PUBLIC HEALTH LABORATORY ISSUES IN BRIEF:

BIOTERRORISM CAPACITY

Association of Public Health Laboratories

May 2006

Since the late 1990s, public health laboratories serving states and large metropolitan areas have been tasked with a growing slate of responsibilities, reflecting the nation's changing health and security environment. Beginning in Fiscal Year (FY) 2001, the Centers for Disease Control and Prevention (CDC) Public Health Preparedness and Response for Bioterrorism cooperative agreement has funded activities to strengthen the public health laboratory system for efficient and effective response to potential acts of bioterrorism, infectious disease outbreaks and related emergencies. In FY04, the scope of the cooperative agreement was broadened to incorporate the concept of all-hazards preparedness. "All-hazards" refers to preparedness for and response to health emergencies, such as biological, chemical, radiological and nuclear terrorism, naturally occurring infectious disease outbreaks, natural disasters and accidents. All-hazards preparedness is now a high priority for the nation and for the public health laboratories that undergird its public health system.

Yet despite a general recognition that all-hazards preparedness requires extensive planning and significant new infrastructure, at the close of FY05 there were still no official performance measures or standards to evaluate the effectiveness of the CDC cooperative agreement that is the principal federal vehicle for building this capacity within the public health laboratory system. Such performance measures are needed to: (a) provide accountability for cooperative agreement funding, (b) provide a synopsis of state and local preparedness needs and (c) ensure that funds are awarded to areas with demonstrable need.

While awaiting a performance measurement system from the federal government—expected to be included in the FY06 cooperative agreement guidance—the Association of Public Health Laboratories (APHL) has periodically surveyed state public health laboratories (SPHLs) to assess the impact of preparedness funding. This is the fourth publication of *Public Health Laboratory Issues in Brief: Bioterrorism Capacity.* This report provides an update on laboratories' bioterrorism response capabilities as of August 31, 2005, as well as baseline data on select measures pertaining to all-hazards preparedness.

This report complements the 2005 APHL Chemical Terrorism Laboratory Preparedness Survey, which contains additional measures pertaining to all-hazards response, with an emphasis on chemical terrorism preparedness. A report of that survey is posted at www.aphl.org/programs/emergency_preparedness/chemical_terrorism.cfm. For a comprehensive view of public health laboratories' current emergency response capabilities, readers are encouraged to consult both the bioterrorism and chemical terrorism survey reports. APHL will continue to survey state public health laboratories at regular intervals to assess their readiness to respond to bioterrorism and other hazards and to identify challenges that might persist.

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The Public Health Laboratory Role in Emergency Response

The concept of all-hazards preparedness is not new to the public health laboratory community. Public health laboratories have traditionally performed testing to support infectious disease surveillance and response, and many also conduct food safety testing to identify foodborne pathogens in human specimens and food samples; environmental testing to assess the quality of water, soil and other environmental samples; and biomonitoring to assess levels of toxic chemicals in defined populations.

"Every bioterrorist attack upon the United States would be a unique event, placing stringent demands upon our nation's public health infrastructure and requiring effective cooperation between local, state and federal agencies."[1]

Public health laboratories continue to serve as the backbone of the Laboratory Response Network (LRN). Founded in 1999 by CDC, APHL and the Federal Bureau of Investigation (FBI), the LRN is the nation's premier laboratory system for detecting, confirming, and reporting agents of biological terrorism in all matrices and agents of chemical terrorism in clinical specimens.[2] State and local public health laboratories comprise roughly 70% of the 140 LRN reference level 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.

All-hazards response capabilities build on core public health laboratory functions. Assessing exposure to chemical, radiochemical or biological warfare agents, for example, depends upon a familiar series of laboratory activities: ongoing disease surveillance, rapid agent detection, confirmatory testing, data reporting, laboratory analyses to support epidemiologic investigations and networking with relevant partners. To develop analytical capabilities for new threat agents, SPHLs must enhance both the existing workforce and physical infrastructure of the laboratory, while expanding the focus of partnerships with local, state and federal entities.

Enhancing the laboratory infrastructure will require a long-term investment on the part of state and federal governments. Sustainable funding is a prerequisite to attract skilled scientists, maintain staff competency through continuing education and proficiency testing, obtain modern testing platforms and information management systems, assure timely transfer of new testing technology, maintain adequate stores of laboratory reagents and supplies, support outreach activities and assure national laboratory leadership.

Methods

Data for this issue brief were collected in November 2005 by APHL when it conducted its fourth survey of state public health laboratory readiness for bioterrorism. This brief is a follow-up to previous studies that collected 2001 data used to establish a baseline of SPHL capability and capacity prior to the availability of emergency supplemental funds for terrorism preparedness,[3] 2002 data used to measure what progress had been made after one year of federal funding for bioterrorism,[4] and 2003-2004 data used to assess progress and needs for bioterrorism laboratory preparedness.[5] Reports from the previous three surveys are available online at APHL's website, www.aphl.org.

For the current survey, participants were asked to report on bioterrorism capability and capacity as of August 31, 2005. Unless otherwise noted, data were collected for a period of 12 months, covering activities from September 1, 2004 to August 31, 2005, representing cooperative agreement FY04 funds awarded in August 2004. The survey was sent to the 50 states, the District of Columbia (DC), and four territories.

Fifty-two responses were received, representing all states, DC, and Puerto Rico. Unless otherwise noted, 52 responses were given to each question. For the purposes of this report, the term "states" or "state public health laboratories" will be used to refer to all respondents, including Puerto Rico and DC.

The survey was administered via APHL's LabNet, a Web-based repository and survey tool designed for APHL members. Results were coded for entry into SPSS for Windows Version 13.0. Descriptive statistics were gathered for all of the variables. Results are reported for the following categories:

- Testing: Sample Volume and Matrices
- Funding and Benchmarks
- Laboratory Connectivity and Training
- Workforce
- Facilities and Biosecurity
- Reagents and Equipment
- Smallpox Preparedness
- Transportation and Courier Service
- All-Hazards Laboratory Preparedness

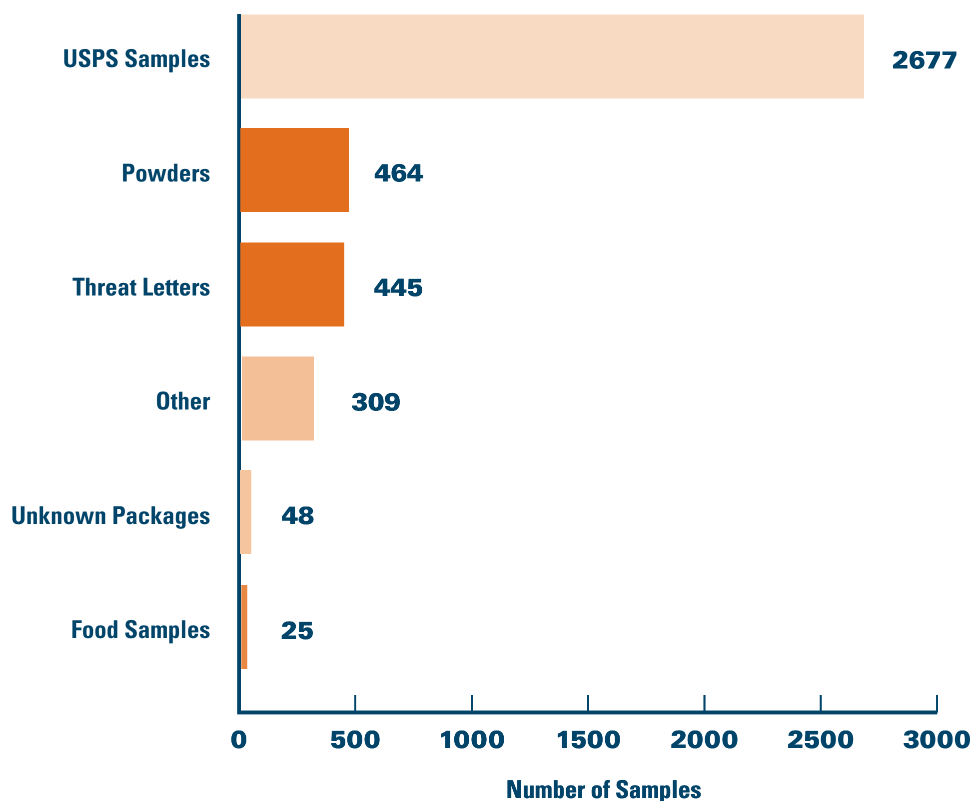
APHL members are able to view aggregate data on APHL's LabNet at www.aphl.org/labnet. APHL will continue to survey state public health laboratories at regular intervals to assess their readiness to respond to bioterrorism and to identify challenges that might persist.

Testing: Sample Volume and Matrices

Although there has not been a national bioterrorism event since 2001, SPHLs routinely respond to various threats and emergencies in support of law enforcement and public health partner agencies.

Between September 1, 2004 and August 31, 2005 SPHLs collectively received over 1,000 clinical specimens and over 3,500 environmental samples to test for potential agents of biological terrorism, including toxins such as ricin. While United States Postal Service (USPS) samples—mostly remediation samples taken from postal facilities affected by the 2001 anthrax attacks—constituted the bulk of the environmental samples tested, **Figure 1** shows that SPHLs also performed testing for biological threat agents on numerous other sample types, including threat letters, powders, food samples and unknown packages. On an ongoing basis, LRN reference laboratories also receive thousands of unknown samples for all-hazards screening.

Figure 1 Testing Environmental Samples for Agents of Biological Terrorism

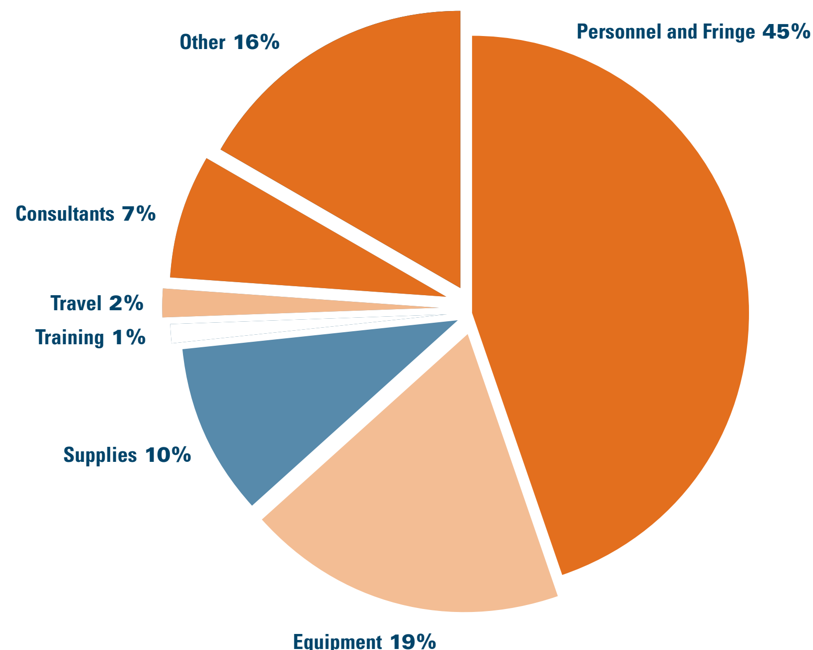


Funding and Benchmarks

State public health laboratories receive funding for bioterrorism preparedness through the CDC Cooperative Agreement on Public Health Preparedness and Response for Bioterrorism. The Department of Health and Human Services (HHS) first distributed funds through this cooperative agreement in 2002. All fifty states, DC, the country's three largest municipalities (New York City, Chicago, and Los Angeles), American Samoa, Guam, the US Virgin Islands, Northern Mariana Islands, Puerto Rico, Palau, the Marshall Islands and Micronesia have received bioterrorism preparedness funding from this CDC cooperative agreement.

- **In FY04, state and local health departments received $934 million from CDC for public health emergency preparedness activities. Of this, laboratories received $104 million, a $49 million decrease from FY02, to develop and maintain capacity and capability for detecting potential agents of biological terrorism.**
- **On average, respondents reported receiving $1,850,000 (range $136,902 to $9,207,872) for laboratory bioterrorism preparedness from the CDC Cooperative Agreement.** CDC preparedness funding enabled states to hire and train new personnel, purchase equipment and supplies, conduct training exercises and rebuild a crumbling public health infrastructure. **Figure 2** illustrates the allocation of these expenditures.
- **16 SPHLs (31% of respondents) reported an average reduction of 15% in state funding.**
- Seven SPHLs (13%) received additional funding from the Department of Justice (DOJ) for terrorism preparedness representing a minor increase from the previous year when six states received DOJ funding.
- **Only 8 of 51 SPHLs (16%) received funding from the Department of Homeland Security for preparedness activities.** These eight states received small amounts of funding to train first responders and purchase instrumentation for the laboratory and personal protective equipment for workers.

Figure 2 FY 2004 Allocation of CDC Cooperative Funding in State Public Health Laboratories



Total Expenditures = $73,504,133 (as reported by 50 respondents)

- **23 respondents (44%) indicated that they anticipate including new laboratories to the LRN reference level within the next five years, mainly to provide better geographic coverage within the state or territory and/or to provide additional surge capacity for high-volume testing.**

Food Safety Funding

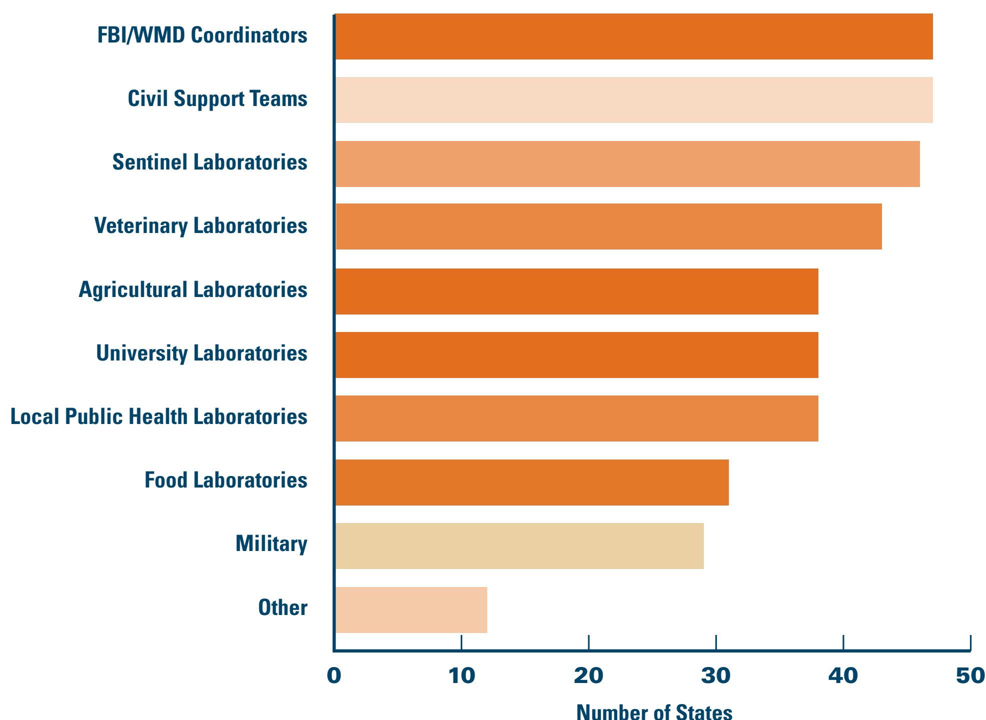
According to many experts, the malicious contamination of food is a real and ongoing threat. For over 10 years, state public health laboratories have played a vital role in the rapid detection of intentional or unintentional foodborne outbreaks through their participation in PulseNet, CDC's national molecular subtyping network for foodborne disease surveillance. In 2004, the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA) began developing the Food Emergency Response Network (FERN). This network consists of state and federal laboratories with advanced capabilities to analyze food samples in the event of a biological, chemical, or radiological terrorist attack. **Many FERN laboratories are also LRN members; however, current FERN funding at the state and local levels has been minimal, forcing SPHLs to rely on CDC and state funding to support food preparedness activities.**

- **In FY04, 48 SPHLs did not receive any funding from FERN.**
- 36 SPHLs (69%) indicated that they received state or CDC funding to test food while investigating outbreaks of foodborne illness in humans.
- 22 respondents (42%) received state or CDC funding to test food for routine regulatory monitoring or surveillance purposes.
- Only 14 SPHLs (27%) received funding to test food after a recognized intentional contamination—a significant decline from 2003-2004, when 25 states received funding.

Laboratory Connectivity and Training

State public health laboratories have established and maintained functional working relationships with many important preparedness partners. Among them are sentinel clinical laboratories, local public health laboratories, veterinary, agricultural, food safety, university and military laboratories, as well as local law enforcement, FBI Weapons of Mass Destruction (WMD) Coordinators, and National Guard Bureau/Civil Support Teams. *(See Figure 3.)*

Figure 3 **Working Relationship with Partners**



Additionally, the USPS deployed Biohazard Detection System (BDS) has been placed in over 200 postal facilities across the country. BDS utilizes Cepheid's GeneXpert system to screen for *Bacillus anthracis* in the mail.[6] Fifty SPHLs (96%) participated in pre-event planning with officials from the USPS for the implementation of the BDS.

Sentinel Laboratories

One of the original benchmarks in the 2002 and 2003 preparedness grants required the state public health laboratories, in their role as LRN reference laboratories, to reach out to the clinical laboratory community, who would serve as sentinels in the event of a covert bioterrorism attack. In the broadest sense, any laboratory capable of analyzing or referring specimens or samples that may contain microbial agents or biological toxins functions as a sentinel laboratory within the LRN. It is a vital SPHL function to assure that all sentinel laboratories within their jurisdiction are able to perform tests of public health significance with a high degree of proficiency and are thoroughly familiar with reporting, packaging and shipping protocols for referring specimens to the appropriate state or local LRN reference laboratory for routine disease surveillance and specialized testing.

To assist SPHLs with their outreach efforts, in 2005 APHL, CDC and the American Society for Microbiology formalized a definition for clinical laboratories that handle human specimens and serve as sentinel clinical laboratories. This definition includes criteria to classify sentinel clinical laboratories as basic or advanced.[7] Advanced sentinel clinical laboratories function at the local front line and have more sophisticated analytical capabilities than basic sentinel clinical laboratories.

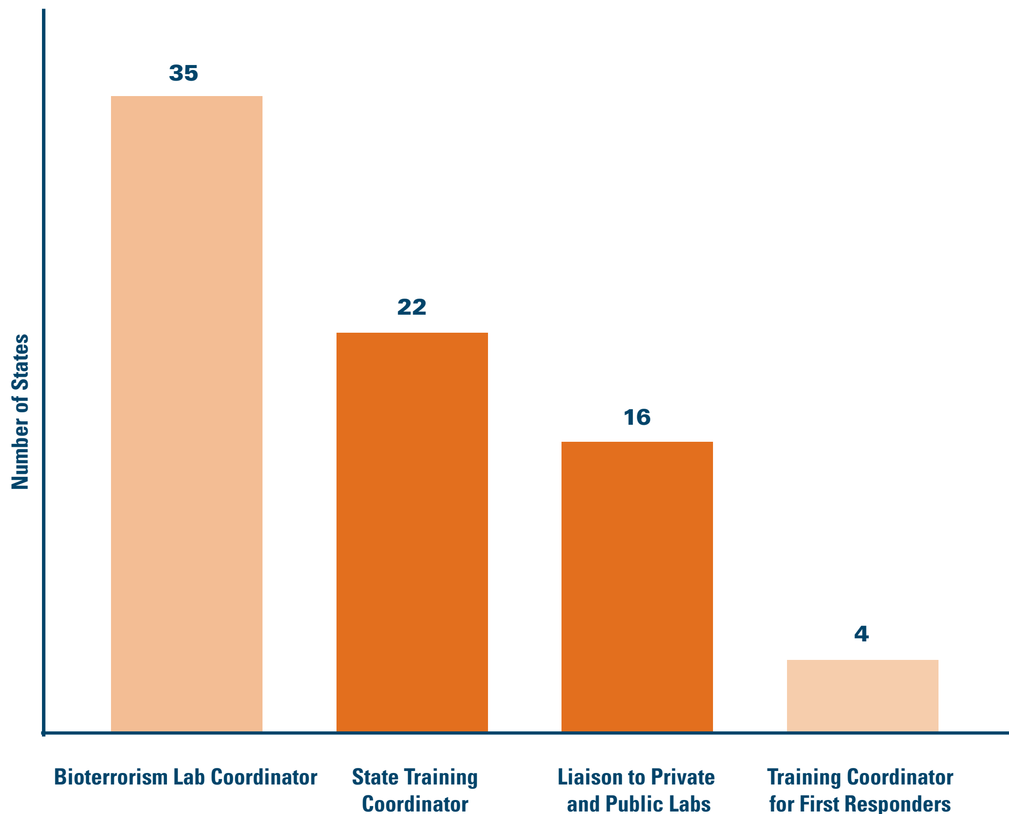
Over the past five years, SPHLs have made great strides in improving outreach and connectivity with the clinical sentinel laboratory community.

- **50 of 51 SPHLs (98%) have a means to communicate rapidly via blast fax and e-mail with sentinel laboratories. This represents a significant improvement from 2002 when only 38 SPHLs reported having this capability.** Forty-four of the 50 SPHLs with a rapid communications system utilized it during the 12-month period September 2004-August 2005 to provide health alerts, infectious diseases updates, notifications about training courses and information on bioterrorism drills and exercises.
- **34 of 52 SPHLs (65%) have a bioterrorism advisory committee or equivalent group in place that includes representatives from the clinical microbiology laboratory community. This is an increase from FY04, when 29 states indicated that they had such a committee in place.**
- 48 of 52 SPHLs (98%) maintain a database of contact information and capabilities for all clinical sentinel laboratories in their state, the same number as in 2003-2004 and a significant improvement from 2002, when 44 SPHLs had established a sentinel laboratory database and just 34 had documented the capabilities of these sentinel laboratories.

The ability to sustain and enhance these relationships through outreach and training is hampered by lack of full-time staff devoted to these functions. This omission is particularly important in light of findings from a CDC-funded, formative evaluation of the first round of National Laboratory System demonstration projects, indicating that a full-time coordinator is the single most important resource for building effective statewide laboratory networks.[8]

- 49 SPHLs (94%) have a state training coordinator (STC) designated to develop and implement the necessary bioterrorism laboratory preparedness training courses for the sentinel laboratory community. However, only 22 states (42%) have a full-time STC dedicated to this position.
- 50 SPHLs (96%) have a bioterrorism laboratory coordinator designated to train staff and oversee bioterrorism-related testing. However, only 35 SPHLs (67%) have a full-time person for this position.
- Many SPHLs lack full-time staff for other important connectivity and training positions within their laboratories. ***(See Figure 4.)***
- Only 32 states conducted drills with their sentinel laboratory community to test the PHL's 24-hour emergency response system.

Figure 4 Full Time Personnel Dedicated to Laboratory Connectivity and Training

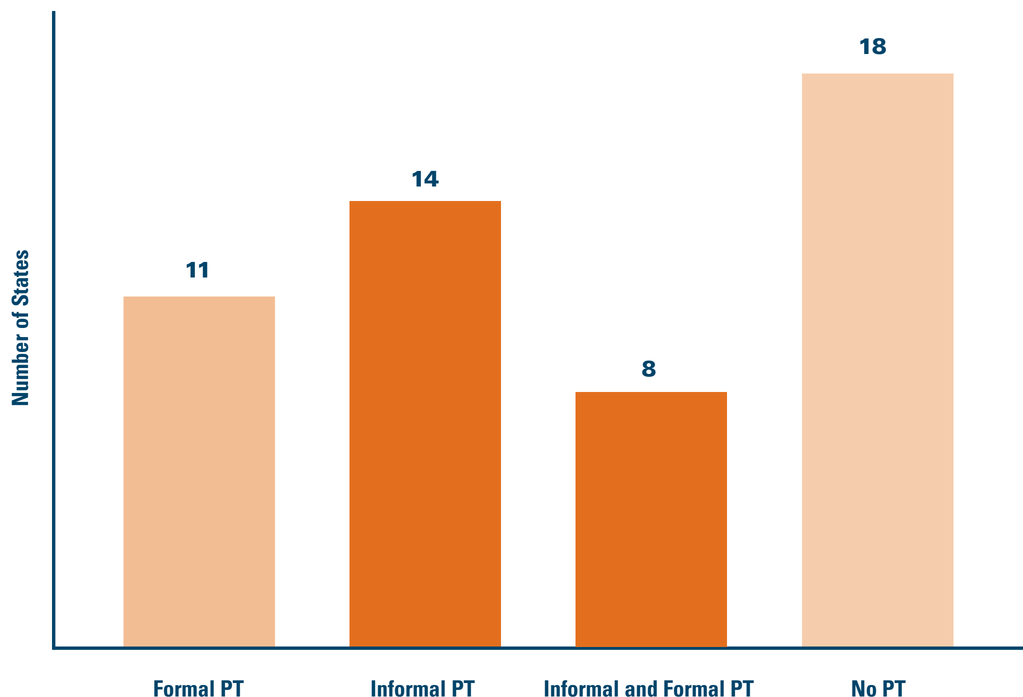


Training for Sentinel Laboratories

Training and education for laboratory staff in both the public and private sectors is a recognized core function of state public health laboratories.[9] It is particularly important as it relates to surveillance for infectious diseases, including potential agents of bioterrorism. Such training ensures that sentinel laboratorians are able to rule out and refer specimens of potential public health significance to their designated LRN reference laboratory.

- 40 of 51 SPHLs (78%) reported that their bioterrorism coordinator or other staff conducts on-site visits to sentinel laboratories within their state. States have an average of 91 (range 4-457) sentinel laboratories within their jurisdiction.
- **As of August 31, 2005, 47 of 51 SPHLs (92%) sponsored clinical sentinel laboratory training and offered a total of 515 courses to over 5000 laboratorians.** The training covered rule-out testing, packaging and shipping, and biosafety guidelines.
- **33 of 51 SPHLs (65%) have some form of proficiency testing (PT) system in place to assess the competency of sentinel laboratories to rule out agents of biological terrorism *(See Figure 5).*** In 2003-2004 only 24 SPHLs had a PT system in place.

Figure 5 **Proficiency Testing (PT) of Sentinel Laboratories**



Training for Reference Level Laboratories

In order to confirm potential agents of biological terrorism, SPHLs must have staff with specialized training in LRN reference level, select agent test methods. CDC provides this standardized training to grantees as resources permit. **Table 1** underscores the importance of such training. It shows that while overall the nation's SPHLs are adequately prepared to perform testing for many select agents, serious gaps remain that will impact the LRN's ability to meet surge testing needs in a bioterrorism event. For example, eight states have no scientists trained to perform testing for Staphylococcal enterotoxin B and a majority of SPHLs have no staff trained to perform confirmatory or screening assays for Clostridium botulinum toxin. **Fifty respondents (96%) indicated that there is an ongoing need for CDC to provide LRN reference laboratories with confirmatory methods training courses.**

Workforce

According to a 2004 report from the Association of State and Territorial Health Officials (ASTHO), **"the most significant challenge state and local public health agencies face in developing the capacity to respond to terrorist events, emerging infectious diseases, and other public health threats and emergencies is assuring a qualified workforce is available to carry out these functions."**[10] An aging public sector workforce with large numbers of individuals nearing retirement and a shrinking pool of job-seekers interested in government service pose serious challenges to state agencies. Within the public health laboratory, these challenges are compounded by a shortage of laboratory professionals in general and a dire lack of individuals with the experience and credentials needed to assume senior laboratory positions.[11] SPHLs are struggling to recruit highly skilled personnel.

Table 1 **Training State Public Health Laboratorians**

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 (98%)	3	40
Time-Resolved Fluorescence (TRF)	49 (94%)	3	39
Bacillus anthracis	50 (96%)	3	30
Yersinia pestis	50 (96%)	3	30
Francisella tularensis	50 (96%)	3	30
Brucella species	50 (96%)	3	30
Burkholderia species	47 (90%)	3	28
Ricin toxin	50 (96%)	3	29
Staphylococcal enterotoxin B	44 (85%)	3	30
Clostridium botulinum toxin (confirmatory assay)	22 (42%)	2	23
Clostridium botulinum toxin (DIG ELISA screening assay)	19 (37%)	4	30

Uncertain funding has exacerbated this problem. Federal grants now support a number of important laboratory positions. Within the past five years of CDC cooperative agreement funding, for example, SPHLs have been able to fund and recruit for new positions to support bioterrorism-related work. However, given the level of private sector competition, SPHLs may not be able to retain these new recruits in the face of state and/or federal budget cuts. As funding and staff levels decline, public health laboratory preparedness will inevitably decline as well.

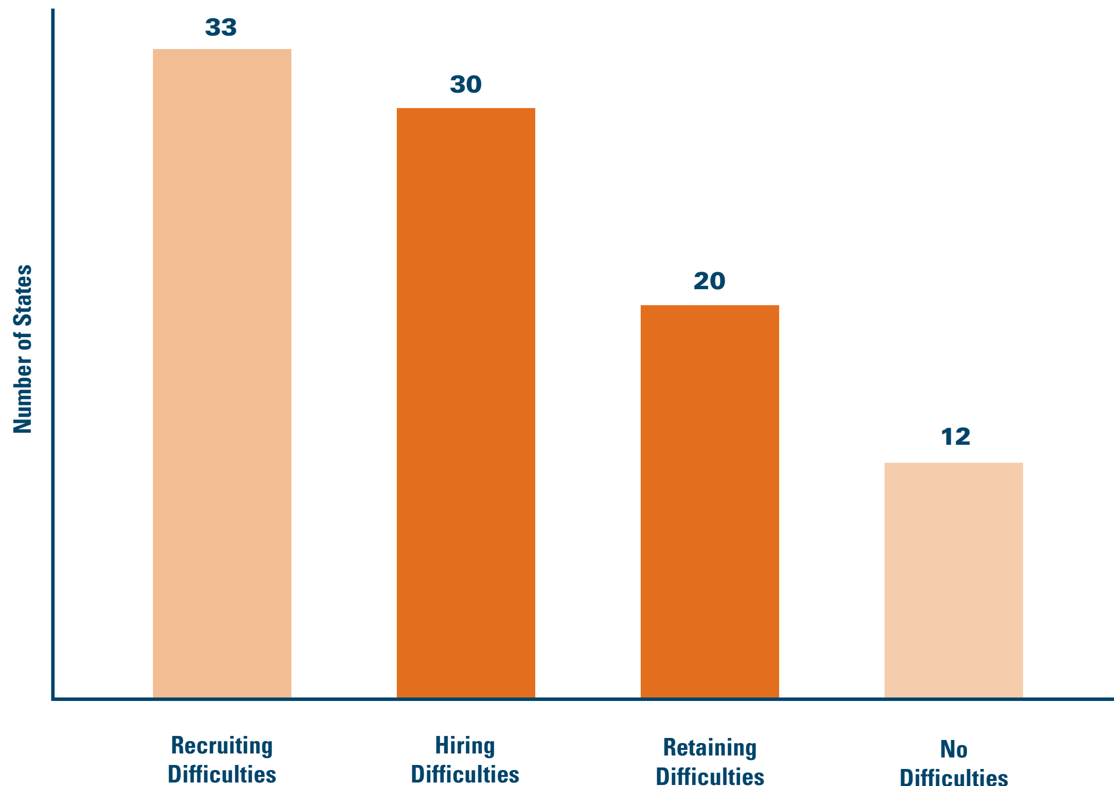
- On average, SPHLs reported having two (range 0–6) vacant laboratorian positions. While vacancy rates are highest for technical laboratory positions, they are also problematic for administrative, information technology and security positions.
- **40 SPHLs (77%) experienced difficulties recruiting and retaining staff to work in bioterrorism preparedness.** ***(See Figure 6.)***
- On average, SPHLs have at least one full time equivalent (FTE) doctoral-level bioterrorism staff position that is completely federally-funded and at least half a FTE doctoral-level bioterrorism staff position that is completely state-funded.
- From September 2004 to August 2005, eight SPHLs hired a full time equivalent doctoral-level bioterrorism staff person. However, as of August 31, 2005, 28 SPHLs (54%) reported needing at least one FTE doctoral-level bioterrorism staff person. The gap between hiring needs and recruitment success likely indicates that SPHLs are having difficulty finding, attracting and/or retaining these high-level scientists. Moreover, the percentage of SPHLs looking to hire a high-level scientist has risen since the previous survey when only 40% of SPHLs reported needing an FTE doctoral-level molecular scientist.

Facilities and Biosecurity

Since the inception of the CDC Preparedness Cooperative Agreement, SPHLs have used the funding to build, expand and maintain biosafety level 3 (BSL-3) suites.[12]

- 47 SPHLs (90%) have at least one BSL-3 suite within their facility. Five SPHLs (10%) lack a BSL-3 suite, compared with six from the last assessment and at least 10 prior to the 2001 influx of federal funding.
- 34 of 49 SPHLs (69%) reported needing at least one additional BSL-3 suite in the state public health system. A total of 77 BSL-3 suites are still needed to provide adequate geographic coverage and surge capacity. Additionally, many of the existing facilities will need to be replaced or renovated in the near future.

Figure 6 **State Workforce Barriers in Bioterrorism Preparedness**



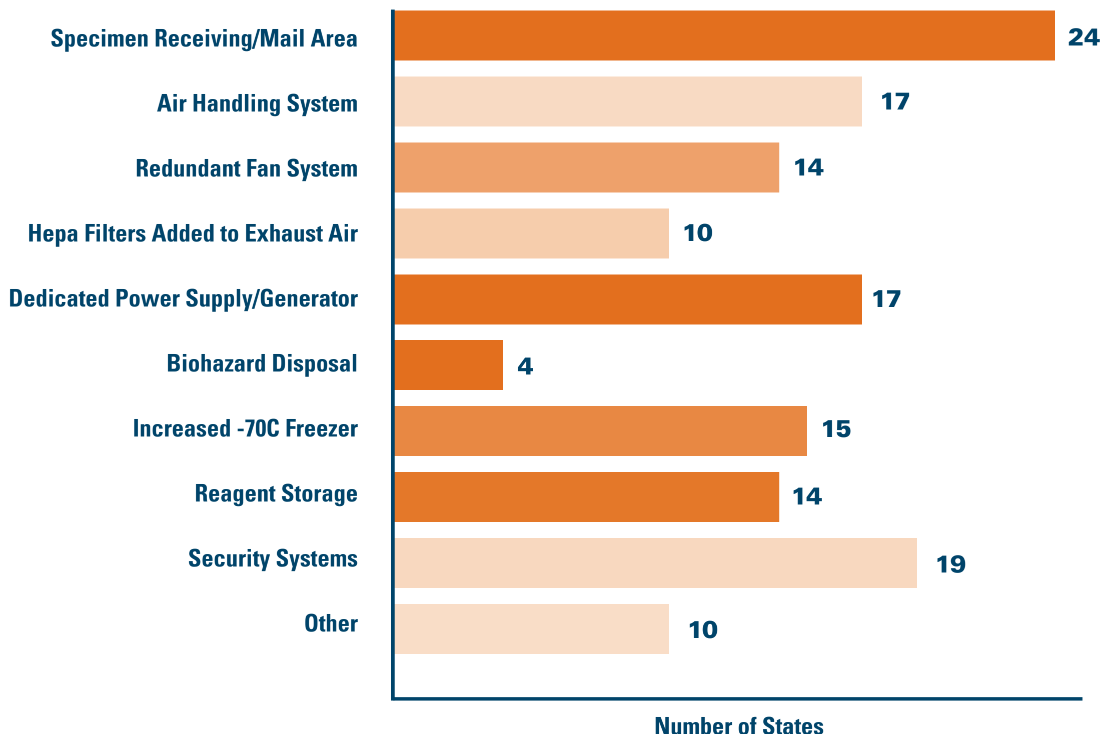
Because USDA regulations mandate that isolation of the highly pathogenic avian influenza A (H5N1) virus be conducted only in a BSL-3 enhanced facility, many states are concerned about the need to upgrade existing BSL-3 suites. **Thirty-six of 51 SPHLs (71%) do not have a BSL-3 enhanced laboratory and therefore cannot culture the avian influenza A virus.** These SPHLs are allowed only to screen specimens for the presence of the virus using the real-time reverse transcriptase PCR assay provided by CDC. **Testing of samples where live virus confirmation is required will need to be referred to CDC or other federal or agricultural laboratories, which may delay confirmation.**

Since August 2004—the end period of the previous bioterrorism survey—SPHLs have made considerable upgrades to many other areas of their facilities and safety operations: specimen and mail receiving areas, air handling systems, HEPA filtration systems, redundant fan systems, dedicated power/generator systems, biohazard disposal processes, sub-zero freezer capacity and reagent storage facilities. However, half of the SPHLs report that they still require some additional upgrades to many of these items, most notably the specimen and mail receiving areas and the security systems. ***(See Figure 7.)***

Reagents and Equipment

State and local LRN reference laboratories typically respond to bioterrorism threats and hoaxes several times a week. To meet these ongoing public health and law enforcement testing needs and assure adequate capacity to respond to an actual outbreak situation, SPHLs must continually replenish stores of testing supplies and standardized LRN reagents. In 2004, APHL called attention to an ongoing national shortage of the LRN reagents needed for reliable identification of agents of biological terrorism.[13] Last year, association leaders met with key US Senate and House staff to discuss the reagent crisis.[14] **Early this year, APHL released data from a current assessment of LRN laboratory reagent needs showing 51 of 83 state and local LRN reference**

Figure 7 **Facilities Upgrades Still Needed**



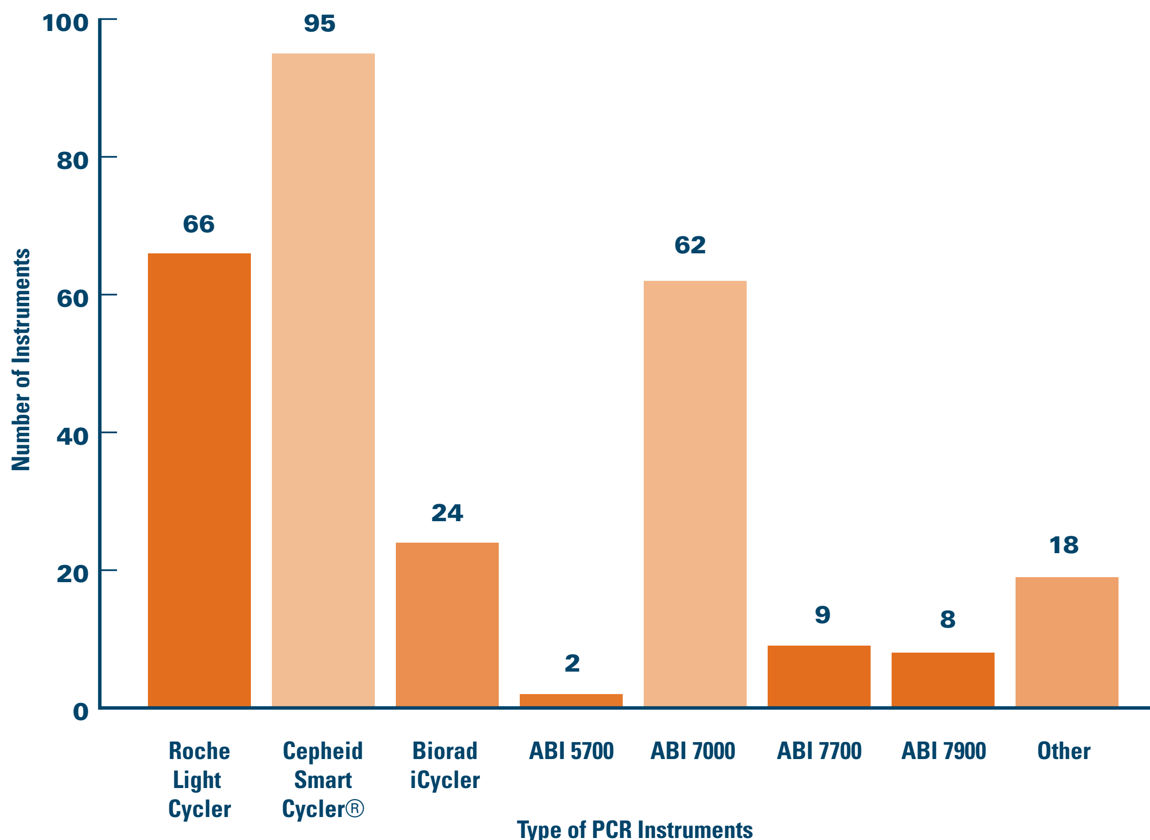
laboratories (61%) have experienced delays receiving CDC-supplied LRN reagents for detection of potential agents of biological terrorism.[15]

APHL recommendations to resolve the LRN reagent crisis are outlined in the publication, *Public Health Issues in Brief: Critical Shortage of LRN Reagents for Analysis of Bioterrorism Agents.*[16] Chief among these is a long-term strategy for sustained CDC funding.

In addition to the use of standardized reagents, LRN's rapid response capabilities require the use of various real-time molecular and antigen detection systems. New and improved rapid testing technologies continue to emerge, and laboratories will need to purchase upgraded instrumentation and develop new skills in this fast-paced environment.

- All states have at least one real-time polymerase chain reaction (PCR) instrument for rapid detection of agents of biological terrorism. Enhanced molecular testing capability for rapid bioterrorism agent detection at the SPHLs is one of the most notable achievements resulting form the terrorism funding. Additional PCR instruments are needed for surge capacity and as a back-up system in case one instrument is incapacitated. **Figure 8** illustrates the number and types of PCR instruments available in SPHLs as of August 31, 2005.
- **41 of 50 SPHLs (82%) have a Luminex instrument, representing a significant increase from FY04 when just 18 SPHLs (35%) had this instrumentation.** The Luminex instrument provides enhanced detection capacity via multiplexing, the ability to measure multiple analytes simultaneously.

Figure 8 **PCR Instruments in SPHLs**



- **48 of 50 SHLs (94%) have a Victor time-resolved fluorescence instrument.** This instrument is primarily used to analyze samples for ricin and Staphyloccal enterotoxin.

Smallpox Preparedness

Federal agencies remain concerned that smallpox virus could be used as a bioweapon. Laboratory-based identification and reporting of suspected or actual smallpox cases are essential to national smallpox preparedness. SPHLs are making strides in closing the gaps in smallpox preparedness.

- 49 of 51 SPHLs (96%) have validated PCR and direct fluorescent assays for the detection of varicella zoster virus, the causative agent for chicken pox, the disease most likely to be confused with smallpox. At the end of FY04, all but two states had implemented at least one of the above methods.
- 22 of 51 SPHLs (43%) have a validated PCR assay for smallpox, a slight increase from FY04 when only nineteen states had a validated PCR assay for this agent. **An additional 20 laboratories expressed interest in establishing smallpox-specific testing capability.** Due to the strict criteria for biocontainment of the smallpox virus, CDC continues to evaluate the feasibility of expanding smallpox testing capability.
- **34 of 48 SPHLs (71%)—compared to 27 in FY04—have identified a nearby site with an electron microscope and the expertise to provide assistance.**

Transportation and Courier Service

An intra-state courier service that provides full-state coverage and operates 24-hours-a-day is considered the optimal system for timely transport of specimens and samples. Depending on the agent and packaging, delayed transport can render many specimens and samples unsuitable for testing. In all cases, delayed transport pushes back the timing of testing and hence of informed public health and law enforcement decision making.

- **Only 20 SPHLs (39%) have access to an intra-state courier system that operates 24 hours a day for specimen pick up and delivery.** Of these 20 SPHLs, 15 (29%) use courier systems that provide full-state coverage for some types of specimens, an improvement from 2002 when just seven SPHLs had access to such a system.

In the absence of a public or private courier system, many SPHLs rely on law enforcement or public safety partners (e.g., state police, local FBI bureau, fire departments, HAZMAT crews) to transport specimens and samples suspected of contamination with bioterror agents.

All-Hazards Laboratory Preparedness

Much of the workforce and physical laboratory infrastructure developed for bioterrorism response can, and indeed, is intended to do double-duty for other public health emerging threats. For example, biosafety enhancements put in place for safe handling of select agents can also be used for more common pathogenic microbes, such as *Mycobacterium tuberculosis,* or for highly infectious emerging microbes, such as Severe Acute Respiratory Syndrome (SARS).

Increasingly, however, SPHLs are being called upon to respond to crises beyond their traditional areas of clinical expertise. In 2001, SPHLs across the country accepted unidentified powders, letters and countless other environmental samples suspected of possible anthrax contamination. A small group of public health laboratory leaders literally worked around the clock to devise a standard protocol to test such items, as LRN laboratories had geared up to test human specimens rather than environmental samples.

Today, SPHLs have been tapped as frontline players in what is known as all-hazards response. **These laboratories are responsible for accepting, screening and testing unknown samples that may contain anything from weaponized select agents to chemical warfare agents or a mixture of the two.** However, funding has not kept pace with this increased burden of responsibility and expectations. As survey data show, many SPHLs do not have the infrastructure in place to safely support the full array of activities associated with all-hazards response.

- **Only 23 of 51 SPHLs (45%) have a designated screening or triage area for receiving unknown samples.**
- 38 of 51 SPHLs (75%) reported needing a separate triage area to safely receive and process unknown

hazard samples. In most of these laboratories, the triage area may need to be contained within a separate, freestanding facility, since only 12 SPHLs reported that they could integrate an all-hazards receipt area into the laboratory's existing physical structure.

- 43 of 51 SPHLs (84%) require law enforcement officers and first responders to screen unknown samples prior to accepting them. Samples are screened for chemical, radiological, nuclear, explosive and incendiary unknowns.

Effective response to any emergency requires rapid communication of test results and other laboratory-generated information. Interoperable electronic data management systems are one piece of the state-of-the-art means for achieving such communication. In the SPHL, this means a laboratory information management system (LIMS) designed to meet Public Health Information Network (PHIN) standards.

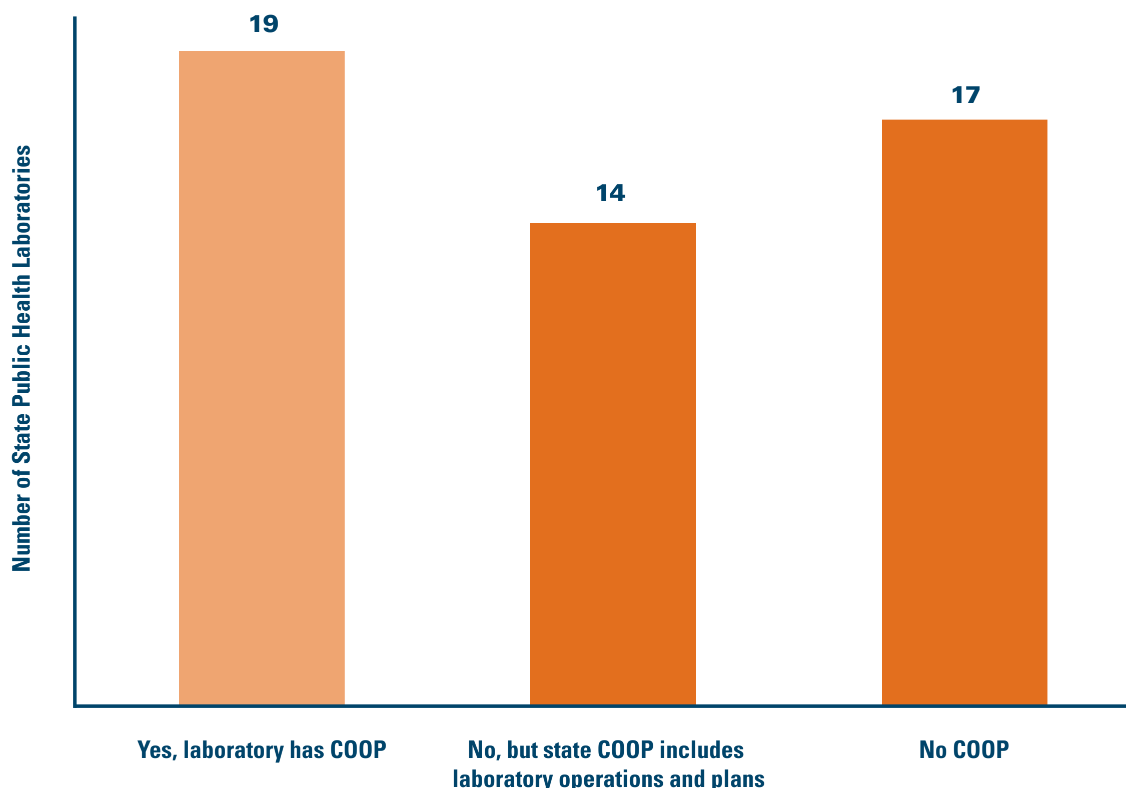
- **41 of 50 SPHLs (82%) do not have a PHIN-compliant LIMS in place.** Further, 42 of 50 SPHLs (84%) do not have the means to electronically migrate test results to their state's central data repository used for PHIN and National Electronic Disease Surveillance System-based initiatives.
- While e-mail and online data reporting are available in some states, 50 SPHLs (96%) still rely on a combination of telephone, 40 (77%) on mail and 32 (62%) on fax transmissions to communicate bioterrorism and chemical terrorism laboratory results. Only 25 SPHLs (48%) use e-mail and 23 (44%) use online results reporting to communicate laboratory results.

Continuity of Operations

Public health laboratories must be prepared both to respond to natural disasters and to maintain critical operations when these disasters impact their facilities and staff. Both hurricanes Katrina and Rita impacted public health laboratory capacity in the Gulf region, especially in Louisiana. Due to the nature of the disaster, the need to test for water and food contamination was intensified in all affected states. Since the central branch of the Louisiana state public health laboratory was damaged by the storm and inaccessible to staff, the laboratory tests usually performed in New Orleans were transferred to selected local public health laboratories or laboratories in other states. In light of these recent natural disasters and other global threats, it is essential that each state health department and public health laboratory have a continuity of operations plan (COOP) in place. The COOP is essential to assure that vital public health assays, such as newborn screening, can still be performed by other public health or non-public health laboratories during an emergency.

- **33 of 50 respondents (66%) indicated that they have some form of a COOP in place.** However, 17 (34%) SPHLs do not have a COOP in place and the overall state plan does not address continuity of laboratory operations. ***(See Figure 9.)***

Figure 9 Continuity of Operations Plans (COOP)



Conclusions

Since APHL's first assessment of SPHL bioterrorism preparedness, SPHLs have made incremental progress in hiring and training new personnel, conducting outreach activities to build statewide laboratory networks and expanding biosafety facilities. Data from the current survey show that such progress continues. However, much remains to be done to ensure that SPHLs achieve the state-of-the-art in essential areas.

Reduction of federal and state funds for laboratory preparedness, a national reagent shortage, persistent workforce shortages and a scarcity of highly skilled laboratory scientists pose serious challenges to SPHLs. Additionally, there are ongoing needs to improve facilities and implement newly emerging technologies. These shortfalls are not limited to the bioterrorism arena, but will impact the public health laboratory response to chemical, radiologic or "unknown" hazard threats as well as emerging disease outbreaks such as pandemic influenza.

In addition to ongoing assessment of SPHL capabilities and needs, APHL is working with partners at the national level to develop measurable goals for preparedness that will enable state and local public health agencies and public health laboratories to better allocate scarce resources, benchmark performance levels, measure improvements, and identify gaps. The association is committed to achieving optimal public health laboratory preparedness for bioterrorism as well as all-hazards response. This goal will ultimately depend on a comparable, sustained commitment from state and federal government partners.

Endnotes

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12 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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