September 11, 2001, stands as a dividing line in American life: we speak of the world pre-9/11 and post-9/11. The terrible events of that day, and the anthrax attacks that followed, prompted profound changes in the national psyche. They also triggered a wholesale shake-up of American institutions, including the public health laboratory (PHL) system.

Jim Pearson, DrPH, BCLD, director of the Virginia Division of Consolidated Laboratory Services (DCLS), called 9/11 “a wake-up call for all of us.” He said, “The CDC had put a little bit of money out to try to get the Laboratory Response Network started because they saw there might be a problem. The first problem was a massive coordinated attack against the United States. That was the wake-up call: that we were vulnerable.”

In the wake of disaster, new federal funding remade the nation’s PHL system, which had been so starved for resources that key infrastructure components were wearing out or heading toward obsolescence.
TESTING FOR AGENTS OF TERRORISM

The Laboratory Response Network (LRN) mentioned by Pearson is widely regarded as the feather in the cap of the revitalized system. The LRN—a multi-tiered network of laboratories with standardized protocols for handling and testing potential agents of terrorism—was established by APHL, CDC and the Federal Bureau of Investigation under Presidential Decision Directive 39, which outlines early anti-terrorism policies. It became operational in August 1999 and was young and untested when four hijacked planes crashed into three American icons and a Pennsylvania field in September 2001.

The network, including diagnostic labs that would be the first to receive specimens from patients sickened by biothreat agents, was placed on alert for signs of further terrorist activity. Fortunately, among the few LRN tests that had been implemented thus far was one for Bacillus anthracis, the anthrax bacterium.

Since then, the LRN has expanded its membership and its mission, which now encompasses response to biological and chemical terrorism as well as “other high priority public health emergencies.” LRN funding—primarily through the Public Health Emergency Preparedness Cooperative Agreement (PHEP)—helped build the infrastructure and train the scientists who responded successfully to everything from the 2001 anthrax attacks to the 2009 H1N1 pandemic and the 2010 Gulf Coast oil spill.

But today, this far-sighted (and still incomplete) investment in laboratory capacity stands imperiled, with steadily declining and uncertain PHEP funding alongside declining and uncertain state and local funding.

“The whole infrastructure is being eroded,” said Eric Blank, DrPH, whose historical perspective stretches back nearly 40 years as former head of the Missouri State Public Health Laboratory and APHL’s current director of public health systems.

WE SAW HINTS OF CRACKS EVEN IN OUR H1N1 RESPONSE, WHICH WAS A GOOD RESPONSE. AND THE NEXT TIME, WHEN WE DON’T HAVE ALL OUR TOOLS AND ALL OUR STAFF AND ALL OUR CAPABILITIES, WE’RE NOT GOING TO BE ABLE TO DO IT.”

—ERIC BLANK, DrPH, FORMER DIRECTOR, MISSOURI STATE PUBLIC HEALTH LABORATORY, AND APHL SENIOR DIRECTOR OF PUBLIC HEALTH SYSTEMS.
He said, “I quite frankly—and this is my personal opinion—I’m really worried about the next pandemic or the next emergency situation. And here’s why: The PHL community will do everything it can to respond. But, we saw hints of cracks even in our H1N1 response, which was a good response. And the next time, when we don’t have all our tools and all our staff and all our capabilities, we’re not going to be able to do it.”

The threat to laboratory preparedness is so stark that when APHL’s then president Pat Luedtke, MD, MPH, asked CDC Director Tom Frieden, MD, MPH, about a possible PHL role measuring health outcomes, Frieden replied, “Your outcome is survival.”

**A BRUTAL BIRTH**

The LRN’s first great trial began on October 4, 2001, at 8:30 AM, when the Florida Department of Health Bureau of Laboratories—using the new LRN protocol—confirmed the presence of the elliptical spores of *Bacillus anthracis* in a specimen from a 63-year-old photo editor at the Florida-based tabloid, *The Sun*.

Not long thereafter, an anthrax-laced letter addressed to NBC news anchor Tom Brokaw at Rockefeller Plaza made its way to the New York City PHL and immediately contaminated the laboratory’s only bioterrorism (BT) response lab. That lab had to be sealed off until HAZMAT workers could come in, do sampling, decontaminate the lab and do further sampling to make sure the decon worked.

Despite this setback, Sara Beatrice, PhD, who oversaw retrovirology testing at the time and now heads the New York City PHL, said BT testing expanded “from one small room on one floor to ten different rooms throughout the building.” Pre- and post-test evidence rooms were set up and health department police officers brought in to guard everything.

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**THE LAB “WENT FROM TWO PEOPLE IN THE BT LAB TO SOMEWHERE BETWEEN 75 AND 100 PEOPLE PER DAY DOING BT TESTING.”**

—SARA BEATRICE, PhD, DIRECTOR, NEW YORK CITY PUBLIC HEALTH LABORATORY
Beatrice said, the lab “went from two people in the BT lab to somewhere between 75 and 100 people per day doing BT testing. The lab went to 24/7 testing for many, many weeks.” Among the scientists handling the thousands of suspect samples that poured into the PHL were people pulled from every testing area, as well as scientists from CDC and three teams of Department of Defense scientists performing classified work.

Although the PHLs in Florida, New York City and the other jurisdictions directly targeted in the anthrax attacks were especially overwhelmed, similar scenarios played out in PHLs across the country. The Arizona PHL, for example, was far from any confirmed case of anthrax. Yet it received over 1,000 suspect samples and had staff doing anthrax testing on Thanksgiving, Christmas Eve and Christmas, with three shifts per day.

When all was said and done, LRN laboratories successfully identified the method of exposure and tested over 125,000 samples to rule out anthrax contamination.

If the federal support that followed 9/11 gave the PHL system new life, it was a brutal birth in time of crisis.

Speaking at the one-year anniversary of the attacks, Stephen Ostroff, MD, MPH, then deputy director of CDC’s National Center for Infectious Diseases, said “…very, very clearly we [at CDC] would not have been able to respond” to the crisis alone. He said it was only “because the [LRN] capacity was out there and existed” that the public health system could handle the high volume of samples submitted for testing.
A LIFELINE FOR AN ANTIQUATED SYSTEM

After the anthrax attacks, PHEP funding increased tenfold, going from about $75 million in fiscal year 2001 to nearly $1 billion in fiscal year 2002. Even though, on average, PHLs have received only about 10% of the money disbursed to state health agencies, the new funding was a lifeline for an antiquated system, enough to move PHLs from 1970s or 1980s technology and into the 1990s or better.

Beatrice said the New York City PHL used the money to hire additional laboratorians and purchase everything from thermocyclers for molecular assays to “items as simple as pipettes and refrigerators.”

She noted, “In emergency response, you do the work that needs to be done. But to institutionalize that, we had to establish a quality management office and hire people who could bring structure and quality systems to emergency response.”

This mammoth undertaking, in New York and elsewhere, required developing standard operating procedures, conducting training drills, hiring safety officers, cross-training staff for surge capacity, setting up incident management teams, hiring trainers to strengthen relationships with diagnostic laboratories, formalizing relationships with security and law enforcement officials and more.

The sudden recognition of PHLs as a crucial element of homeland security led to other laboratory initiatives. In 2004, the US Department of Agriculture and the US Food and Drug Administration took the first steps toward establishing the Food Emergency Response Network (FERN)—essentially, an LRN for food. And CDC expanded funding for PulseNet, a national network of public health and food regulatory laboratories able to detect foodborne disease case clusters using standardized molecular subtyping of pathogenic foodborne bacteria.

These efforts, though independent of the LRN, were boosted by the infrastructure built with LRN dollars. Said Pearson, “It was critical to get that first molecular biologist on board.”
The infrastructure was quickly put to use for all manner of public health threats. When, in early 2007, imported animal feed was found to be adulterated with melamine (a toxic substance used to artificially boost the feed’s protein content), the Virginia DCLS used methods and equipment from the LRN for Chemical Threats (LRN-C) and from the FERN to test urine from East Coast hogs to determine if they were safe for human consumption.

“That capability would not have existed without the federal funding,” said Pearson. Having it, meant there were quick answers for hog producers.

“OUR ONE BOTTLENECK WAS DATA ENTRY.”

But even before the steady erosion of funding, the PHL system had serious gaps. Blank said, “After 9/11, I think the system vastly improved. Did it get to where it needed to be? No.”

One obvious gap is the ability to assess human radiation exposure, an asset Pearson calls “almost non-existent” in the US. CDC is the country’s primary resource for human radiation monitoring, but, Pearson said, “If something major happened, they wouldn’t be able to touch it; there just isn’t enough capacity.”

The Washington State Public Health Laboratories has what many consider to be the best radiation lab in the nation outside CDC. After Japan’s Fukushima Daiichi nuclear power plant was struck by earthquake and tsunami this past March, the laboratory tested 145 samples—from air, rainwater, shipping containers, food and particulate deposition—as the Pacific Northwest is 5,000 miles directly downwind of the plant. In concert with the state Radiation Protection Program, Gautom was able to report to state and national authorities that although radiation levels were higher than normal, they were well below the threshold at which public health could be threatened.

ONE OBVIOUS GAP IS THE ABILITY TO ASSESS HUMAN RADIATION EXPOSURE, AN ASSET PEARSON CALLS “ALMOST NON-EXISTENT” IN THE U.S.
Said Gautom, “With a little bit of extra federal funding, we could enhance our clinical radiation work. We could be an LRN response laboratory for radiation; the infrastructure is already in place.”

Although there has been talk about developing an LRN for Radiation Threats (LRN-R) to complement the biological and chemical segments of the LRN, funding is inadequate to proceed.

Two other gaps now pose significant challenges for any kind of laboratory outsourcing: limited ability to conduct electronic test ordering and results reporting (ETOR) and limited availability of courier systems for specimen delivery.

APHL’s two hallmark informatics projects—the five-year-old Public Health Laboratory Interoperability Project (PHLIP) and the relatively new Laboratory Technical Implementation Assistance for Public Health (LTIAPH)—have made slow progress toward ETOR. Thanks to PHLIP, virtually all state PHLs are or will soon be able to send influenza surveillance data to CDC electronically. And the infrastructure created for that process will make it easier to add electronic reporting capability for other diseases.

LTIAPH is working with ten states to improve electronic data exchange among state health agencies, PHLs and hospitals/medical records. Some states are also working on their own informatics efforts.

Yet, Michelle Meigs, manager of APHL’s informatics program, noted that “informatics projects are still not being funded as mission-critical to laboratory operations.” Funding, she said, is “always attached to a project deliverable rather than just maintaining and strengthening the infrastructure.”

Lack of ETOR capability was a considerable problem during the 2009 H1N1 pandemic. When the pandemic began, Gautom said, “Our laboratory was absolutely ready. We were part of the CDC validation system [for the agency’s molecular influenza assay]. As soon as CDC approved...
the procedures [for H1N1], we were ready to go. Our one bottleneck was doing data entry and sending results for thousands of specimens.” Those results had to be individually printed and transmitted via phone or through the US Postal Service.

Access to reliable, affordable courier service is also a problem. Most commercial shippers are prohibitively expensive for routine use and their pilots may refuse to accept infectious pathogens, as happened to the Hinton State Laboratory Institute during the 2009 H1N1 pandemic, delaying detection of Massachusetts’ first case. The Delaware Public Health Laboratory used its own staff and van to pick up suspected H1N1 specimens from hospitals and other collection points, but this strategy may not be suitable for larger jurisdictions.

“ON THE CUSP OF LOSING THE INFRASTRUCTURE”

Even with these gaps, however, LRN funding boosted and sustained much of the PHL infrastructure for several years, supporting staff, staff training, supplies and reagents, and costly maintenance contracts for laboratory equipment.

But as memory of the anthrax attacks receded, so too did PHEP funding, falling from almost $1 billion at its peak to about $632 million in fiscal year 2011. The slide continues. A bill now pending in the US House of Representatives would cap PHEP funding at the current level for the next five years, meaning that $632 million would be the maximum funding possible. The US Senate has so far taken no action to address the issue.

Said Pearson, “So there’s this big gorilla [the LRN] hanging over all of our shoulders holding us up and sustaining us with federal funding, and all of a sudden that big gorilla is sitting on our backs.” Already, he said,
PHLs are feeling the impact.

According to APHL’s 2011 All-Hazards Laboratory Preparedness survey, 20% of the 51 state and Washington, DC PHLs are unable to renew service contracts for laboratory instrumentation used to detect and characterize biothreat agents, about 16% are unable to expand capabilities for new biological assays and about 13% cannot purchase critical equipment, such as PCR instrumentation, automated DNA extractors or biosafety cabinets.

The Texas Department of State Health Services Laboratory (DSHSL) has seen its PHEP funding decline 30% in the past year, on top of the most recent cut, 15%, to its state funding, which is $4 million in fiscal year 2012. Grace Kubin, PhD, who heads the laboratory, said state officials considered closing one of Texas’s ten LRN laboratories, located in population centers throughout the state. Instead, they debated “how much [PHEP funding] could be cut and not significantly impact the personnel needed to perform critical tasks.” The answer was 7.5% each, with the state PHL in Austin taking the 30% hit to close the funding gap.

The DSHSL has 425 staff positions and more than 60 vacancies. It is unable to recruit because of a hiring freeze. The two-day classroom portion of the laboratory’s advanced biosafety training course has been moved on-line to reduce participants’ travel costs, and Kubin expects other training efforts to be pared back as well.

A 12% cut to Texas’s federal hospital preparedness grant means the PHL will also have to curtail training for hospital laboratorians and hospital safety officers and infection control practitioners.

Gautom said that even though he and his staff have been creative in finding outside resources to supplement his budget, the general economic situation is becoming more and more challenging. He said, “Every day, I worry about future budget reductions that may result in having to curtail our services.”

Both Gautom and Kubin are worried about the future of their federal Early

OTHER GRANTS AND COOPERATIVE AGREEMENTS THAT FUND PHL PREPAREDNESS ALSO FACE PROBABLE CUTS. FUNDING FOR FERN, IN PARTICULAR, IS IN SERIOUS JEOPARDY.
Warning Infectious Disease Surveillance (EWIDS) grants, intended to strengthen cross-border disease monitoring. The Texas grant has already been slashed by almost a third and the Washington grant by 40%. Next year, Gautom fears his EWIDS funding may not be continued at all.

Other grants and cooperative agreements that fund PHL preparedness also face probable cuts. Funding for FERN, in particular, is in serious jeopardy.

NEW YORK CITY LAB STRUGGLING

In a nation of struggling PHLs, the New York City PHL has been especially hard hit. Beatrice said there “easily could have been a third of our staff lost since 2002.” The laboratory has fewer people in its safety office, fewer people in its biothreat laboratory, fewer people doing outreach and training for diagnostic laboratory workers and first responders. “Across the board, there has been an impact,” she said.

Over the past several years, Beatrice said, “what we have done is take a very hard look at every test we do and systematically stopped testing.” Just in the last two months, the New York City PHL has discontinued some pertussis testing, as well as testing for blood-borne and enteric parasites, hepatitis, asbestos, blood lead measurement, volatile organic compounds and metals in drinking water.

The loss of capacity threatens preparedness twice over. First, there are fewer people available to be cross-trained and to secure the security clearances needed for select agent work, a time-consuming process. Plus, when the laboratory is chronically short-staffed, it is difficult to pull people from day-to-day work for the training and periodic proficiency testing necessary to maintain competence in a second or third area of laboratory practice. With no personnel buffer, the laboratory is dependent on very few scientists to perform specialized testing for emergency response.
Second, with fewer people performing non-critical testing, there are fewer people familiar with the laboratory’s operations who can be instantly reassigned to priority work during an emergency—even if it is sample intake, answering phones or printing test results.

Beatrice said, “It’s not like this fleet of people and equipment are warehoused somewhere and waiting for something to happen. That’s one of the messages that gets lost. Everyone has dual roles. The people in the BT lab and the equipment in the BT lab were used during surge for H1N1.”

Said Pearson, “Preparedness is not just for the spectacular event. Preparedness is being able to handle the day-to-day and stretch to handle the unusual. That requires an infrastructure. You have to have the infrastructure up and running and in use in order to be able to handle any type of emergency.”

“PREPAREDNESS IS NOT JUST FOR THE SPECTACULAR EVENT. PREPAREDNESS IS BEING ABLE TO HANDLE THE DAY-TO-DAY AND STRETCH TO HANDLE THE UNUSUAL.”

—JIM PEARSON, DrPH, BCLD, DIRECTOR, VIRGINIA DIVISION OF CONSOLIDATED LABORATORY SERVICES

In fact, PHLs perform emergency testing routinely. Between August 10, 2009 and August 9, 2010, the 51 state and DC PHLs received nearly 2,000 clinical, 1,336 environmental and 146 food samples suspected of contamination with biological, chemical or radiological threat agents. There were more than 500 threat letters alone.

And yet, APHL Executive Director Scott Becker said, “We are on the cusp of losing the infrastructure” that enables this work.

Beatrice noted, “Emergency preparedness is now business-as-usual, at least in our PHL.” She recalled a summer day in 2003 when a massive power outage triggered a blackout across parts of Canada and half a dozen US states:

“That very day, we were in the process of testing an animal head that was involved in a potential rabies case. At the same time, the outage caused a sewage plant to fail and hundreds of millions of gallons of raw
sewage went into the rivers that were feeding the beaches. At the same time, there were news reports urging people to go to the beaches to cool off in the nearly 100-degree heat. Plus, we continued to monitor for West Nile virus, and the BioWatch lab tested a full battery of samples without missing a beat. That’s business as usual. That is what public health is, and it is invisible. On a day there was no power in the entire Northeast, this is what was going on inside this building.”

Ironically, Becker said, part of the reason the plight of America’s PHLs is so little noticed is the “resilience” of public health professionals. At APHL’s June annual meeting, he said, “The nation’s public health labs have spent the past few years being stretched beyond what most of us thought was possible. And every time, lab workers have managed to save lives, help people and even advance quality. . . But how much longer can we keep this up?”