

FOCUS AREA 9

WORKSHEET:

Laboratory Investigation

Complete this worksheet if “laboratory investigation” is a high-priority Focus Area for efforts to improve foodborne disease outbreak-related activities in your agency or jurisdiction. (NOTE: The term “agency/jurisdiction” refers to the entity for which your workgroup is making decisions. See your completed “Preliminaries” worksheet for a definition.)

List the individuals participating in the discussion of this Focus Area (and their affiliations).

To help you understand what is included in this Focus Area, review the following goals and keys to success.

GOALS FOR THE LABORATORY INVESTIGATION:

Agency/jurisdiction staff provide guidance on collection, storage, and shipment of patient specimens and food/environmental samples. Agency/jurisdiction staff test patient specimens and suspect vehicles to identify the etiologic agent, mode of transmission, and vehicle in an outbreak and explore the ability of the agent to survive and grow in the implicated vehicle and how the vehicle might have become contaminated.

1. PRIORITIZE THE KEYS TO SUCCESS FOR THE LABORATORY INVESTIGATION

“Keys to success” are activities, relationships, and resources that are critical to achieving success in a Focus Area. Determining whether an agency/jurisdiction has a particular key to success in place is somewhat subjective. Metrics, such as measures of time (e.g., rapidly, timely, and quickly), have not been defined. Your workgroup should provide its own definitions for these terms, as is appropriate for your agency/jurisdiction, and use its best judgment in deciding whether a particular key to success is fully or partially in place. Rate the priority for implementing each key to success based on its likely impact on foodborne outbreak response at your agency/jurisdiction and available resources. Use a scale of 1 to 5 to rate each key to success (1=low priority for implementation, and 5=high priority for implementation). If a key to success is already in place in your agency/jurisdiction, check the appropriate box. If a key to success is not relevant to your agency/jurisdiction, select N/A.

Already in Place	Priority for Implementation or Improvement in Your Agency/Jurisdiction LOW ----- HIGH
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Staff skills and expertise

- Staff have expertise in appropriate laboratory testing methodologies and access to necessary equipment, reagents, and supplies to perform testing.

Notes (activities, procedures, or comments):

 (1) (2) (3) (4) (5) (N/A)

Already in Place	Priority for Implementation or Improvement in Your Agency/Jurisdiction LOW ----- HIGH					
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Specimen collection and testing

- In collaboration with laboratory, epidemiology, and environmental health staff, collect appropriate clinical specimens and food and environmental samples, then store and transport them properly (e.g., chain of custody).

Notes (activities, procedures, or comments):

1 2 3 4 5 N/A

- Staff properly receive and record receipt of specimens and food/environmental samples.

Notes (activities, procedures, or comments):

1 2 3 4 5 N/A

- Staff link patient and clinical specimen information in an appropriate database.

Notes (activities, procedures, or comments):

1 2 3 4 5 N/A

- Staff isolate etiologic agent (if necessary) and characterize isolates (e.g., subtyping) in a timely fashion.

Notes (activities, procedures, or comments):

1 2 3 4 5 N/A

- Staff use approved methods to analyze specimens/samples and subtype isolates.

Notes (activities, procedures, or comments):

1 2 3 4 5 N/A

Communication

- Staff communicate in a timely fashion and coordinate activities with epidemiology and environmental health staff.

- Staff report results of laboratory tests to epidemiologic and environmental health investigators, regulatory personnel (if applicable), and appropriate national databases in a timely fashion.

Notes (activities, procedures, or comments):

1 2 3 4 5 N/A

Already in Place	Priority for Implementation or Improvement in Your Agency/Jurisdiction LOW ----- HIGH					
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Making changes

- Agency/jurisdiction has performance indicators related to the laboratory investigation and routinely evaluates its performance in this Focus Area and tracks progress as part of its continuous process improvement program(s).

1 2 3 4 5 N/A

Notes (activities, procedures, or comments):

- Agency/jurisdiction involves investigation and response team members in a debriefing or after-action review following each outbreak response to improve future investigation practices or to prevent future outbreaks based on lessons learned.

1 2 3 4 5 N/A

Notes (activities, procedures, or comments):

2. PRIORITIZE CIFOR GUIDELINES RECOMMENDATIONS TO ADDRESS NEEDED IMPROVEMENTS

Having identified activities and procedures in need of improvement, review the CIFOR Guidelines recommendations related to this Focus Area (listed below). Rate the priority for implementing each recommendation based on its likely impact on foodborne outbreak response at your agency/ jurisdiction and available resources. Use a scale of 1 to 5 to rate each recommendation (1=low priority for implementation, and 5=high priority for implementation). If a recommendation is already in place in your agency/jurisdiction, check the appropriate box. If a recommendation is not relevant to your agency/jurisdiction, select N/A. **Refer to the blue underlined section number following each recommendation to view the recommendation as it appears in the CIFOR Guidelines.**

Already in Place	Priority for Implementation or Improvement in Your Agency/Jurisdiction LOW ----- HIGH					
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Staff skills and expertise

- Ensure that laboratory scientists have the necessary training and skills to analyze and interpret results from testing clinical specimens and food and environmental samples as is appropriate for a particular outbreak and that they can guide other outbreak response team members on optimal specimen type and collection, transport, and storage conditions. [\(4.1.2\)](#)
- Provide continuing education to laboratory scientists to maintain and improve skills in their specialty. [\(3.2.2\)](#)
- Train laboratory scientists in the agency's/jurisdiction's outbreak response protocols and the laboratory scientist's role in an investigation. [\(3.2.2\)](#)

1 2 3 4 5 N/A

1 2 3 4 5 N/A

1 2 3 4 5 N/A

	Already in Place	Priority for Implementation or Improvement in Your Agency/Jurisdiction LOW ----- HIGH					
<ul style="list-style-type: none"> Assemble a reference library with information about foodborne diseases, enteric illnesses, and laboratory-testing methodologies. (3.4.5) 		1	2	3	4	5	N/A
<ul style="list-style-type: none"> Assemble a list of resource persons who have expertise in specific disease agents and laboratory-testing methodologies. (3.5.1) 		1	2	3	4	5	N/A
<ul style="list-style-type: none"> Exercise outbreak response team members together to ensure that each team member understands and can perform their role according to agency-specific protocols and legal authorities and understands the roles and responsibilities of other team members. (3.2.2) 		1	2	3	4	5	N/A

Additional ideas:

Specimen collection and testing

<ul style="list-style-type: none"> Ensure that epidemiologists and environmental health investigators know how to collect appropriate clinical specimens and food and environmental samples and store and transport them properly. (3.2.1) 		1	2	3	4	5	N/A
<ul style="list-style-type: none"> Ensure that necessary laboratory supplies and equipment are available and are routinely assessed and replaced. (3.4.1) (3.4.2) 		1	2	3	4	5	N/A
<ul style="list-style-type: none"> Collaborate with epidemiology partners to contact clinical laboratories that have performed primary cultures on cases and obtain patient specimens or isolates. (4.1.2) (Table 5.1) 		1	2	3	4	5	N/A
<ul style="list-style-type: none"> Collaborate with the outbreak investigation team to contact clinical laboratories to identify additional stool specimens being cultured to better determine persons at risk for the outbreak exposure and whether outbreak-related transmission is ongoing. (Table 5.1) 		1	2	3	4	5	N/A
<ul style="list-style-type: none"> If an outbreak is related to an event or establishment, establish the etiology through testing of clinical specimens (or food item, if implicated by epidemiology or environmental investigations) to better understand the outbreak and establish links to other outbreaks or cases. (Table 5.1) 		1	2	3	4	5	N/A
<ul style="list-style-type: none"> Store food or environmental samples, pending results of epidemiologic and environmental investigations. Test when food has been implicated by these investigations. (4.2.5) (Table 5.1) 		1	2	3	4	5	N/A
<ul style="list-style-type: none"> Refrigerate perishable food samples but keep foods that are frozen when collected frozen until examined. In general, if perishable food samples cannot be analyzed within 48 hours after receipt, freeze them (-40 to -80°C). NOTE: The allowable length of refrigeration and desirability of freezing is pathogen and food dependent. (4.2.5) 		1	2	3	4	5	N/A
<ul style="list-style-type: none"> Test foods (rather than clinical specimens) for outbreaks thought to involve preformed toxins, because detection of toxin or toxin-producing organisms in clinical specimens can pose challenges. (4.2.5) 		1	2	3	4	5	N/A

	Already in Place	Priority for Implementation or Improvement in Your Agency/Jurisdiction LOW ----- HIGH					
• Work with the appropriate regulatory authority to ensure that food samples are collected and maintained with appropriate chain of custody. (4.2.5) (Table 5.1)		1	2	3	4	5	N/A
• Use official reference testing methods for regulated food products. (4.2.5)		1	2	3	4	5	N/A
• Streamline submission and testing of specimens to reduce turnaround time. (4.1.7)		1	2	3	4	5	N/A
• Conduct whole genome sequencing to further characterize pathogens and rapidly post subtyping results to PulseNet and other national databases that support foodborne surveillance and outbreak investigations (4.1.3)		1	2	3	4	5	N/A
• Evaluate results of all outbreak-associated cultures to highlight possible relationships among isolates from clinical, food, and environmental samples. (Table 5.1)		1	2	3	4	5	N/A
• Conduct applied food-safety research to determine the ability of the agent to survive or multiply in the implicated vehicle and how the vehicle might have become contaminated with the agent. (Table 5.1)		1	2	3	4	5	N/A

Additional ideas:

Communication

• Ensure that the laboratory scientist knows the other members of the outbreak response team before an outbreak occurs. (3.2.2)		1	2	3	4	5	N/A
• Establish and use routine procedures for communicating with outbreak response team members and their organizational units before an outbreak occurs. (3.5.2)		1	2	3	4	5	N/A
• Maintain close communication and coordination with members of the outbreak response team during an investigation. Update all members of the outbreak response team daily. (3.5.2)		1	2	3	4	5	N/A
• Help outbreak response team members to interpret results of testing. Provide background statistics on pathogen prevalence and problems with interpretation of food testing results. (Table 5.1)		1	2	3	4	5	N/A

Additional ideas:

Already in Place	Priority for Implementation or Improvement in Your Agency/Jurisdiction LOW ----- HIGH					
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Making changes

<ul style="list-style-type: none"> Participate in a debriefing/after-action meeting following each outbreak investigation with all members of the outbreak response team to identify lessons learned and compare notes on ultimate findings. Identify factors that compromised the investigation and clarify changes to procedures, resources, training, and agency structure to optimize future investigations. (Box 6.6) (6.6.4) 	1	2	3	4	5	N/A
<ul style="list-style-type: none"> Work with outbreak response team to summarize investigation findings, conclusions, and recommendations in a written report, consistent with the size and complexity of the investigation, including lessons learned and action items for follow-up and quality improvement. (6.6.5) 	1	2	3	4	5	N/A
<ul style="list-style-type: none"> Work with outbreak response team to submit summary data about the outbreak to CDC’s National Outbreak Reporting System (NORS) database using CDC’s form 52.13. Make every effort to complete both Part 1 and Part 2. (6.6.5) 	1	2	3	4	5	N/A
<ul style="list-style-type: none"> Track relevant corrective action items as part of agency/jurisdiction continuous quality improvement program(s). (6.6.4) 	1	2	3	4	5	N/A
<ul style="list-style-type: none"> Share investigation and response findings more broadly if the outbreak involved an unusual exposure, pathogen, or root cause. (6.6.7) 	1	2	3	4	5	N/A

Additional ideas:

3. MAKE PLANS TO IMPLEMENT SELECTED CIFOR GUIDELINES RECOMMENDATIONS

For each CIFOR Guidelines recommendation selected in the previous steps (or idea formulated by the workgroup), identify who will take the lead in implementing the recommendation and the time frame for implementation (e.g., a specific completion date or whether the change is likely to require short-, mid-, or long-term efforts). If certain actions must precede others, make a note of this and adjust the time frame. In addition, consider factors that could positively or negatively influence implementation of the recommendation and ways to incorporate the recommendation into your agency's/jurisdiction's standard operating procedures.

CIFOR recommendations or other ideas from previous steps	Lead person	Time frame for implementation	Notes (e.g., necessary antecedents, factors that might influence implementation, ways to incorporate the recommendation into standard operating procedures)

One person should be given responsibility for monitoring progress in implementing the above CIFOR Guidelines recommendations. Follow-up should occur at specified checkpoints (e.g., 3, 6, 9, and 12 months after the start of the Toolkit process), and results should be shared with the entire workgroup.

DATE WORKSHEET COMPLETED: _____

NEXT DATE FOR FOLLOW-UP ON PROGRESS: _____