any analytical results are viewed as reliable during any legal proceedings that may result from the investigation. Chain of custody procedures begin with sample collection and follow the sample through until its destruction by the laboratory.

After food samples are collected, a chain of custody form should be initiated (Appendix E). The chain of custody form should indicate when, where and from whom the sample was obtained. A description of the sample container and transportation methods of the sample also is included on the chain of custody form. Signatures and dates are required from all people who had custody of the sample during transfers to the laboratory.

Method for Collecting Food Samples

The value of laboratory results in microbiology depends on the quality of the samples submitted. Suspected foods should be collected as early in the investigation as possible. Food samples must be collected using aseptic techniques and appropriate containers (Table 1). Samples must be refrigerated during storage and transport and must arrive at the Division of Laboratory Services within three days of collection. Samples collected frozen should be stored and transported frozen on dry ice.

The following list describes the steps that should be taken when collecting food samples:

1. Whenever possible, food samples should be submitted in the original container as contamination of a sample may occur during manipulation.
2. If the food is a solid food item and shipping in the original container is not feasible, a representative sample should be taken. Take a sample from the geometric center, and also take samples from several other locations in the food item.
3. If the food item is liquid and shipping in the original container is not feasible, stir or shake the liquid food item and pour or ladle the sample into a sterile leak-proof container.
4. Samples collected that are not in their original container should be collected using sterile collection implements and sterile collection containers that are leak-proof.
5. Collect an adequate amount of the food sample — a minimum of 4 to 6 ounces or 100 grams (1/4 pound), if possible.
6. Fill containers no more than $\frac{3}{4}$ full and use adhesive tape to seal containers.
7. Keep food cold by placing in styrofoam coolers with ice packs.
8. Clearly document how the product was handled and who handled it after the sample is taken.

Labeling Food Samples

Information about the food samples should be properly documented, including the following:

- Name and type of product
- Brand of product
- Product manufacturer and code or lot number
- Inspector name
- Date, time, and place of collection
- Establishment name
- Contact person

Recommended List of Sampling Equipment

- Sterile sample containers
 - o Plastic bags (Whirl-Pak)
 - o Screw-capped jars or tubes
- Sterile individually-wrapped sample collection implements
 - o Spoons
 - o Knives/Scalpels
 - o Spatulas
- Supporting equipment
 - o Individually-wrapped disposable gloves
- Sterilizing and sanitizing agents
 - o Alcohol swabs
- Refrigerants
 - o Ice pack
 - o Thermometer
 - o Insulated container (Styrofoam cooler)

Table 1. Sample Collection and Shipping of Implicated Product*.

Product	Collection	Packing and Shipping
Solid Food	Aseptically collect at least 200 g of sample and transfer to a sterile container. Refrigerate sample.	Label container and pack refrigerant around. Take sample to lab or ship by most rapid means.
Liquid food or beverage	Stir or shake. Pour or ladle with sterile instrument at least 200 ml into sterile container. Refrigerate sample.	Label container and pack refrigerant around. Take sample to lab or ship by most rapid means.
Raw meat or poultry	Aseptically cut portion of meat or skin from different portions of carcass or cut of meat. Put at least 200 g of sample in sterile container.	Label container and pack refrigerant around. Take sample to lab or ship by most rapid means.
Frozen Food	Keep frozen. Ship to lab without thawing or opening.	Use dry ice for shipping. If driving to lab, keep on ice to prevent thawing.
Dry or dehydrated food	Aseptically scoop 200 g of food into a sterile container.	Ship at ambient temperature in a tightly sealed container.
Environmental swab	Moisten sterile swab or gauze with sterile water. Swab environmental surface and place swab/gauze in transport media.	Label and ship at ambient temperature.
Water	Take samples in sterile container, preferably treated with sodium thiosulfate. Most public water systems have these containers. Collect at least 100 ml (4 oz).	Label and ship at ambient temperature.
Stool	Collect in sterile container and transfer to transport media when appropriate.	Label and ship at ambient temperature.
Urine	Collect in sterile container.	Label and ship at ambient temperature.
Serum	Collect in clean or sterile tube. (2 ml minimum)	Label and ship at ambient temperature.
Vomit	Collect in sterile container.	Label and ship at ambient temperature.

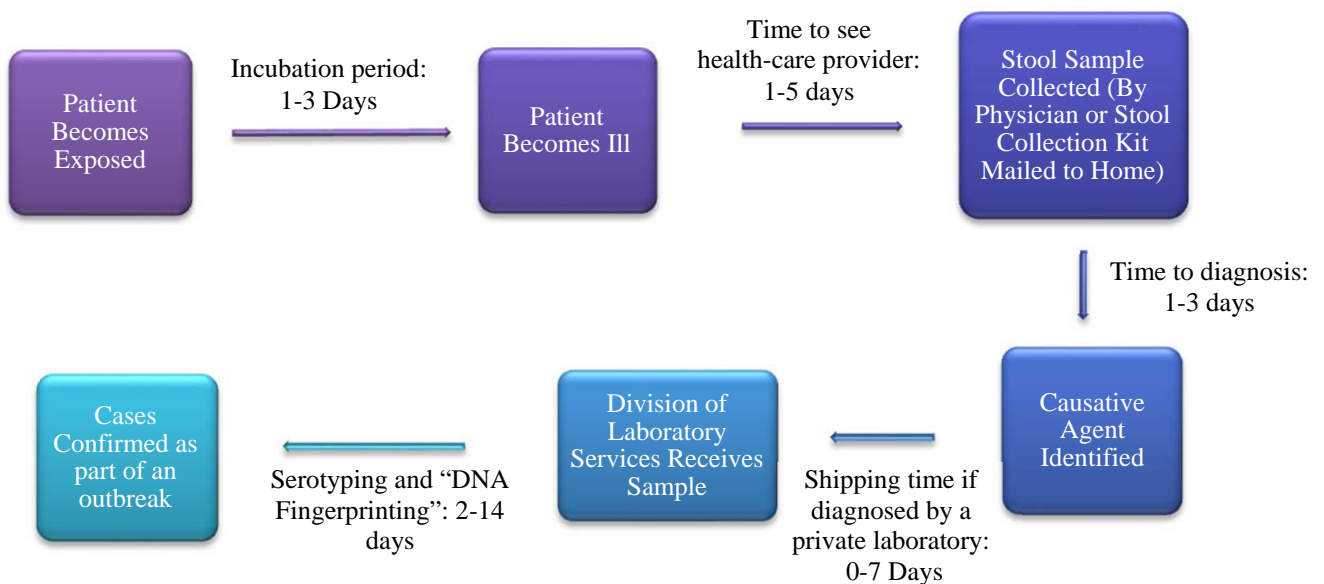
*Contact the Division of Laboratory Services for additional collection and shipping instructions.

Clinical Specimen Testing and Collection

One of the most important factors in the identification of etiologic agents responsible for foodborne disease outbreaks is the collection of clinical specimens as early in the course of the investigation as possible. Most foodborne infections are diagnosed through the identification of the pathogen in stool collected from infected people. Vomitus also has been used to detect certain organisms and confirm the etiology. Serology and blood cultures are recommended for the laboratory diagnosis of systemic infections.

The Division of Laboratory Services will perform laboratory analysis on clinical specimens from public and private health-care providers as well as specimens submitted through the Division of Disease Control using self-collected stool kits. Clinical specimens undergo several laboratory analyses to determine the diagnosis. A pure culture, or isolate, must first be identified from a clinical specimen. Appendix F provides a list of reportable conditions in North Dakota and indicates when an isolate is required to be sent to the Division of Laboratory Services for further confirmatory testing. When indicated, isolates are then serotyped and DNA fingerprinted. Serotyping and DNA fingerprinting are laboratory techniques used to characterize bacteria. The laboratory technique used for DNA fingerprinting is called pulse field gel electrophoresis (PFGE); hence, DNA fingerprints are often referred to as PFGE patterns. A national database called PulseNet compares isolates and identifies matches both statewide and nationwide. Cases that have matching serotypes and PFGE patterns are reported to the Division of Disease Control.

The following timeline is an example of the time required to complete a laboratory investigation during a foodborne outbreak. Total time from exposure ranges from five to 32 days.



Appendices

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Appendix A

Incubation, Infectious Periods and Exclusion Criteria of Enteric Pathogens*

Enteric Pathogen	Incubation ¹	Infectious Period ¹	Day Care Exclusion ²	Food ³ Employment Exclusion ¹	Health-Care ⁴ Employment Exclusion ¹
Hepatitis A	15 - 50 days	<ul style="list-style-type: none"> ● Prior to symptom onset until one week after jaundice onset ● Few cases have prolonged shedding up to 6 months 	Exclude for one week after the onset of illness.	Exclude if jaundiced within 7 calendar days or diagnosed with Hepatitis A within 14 days of illness onset	Restrict from patient care areas or food handling. Return to regular duties 1 week after onset of illness.
Norovirus	12 - 48 hours	<ul style="list-style-type: none"> ● Often 5- 7 days ● Can be as long as 3 weeks 	Exclude until 48 hours after symptoms have resolved.	Exclude until 48 hours after symptoms have resolved.	Exclude until 48 hours after symptoms have resolved.
Salmonella (Non-Typhi)	6 - 72 hours	<ul style="list-style-type: none"> ● Possible during entire period of infection ● Several days to weeks ● Carrier state for months is possible 	Exclude until asymptomatic	Exclude until asymptomatic and 2 consecutive negative stool specimens collected 24 hours apart and 48 hours after completion of antibiotics	Exclude until asymptomatic and 2 consecutive negative stool specimens collected 24 hours apart and 48 hours after completion of antibiotics
Shiga Toxin Producing E. coli, including O157:H7	2 - 10 days	<ul style="list-style-type: none"> ● Possible during the entire period of infection ● Typically 1 week but can be as long as 3 weeks 	Exclude until asymptomatic and 2 consecutive negative stool specimens collected 24 hours apart and 48 hours after completion of antibiotics	Exclude until asymptomatic and 2 consecutive negative stool specimens collected 24 hours apart and 48 hours after completion of antibiotics	Exclude until asymptomatic and 2 consecutive negative stool specimens collected 24 hours apart and 48 hours after completion of antibiotics
Shigella	12 - 96 hours	<ul style="list-style-type: none"> ● Possible for 4 weeks after illness ● Appropriate antibiotic treatment can reduce carriage to a few days 	Exclude until asymptomatic and 2 consecutive negative stool specimens collected 24 hours apart and 48 hours after completion of antibiotics	Exclude until asymptomatic and 2 consecutive negative stool specimens collected 24 hours apart and 48 hours after completion of antibiotics	Exclude until asymptomatic and 2 consecutive negative stool specimens collected 24 hours apart and 48 hours after completion of antibiotics
Typhoid Fever	3 - 60 days	<ul style="list-style-type: none"> ● Possible during entire period of infection ● Several days to weeks ● Carrier state for 3 months is possible 	Exclude until asymptomatic and 3 consecutive negative stool specimens collected 24 hours apart and 48 hours after completion of antibiotics	Exclude until asymptomatic and 3 consecutive negative stool specimens collected 24 hours apart and 48 hours after completion of antibiotics	Exclude until asymptomatic and 3 consecutive negative stool specimens collected 24 hours apart and 48 hours after completion of antibiotics

¹*Control of Communicable Disease Manual*, 19th Edition-2008, Heymann, David, MD ed.

²*Red Book 2009*, 28th ed, American Academy of Pediatrics.

³Exclusion recommendations only. Employees should refer to facility policy and NDCC 33-33-04-28-28.8 regarding exclusion and restriction requirements.

⁴Exclusion recommendations only. Health-care employees should refer to facility policy regarding exclusion and restriction requirements

Foodborne-Illness Complaint Form

Interviewer _____ Date: _____

Patient's Name (last, first): _____ DOB: ____ / ____ / ____
 Parent's Name (if child): _____
 Address: _____ phone: (____) _____ - _____

 Name and Address of employer, daycare or school:

How many were ill? _____ out of _____

Symptom History

Nausea	Y	N	Chills	Y	N	What was first symptom? Date of onset: (mo/day/yr) ____ / ____ / ____ Time of onset: (military) _____ Date of onset of diarrhea: ____ / ____ / ____ Time of onset of diarrhea: _____ Duration of diarrhea: _____ Date of Recovery: ____ / ____ / ____ Time of Recovery: _____
Vomiting	Y	N	Headache	Y	N	
Diarrhea	Y	N	Backache	Y	N	
Stools/24 hr _____			Muscle Aches	Y	N	
Blood in Stool	Y	N	Fatigue	Y	N	
Cramps	Y	N	Other _____			
Constipation	Y	N	_____			
Fever	Y	N	temp _____			

Comments:
 Physician: _____ Hospitalized: _____

Suspected Food (s): _____

Source _____

Brand ID _____ Lot #: _____

Nature of Complaint:

- | | |
|---|---|
| <input type="checkbox"/> Illness | <input type="checkbox"/> Contaminated, Spoiled Food |
| <input type="checkbox"/> Unsanitary Establishment | <input type="checkbox"/> Other _____ |

Did you attend any large gatherings the week before your illness (wedding receptions, showers, parties, fairs, festivals, etc.)? Yes No if yes, When? ____ / ____ / ____ Where? _____

Food History

Date/day prior	Meal	Ate at home	Ate outside of home	Outside location	Foods eaten
To onset ____/____/____ time_____	Breakfast	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
time_____	Lunch	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
time_____	Dinner	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
time_____	Other	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
2 days prior ____/____/____					
time_____	Breakfast	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
time_____	Lunch	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
time_____	Dinner	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
time_____	Other	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
3 days prior ____/____/____					
time_____	Breakfast	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
time_____	Lunch	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
time_____	Dinner	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
time_____	Other	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____

Did you eat at any restaurants during the seven days before your illness? Yes No

If yes, complete the information in the box below:

Restaurant Information

Name_____	date_____	Foods eaten_____
Address_____	time_____	_____
City_____		_____
Name_____	date_____	Foods eaten_____
Address_____	time_____	_____
City_____		_____
Name_____	date_____	Foods eaten_____
Address_____	time_____	_____
City_____		_____



FOOD-RELATED ALERT/COMPLAINT REPORT

North Dakota Department of Health
SFN 13984 (11-11)

						Complaint Number			
COMPLAINANT				RESPONSIBLE PARTY OR ESTABLISHMENT					
Name				Name					
Address				Address					
City		State	Zip Code	City		State	Zip Code		
Telephone Number		Received By: <input type="checkbox"/> Phone <input type="checkbox"/> Letter <input type="checkbox"/> Referral		Telephone Number			License Number		
Nature of Complaint <input type="checkbox"/> Illness <input type="checkbox"/> Contaminated, Adulterated, Spoiled Food <input type="checkbox"/> Unsanitary Establishment <input type="checkbox"/> Other (specify)			Complaint						
Received By		Date	Time	Referred To		Date	Time		
Was Anyone Ill? (1)(2) How Many?		Date Illness Began		Time	Symptoms				
Was Physician Consulted? If Yes, Name and Address of Physician						Telephone Number			
Was Anyone Hospitalized? If Yes, Name and Address of Hospital									
Suspected Foods(3) If Adulterant		Source		Brand ID		Lot Number			
Investigation Results									
Investigated By		Date		Time		Further Action			
Notified <input type="checkbox"/> Disease Control – 701.328.2378 <input type="checkbox"/> FDA – 612.334.4100 <input type="checkbox"/> USDA – 612.370.2400 <input type="checkbox"/> Other (Specify)				North Dakota Department of Health 600 East Boulevard Avenue, Dept 301 Bismarck, ND 58505-0200 701.328.1291					

Footnotes

- (1) If "Yes", professional staff member should obtain information about patient and record it on *FOODBORNE SURVEILLANCE FORM (SFN 7297)*.
- (2) Ask person to collect vomitus, stools and urine. The specimens that are collected are to be wrapped, labeled with identification, and refrigerated. Arrange for blood serum to be drawn.
- (3) Determine if the person has possession of uneaten portions or leftovers of the same servings of foods from which they had eaten during the 72 hours before onset of the illness. If so, such food should be wrapped, properly identified and refrigerated. Original containers or packages for the food should also be saved and held until the health official makes further arrangements.

Date Complaint Received: _____

Date of Investigation: _____

Investigator: _____

Agency: _____

Phone Number: _____



Foodborne Outbreak Environmental Investigation Report

Establishment:	
Address:	
City, State, Zip:	Phone Number:
Contact Person and Title:	
Implicated Food (s):	
Implicated Pathogen:	
Were any food employees ill* in the two weeks prior to the suspected event? Number Ill:	
Did any food employee become ill* after the suspect event?	
Food Samples Collected^ From: <ul style="list-style-type: none"> ○ Consumer ○ Food Establishment ○ Wholesale Manufacturer/Distributor 	
^Complete Chain of Custody for Samples Collected	

*ill: vomiting and/or diarrhea, abdominal cramps

Compliance Key: **Y**= In Compliance, **N**=Not in Compliance, **N/O**=Not Observed, **NA**=Not Applicable, **C**=Corrected On-Site During Investigation, **R**=Repeat Violation

Foodborne Illness Risk Factors and Interventions

Demonstration of Knowledge	Y	N	N/O	N/A	C	R
1. Certification by accredited program, compliance with code or correct responses. Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Employee Health	Y	N	N/O	N/A	C	R
2. Management awareness; policy present.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Proper use of reporting, restriction and exclusion. Comments:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Good Hygienic Practices	Y	N	O	NA	C	R
4. Proper eating, tasting, drinking or tobacco use.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. No discharge for eyes, nose and mouth.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Comments:</u>						

Preventing Contamination by Hands	Y	N	O	NA	C	R
6. Hands clean and properly washed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. No bare hand contact with ready-to-eat foods or approved alternate method properly followed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Adequate hand washing facilities supplied and accessible.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Comments:</u>						

Approved Source	Y	N	O	NA	C	R
9. Food obtained from approved source.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Food received at proper temperature.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Food in good condition, safe and unadulterated.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Required records available: shellstock tags, parasite destruction.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Comments:</u>						

Protection from Contamination	Y	N	O	NA	C	R
13. Food separated and protected.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Food-contact surfaces: cleaned and sanitized.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Proper disposition of returned, previously served, reconditioned and unsafe food.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Comments:</u>						

Compliance Key: **Y**= In Compliance, **N**=Not in Compliance, **N/O**=Not Observed, **N/A**=Not Applicable, **C**=Corrected On-Site During Investigation, **R**=Repeat Violation

Potentially Hazardous Food Time/Temperature	Y	N	N/O	N/A	C	R
16. Proper cooking time and temperature.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Proper reheating procedures for hot holding.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Proper cooking time and temperatures.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Proper hot holding temperatures.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Proper cold holding temperatures.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Proper date marking and disposition.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Time as a public health control: procedures and record.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Comments:</u>						

Consumer Advisory	Y	N	N/O	N/A	C	R
23. Consumer advisory provided for raw or undercooked foods.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Comments:</u>						

Highly Susceptible Populations	Y	N	N/O	N/A	C	R
24. Pasteurized foods used; prohibited foods not offered.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Comments:</u>						

Chemical	Y	N	N/O	N/A	C	R
25. Food additives: approved and properly used.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Toxic substances properly identified, stored and used.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Comments:</u>						

Conformance with Approved Procedures	Y	N	N/O	N/A	C	R
27. Compliance with variance, specialized process and HACCP plan.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Comments:</u>						

Compliance Key: **Y**= In Compliance, **N**=Not in Compliance, **N/O**=Not Observed, **N/A**=Not Applicable, **C**=Corrected On-Site During Investigation, **R**=Repeat Violation

Please check the type(s) of control measures or corrective actions that were taken in response to this complaint.

- Food Employee/Food Handling Procedures & Policies Modified
- Embargo
- Voluntary Disposal
- Food Employee Exclusion
- Emergency Suspension or Closure
- Food Employee/PIC Training
- Press Release/News Alert
- Equipment/Physical & Sanitary Facilities Modified/Upgraded
- None
- Other: _____

Additional Comments: _____

Appendix E



CHAIN OF CUSTODY
NORTH DAKOTA DEPARTMENT OF HEALTH

TO BE COMPLETED BY COLLECTION SITE PERSONNEL

Lab Number:	Collected By:
Facility /Event under investigation:	
Date / Time of sample collection: ____/____/____ : ____	Temperature/Conditions of sample:
Description of sample:	
Collection location contact person:	Contact Person Telephone Number:
Lab testing requested if known:	

Sample Transfer Register- to be completed by each sample custodian

Date	Time (24-hour)	Relinquished by (signature)	Received by (signature)

FOR DEPARTMENT OF HEALTH LABORATORY USE ONLY:

Temp received:	Delivery Method:	Lab Storage Location:
----------------	------------------	-----------------------

Laboratory Sample Transfer Register- to be completed by each sample custodian

Date	Time (24-hour)	Relinquished by (signature)	Received by (signature)

Test Results:

Date Tested	Test Performed	Test Result	Date Reported	By

Disposed of By:	Method of Disposal:	Date:
-----------------	---------------------	-------

Appendix F



North Dakota Department of Health

Mandatory Reportable Conditions

~Report within 7 days unless otherwise specified~

<ul style="list-style-type: none"> ▪ AIDS ☞ Anthrax ☞ ▪ Arboviral Infection (specify etiology) ☞ Botulism ☞ ☞ Brucellosis ☞ ▪ Campylobacteriosis ☞ ▪ Carbapenem-resistant <i>Enterobacteriaceae</i> (CRE) ☞ ▪ Cancer ☞+ ▪ CD4 Test Results (any CD4 value) ▪ Chickenpox (varicella) ▪ Chlamydial infection ▪ Cholera ☞ ☞ <i>Clostridium perfringens</i> intoxication ☞ ☞ Coccidiomycosis ☞ ▪ Creutzfeldt-Jakob disease ▪ Cryptosporidiosis ▪ Diphtheria ☞ ▪ <i>E. coli</i> (shiga-toxin producing strains) ☞ ▪ Enterococcus, Vancomycin-resistant (VRE) ☞ ▪ Foodborne/waterborne outbreaks ☞ ▪ Giardiasis ☞ Glanders ☞ ▪ Gonorrhea ▪ <i>Haemophilus influenzae</i> (invasive) ☞ ▪ Hantavirus ☞ ▪ Hemolytic uremic syndrome ☞ ▪ Hepatitis A ☞ ▪ Hepatitis B ▪ Hepatitis C ▪ HIV infection(confirmed and all HIV positive rapid screens) ☞ ▪ Influenza ▪ <i>Klebsiella pneumoniae</i> Carbapenemase (KPC) - producers ☞ ☞ Laboratory incidences with possible release of category A agents or novel influenza virus ☞ ▪ Lead level $\geq 10\mu\text{g/dL}$ ▪ Legionellosis ▪ Listeriosis ☞ ▪ Lyme disease ▪ Malaria ☞ ▪ Measles (rubeola) ☞ ☞ Melioidosis ☞ ▪ Meningitis (bacterial – specify etiology) ☞ 	<ul style="list-style-type: none"> ▪ Meningococcal disease (invasive) ☞ ▪ Mumps ☞ ☞ Nipah virus infections ☞ ▪ Nosocomial outbreaks in institutions ▪ Pertussis ☞ ☞ Plague ☞ ▪ Poliomyelitis ☞ ▪ Pregnancy in person infected with perinatally transmissible disease (such as hepatitis B and HIV) ▪ Psittacosis ☞ Q fever ☞ ▪ Rabies <ul style="list-style-type: none"> ▪ Animal ▪ Human ☞ ☞ Rocky Mountain spotted fever ▪ Rubella ☞ ▪ Salmonellosis ☞ ▪ Scabies outbreaks in institutions ▪ Severe Acute Respiratory Syndrome (SARS) ☞ ▪ Shigellosis ☞ ☞ Smallpox ☞ ▪ <i>Staphylococcus aureus</i>: <ul style="list-style-type: none"> ▪ Methicillin-resistant (MRSA) – exclude urine; invasive sites only ☞ ▪ Vancomycin-resistant and intermediate resistant (VRSA and VISA) – any site ☞ ☞ <i>Staphylococcus enterotoxin B</i> intoxication ☞ ▪ Streptococcal infection (invasive) ☞ ▪ Syphilis ▪ Tetanus ▪ Tickborne diseases (any tickborne encephalitis or tickborne hemorrhagic fevers ☞☞) ▪ Toxic Shock Syndrome ☞ ▪ Trichinosis ▪ Tuberculosis ☞ ☞ Tularemia ☞ ▪ Tumors of the central nervous system + ▪ Typhoid fever ☞ ▪ Unexplained critical illness/death in otherwise healthy person ☞ ▪ Unusual disease clusters ☞ ▪ Vibriosis ☞ ☞ Viral hemorrhagic fevers ☞ ☞ Weapons of Mass Destruction suspected event ☞ <ul style="list-style-type: none"> ▪ Yellow fever ☞
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☞ Report Immediately: 1.800.472.2180 or 701.328.2378

☞ Send isolate or sample to NDPHL ☞ This is a Select Agent when confirmed. Notify NDPHL 701-328-6272. Report any possible laboratory exposures.
 ☞ See website for complete definition www.ndhealth.gov/Disease/Rules ☞ Submit report to the North Dakota Cancer Registry. Call 800-280-5512 for assistance.

North Dakota Administrative Code 33-06-01 Statutory authority NDCC 23-07-01 Updated 01-01-2011

Report can be found online at www.ndhealth.gov/Disease/Documents/ReportableConditions.pdf.

Appendix G

Glossary of Terms*

Ambient Temperature: The temperature of the room. Normal room temperatures can vary from 68 to 77 degrees Fahrenheit (20 to 25 degrees Celsius).

Asymptomatic: Showing no symptoms of illness.

Attack rate: The occurrence of disease observed among a defined population over a limited period of time.

Bacteria: A one-celled living microorganism that can cause foodborne infections and intoxications.

Bare hand contact: Having bare hands in direct contact with prepared or ready-to-eat food items.

Case definition: A set of criteria for determining who should be classified as a case. The definition is comprised of clinical information and should include information related to time, place and person.

Case: A person with the particular disease, health disorder or condition under investigation.

Case-control study: An observed analytical study in which individuals are included into the study dependent upon the presence or absence of illness or disease.

Cohort study: An observed analytical study involving a group of individuals with a common exposure.

Confidence intervals: An estimated range of values within which the true relative risk (RR) or odds ratio (OR) is likely to fall.

Confirmed foodborne disease outbreak: A foodborne disease outbreak in which laboratory analysis of appropriate specimens confirms a causative agent and epidemiologic analysis implicates the food as the source of the illness.

Consumer: A person, who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale.

Control: In a case-control study, a person without illness or disease.

Control measure: Any action or activity that can be used to prevent, eliminate or reduce a significant hazard.

Control point: Any step at which biological, chemical or physical factors can be controlled.

Corrective action: Procedures that are initiated when a deviation or problem in the flow of food preparation is identified.

Critical limit: The maximum and/or minimum value at which a biological, chemical or physical hazard must be controlled at a given critical control point to ensure food safety.

Critical control point (CCP): A step at which control can be applied to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Cross-contamination: The transfer of pathogens from one food item to another food item during food storage or preparation through cooking equipment, surfaces, utensils and the hands of food handlers.

Epidemic curve (epi curve): A histogram or graph that provides a visual depiction of the outbreak over time.

Epidemiology: The study of the distribution and determinants of health-related states or events within a specific population, and the application of this study to control health problems.

Fecal-oral route: The ingestion of stool from an infected person or animal through food, liquids or direct contact.

Food establishment: An operation that stores, prepares, packages, serves, vends or otherwise provides food for human consumption. Food establishments include a restaurant, satellite or catered feeding location, catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people, market, vending location, conveyance used to transport people, institution or food bank.

Food handler: A person who directly handles or prepares food.

Foodborne disease outbreak: (1) Two or more individuals who experience a similar illness after eating a common food or different food from a common place or (2) an unexplained, unexpected increase of a similar illness, and food is a likely source.

Foodborne illness: A disease acquired through eating or drinking contaminated food or liquids.

Foodborne intoxication: A disease caused by consuming food or liquids contaminated with toxins.

Hazard: A biological, chemical or physical agent that may cause foodborne illness.

Hazard Analysis Critical Control Point (HACCP): A science-based, systematic approach of identifying, evaluating and controlling food safety hazards.

HACCP plan: Written documentation that delineates the formal procedures for following the HACCP principles developed by the national advisory committee on microbiological criteria for foods.

Highly susceptible population: A group of people who are more likely than other populations to experience foodborne disease because they are immunocompromised or older adults and in a facility that provides health care or assisted living services, such as a hospital or nursing home; or preschool age children in a facility that provides custodial care, such as a day care center.

Hypothesis: An educated guess based on observations.

Incubation period: The interval from the time an individual is infected to the time when symptoms first appear.

Odds ratio (OR): Odds of having the exposure given the disease.

Onset: The date and time when clinical signs or symptoms first appear.

Parasite: A single or multi-celled organism that can cause foodborne infections.

Pathogen: A disease-causing organism.

Potentially Hazardous Food (PHF): Any food or food ingredient (natural or synthetic) that is capable of supporting rapid growth of microorganisms under certain temperatures. Examples include cooked or raw animal products, heat treated vegetables and starches, sprouts and melons.

Pulsed-field gel electrophoresis (PFGE): A laboratory method used to separate bacterial isolates into genetic fragments, thus forming a unique “DNA fingerprint.”

***p*-value:** The probability that a difference observed could have occurred by chance alone.

Questionnaire: A predetermined set of questions used to collect data. The main components include identifying information, demographics, clinical information, exposure or risk factor information, and knowledge of illness in others.

Ready-to-eat food: A food item that can be consumed without further preparation. Examples include raw vegetables and fruits, deli meats, bread and ice.

Relative risk or relative risk ratio (RR): The ratio of the attack rate for ill people who were exposed and the attack rate for ill people who were not exposed.

Reportable Condition: A disease that is required by law to be reported to the public health authority.

Risk factor: An attribute or exposure that is associated with an increased occurrence of disease or other health-related event or condition.

Stool: Feces.

Toxin: A poison produced or released by certain bacteria that can cause foodborne intoxications.

Traceback: The method of tracing implicated food items backwards through the production and distribution chain to identify the contaminated item and remove it from the food market.

Virus: A minute organism that can cause foodborne infections.

*Sources of Definitions: Last, J.M. ed. *A Dictionary of Epidemiology*, 4th ed. New York: Oxford University Press, 2001 and the North Dakota Requirements for Food and Beverage Establishments.

Appendix H

Contact Information

Division of Disease Control

2635 East Main Avenue

Bismarck, ND 58506

Ph: 701.328.2378

Fax: 701.328.2499

ND Toll Free: 800.472.2180

www.ndhealth.gov/disease

Division of Laboratory Services

2635 East Main Avenue

P.O. Box 5520

Bismarck, ND 58506-5520

Ph: 701.328.6272

Fax: 701.328.6280

www.ndhealth.gov/microlab

Division of Food and Lodging

600 E. Boulevard Avenue, Dept. 301

Bismarck, ND 58505

Ph: 701.328.1291

Fax: 701.328.1890

www.ndhealth.gov/FoodLodging

Division of Health Facilities

600 East Boulevard Ave., Dept. 301

Bismarck, ND 58505-0200

Ph: 701.328.2352

Fax: 701.328.1890

www.ndhealth.gov/HF

Local Public Health Units and Tribal Health

www.ndhealth.gov/localhd/

State Meat/Poultry/Dairy Inspection Programs

N.D. Department of Agriculture

600 E. Boulevard Ave., Dept. 602

Bismarck, ND 58505-0020

Ph: 701.328.2231

ND Toll Free: 800.242.7535

Fax: 701.328.4567

www.nd.gov/ndda



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