APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

MARCH 2009

State Public Health Laboratories:

Sustaining Preparedness in an Unstable Environment

The Association of Public Health Laboratories (APHL) is a national non-profit organization dedicated to working with members to strengthen governmental laboratories that perform testing of public health significance. By promoting effective programs and public policy, APHL strives to provide member laboratories with the resources and infrastructure needed to protect the health of US residents and to prevent and control disease globally.

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Cover photo courtesy of CDC/ Hsi Liu, PhD, MBA; James Gathany (2007).

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Courtesy of Maureen Sullivan, MPH, Minnesota Department of Health

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EXECUTIVE SUMMARY

The Association of Public Health Laboratories (APHL) conducted its first assessment of state public health laboratories' (SPHL) all-hazards preparedness in 2007. Since then SPHLs have made incremental progress in building and maintaining new partnerships, hiring and training new personnel, conducting outreach to build statewide laboratory networks, providing training to other laboratories and partners, and implementing formal exercises and drills to assess gaps in planning, testing capability and capacity. However, in this era of budget deficits, increasing expectations and evolving threats, the ability of state public health laboratories to sustain core preparedness functions is in jeopardy.

APHL conducted data collection for its second All-Hazards Laboratory Preparedness Survey in fall 2008 to document both the improvements that laboratories have made and the challenges that they face. Participants reported on laboratory capability and capacity for biological, chemical and radiological terrorism preparedness for a period of 12 months from August 31, 2007 to August 30, 2008, representing the Centers for Disease Control and Prevention (CDC) Public Health Emergency Preparedness (PHEP) Cooperative Agreement Fiscal Year 2007 (FY 07), also known as Budget Period 8. The 2008 survey was sent to the 50 states, the District of Columbia (DC) and Puerto Rico. Fifty-one responses were received, representing all states and the District of Columbia for a response rate of 98%.

Despite notable improvements, serious gaps in workforce and real-time electronic data messaging still remain. The area most impacted by funding cuts is workforce, the core of a laboratory's ability to respond. Many laboratories are being forced to combine positions, such as scientists and training coordinators, when both jobs are necessary for an effective response. Not only is the ability to respond to an event compromised with fewer staff, but so is the ability to take on mounting responsibilities, such as training partners and adding new detection methods.

Key findings include:

FUNDING

Federal funding for state and local preparedness has been significantly reduced despite increased responsibilities. In FY 07, state and local health departments received approximately $897 million (this amount includes a $175 million pandemic influenza supplement) from the CDC PHEP Cooperative Agreement, which represents a more than $40 million reduction from the previous fiscal year. **Of this amount, 51 SPHLs reported receiving approximately $78 million to develop and maintain capacity and capability for detecting potential agents of biological and chemical terrorism. This represents only about 9% of the total amount awarded to the states and a continued decrease from previous years' funding.**

Bioterrorism Preparedness Funding

State public health laboratories, which are tasked with performing testing for biological terrorism agents, are being asked to take on even more responsibilities with drastically less funding.

- Fifty-one SPHLs reported receiving approximately $48.6 million from the CDC PHEP Cooperative Agreement to develop and maintain capacity and capability for detecting potential agents of biological terrorism. This represents only about 5% of the total amount awarded to the states, and is a far cry from the nearly $104 million received in FY 2004.

Chemical Terrorism Laboratory Funding

In 2006, CDC expanded the number of level 1 laboratories from five to ten but was unable to add funding to cover these additional laboratories. As a result, ten laboratories are sharing the $7.2 million funding that was intended for five laboratories. Level 2 and level 3 SPHLs receive funding based on state allocations of CDC's PHEP Cooperative Agreement. These laboratories received approximately $22 million in FY 07, less than half of what they received in 2003.

As a result of these cuts, SPHLs found themselves unable to expand their capabilities or purchase new equipment, unable to participate in large conferences and national meetings and reported difficulties retaining staff.

Radiological Preparedness

Laboratories lack sufficient funding, staff, methods and equipment to respond to incidents which may involve a radiological agent.

- In FY 07, the majority of SPHLs reported that they did not have any staff trained to test for radionuclides, while few states had only one or two trained staff.
- Only 15 SPHLs (29%) can measure clinical specimens for radionuclides. Of those, only 12 can measure uranium and a few can measure other radionuclides, such as cesium, cobalt or plutonium.
- **Thirty-six SPHLs (71%) cannot measure clinical specimens for radionuclides; only 25% of these laboratories have another department to which they can send the sample for analysis.**

WORKFORCE

Several issues, namely funding, have continually diminished the capability of state public health laboratories to build and sustain the necessary workforce to carry out their duties to protect the public's health. SPHLs face a shortage of laboratory professionals entering the workforce, pay discrepancies between private and governmental enterprises, a scarcity of individuals with the experience and credentials needed to assume senior management roles, and an aging worker population that nears retirement. Without significant changes in the workforce pipeline, public health laboratories cannot staff vacant positions. This leads to a lack of properly skilled workers to ensure effective detection and response during emergency events.

- When asked to rank their most common workforce difficulties, 20 SPHLs (41%) cited hiring as their top difficulty, 13 SPHLs (28%) choose retention, and 11 (22%) choose recruitment. Only 7 (14%) SPHLs did not experience any workforce challenges in FY 07.
- Of those laboratories who identified hiring as the chief concern, 36% ascribed it to a lack of funding and 31% to hiring freezes. Of those that felt retention was the most pressing concern, 61% believed that non-competitive wages were at fault. Finally, of the SPHLs that believed recruitment was the largest issue, 54% cited lack of qualified applicants and 45% cited non-competitive salaries as the reasons. **Overall the key issues were non-competitive salaries, lack of qualified applicants, hiring freezes and lack of funding. These factors make it difficult for SPHLs to compete with private and governmental agencies for qualified candidates.**

In addition to the previously noted workforce challenges, state public health laboratories are faced with shrinking budgets and are forced to combine many positions, placing significant responsibilities on few personnel. Responsibilities of positions, such as Biological Laboratory Coordinators, Chemical Terrorism Laboratory Coordinators, State Training Coordinators, Assistant Chemical Terrorism Laboratory Coordinators, Liaisons to Hospitals/Sentinel Laboratories and Coordinators for First Responders are often being combined.

- Thirty-three SPHLS (65%) have combined the duties of their state training coordinator (STC) with another position. This is a substantial increase from last year when only 16 states reported that they combined duties of the STCs with another position. Thirty-one SPHLs (61%) have a full time Biological or Chemical Terrorism Laboratory Coordinator. Only 15 respondents (29%) have a full time staff liaison to sentinel laboratories or hospitals, while 34 (67%) have combined these duties with another position. Thirty-eight SPHLs (74%) have combined the duties of their first responder coordinator, up from 28 in FY 07.

SAMPLE RECEIPT AND ANALYSES

The workforce issues facing the SPHLs are even more daunting given the volume of samples flooding the laboratories.

- **In FY 07, 48 SPHLs received a total of 3,583 clinical specimens and 47 SPHLs received 1,675 environmental samples for analysis of threat agents.** As a result, laboratories performed 5,937 tests on the clinical specimens and 3,152 tests on environmental samples, a total of more than 9,000 tests. SPHLs received approximately the same number of samples in FY 06 with 98% being tested for biological agents and 66% for chemical agents.

Of note, fewer tests are performed for chemical threat agents because many states lack the capability to analyze environmental samples for chemical threat agents. All SPHLs (100%) accept clinical specimens for analysis of chemical threat agents, while only 35 (69%) accept environmental samples for similar analyses. **Often, laboratories receive an environmental sample for analysis before they do a clinical specimen; therefore, the ability to test environmental samples for chemical threat agents could result in an earlier identification of a chemical threat.**

Given the volume of testing it is essential that state-wide courier services are available to the SPHLs. This entails having an effective method to quickly move samples as needed for routine and emergency situations. Without a reliable service, substantial delays will occur between sample receipt, testing and reporting of results.

- **Discouragingly, only 21 state public health laboratories (41%) have a 24-hour intrastate courier system for specimen pickup and delivery, which is only a slight improvement from last year.**

PREPARING, PARTNERING, EXERCISING AND RESPONDING

Building strong partnerships is only one step in the process of maximizing effectiveness in emergency preparedness and response. By performing drills, exercises and proficiency tests, public health laboratories can better understand their true capabilities, capacity, and assess their training efforts. No test, however, can substitute for practice during a real event. Even though there have not been any large scale terrorist events since the anthrax attacks of 2001, the laboratories perform vital roles in public health preparedness and disaster response.

- **Respondents have either developed their own Continuity of Operations Plan (COOP) (23 SPHLs), are part of their broader state's COOP (15 SPHLs) or are in the process of developing a COOP (13 SPHLs).** Of the 23 SPHLs that have a COOP in place, only 16 tested their COOP to ascertain its strengths and weaknesses. This is a marked improvement from FY 04, when only 18 SPHLs had a COOP and 14 states included laboratory operations in their COOP. To better understand the capabilities and weaknesses of the COOP, it is imperative that laboratories exercise this plan.

Forty-nine states (96%) assessed the competency of sentinel clinical laboratories to rule out biological terrorism agents. Comparable to last year, 42 states used the Laboratory Preparedness Exercise (LPX), which is jointly developed by the College of American Pathologists, CDC and APHL, to assess the preparedness competency of sentinel clinical laboratories.

One area where SPHLs have shown marked improvement over the years is sentinel laboratory and first responder connectivity. These relationships have been cultivated to allow for faster response time and more effective communication during an emergency event.

- **Forty-eight SPHLs (94%) provided training for sentinel laboratories reaching thousands of laboratorians.**

From August 2007 to August 2008, state public health laboratories sponsored sentinel clinical laboratory training and offered 233 rule-out testing classes to more than 2,100 laboratorians; about 250 packaging and shipping classes to more than 3,500 laboratorians; about 530 biosafety guidelines classes to approximately 2,300 laboratorians; and more than 250 classes on broad laboratory practices to more than 2,700 laboratorians.

- The majority of SPHLs communicate on a frequent basis with partners such as environmental laboratories (52%), local law enforcement and first responders (54%), local public health laboratories (57%), Civil Support Teams (58%), and FBI/Weapons of Mass Destruction Coordinators (61%).
- Forty-one SPHLs (80%) conducted outreach activities, 36 SPHLs (71%) provided training to first responders, nine SPHLs (18%) issued a proficiency test and eight SPHLs (16%) provided other services to first responders. For the few states unable to reach out to first responders, the most commonly cited roadblocks to outreach were lack of funding, lack of staff and lack of national guidance on training and proficiency tests for first responders.

SPHLs are also responding to real events to ensure public health preparedness in their communities. Recently, the University of Iowa Hygienic Laboratory, Iowa's State Public Health Laboratory, responded to epic Midwest flooding. Further, public health laboratories in Minnesota and Colorado ramped up their preparedness to provide coverage for political conventions.

CONCLUSIONS

State public health laboratories have made great strides in preparedness since first receiving funding from CDC in 1999. These laboratories have steadily built a strong network to respond to both biological and chemical threats. Each year of the PHEP Cooperative Agreement, APHL's data showed progressive improvements on both the biological and chemical components of the laboratories. However, data from this year's assessment revealed that the progress has slowed and this is attributed to the funding reductions.

APHL is calling for restoration of preparedness funding for state public health laboratories, designated funding for SPHLs to develop radiological capability and capacity, continued development of training programs for public health laboratorians, implementation of integrated, standardized laboratory data exchange to support real-time transmission of pertinent laboratory data in SPHLs and coordination of these efforts across the multiple laboratory networks, and more outreach between the first responder, sentinel clinical laboratory and public health laboratory communities.

Photo courtesy of CDC. Photo credit: James Gathany (2004).

State Public Health Laboratories:
Sustaining Preparedness in an Unstable Environment

INTRODUCTION

The Association of Public Health Laboratories (APHL) conducted the first assessment of state public health laboratories' (SPHL) all-hazards preparedness in 2007 to document the significant advances that laboratories have made in preparedness since the inception of the Centers for Disease Control and Prevention (CDC) Public Health Emergency Preparedness (PHEP) Cooperative Agreement. APHL concluded data collection for the second such assessment in December 2008. Over the years, SPHLs have made incremental progress in building and maintaining new partnerships, hiring and training new personnel, conducting outreach to build statewide laboratory networks, providing training to other laboratories and partners, and implementing formal exercises and drills to assess gaps in planning, and capability and capacity to respond to all-hazard threats.

However, in this era of budget deficits, increasing expectations and evolving threats, the ability of state public health laboratories to sustain core preparedness functions is in jeopardy. Despite notable improvements, serious gaps in workforce and real-time electronic data messaging still remain. One of the key findings of the 2008 survey was that the laboratory asset most impacted by these funding cuts is workforce, the core of a laboratory's ability to respond. Many laboratories are being forced to combine positions, such as bench scientists and laboratory training coordinators, when both jobs are necessary for an effective response. Not only is the ability to respond to an event compromised with fewer staff, but so is the ability to take on the mounting responsibilities, such as participation in additional, threat-specific preparedness networks, training of new partners, and adding new detection methods.

Emergencies, infectious diseases, natural disasters, toxic spills: Public health laboratories must be prepared to respond instantly to any health threat.

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THE LABORATORY RESPONSE NETWORK STRUCTURE

Formed in 1999 by the CDC, the Federal Bureau of Investigation (FBI) and APHL, the Laboratory Response Network (LRN) is the nation's premier system for identifying, testing and characterizing potential agents of biological and chemical terrorism.[1]

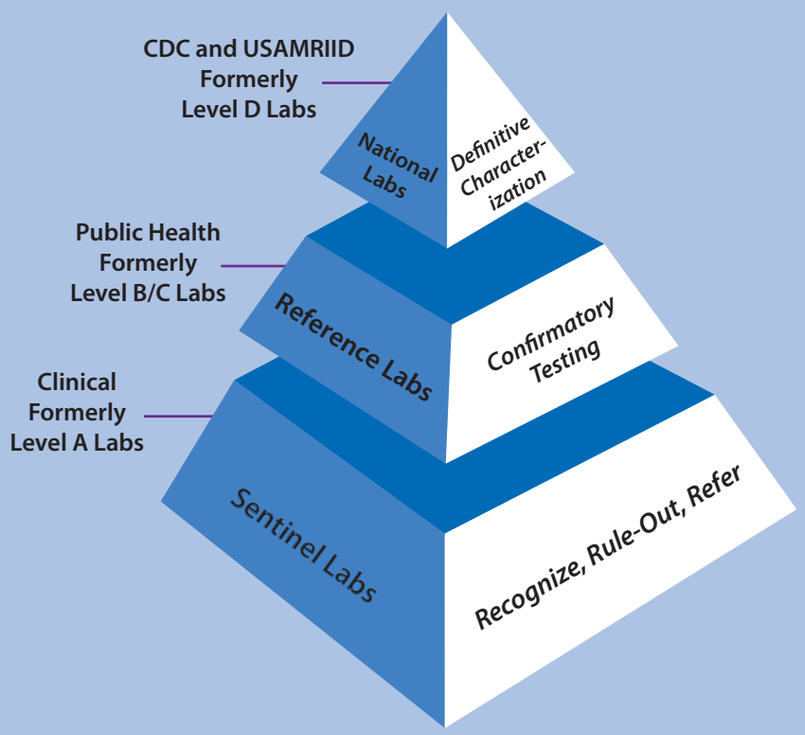
State and local public health laboratories comprise approximately 70% of the 165 LRN Biological Reference Laboratories and almost 100% of the LRN Chemical Laboratories. These laboratories produce high-confidence test results that are the basis for threat analysis and intervention by both public health and law enforcement authorities.

THE LABORATORY RESPONSE NETWORK FOR BIOLOGICAL TERRORISM PREPAREDNESS

The LRN for Biological Terrorism preparedness is organized as a three-tiered pyramid (See Figure 1). At the foundation are thousands of sentinel clinical laboratories, which perform initial screening for potential pathogens. When sentinel clinical laboratories cannot rule out the presence of a biological terrorism agent, they refer specimens and isolates to an LRN reference laboratory. More than 160 state and local public health, military, international, veterinary, agriculture, food, and water testing laboratories serve as reference laboratories, performing complex analyses and providing support to law enforcement for threat investigations.

In addition to laboratories located in the United States, facilities located in Australia, Canada, and the United Kingdom serve as reference laboratories abroad. At the apex of the pyramid are national laboratories, such as those at the CDC and the Department of Defense (DoD). These laboratories test and characterize samples that pose challenges beyond the capabilities of reference laboratories, and provide support for other LRN members during a serious outbreak or terrorist event. The most dangerous or perplexing pathogens are handled only at BSL-4 laboratories at CDC and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID).

FIGURE 1: **The Laboratory Response Network for Biological Terrorism Preparedness**

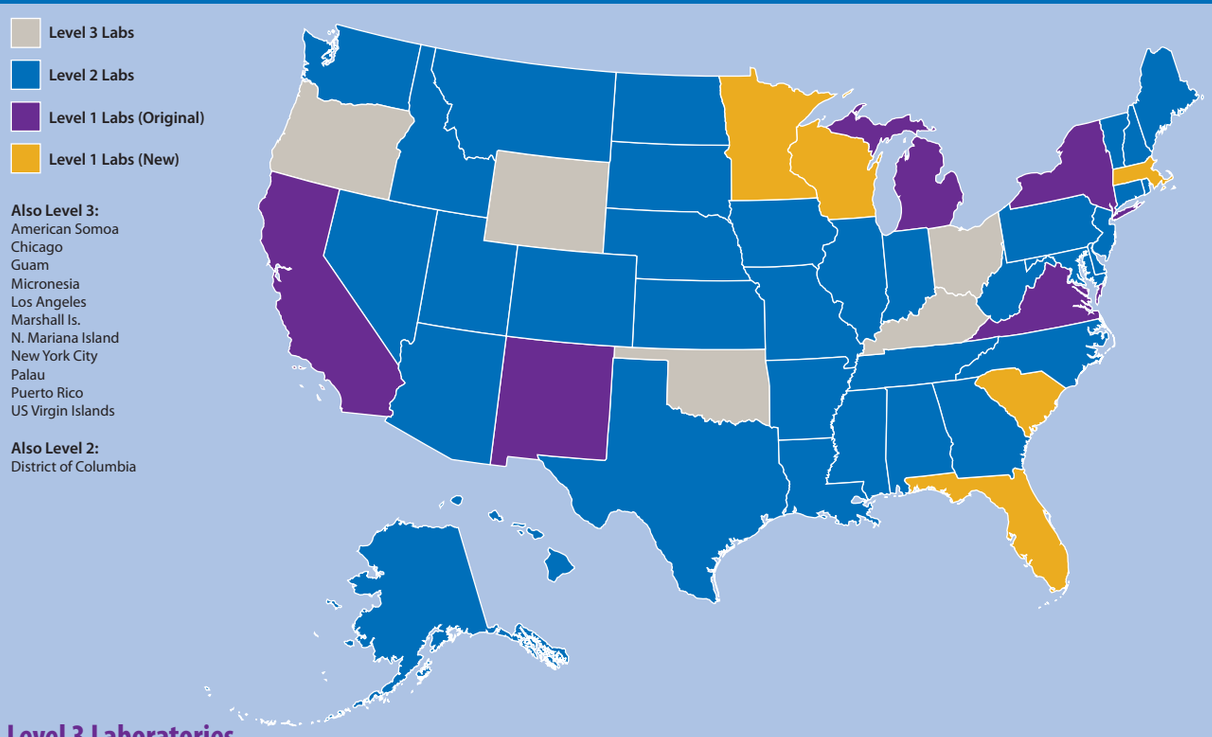


(LRN) Structure for Bioterrorism Response
National, reference, and sentinel laboratories work as an integrated network that builds upon individual laboratory capacity in order to respond to public health emergencies.

THE LABORATORY RESPONSE NETWORK FOR CHEMICAL TERRORISM PREPAREDNESS

The chemical component of the LRN (LRN-C) consists of 62 state, territorial and metropolitan public health laboratories. Laboratories are designated Level 1, 2 or 3 based on the laboratory's capabilities; these designations in turn define the laboratory's network participation (See Figure 2).

FIGURE 2: Laboratory Response Network for Chemical Terrorism Preparedness



Level 3 Laboratories

All 62 LRN member laboratories have Level 3 characterization and are responsible for Level 3 activities. These activities include working with hospitals and first responders in their jurisdiction to maintain competency in clinical specimen collection, storage and shipment; familiarity with chemical agents and their associated health effects; and maintaining an up-to-date coordinated response plan for their respective states.

Level 2 Laboratories

Thirty-seven laboratories are designated as Level 2 laboratories within the LRN. These laboratories can detect exposure to a limited number of toxic chemicals—such as cyanide or toxic metals—in human specimens such as blood or urine.

Level 1 Laboratories

Ten laboratories in the nation are Level 1 laboratories within the chemical LRN. These laboratories can detect an expanded number of chemical agents in human specimens, including all Level 2 laboratory analyses plus analysis for mustard agents, nerve agents and other toxicants that could be used in chemical warfare. These laboratories are intended to provide the CDC with much needed surge capacity during a large scale event. However, the 10 designated Level 1 laboratories are not fully funded to sustain Level 1 surge capacity and if funding levels continue to decrease, surge capacity may be lost.

THE LABORATORY RESPONSE NETWORK FOR RADIOLOGICAL TERRORISM PREPAREDNESS

CDC is planning to develop a radiological terrorism preparedness component to the LRN (LRN-R). They are currently working on newer and more rapid methods to analyze clinical specimens for radioactive materials, a vital component of the response to an event involving human radiation exposure. Once funded, the LRN-R will be structured similarly to the LRN-C with some laboratories having full capability to analyze radiological specimens, others more limited capability and others with capability for packaging and shipping the specimens to a laboratory with higher functionality.

BACKGROUND

Bioterrorism preparedness activities and some chemical terrorism preparedness activities have been funded since 1999. It was not until 2002, shortly after the events of 9/11 and subsequent anthrax attacks, that Congress authorized supplemental funding via the Public Health Emergency Preparedness (PHEP) Cooperative Agreement to support nationwide preparedness in state and local public health departments.[2] The PHEP Cooperative Agreement is administered by CDC and has become the primary mechanism for funding states and larger local jurisdictions to better prepare and respond to public health threats.

Because the 2001 incidents involved a biological agent, *Bacillus anthracis* (anthrax), the PHEP program originally focused on biological terrorism preparedness. In 2002, CDC created the LRN for Chemical Terrorism Preparedness (LRN-C), and by 2003, states used PHEP funding to develop varying levels of chemical threat preparedness, with specific funding set aside by CDC to build five chemical threat surge capacity laboratories. Recognizing the need to broaden the focus of public health preparedness even further, in 2004, CDC expanded the Cooperative Agreement's scope to include all-hazards preparedness, although it did not provide additional funding.[3] "All-hazards" refers to any public health emergency, including biological, chemical, radiological or nuclear terrorism, naturally occurring infectious disease outbreaks (such as pandemic influenza), natural disasters and accidents. Today, state public health laboratories are striving to develop the capacity and capabilities needed to fulfill their role in such an all-hazards preparedness system.

METHODS

Data were collected in the fall of 2008 when APHL fielded its second annual All-Hazards Laboratory Preparedness Survey. Participants reported on state public health laboratory (SPHL) capability and capacity to respond to biological, chemical and radiological threats. The current survey covers the 12 months from August 31, 2007 to August 30, 2008, representing CDC PHEP Cooperative Agreement Fiscal Year (FY) 2007, also known as Budget Period (BP) 8. Reports and briefs from previous all-hazards, biological and chemical terrorism laboratory preparedness surveys are available at APHL's website, www.aphl.org.

The 2008 survey was sent to the 50 states, the District of Columbia (DC) and Puerto Rico. Fifty-one responses were received, representing all states and the District of Columbia for a response rate of 98%. Unless otherwise noted, 51 responses were received for each question. For the purposes of this report, the term "states" or "state public health laboratories" will refer to all respondents, including DC.

The survey was administered via mrInterview, a web-based repository of data and a survey tool. Results were coded for entry into SPSS for Windows Version 15.0. Descriptive statistics were gathered for all of the variables. Results are reported for the following categories:

- Funding for Laboratory Preparedness Activities
- Workforce
- Sample Receipt and Analyses
- Planning, Partnering, Exercising and Responding

RESULTS

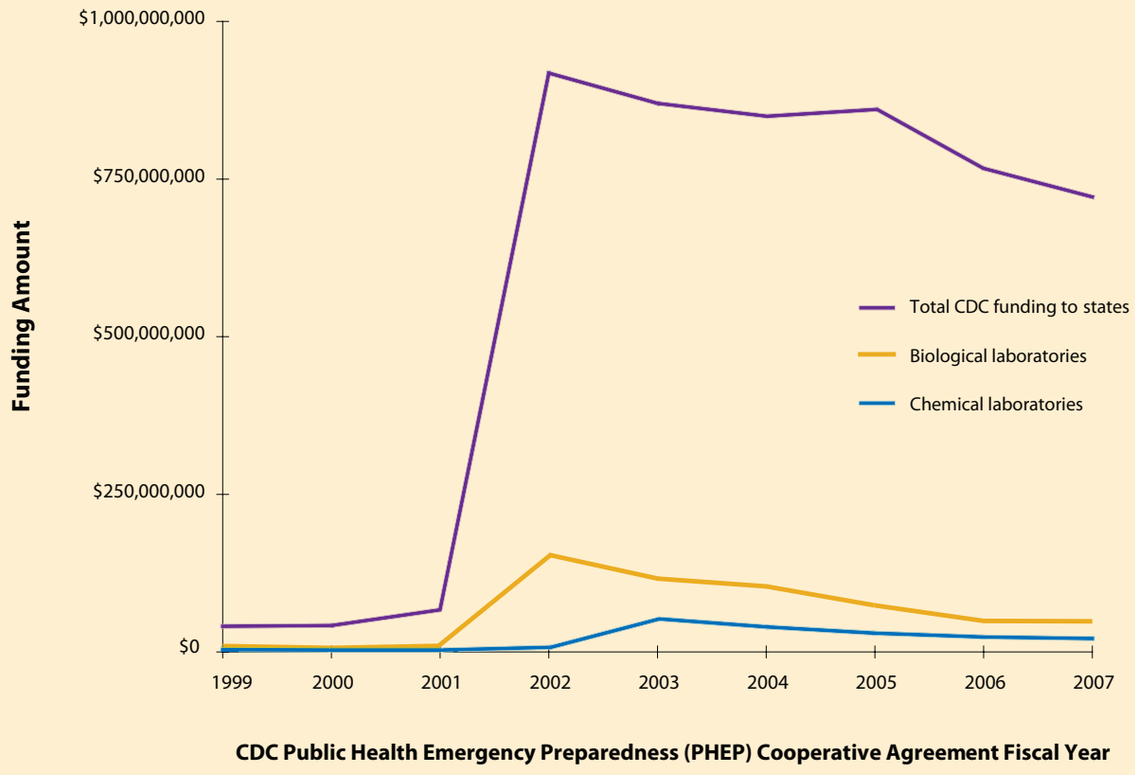
FUNDING FOR LABORATORY PREPAREDNESS ACTIVITIES

In 2002, following the anthrax attacks, state and local health departments received a total of $918 million under the program, and dedicated just over $146 million for state and local public health laboratory improvements. Since then, overall PHEP funding has continued to decline and with it, funding levels for both biological and chemical laboratory preparedness (See Figure 3).

Federal funding for state and local preparedness has been significantly reduced despite increased responsibilities. In FY 07, state and local health departments received approximately $897 million (this amount includes a $175 million pandemic influenza supplement) from the CDC PHEP Cooperative Agreement, which represents a more than $40 million reduction from the previous fiscal year. Of this amount, 51 SPHLs reported receiving approximately $78 million to develop and maintain capacity and capability for detecting potential agents of biological and chemical terrorism. This represents only about 9% of the total amount awarded to the states and a continued decrease from previous years' funding.

FIGURE 3: FY 99 – FY 07 Public Health Emergency Preparedness Funding from CDC to States

*(Note: FY 05–07 does not include the Pandemic Influenza Supplemental Funding)



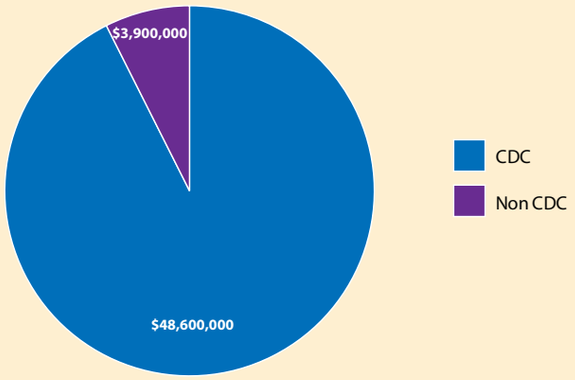
APHL's president, Frances Pouch Downes, DrPH, testifying before the House Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology of the Homeland Security Committee.

Downes's testimony addressed the impact of an under-funded federal program on public health laboratories.

RESULTS

In FY 07, only 10 SPHLs received federal support from non-CDC sources for a combined total of approximately $3.9 million. Given the funding streams, laboratory competency and capacity are very tightly tied to CDC PHEP funding levels (Figure 4).

FIGURE 4: FY 07 Federal Funding Sources for State Public Health Laboratory Preparedness, Based on a Reported Total of $52.5 million



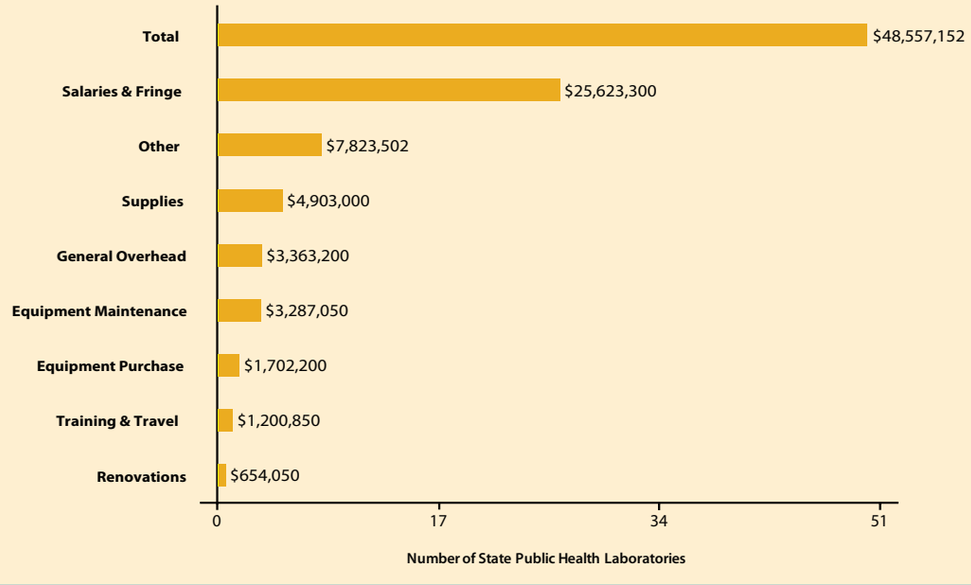
Biological Terrorism Laboratory Preparedness Funding

The PHEP Cooperative Agreement is the primary—and in many cases the only—source of funds for state public health laboratories to develop and maintain capacity and capability for detecting potential agents of biological terrorism. Since the program's inception, SPHLs have made enormous progress in recruiting highly skilled laboratorians and other laboratory personnel, purchasing and maintaining the sophisticated equipment and instrumentation needed to detect a growing number of potential pathogens, acquiring safety equipment and building other critical infrastructure.

For example, in 2003, only six states had Biosafety Level-3 suites,[4] which are specialized units equipped with technology requiring highly trained staff and which can safely handle highly infectious agents. That number has grown steadily to 16 states in 2004, 37 in 2005, 39 in 2006 and 42 in 2007. SPHLs also use PHEP funding to develop and implement biosafety and biosurveillance training exercises, drills, and communication networks with other laboratories, first responders, and law enforcement agencies; and to support and upgrade critical information technology systems that enable rapid sharing of information.

In FY 07, 51 SPHLs reported receiving approximately $48.6 million for bioterrorism preparedness under the PHEP Cooperative Agreement, a decrease from the previous year when 47 SPHLs received $51 million, and a 33% reduction over FY 05. Figure 5 illustrates how SPHLs allocated PHEP funds.

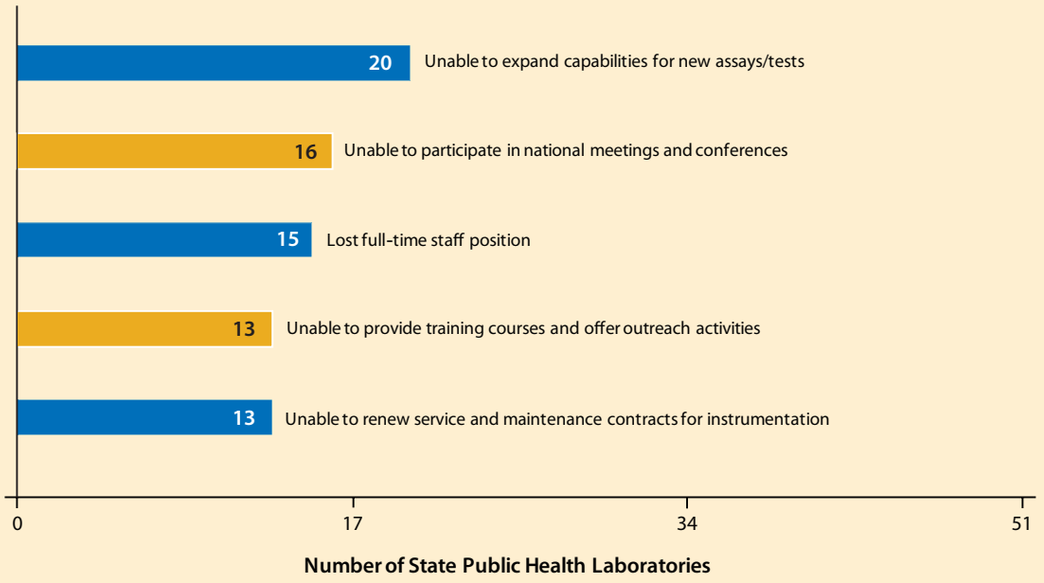
FIGURE 5: FY 07 Allocation of CDC Public Health Emergency Preparedness (PHEP) Cooperative Agreement Funds for Biological Terrorism Laboratory Preparedness



RESULTS

Laboratories reported that continued budget reductions are negatively affecting their preparedness efforts, including their ability to maintain or upgrade detection capabilities, to participate in national coordinating meetings and scientific conferences, to recruit and retain qualified staff, to service and maintain instrumentation, and to deliver training to preparedness partners (Figure 6).

FIGURE 6: Top Five Impacts of Funding Cuts for Biological Terrorism Laboratory Preparedness Activities



Technology that is rapidly evolving not only brings unanticipated costs, but also significant learning demands to laboratory practice.

Michael Pentella, PhD, Associate Director of Disease Control, University of Iowa Hygienic Laboratory

So what are the federal funds really used for?

University of Iowa Hygienic Laboratory

Budgeting for a public health laboratory includes many costs. Critical but often overlooked components needed to sustain the laboratory response infrastructure include: maintenance contracts, equipment replacement, reagents and controls. Michael Pentella, PhD, Associate Director of Disease Control at the University of Iowa Hygienic Laboratory (UHL), Iowa's State Public Health Laboratory, reports that maintenance contracts for essential equipment used for biological threat agent detection alone cost the UHL close to $100,000 last year.

In addition to maintaining current techniques and equipment, methodologies must be updated to keep pace with the latest technology and meet current standards. For example, in 2001 real-time PCR, a DNA amplification technique, was not the standard practice; it is in 2008. Every state public health laboratory has had to adopt this new technology in order to quickly identify potential biological threat agents. Pentella stated that, "Technology that is rapidly evolving not only brings unanticipated costs but also significant learning demands to laboratory practice."

Pentella noted that highly trained laboratorians are the lynchpin for accurate analyses. To maintain their skills, each laboratorian must spend approximately 25% of their time, or 520 hours annually, performing competency assessments and training on new techniques.

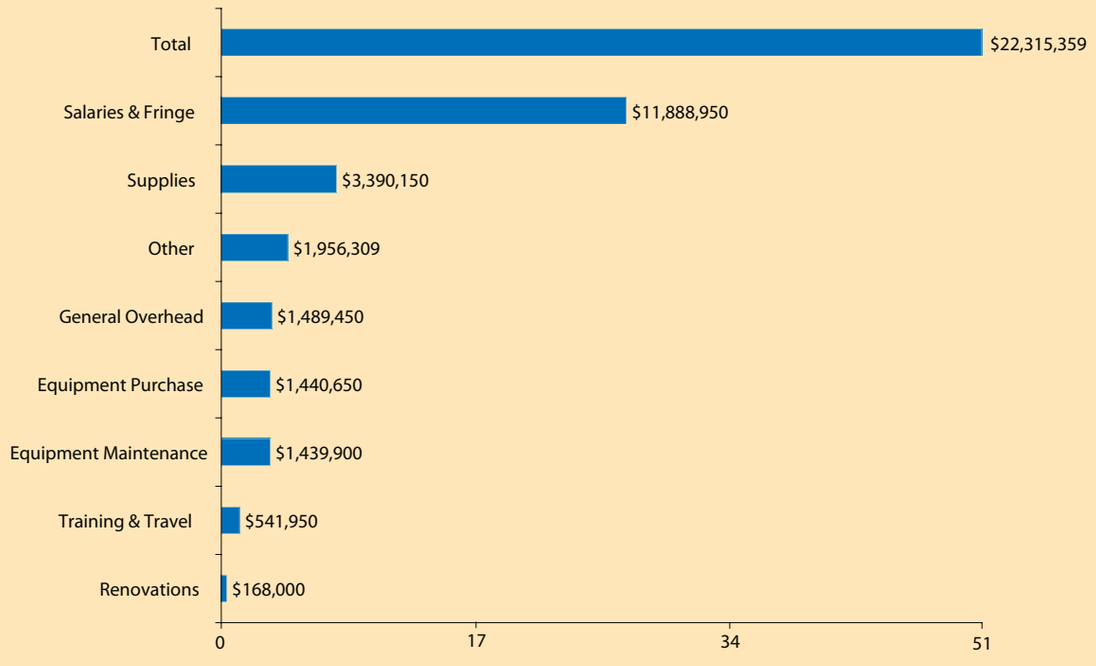
Chemical Threat Laboratory Preparedness Funding

Most preparedness funding for chemical threat laboratories is provided through the PHEP Cooperative Agreement and is based on the laboratory's LRN-C level (1, 2 or 3). In 2006, CDC expanded the number of level 1 laboratories from five to ten but was unable to add funding to cover these additional laboratories. **As a result, ten laboratories are sharing the $7.2 million funding that was meant to cover only five laboratories. Level 2 and 3 SPHLs received approximately $22 million under the PHEP Cooperative Agreement in FY 07, less than half of what they received in 2003.**

Twelve chemical threat laboratories reported receiving some funding from their states, representing an increase of seven over last year's number. However, such funding increases tend to be episodic. To address the considerable challenges of building a robust chemical terrorism preparedness network, SPHLs remain highly dependent upon funding from the PHEP Cooperative Agreement (See Figure 4).

Chemical preparedness laboratories reported allocating more than 50% of their PHEP funding for personnel (salaries and fringe). Another 29% of the funding was devoted to updating older equipment and purchasing state-of-the-art instruments and supplies (Figure 7). Improved technologies have markedly enhanced laboratories' ability to analyze both clinical specimens and environmental samples for potentially dangerous chemical contaminants. However, instruments are aging and many of the service contracts will soon expire. Shrinking budgets will make it difficult for laboratories to continue to maintain or replace critical equipment and recruit and maintain a highly skilled workforce.

FIGURE 7: **FY 07 Allocation of CDC Public Health Emergency Preparedness (PHEP) Cooperative Agreement Funds for Chemical Threat Preparedness** ***(This total does not include the $7.2 million received by Level 1 Chemical Threat Laboratories)***



Sophisticated chemical detection and identification capabilities purchased with preparedness funds can have broader public health application.

"Using instrumentation and personnel supported by preparedness funding, the University of Iowa Hygienic Laboratory (UHL), Iowa's State Public Health Laboratory, developed a method to determine which fungicides were used to combat the recent emergence of soybean rust in Iowa. This ability was of critical importance for waste management and cleanup after a tornado severely damaged the community of Parkersburg in May 2008."

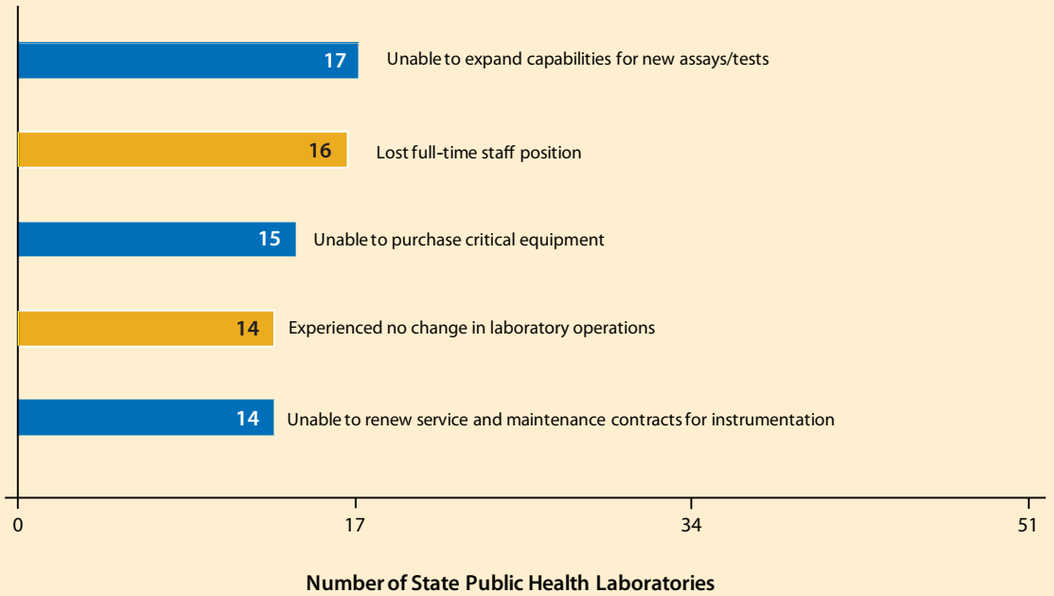
Michael Wichman, PhD, Associate Director, Environmental Health, UHL

Laboratories need sustained investment in training as methods and technology evolve. In FY 07, 43 SPHLs (84%) participated in CDC methods training and 33 (65%) participated in vendor/instrument training for detection of chemical threat agents. Only 16 SPHLs (31%) participated in LRN-C field training, which helps the laboratorians better understand the nuances of instrumentation in practice, while even fewer (11 or 22%) participated in academic training.

Despite diminishing funds, many chemical preparedness laboratories were resourceful in FY 07 and managed to make incremental progress. Fourteen laboratories (27%) added one additional LRN-C method, while 15 (29%) added two. Another 15 laboratories (29%) enhanced capability and capacity by purchasing equipment.

On the other hand, there is little doubt that budget reductions have slowed the pace at which laboratories are able to close the gaps in preparedness capacity and capability. Many SPHLs reported that they were not able to add one or more important new assays to their panel of tests, that they were unable to purchase or maintain critical equipment, or that they had lost a full time staff position (See Figure 8).

FIGURE 8: Top Five Impacts of Funding Cuts for Chemical Laboratory Preparedness Activities



Radiological Laboratory Preparedness Funding

Laboratory radiological capability is a well-recognized gap in public health preparedness. **SPHLs have not received funding to support radiological capability and capacity building.** In FY 07, the majority of SPHLs reported that they did not have any staff trained to test for radionuclides, while few states had only one or two trained staff. Laboratories looking to build radiological testing capacity face daunting prospects—current workers are retiring, there is a scarcity of trained radiochemists entering the workforce and there are few remaining radiochemistry training programs in the nation. Without additional training programs and funding support, radiological preparedness is severely compromised.

A particular concern is public health laboratories' scant ability to analyze clinical specimens for radioactive contaminants. **Only 15 SPHLs (29%) can measure clinical specimens for radionuclides.** Of those, 12 (75%) can measure uranium and a few can measure other radionuclides, such as cesium, cobalt or plutonium. Even with the capability to measure the analyte of interest, the number of specimens that would result from a radiation event would easily overwhelm these laboratories. Of the 36 SPHLs who cannot measure clinical specimens for radionuclides, only nine (25%) have partnership with another department to which they can send the sample for analysis.

CDC recently began developing rapid methods to analyze clinical specimens for radionuclides. Plans exist to develop a radiological component of the LRN (LRN-R); however both CDC and the states need funds in order to transfer the methods to SPHLs. In addition, SPHLs need to purchase the necessary equipment, such as high-resolution inductively coupled plasma mass spectrometers (ICP-MS) to be dedicated solely to radiation testing in order to avoid contaminating non-radioactive samples. CDC requested $10 million from Congress in FY 07 and the President's Budget included this figure, however Congress has yet to appropriate funds for these activities.

Influenza Laboratory Funding

Public health officials remain concerned about the continued spread of a highly pathogenic avian H5N1 virus and the emergence of other novel strains. Public health laboratories are the vanguard of influenza preparedness, maintaining first-line surveillance capabilities, testing and identifying circulating virus subtypes and keeping other public health partners informed. SPHLs also work closely with private sector and clinical laboratories to provide confirmatory testing of suspect strains, education on the uses and interpretation of rapid influenza tests, and guidance on handling potentially dangerous viral samples.

Under the PHEP Cooperative Agreement, state and local health departments received $100 million in FY 05, $225 million in FY 06 and $175 million in FY 07 for pandemic influenza preparedness activities. However, much of this funding did not make it to SPHLs . These funds are not considered base funding for public health departments and are not guaranteed each year. SPHLs do not have another designated funding stream for pandemic influenza preparedness.

Despite the minimal level of support for pandemic influenza preparedness activities, SPHLs have been intimately involved in influenza planning and continue to develop capability and capacity to detect the introduction of a novel influenza virus and respond to a potential pandemic. **Fifty SPHLs (98%) were involved in developing their state's pandemic influenza plan, and are familiar with the expectations for laboratory capabilities described in the plan. Forty-eight SPHLs (94%) believe that they can meet the expectations described in the pandemic influenza plan. Forty-nine (96%) SPHLs reported that their staff has developed coordinated plans for enhanced surveillance and surge testing during a pandemic.**

Preparing for Influenza

A recent success in influenza preparedness was the collaboration between APHL and CDC in the development of a new test for influenza, which received 510(k) clearance by the Food and Drug Administration (FDA). The importance of the test is that it can accurately detect and identify all commonly circulating human influenza viruses including avian influenza A (H5N1) virus.

This new highly sensitive and rapid PCR (polymerase chain reaction) test uses CDC's PCR reagents and the Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR Instrument. This test will improve public health laboratory capacity to conduct seasonal influenza surveillance and pandemic response. Developing and maintaining this capacity requires sustainable funds to acquire the FDA approved ABI instrument platforms and maintain the required yearly service agreements, to purchase testing supplies and to provide timely reporting of results via electronic systems to state and national influenza surveillance programs.

Food Safety Laboratory Preparedness Coordination and Funding Support

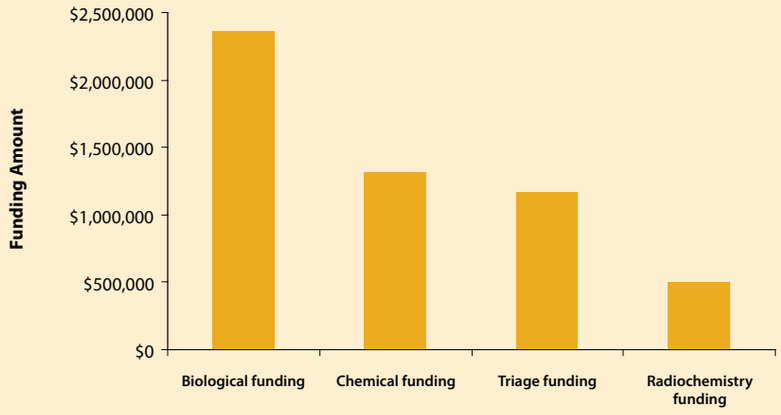
As stated in an article published in *The Lancet, "Deliberate contamination of food with biological agents has already been perpetrated in the USA. The US food supply is increasingly characterized by centralized production and wide distribution of products. Deliberate contamination of a commercial food product could cause an outbreak of disease, with many illnesses dispersed over wide geographical areas. Depending on the biological agent and contaminated food, such an outbreak could either present as a slow, diffuse, and initially unremarkable increase in sporadic cases, or as an explosive epidemic suddenly producing many illnesses. Preparedness for a bioterrorist event affecting the food supply, therefore, entails augmentation of the traditional public-health infrastructure to enhance disease surveillance, improve capacity of laboratory detection, accelerate the investigation and control of outbreaks, and develop capacity for response to mass-casualty disasters."* [5]

State public health laboratories are critical stakeholders in the nation's overall food safety efforts. For more than ten years, SPHLs have carried out crucial functions of food safety by rapidly detecting intentional and naturally occurring foodborne outbreaks through their participation in PulseNet, CDC's national molecular subtyping network for foodborne disease surveillance. PulseNet was a valuable tool in the 2006 investigation of a major nationwide outbreak of *Escherichia coli* O157:H7 that was associated with the consumption of contaminated fresh spinach.

Principally, PulseNet is funded through the CDC's Epidemiology and Laboratory Capacity (ELC) Cooperative Agreement program. Relying on this single resource means that declining ELC funds jeopardizes PulseNet's future. The CDC PHEP Cooperative Agreement has specific performance metrics linked to PulseNet, but yet does not provide any direct funding support to achieve these established performance measures.

In 2004, the United States Department of Agriculture and the FDA collaborated with CDC, the Environmental Protection Agency (EPA), the Department of Energy and states to develop a nationwide Food Emergency Response Network (FERN). This network integrates the nation's food-testing laboratories at the local, state and federal levels in order to enable a coordinated response to emergencies involving biological, chemical or radiological contamination of food. Many state public health laboratories are members of both FERN and LRN, and thus, carry a heavy testing and reporting burden. This current strategy of relying on the SPHLs without adequately resourcing them is not sustainable. During FY 07, 44 states (86%) participated in the FERN, but only 20 respondents (39%) reported receiving funding from FERN. As Figure 9 shows, the bulk of the FERN funding went toward biological agent testing, while the funding for chemical and radiochemistry testing lagged far behind.

FIGURE 9: Food Emergency Response Network (FERN) Funding Distribution to State Public Health Laboratories, FY 07



Though this survey did not specifically assess real-time data exchange, state public health laboratory directors anecdotally reported significant challenges with being members of several laboratory networks and having multiple reporting mechanisms.

Electronic Laboratory Messaging

The capacity to provide mutual assistance, call upon surge capacity aid and maintain and monitor the core operations of a laboratory when a natural or manmade disaster strikes is a critical piece of the preparedness puzzle. A widely recognized gap in this area is the lack of integrated, standardized laboratory data exchanges to support real-time transmission of pertinent laboratory data. Such data are critical to first responders and others who need to act swiftly and decisively in an emergency, to sentinel laboratories and clinicians who need to order laboratory tests and receive results within an actionable timeframe; and to other SPHL and CDC threat detection and surveillance partners.

Although there is movement toward standardized electronic laboratory information exchange through the Laboratory Information Management Systems Integration (LIMSi) project and the Public Health Laboratory Interoperability Project (PHLIP), progress has been slow. To date, data exchange capabilities have been based on funding availability for a single disease or initiative—a piecemeal and ineffective strategy. Laboratories receive no core funding to allow their IT infrastructure and systems to evolve with the business needs of the laboratory and the changing role of laboratory science. In 2008, the Healthcare Information and Management Systems Society (HIMSS) Leadership Survey reported for the 8th year in a row that inadequate financial resources continues to be the most significant barrier to successful IT implementations.[6]

In partnership with CDC, APHL is striving to fill this gap through PHLIP, which brings together public health laboratory science and information technology experts from APHL member laboratories and CDC. The PHLIP team is defining the necessary infrastructure and expertise that a public health laboratory must have to enable two-way electronic data transmission with public health partners in a standardized format.

WORKFORCE

Across the nation, public health laboratories are experiencing significant difficulty maintaining the highly skilled workforce needed to ensure threat detection capability and capacity. SPHLs face a shortage of laboratory professionals entering the workforce, pay discrepancies between public and private sector laboratory staff positions, a scarcity of scientists with the experience and credentials needed to assume senior management roles, and an aging worker population that is rapidly entering retirement. Without significant changes in the workforce pipeline and the ability to offer competitive compensation, public health laboratories may soon find themselves unable to fill critical vacant positions.

In FY 07, the majority (86%) of SPHLs reported significant workforce challenges. Asked to rank their severity, SPHL directors reported that their primary difficulties were hiring (41%), retention, (28%), and recruitment (11%) (See Figure 10).

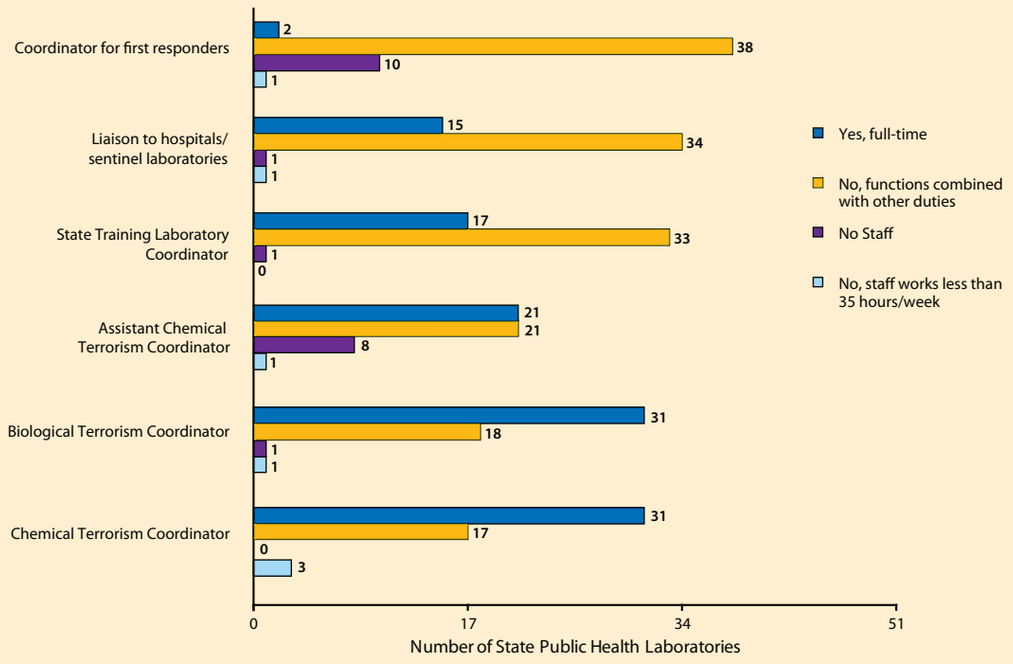
FIGURE 10: Rankings of Staffing Difficulties at State Public Health Laboratories

Staffing Difficulties	Ranked "#1"	Ranked "#2"	Ranked "#3"
Recruitment	11 (22%)	25 (51%)	13 (27%)
Hiring	20 (41%)	14 (29%)	15 (31%)
Retention	13 (28%)	12 (26%)	21 (46%)
No difficulties experienced	7 (14%)	0 (0%)	2 (4%)

Of those who identified hiring as the primary concern, 8 (36%) identified lack of funding and 7 (31%) hiring freezes—common during times of economic downturn—as reasons for hiring difficulties. Among those for whom retention was the chief concern, 8 (61%) indicated that non-competitive wages were at fault. Anecdotally, laboratorians are being offered at least $20,000 more in salaries along with signing bonuses and other benefits by other federal or private laboratories. Finally, among SPHLs that struggled most with recruitment, 6 (54%) cited lack of qualified applicants and 5 (45%) cited non-competitive salaries as the reasons. **Overall the key workforce issues were non-competitive salaries, lack of qualified applicants, hiring freezes and lack of funding. These factors make it difficult for SPHLs to compete with private and federal agencies for qualified candidates.**

State training coordinators, liaisons to private and public laboratory communities, and biological and chemical terrorism laboratory coordinators are all positions critical to developing and implementing preparedness plans. They are the link between the laboratory and external partners such as the first responders, hospitals, and other state or federal agencies. To cope with workforce shortages and declining budgets, SPHL directors report that they are combining some of these positions and placing greater responsibilities on fewer personnel. As Figure 11 shows, 33 SPHLS (65%) have combined the duties of their state training coordinator (STC) with another position. This is a substantial increase from last year when only 16 states reported that they combined duties of the STCs with another position. Thirty-one SPHLs (61%) have a full time Biological or Chemical Terrorism Laboratory Coordinator. Only 15 respondents (29%) have a full time staff liaison to sentinel laboratories or hospitals, while 34 (67%) have combined these duties with another position. Thirty-eight SPHLs (74%) have combined the duties of their first responder coordinator, up from 28 in FY 2007.

FIGURE 11: State Public Health Laboratories: Staff Positions For Laboratory Connectivity and Training



To cope with workforce shortages and declining budgets, SPHL directors report that they are combining some of these positions and placing greater responsibilities on fewer personnel.

IN FOCUS: Workforce Issues at the New York City Public Health Laboratory

According to Sara T. Beatrice, PhD, Assistant Commissioner, Public Health Laboratory, New York City Department of Health and Mental Hygiene, noncompetitive salary levels at the New York City public health laboratory have resulted in the loss of highly trained staff and empty positions.

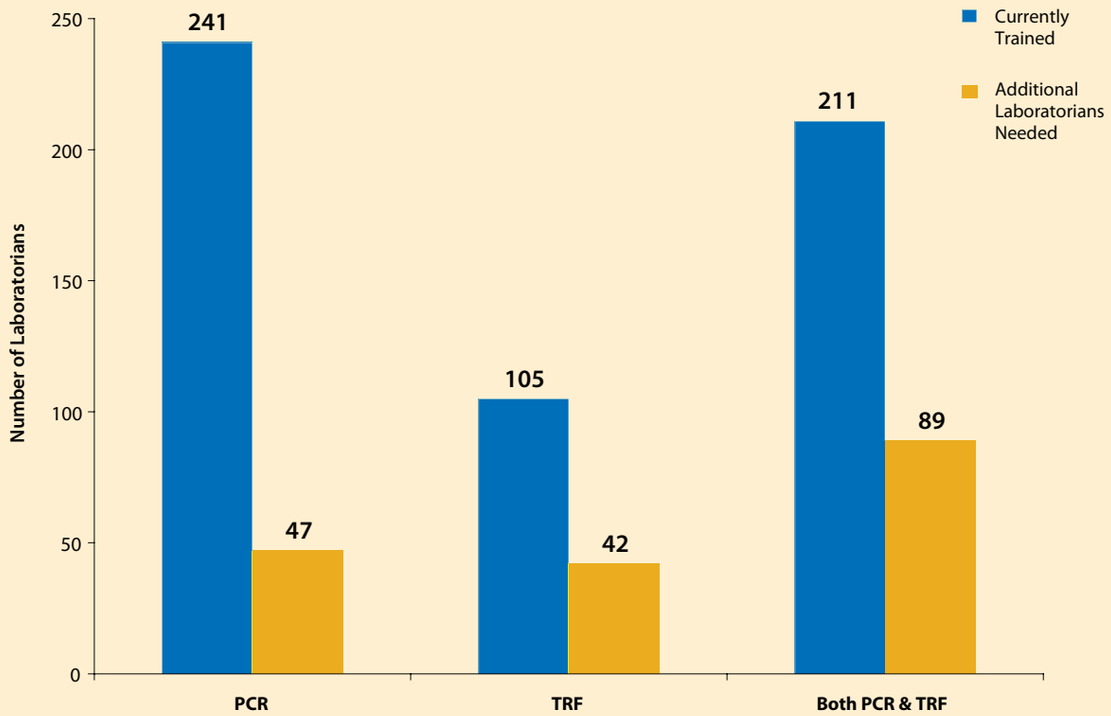
"The Department of Health and Mental Hygiene has a base salary for an incoming Laboratory Microbiologist II, which is 20-25% less than applicants' request. Not only is the public health laboratory not budgeted for the higher salaries being requested, but there is a morale issue when an outside candidate is hired at a salary significantly higher than what current staff are making, many of whom have been working for years at the lower base salary. To add to the problem, candidates who come on board at base salary often stay at the public health laboratory to be trained and then move on to higher paying positions outside the laboratory. In addition, the city of New York has a residency requirement for most of its civil service titles, including Laboratory Microbiologists and City Research Scientists. This prevents qualified persons from applying to or accepting positions at the public health laboratory who are unwilling or unable to relocate to the five boroughs of New York City within three months after their hire, since establishing residency outside of the five boroughs is often more affordable.

Over the last several years, the NYC PHL has lost eight highly skilled doctoral level professionals to other institutions: five to other PHLs, two to other government labs (FDA, state agriculture lab) and one who returned to the hospital sector. Almost all of these positions were at the director, manager or chief level. During this same time period, four other doctoral level staff and two senior administrators retired. Because of lower salaries and a lack of sufficient clinical experience, replacement of this talent has been slow. The result is a serious staffing shortage at all levels and a highly pressured working environment.

Since positions are difficult to fill, they often remain open for extended periods and are vulnerable to being eliminated. During the past year, the NYC PHL has lost 20 positions (10%) in this way. This makes an already difficult staffing situation worse. Further, this situation is likely to be compounded by projected future budget cuts in 2009."

Bioterrorism preparedness laboratories must recruit and retain staff with specialized training in microbiology, molecular methods and other laboratory procedures. These staff must meet federal requirements to work with select agents and toxins such as those contained in the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001 and the Public Health Security and Biological Terrorism Preparedness and Response Act of 2002. **In FY 07, 30 SPHLs (59%) had at least one laboratorian trained to perform time-resolved fluorescence (TRF) and 41 SPHLs (80%) had at least one laboratorian trained to perform real-time polymerase chain reaction (PCR)—two essential assays for bioterrorism laboratories.** However, this represents a decrease from last year when 49 SPHLs had at least one laboratorian trained to perform PCR and 51 SPHLs had at least one laboratorian trained to perform TRF. **Twenty-three SPHLs (45%) indicated a need for real-time PCR-trained staff, 18 respondents (35%) for TRF-trained staff and 28 (55%) for staff trained in both methods** (See Figure 12).

FIGURE 12: Laboratorians Trained and Additional Laboratorians Needed to Perform Real-Time PCR and TRF Assays for Biological Terrorism Agents



Chemical threat laboratories also reported a need for more highly trained staff. Most laboratories need at least three chemists on staff to maintain the laboratory and provide the capacity and capability to respond 24/7. Laboratories with only one chemist would not be able to maintain 24/7 response for more than a day. Most SPHLs meet or exceed this threshold; however 16 SPHLs (32%) do not, while five of those 16 have no full-time chemical terrorism scientists on staff.

RESULTS

SAMPLE RECEIPT AND ANALYSES

In the era of multiple hazards and constant threats, SPHLs are doing more tests for more types of hazards, using more types of advanced equipment, and coordinating with more partners.

Sample Intake and Testing

SPHLs work closely with FBI and other first responders to investigate potential threats. In FY 07, SPHLs received over 5000 samples (3,583 clinical specimens and 1,675 environmental samples) for analysis of potential threat agents. SPHLs performed a combined total of 5,937 tests on the clinical specimens and 3,152 tests on environmental samples, a total of more than 9,000 tests. These figures are consistent with laboratory reports from FY 06.

Virtually all samples (98%) were tested using CDC LRN biological methods and more than two-thirds (66%) were tested using LRN chemical methods for potential agents of terrorism. Fewer tests are performed for chemical threat agents because many SPHLs still lack the capability to analyze environmental samples for chemical threat agents. All SPHLs (100%) accept clinical specimens for such analysis whereas only 35 (69%) accept environmental samples. Since laboratories often receive an environmental sample for analysis before they do a clinical specimen, the ability to test environmental samples for chemical agents could result in earlier identification of a chemical threat.

Timely delivery of samples is essential to ensure the rapid detection of an event, so SPHLs need an effective, reliable system for rapidly transporting samples on both a routine and emergency basis. SPHLs that lack such a system risk delays in receiving specimens, lengthening the time from sample collection to result reporting. In FY 07, just 21 state public health laboratories (41%) had a dedicated or contracted 24-hour intrastate courier system for specimen pickup and delivery. Other SPHLs relied on a patchwork of couriers, other agencies and law enforcement to transport samples. Such arrangements may not be reliable in an emergency situation.

Pre-Screening Samples

Samples brought to SPHLs for analysis have taken the form of powders, threat letters, unknown packages, air, water, mixed liquids, syringes and swabs. To protect their workers from exposure to unknown agents, 45 SPHLs (88%) require law enforcement or other first responders to screen unknown samples for radiation, explosives and provide preliminary screening information for chemical threats prior to accepting them into the laboratory.

First responders—such as HazMat and Civil Support Teams (CSTs)—typically use handheld devices to prescreen samples in the field. These devices are important safety-screening tools when used properly; however, many of them are not validated, often require extensive training, may produce false positive and false negative results, and may require such a volume of sample material that not enough is left for confirmatory testing by the SPHL.

In the absence of reliable field screening techniques and to account for samples that are not field screened, SPHLs need to implement their own safety precautions for unknown hazards, including laboratory-based screening protocols and separate areas for processing these potentially dangerous samples. In FY 07, six SPHLs (12%) used the EPA/DHS Interim All-Hazards Receipt Facility Protocol for screening and triaging environmental samples, down from 22 SPHLs in FY 06. Thirty-one SPHLs (61%) used laboratory-developed all-hazard screening protocols.

Twenty-one SPHLs (41%) reported that they have a designated space for safely receiving and triaging samples within their building while another four (8%) have a separate facility, up from 20 SPHLs in FY 06. Seven SPHLs (14%) indicated that they plan to design and build a unique screening space in the same building as the laboratory and two (4%) plan to build elsewhere. Seventeen SPHLs (33%) have no designated screening facility or plans to create one. These laboratories cited lack of space, lack of funding from state and federal governments, and lack of federal guidance as reasons for this gap.

PLANNING, PARTNERING, EXCERCISING and RESPONDING

It takes significant coordination at the local, state and federal levels to develop and maintain the partnership networks, which enable a timely and effective response to a potential terrorism threat. A vital part of preparedness is the relationships between the state public health laboratories and other partners, such as the FBI, first responders and sentinel clinical laboratories.

Planning

A Continuity of Operations Plan (COOP) is critical in an emergency situation to ensure that core functions of the state public health laboratories are not disrupted. These plans should be consistent with the National Incident Management System (NIMS) guidelines. Respondents have either developed their own COOP (23 SPHLs), are part of their broader state's COOP (15 SPHLs) or are in the process of developing a COOP (13 SPHLs). Of the 23 SPHLs that have a COOP in place, only 16 tested their COOP to ascertain its strengths and weaknesses. This is a marked improvement from FY 04, when only 18 SPHLs had a COOP and 14 states included laboratory operations in their COOP. This is an area that continues to need improvement.

Preparing for Real Events – Colorado Public Health Laboratory

Preparation for the Democratic National Convention (DNC) began eight months prior to the event, however event planning had been ongoing for several years. Staff from the Laboratory Services Division at the Colorado Department of Public Health and Environment prepared for the potential release of select agents or foodborne pathogens using small-scale exercises to simulate the response. Using a recent West Nile virus surveillance event, which had dedicated staff performing sustained testing of 200–300 samples for a two-week period, the laboratory refined their surge capacity and capability for responding to a potential large-scale terrorist event. With these lessons learned from the simulations and surveillance, the laboratory staff and partners were better prepared to anticipate any incidents during the DNC.

According to Hugh F. Maguire, PhD, Physical Science Researcher at the Laboratory Services Division in Colorado, "the keys to preparing for such a large-scale event were proper lines of communication and the creation of strong internal and external partnerships. Groups made up of state public health division representatives (laboratorians, communicable disease epidemiologists, air quality control experts, consumer protection employees and local public health and local environmental health workers), first responders, FBI and EPA, were able to rapidly and clearly define limitations and capabilities of the lab system, and determine an appropriate response plan."

Partnering

Communication, collaboration and training that strengthen the relationships between SPHLs and others in the chain of preparedness enable faster, more efficient responses during an emergency event (see text boxes below for examples of partnerships). The majority of SPHLs communicate frequently with partners such as environmental laboratories (52%), local law enforcement and first responders (54%), local public health laboratories (57%), civil support teams (58%), and FBI/WMD Coordinators (61%). More attention is needed to opening lines of communication with university, agricultural and veterinary laboratories and well as poison control centers.

In order to rapidly communicate with sentinel clinical laboratories and other partners, SPHLs relied heavily on CDC's Health Alert Network (HAN), blast emails or faxes. In FY 07, states used HAN 230 times for outbreak communication, 817 for routine communication, 788 times for communication on training courses, and another 137 times for other applications.

Courtesy of Maureen Sullivan, MPH, Minnesota Department of Health

"Working with the LRN Laboratories has been a great success in that we can rely on the labs to call us when there is a threat and the reverse is also true."

Doug Anders, PhD, Science Program Coordinator, FBI Hazardous Materials Response Unit

Texas: LRN Partnerships for Preparedness

Texas public health laboratories serve as a model of creating partnerships both with public health departments and other healthcare organizations. Within the state, Texas has created the Texas LRN (TxLRN), which is made up of 11 public health laboratories that participate in the LRN for Biological Terrorism Preparedness. The benefit of this network is a large geographical distribution of laboratories that can provide a more rapid response in an emergency event. In addition, the laboratory in Austin provides the entire partnership with a Level 2 Chemical LRN laboratory to respond to chemical threats.

To establish and maintain such a network requires strong lines of communication. The lead team at the Department of State Health Services Laboratory convenes with each representative TxLRN laboratory coordinator annually to discuss current and future testing capabilities, training strategies for sentinel laboratories and first responders, and strategies for working as a network to share information on best practices, surge capacity, and new training programs. In addition, the TxLRN laboratory coordinators participate in Texas-specific LRN monthly conference calls to discuss laboratory issues, progress on implementation of new methods, and new ways to meet grant deliverables. The annual meeting and monthly conference calls foster a collegial atmosphere among the TxLRN laboratories to build a more successful public health preparedness program.

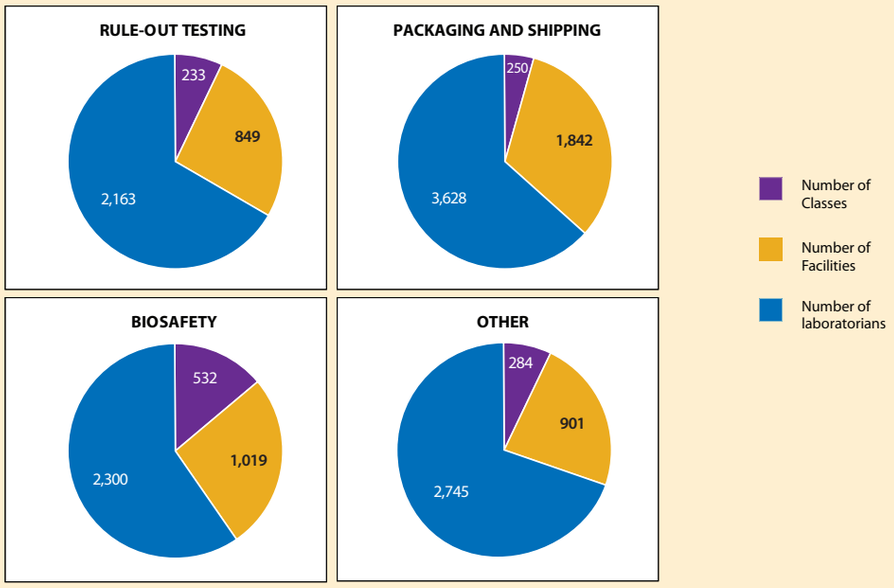
Establishment of the TxLRN paved the way for the recently installed public health Laboratory Information Management System (LIMS) that provides a secure network for electronic exchange of laboratory information during a surge event. This system further enables smooth communication between the conglomerates of PHLs.

TxLRN personnel also have partnered with universities, sentinel laboratories and the military on several projects. They participated in Operation Lone Star, a military and public health project, which provided basic medical exams for residents along the southern Texas-Mexico border. The participation of the TxLRN staff facilitated the availability of basic laboratory testing to this under-served population. Similarly, a TxLRN laboratory partnered with the local university to provide laboratory training to interested sentinel clinical staff. The university laboratory provided a larger space with more equipment, and increased the number of hospital laboratory personnel able to participate in the training.

State public health laboratories make a significant commitment to preparedness training for other laboratories within their states. **In FY 07, forty-eight SPHLs (94%) sponsored training for their sentinel laboratories at levels comparable to FY 06. As illustrated in Figure 13, SPHLs offered more than 230 rule-out testing classes to about 2,100 laboratorians; about 250 packaging and shipping courses to more than 2,600 laboratorians; more than 530 biosafety guidelines classes to about 2,300 laboratorians; and more than 280 classes on broad laboratory practices to more than 2,700 laboratorians.**

SPHLs are working toward formally recognizing sentinel laboratory training efforts within the LRN. **In FY 07, 23 SPHLs (45%) issued formal certificates of recognition to 924 sentinel clinical laboratories upon their completion of training. These included 221 LRN Joint Leadership Council (JLC) Basic certificates, 253 JLC Advanced certificates, 175 State-developed basic certificates and 275 State-developed advanced certificates. This represents an increase from last year when 20 SPHLs issued formal certificates to 860 sentinel clinical laboratories. More outreach to the estimated 4,000 sentinel laboratories is still needed to maintain this vital partnership.**

FIGURE 13: State Public Health Laboratories' Sponsored Training for Sentinel Laboratories



State public health laboratories also provided direct assistance, such as purchasing Class II Biological Safety Cabinets and other personal protective equipment, to sentinel clinical laboratories. Thirty SPHLs (59%) used funding from the PHEP Cooperative Agreement, 28 (55%) used funding from the Hospital Preparedness Program funded by the Department of Health and Human Services (HHS)/Assistant Secretary for Preparedness and Response Office, three (6%) used state funding and nine (18%) used other sources to support sentinel laboratory outreach and training activities.

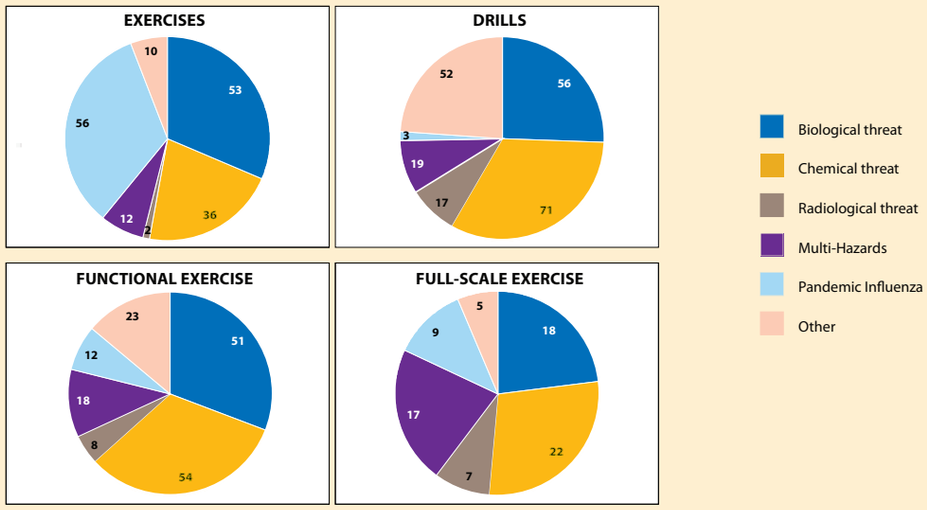
Laboratories also continued to provide outreach and training to their local first responders, including training on proper methods for collecting and screening samples as well as safely transporting them to the laboratories for further testing. **Forty-one SPHLs (80%) conducted outreach to first responders, 36 (71%) provided training, nine (18%) issued a proficiency test and eight (16%) provided other services. For the few SPHLs unable to reach out to first responders, the most commonly cited impediments were lack of funding, lack of staff and lack of national guidance on training and proficiency tests for first responders.**

Jason Lemaster, HazMat team member samples the area surrounding a mock radiological spill. Photo by Sgt. Tommi Meyer.

Exercising

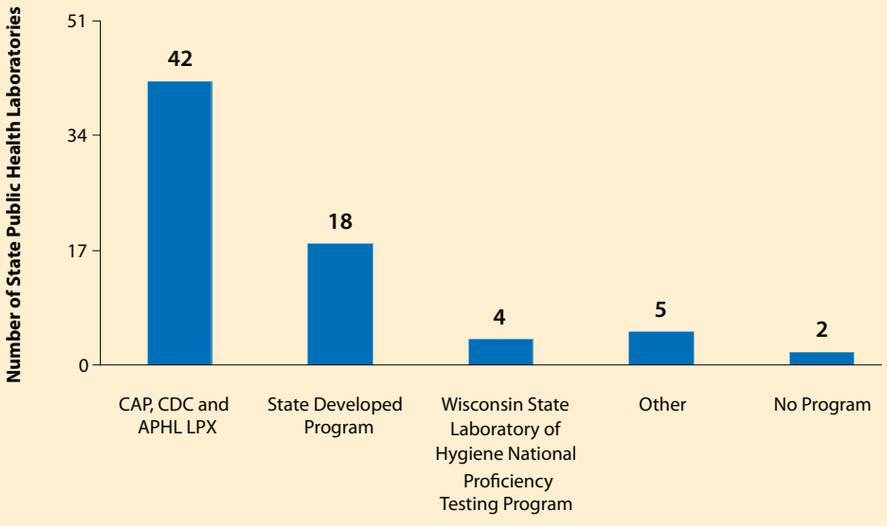
Exercises and drills are the best way, other than real events, to test detection and response systems and evaluate the effectiveness of training sessions. In FY 07, public health laboratories developed, conducted and participated in preparedness activities ranging from table-top to full scale exercises in biological, chemical, radiological, multi-hazard, pandemic flu and other threats (Figure 14).

FIGURE 14: State Public Health Laboratories' Participation in Preparedness Exercises



Nearly all SPHLs (49 or 96%) conducted exercises to assess the competency of sentinel clinical laboratories to rule out and refer biological terrorism agents. The most common exercise used (42 SPHLs) was the Laboratory Preparedness Exercise (LPX), which is jointly developed by the College of American Pathologists, CDC and APHL, to assess the preparedness competency of sentinel clinical laboratories (See Figure 15). This figure is very similar to what was seen last year. Eighteen respondents used a state-developed program to perform this assessment. This represents a decrease from last year, when 22 laboratories issued a state-developed program.

FIGURE 15: Types of Programs Used by States to Assess Preparedness Competency of Sentinel Clinical Laboratories



RESULTS

Stepping Out: Proficiency Programs for Unknown Powders

The Iowa Unknown Powder Proficiency Program tests the knowledge of diverse groups of first responders including HazMat, Postal Inspection Service, CSTs, and neighboring SPHL teams. The program's initial focus was on the use of field Fourier Transform Infrared Spectroscopy (FTIR) technology, but the program has evolved into a broader unknown detection test. The teams test samples using various hand-held equipments and then compare their findings to wet chemistry techniques used for result confirmation. Samples included are agents likely to be encountered in real-life situations.

"These proficiency tests have been a valuable asset to the first responders. They have strengthened the relationship with first responders and confirmatory lab members, and most importantly have taught participants to rely on multiple methods of agent detection instead of only one. Getting away from reliance on hand held devices, and the use of multiple testing methodologies have given our responders the suite of tools necessary to handle an unknown event."
—Steve Treimer, PhD, Chemical Threat Response Chemist, University of Iowa Hygienic Laboratory.

The Nebraska public health laboratory also implemented an FTIR Proficiency Testing Program as an outreach effort to first responders state-wide and has since expanded it nationwide. The program has assisted first responders in maintaining proficiency on FTIR devices while educating responders on the limitations and applicability of hand-held instruments. In 2009, a Raman Proficiency Program will be introduced, to assist first responders with their Raman identifications. According to Dana El-Hajjar, MBA, BA, Technical Director, Chemistry Section, Nebraska PHL, "Prepare. Respond. Succeed" is the motto of the Nebraska FTIR and Raman Proficiency Program.

Responding

SPHLs perform many duties that aren't related to terrorism, but are broadly focused on public health preparedness. These laboratories coordinate and support public health responses to foodborne disease outbreaks, such as salmonella in peanut butter; natural disasters, such as hurricanes; and other emerging threats. Recently, the University of Iowa Hygienic Laboratory, Iowa's State Public Health Laboratory, responded to the Midwest flooding to detect disease and environmental contaminants to protect Iowa residents and visitors.

Flooding in Cedar Rapids, IA. Photographer: Don Becker, U.S. Geological Survey.

University of Iowa Hygienic Laboratory Responds to Midwest Floods

During the summer of 2008, the eastern section of Iowa was hit hard with flooding. Many local businesses, homes, churches and schools were damaged. The University of Iowa was no exception, sustaining millions of dollars in damages. Once the emergency situations were handled, the long recovery phase began. During the recovery phase, the University of Iowa Hygienic Laboratory (UHL) dramatically increased its testing volume to detect disease and environmental contaminants to protect Iowa residents and visitors.

The dedication of laboratory staff ensured that necessary water supplies were safe for consumption and that public health dangers were identified quickly. Specific duties included: monitoring for contamination in Iowa waterways, testing to ensure municipal and private well water was safe, performing vector-borne disease surveillance, screening for asbestos in debris, performing disease control methods and providing environmental expertise to public health partners. According to Bonnie Rubin, MHS, MBA, UHL's Assistant Director for Planning and Development, Mason City officials recognized the laboratory's hard work, dedication and true compassion during the recent flooding with a certificate of appreciation that stated UHL efforts lessened the impact of the damage to the community.

UHL performed thousands of tests at a cost of $839,710 for equipment and resources. In addition, 10,580 staff-hours or 440 24-hour days of staff time were dedicated to this emergency and its aftermath. "UHL's ability to respond quickly and effectively was largely due to the emergency response partnerships, processes and systems we have been able to implement using emergency response funding from the CDC and the Hospital Preparedness Program," stated Rubin. She further noted that, "without this funding, UHL would not have had the staff, results notification systems and integration into the Iowa response network that enabled us to successfully respond to the floods and other emergency events."

CONCLUSIONS

State public health laboratories have played a critical role in preparedness activities even before the need for nationwide public health preparedness had been explicitly recognized. Since the inception of the CDC PHEP Cooperative Agreement, SPHLs have steadily built a strong network to respond to both biological and chemical threats. Each year of the grant, APHL's data have shown improvements on both the biological and chemical side of the laboratories. However, data from the current all-hazards laboratory preparedness survey indicates that progress has slowed. The loss of momentum is attributable to funding cuts that force laboratories to try to meet growing expectations with fewer resources. The results show up across the board, but are particularly devastating in the area of workforce: laboratories are struggling to compete for qualified scientific talent while combining important coordinating, outreach and training positions to save dollars.

Smaller budgets distributed over more diffuse and demanding responsibilities threaten SPHLs' ability to close the gaps in public health preparedness. To ensure the sustainability of partnerships as well as the rapid identification and reporting of public health threats, core elements of the system, such as a highly skilled workforce and standardized laboratory information management systems, need to be in place and need to be properly maintained. In a February 2008 report, the CDC noted, "a prepared public health system involves continual improvement of the system's ability to prevent, protect against, respond to and recover from the consequences of emergencies."[7] A recent report by the Trust for America's Health and Robert Wood Johnson Foundation calls for funding the CDC PHEP Cooperative Agreement at $1.03 billion, which is the FY 05 level adjusted for inflation.[8] Without a sustained funding stream for public health preparedness, public health laboratories will not be able to improve and will not be ready for the next threat.

APHL is calling for restoration of preparedness funding for state public health laboratories, designated funding for SPHLs to develop radiological capability and capacity, continued development of training programs for public health laboratorians, implementation of integrated, standardized laboratory data exchanges to support real-time transmission of pertinent laboratory data in SPHLs and coordination of these efforts across the multiple laboratory networks, and more outreach between the first responder, sentinel clinical laboratory and public health laboratory communities.

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[4] A BSL-3 suite is a contained area that must meet stringent biosafety requirements, including biosafety cabinets, controlled double door access and engineering controls, such as negative air pressure relative to surrounding rooms, microfiltration of air and air-lock buffer zones.

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