



Newborn Screening Preparedness/Contingency Planning Framework

During the past several years, APHL members have experienced newborn screening service interruptions due to both natural disasters and manufacturer inability to provide testing materials. APHL served as the central point of contact during these emergencies and assisted programs to maintain services. Contingency planning can lessen the effect of disasters that involve newborn screening program operations.

Newborn screening is an essential, preventive public health program for early identification of medical conditions that can lead to catastrophic health problems. The cost of these conditions if left untreated is enormous, both in human suffering and in economic terms. Therefore, continuity of services is a priority for newborn screening programs.

In 2004, a subcommittee of the APHL Newborn Screening and Genetics in Public Health Committee was established to develop a framework to assist public health laboratories to prepare for and respond to disasters caused by nature, terrorism, and interruptions of testing materials supplies. 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 to prepare for disasters that disrupt newborn screening program operations. Based on experiences of some states, the subcommittee prepared a generic Memorandum of Understanding/Agreement (MOU/MOA) tool that includes elements to be considered by states requiring or preferring this type of mutual assistance agreements. 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 preparing appropriate contingency plans. The subcommittee also recognizes that this checklist may not meet all the requirements for local, regional, and national disasters that may disrupt program operations beyond newborn screening.

PARTNERS

Local Partners

- Hospitals
- Clinics
- Physicians
- Medical Associations
- Hospital Associations
- Case Managers
- Specimen Delivery Systems
- Homeland Security State Agency

City/State Agencies Identified

- Emergency Response Centers

- City
- State
- EMAC (Emergency Management Assistance Compact): national Governor's interstate mutual aid compact that facilitates the sharing of resources, personnel & equipment across state lines during times of disaster & emergency
- Press Offices
 - City
 - State
 - Public Health

National Partners

- APHL
- CDC
- HRSA
- NNSGRC
- Other NBS Programs
- Parent Advocacy Groups
- Manufacturers
- Regional Disaster Organizations
- National DBA of test methods and Capabilities of all NBS

Other Laboratories' Role or No Role Determined

- Reference Laboratories
- Local Public Health Department Laboratories

EMERGENCY LABORATORY TESTING

On-site Operation – Short Term

- Emergency Electrical Power Available for
 - Specimen acquisition
 - Demographic entry / test reporting
 - Case managers
 - Instruments
 - Laboratory information management system
 - Refrigeration
 - Heating and cooling work areas
- Three-Month Supply of Testing Materials Maintained
- Alternate Water Sources Identified

On-site Operation – Long Term

- Tests to be reported are prioritized
- States with same screening materials are identified
- States with similar reporting mechanisms (web based, fax, voice response system, etc) identified

Off-Site Operation

- Contacts identified

- ❑ Memoranda of Understanding established
- ❑ Plan established for compensation
- ❑ Plan established for specimen transport
- ❑ Plan established for communication of abnormal tests results to submitters/specialists
- ❑ Plan established for communication of all test results to submitters
- ❑ Preparation for temporary relocation of staff
 - In-house staff identified
 - Financial mechanisms for travel and housing identified
- ❑ Plan established for access, retrieval, and entry of all data into local information system after local operation re-established

TESTING MATERIALS PROCUREMENT

Manufacturer/Supplier Responsibilities

- ❑ Adequate forward stocking established
- ❑ Alternate transportation plans established
- ❑ Plan to provide equipment to alternate site(s) with timeframe

Laboratory Responsibilities

- ❑ Backup testing methods/plans established
- ❑ Obtained documentation that manufacturer/supplier has
 - Adequate forward stocking established
 - Alternate transportation plans established
- ❑ Contracts hold manufacturer/supplier responsible when materials are not delivered, including
 - Cost of alternate testing instruments, materials, and/or outsourced testing
 - Cost of staff time to implement alternate testing
 - Liability for litigation due to delay in reporting abnormal test results

COMMUNICATIONS

Define/Establish Public Health Laboratory Emergency Response System

- ❑ Incident command system established
- ❑ Chain of command defined
- ❑ Record keeper for events defined
- ❑ Contacts identified
 - At manufacturer/supplier
 - At APHL
 - In other states
- ❑ Call back system for in-house staff defined
- ❑ System tested at least annually
- ❑ System reviewed and updated at least semi-annually

Modes

- ❑ Telephones with Email
 - Landlines

- Cell
- Satellite
- Trunked communication system – computer controlled radio system
- Courier
- Alternate communication systems

MODEL
MEMORANDUM OF UNDERSTANDING
(Some states prefer Memoranda of Agreements)
Between
State A Department of Health
And
State B Department of Health

Purpose

This Memorandum of Understanding (MOU) is being established between State A Department of Health and State B Department of Health to provide reciprocal coverage, to the extent facilities and materials are available, for each other in case of natural disasters, terrorism or other emergencies that could temporarily cause a discontinuation of laboratory services to the citizens of the State.

Emergency Support Services

State A and State B agree to provide, on a temporary basis, laboratory support services to each other, and/or permit the affected laboratory's staff to work in the other's public health laboratory to perform examinations in the event of a natural disaster, terrorist event, or other emergency that could close down "mission critical" functions of State A or State B.

Laboratory services provided on a "temporary basis" means no more than four weeks continuous service for a single occurrence, unless the parties mutually agree in writing to extend the time. Where appropriate, laboratory staff from the affected laboratory may be assigned to work in the public health laboratory that is designated to provide the support services. Assigned employees will comply with rules and regulations of the support laboratory.

Funding

The state laboratory that is confronted with a temporary emergency due to a disaster agrees to reimburse at a reasonable cost the laboratory providing the support services for the cost of reagents, supplies, reproduction of laboratory reports, telephone costs, and shipping and postage fees upon submission of an itemized invoice.

Transportation and Delivery of Specimens/Samples

It shall be the responsibility of the state laboratory confronted with the emergency to arrange for transport of specimens/samples to the laboratory providing support services or space for laboratory examinations.

Chain-of-Custody

All samples/specimens and physical evidence received under chain-of-custody will be maintained under secure conditions during storage, testing and retention of evidence until the case is resolved. Laboratory staff involved in receipt of samples/specimens, storage and testing agrees to respond to court ordered

subpoenas related to these samples/specimens and to testify in court, if necessary. The State agency or attorney(s) who requested the subpoenas will pay for all expenses associated with court appearances. Disposal of samples/specimens and physical evidence received under chain-of-custody must be approved in writing by the submitter or returned to the submitter for disposal.

Contact Persons

A contact person will be identified for laboratory testing in the cooperating laboratories named in this Understanding to allow immediate interaction, assessment of the situation, and appropriate arrangements necessary for the unimpeded flow of services. The contact persons for each laboratory will be the Laboratory Director whose signature is on this Understanding or their successor or designated representative.

Liability

Nothing in this Understanding will create any right of indemnification for the benefit of either party, and each party shall be responsible for its conduct as provided by law. Nothing in this Understanding will be deemed to waive any immunity available to either party, including sovereign immunity.

Terms and Termination

Subject to any rights of termination hereinafter set forth, this Understanding shall become effective immediately, upon all parties signing and shall remain valid for 12 months. This Understanding may be reviewed, and it may be renewed, annually.

This Understanding may be terminated by either party with or without cause upon thirty (30) days advance written notice.

This Understanding shall not be altered, changed, modified or amended except by written consent of all parties to the Understanding.

Signatories

The signatories of this Memorandum of Understanding will be responsible for activating this Understanding whenever a disaster occurs in the Public Health Laboratory operation.

For their respective State Laboratories:

Laboratory Director

Laboratory Director

Date: _____

Date: _____

For the State Agencies:

Commissioner
Department of Health

Commissioner
Department of Health

Date: _____

Date: _____