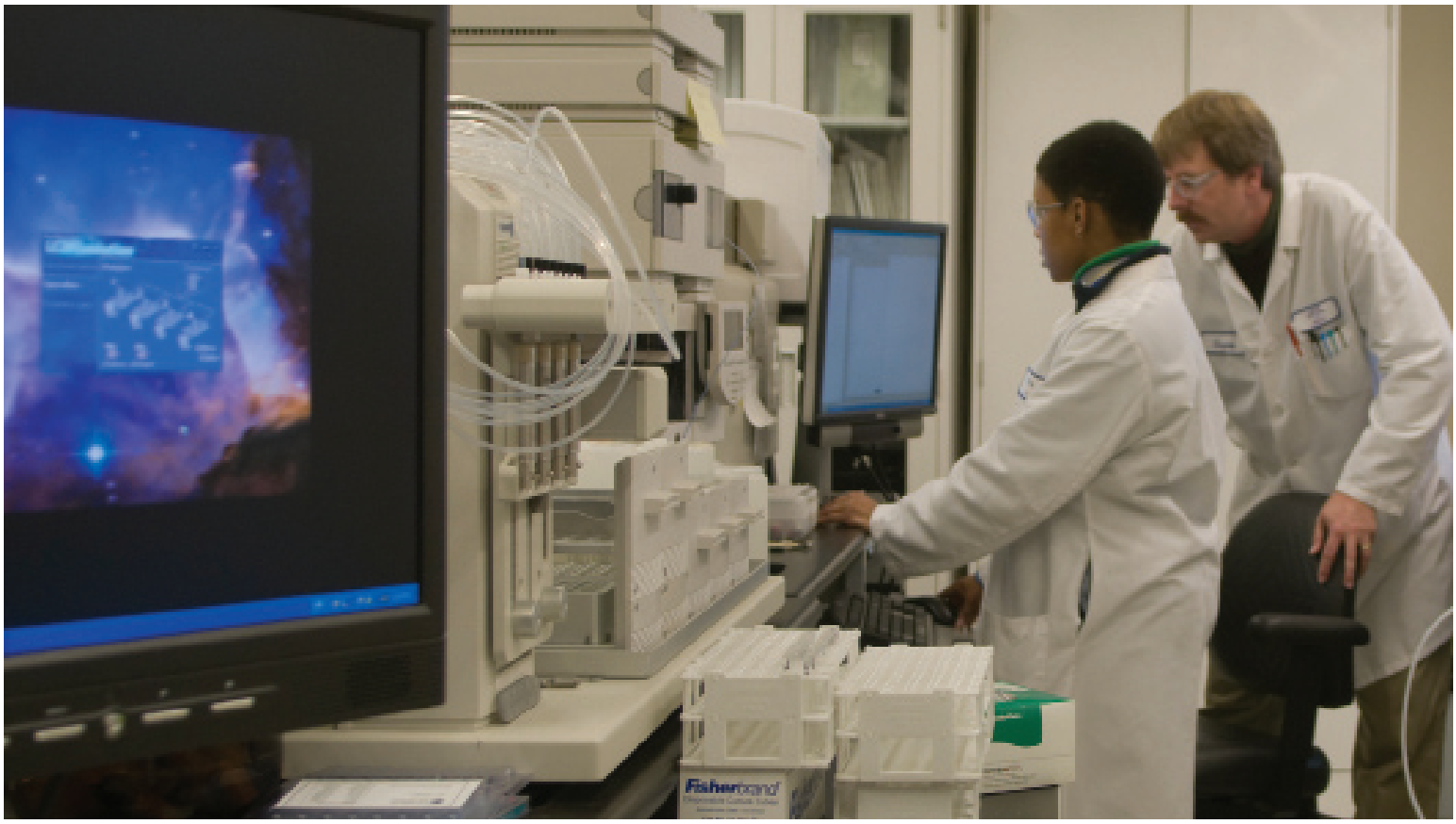
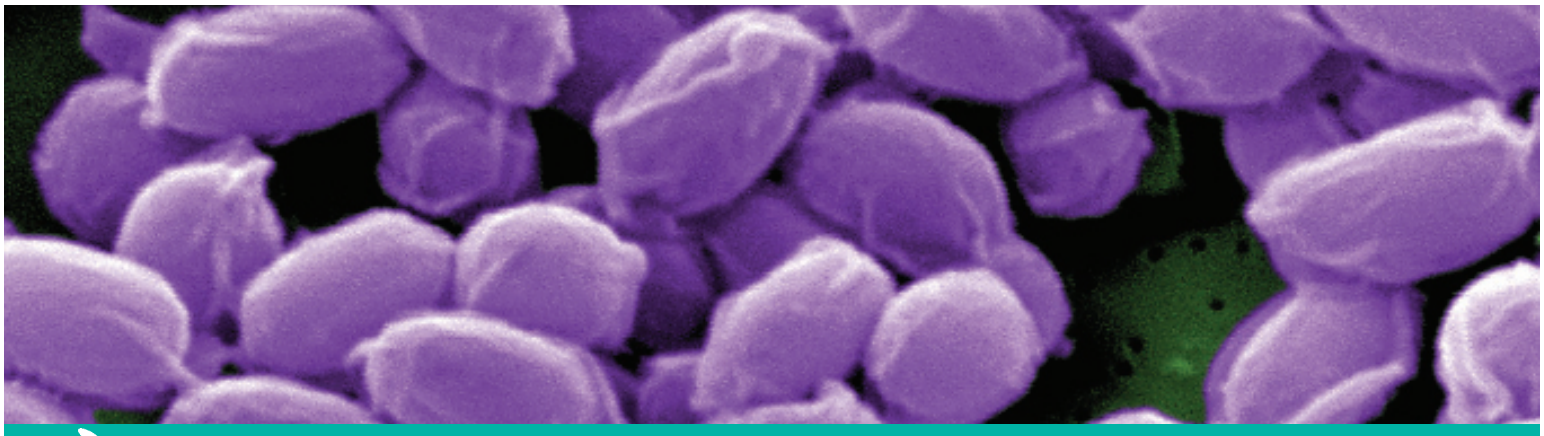
Public Health Laboratory Preparedness: Ready, Set, Respond

An APHL Report on the Preparedness of State Public Health Laboratories





APHL

Public Health Laboratory Preparedness Report

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The Association of Public Health Laboratories (APHL) is a national non-profit dedicated to working with members to strengthen laboratories with a public health mandate. By promoting effective programs and public policy, APHL strives to provide public health 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 Photos
Top photo: Chemical Response & Terrorism Preparedness Group Laboratory, Virginia Division of Consolidated Laboratory Services, one of 10 Level 1 laboratories in the Chemical Laboratory Response Network. Level 1 laboratories provide the CDC with much-needed surge capacity for handling samples in a chemical event. Photo (c) 2007 Walter P. Calahan. Bottom photo: Scanning electron micrograph of spores from the Sterne strain of *Bacillus* anthracis bacteria at a magnification of 31,207X. Photo 2002, courtesy of the Public Health Image Library, the Centers for Disease Control and Prevention.

Executive Summary: Public Health Laboratory Preparedness: Ready, Set, Respond

The United States increasingly faces threats from not just biological, chemical and radiological terrorism, but also sudden, unexpected outbreaks of pandemic influenza, tuberculosis, environmental threats such as mercury poisoning, and a whole host of other natural disasters and emerging infections. As such, it is vitally important that public health laboratories are prepared to respond to a myriad of threats on a day-to-day basis. However, though the list of threats is ever-growing, critical areas such as sustained funding, recruiting and training laboratory personnel and electronic reporting of test results have seen substantial setbacks in recent years. While public-health laboratories have made important progress in preparedness, without a concerted effort at both the state and federal levels to address these gaps, public health laboratories cannot ensure America's health in the upcoming years.

In January 2008, the Association of Public Health Laboratories (APHL) finalized data collection on its first All-Hazards Laboratory Preparedness Survey, which expanded past assessments on biological and chemical terrorism preparedness. The new survey reflected the growing slate of responsibilities for state public health laboratories, and is a more comprehensive assessment of state public health laboratory capability and capacity to respond to terrorism events, natural disasters and emerging infections.

The survey was administered via mrInterview, a web-based repository and survey tool. Results were coded for entry into SPSS for Windows Version 15.0. Unless otherwise noted, data were collected for a period of 12 months, covering activities from August 31, 2006, to August 30, 2007, representing CDC Cooperative Agreement FY 2006 funds awarded in August 2006 (Budget Year 7). The survey was sent to the 50 states, the District of Columbia (DC) and Puerto Rico. Fifty-one responses (a response rate of 98%) were received, representing all states and DC. For the purposes of this Executive Summary, "states" or "state public health laboratories (SPHLs)" will refer to all respondents, including DC.

Key findings include the following:

Funding

In FY 2006, state and local health departments received approximately $770 million from CDC for Public Health Emergency Preparedness (PHEP) and Early Warning Infectious Disease Surveillance activities via the PHEP Cooperative Agreement. Of this amount, state public health laboratories received approximately $74 million (less than 10% of the total) to maintain and enhance capability and capacity for the detection of biological and chemical terrorism agents.

Biological Terrorism Preparedness Funding

- Forty-seven SPHLs reported receiving $51 million—almost $23 million (31%) less than FY 2005 and $54 million (51%) less than FY 2002—to develop and maintain capacity and capability for detecting potential agents of biological terrorism. SPHLs used these funds for personnel, equipment and supplies, training exercises and other activities, such as communications and information technology (IT) support.
- For FY 2006, 42 SPHLs (82%) reported that their overall bioterrorism funding was reduced. Laboratories reported an average reduction of 18% in federal funding and approximately 1% in state funding. As a result of the reduced funding, SPHLs reported the following consequences: inability to hire and maintain personnel, reduced analytical capabilities, reduced attendance at national meetings and training courses, fewer training courses provided, and inability to purchase critical equipment and supplies.

Chemical Terrorism Preparedness Funding

- SPHLs received approximately $24 million from CDC for FY 2006 chemical threat preparedness activities, a decrease of more than $6 million (20%) from FY 2005.
- Forty-five laboratories (88%) did not receive money for chemical terrorism preparedness from their state, which represents an increase from 44 in FY 2005. In FY 2006, federal dollars accounted for 92% of all funding for chemical terrorism preparedness, an increase from 88% in FY 2005.
- Twenty-five laboratories (49%) indicated a decrease in federal funding; the average decrease was $124,924 (18%) per laboratory from FY 2005. The average decrease in state funding was $5,819 (2%) per laboratory. As a result of these decreases, many laboratories (92%) experienced an increase in their sample testing turnaround time, and could not purchase or upgrade their Laboratory Information Management Systems.

Workforce

A highly skilled laboratory workforce is essential to protect the public's health. With funding cuts and other workforce challenges, SPHLs cannot maintain the full complement of trained staff.

- More than half (59%) of all SPHLs experienced difficulty in recruiting or retaining staff and 65% experienced hiring difficulties.
- Approximately half of SPHLs have a full time staff person in the bioterrorism laboratory coordinator (61%) and chemical terrorism laboratory coordinator (55%) roles. Many laboratories either have staff working fewer than 35 hours per week on preparedness activities, or have combined functions with other duties, such as state training laboratory coordinator (49%), liaison to private and public laboratory communities (73%) and training coordinator for first responders (61%).

Planning, Partnerships and Exercises

Planning

Preparedness planning is a vital step to ensure that the necessary resources are available when they are most needed. Beyond emergency and continuity of operation planning, it is critical for state public health laboratories to participate in exercises and drills.

- All 51 SPHLs either have a continuity of operations plan (COOP) in place or are developing one that includes laboratory operations. This number is a marked improvement from FY 2004, when only 18 state public health laboratories had a COOP and 14 states included laboratory operations in their COOP.
- Of the state public health laboratories that have a COOP in place, 58% did not test or exercise their COOP in FY 2006.
- All states and DC public health laboratories have a 24/7/365 emergency contact system in place.

Partnerships

In this era of constant threats, such as unknown white powders in a federal building, ricin in a hotel room and emerging infectious diseases across the globe, public health laboratories must be ever vigilant to protect the public's health. As such, the scope of work for public health laboratories continues to expand. These laboratories have built and maintained partnerships with a number of agencies, laboratories and first responder communities.

- Thirty-six laboratories (71%) provide training and outreach to their first responders, such as the Hazardous Material (HAZMAT) and Civil Support Team (CST) units.
- Forty-eight SPHLs (94%) sponsored training for their sentinel clinical laboratories. From August 2006 to August 2007, state public health laboratories sponsored sentinel clinical laboratory training and offered more than 250 rule-out testing classes

to about 2,500 laboratorians, about 350 packaging and shipping classes to more than 3,500 laboratorians, about 130 biosafety guidelines classes to about 2,300 laboratories and more than 100 classes on broad laboratory practices to more than 3,000 laboratorians.

- Fifty SPHLs (98%) maintained a database of all sentinel clinical laboratories and pertinent laboratorians in their states.
- Twenty SPHLs (39%) have issued formal certificates of recognition to 860 sentinel clinical laboratories.

Exercising

Beyond planning and building partnerships, it is important for laboratories to test their system by conducting exercises. Public health laboratories continue to make progress in developing and implementing exercises for the first responder and laboratory communities.

- Forty-six SPHLs (90%) conducted drills or exercises with their sentinel clinical laboratories, first responders and other state agencies to test their state laboratory's 24/7 emergency response system.
- Fifty SPHLs (98%) have a performance measurement system in place to assess the competency of sentinel clinical laboratories to rule out potential agents of biological terrorism.

Sample Receipt and Analyses

The scope of work for state public health laboratories continues to include all-hazards testing. These laboratories accept samples from a host of federal agencies, first responders and other laboratories.

- From August 31, 2006, to August 30, 2007 (CDC PHEP Grant FY 2006), state public health laboratories received 5300 unknown samples (1686 clinical specimens and 3614 environmental samples) to test for suspected terrorism agents. State public health laboratories tested 98% (5,100) of these unknown samples using CDC Laboratory Response Network (LRN) biological methods and more than 66% (3,500) of the samples using CDC LRN chemical methods for potential agents of terrorism.
- More than half of all SPHLs (59%) do not have an intra-state courier system that operates 24 hours a day for specimen pick-up and delivery. Lack of these systems could result in delays in receiving specimens, increasing the time from sample collection to result reporting.
- Only 20 SPHLs (39%) have a unique space or a separate facility for screening and triaging unknown samples.
- Fewer than 25% of SPHLs can screen or test clinical specimens for radiation and of those, the majority can only test blood and urine.

Reporting Capabilities

In the face of a potential terrorism attack, infectious diseases outbreak or natural disaster, laboratory data should be transmitted electronically for local and federal agencies to react quickly and decisively. Currently this is not the case.

- Forty-five SPHLs (88%) have a Laboratory Information Management System (LIMS). Of these 45 laboratories, 36 indicated that their LIMS has a bioterrorism component, 27 have a chemical component, 13 have a radiological component and eight have no terrorism preparedness component. Many of the laboratories that have a LIMS with a bioterrorism, chemical or radiological component indicated that they are not currently using their LIMS to send data and test results to other local, state or federal agencies.
- SPHLs mainly use the telephone to transmit bioterrorism, chemical terrorism and radiological terrorism data/test results for clinical and environmental samples to local, state and federal partners.

Summary

State public health laboratories have made great strides in the area of preparedness since first receiving CDC PHEP Cooperative Agreement funding in 2000. Examples of this success include enhanced training and outreach to partners, implementing formal exercises and drills to assess gaps in planning, testing capacity and capability, and developing partnerships with new agencies, first responders and laboratories. The combination of these efforts has resulted in a stronger public health system and a nation with enhanced preparedness capacity and capability. However, despite these improvements, notable gaps in laboratory preparedness remain. These include complacency, funding gaps, workforce shortages, lack of standardized platforms to exchange data electronically and lack of a national strategy to address gaps in laboratory capacity for chemical and radiological terrorism preparedness. Continued funding constraints and decreases in funding for laboratory initiatives, such as drills and exercises, may jeopardize much of this progress.

"When people ask me what's the biggest challenge in public health, I have an easy answer. For large-scale disasters and more routine threats to health, the major problem we face in public health is complacency. We've made a lot of progress in our preparedness efforts, but we're not done yet. We need long-term investment to really get us where we want to be."[1]

—Dr. Julie Gerberding, CDC Director, 2007

BACKGROUND

In an emergency involving biological, chemical, or radiological agents—whether linked to terrorism or not—a key response activity is laboratory testing. The nation's public health system is vital to protecting against and responding to terrorism, natural disasters and emerging diseases. Laboratories within the public health system operate as a first line of defense to guard the American people against diseases and other health threats. Working in collaboration with other branches of the system, public health laboratories provide surveillance and diagnostic testing to support ongoing preparedness initiatives.

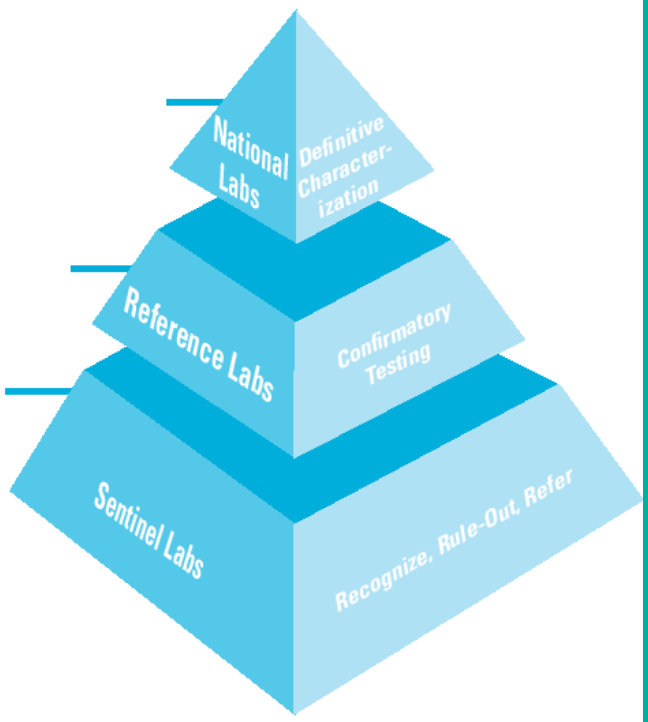
Public health laboratories continue to face a growing slate of responsibilities, known as "all-hazards preparedness," which refers to preparedness for and response to health emergencies, such as chemical, biological, radiological, nuclear and explosive (CBRNE) threats, naturally occurring infectious disease outbreaks, natural disasters and accidents, such as toxic spills. However, despite the increased responsibilities and expectations, funding to support these activities continues to decline both at the federal and local levels.

METHODS

Data for this report were collected in the winter of 2007 when APHL fielded its first All-Hazards Laboratory Preparedness Survey of state public health laboratories. This all-encompassing survey combined previous bioterrorism and chemical terrorism assessments, as well as included questions on radiological terrorism preparedness to reflect the growing slate of responsibilities for state public health laboratories. Briefs from the previous bioterrorism and chemical terrorism laboratory preparedness surveys are available at APHL's website, www.aphl.org.

For the current survey, participants reported on laboratory capability and capacity as of August 30, 2007. Unless otherwise noted, data were collected for a period of 12 months, covering activities from August

Figure 1



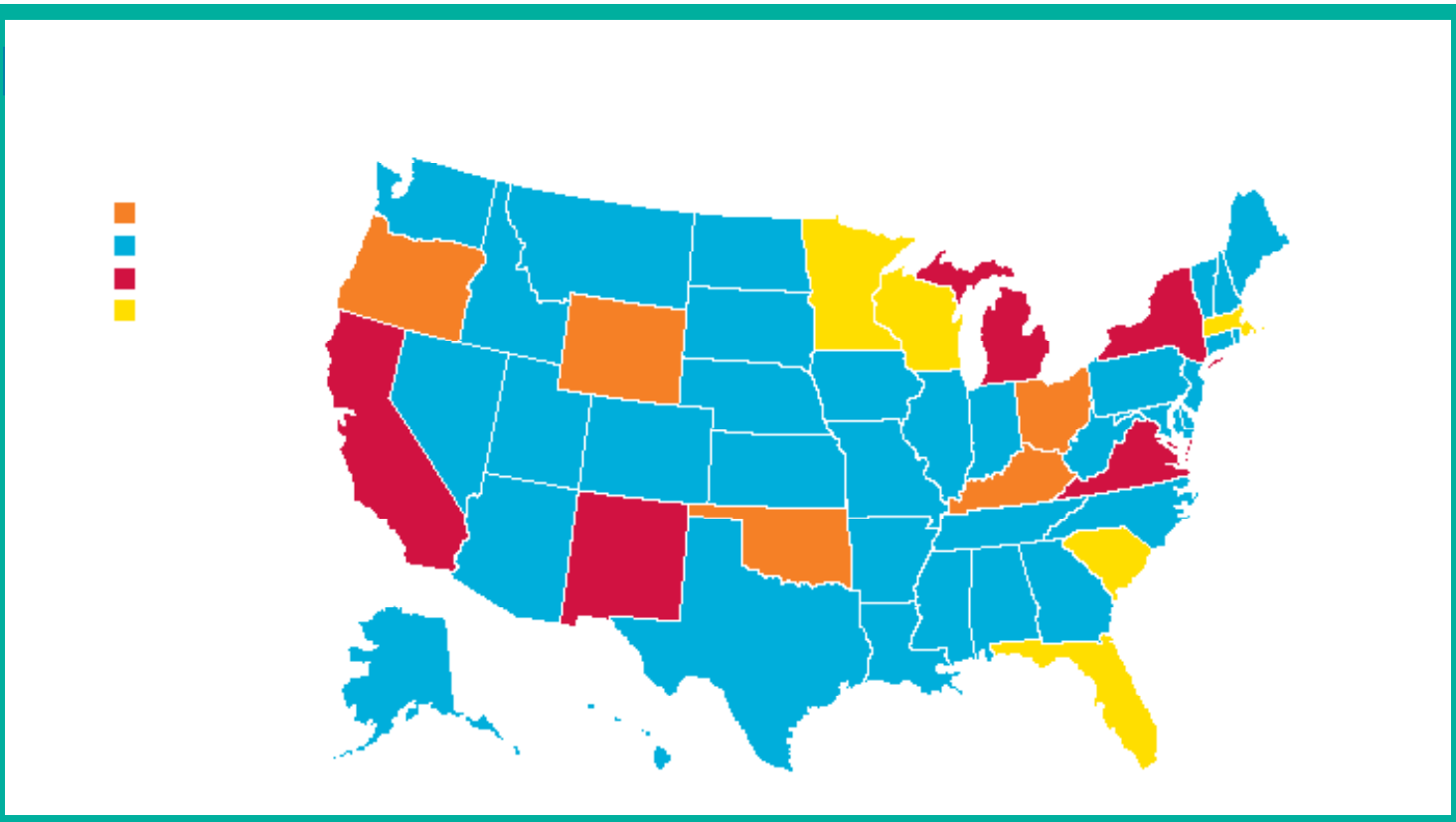
The Laboratory Response Network for Biological Terrorism

High quality laboratory testing is an essential component to initiating a public health response to terrorism. It allows for effective decision-making to close buildings or entire geographic areas, to treat exposed persons and to deploy the Strategic National Stockpile.

Formed in 1999 by the Centers for Disease Control and Prevention (CDC), the Association of Public Health Laboratories (APHL) and the Federal Bureau of Investigation (FBI), the Laboratory Response Network (LRN) is the nation's premier system for identifying, testing and characterizing potential agents of biological and chemical terrorism. [2]

State and local public health laboratories comprise approximately 70% of the 164 Laboratory 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 LRN for Bioterrorism is organized as a three-tiered pyramid. At the base are thousands of sentinel clinical laboratories, which perform initial screening of potential pathogens. When sentinel clinical laboratories cannot rule out the presence of a bioterrorism agent, they refer specimens and isolates to an LRN reference laboratory. More than 160 state, local and federal facilities provide reference testing. At the apex are national laboratories, such as those at the CDC and the Department of Defense. 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).



The chemical component of the LRN (chemical LRN) 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.

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 state.

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 ten 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.**

31, 2006, to August 30, 2007, representing CDC Cooperative Agreement FY 2006 funds awarded in August 2006 (Budget Year 7). The survey was sent to the 50 states, the District of Columbia (DC) and Puerto Rico.

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

The survey was administered via mrInterview, a web-based repository and 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
- Workforce
- Planning, Partnerships and Exercising
- Sample Receipt and Analyses
- Reporting Capabilities

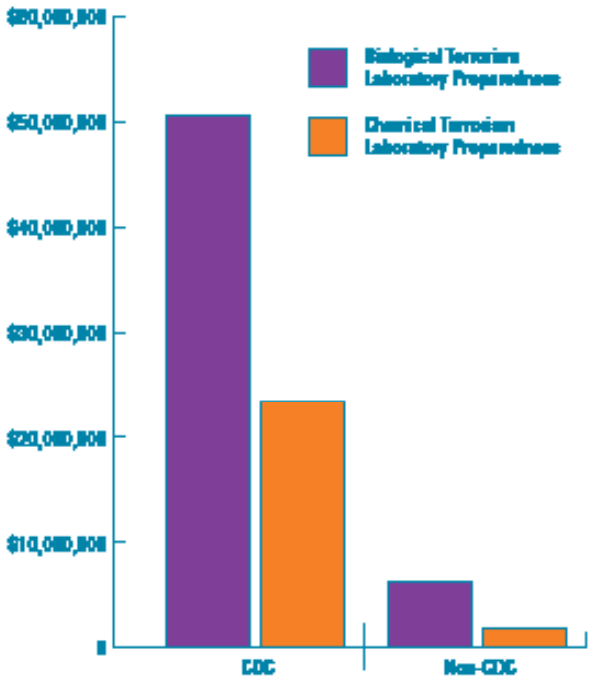
RESULTS

Funding

In 2002, Congress authorized funding for the Public Health Emergency Preparedness (PHEP) Cooperative Agreement to support nationwide preparedness in public health departments. The PHEP Cooperative Agreement, which is administered by CDC, funds 50 states, four metropolitan areas (Chicago, Los Angeles County, New York City and Washington, DC), five territories (Puerto Rico, the Northern Mariana Islands, American Samoa, Guam and the U.S. Virgin Islands), and three freely associated states (the Federated States of Micronesia, Palau and the Marshall Islands). While the Cooperative Agreement funding for these 62 jurisdictions did not begin until 2002, CDC began funding selected public health departments in 1999.

In FY 2006, state and local health departments received approximately $770 million from CDC via the PHEP Cooperative Agreement.[3] Of this amount, state public health laboratories received approximately $74 million (less than 10% of the total) to maintain and enhance capability and capacity for detecting biological and chemical terrorism agents. However, as Figure 3 shows, SPHLs received minimal funding from other sources outside of CDC to support preparedness activities.

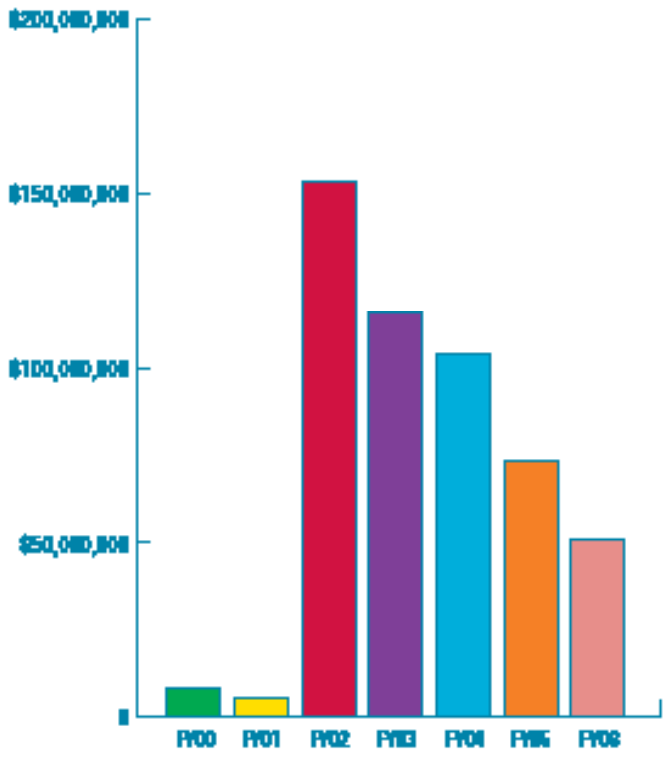
Figure 3 **FY 2006 Funding for State Public Health Laboratories**



Bioterrorism Laboratory Preparedness Funding

- **As Figure 4 shows, 47 state public health laboratories reported receiving $51 million—almost $23 million (31%) less than FY 2005[4] and $54**

Figure 4 **Biological Terrorism Preparedness Funding for State Public Health Laboratories**



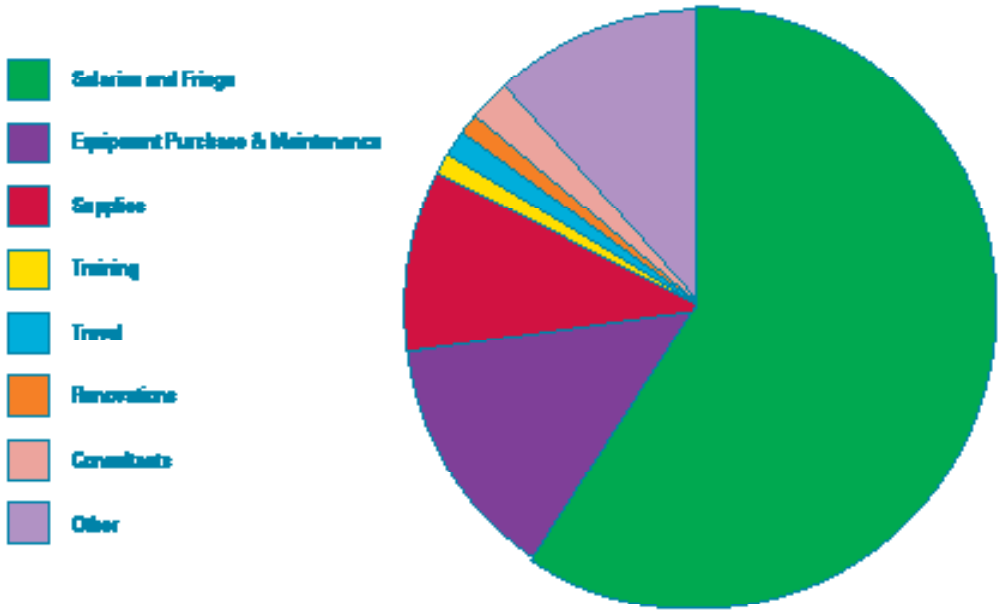
million (51%) less than FY 2002[5] —to develop and maintain capacity and capability for detecting potential agents of biological terrorism. State public health laboratories used these funds for personnel, equipment and supplies, training exercises and other activities, such as communications and information technology (IT) support. **Figure 5** illustrates how SPHLs allocated these expenditures.

- **For FY 2006, 42 SPHLs (82%) reported that their overall bioterrorism funding was reduced. Laboratories reported an average reduction of 18% in federal funding and approximately 1% in state funding.** SPHLs reported the following consequences as a result of the reduced funding: inability to hire and maintain personnel, reduced analytical capabilities, reduced attendance at national meetings and training courses, fewer training courses provided, and inability to purchase critical equipment and supplies. Without trained personnel and the ability to provide core services, public health laboratories will be unable to quickly respond to biological threats, or analyze clinical and environmental samples for biological agents.

Chemical Threat Laboratory Preparedness Funding

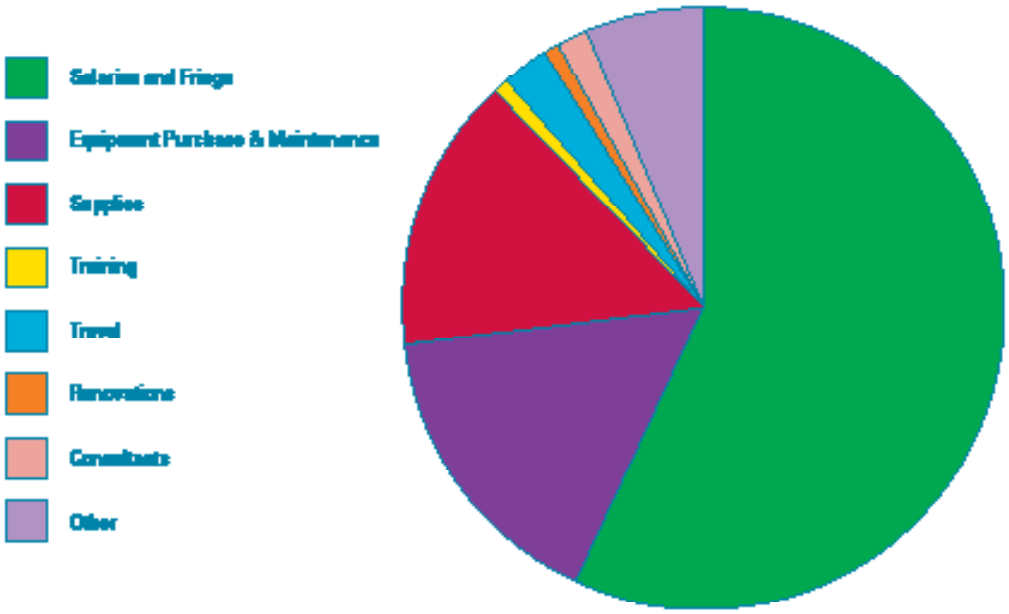
State public health laboratories receive the majority of their chemical threat preparedness funding from CDC, based on their LRN level (1, 2 or 3). CDC allocates a specific amount of funding to support level 1 activities. Level 1 laboratories must then compete for state funding for the level 2 and 3 activities, which are required of them under the current PHEP Cooperative Agreement.

Figure 5 **FY 2006 Allocation of CDC Public Health Emergency Preparedness Cooperative Agreement Funds in State Public Health Laboratories: Bioterrorism Preparedness (based on a reported total of $50,639,058)**



- **SPHLs received approximately $24 million from CDC for FY06 chemical threat preparedness activities, a decrease of more than $6 million (20%) from FY 2005.**
- Laboratories used the majority of the funding (88%) for salaries, supplies and equipment **(See Figure 6.)** In FY 2005, laboratories allocated only 51% of the CDC chemical terrorism preparedness funds to salaries and fringe. Since funding continues to decrease in FY06, laboratories increasingly use the CDC PHEP Cooperative Agreement funds to pay for personnel. Relying on a funding stream that continues to decrease could lead to loss of personnel for many SPHLs. Without personnel, laboratories cannot respond to chemical threats, or analyze clinical and environmental samples for chemical threat agents.
- **Forty-five laboratories (88%) did not receive money for chemical terrorism preparedness from their state, which represents an increase from 44 in FY 2005.**
- In FY 2006, federal dollars accounted for 92% of all funding for chemical terrorism preparedness, an increase from 88% in FY 2005. Due to the lack of state funding, SPHLs increasingly rely on federal funding to develop and enhance laboratory capability and capacity to respond to chemical threats.
- **Twenty-five laboratories (49%) indicated a decrease in federal funding; the average decrease was $124,924 (18%) per laboratory from FY 2005.** The average decrease in state funding was $5,819 (2%) per laboratory. As a result of these decreases, many laboratories (92%) experienced an increase in their sample testing turnaround time, and could not purchase or upgrade their Laboratory Information Management Systems. Some laboratories (88%) lost full time staff, and neither sent their remaining staff to training courses nor purchased

Figure 6 **FY 2006 Allocation of CDC Public Health Emergency Preparedness Cooperative Agreement Funds in State Public Health Laboratories: Chemical Terrorism Preparedness (based on a reported total of $23,527,643)**



reagents or supplies.

Influenza Laboratory Preparedness Funding

Public health laboratories will be an integral part of any public health response to pandemic influenza and therefore must be included in comprehensive local, state or federal plans for preparedness and response. These laboratories rely on PHEP funding to assist with annual influenza surveillance using state-of-the-art methods.

In recent testimony before the United States House of Representatives' Committee on Homeland Security, APHL member, Dr. Peter Shult, Director Communicable Disease Division, Wisconsin State Laboratory of Hygiene, stated that, "while the public health laboratory focus is on surveillance to support response and control measures, [public health laboratories] must also work closely with private sector laboratories that provide diagnostic testing to support clinician diagnosis and treatment of their patients. Public health laboratories provide confirmatory testing for clinical laboratories, education to clinicians and clinical labs regarding the use and interpretation of rapid influenza tests, and guidance for handling and submission of suspect pandemic strains from clinical and physician office laboratories. These are resource intense activities that are difficult to maintain without funding."[6]

- **In July 2006, CDC released Phase II supplemental Pandemic Influenza funds ($225 million formula award and $25 million competitive award) through the FY 2006 PHEP Cooperative Agreement. Of this $250 million funding for pandemic influenza preparedness, 33 SPHLs received approximately $7 million (3%).**

Food Safety Funding

The malicious contamination of food is a real and ongoing threat. In 2003, former Food and Drug Administration (FDA) Commissioner Mark McClellan stated, "a terrorist attack on the food supply could pose both severe public health and economic impacts, while damaging the public's confidence in the food we eat."

State public health laboratories play a vital role in rapidly detecting intentional and unintentional foodborne outbreaks through their participation in PulseNet, CDC's national molecular subtyping network for foodborne disease surveillance. In 2004, the United States Department of Agriculture (USDA) and the FDA collaborated with CDC, EPA, the Department of Energy (DOE) and states to develop a nationwide Food Emergency Response Network (FERN), which is responsible for analyzing food samples in the event of a biological, chemical or radiological terrorist event.

Many of the laboratories in FERN are also members of the Laboratory Response Network and have a significant testing and reporting burden. Given that CDC PHEP funding for the LRN laboratories continues to decrease, it is even more important for FDA and USDA to support the necessary testing, validation, proficiency testing and training for all FERN laboratories.

- **For FY 2006, 16 SPHLs (31%) received funding from the Food Emergency Response Network (FERN).** Thirteen laboratories received $616,548 for biological testing activities, six laboratories received $959,900 for chemical testing activities and two laboratories received $282,232 for radiological testing activities.

The findings above clearly indicate a sharp decline in funding for laboratory all-hazards preparedness activities. The impacts of this funding decline can be felt throughout the laboratory, but it is hardest felt among the workforce.

Workforce

Across the nation, public health laboratories are experiencing difficulty maintaining a highly skilled and trained workforce, which is essential to protect the public's health. These challenges are compounded by a shortage of laboratory professionals entering the workforce, as well as a lack of individuals with the experience and credentials needed to assume senior laboratory positions. Further, a large portion of the laboratory population is retiring, causing the pool of job-seekers to further shrink.

- More than half of all SPHLs (59%) experienced difficulty in recruiting or retaining staff and 65% experienced hiring difficulties. **(See Figure 7.)**
- States reported a total of 74 vacancies, with a majority of these being laboratorian positions. **(See Figure 8.)**

One area of the laboratory experiencing the greatest number of vacancies is radiochemistry. Many laboratories have, at best, very basic radiochemistry knowledge. Staff is often cross-trained in this area, which results in understaffing and limited testing capabilities.

Figure 7 **State Public Health Laboratories: Workforce Difficulties**

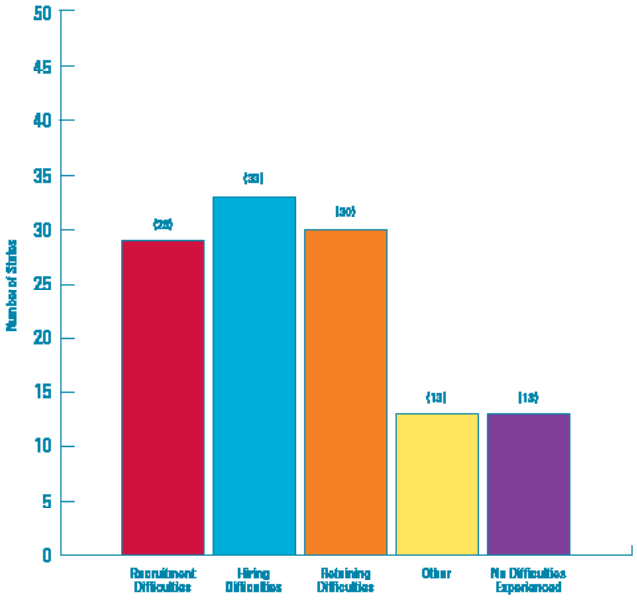
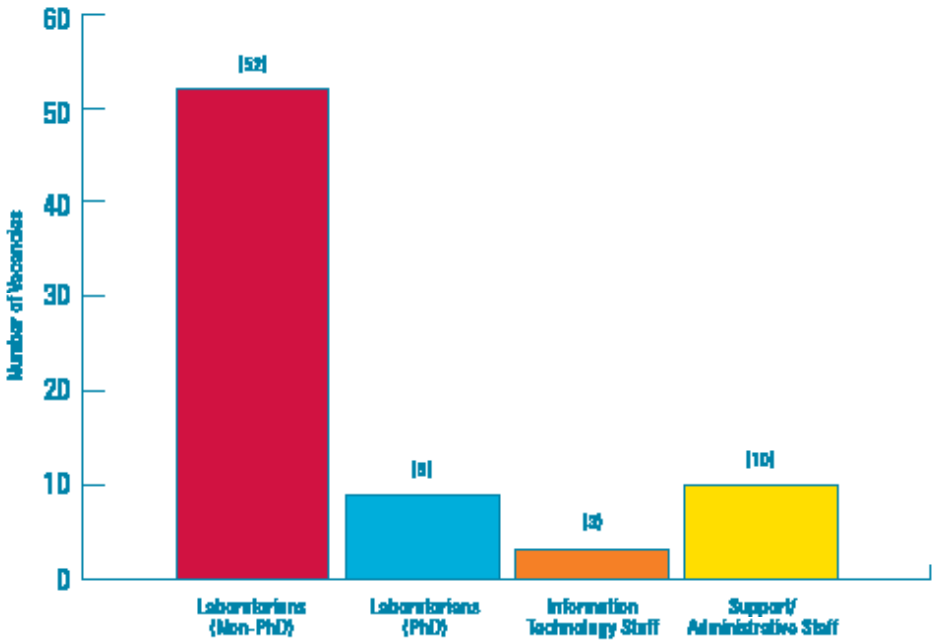


Figure 8 Vacancies in State Public Heath Laboratories



- **Twenty-one SPHLs (41%) do not have any staff trained to test for radionuclides.** Other states have only one or two laboratorians trained to test for radionuclides, which would not be enough staff to test the overwhelming number of samples a laboratory could potentially receive during a radiation exposure event. Those laboratories that do have staff noted that their staff will soon retire. There are few radiological education programs left in the nation and even fewer individuals seeking such jobs in the public health laboratories.

Shortages in the laboratory workforce extend beyond the radiochemistry arena. State Training Coordinators, and Chemical Terrorism and Biological Terrorism Laboratory Coordinators, who provide critical training both internally and externally, are also seeing their activities combined to reduce the number of full-time employees the laboratory needs.

- **Approximately half of SPHLs have a full-time staff person in the bioterrorism laboratory coordinator (61%) and chemical terrorism laboratory coordinator (55%) roles. Many laboratories have staff working fewer than 35 hours per week in the following roles: state training laboratory coordinator (49%), liaison to private and public laboratory communities (73%) and the training coordinator for first responders (61%). (See Figure 9.)**

To maintain the ability to confirm the presence of agents of biological terrorism, SPHLs must recruit and maintain staff with specialized training in microbiology, molecular methods and other LRN procedures. These staff must also 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 Bioterrorism Preparedness and Response Act of 2002.

CDC and APHL collaborate to provide required standardized training to LRN reference laboratories as resources permit. **Table 1** underscores the importance of such training. There have been improvements in the number of states with at least one laboratorian trained to perform time-resolved fluorescence assays (49, up from 43 in FY 05), assays for *Brucella* species (50, up from 48 in FY 05), *Burkholderia* species (50, up from 45 in FY05) and screening assays for *Clostridium botulinum* neurotoxin (40, up from 38 in FY 05 and only 19 in FY 04). However, SPHLs indicate the continuing need for more training and additional staff to perform confirmatory testing of agents of biological terrorism.

The competency of a laboratory's workforce is a major component of how effectively a laboratory can rapidly and accurately detect a potential threat. However, due to the nature of the work and the limited funding available, many laboratories experience high turnover rates (and many vacancies). Further, these workforce shortages may hinder a laboratory's ability to implement broader preparedness plans, form partnerships and develop robust training exercises.

Planning, Partnering and Exercising

Planning

Preparedness planning is a vital step to ensure that the necessary resources are available when they are most needed. Beyond developing emergency plans and continuity of operation planning, it is critical that state public health laboratories participate in exercises and drills. As other agencies develop such exercises, they must consider how best to assess these programs' effectiveness and develop a strategy to address gaps identified during the exercises and drills. According to the Congressional Research Service, *"Exercises and drills test the ability of jurisdictions to execute their plans, and they detect planning gaps. Consequently, assessments of response capability rest not only on assessments of planning, but also on assessments of exercise programs and integration of findings into subsequent rounds of planning."* [8]

- **All state public health laboratories either have a continuity of operations plan (COOP) in place**

Figure 9 **Employees Dedicated to Laboratory Connectivity and Training**

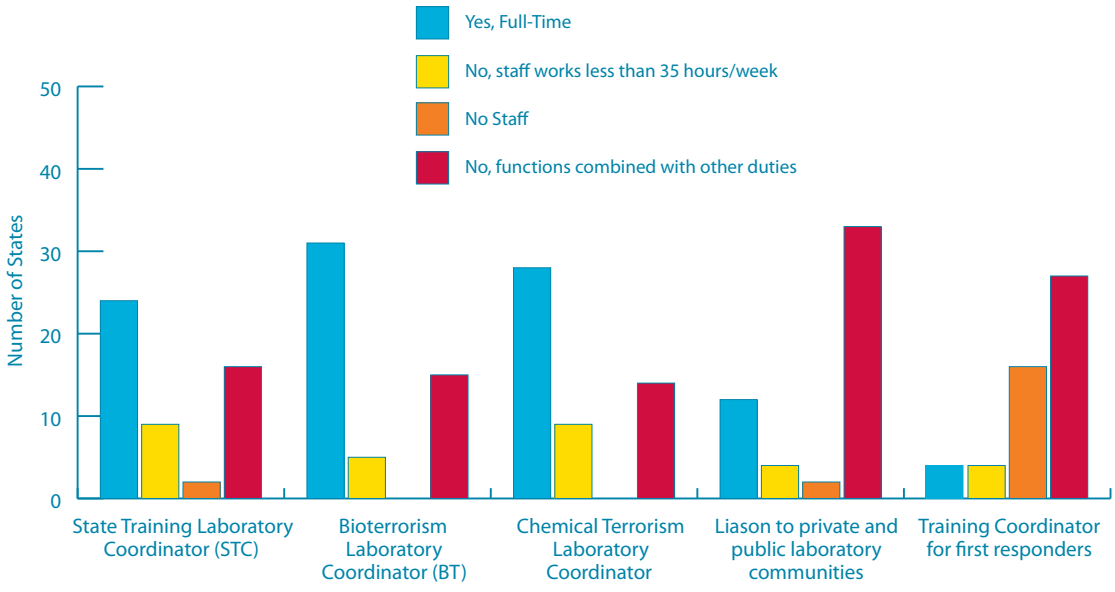


Table 1 Employees Dedicated to Laboratory Connectivity and Training

Agent or Method	States with at least one trained laboratorian to perform testing	Average number of additional staff needed in each state	Number of states reporting need for more staff
Polymerase Chain Reaction (PCR)	51 (100%)	6	28 (55%)
Time-Resolved Fluorescence (TRF)	49 (96%)	4	28 (55%)
Bacillus anthracis	51 (100%)	6	29 (57%)
Yersinia pestis	51 (100%)	6	29 (57%)
Brucella species	50 (98%)	6	29 (57%)
Burkholderia species	50 (98%)	6	30 (59%)
Clostridium botulinum-DIG ELISA Screening Assay	40 (78%)	2	33 (65%)
Clostridium botulinum toxin mouse bio-assay	26 (51%)	2	17 (33%)
Francisella tularensis	50 (98%)	6	29 (57%)
Coxiella burnetii	47 (92%)	5	29 (57%)
Variola and poxvirus	49 (96%)	4	31 (61%)
Ricin-TRF	48 (94%)	4	27 (53%)
Ricin-PCR	50 (98%)	5	27 (53%)
Staphylococcal enterotoxin B-TRF	47 (92%)	4	27 (53%)
Influenza A H5 PCR Assay	50 (98%)	5	28 (55%)

or their state is developing one to include laboratory operations. This is a marked improvement from FY 04, when only 18 state public health laboratories had a COOP and 14 states included laboratory operations in their COOP.

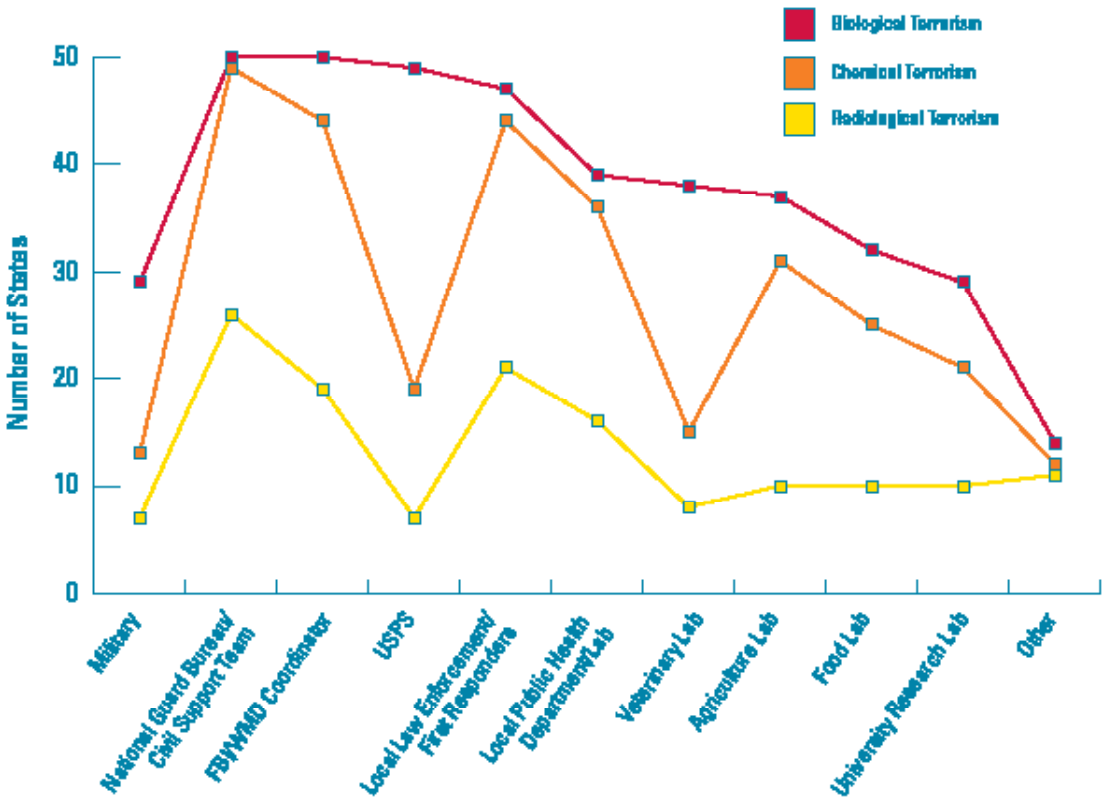
- **Of the state public health laboratories that have a COOP in place, 58% did not test or exercise their COOP in the FY 2006.** This area needs improvement to ensure that these plans will work in an emergency.
- **All states and DC public health laboratories have a 24/7/365 emergency contact system in place.** In collaboration with the CDC Director's Emergency Operations Center (DEOC), the LRN conducts notifications drills to test these 24/7/365 contact systems.

Partnering

Successful relationships between SPHLs and other partners, such as first responders and sentinel clinical laboratories, influence whether response in an emergency is quick and effective. Partnering with the SPHL can ensure a sample is sent to a capable laboratory in a timely-manner—a critical task during an emergency. In addition, first responders often need training on sample collection, handling and risk assessment.

- **Thirty-six laboratories (71%) provide training and outreach to their first responders, such as the Hazardous Material (HAZMAT) and Civil Support Team (CST) units.** Only nine laboratories (18%) provide proficiency testing for first responders and 14 (27%) do not train or otherwise work with first responders. Laboratories that did not provide training or outreach to their first responders cited a lack of staff, expertise and national guidance on these issues as critical reasons for not supporting this activity.
- **Forty-eight SPHLs (94%) sponsored training for their sentinel clinical laboratories.** States mainly used funds from the Cooperative Agreement with the Office of the Assistant Secretary for Preparedness and Response (ASPR) to provide support to sentinel clinical laboratories. **In FY 2006, state public health laboratories sponsored sentinel clinical laboratory training and offered more than 250 rule-out testing classes to about 2,500 laboratorians; about 350 packaging and shipping classes to more than 3,500 laboratorians; about 130 biosafety guidelines classes to about 2,300 laboratories; and more than 100 classes on broad laboratory practices to more than 3,000 laboratorians.**
- Fifty SPHLs (98%) maintained a database of all sentinel clinical laboratories and pertinent laboratorians in their states as required by the CDC PHEP Cooperative Agreement.
- **Twenty SPHLs (39%) issued formal certificates of recognition to 860 sentinel clinical laboratories.** Eleven of those 20 states awarded the LRN Joint Leadership Committee (JLC) approved certificate to 276 sentinel clinical labs and 153 advanced sentinel clinical laboratories, and nine states issued state developed certificates to 431 sentinel clinical laboratories. States must continue their outreach by formally recognizing more sentinel clinical labs, and by providing more training and funding to support participation in ongoing meetings.
- Thirty-nine SPHLs (76%) reported that their bioterrorism laboratory coordinator or other designated bioterrorism staff conducted onsite visits to sentinel clinical laboratories within their state to provide training and enhance relationships with the laboratory staff. This number is a decrease from FY 2005, when 43 SPHLs conducted onsite visits to sentinel clinical laboratories.
- Thirty-one SPHLs (61%) have a bioterrorism advisory committee or equivalent group in place. Respondents noted that funding constraints, lack of staff and minimal management support contributed to the lack of these formal advisory groups. Twenty-five of these laboratories included clinical microbiology laboratory representatives from the sentinel

Figure 10 Working Relationships with Partners



community on their bioterrorism advisory committee or equivalent group. Twenty-nine of these laboratories reported that their bioterrorism advisory committee or equivalent group met in-person at least once, which represents a slight decrease from last year when 35 SPHLs had an advisory group with 33 meeting at least once a year and 32 including clinical microbiology representatives.

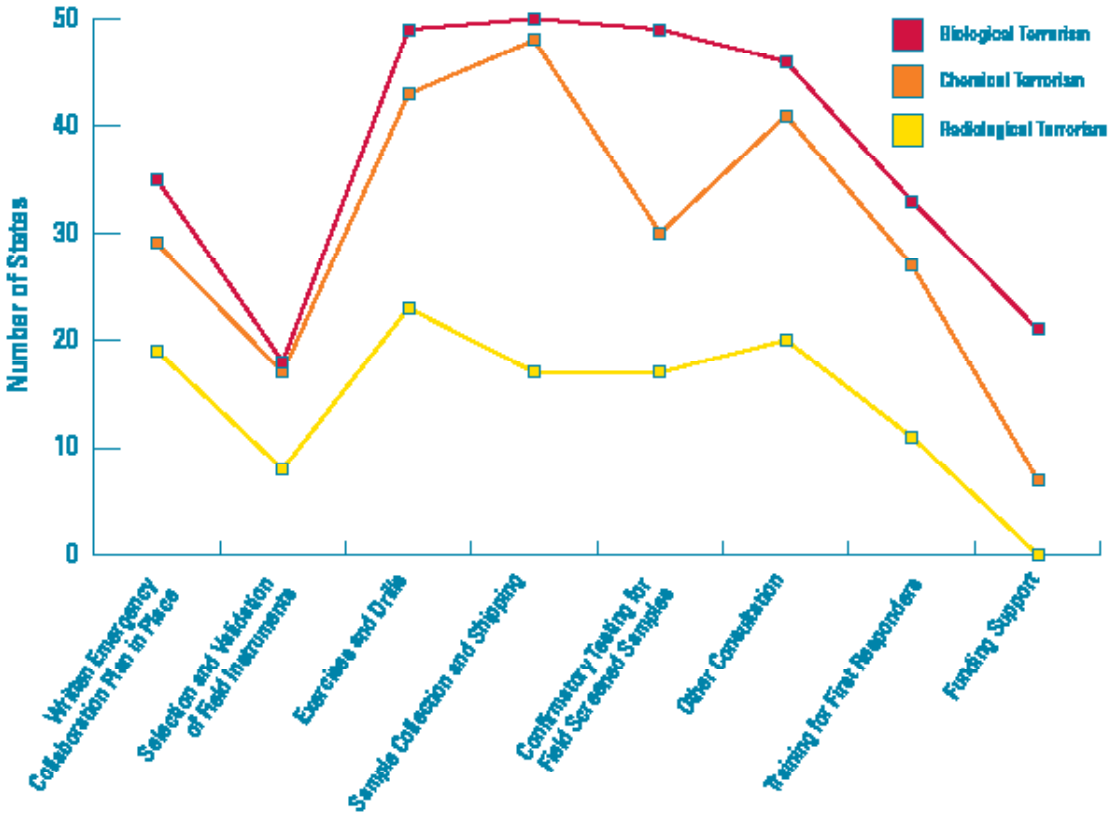
State public health laboratories continue to reach out to a wide variety of partners to build and maintain preparedness links. These partnerships are essential in this era of constant threats, such as unknown white powders in a federal building, ricin in a hotel room and emerging infectious diseases across the globe. **Figure 10** displays the breadth of local, federal, state and other partners who work closely with state public health laboratories.

- To maintain effective relationships with multiple partner agencies and laboratories, SPHLs collaborate using a variety of mechanisms. **(See Figure 11.)**

Exercising

Beyond planning and building partnerships, it is important for laboratories to test their system by conducting exercises. Public health laboratories continue to make progress in this arena by developing and implementing exercises for the local first responder and other laboratory communities. However, many public health laboratories noted that they were often excluded from larger scale national and state-wide exercises.

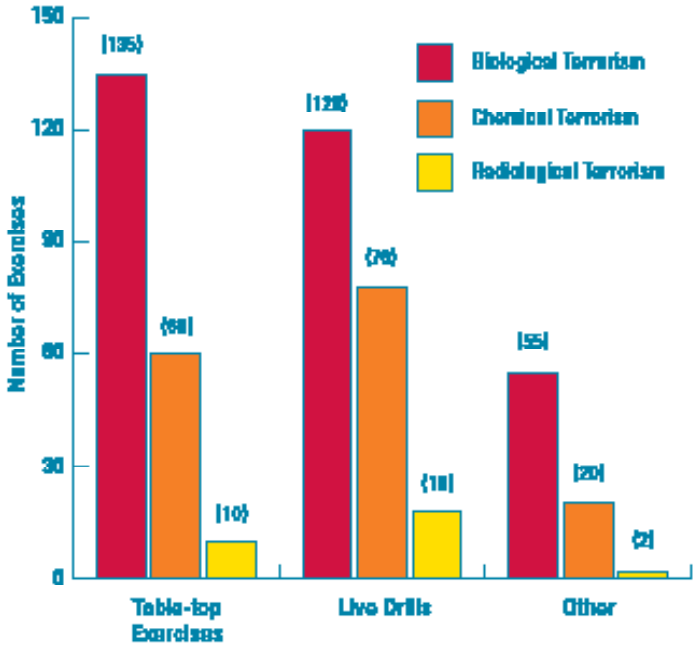
Figure 11 **Methods of Communications/Collaboration between State Public Health Laboratories and Partners**



It is imperative for the federal government and other agencies to include public health laboratories in national and statewide exercises. These exercises provide insight into actual versus perceived capacity and capability, which is critical since public health laboratories are often taken for granted.

- State public health laboratories conducted and participated in several bioterrorism and chemical terrorism preparedness table-top, and live or other drills or exercises. **(See Figure 12.)**
- As Figure 12 shows, SPHLs have participated in many more bioterrorism exercises than chemical and radiological exercises.
- To ascertain what capacity and capability exists in these laboratories, laboratories must conduct much more planning and drilling of the radiological preparedness and response system. **Only 22 SPHLs (43%) participated in radiation emergency response activities, such as planning meetings or trainings.**
- Forty-six SPHLs (90%) conducted drills or exercises with their sentinel clinical laboratories, first responders and other state agencies to test their state laboratory's 24/7 emergency response system.
- **Fifty SPHLs (98%) have a performance measurement system in place to assess the competency of sentinel clinical laboratories to rule out potential agents of biological terrorism.** This is a significant increase from last year when only 39 SPHLs had such a system in place. **(See Figure 13.)**

Figure 12 State Public Health Laboratories Preparedness Exercises



- **In FY 2006, 43 SPHLs (84%) used a rapid method—such as the Health Alert Network (HAN), blast e-mail or fax—an average of 32 times (range 1-500) to send messages to sentinel clinical laboratories and other partners.** These systems sent information on outbreaks, routine updates, training events and other activities.

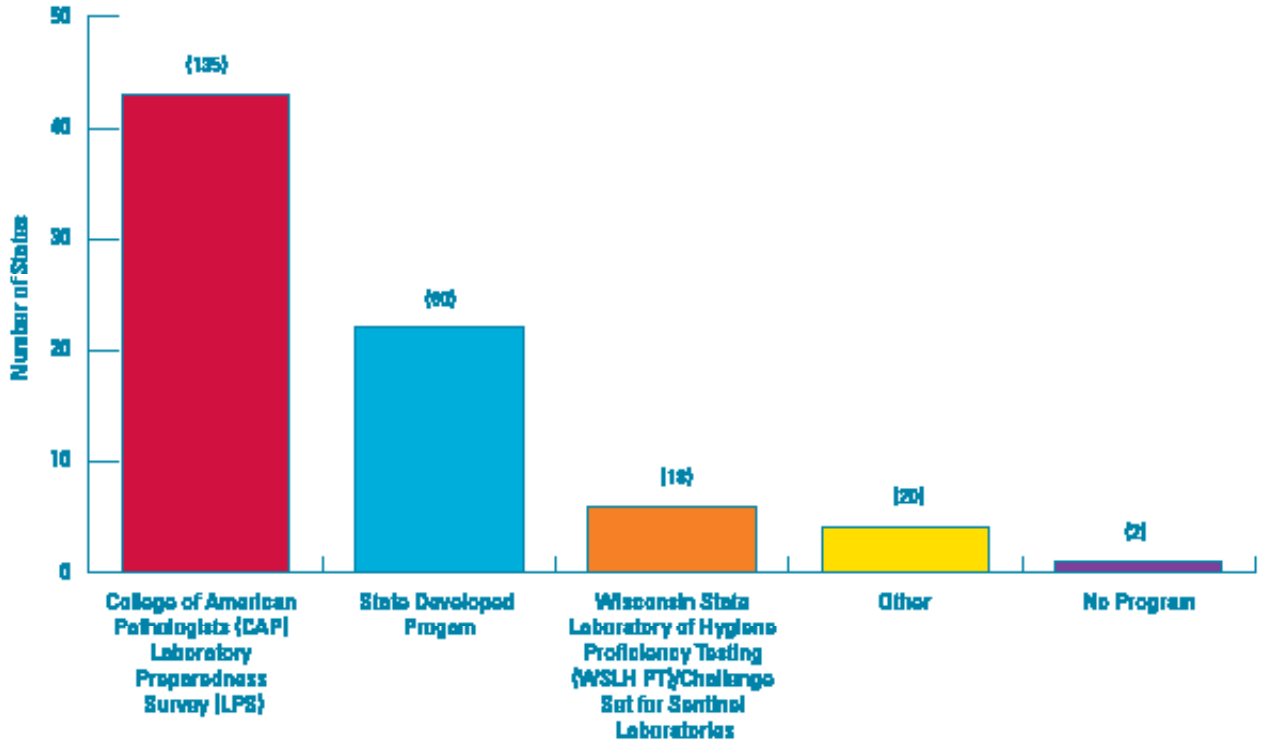
Developing preparedness plans, establishing partnerships and exercising the public health laboratory system before an event are critical for assessing readiness and gaps, especially as it pertains to the rapid detection of biological, chemical, radiological or other threats in an unknown sample.

Most emergencies do not happen during the work hours of 9:00AM to 5:00PM. When there is a chemical plant explosion or threat letter that may contain anthrax sent at 2:00AM on a Saturday, SPHLs need to send samples to CDC or other laboratories for testing.

Sample Receipt and Analyses

While initially structured to test only human clinical samples for biological agents of terrorism, in 2001 the Laboratory Response Network performed more than one million anthrax tests on a wide variety of samples that were both clinical and environmental. Since then, the LRN has continued to evolve and expand. In 2003, the capability to detect chemical terrorism agents in human samples was added. The LRN now provides essential support for several surveillance activities, including the nation's BioWatch program and the United States Postal Service's (USPS) Biohazard Detection System (BDS). With expectations to imple-

Figure 13 Programs to Assess Preparedness Competency of Sentinel Clinical Laboratories



ment new technologies, support early warning surveillance systems and add more tests, the LRN's current available resources are being stretched.

Sample Intake and Testing

Public health laboratories accept samples from a host of federal agencies, first responders and other laboratories. To ensure timely delivery of samples, it is critical SPHLs have reliable state-wide courier systems, which means an effective method to rapidly move samples on both a routine and an emergency basis. Lacking these systems could result in delays in receiving specimens, increasing the time from sample collection to result reporting.

- **More than half of all SPHLs (59%) do not have an intra-state courier system that operates 24 hours a day for specimen pick-up and delivery.**
- **In FY 2006, SPHLs received more than 5,300 unknown samples (3,614 environmental samples and 1,686 clinical specimens) to test for suspected terrorism agents. State public health laboratories tested 98% (5,100) of these samples using CDC LRN biological methods and more than 66% (3,500) of the samples using CDC LRN chemical methods for potential agents of terrorism.** These unknown samples included powders, threat letters, unknown packages, air, water and other unknowns, such as mixed liquids, syringes and swabs.

Prescreening Samples

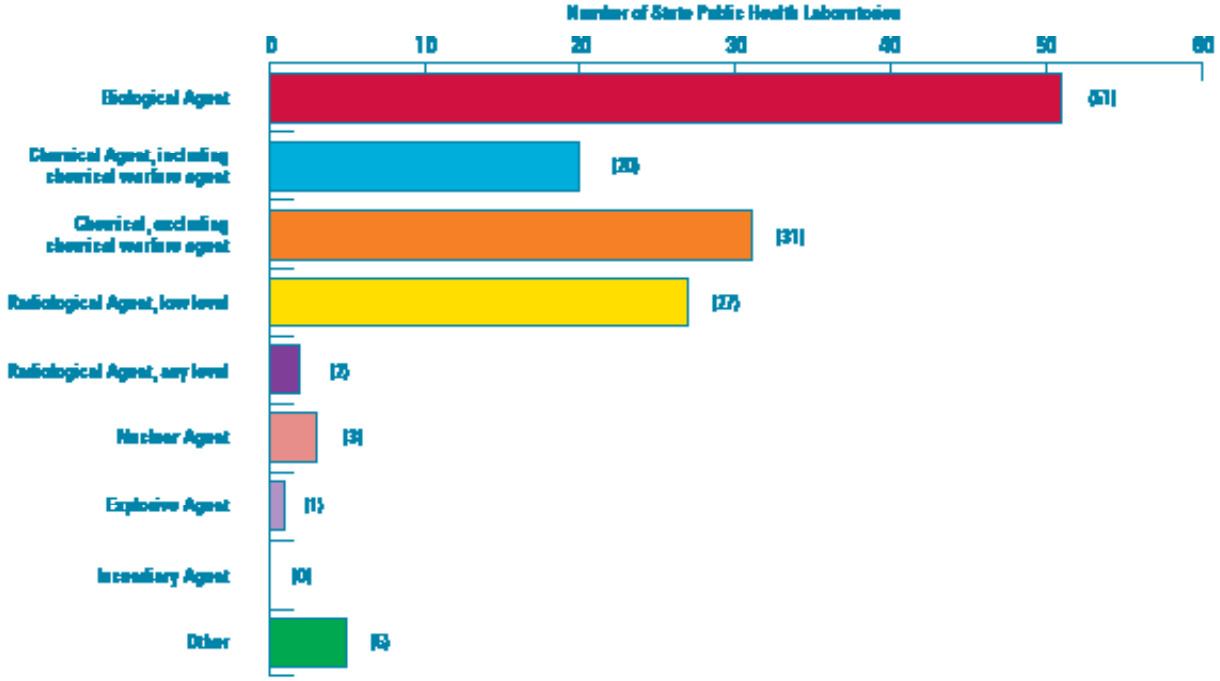
Many first responders, such as HazMat and CST, use portable devices to pre-screen samples in the field. This essential safety step lets first responders manage the scene and protect laboratorians from harmful radiation or explosives; many laboratories require such

a prescreen before accepting the sample. However, the portable devices first responders use have limitations and require hours of training. Laboratorians are beginning to work with first responders to address these issues, as well as sample collection in the field and interpretation of results from the devices.

- **Forty-five SPHLs (88%) require law enforcement or first responders to screen unknown samples prior to accepting them into the laboratory.** Most SPHLs require law enforcement or first responders to screen for radiological compounds (89%) and explosives (98%). These laboratories also request documentation, such as chain of custody forms, before accepting the samples into the laboratory.
- Very few state public health laboratories indicated that they would accept specimens containing nuclear, explosive or high-level radiological substances. **(See Figure 14.)**
- All SPHLs indicated that they would accept specimens containing biological hazards. Forty-eight SPHLs (94%) accepted clinical specimens for chemical analysis.
- Sixty-three percent of SPHLs accepted environmental samples containing chemical threats, 51% accepted food samples and 22% accepted other samples for similar analyses.

APHL and other partners are working to call national attention to close the gaps in the processes for approval and use of field devices. To ensure accurate and reliable results in field conditions, it is essential to standardize and validate the screening kits and devices used on-site. While these kits and devices cannot give definitive results like medical devices, they do need to be reliable in terms of sensitivity and specificity. In the absence of validated field devices and few proficiency testing programs, state public health laboratories are working with first

Figure 14 Types of Hazardous Samples Accepted by State Public Health Laboratories



responder communities to provide guidance on field safety screening. As an added safety precaution and to account for samples that are not field screened, laboratories need to implement their own screening process for unknown hazards.

- **Twenty-two SPHLs (43%) currently use the Draft Interim All-Hazards Receipt Facility Screening Protocol for handling and triaging unknown environmental samples.** The lack of a formal training program has limited implementing and evaluation of this screening protocol at state public health laboratories.
- **Thirty-one SPHLs (61%) do not have a designated area to safely screen and triage unknown samples.** However, 14 of the 31 laboratories are planning to design and build such an area. **Of the 31 laboratories that do not currently have a separate area to safely screen and triage unknown samples, 21 indicated that lack of funding was the primary reason for this gap.** Other reasons include lack of space, lack of support from state government and zoning issues.

Radiation Screening

Radiation screening and testing is one area of preparedness where there are large capacity gaps. Screening for radiation is not as difficult as testing for radiation and usually requires a Geiger counter or similar device. Most laboratorians and first responders can easily be trained to use these devices.

Testing for radiation is more involved and risky than screening. Laboratories that have some of this capability still cannot differentiate between all of the radionuclides that exist. **In fact, only one laboratory in the US can test for Polonium-210, which was recently used in the Litvinenko poisoning case.** The case garnered national attention in the US, elevating radiological testing and terrorism.

- Thirty-eight SPHLs (75%) can screen some of the following samples for the presence of radiation: alpha—35 (69%), beta—38 (75%) and gamma—38 (75%). Little more than half of SPHLs can test for the presence of radiation: alpha—27 (53%), beta—28 (55%) and gamma—25 (49%). **(See Figure 15.)**
- Of those laboratories that can screen or test for

Figure 15 **State Public Health Laboratories: Radiation Capability**

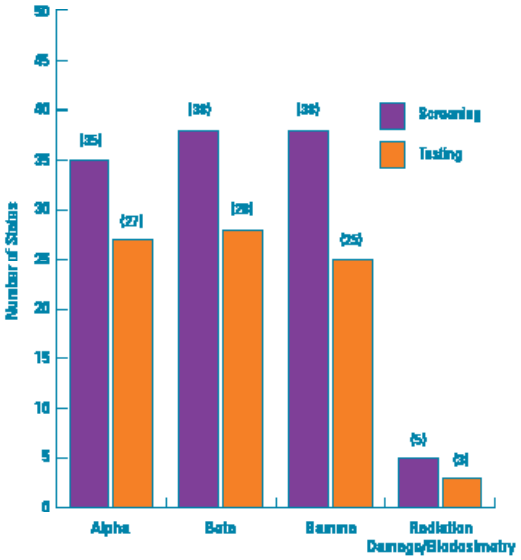
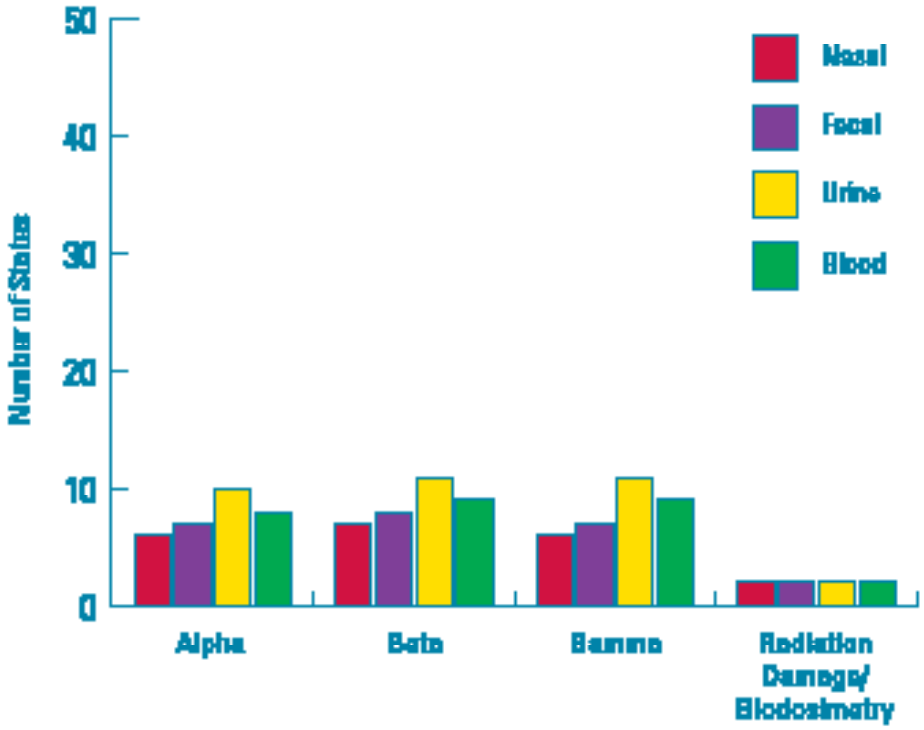


Figure 16 State Public Health Laboratories: Radiation Capability for Clinical Specimens



radiation, less than 25% of SPHLs can screen or test *clinical* samples for radiation. Forty-five SPHLs (90%) do not routinely screen or test clinical samples for radiation. **(See Figure 16.)**

- Of those laboratories that can screen or test for radiation, less than 50% of SPHLs can screen or test samples for radiation in *environmental* samples, which include air, water, soil, vegetation and food. **(See Figure 17.)**

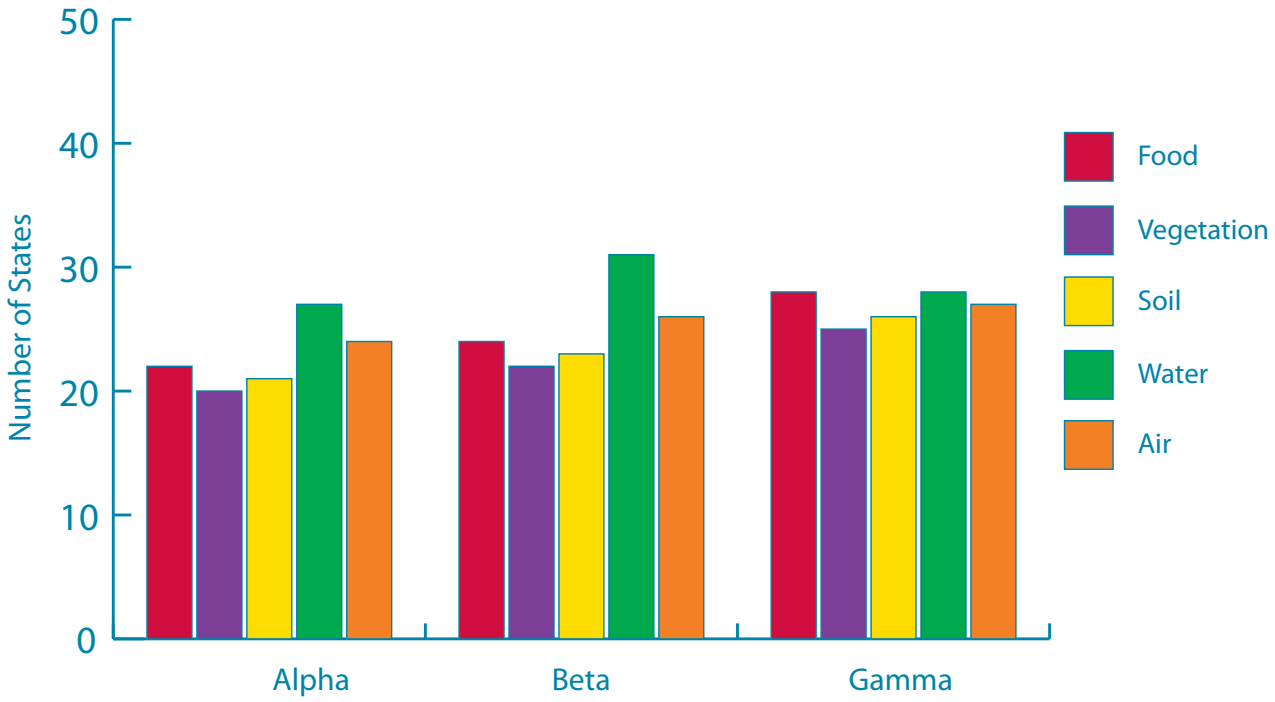
There is a significant gap in laboratory capacity and capability for radiological terrorism preparedness. Most states have the ability to test for radionuclides in water through the Safe Drinking Water Act, but the capability to test human specimens is missing. A large-scale radiation exposure in the US could easily overwhelm the laboratory system.

Reporting Capabilities

As realized during the 2001 anthrax outbreak, public health laboratories not only test and monitor routine conditions such as hepatitis and whooping cough, but also monitor for potential terrorist attacks. Such attacks could involve the use of biological or chemical weapons, and other agents of terrorism. In the face of a potential terrorism attack, infectious diseases outbreak or natural disaster, laboratory data should be transmitted electronically for local and federal agencies to react quickly and decisively. Often this is not the case.

There are two major elements of a public health Laboratory Information Management System (LIMS)—one is the application that supports the daily work and functions of the laboratory to produce relevant disease data, and the other is the electronic

Figure 17 State Public Health Laboratories: Radiation Capability for Environmental Samples



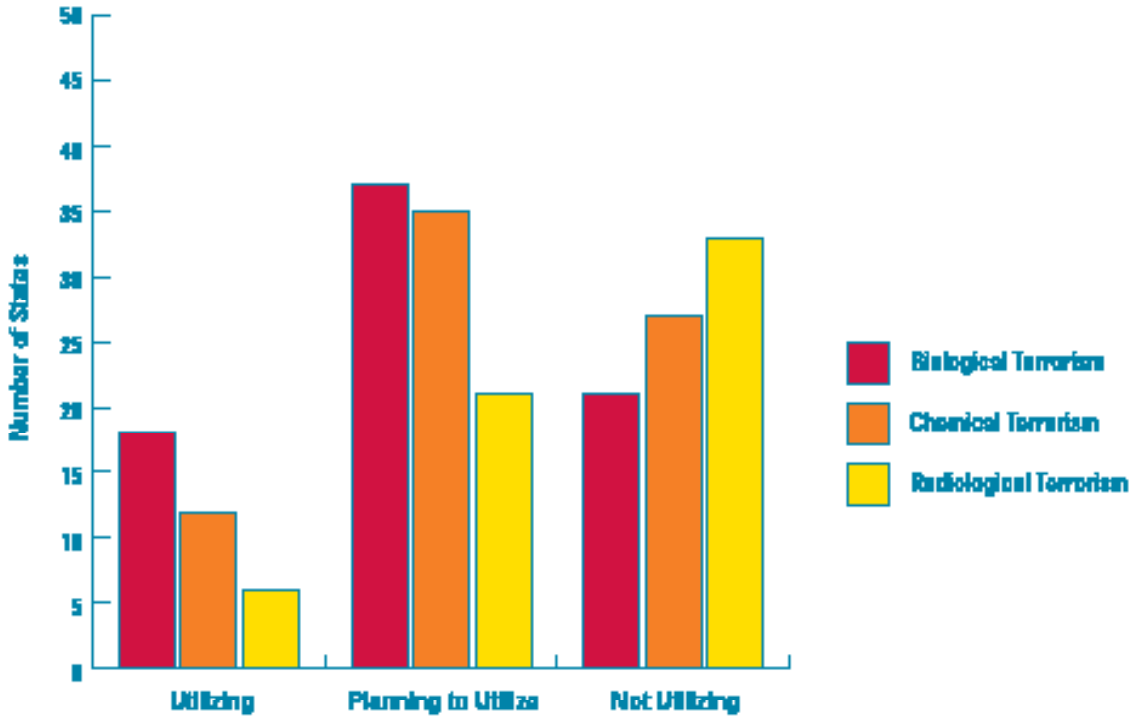
communication of test orders and test results between the laboratory and its private, local, state and federal partners.

The lack of interoperable laboratory systems is well recognized, and many attempts have been made to address the gaps in technology and funding through the creation of a variety of initiatives, programs and networks. Virtually every government agency has created an information network within the past five years, such as the LRN, FERN and eLEXNET to support web-based exchange of data.

- Forty-five SPHLs (88%) have a LIMS. Of these 45 laboratories, 36 indicated that their LIMS has a bioterrorism component, 27 have a chemical component, 13 have a radiological component and 8 have no terrorism preparedness component. **Many of the laboratories that have a LIMS with a preparedness component do not currently use their LIMS to send data and test results to other agencies. (See Figure 18.)** They plan to use their LIMS to exchange data, but lack of funding and guidance has prevented significant progress in this arena.
- Eighteen SPHLS indicated that their LIMS has the ability to create, send and receive a PHIN-compliant HL7v2.5 message.
- **SPHLs use mainly the telephone to communicate terrorism-related data/test results to partners.** Secondary communication mechanisms, such as mail, fax and email were also utilized to communicate test results.

APHL and CDC are striving to fill this electronic data exchange gap through the Public Health Laboratory Interoperability Project (PHLIP), which brings together public health laboratory science and information technology experts from APHL-member laboratories and the CDC. The PHLIP team is defining the necessary infrastructure and expertise that a public health laboratory needs to enable two-way electronic data

Figure 18 State Public Health Laboratories Use of Laboratory Information Management Systems to Report Results to Partner Agencies



transmission with public health and clinical partners in a recognized standard format.

PHLIP fosters collaboration in the areas of information technology and laboratory science, with the immediate goal of developing, piloting and deploying viable IT architecture options and standardized vocabulary tools for the exchange of electronic laboratory data at all levels of public health laboratories. Promoting and supporting this effort will lead to nationwide electronic laboratory reporting capability, a major priority for public health.

CONCLUSIONS

In the era of constant threats and emerging infections, public health laboratories must be ever vigilant to protect the public's health. These laboratories have made great strides in the area of preparedness since first receiving CDC PHEP Cooperative Agreement funding. Examples of this success include,

- Improved training and outreach to sentinel laboratories
- Increased and enhanced training courses for laboratorians
- Implementing formal exercises and drills to assess gaps in planning, testing capacity and capability
- Enhanced collaborations with local, state and federal agencies, laboratories and other partners.

Despite these improvements, notable challenges in public health laboratory preparedness remain.

These include,

- Complacency
- Funding gaps
- Workforce shortages
- Lack of standardized platforms to exchange data electronically
- Lack of a national strategy to address gaps in laboratory capacity for radiological terrorism preparedness.

The challenge of funding sustainability is evident as more and more laboratories see shrinking federal and state dollars and increased priorities. As the preparedness funding continues to decline, much of the capacity and capability that has been built over the past five years will erode and ultimately disappear. In addition to funding challenges, laboratories cannot maintain a highly-skilled workforce due to an inability to offer competitive wages, lack of a qualified pool of applicants and turnover due to retirements.

The issue of complacency is a significant problem for the entire public health system. Without continued national attention to the core functions of public health, long term funding will quickly decline and threaten the viability of programs, such as drills, exercises and training for sentinel clinical laboratories and first responders. This decline in funding—leading to an inability to sustain the progress made in preparedness—will leave the laboratories with few laboratorians and antiquated equipment, meaning laboratories cannot respond to any future acts of terrorism. Imagine being told after a terrorist attack that there was no way to determine whether or not you were exposed to an agent.

APHL is working with federal, state, local and other partners to call attention to the gaps in laboratory preparedness and develop a strategy for addressing and responding to these challenges. The association is committed to achieving optimal laboratory preparedness for responding to the needs of the public and testing of all-hazards.

1 "Public Health Preparedness: Mobilizing State by State," CDC, U.S. Department of Health and Human Services, February 2008.

2 CDC: The Laboratory Response Network, Partners in Preparedness, available at http://www.bt.cdc.gov/lrn/, accessed April 9, 2008.

3 "Public Health Emergency Preparedness Cooperative Agreement," CDC, U.S. Department of Health and Human Services, July 2006, available at http://www.bt.cdc.gov/planning/coopagreement/pdf/fy06announcement.pdf.

4 APHL: Public Health Laboratories Issues in Brief: Bioterrorism Capacity, April 2005, available at https://www.aphl.org/docs/bt_issue_brief_2005_final.pdf, accessed April 10, 2008.

5 APHL: Public Health Laboratories Issues in Brief: Bioterrorism Capacity, October 2002, available at https://www.aphl.org/docs/BTIssuebriefpercent20finalpercent20Oct02.pdf, accessed April 10, 2008.

6 P. Shult, Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness. Testimony of Dr. Peter Shult, Director of the Communicable Diseases Division of the Wisconsin Laboratory of Hygiene, before the U.S. House Committee on Homeland Security. Washington, D.C.: Association of Public Health Laboratories, 2007.

7 APHL. (2004). Who will Run America's Public Health Labs? Educating Future Laboratory Directors.

8 S.A. Lister and H. Stockdale. Pandemic Influenza: An Analysis of State Preparedness and Response Plans. Washington, D.C.: Congressional Research Service, September 24, 2007, http://www.opencrs.com/rpts/RL34190_20070924.pdf, (accessed April 9, 2008).

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