Infectious Disease Planning and Response Framework Checklist

Recent infectious disease threats include novel Influenza strains, novel coronavirus, Infectious Hepatitis , West Nile virus, antibiotic resistant infections, dengue fever and vCJD. Experience has shown that laboratory issues are often not recognized in the early stages of both planning and response to infectious disease threats.

Public health laboratories have a broad role in preparing for and responding to infectious disease outbreaks, 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 developed a framework checklist to assist public health laboratories in preparing for and responding to outbreaks and infectious disease threats. In 2013, this checklist has been reviewed and updated, because the need still exists. This checklist, to be used by public health laboratory leaders and scientists, outlines the various elements public health laboratories must address with each disease outbreak or emerging threat. Effective relationships with both new and traditional partners are critical to effective planning and response. This checklist may be shared with partners as needed to assist in identifying necessary resources and developing appropriate action plans.

Partners and Stakeholders

☐ **Identify Partners**
- ☐ Clinical laboratories
- ☐ Local health department laboratories
- ☐ Civil support teams (CST)
- ☐ Hazmat teams
- ☐ Fire Departments
- ☐ Universities—health centers
- ☐ Rapid testing sites
- ☐ Physicians/Clinicians
- ☐ General 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/states
- ☐ Law enforcement
  - ☐ Local/state
  - ☐ FBI

☐ **Identify City/State agencies**
- ☐ Sanitarians—sewage—waterworks
- ☐ Medical examiners
- ☐ Local health department
- ☐ Epidemiology
- ☐ Agriculture Departments

☐ Environmental Departments
☐ State press office

☐ **Define role or no role**
  ☐ Pharmaceutical industry: local pharmacology laboratories
  ☐ Biotechnology laboratories

☐ **Discuss communication needs/expectations**
  ☐ Explore "synergy" with all partners

Communications

☐ **Define/Implement pubic 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 contact with Public Information Officer (PIO)**
  ☐ Develop draft press releases or other advance messaging that can be easily modified
  ☐ Develop a plan for disseminating information to the public

☐ **Establish/Utilize system to communicate**
  ☐ Fax or email
  ☐ Teleconferences with public health partners
  ☐ Teleconferences with sentinel laboratories
  ☐ Conference calls (identify who to include)
  ☐ Radio phones

☐ **Establish laboratory partner lists with contact information**
  ☐ Sentinel laboratories
  ☐ Veterinary laboratories
  ☐ Agricultural laboratories
  ☐ Academia/Research laboratories
  ☐ Environmental laboratories
  ☐ Surrounding state or local public health laboratories

☐ **Disseminate state health alert network (HAN) information to sentinel laboratories**
  ☐ What is happening
  ☐ What they need to know (including safety)
  ☐ What public health laboratories need to know
  ☐ Who they need to contact
  ☐ What they need to do

☐ **Lab community**
  ☐ Establish relationships

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- ☐ 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 national health laboratory calls

☐ **Private sector**
- ☐ Communicate public health laboratory 24/7 response role
- ☐ Differentiate from "routine" testing
- ☐ Assure PHL reachable 24/7
- ☐ Define what an emergency (beyond bioterrorism) is, if possible; e.g.: botulism, meningitis

☐ **Every PHL should participate in Epi-X**
- ☐ Use Epi-X info to send out state HAN messages

☐ **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

☐ **Obtain information and resources from APHL**
- ☐ Participate in national health laboratory calls for laboratories
- ☐ Use APHL to represent PHLs "voice"
- ☐ Review & share information (states need to move APHL communications out within the state or local PHL and to cities/counties)
  - ☐ Others within state of local PHL
  - ☐ Cities/Counties
- ☐ Provide technical contacts to APHL
- ☐ Public Relations—"Role of Laboratories"
  - ☐ Sample press release for state to use
  - ☐ Issue state press release

☐ **PHL website**
- ☐ Set up educational pages in advance
- ☐ Keep contact information updated

☐ **Optimize use of available electronic lab capabilities**

Safety

☐ **Provide training and send updated or emergency information**
- ☐ Sentinel laboratories
- ☐ PHL staff

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☐   ☐ Transportation requirements

☐ **Develop a contingency plan for breach of biosafety level (BSL) (e.g. unknown that was processed without proper containment, nonsubtypeable Influenza put into cell culture)**

☐ **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 lab (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**

☐ **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 baseline 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 BSL stop points
    ☐ Define algorithm

☐ **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)**

☐ **Coordinate with epidemiology to implement institutional review board (IRB)/informed consent requirements**

☐ **Assure select agent registration is updated and review select agent requirements**

☐ **Maintain updated knowledge of packaging and shipping regulations and assure compliance**

Samples—Specimens—Transport

☐ **Establish a directory of services**

☐   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)

☐ **Establish repositories of kits in local-regional jurisdictions (e.g. local health departments)**

☐ **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)

☐ **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 advance training or resources for training to sentinel laboratories (if available) and law enforcement
    ☐   Define and distribute PHL expectations for this event to providers, lab community, and law enforcement
    ☐   Assure compliance with 24/7 contact number on shipping documents

☐ **Identify courier options already in use by sentinel laboratories or other partners (tap in where possible).**

☐ **Plan for various alternatives and packaging requirements**
    ☐   Local transport
    ☐   Courier
    ☐   Overnight

☐ **Develop a plan and communicate requirements and facilitate direct shipping of samples from local to CDC when urgent**

☐ **Develop and implement a plan for sample triage and prioritization (link with epidemiology and law enforcement)**

☐ **Plan for things to change**
    ☐   Be prepared to communicate changes to partners quickly

☐ **Communicate role of environmental testing and sample requirements for the event**
    ☐   Establish advance plan if possible
    ☐   Just in time decisions—who needs to be included
    ☐   Who can do BT vs. infection control?

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Testing

- ☐ **Determine minimal verification—validation plan acceptable by CMS/CLIA**

- ☐ **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 confirmatory testing requirements**
  - ☐ Where, what?
  - ☐ QC ⎫
  - ☐ PT ⎬ Determine what is available and how to access it
  - ☐ Discrepant result analysis

- ☐ **Determine and communicate role of testing for other agents**
  - ☐ Rule out/rule in
  - ☐ How far to go with unknowns

- ☐ **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)**

- ☐ **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 need to be on same page
  - ☐ CDC guidance on test performance

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☐   Deal with delays in CDC testing
☐   Coordinate with state press office

☐ **Address state regulations that may impede additional testing—"public health surveillance testing"**
     ☐ Need to find out who/what is available
     ☐ Where is expertise
     ☐ State licensure requirements

Testing In the Private Sector

☐ **Assess private sector capabilities/capacity**
     ☐ Identify who and what can be tested in advance
     ☐ Determine capabilities beyond BT (e.g. rapid influenza diagnostic tests)
     ☐ 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**

☐ **Need to involve state public health agency pre-testing (e.g. SARS)-case definition fit**

☐ **Share protocols with private sector**

☐ **Communicate public health need for private sector test results (e.g. food-borne outbreaks, surveillance)**

☐ **Communicate need/impact on public health response**

☐ **Communicate messages on quality of private laboratory developed testing**

☐ **Communicate need to obtain specimens for confirmatory testing, sub-typing, characterization**

☐ **Public health impact of positive, false positive, false negative results**

Reporting/Data Management

☐ **Establish and clarify role of chief communications officer**

☐ **Assess Data management requirements**

☐ **Identify lead staff and surge staff, 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 during the event**

Staffing

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☐ **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, as necessary**
    ☐ 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

☐ **Provide cross-training, assess competency**
    ☐ By methods groups
    ☐ Across disciplines (bacteriology—virology)

☐ **Identify available reagent sources**
    ☐ CDC
    ☐ Commercial: talk to vendors about emergency supplies (e.g. extraction reagents)
    ☐ Stockpile appropriate reagents

☐ **Inventory and stockpile PPE supplies**

☐ **Assess clinical lab capacity**
    ☐ Define clinical laboratory role in the event and communicate quickly with laboratories

☐ **Define role of CDC or State Referral Centers 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
    ☐ Novel Coronavirus