PUBLIC HEALTH LABORATORIES:

LEVERAGING PARTINERSHIPS TO STRENGTHEN PREPAREDNESS & RESPONSE

2013 APHL ALL-HAZARDS LABORATORY PREPAREDNESS REPORT



MAY 2013



TABLE OF ACRONYMS

BDS Biohazard Detection System

BT Bioterrorism

CBRN Chemical, Biological, Radiological, Nuclear
CDC Centers for Disease Control and Prevention
CLIA Clinical Laboratory Improvement Amendments

COOP Continuity of Operations Plan

CST Civil Support Team
Chemical Terrorism

DHS Department of Homeland Security
DPHL Delaware Public Health Laboratory
FBI Federal Bureau of Investigation

FERN The Food Emergency Response Network

FY Fiscal Year

HAN Health Alert Network
HazMat Hazardous Materials
HCV Hepatitis C Virus

HHS US Department of Health and Human Services ICP/MS Inductively Coupled Plasma/Mass Spectrometry

LRN Laboratory Response Network

LRN-B Laboratory Response Network for Biological Threats Preparedness and Response

LRN-C Laboratory Response Network for Chemical Threat Preparedness

MSPHL Missouri State Public Health Laboratory **NH PHL** New Hampshire Public Health Laboratories

PHEP Public Health Emergency Preparedness Cooperative Agreement

PHL Public Health Laboratory
WMD Weapons of Mass Destruction

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Dear Readers.

Federal support for public health laboratories through the Public Health Emergency Preparedness (PHEP) Cooperative Agreement has earned a significant return on investment since 2002. The \$8 billion invested under this Centers for Disease Control and Prevention (CDC) program has built a stronger preparedness infrastructure, enhanced national laboratory capability and public health surveillance systems, and forged partnerships between laboratories and their collaborators in emergency response.

The American people are the beneficiaries of this investment. In 2013 they are better protected from all hazards: biological, chemical, radiological threats and emerging infectious diseases such as pandemic influenza. Without this investment in modern equipment and technologies, professional staff and outreach, public health laboratories could not have responded quickly and efficiently to the 2001 Amerithrax threats, 2003 SARS outbreak, 2009 influenza A H1N1 pandemic and the 2011 Fukushima disaster. Nor would they have had the capability and capacity to provide laboratory services for the Super Bowl or the Democratic and Republican National Conventions, or to detect the emergence of the dengue virus in Florida, not to mention routine testing to distinguish potentially lethal white powders from their benign look-alikes.

Specifically PHEP funding has underwritten a wide range of biological and chemical threat preparedness laboratory activities including:

- Biosafety Level 3 (BSL-3) facilities, now in all states, allow scientists to work safely with biological threat agents
- Expansion of Laboratory Response Network for Chemical Threat Preparedness (LRN-C) testing methods for clinical specimens
- Development of training courses on biosafety, packing and shipping of infectious substances, and the detection and transfer of threat agents
- Participation in nationwide competency programs and full-scale preparedness exercises
- Outreach to first responder communities
- Evaluation of new assays and platforms for rapid detection of threats.

PHEP funding also has strengthened the entire public health laboratory infrastructure via:

- Recruitment of highly skilled personnel
- Training of laboratorians to enable response to multiple threats
- Purchase of state-of-the-art equipment, maintenance contracts, critical reagents and supplies
- Implementation of new systems for electronic communications and data messaging
- Enhancement of partnerships with private clinical, local public health, food, agricultural, environmental, military and academic laboratories
- Continuity of Operations Planning to support critical testing
- Improved engagement of state laboratory network partners, notably during the H1N1 pandemic when states effectively utilized their networks during the response.

Yet though we have made progress in forging an effective US laboratory system over the last decade, we dare not become complacent. After all, preparedness is not a destination; it's a journey requiring constant vigilance, hard work and a sustained commitment to supporting the public health institutions that keep us safe.

Sincerely,

Scott J. Becker. MS Executive Director, APHL

Scott J. Beck -

LABORATORY RESPONSE NETWORK (LRN)

In accordance with Presidential Decision Directive 39, the CDC, the FBI and APHL formed the LRN in 1999. This network is the nation's premier system for identifying, testing and characterizing potential agents of biological and chemical terrorism. The LRN's vast, integrated network of state and local public health, federal, military and international laboratories enables it to respond quickly to all-hazards threats.

State and local public health laboratories comprise approximately 70% of the 160 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.



MISSION STATEMENT

The LRN is a national security asset that, with its partners, will develop, maintain and strengthen an integrated domestic and international network of laboratories to respond quickly to biological, chemical and radiological threats and other high priority public health emergencies needs through training, rapid testing, timely notification and secure messaging of laboratory results.



LRN-B AND LRN-C BACKGROUND

Laboratory Response Network for Biological Threats Preparedness and Response¹

The LRN for Biological Threats Preparedness and Response (LRN-B) is organized as a three-tiered pyramid (see Figure 1). At the foundation are sentinel clinical laboratories, which are tasked with initially screening for potential pathogens and either ruling-out biological terrorism agents or referring potential threat agents to a designated LRN Reference Level Laboratory, typically a state or large local public health laboratory. More than 160 state and local public health, military, international, veterinary, agriculture, food and water testing laboratories serve as reference laboratories by performing complex analyses and providing support to law enforcement for threat investigations.

At the apex of the pyramid are national laboratories, such Sentinel Labs as those at the CDC and the Department of Defense (DoD). These laboratories test and characterize samples that pose challenges beyond the capabilities of Reference Level laboratories (e.g., specialized strain characterizations, bioforensics) and provide support for other LRN members during serious outbreaks.

FIGURE 1LRN-B

National

public health emergencies or terrorist events. The most dangerous or perplexing pathogens are handled only at biosafety level 4 (BSL-4) laboratories at the CDC and the US Army Medical Research Institute of Infectious Diseases (USAMRIID).

Laboratory Response Network for Chemical Threat Preparedness²

The LRN for Chemical Threat Preparedness (LRN-C) comprises laboratories that provide emergency response capabilities and chemical threat support to their local jurisdictions. the nation or both. Laboratories are designated Level 1, 2 or 3 based on the laboratory's capabilities; these designations define the laboratory's LEVEL3 network participation (see Figure 2).

LEVEL 3 LABORATORIES

Eight laboratories designated as Level 3, work with hospitals and first responders to maintain competency in clinical specimen collection, storage and shipment.

LEVEL 2 LABORATORIES

Thirty-six laboratories designated as Level 2, are capable of detecting exposure to a number of toxic chemical agents (e.g., cyanide, nerve agents and toxic metals in human samples). These laboratories also have the capacity of Level 3.

LEVEL 1 LABORATORIES

Ten laboratories designated as Level 1, serve as surge-capacity laboratories for the CDC. In addition to Level 2 and 3 capacities, they also can detect exposure to more chemicals, including mustard agents, nerve agents and other toxic industrial chemicals. These laboratories are

FIGURE 2LRN-C

LEVEL1

CDC

intended to provide the CDC with much needed surge capacity during a large scale event.

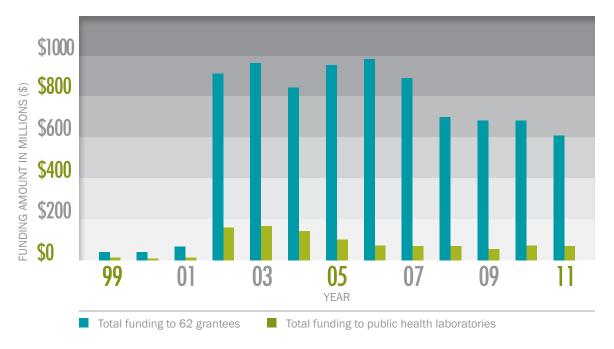
INTRODUCTION

Following the events of September 11, 2001, preparedness and response have been public health priorities to ensure the nation's security. Public health laboratories serve as the nation's first line of defense when assessing clinical, environmental, or food specimens and samples for all-hazards threats that could be of chemical, biological, radiological or nuclear (CBRN) origin. Public health laboratories provide training to ensure proper preparedness, conduct timely and effective testing during events and report results to expedite the response to threats. Simply stated, these laboratories remain a crucial asset for national security.

At the core of national security is the ability for the United States to prepare for, rapidly detect and respond to all-hazards threats. This preparation and response increases the need for collaboration among state and local public health agencies and federal partners. To foster this collaboration, public health laboratories maintain strong working partnerships with other laboratories (e.g., sentinel clinical, veterinary, military, environmental) as well as federal agencies such as the Centers for Disease Control and Prevention (CDC), Department of Homeland Security (DHS),the Federal Bureau of Investigation (FBI), and the Environmental Protection Agency (EPA). Additionally, public health laboratories engage first responders, such as law enforcement, fire departments, Hazardous Materials (Hazmat) teams and Civil Support Teams (CSTs).



FIGURE 3 CDC PHEP FUNDING BY FISCAL YEAR: FY99-FY11



As the laboratories work to maintain testing and efficient response with less funding, they increasingly rely on partnerships, networks, exercises and training.

APHL annually assesses all-hazards preparedness and response at public health laboratories in all 50 states, the District of Columbia and Puerto Rico to document the successes and challenges experienced since the establishment of CDC's PHEP Cooperative Agreement.

This report summarizes the survey data from the CDC PHEP Fiscal Year (FY) 2011 representing the 12-month period from August 10, 2011 to August 9, 2012. Additionally, this report provides a snapshot of laboratories in action highlighting their value in protecting the American people.

BACKGROUND

In 1999, public health laboratories began receiving limited federal funding for preparedness activities. Following the terrorist attacks on September 11 and the subsequent anthrax letter attacks in October 2001, the United States Congress authorized supplemental funding via the PHEP Cooperative Agreement to support nationwide preparedness through state and local public health departments. This funding, which is administered by CDC, is the primary mechanism of support for state and local public health preparedness.

Since 2002, the PHEP Cooperative Agreement has provided approximately \$8 billion to public health departments across the nation. In FY 11 ("Budget Period 11"), the CDC provided 62 awardees with approximately \$613 million for preparedness and response to all-hazards threats, including infectious diseases, natural disasters and CBRN events. The PHEP awardees include the 50 states, Chicago, Los Angeles County, New York City, the District of Columbia, American Samoa, Guam, the US Virgin Islands, the Northern Mariana Islands, Puerto Rico, the Federated States of Micronesia, the Republic of the Marshall Islands and the Republic of Palau.³

After the 2001 incidents involving the biological agent, *Bacillus anthracis* (anthrax), the PHEP Cooperative Agreement initially focused resources on bioterrorism preparedness. This coincided with the original mission of the Laboratory Response Network (LRN), which brought together a small number of CDC-funded laboratories for biological and chemical terrorism preparedness. Later CDC expanded the scope of the PHEP Cooperative Agreement to encompass preparedness for chemical threats and subsequently all-hazard threats.

METHODS

APHL collected data in the fall of 2012 during its sixth annual All-Hazards Laboratory Preparedness Survey. Public health laboratories reported on their capability and capacity to respond to biological, chemical, radiological and other emerging infectious diseases such as influenza. The survey covered the 12-month period from August 10, 2011 to August 9, 2012, representing the CDC PHEP Cooperative Agreement FY 11.4

The survey generated a 100% response rate, representing public health laboratories in all the 50 states, the District of Columbia and Puerto Rico. Complete aggregate survey assessment results are available online at http://www.aphl.org/aphlprograms/preparedness-and-response/biological-threats/pages/default.aspx. For the purposes of this report, the term "state public health laboratories" will be used to describe all 52 respondents.

Data were collected using Qualtrics,⁵ a Web-based survey tool and data repository. Descriptive statistics were gathered for all categories: workforce, planning and response, biological threat preparedness, chemical threat preparedness and radiological threat preparedness. The following sections present stories and accompanying data that highlight the role of the laboratories and the importance of their partnerships.

PHEP SUCCESS:

Water Testing, LRN-B and -C Exercises, and a Sprinkling of Paprika in Missouri

Following a severe drought season in 2011, Missouri citizens became concerned about the safety of their private wells, and the Missouri State Public Health Laboratory (MSPHL) received an influx of samples, double the number from previous years. How was the MSPHL to handle this influx? Fortunately the lab had purchased through PHEP funds an Inductively Coupled Plasma/Mass Spectrometry (ICP/MS) instrument that could test drinking water. This same instrument also quantified the amount of lead present in a brand of paprika suspected of poisoning a child with an elevated blood lead level. Results showed that the paprika was contaminated, and the product was removed from the market.

Additionally, PHEP funding supported the MSPHL's participation in preparedness exercises. In September 2011, the laboratory participated in a multistate LRN/CDC Bio-Response Operational Testing and Evaluation exercise designed to assess laboratories' capability to test surface sample swabs, wipes and socks for a *Bacillus anthracis* surrogate. The following month, the MSPHL participated in a weeklong full-scale EPA Region 7 and 8 exercise testing laboratory response plan procedures for sample collection, shipment, analysis and data reporting based on scenarios of chemical and biological origin. In 2012 the MSPHL participated in a Biohazard Detection System (BDS) exercise that tested laboratory response time after postal inspectors delivered a BDS cartridge for threat analysis.

These exercises tested the MSPHL's ability to effectively utilize its LRN-B and LRN-C methods, and evaluated the level of cooperation between the laboratory and federal partners. Results showed that the exercises strengthened relationships with federal agencies, and reinforced the importance of the laboratory as integral to national preparedness.



FINDINGS: PUBLIC HEALTH LABORATORY FUNDING

For FY11, the 52 state public health laboratories reported receiving a total of \$80 million in funding from the CDC PHEP Cooperative Agreement, non-CDC federal, state and other sources for biological, chemical and radiological threat preparedness. This funding underwrites salaries, renovations, training, and equipment purchases and maintenance (see Figure 4).

FIGURE 4 Allocation of CDC PHEP FY11 Funds for Biological and Chemical Laboratories

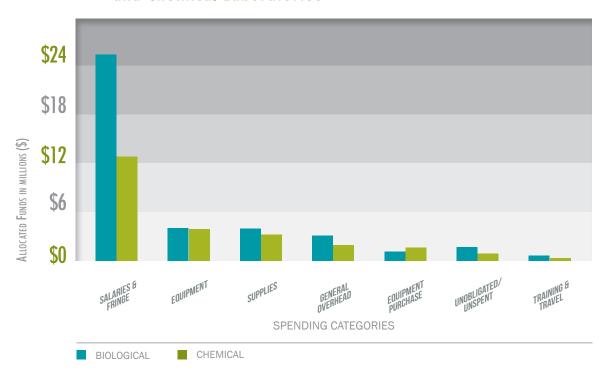


FIGURE 5 CDC PHEP Funding for Biological and Chemical Laboratories: FY99-FY11

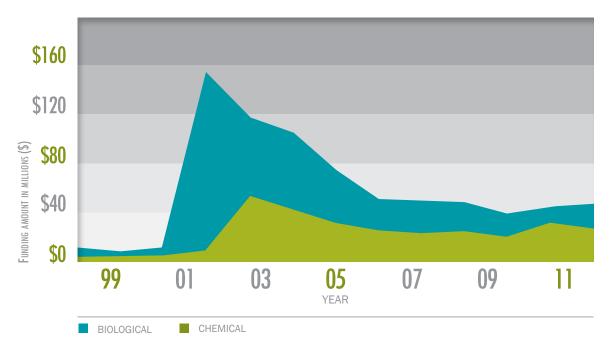


FIGURE 6 Top 5 Impacts of Funding Cuts for Biological and Chemical Threat Preparedness During FY11

	BIOLOGICAL	CHEMICAL
1	Loss of full-time staff positions	Unable to renew service/maintenance contracts for instrumentation
2	Unable to renew service/maintenance contracts for instrumentation	Unable to expand capabilities for new assays and tests
3	Unable to expand capabilities for new assays and tests	Unable to purchase critical equipment
4	Unable to provide or reduced the number of training courses and other outreach activities	Unable to attend training courses
5	Increased staff turnover	Unable to participate in national meetings or conferences

FINDINGS: PLANNING AND RESPONSE

During FY11, the majority of state public health laboratories utilized rapid communication methods to contact sentinel clinical laboratories and other partners for outbreaks (85%), for training events (73%) and for routine updates (71%). For example, the New Hampshire Public Health Laboratories (NH PHL) utilized the Health Alert Network (HAN) during a hepatitis C outbreak during the summer of 2012.



PLANNING: Forty-seven laboratories (90%) reported that they have either a state agency or department-wide Continuity of Operations Plan (COOP) or a laboratory-specific COOP. This number is up from 42 laboratories in FY10.

RESPONSE: Fifty laboratories received a total of 4,322 specimens and samples for LRN threat testing from the following partners: FBI, local or branch PHLs, local/state law enforcement, CSTs, the US Postal Service, Hazmat teams or sentinel clinical laboratories. These samples ranged from clinical specimens for referral or rule-out testing to highrisk environmental samples (e.g., suspicious letters to political officials) received for testing of suspect threat agents.

PHEP SUCCESS:

LRN Connects New Hampshire Labs to Fight Hepatitis C Outbreak

The medical community considers hepatitis C virus (HCV) to be among the most serious of the hepatitis viruses. Most people who contract it don't even know they have the disease until decades later when liver damage becomes apparent. Early detection of the disease can lead to treatment or lifestyle changes that may slow liver damage. In May 2012, after a cluster of cases presented with matching HCV sequences, the Division of Public Health Services (DPHS) in New Hampshire moved quickly to investigate.

DPHS determined that the cluster of cases had been treated in the Cardiac Catheterization Lab at the Exeter Hospital. To track down any additional cases, testing clinics were set up in various locations in the southern region of the state. The clinics obtained blood samples, performed rapid testing on-site, and packaged and transported samples to the New Hampshire public health laboratory (NH PHL). The CLIA-waived OraQuick® HCV Rapid Antibody Test provided on-site results to physicians who counseled patients at the testing facility.

The clinics' mission was to test all patients who requested the service. To handle the volume of testing required, the NH PHL reached out to all of its employees and to LRN sentinel clinical partners. Volunteers came from all sections of the lab: Water analysis, chemistry, molecular diagnostics, information technology, virology, microbiology and administration, including clerical staff and interns, all contributed to the outbreak response from pre-analytical through post-analytical processes. In addition, partners from five hospitals and an LRN Reference Level Laboratory volunteered to assist at the clinics. The response was overwhelming: NH PHL received an ample number of volunteers to conduct phlebotomy and on-site testing; laboratorians even assisted during their off hours and vacations.

The NH PHL communicated with sentinel clinical labs through the Health Alert Network (HAN) and the NH LRN listserv, with the HAN providing situational updates to healthcare providers and sentinel clinical labs, and the listserv serving as a mechanism to request assistance from LRN partners.

Though the LRN is most commonly known for response to acts of biological or chemical terrorism, its mission applies to all high priority public health emergencies requiring rapid testing, timely notification and secure messaging of results. In this instance, LRN infrastructure enabled the NH PHL to quickly and efficiently respond to the HCV outbreak, which was eventually linked to an infected medical technician.



FINDINGS: BIOLOGICAL THREAT PREPAREDNESS

In FY11, 44 state public health laboratories (85%) reported sponsoring sentinel clinical laboratory trainings in their respective states; this represents an increase from FY10 when 41 laboratories reported sponsoring these trainings, which improve detection and response to biological threats, as evidenced by an incident in Delaware.



SENTINEL CLINICAL LABORATORIES: All 52 state public health laboratories indicated that they maintain a database of sentinel clinical laboratories, with a total of 4,147 active laboratories. In FY10, 48 laboratories reported a total of 4,415 active sentinel clinical laboratories.

PHEP SUCCESS:

Clinical and Public Health Labs in Delaware Collaborate to Confirm *Francisella tularensis*

On September 28, 2011, a local hospital in Delaware admitted a 46-year-old man who presented with fever, chills and chest pain. Blood cultures revealed no bacterial growth after five days, but a pleural fluid specimen was collected for further laboratory testing. The cultures and Gram stain concerned the bench laboratorian and microbiology supervisor so much that they moved the specimens and cultures to a biosafety cabinet to perform sentinel laboratory testing for the rule-out or referral of a potential biological threat. When the hospital laboratory was unable to rule-out the organism as a potential threat, the supervisor contacted the Delaware Public Health Laboratory (DPHL) to request testing for F. tularensis, a CDC select agent that causes the disease tularemia in humans and animals. Humans can become infected via tick or deer fly bites, skin contact with infected animals (e.g., rabbits, hares, rodents), ingestion of contaminated water or inhalation of contaminated dusts or aerosols. Humans can also become infected as a result of a bioterrorism attack.7

On October 5, 2011, the hospital laboratory shipped the pleural fluid specimen to the DPHL where the bioterrorism staff quickly initiated preliminary testing by real-time polymerase chain reaction (RT-PCR). Preliminary results indicated the presence of *F. tularensis* and laboratorians contacted the hospital the night of October 5, 2011. Final cultures confirmed the presence of the organism on October 6. Following this confirmation, the DPHL promptly began communications with the CDC and shipped the specimens to the CDC for further analysis and characterization. The patient was placed on intravenous antibiotics and made a full recovery. He revealed that he had previously mowed over a rabbit carcass with his lawnmower, thus putting him at risk for infection by a contaminated aerosol.

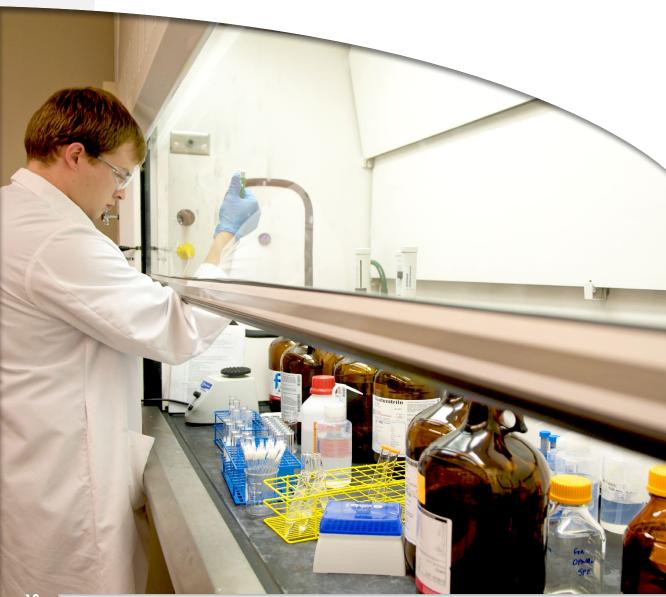
The successful detection and identification of *F. tularensis* within eight days of a patient presenting with symptoms was possible due to the ongoing partnership and collaborations between the DPHL and sentinel clinical laboratories. The hospital microbiology supervisor and several bench technologists had attended DPHL's "Agents of Bioterrorism: Sentinel Laboratory Training" workshops that discuss laboratory safety, the LRN, select agents and organisms that resemble select agents. It was this training that enabled them to identify *F. tularensis*.



A microbiologist from the Delaware Public Health Laboratory performs testing on *Francisella tularensis*. Photo courtesy of Debra Rutledge.

FINDINGS: CHEMICAL THREAT PREPAREDNESS

For FY11, 50 state public health laboratories either maintained (62%) or increased (35%) their LRN-C capabilities. This level of preparedness ensures effective and timely laboratory response to any chemical event.



PHEP SUCCESS: LRN-C Lab Analysis Reopens School After Mercury Spill in North Carolina

Mercury exposure is highly dangerous. It can result in fever, fatigue and clinical signs of pneumonitis. Chronic exposure can lead to neurological, dermatological or renal effects. As happens periodically, in 2012 a student brought a vial of mercury to a North Carolina school. When the 15 milliliter vial broke spilling 203 grams of mercury, the teacher attempted to clean it up with a broom (one of the worst things to do,⁸ as it can disperse the mercury). School officials evacuated students, and the EPA On-Scene Coordinators advised them to shut down the ventilation system and open windows. Students in the spill zone were asked to remove their shoes and bag them. Four students and one teacher suspected of exposure were transported to the local hospital.

The laboratory director at the North Carolina State Laboratory of Public Health informed the primary contact for the incident that the Chemical Terrorism (CT) Unit at the State Lab could perform blood mercury testing on the exposed individuals. Samples were taken and the hospital contacted the CT unit to ensure proper containers and shipping protocols were being used.

The CT Unit guided the hospital as to what type of blood tubes to use, how to label them for the CT lab and how to properly package the samples for shipment. Though none of the hospital staff had attended training on CT packaging and shipping, they were familiar with how to ship general specimens to the lab. The samples were successfully received by the CT lab, which found no elevated mercury levels in the blood. With fears calmed, just a few days later, the school re-opened.

FINDINGS: RADIOLOGICAL THREAT PREPAREDNESS

Radiological threat preparedness remains a major gap for state public health laboratories. For FY11, only 27 laboratories (52%) indicated that they are responsible for performing radiological testing: All 27 test environmental samples, while only 19 test food samples and six test clinical samples. While the majority of these laboratories are not certified or accredited, five are accredited by the Nuclear Regulatory Commission.

These gaps are a direct result of the lack of radiological threat preparedness funding:

- Three laboratories reported receiving a total of \$785,000 from non-CDC federal sources.
- Four laboratories reported receiving a total of \$320,000 from their states.
- Three laboratories reported receiving a total of \$50,000 from other sources.

Significant investments are needed to ensure laboratories have the capacity and capabilities to respond to radiological threats, such as the 2011 Fukushima disaster.



PHEP Success: No Cyanide for Dinner Courtesy of LRN-C Lab in Washington

Of the 35% of laboratories that increased their LRN-C capabilities in 2012, two-thirds added at least one new method to their skillset. The Washington State Level 2 Chemical Incident Response Laboratory was one of these. It chose to add cyanide testing.

Cyanide is a rapidly acting, potentially deadly chemical that can exist in multiple forms. For the 2012 national political conventions, the Food Emergency Response Network (FERN) was concerned about cyanide poisoning of food served at the conventions, a threat that could potentially affect thousands of people. It reached out to the Washington Public Health Laboratories for help.

With its highly trained LRN-C chemists and state-of-the-art equipment, the Washington State Laboratories adapted the LRN method to rapidly and accurately screen for cyanide at the limits desired by the FERN. The adapted method — now under consideration for nationwide implementation as a FERN method — was used to test 20 composite samples for the 2012 Republican Convention and 20 samples for the 2012 Democratic National Convention. Washington State Laboratories attributes its success to the skills and instruments funded through CDC's LRN.



CONCLUSION

Public health laboratories are first responders working on the front lines of public health to protect communities from all hazards. They provide timely data on biological and chemical threats; perform routine surveillance and diagnostics; and train clinical laboratories to recognize, rule-out and refer potential threat agents. Their role in protecting public health and safety continues to expand even as federal and state funding shrinks.

Without sustained support for this critical health resource, the nation's security will be compromised.



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- 5. The data for this report was generated using Qualtrics software. Copyright © 2009 Qualtrics. Qualtrics and all other Qualtrics product or service names are registered trademarks or trademarks of Qualtrics, Provo, UT, USA. http://www.qualtrics.com.
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8515 Georgia Avenue, Suite 700

Silver Spring, MD 20910 Phone: 240.485.2745 Fax: 240.485.2700

Web: www.aphl.org