



Emerging Infectious Diseases Planning and Response Framework

Recent domestic infectious disease threats include SARS, monkeypox, Hepatitis A, West Nile virus, influenza, antibiotic resistant infections, dengue fever and vCJD. Experience over the past five years has shown that laboratory issues are often not recognized in the early stages of both planning and response.

Public health laboratories have a broad role in preparing for and responding to emerging diseases, and public health threats and emergencies. In addition to the recognized role of providing high quality testing, public health laboratories also perform research and validation of new testing methodologies, provide training, develop and disseminate critical information on specimen collection and transport, biosafety, test limitations and result interpretation, and regulatory requirements to many partners in both the clinical, private and public health sectors.

In 2004, a subcommittee of the APHL Infectious Diseases Committee was established to develop a framework to assist public health laboratories both in preparing for and responding to outbreaks and bioterrorism threats. To meet this charge, the subcommittee designed a checklist to be used by public health laboratory leaders and scientists that outlines the various elements public health laboratories must address with each disease outbreak or emerging threat. Because the subcommittee recognizes that effective relationships with both new and traditional partners are critical to effective response, this checklist may be shared with partners as needed to assist in identifying necessary resources and developing appropriate action plans.

PARTNERS

- Identify Partners**
 - Clinical laboratories
 - Civil support teams (CST)
 - Hazmat teams
 - Universities—health centers
 - Rapid testing sites
 - Physicians/Clinicians
 - Public
 - Food and Drug Administration (FDA) laboratories
 - Environmental and Protection Agency (EPA) laboratories
 - Veterinary laboratories
 - Agricultural laboratories
 - Toxicology laboratories
 - Homeland Security State Agency
 - Bordering countries
 - Law enforcement
 - Local/state
 - FBI
- Identify City/State agencies**
 - Epidemiology
 - Medical examiners
 - Local health department laboratories
 - Sanitarians—sewage—waterworks
 - State press office
- Define role or no role**
 - Local pharmacology laboratories
 - Biotechnology laboratories
- Discuss communication needs and expectations**
 - Explore “synergy” with all partners

COMMUNICATIONS

- Define/Implement public health laboratory (PHL) emergency response system (outbreak plan beyond bioterrorism)**
 - Establish incident command system
 - Establish who's in charge
 - Keep system updated
 - Define record keeper for event
 - Define call back system for technical staff (beyond bioterrorism) and packaging staff
 - Exercise the system and test the call back system
- Establish contact with state health officer (SHO)**
- Establish/Utilize system to communicate**
 - Fax or email
 - Teleconferences with public health partners
 - Teleconferences with sentinel laboratories
 - Conference calls (identify who to include)
 - Just in time decisions—who needs to be included
- Establish laboratory partner lists with contact information**
 - Sentinel laboratories
 - Veterinary laboratories
 - Agricultural laboratories
 - Academia/Research laboratories
 - Environmental laboratories
 - Surrounding state public health laboratories (SPHL)
- Disseminate state health alert network (HAN) information to sentinel laboratories**
 - What is happening
 - What they need to know (including safety)
 - What public health laboratories needs to know
 - Who they need to contact
 - What they need to do
- Laboratory community**
 - Establish relationships
 - Establish one stop shop numbers and 24/7 numbers
 - Pre-establish state testing and data sharing capabilities
 - Arrange face to face interactions
- Communication with epidemiology and clinical consultant**
 - Establish routine communication with epidemiology in advance
 - Plan for emergency communications
 - Connect with epidemiology for CDC fifty-state calls
- Private sector**
 - Communicate public health laboratory 24/7 response role
 - Differentiate from “routine” testing
 - Assure PHL is reachable 24/7
 - Define what is an emergency (beyond bioterrorism), if possible; e.g.: botulism, meningitis, foodborne outbreak
- Every PHL should participate in Epi-X**
 - Use Epi-X info to send out state HAN messages

COMMUNICATIONS

- Public health laboratory (PHL) to CDC**
 - Establish how to connect with laboratories
 - Establish role of emergency operations center (EOC)
 - Establish role of APHL to help you connect with CDC
- Clarify expectations from CDC (with APHL) to obtain information and resources needed**
 - Disease, technical information
 - Who to contact
 - Conference calls as much as needed with effected areas
 - Larger communication to all states
 - Laboratory specific communications
- Optimize use of available electronic laboratory capabilities**
- Utilize public information officer (PIO) where available to develop advance messages and communicate messages or data/information changes during the event**
- Establish and clarify role of chief communications officer**
- Obtain information and resources from APHL**
 - Participate in 50 state calls for member laboratories
 - Use APHL to represent PHLs “voice”
 - Review and share information with staff in SPHL, branch, city and county laboratories
 - Others within SPHL
 - Cities/Counties
 - Provide names of technical contacts to APHL
 - Public Relations—“Role of Laboratories”
 - APHL may develop sample press releases for states to use
 - Issue state press release
- PHL website**
 - Set up educational pages in advance
 - Keep contact information updated

SAFETY

- Provide training and send updated or emergency information**
 - Sentinel laboratories
 - PHL staff
 - Transportation requirements
- Develop a contingency plan for breach of biosafety level (BSL) (e.g. unknown that was processed without proper containment)**
- Communication with epidemiology**
 - Epidemiology-clinical indicators of increased BSL risk organism
- Make sure appropriate biosafety equipment is available and used**
- Must have standard BSL practices well established and monitor practices in the laboratory (e.g. standard precautions for respiratory samples)**
- Establish, update and implement criteria for use of personal protective equipment (PPE) and powered air purifying respirators (PAPRs) including certification**

SAFETY

- Update and maintain safety documents**
 - Identify safety officer
 - Participate in BSL-3 training (e.g. Eagleson Institute)
- Develop vaccination requirements/plans and monitor/implement any new CDC guidance**
- Establish plan for medical surveillance of laboratory staff**
 - Identify an infectious disease expert consultant (work through medical director)
 - Bank sera—define storage requirements (if off-site)
- Develop and implement a contingency plan and risk assessment for:**
 - BSL3 enhanced
 - BSL3 with agriculture enhancements (USDA requirements)
 - Unknown virus/unknown organism
 - Define algorithm for high risk samples and suspicious culture results
 - Define BSL stop points for unusual or suspicious growth in culture
- Define and review criteria for role of environmental monitoring (implement, if needed)**

REGULATORY

- Maintain knowledge of CLIA requirements for new test implementation & reporting non-FDA approved test results and evaluate impact to laboratory**
- Maintain knowledge of federal partner requirements/role (e.g. FDA, USDA/APHIS)**
- Maintain updated knowledge of packaging and shipping regulations and assure compliance**
- Coordinate with epidemiology to implement institutional review board (IRB)/informed consent requirements, e.g. Investigational New Drug (IND), Investigational Device Exemption (IDE)**
- Assure select agent registration is updated and review select agent requirements**

SAMPLES—SPECIMENS—TRANSPORT

- Establish a directory of services**
 - Refer to examples available from public health laboratories and clinical laboratories
 - Keep specimen collection information guide for “routine” types of specimens up to date
- Identify specimen types (coordinate with epidemiology department where appropriate)**
 - From CDC case definition
 - From best available science (pre-plan messages)

SAMPLES—SPECIMENS—TRANSPORT

- Collection devices/kits**
 - Define what is needed
 - Define what is/will be available from public health laboratory
- Review test order form and distribute if unique to event**
 - Update if needed
 - Ask only for essential information (partner with physicians) e.g. travel history, animal exposure only if appropriate to outbreak
- Establish repositories of kits in local-regional jurisdictions (e.g. local health departments)**
- Plan for informed consent (link with epidemiology)**
 - Do you need local IRB and CDC approval?
 - What to do if informed consent is not received
 - Update and distribute forms; provide on website
 - Communicate informed consent requirements to laboratory and clinical partners
- Packaging and Shipping**
 - Provide advanced training or resources for training to sentinel laboratories (if available) and law enforcement
 - Define and distribute PHL expectations for this event to providers, laboratory community, and law enforcement
 - Assure compliance with 24/7 contact number requirement on shipping documents
 - Assure chain of custody
- Identify courier options already in use by sentinel laboratories (tap in where possible)**
- Plan for various alternatives and packaging requirements**
 - Local transport
 - Courier
 - Overnight
- Develop and implement a plan for sample triage and prioritization (link with epidemiology and law enforcement)**
- Develop a plan and communicate requirements for direct shipping of samples from local to CDC when urgent**
- Plan for things to change (e.g. sampling and testing guidance)**
 - Be prepared to communicate changes to partners quickly
- Communicate role of environmental testing and sample requirements for the event**
 - Establish advance plan if possible
 - Clarify responsibilities for testing (e.g. BT vs. infection control—hospital outbreak)

TESTING

- Determine minimal verification— validation plan for tests developed and released in an emergency**
- Identify available reagent sources and stock reagents where possible**
- Obtain emergency reagents if needed**
- Identify testing/resources in academia**
- Technology**
 - Establish testing on multiple platforms (if possible)
 - Participate in vendor user groups
- Identify and define role of available tests**
 - Validate methods where possible
 - Assist CDC/partners in validation when needed
 - Participate in proficiency testing (PT) when available
 - Determine appropriate use of in-house developed tests
 - Carefully justify legal implications of any in-house modification of CDC procedures
- Plan communication to “qualify” test results of new tests/technologies**
 - Add qualifiers to reporting forms
- Determine and communicate role of testing for other agents**
 - Rule out/rule in
 - How far to go with unknowns
- Determine and communicate confirmatory testing requirements**
 - Where, what?
 - Quality Control—determine what is available and how to access
 - Proficiency testing—determine what is available and how to access
 - Discrepant result analysis
- Define and communicate role of/need for molecular subtyping**
- Define and communicate role of sequencing**
 - For identification of unknowns
 - Safety issues
- Establish criteria for role of surveillance or environmental testing and communicate plan**
- Implement and communicate appropriate testing algorithms (CDC guidance) to essential partners**
- Develop and implement contingency plan if you don’t have needed technology (memorandum of understanding, MOU)**
- Address state regulations that may impede additional testing— “public health surveillance testing”**
 - Need to find out who/what is available
 - Where is expertise

TESTING IN THE PRIVATE SECTOR

- Assess private sector capabilities/capacity**
 - Identify who and what can be tested in advance
 - Determine capabilities beyond bioterrorism (e.g. rapid flu)
 - Determine biosafety capabilities
 - Communicate with private sector expectations for testing
 - Communicate expectations for sending samples to PHL
- Communicate messages on role of public health/private testing**
- Communicate need/impact on public health response**
- Share protocols with private sector**
- Communicate public health need for private sector test results (e.g. food-borne outbreaks, surveillance)**
- Need to involve state public health agency pre-testing (e.g. SARS)-case definition fit**
- Communicate messages on quality of private homebrew testing**
- Communicate need to obtain specimens for confirmatory testing and sub-typing**
- Public health impact of positive, false positive, false negative results**

REPORTING/DATA MANAGEMENT

- Develop standardized reporting algorithms**
 - Continue to assess and implement reporting algorithms
- Communicate reporting plan in advance to essential partners**
- Develop plan for dealing with pressure to release results**
 - Epidemiology and laboratory staffs need to be on same page
 - CDC guidance on test performance
 - Deal with delays in CDC testing
 - Coordinate with state press office
- Establish and clarify role of chief communications officer in releasing results**
- Assess Data management requirements**
- Identify lead staff and surge staff for reporting and provide training**
- Know reporting requirements (expectations) of**
 - Local health departments
 - State epidemiologists
 - CDC
- Provide media training for Laboratory Director, Deputy Director, and Communications Officer**
- Utilize public information officer (PIO) where available to develop advance messages and communicate messages or data/information changes during the event**

STAFFING

- Participate in CDC training, assess competency**
- Identify expertise/special skills**
- Implement cross-training, assess competency**
- Develop a plan for shift coverage**
- Maintain select agent registration of new staff**
 - Assess select agent registration impact on staff responsibilities

SURGE

- Establish emergency response plans**
 - Define potential needs
 - Develop a plan for shift coverage
 - Define roles of all staff in the event
 - Implement emergency staffing plans if needed
 - Develop contingency plan to prioritize testing (routine clinical vs. response), outsource or reduce routine testing
 - Establish and implement MOUs where needed
 - Link to state continuity of operations (CoOp) plan
- Assess PHL capacity**
 - Testing
 - Staff and supervisory staff
 - Security
 - Space
 - Information technology (IT)
- Provide cross-training, assess competency**
 - By methods groups
 - Across bacteriology—virology
- Identify available reagent sources**
 - CDC
 - Commercial: talk to vendors about emergency supplies (e.g. extraction)
 - Stockpile appropriate reagents
- Inventory and stockpile PPE supplies**
- Assess clinical laboratory capacity**
 - Define clinical laboratory role in the event and communicate quickly with laboratories
- Define role of CDC for back-up, surge, confirmatory testing**

MISCELLANEOUS

- Identify funding opportunities**
- Establish and maintain a security plan**
- Identify common elements to existing plans**
 - Emergency response
 - Influenza
 - SARS

This Emerging Infectious Diseases Planning and Response Framework was supported under Cooperative Agreement #U60/CCU303019 between the Centers for Disease Control and Prevention, Bioterrorism Preparedness and Response Program and the Association of Public Health Laboratories.