Focus Area 9 Worksheet: Laboratory Investigation



FOCUS AREA 9: LABORATORY INVESTIGATION

Complete this worksheet if "Laboratory Investigation" is a high priority Focus Area for efforts to improve foodborne disease outbreak response in your agency/jurisdiction. (NOTE: The term "agency/jurisdiction" refers to the entity for which your workgroup is making decisions. See your completed "Document D: 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.

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.

Staff skills and expertise

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

Specimen collection and testing

- o In collaboration with laboratory staff, epidemiology and environmental health staff collect appropriate clinical specimens and food and environmental samples and store and transport them properly.
- Staff link patient and clinical specimen information.
- o Staff isolate etiologic agent (if necessary) and characterize isolates (e.g., subtyping) in a timely fashion.
- o Staff use standardized (currently approved) methods to analyze specimens/samples and subtype isolates.

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.

Making changes

- Agency/jurisdiction conducts a debriefing among investigators following each outbreak response and refines outbreak response protocols based on lessons learned.
- Agency/jurisdiction has performance indicators related to the laboratory investigation and routinely evaluates its performance in this Focus Area.

1. DESCRIBE YOUR CURRENT ACTIVITIES AND PROCEDURES IN THIS FOCUS AREA.

Considering the keys to success on the previous page, describe your agency's/jurisdiction's current activities and procedures in this Focus Area. Refer to written protocols, if available, and materials related to ongoing efforts in capacity development or quality improvement (e.g., FDA Retail and Manufactured Food Regulatory Program Standards). As you list current activities and procedures related to this Focus Area, indicate those which could be changed to improve your agency's/jurisdiction's response to foodborne disease outbreaks.

Activity/Procedure	Needs Improvement?

2. PRIORITIZE CIFOR RECOMMENDATIONS TO ADDRESS NEEDED IMPROVEMENTS.

Having identified activities and procedures in need of improvement, review the CIFOR 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			1		
Staff skills and expertise		LOW			HIGH		
Ensure that laboratory investigators have the necessary training and skills to analyze and interpret clinical specimens and food and environmental samples as is appropriate for a particular outbreak and can guide other outbreak response team members on optimal specimen type and collection, transport, and storage conditions. (3.2.2.4) (4.2.10.2)		1	2	3	4	5	N/A
Provide continuing education to the laboratory investigator to maintain and improve skills in their specialty. (3.2.3.4)		1	2	3	4	5	N/A
Train the laboratory investigator in the agency's/jurisdiction's outbreak response protocols and the laboratory investigator's role in an investigation. (3.2.3.4)		1	2	3	4	5	N/A
Assemble a reference library with information about foodborne diseases, enteric illnesses, and laboratory-testing methodologies. (3.2.3.3)		1	2	3	4	5	N/A
Assemble a list of resource persons who have expertise in specific disease agents and laboratory-testing methodologies. (3.2.3.3)		1	2	3	4	5	N/A
Exercise outbreak response team members together to ensure that each team member understands and can perform his or her role according to agency-specific protocols and legal authorities and understands the roles and responsibilities of other team members. (3.2.3.4)		1	2	3	4	5	N/A
Ensure that all outbreak response team members regularly participate in outbreak investigation and control efforts, even if it means working with another jurisdiction because the team's home jurisdiction does not have many outbreaks. (3.2.3.4)		1	2	3	4	5	N/A
Additional ideas:							
Specimen collection and testing Ensure that epidemiologic and environmental health investigators know how to collect appropriate clinical specimens and food and environmental samples and store and transport them properly. (3.2.2.4)		1	2	3	4	5	N/A

	in place	Priority for Implementation or Improvement in Your Agency/Jurisdiction					
Specimen collection and testing (cont'd)		LOW		HIGH		Н	
Ensure that necessary laboratory supplies and equipment are available and are routinely assessed and replaced. (3.3.2.4)		1	2	3	4	5	N/A
Contact clinical laboratories that may have performed primary cultures on cases and obtain patient specimens or isolates. (<u>Table 5.1</u>) (<u>Table 5.2</u>)		1	2	3	4	5	N/A
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) (Table 5.2)		1	2	3	4	5	N/A
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. (<u>Table 5.1</u>)		1	2	3	4	5	N/A
Store food or environmental samples, pending results of epidemiologic and environmental investigations. Test when food has been implicated by these investigations. (<u>Table 5.2</u>) (<u>4.3.9.4</u>)		1	2	3	4	5	N/A
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. (4.3.9.4)		1	2	3	4	5	N/A
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 be problematic. (4.3.9.4)		1	2	3	4	5	N/A
Work with the appropriate regulatory authority to ensure that food samples are collected and maintained with appropriate chain of custody. (Table 5.2)		1	2	3	4	5	N/A
Use official reference testing methods for regulated food products. $(\underline{4.3.9.4})$		1	2	3	4	5	N/A
Streamline submission and testing of specimens to reduce turnaround time. $(\underline{4.2.6})$		1	2	3	4	5	N/A
Undertake subtyping as isolates are submitted to reduce turnaround time. (4.2.10.2)		1	2	3	4	5	N/A
Undertake PFGE and serotyping concurrently to reduce turnaround time. (4.2.10.2)		1	2	3	4	5	N/A
Maintain a laboratory tracking and analysis log/database. (4.2.5)		1	2	3	4	5	N/A
Rapidly post subtyping results to PulseNet. (4.2.10.5)		1	2	3	4	5	N/A

	Already in place	Priority for Implementation or Improvement in Your Agency/Jurisdiction					
Specimen collection and testing (cont'd) Evaluate results of all outbreak-associated cultures to highlight possible	LOW		LOW		HIG	iH	
relationships among isolates from clinical, food, and environmental samples. (<u>Table 5.1</u>) (<u>Table 5.2</u>)		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. (<u>Table 5.1</u>) (<u>Table 5.2</u>)		1	2	3	4	5	N/A
Additional ideas:							
Communication							
Ensure that the laboratory investigator knows the other members of the outbreak response team before an outbreak occurs. (3.6.2.2)		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. (3.6.2.2)		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. (5.1.2.3) (5.2.5) (6.5.1)		1	2	3	4	5	N/A
Help outbreak response team members interpret results of testing. Provide background statistics on pathogen prevalence and problems with interpretation of food testing results. (<u>Table 5.2</u>) (<u>3.2.2.4</u>)		1	2	3	4	5	N/A
Additional ideas:							
Making changes							
Participate in a debriefing 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. (6.7) (3.2.3.4) (5.2.8)		1	2	3	4	5	N/A
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. (3.7.2) (5.2.9) (6.8)		1	2	3	4	5	N/A
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. (5.2.9)		1	2	3	4	5	N/A
Additional ideas:							

Additional ideas:

3. MAKE PLANS TO IMPLEMENT SELECTED CIFOR RECOMMENDATIONS.

For each CIFOR recommendation selected in the previous step (or idea formulated by the workgroup), identify who will take the lead in implementing the recommendation and the timeframe 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 timeframe. 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.

One person should be given responsibility for monitoring progress in implementing the above CIFOR 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.

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

DAIL	WORKSTILL COMI LL	71 LD	
NEXT DATE FOR FOLLO	W-IIP ON PROGRESS.		
NEAT DATE FOR FOLLS	W'-OI ON I ROOKESS.		

DATE WORKSHEET COMPLETED.