Environmental Health Foodborne Illness Investigation & Response Protocol

Purpose

This protocol outlines the Missoula City-County Health Department's response to outbreaks or complaints of food and waterborne illness, food-related injury, and intentional food or water contamination.

Introduction

There are many pathogens known to cause foodborne illness. The top five pathogens associated with food in the United States are Norovirus, *Salmonella* spp., *Clostridium perfringens, Campylobacter*, and *Staphylococcus aureus.* There are other pathogens like *Clostridium botulinum, Listeria,* Shiga toxin producing *Escherichia coli* (*E. coli*) O157, and *Vibrio* that don't cause as many illnesses but are more likely to lead to hospitalization (*CDC Estimates of Foodborne Illness in the United States*, 2018).

Contaminated drinking water and recreational waters cause waterborne illnesses. Common waterborne pathogens include *Giardia* and *Cryptosporidium.*

Foodborne Illness Complaints

The health department receives foodborne illness and injury complaints through a few different sources including:

- Confirmed illnesses from a medical provider or lab;
- Complaints received by Environmental Health (Env Health) by phone, email, and online report submissions;
- The state complaint system called WuFoo;
- Social media; and,
- The medical community reporting an unusually high incidence of GI illnesses via the Infection Disease (ID) nurse.

Initial Contact

When a person contacts Env Health with a foodborne illness complaint, the Environmental Health Program Support Specialist (PSS) will check to see if the Environmental Foodborne Illness Lead (Lead) is available to take the call. If not, the PSS must collect basic information from the caller and generate a foodborne illness (FBI) complaint in the licensed establishment database, known as Paragon.

The PSS collects basic contact information including:

1. Name;
2. Contact phone number (daytime);
3. Good time to call (note if the sanitarian needs to call outside of business hours); and,
4. Email address, if they have one.

Often people will want to tell the person who answers the phone the food that they suspect made them sick and where they got it. While it's fine to collect that information, do not encourage the caller to provide more details as the Lead will call and ask for specifics. Callers get frustrated during the follow-up call if they feel that they have already provided the information requested. However, it is a good idea to suggest that the caller start thinking about the foods and beverages that they consumed in the 72-hours before their symptoms started.

After receiving a complaint of illness, the PSS will contact the Lead, even if they are in the field so that that information gathering can happen as soon as possible. If the Lead is gone, the complaint should go to the backup FBI sanitarian.

Complaint Data Entry

Currently, all foodborne illnesses are entered in Paragon under "Foodborne Illness Complaints" so that they are all logged in one area regardless of an association with a food establishment. The PSS must save the complaint with "inspection required" (default field) selected so that the Lead gets an email letting them know there was a foodborne illness complaint. After entering the complaint, the PSS will then create an electronic note in the establishment record with the title "FBI Complaint Received {Date}" so that we can link complaints to establishments without disclosing HIPAA protected information or altering reporting methods.

Investigation Procedures

All complaints will go to the Lead. The Lead will typically make the initial contact with the complainant; however, if there are many complaints or an outbreak, the Lead may request other inspecting sanitarians to help make calls to facilitate the process.

Foodborne illness complaints must be treated as a priority and responded to within 24 hours or less.

Investigations typically consist of two parts:

1. **The Interview:** The Lead will contact the complainant to gather information regarding recent exposure history and obtain a food history using a standardized questionnaire (see 2016 FBI Questionnaire).

   It is important to collect as much information as possible during the interview, even if the information seems insignificant as it may become important later in the investigation.

   The information needed includes:

   - A detailed account of their complaint. Try to ask questions as they present themselves during this process (other activities that day; daycare age children (diapers); any sick family members; travel; occupation (to see if there is something that may expose them to GI illnesses such as a farmer, lab tech, garbage collector, custodian, etc.);
   - If they received any medical attention for their illness including testing;
   - Whether they work in a sensitive occupation (for reasons of exclusion: food handler; daycare worker; nurse/doc; etc.);

- Depending on the time of year, ask about gatherings that may expose them to illness (holidays, BBQs, weddings; graduation; etc.) Discuss these activities to get a better food history as it can be easier for people to remember what they ate when discussing what they were doing;
- Exposure to others who have had GI illnesses, sick animals, reptiles/snakes/lizards;
- Where they routinely shop for groceries to see if there are common sources or any foods associated with current recalls or outbreaks; and,
- The foods that they ate in a time frame based on the incubation period for the organism. If the organism is unknown, a 72-hour food history is a great place to start. *

If the person is not able to be reached by phone or email, the Lead will leave a message indicating that they will try to complete the investigation as best they can with the limited information collected.

* Occasionally, the 72-hour food history is not necessary. For instance, if several people ate together at one meal, all got ill in the same timeframe with similar symptoms, and they do not have day-to-day contact with each other, then efforts can be concentrated on the suspect meal.

2. **The Inspection:** The Lead will determine if an inspection is warranted and then connect with the sanitarian assigned to the suspected establishment. The assigned inspector may help with the investigation if time allows. Two inspectors work better for the larger or more complex establishments. If the assigned inspector does not do the onsite investigation, the Lead will keep the inspector updated. The inspection may serve as a routine inspection but must focus on the factors that could have led to the illness/symptoms under investigation.

   When inspecting because of suspected foodborne illness, it is important to do the following in addition to a risk-based inspection:
   - Interview cook staff about the details of preparing the foods in question;
   - Look at records of staff illnesses for the two weeks before the exposure;
   - Ask about any unique issues during the time of exposure that may have contributed to an illness (refrigeration not holding temperature; power failure; etc.);
   - Ask about changes in food sources, staff, or management during the time in question; and,
   - Ask whether the establishment has received complaints of illness from patrons.

   When the facility inspector can assist, it is helpful to have the facility inspector look for the facility and operational issues while the Lead talks to the cook and managers about the items above.

   The facility and operational aspects of the inspection include:

   - Observing staff practices for handwashing, hygiene, food handling, health;

- Observing time and temperature controls;
- Observing cleaning and sanitizing practices;
- Evaluating storage practices; and,
- Checking sources.

The inspector should also ask how the suspected meal is made and pay attention to the items above concerning the suspected meal. If food associated with the suspect meal remains, the inspector should request that the establishment hold it separately and not serve it. The food should be labeled, "do not use/do not discard" in case testing is needed. The inspector must document information about the product, including how much food was made initially, how much remains, and the actions taken by the facility to restrict the product from service. Do not freeze food set aside for potential testing. Ask the establishment to keep it refrigerated.

Important Considerations

Many incidents of foodborne illness are sporadic and isolated occurrences, which constitute normal and expected background levels of disease in a community. Some calls have more to do with complaining about an establishment than contracting an illness.

Even if an establishment is not the cause of the foodborne illness under investigation, the process provides a teachable moment for food safety practices that they need to improve.

It is important not to automatically blame an establishment for a foodborne illness, especially when there is no lab test confirming the diagnosis (there are often a lot of unknowns in foodborne illness investigations). Instead, let them know of the complaint, let them know it's possible that they were the source, and concentrate on correcting poor food safety practices.

Coordination with Infectious Disease Staff

Reportable diseases come through the ID nursing staff. They will contact the Lead when they learn of a confirmed illness, which may have a link to food or water, with or without a link to a food establishment. The Lead will contact the ID nurse if Env Health receives complaints that may indicate a potential outbreak in the community that hasn't gone through the reporting channels. When complaints come through the ID nursing staff to the Lead, the Lead must log the complaint in Paragon, and if there is a suspected establishment, create an electronic sticky note in the establishment file.

Labs and health care providers are required to tell the health department about cases of reportable communicable diseases. When the ID nurse gets a lab result or a healthcare provider report, the nurse follows up with the patient following the Infectious Disease Case Interview. When licensed establishments are involved, the Lead will evaluate if an inspection is warranted. The Lead will coordinate with and keep the ID nurse updated with Environmental Health inspection findings.

If an outbreak is suspected, the Env Health and ID teams will meet with supervisors to discuss the situation and may use emergency response plans and ICS for the remainder of the response.

Information is tabulated to see if there are any commonalities; and then, the team formulates an action plan. The Montana Department of Public Health and Human Services (MT DPHHS) is also notified and updated.

Additionally, the ID team meets monthly to discuss recent trends and issues seen by the ID nurses and Env Health staff.

Outbreaks

Distinguishing between foodborne illness incidents and foodborne illness outbreaks is important.

- An outbreak is the occurrence of two or more unrelated cases (i.e., cases do not live together; do not have any routine contact with each other; separate and isolated; etc.)

- In some situations, a single case may constitute an outbreak. Example include a single, confirmed case of botulism.

In the event of an illness outbreak, the ID team which includes Env Health, ID nurses and staff, all respective managers, and the Health Officer will meet throughout the investigation to discuss what may be happening and how best to limit further spread. The Env Health team will still follow the investigation procedures above. Depending on the findings of testing, inspections, or statistical analysis, Env Health may need to take further action such as Notices of Violation, temporary closure, training, or other actions to be determined in conjunction with the management team.

While the goal is to determine a specific source or food establishment, sometimes no clear source or link may be identified.

At the end of an outbreak investigation, all departments involved will generate an After Action Report (AAR) to discuss what went well with the investigation and what they could improve upon during future outbreak investigations. These reports are made available to MT DPHHS who may report findings to the CDC.

Jurisdictional Concerns

If MCCHD receives a complaint about a packaged commercially manufactured item made outside of our jurisdiction, the Lead completes a Consumer Complaint form. A Consumer Complaint form collects the following information:

- Product information such as brand, size, lot, manufacturing information, best-by date, etc.;
- Where they purchased the product;
- When the customer noticed the adulteration; and,
- If illness or injury resulted.

When possible, we will collect the packaging to confirm specific product details. When that is not possible, we will gather information through pictures of the product provided by the consumer.

We submit the completed Consumer Complaint form to MT DPHHS, Food and Consumer Safety Section (FCSS), who will submit it to the FDA. The FDA may contact the MCCHD for specifics about the product (again, having pictures or the packaging is helpful) and occasionally, FDA will inform us that they intend to contact the consumer for details.

If the product came from our jurisdiction, we would ask for the same information outlined in the Consumer Complaint form; however, we will do the investigation and may ask for the state's assistance.

Adulteration or Intentional Contamination Event
If we get a complaint regarding or suspect an intentional contamination event, we first need to determine who has jurisdiction over the product. If it is a packaged commercially made item, we follow the protocol above and depending, contact law enforcement. If the product came from our jurisdiction, we will investigate the complaint and call law enforcement.

If there is an adulterated product that can still go into commerce, we may need to embargo or seize the product. In this instance, an inspector would need to document in an order inspection report the amount of product held from commerce, and how they secured or disposed of the product.

Access to Information

It is uncommon to provide any information to the public about a foodborne illness complaint because of HIPAA. If information, such as a line list, is shared with people outside of the response team, information needs to be coded or redacted. We can only share number affected, sex, age, symptoms, and suspected foods.

Store HIPAA protected information in the Infectious Disease folder where access to general staff is restricted.

Reporting and Documentation

Maintaining documentation from the complaint through to the AAR is important. The following documents need to be created with the identified information:

- Complaint record: The complaint needs to be logged in Paragon even if it originated from WuFoo. The PSS must obtain as much contact information from the complainant as possible, and the Lead is responsible for logging the interview information. If an illness or outbreak is linked with an establishment, we need to link the complaint file with the establishment file via electronic sticky notes and the inspection documents.
- Inspection Reports: Inspectors need to log violations and note potential contributing factors in the Paragon inspection report. Document additional information obtained during the investigation that may not be a violation (e.g., source information, traceback info, policy issues, past employee illnesses). If the inspector chooses to use the routine inspection as the investigation inspection, they must note that the inspection is not only routine but is also in response to a foodborne illness investigation. The Lead must connect any inspection reports to the complaint in Paragon (e.g., "See routine inspection of restaurant A completed 01/01/2018).
- The ID team retains ID reports and medical information.

- The Lead will "close the loop" on cases reported via the WuFoo state system.
- The Lead or their designee will draft an AAR summarizing the investigation and findings with input from members of the investigation team. The Lead will forward the AAR to the state. The state lab will send reports and information to the CDC when appropriate.
- All complaints are tracked in the Env Health FBI tracking sheet in Excel by the Lead. Each complaint is logged individually using the information in the complaint (implicated food, establishment, suspected process); the information garnered during the investigation (likely food, establishment, process); whether the complaint was a part of an outbreak or the result of an intentional contamination event; as well other notable information associated with the complaint.

Laboratory Support

MT DPHHS provides laboratory and epidemiological support as per the Memorandum of Understanding in our cooperative agreement.

Traceback Procedures

Traceback procedures are difficult in a foodborne illness investigation because products and ingredients may originate from a common manufacturer/distributor and then repacked under various brand names or companies. Further, these repacks can be repacked several times further into distribution.

Traceback is vital for outbreaks where the investigator can compile food histories, activities, etc. from several cases to compare any common links. Traceback has been done on a local level when there have been nationwide illness outbreaks, and there are common foods to investigate. In the recent past, FDA and CDC have released statements when they suspect a certain source as the result of a nationwide outbreak even without laboratory evidence. For example, in several of the Romaine lettuce outbreaks, the FDA and CDC suspected that leafy greens caused the illnesses, but the source was hard to trace to a specific grower or field. Local sanitarians visited retail/wholesale outlets to determine what brands of leafy greens people purchased in the community. Any confirmed cases linked to the nationwide outbreak were interviewed in detail to determine where they routinely shopped; what kinds of lettuce products they ate; and, if they used whole heads, premade salad mixes, or ate processed foods (sandwiches, salads with eggs/meat/garnishes, meal to-go kits, etc.). In some cases, investigators went to the store with the complainant to have them physically identify the products they bought. When cases were not able to do that, the investigator went to the store where the case routinely shopped, took pictures and emailed them to the case for identification. Once the product was identified, we determined the distributor from the packaging and then contacted them to figure out the name of their suppliers or who was responsible for the co-pack or rebranding. We also found out which stores received products from a similar source, company, etc. by using the company's documents.

It is challenging to do traceback on nationwide and internationally distributed products. We may need assistance from the FDA or FSIS for larger-scale traceback.

If the traceback investigation can identify a common brand/distributor and the outlets that may carry the product(s), this information is shared with DPHHS to see if any of our partner counties

are showing similar trends. We did this during the salmonellosis outbreak associated with JBS ground beef purchased at Lucky's markets in Missoula and Billings. There were several cases of salmonellosis linked by laboratory analysis in the state. Investigators made calls to determine a common source of food. All shoppers indicated consuming products from Lucky's markets from either Missoula or Billings.

Further investigation was done at the stores to look at ground beef logs, the source of the pre-ground meat used for retail grind, etc. At that time, nothing implicated JBS; however, after CDC linked other cases nationwide, attention shifted to JBS, Lucky's supplier.

Key steps during traceback include:

- Finding commonalities in food histories or shotgun questionnaire data.
- Following-up with cases or restaurants to ensure that you have accurate product information including brand, size, UPC or item number, date or product code. If the product was purchased at retail, ensure that you get the name of the retailer (e.g., grocery store, c-store, farmer, market booth) from the case. If you are following up with a retail establishment regarding sources, obtain distributor/supplier information, and when possible, obtain invoices or packing slips. You may need to meet with cases at home or the grocery store and have them identify a product or have them send you pictures of the product packaging.
- Use the information obtained to follow the supply chain back as far as possible. For example, if you find out that Supplier 1 distributed the leafy greens to restaurant A and Supplier B distributed leafy greens to restaurant B, you will need to work through supplier 1 and 2 to identify their source for the product. If you do not find a commonality, you may need to go back yet another layer, and so on.
- If more than one county is involved in the traceback efforts, MT DPHHS or Department of Livestock may coordinate traceback efforts. If more than one state is involved, the FDA or FSIS will likely spearhead traceback and use us as a reference.

Our office shares traceback information with MT DPHHS and other counties agencies involved. The state will send information along to the FDA, FSIS, and CDC when necessary.

Recalls

We receive recall information in several different ways including local/national news, distributors or food retailers, the FDA website, DPHHS email notifications to state sanitarians, and public inquiries.

When MT DPHHS notifies us of a recall, they include an action level that indicates the type of response required. In many cases, the notification is informational to let us know there is a recall, but it requires no action because of the lack of information or an associated illness. In cases that do require action, a specific response is described such as contacting food outlets that may have the recalled product to remind them that they cannot sell the product. We will follow-up when the recall issue is significant, like botulism. In these cases, we will physically visit the local

outlets to ensure responsible disposition of the food item so people cannot salvage it. Sometimes we may collect the recalled food product so that we know its disposition.

Recalls by are routinely done for imminent health issues, like bacterial contamination of ready-to-eat food that can pose a risk to the general population. It is not typical that we would follow-up on an undeclared allergen or physical contamination that does not pose a health risk (cardboard bits in dry pasta, rubber in chicken nuggets, etc.).

Food recalls are so common today that it is vital not to oversaturate the market with information that may or may not affect people so that they are more alert when we do issue a recall notice. We will typically alert the public through social media or our website.

Media Management

The media may be a huge asset during a foodborne illness investigation, but they can also hinder or complicate matters if not appropriately used. Reaching out to the media for a single complaint of illness or in the early stages of an outbreak investigation may cause panic with little payoff and is not encouraged.

A media release is warranted in the following instances:

- The source of the illness has been identified, and awareness is needed to prevent more illnesses (e.g., Del Monte fresh vegetables identified as the source; message – discard and do not eat the product);
- The source has not been identified, but there are actions that people can take in the community to decrease their risk (e.g., romaine is linked with the cases—FDA warns consumers not to eat any romaine lettuce);
- We need the community's help in reporting cases and stemming the outbreak (e.g., a high number of Norovirus cases in the community; messages about hand washing, staying home when ill, calling to report illness; messages to food places about exclusion).

There may be times when the media reaches out to us because they have heard that we are investigating an outbreak. It's important that we get them the right message from the right person right away. Get the reporter's name, phone, and write down as much as you can about their inquiry, and ask for their deadline. Tell them that you will have someone get back with them and contact the Public Information Officer (PIO) for Env Health.

Whether the department reaches out to the media or we're responding to a media inquiry, it is important that the PIO manages media engagement so that a uniform message gets to the public in the right manner at the right time. If the Env Health PIO cannot serve on the event, work with the Health Department PIO. An inspector should not give information to a reporter unless it's from a talking points sheet put together for that purpose, and they should never, say "no comment." Instead, they should say "let me get you to the person who can better address this," and get them to the PIO.

When dealing with outbreaks, intentional contamination events, or recalls where multiple jurisdictions are involved. The PIO must coordinate with other agencies to ensure uniform

messaging and to make sure that the information released does not compromise the activities of another entity. For example, if the police are investigating an intentional contamination event, they may not want certain information released to the public. When many agencies are involved, it may be beneficial to form a Joint Information Center (JIC) and designate a lead PIO from one of the agencies to run point.

Data Tracking and Analysis

The Lead logs all complaints in the Env Health FBI tracking spreadsheet. At the end of the year, the Lead analyzes the information to identify trends in illness or injury, implicated establishment, food, type of food service, and preparation process. Based on the information, the department can determine if outreach efforts or investigation procedures need to change.

Specifically, the Lead will look at the following each year:

- Multiple complaints from the same establishment;
- Multiple complaints on the same establishment type;
- Multiple complaints implicating the same food;
- Multiple complaints associated with similar food preparation processes;
- Number of confirmed foodborne disease outbreaks;
- Number of foodborne disease outbreaks and suspected foodborne disease outbreaks;
- Contributing factors most often identified;
- Number of complaints involving real and alleged threats of intentional food contamination;
- Number of complaints involving the same agent; and,
- Number of complaints involving unusual agents when agents are identified.

If there is no foodborne illness or food-related injury outbreak during the year, MCCHD will conduct a tabletop exercise to simulate a response following this protocol. Whenever possible, multiple agencies should be involved in the tabletop.

Authority

1. **50-2-118 MCA. Powers and duties of local health officers.** In order to carry out the purpose of the public health system, in collaboration with federal, state, and local partners, local health officers or their authorized representatives shall:

(1) make inspections for conditions of public health importance and issue written orders for compliance or for correction, destruction, or removal of the condition;

(2) take steps to limit contact between people in order to protect the public health from imminent threats, including but not limited to ordering the closure of buildings or facilities where people congregate and canceling events;

(3) report communicable diseases to the department as required by rule;

(4) establish and maintain quarantine and isolation measures as adopted by the local board of health; and

(5) pursue action with the appropriate court if this chapter or rules adopted by the local board or department under this chapter are violated.

2. **50-2-116 MCA states in part:**

50-2-116. Powers and duties of local boards of health. (1) In order to carry out the purposes of the public health system, in collaboration with federal, state, and local partners, each local board of health shall:

(f) identify, assess, prevent, and ameliorate conditions of public health importance through:

(i) epidemiological tracking and investigation;

(ii) screening and testing;

(iii) isolation and quarantine measures;

(iv) diagnosis, treatment, and case management;

(vi) inspections;

(vii) collecting and maintaining health information;

(ix) other public health measures as allowed by law;

(g) protect the public from the introduction and spread of communicable disease or other conditions of public health importance, including through actions to ensure the removal of filth or other contaminants that might cause disease or adversely affect public health;

(h) supervise or make inspections for conditions of public health importance and issue written orders for compliance or for correction, destruction, or removal of the conditions;

(i) bring and pursue actions and issue orders necessary to abate, restrain, or prosecute the violation of public health laws, rules, and local regulations;

3. **50-31-106 MCA :**

50-31-106. Inspections and taking of samples authorized. (1) The department or its authorized agents have free access at all reasonable hours to any factory, warehouse, or establishment in which foods, drugs, devices, or cosmetics are manufactured, processed, packed, or held for introduction into commerce or to any vehicle being used to transport or hold the foods, drugs, devices, or cosmetics in commerce, for the purpose of:

(a) inspecting the factory, warehouse, establishment, or vehicle to determine if any of the provisions of this chapter are being violated; and

(b) securing samples or specimens of any food, drug, device, or cosmetic after paying or offering to pay for the sample.

(2) The department shall make or cause to be made examinations of samples secured under the provisions of this section to determine whether or not any provision of this chapter is being violated.

4**. 50-31-510 MCA:**
50-31-510. Condemnation of perishables. Whenever the department or any of its authorized agents find in any room, building, vehicle of transportation, or other structure any meat, seafood, poultry, vegetable, fruit, or other perishable article which is unsound or contains any filthy, decomposed, or putrid substance or that may be poisonous or deleterious to health or otherwise unsafe, the article being hereby declared to be a nuisance, the department or its authorized agent shall immediately condemn or destroy the article or in any other manner render the article unsalable as human food.

Contact List

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For all law enforcement, contact: 911