Public Health Laboratories:
Protecting the Nation’s Health
2012 APHL All-Hazards Preparedness Report

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A decade since that clear, crisp September morning so indelibly etched into the nation’s collective memory, one of the greatest blows to public health preparedness once again threatens to befall the US. It does not involve a hijacked airliner, anthrax in the mail, or a bomb fashioned from a man’s walking shoe. It is a devastation of an entirely different sort and, if effective, has the potential to send achievements in the field of public health preparedness reeling backwards. It is being executed in the form of deep federal funding cuts capable of undoing the major progress that has been achieved in the field of preparedness over the past 10 years.

As front-line defenders of the nation’s public health preparedness and response system, state public health laboratories (SPHLs) provide indispensable services to effectively plan for and respond to public health emergencies of all kinds. SPHLs work to detect, diagnose, and respond to infectious disease outbreaks such as novel influenza strains. Far from nightly news cameras, SPHLs examine mysterious “white powder” letters sent to political officials on a near daily basis. They respond to environmental testing needs in the wake of natural disasters and perform detailed analyses on human clinical specimens to detect and identify chemical threat agents or other contaminants. These examples provide just a taste of the duties routinely performed by SPHLs in the interest of protecting US public health and safety. The ever-diminishing state of preparedness funding is increasingly challenging the ability of SPHLs to continue providing these essential services.

The Association of Public Health Laboratories (APHL) works to assure that state and local laboratories serving the public’s health have the resources and infrastructure necessary to protect the health of the US population and to prevent and control disease globally. In fulfilling this mission, APHL conducts an annual assessment of the ability of state public health laboratories (SPHLs) in all 50 states and the District of Columbia (DC) to respond to various types of emergencies, including deliberate or accidental events involving chemical, biological and radiological contaminants, natural disasters, and environmental catastrophes. These annual assessments provide valuable benchmarks against which to measure both progress and setbacks in laboratory preparedness.
Data obtained from this year’s survey, the 2011 APHL All-Hazards Laboratory Preparedness Survey, highlight the countless contributions made by SPHLs since the establishment of the Centers for Disease Control and Prevention (CDC) Public Health Emergency Preparedness (PHEP) Cooperative Agreement. Survey data also provide a means of identifying gaps and remaining areas of need within the public health laboratory preparedness setting.

Despite the pervasive funding obstacles plaguing the SPHL system, the data contained within the pages that follow will show that not all is gloom and doom. Even in the shadow of turbulent economic and political times, SPHLs have shown hallmark resilience, continuing to thrive in their commitment to moving forward with strengthening laboratory preparedness and response capability and capacity.
Public Health Laboratories: Sustaining the Impact of Reduced Funding

The nation’s SPHLs are not immune to the impacts of proposed funding cuts on the American public health system. While the expectations placed upon SPHLs continue to grow by the day, the funding and resources required to meet these expectations have been declining since 2004. Suddenly, even the most basic elements of laboratory preparedness are in danger of becoming unsustainable.

Figure 1 depicts the ten-year history of PHEP funding allocation as it pertains to the nation’s SPHLs. PHEP funding designated for laboratories (noted by the red bar) was initiated at extremely limited levels between 1999 and 2001. In 2002, post-9/11, laboratory funds increased dramatically and were sustained at roughly the same level throughout 2003. Beginning in 2004, a fairly steady decline can be observed, continuing up to the present funding cycle. The graph illustrates that from funding initiation in 1999, funding allocated for chemical laboratories (noted by the purple bar) lagged significantly behind that allocated for biological laboratories (noted by the green bar).

“We’re seeing a decade’s worth of progress eroding in front of our eyes. Preparedness had been on an upward trajectory, but now some of the most elementary capabilities – including the ability to identify and contain outbreaks, provide vaccines and medications during emergencies, and treat people during mass traumas – are experiencing cuts in every state across the country.”

Jeff Levi, PhD, Executive Director of Trust for America’s Health
While making sense of the funding data depicted by the graph is simple, interpreting the deeper meaning behind the data is anything but. The repercussions of this downward trend in laboratory-specific PHEP funding are both considerable and troublesome for the SPHL community and for overall national preparedness. The 2011 APHL All-Hazards Laboratory Preparedness Survey captured data from SPHLs regarding the impacts of reduced PHEP funding on their organizations. The top five impacts reported by SPHLs included:

1. **Inability to renew service/maintenance contracts for instrumentation**
2. **Loss of full-time staff positions**
3. **Inability to attend training courses**
4. **Inability to provide training courses (or reduced the number of courses) and other outreach activities within their jurisdictions**

5. **Inability to participate in national meetings/conferences**

Moreover, chemical threat activities have been particularly impeded by reduced funding, with many SPHLs reporting inability to purchase critical equipment, hire staff, expand capabilities for new assays/tests, and/or renew service/maintenance contracts for instrumentation.

These serious funding impacts place public health laboratories in the difficult and dangerous position of needing to make choices between hiring and preserving skilled staff, receiving necessary training, and maintaining equipment. All of these activities are critical to SPHLs and to ensuring a sound nationwide preparedness and response system. Leveraging resources such that laboratories are forced to choose between fundamental activities creates enormous vulnerability in the nation’s ability to respond to public health threats.
Background:

Since 1999, public health laboratory preparedness activities have received limited funding support. Following the terrorist attacks of 9/11 and the ensuing Amerithrax events, Congress authorized supplemental funding via the Public Health Emergency Preparedness (PHEP) Cooperative Agreement. The PHEP funding was intended to support nationwide preparedness in state and local public health departments. Administered by the Centers for Disease Control and Prevention (CDC), the PHEP Cooperative Agreement is the primary mechanism for providing funding support to state and large local jurisdictions to support their efforts to prepare for and respond to public health threats. In 1999, CDC, the Federal Bureau of Investigation (FBI) and APHL established the Laboratory Response Network (LRN) – the nation’s premier system for identifying, testing and characterizing potential agents of biological and chemical terrorism. With limited funding, the CDC first supported a small number of laboratories for biological terrorism preparedness and just five laboratories for chemical terrorism preparedness.
At the outset, the PHEP Cooperative Agreement focused the bulk of available resources, time and money on biological terrorism preparedness. In 2002, the CDC determined a hazard gap existed and expanded funding for the LRN to include Chemical Terrorism Preparedness (LRN-C). CDC created plans to build a radiological preparedness component to the LRN, the LRN-R, however funding has yet to become available. A more detailed explanation of the LRN can be found on the CDC website.ii

In 2004, the CDC again acknowledged the need to extend the scope of public health preparedness efforts. As before, the scope of the PHEP Cooperative Agreement was expanded, this time, to mandate adoption of an “all-hazards” approach to public health preparedness and response activities.iii “All-hazards” refers to any public health emergency including biological, chemical, radiological or nuclear. It could involve naturally-occurring incidents such as the H1N1 pandemic, natural disasters such as the 2011 tornado outbreaks that devastated parts of the Midwest, and environmental accidents, such as the 2010 Deepwater Horizon oil spill in the Gulf. Despite this change in scope, no additional funds were allocated.
The challenge of being prepared to address these myriad threats to public health is daunting yet essential. SPHLs must have access to the funding and resources required to develop and maintain the ability to prepare for and respond to all-hazard threats on an ongoing basis.

**Methods:**

Data collection for APHL’s 2011 All-Hazards Laboratory Preparedness Survey occurred during the fall and winter of 2011. The 2011 Survey represents the fifth consecutive year that data on All-Hazards Laboratory Preparedness has been collected by APHL and covers the 12-month time period beginning August 10, 2010 and ending August 9, 2011, representing the CDC PHEP Cooperative Agreement Fiscal Year (FY) 2010, also known as Budget Period 10 Continuation Year. Through participation in the survey, SPHLs reported on their capability and capacity to respond to biological, chemical, radiological and other threats, such as pandemic influenza.

CDC Laboratory Preparedness and Response Branch staff provide training on rapid methods and use of glove boxes to LRN laboratories.
The APHL 2011 All-Hazards Laboratory Preparedness Survey was distributed to laboratories in all 50 states and the District of Columbia. Data were collected using the mriInterview™ platform, a Web-based survey tool and data repository. Results were coded for entry into SPSS for Windows Version 15.0. Descriptive statistics were gathered for all variables. Aggregate survey assessment results for all questions are available at http://www.aphl.org/AboutAPHL/publications/Documents/PHPR_2012_All-Hazards-Survey-Data.pdf.

This year’s report differs from previous All-Hazards Laboratory Preparedness Reports in that it not only showcases data from the 2011 survey, but also highlights prominent data obtained via past APHL preparedness surveys, dating back to 2001. In the following pages, results are reported in six categories: personnel, biological safety level 3 suites (BSL-3 suite), continuity of operations planning (COOP), training, chemical threats and radiological threats. For each category, salient data points derived from the 2011 (FY10) data will be presented alongside related data points from past surveys from 2001 (FY00) and 2005 (FY04) to provide a timeline of the evolution of SPHL preparedness and response activities from funding inception to the present day. For the purposes of this report, the term “states” or “state public health laboratories” will refer to all respondents, including DC.

Reports and briefs from previous all-hazards, biological and chemical threat laboratory preparedness surveys are available online at http://www.aphl.org/aphlprograms/phpr/ahr/pages/default.aspx.

Findings

The 2011 All-Hazards Laboratory Preparedness Survey achieved a 94% response rate, comprised of respondents from 47 of the 50 SPHLs and the DC public health laboratory (n=51).
State public health laboratories provide indispensables services to effectively plan for and respond to public health emergencies of all kinds.
PERSONNEL:

In **2001**, 65% of SPHLs noted that they lacked adequate staff, such as a Biological Terrorism (Threat) Laboratory Coordinator, to manage the anthrax events, and noted the need for additional staff to handle, managerial, clerical, information, communications, training and worker safety. During this same year, funding was not yet in place to help the majority of SPHLs establish a Chemical Terrorism Laboratory Coordinator position.

In **2005**, 83% of SPHLs reported having successfully filled their Chemical Terrorism Laboratory Coordinator position. While 96% of SPHLs reported having a Biological Laboratory Coordinator designated to train staff and oversee relevant testing, only 67% reported having a full-time person designated for this position.

In **2011**, only 44% of SPHLs reported having a Biological Terrorism (Threat) Laboratory Coordinator on staff full-time. Additionally, 46% of SPHLs reported having a full-time Chemical Terrorism (Threat) Laboratory Coordinator on staff.
Workforce Woes

Public health laboratories nationwide continue to grapple with issues pertaining to workforce shortages. Some of the more common challenges faced by SPHLs include a shortage of laboratory professionals entering the workforce, pay discrepancies between the public and private sector, a paucity of scientists with the credentials and experience requisite for upper level management, mandated hiring freezes stemming from the continued economic downturn, and the impending retirement of a significant portion of the workforce. Given that public health laboratories require a highly-skilled and well-trained workforce, these challenges are especially detrimental to SPHL infrastructure. Activities such as investing in laboratory workforce development programs, enhancing recruitment tactics and providing training opportunities for existing laboratorians are pivotal to cultivating and preserving a pool of highly skilled and qualified workers from which to draw.
BIOLOGICAL SAFETY LEVEL (BSL)-3 SUITE:

- In 2001, 21% of SPHLs noted that they lacked BSL-3 capability entirely.\textsuperscript{ix}

- In 2005, while 90% of states reported having a BSL-3 suite on-site, 69% of these laboratories reported needing at least one additional BSL-3 available.\textsuperscript{x}

- In 2011, 100% of SPHLs reported having BSL-3 suites available on-site.
BSL-3 Suites Explained

A Biological Safety Level-3 suite, or BSL-3 suite, is a contained area within a laboratory that must meet stringent requirements for biosafety. For example, BSL-3 suites must include biosafety cabinets, controlled double door access, and engineering controls, including maintaining negative air pressure relative to the surrounding rooms (which direct all air flow into the BSL-3 suite, not out into the surrounding rooms), microfiltration of air, and air-lock buffer zones. The number of existing suites and need for additional ones is a strong indicator of overall biothreat capacity in the nation. In the absence of these safe and secure work spaces, even laboratories operating with top-notch staff and state-of-the-art instrumentation face major limitations in terms of capacity and capability for testing biological threat agents.\textsuperscript{xi}
CONTINUITY OF OPERATIONS PLAN (COOP):

- In **2001**, pre-anthrax, most public health laboratories did not have a continuity of operations plan (COOP) – in fact, COOP was not even part of the standard vocabulary.

- In **2005**, 66% of SPHLs reported having some form of a COOP in place. Just 38% of SPHLs reported having a COOP in place that was specific to the laboratory.

- In **2011**, 88% of SPHLs reported having a laboratory-specific COOP or a state agency or department-wide COOP in place that included the laboratory functions. The remaining 12% of laboratories noted that they are developing a COOP.
The Scoop on COOP

A public health laboratory Continuity of Operations Plan, or COOP, is a comprehensive, pre-event plan that describes the procedures, policies, and arrangements necessary for the laboratory to respond quickly and effectively to a wide variety of possible disruptions or threats. A COOP describes what is in place, what the laboratory does to respond, and what is required to maintain the COOP. APHL created model guidelines to assist public health laboratories in developing a plan to assure continuity of operations during an emergency. The Guidelines for the Public Health Laboratory Continuity of Operations Plan can be accessed on the APHL website at: http://www.aphl.org/aphlprograms/phpr/Documents/PHL_COOP_Guidelines.pdf.
• In 2001, 75% of SPHLs reported having sponsored some sentinel clinical laboratory training in their state.\textsuperscript{xii}

• In 2005, 92% of SPHLs sponsored sentinel clinical laboratory training in their state, offering a total of 515 courses to over 5,000 laboratorians. Training topics covered rule-out testing, packaging and shipping, and biosafety guidelines. Only 62% of SPHLs conducted drills with their sentinel clinical laboratory community to test the SPHLs 24-hour emergency response system in 2005.\textsuperscript{xiv}

• In 2011, 85% of SPHLs reported sponsoring sentinel clinical laboratory training in their state, offering a total of 477 courses to over 8,360 laboratorians from 3,187 different facilities. Training topics covered rule-out testing, packaging and shipping, and biosafety, or some combination of these topics. Also in 2011, SPHLs conducted over 496 preparedness exercises ranging from table-top exercises, to drills, to functional exercises, to full-scale exercises to real-life events. Exercise scenarios involved handling chemical, biological, radiological and multi-hazard threats, pandemic influenza, COOP, and other preparedness topics.
Training and Outreach Education:  
A Cornerstone of Nationwide Laboratory Preparedness

Training and education for laboratory staff in both the public and private sectors is a recognized core function of state public health laboratories. Broadly speaking, any laboratory (public or private) capable of analyzing or referring specimens or samples that may contain microbial agents or biological toxins constitutes a sentinel clinical laboratory in the LRN. SPHLs assume primary responsibility for assuring that the sentinel clinical laboratories in their jurisdictions are able to perform tests of public health significance with a high degree of proficiency. SPHLs engage in continuous training and outreach efforts with sentinel clinical laboratories, providing guidance on proper rule-out and referral of specimens of potential public health significance to their designated LRN reference laboratory. Additionally, SPHLs educate sentinel clinical laboratory staff about required specimen reporting, packaging and shipping protocols. Beyond sentinel clinical laboratories, SPHLs also work to establish and maintain training and outreach relationships with local public health laboratories; veterinary, agricultural, food safety, university and military laboratories; as well as local law enforcement, FBI Weapons of Mass Destruction (WMD) Coordinators, and National Guard Bureau/Civil Support Teams.
CHEMICAL THREATS:

• In 2001, a mere 5 SPHLs (California, Michigan, New Mexico, New York, and Virginia) possessed any capability and capacity to perform testing and analysis for chemical threat agents.

• In 2005, few SPHLs reported capability to detect chemical warfare agents such as vesicants and incapacitating agents (2%), choking agents (4%), blood agents (25%) and nerve agents (0%).

• As of 2011, 63% of SPHLs reported being qualified in eight or more core methods to detect chemical threats including chemical warfare agents such as vesicants, choking agents, blood agents, incapacitating agents and nerve agents.
Anatomy of a Chemical Threat

When it comes to preparing for and responding to chemical threats, timing is truly everything. In most cases, a chemical event does not involve any type of incubation period. As such, people experience a rapid onset of illness, typically occurring well in advance of the cause being identified. A chemical event necessitates that first responders and clinicians take immediate action, often in the absence of any cold, hard facts regarding the nature of the event. The healthcare system must obtain information and facts as quickly as possible in order to help direct their response efforts. Given the sheer unpredictability of chemical threat scenarios, anticipating the most serious risks posed to the surrounding community and preparing for those risks is of paramount importance. Activities required include aligning laboratory identification, detection and analytical capability and capacity, highlighting available just-in-time training resources, and having awareness about other preparedness and response tools in order to meet the challenges likely to arise. Chemical incidents generate a strong sense of fear, uncertainty, and crisis, so risk communication efforts must be coordinated and clear. Conflicting messages between and amongst response agencies only serve to increase anxiety. If laboratory diagnostic testing is available and well-coordinated communications are in place, then test results can help to facilitate risk communication messages being sent to relevant partners who, in turn, communicate effectively with the public.\textsuperscript{xvii}
Despite progress made in laboratory preparedness for chemical and biological threats, readiness for radiological threats persists as a significant and critical gap in overall laboratory preparedness infrastructure. With the exception of limited funding targeted for radiochemistry testing in food via the Food Emergency Response Network (FERN), funding support for radiological analysis of clinical specimens in SPHLs is virtually non-existent.

Based on data from a 2009 survey as well a 2011 survey focused exclusively on radiation readiness, 27% of respondents reported the ability to measure radionuclides in clinical specimens; 6% reported that another state agency or department accepts and analyzes these samples via a radio-analytical method. Additionally, 60% reported the ability to test environmental samples, such as air, soil or surface water, for radiation; 48% reported the ability to test non-milk food samples; 47% reported the ability to test milk; and 56% reported sending data for drinking water to EPA.
In 2007, federal experts estimated it would take more than four years to screen 100,000 individuals for radiation exposure and six years to test environmental samples from a large-scale radiological emergency, relying on then-existing laboratory assets. Adequate preparation requires significant new investment to build and enhance laboratory emergency response networks, as well as investments in the broader public health system in which public health laboratories function. Although there is a well-documented gap in laboratory preparedness for radiological threats, Congress has yet to appropriate funding. Attempts to move forward in addressing radiological preparedness needs in the laboratory have been formidable given the expense of equipment required for the complex analyses and the extensive nature of the training needs involved.

APHL Member Laboratories Assist in Radiochemical Surveillance and Monitoring, Following the Devastating Earthquake/Tsunami in Japan

On March 11, 2011, a 9.0 magnitude earthquake in northwest Japan triggered a string of events that endangered the Japanese and put the US on high alert. The subsequent tsunami caused flooding, a series of explosions and the destabilization of the Fukushima Nuclear Power Plant in Japan, releasing radiation into the environment. Given the phenomenon of transboundary pollution, which occurs when pollution originating in one country damages another country’s environment by crossing borders through pathways like water or air, the events in Japan posed a valid and serious threat to the US. State public health laboratories in Washington, Massachusetts, Vermont, Oregon and Maryland quickly sprung into action, collecting and analyzing numerous environmental samples including air, precipitation, surface, ground and drinking water, sea water, soil, vegetation and milk for the presence of radiochemical contamination.
CONCLUSION

This report illustrates many notable strides made by SPHLs in enhancing their preparedness infrastructure over the past decade, even in the face of continual funding and resource allocation obstacles. In addition to demonstrating the enormity of the progress and significance of the contributions made since the inception of public health laboratory preparedness funding, this report has also cast a spotlight on the remaining needs of the SPHL system. Data points presented in this report recognize advancements in nearly every aspect of SPHL operations, including capacity and capability for chemical and biological threat detection and analyses, emergency planning, workforce development, and training. Still, many issues go unaddressed; among the more serious are funding shortfalls, gaps in radiological testing capability and capacity, and a continued scarcity of qualified laboratory workforce members.

In the absence of funding designated for continued technology acquisition, workforce development, training and education in the laboratory preparedness field, the momentum and successes gained in the past decade seem poised to come to a screeching halt, followed by a series of unfortunate steps backward.

APHL continues to offer unwavering support to SPHLs in their need for sustained funding and resource allocation. Only through a continued investment in SPHLs can appropriate capacity and capability for all-hazards preparedness be guaranteed. Creating a lasting culture of preparedness is not a one-shot deal. Funding and support must instead be constant and designed to evolve in tandem with the ever-changing needs and untold hazards encountered daily by the US public health laboratory system.
Leveraging resources such that laboratories are forced to choose between fundamental activities creates enormous vulnerability in the nation’s ability to respond to public health threats.
Laboratories in Action: A Decade of Preparing, Detecting and Responding to Public Health Threats

2001
- World Trade Center Attacks and Anthrax Attacks

2002
- West Nile Virus
- SARS
- Pilgrim’s Pride frozen and prepared poultry recall (Listeria outbreak)

2003
- Global SARS alert issued by the World Health Organization
- 37 confirmed cases of Monkeypox virus in Midwestern States
- Hepatitis A Outbreak
- Mad Cow Disease discovered in the USA
- Testing for Ricin Toxin, Tularemia, Anthrax
- Hurricane Isabel

2004
- Ricin detected in US Senate mailroom
- Salmonella outbreak linked to raw almonds
- Tomatoes contaminated with Salmonella caused >400 illnesses
- Hurricanes Charley and Frances
- Flu vaccine shortage
- H5N1 avian influenza
- G8 Summit
- Special Events: Summer Olympics; Democratic and Republican National Conventions

2005
- Tomatoes contaminated with Salmonella sicken 29 people in 16 states.
- Hurricanes Katrina, Rita and Wilma
- Major Salmonella outbreak
- Marburg Virus

2006
REFERENCES:


