Pandemic Flu Preparedness Bolstered by Federal Funding

Expected Increase to Help (page 4)
APHL’s Strategic Plan for 2006-2008

Realigning Resources and Priorities

Every three years, APHL identifies the key needs of the public health laboratory community and the association through a comprehensive strategic planning process. Association leadership pulls together survey data, committee work, member and partner input, as well as their own field experience, to create a three-year plan for the organization that establishes priorities. Devised to align the entire organization into a direct trajectory, the document lays out objectives that, when accomplished, will effect maximum, positive impact on the field of public health laboratory science.

The new strategic plan is in the final stages of development. There are six overarching goals: Workforce; Advocacy and Outreach; Communication; Informatics and Knowledge Management; Standards and Practices; and Infrastructure. Under each goal, a list of objectives pinpoints areas for the association to address.

APHL’s president, Kati Kelley, and executive director, Scott Becker, discuss the new plan and their objectives for the future.

How did you develop the strategic plan?

Kelley: The board spent two full days in July getting a solid draft of this put together. In September, the document went to the Council of Chairs, where it underwent extensive discussion and revision.

Becker: After the leadership finished with the document, we forwarded it to about fifteen of our closest partners for their input and analysis.

Why turn to partners for help? Isn’t this an internal document?

Becker: APHL has always been a very collaborative organization. We want our partners to understand our direction and our goals. And we do want their input; we’re seeking the collective value of their years in public health.

Kelley: We approached organizations like ASTHO, NACCHO, CLSI, CSTE—as well as our close colleagues at CDC. They know APHL well, and they share many of the same issues. We can count on them to provide unique perspectives and fresh eyes.

How did you prioritize the major issues?

Becker: First we used the old plan as a guide. But, it’s important to point out that it was a guide, not a crutch. We asked ourselves, “What’s new? How do we strengthen this for current needs?”

Kelley: Then we looked to the committees. In the past year or so the committees spent an intensive amount of time creating their own strategic plans. We used their priorities as a model for the truly important issues. What better way to create a strategic plan for the organization?

Becker: Through this process, we updated the six goals. Then we nailed down the new objectives that will allow us to meet those goals.

Why expend all of this energy to write a planning document?

Kelley: Take workforce as an example. The strategic plan begins with workforce—it is the issue that has risen to the top of the pot again and again. In the plan, we have crafted some specific objectives to relieve the burden on labs—leadership training programs, succession planning, promotions of the public health laboratory career path. There are many ways we could tackle this; we could pursue any number of avenues. But the ones that we have selected are things that APHL can achieve. We can help train emerging public health laboratory leaders. In
contrast, we could have aimed to alleviate the more
general shortage of laboratorians—but that’s an issue
that spans the entire field of laboratory science and we
can only impact that marginally...but the challenges of
public health laboratory leadership—no one else will
tackle that if we don’t.

**Becker:** We are focusing our organizational efforts to get
the greatest impact. By strategizing, we bring together
our resources, our members and our staff, and we face
them in the same direction. We’re saying, “Here. This is
the consensus of the organization. These are the most
burning issues of the day and this is how we’re going to
address them.”

**What else has risen to the
top of the pot recently?**

**Kelley:** Crisis coordination. It’s an issue that has
surfaced in relation to potential terrorist attacks, infec-
tious disease outbreaks, and now again with natural
disasters. APHL should serve as a nexus of information
during emergencies. There are many things the associa-
tion can do to relieve the burden on labs during a crisis.
We need to lay out these things so that labs know what
they can expect help with—where to look and who to ask.

**Becker:** I agree, Kati. Crisis coordination—whether that
means defining APHL’s role during a crisis or refining
public health laboratories’ emergency plans to ensure
continued testing during a crisis—is the perfect example
of how the strategic plan mirrors the current work of the
committees. Right now, the EPR Committee and the
NBS Committee have identified significant need in this
area and are in the process of developing contingency
plans... so it’s in the association’s strategic plan.

**Public health laboratory accreditation is an
objective in the Standards and Practices
section. What is the intention there?**

**Kelley:** It’s a bold move. Tackling a sensitive issue like
accreditation will no doubt cause some controversy.

**Becker:** And yes, we do realize that labs are accredited
and reviewed by CLIA, NELAC and others, and our
members are credentialed to death through personal
certifications, you name it. We’re talking about the first
stages of accreditation. It may be as simple as a checklist
but will likely focus on the performance of public health
laboratories.

**Kelley:** Basically we want to be ahead of the curve on
this issue. If there is ever going to be a formal public
health laboratory accreditation process, APHL wants to
be involved at the start by shaping it.

**Becker:** There is a current
ASTHO/NACCHO project on
accreditation of health depart-
ments that is funded by the
Robert Wood Johnson Founda-
tion and CDC. This is a study
that we are watching with
interest because we don’t want to
have laboratories end up as a
footnote. [See www.exploringac-
creditation.org for more infor-
mation on that initiative.]

**Why isn’t there a specific
mention of APHL’s global
presence?**

**Kelley:** It’s imbedded throughout
the document. The objectives
apply dually to our global and national work. Our objec-
tives in Standards and Practices apply to our laboratory
development work in Africa; our LIMS work is interna-
tional... our technical assistance.

**Becker:** Our work with WHO in Lyon is included in
the Advocacy section. It’s all there. APHL’s vision state-
ment has not changed. Global work is still a focus.

**You keep mentioning ‘focus’ –
are there already specific actions
associated with each objective?**

**Becker:** As in a task list? In most cases, yes. It’s definitely
a framework for projects. For our internal documents
we will have a timeframe and an “owner” for each objec-
tive so that there can be full accountability.

**Kelley:** Some of these projects are already underway.
Some have been planned, but not implemented. And
then there are projects that we have only talked about,
but will now become part of our efforts to meet our
strategic plan.

**So, success would look like...**

**Kelley:** In 2009, we should be able to go through each
goal and objective, and answer it with a list of accom-
plishments. Goal 1, Objective 1: we’ve done this, this
and this.

**Becker:** And then we start the process again and we ask,
“What can we do to make this better?”

_The Strategic Plan for 2006-2009 will be finalized in mid-
January by the Board of Directors. It will be available at
www.aphl.org._
Expected Increase in Federal Funding to Bolster Preparedness for Pandemic Flu

“How should they have given a thought to anything like plague, which rules out any future, cancels journeys, silences the exchange of views. They fancied themselves free, and no one will ever be free so long as there are pestilences.”

Albert Camus
The Plague

Even in Camus’ fictional world of Oran, laboratory data were used to confirm the identity of the plague bacillus. New Hampshire’s public health laboratory director, Christine Bean, points out that today laboratory data is as crucial as ever to identify microbes: “The #1 way to stop the spread of [infectious] disease is containment. And without the laboratory, containment is not possible.”

This is an important message for policymakers as they formulate plans and proposals for pandemic influenza preparedness—a topic that has finally made its way onto the agendas of leaders on both ends of Pennsylvania Avenue. This past October the White House invited members of Congress to an unusual top-secret briefing on the subject, which galvanized legislative activity—including the adoption of two amendments in the Senate to increase federal spending on pandemic preparedness by anywhere from $4 to $8 billion.

And in November the Department of Health and Human Services unveiled a national pandemic influenza plan.

In late December, Congress approved at least an additional $350 million for state and local public health systems to prepare for worst-case scenarios. Although this sum is far short of the $1.03 billion recommended by the Association of State and Territorial Health Officials (excluding the cost of anti-viral drugs), the good news is that the legislative language makes it likely that an appropriate amount of this new funding will be allocated for public health laboratory improvements. Indeed, the funding vehicle—the Department of Defense appropriations bill (HR 2863)—makes frequent reference to the importance of laboratory diagnostics in the joint explanatory statement from the House and Senate conferees.

Once enacted, the bill will also provide an additional $50 million for CDC laboratory capacity improvements and an additional $150 million for CDC’s global and domestic surveillance activities. It would also require the Health and Human Services’ secretary to report to Congress next spring during hearings on fiscal year 2007 appropriations, on a plan for using diagnostics during the early stage clinical response to a pandemic. “All told,” said Peter Kyriacopoulos, APHL’s public policy director, “this is a welcome recognition of a critical aspect of pandemic preparedness that received scant attention previously.”

Squeezing Every Last Penny

While politicians finalize the numbers, public health laboratories are doing their best to plan with the limited resources on hand. Jane Getchell, APHL president-elect and director of the Delaware public health laboratory, said her facility is “not yet ready” for an influenza pandemic. The CDC, she said, recommends real-time polymerase chain reaction (PCR) testing as the gold standard for virus detection. “We can’t afford to buy those reagents,” she said. “They’re expensive, so we’re sticking with the culture as our gold standard test. Of course that takes longer [at least 2-3 days compared to 2-4 hours] and probably doesn’t have the sensitivity of the PCR, which will detect even dead virus.”

Pete Shult, an influenza expert who oversees communicable disease testing at
the Wisconsin State Laboratory of Hygiene, said, “I have no doubt with the first emergence of a pandemic influenza strain—particularly if it happens to be H5N1—there will be a panic.” Yet he said, “If I could maintain the staffing I have right now, with cost-of-living increases, I could hold the fort. We don’t have room to lose any staff... If I had to take a cut and lose 10 to 20 percent of my staff—which has happened once in my tenure here—we would lose much of my emergency response capacity.”

This past November, the New Hampshire public health laboratory participated in an avian influenza drill. Bean said, “We actually did a lot of work in preparation for this drill to see what we wanted to test and what were our objectives for the laboratory. How will we know that we have the capacity that we need?”

The exercise is still being evaluated by outside consultants, but several needs were immediately apparent: greater courier capacity to assure that specimens reach the laboratory without delay, additional employees to process specimens in the laboratory’s central receiving area and at least one additional $50,000 high-throughput thermocycler to test specimens. Bean said, “...our limitation was in our instrumentation. Once they’re put on the instrument for testing, it takes at least two hours for samples to run; that gave us some downtime.”

Bean noted that, like virtually all public health laboratories, her facility does not charge on a per test basis for surveillance and emergency response services. “We are supported in doing this work by grants. A lot of federal funds are used to fund positions and reagents and supplies. Federal grant money is mandatory for all of these efforts to continue.”

In New York, Kirsten St. George, who oversees the state laboratory’s clinical virology and virus reference and surveillance programs, said she is “very comfortable” with the level of expertise among her staff. But equipment is another matter. “My wish list,” she said, “would include more automated equipment to cope with that [pandemic] surge. And I think that is probably the case for most, if not all, the public health laboratories. The equipment situation could definitely be improved.” St. George figures it will cost several hundred thousand dollars to purchase the instruments on her wish list.

**PHL Testing Fills Important Niche**

Without adequate public health laboratory capacity, all of the scientists interviewed for this article agreed that routine and emergency influenza-related activities would be compromised. There is simply no other facility with the ability or the mission to carry out the functions performed by public health laboratories. Wisconsin’s Shult, who has weathered SARS, monkeypox, pertussis and anthrax crises, said, “The state public health laboratory is the only lab with the culture and the mentality of emergency response. There is an expectation that we follow incident command structure, that we have continuity-of-operations plans... We’re emergency responders from the lab perspective.”

While public health laboratories would play an important role throughout an influenza outbreak, their work is especially critical at the onset of an outbreak—to figure out what’s going on—and again at the end—to sound the ‘all clear,’ and gauge what is likely to emerge as the dominant virus strain in the next season.

**Rapid Test Sites Aid Surveillance**

Shult explained that most state and large local public health laboratories conduct laboratory-based surveillance to monitor influenza activity early in the flu season. Such surveillance requires a network of frontline hospital clinical laboratories, sentinel clinicians and rapid test sites scattered throughout the community.

In Wisconsin this network includes about 30 sentinel clinicians that routinely submit specimens, 10 virology laboratories and over 100 rapid test sites in small clinics, emergency rooms, long-term care facilities and other locations. Plus, the public health lab works with the state veterinary diagnostic laboratory to keep abreast of animal influenza outbreaks that might have implications for human surveillance.

Rapid test sites, in particular, have the potential to expand the scope of influenza surveillance. Last year, Shult said, the rapid test sites known to the state performed over 50,000 influenza tests throughout Wisconsin. “That means that 50,000 ill individuals went in for these tests,” he said. “That greatly expands the sensitivity of our surveillance. We have identified our first influenza in the state each year for the last four years from specimens that were submitted from these rapid testing sites. And over those four years, the identification was up to three weeks earlier than would have been the case relying on sentinel submitters alone.”

Rapid test sites and other network members report the number and type of specimens they receive and the number of positive test results. They also send selected patient specimens or isolates—including the first few specimens that test positive for influenza—to the public health laboratory for specialized testing that is beyond the scope of routine lab work.

Federal grant money is mandatory for all of these efforts to continue.

The public health laboratory is then able to:

- Determine whether positive screening results are true positives.
- Identify the types and subtypes of influenza circulating.
- Monitor laboratory-confirmed influenza activity across the state.
- Send information back to the
sentinel laboratories to help them optimize the use of their screening tests.

- Send selected viral samples to the CDC and to the World Health Organization to contribute to national and global influenza surveillance and vaccine development.

All these activities are of vital importance.

“While public health laboratories would play an important role throughout an influenza outbreak, their work is especially critical at the onset of an outbreak—to figure out what’s going on—and again at the end—to sound the ‘all clear,’ and gauge what is likely to emerge as the dominant virus strain in the next season.”

Confirmatory Testing is Vital

First of all, without definitive laboratory data, health officials can’t be sure that a flu-like illness is actually flu. And the key word here is definitive. There are more than a dozen influenza screening test kits available commercially, of varying quality. In general these screening tests tend to have high positive predictive value—that is, to render a high probability that a person actually has influenza given a positive test result—only when there is a high prevalence of influenza among those being tested. When the prevalence of influenza is low—as it always is at the very beginning and the tail end of flu season—many rapid tests are prone to false-positive results.

On the other hand, screening tests can also miss true positives. Shult said some screening tests are reported to have a sensitivity as low as 60-70%, meaning that as many as 4 out of 10 true positive specimens might be reported as negatives.

Obviously, an incorrect test result can lead to misdiagnosis and mistreatment or possibly lack of treatment and prolonged infectiousness. Hence the importance of definitive, confirmatory testing by the public health lab. Shult said, “If [sentinel laboratories] get a positive result in October and we know we have no influenza in Wisconsin, that’s probably a false-positive. We would encourage them to send that specimen to us for confirmatory testing.”

In Wisconsin, as in many states, the laboratory makes recommendations about the appropriate use and interpretation of these tests, but it also shares data about the local prevalence of influenza and teaches both laboratorians and clinicians how to use surveillance data to interpret screening results. Carol Kirk, who coordinates the laboratory network for the state of Wisconsin, noted that some laboratories are now putting qualifiers on their test reports, indicating that early positives should be confirmed.

Typing the Strain Helps Vaccine Development

But public health laboratories not only have the ability to differentiate between influenza and no influenza, they can also discern exactly what kind of influenza it is. Is it familiar and relatively benign? Or is it a potentially pandemic mutant?

There are three types of influenza virus: Type A (which infects birds, humans and other mammals), Type B (which infects only humans) and Type C (which is rarely identified and usually of little clinical concern). The laboratory can distinguish among these and also identify subtypes of influenza A based on differences in two major glycoprotein molecules found on the virus’ outer surface or envelope: hemagglutinin and neuraminidase. (There are 16 hemagglutinin and 9 neuraminidase subtypes that have been identified in wild waterfowl, the natural hosts for influenza A viruses.) And, peering ever more closely, some laboratories can perform what is called strain analysis by mapping out the actual genetic sequences that code for the hemagglutinin and neuraminidase molecules.

This level of detail is extremely valuable. St. George, who runs one of the most sophisticated influenza diagnostic laboratories in the country, pointed out that for vaccine development “subtype alone is grossly insufficient.” She said, “Knowing exactly what’s circulating helps CDC and WHO determine what to put into the vaccine in the following year and to assure that what’s in the current vaccine is protective.”

St. George also explained that most influenza pandemics have been caused by novel subtypes of influenza A virus that tend to have major changes in the hemagglutinin gene; changes that can be documented and monitored with the appropriate technology.

Outside of public health laboratories, though, extremely few laboratories can perform such advanced analyses. “Most [private clinical laboratories] do not do subtyping,” said St. George, “and I don’t think any of them do strain analysis.” Bean mentioned that in New Hampshire the state public health laboratory is the only laboratory capable of performing virus subtyping. She said, “We are using methodology from the CDC. The methodology is not approved by the FDA for just any clinical or private laboratory to do.”

As part of their responsibility to provide this expertise, public health labs must
acquire and maintain costly instruments and complex skillsets. St. George said that she and her staff “keep a close watch” on scientific communications to continually assess and investigate new testing platforms and analytical techniques. They also monitor national and global surveillance data from various sources to assure that the New York state virology laboratory has the appropriate oligonucleotide sequences used in molecular assays to detect the viruses known to be circulating even beyond New York state. As the 2003 SARS scare demonstrated, microbes can cross political boundaries with no advance warning.

Using the Data to Protect the Public

Collectively, the detailed data provided by public health laboratories across the country enables health officials to know when, where and which influenza viruses are circulating within states and nationally. This information, in turn, enables health officials to make the best use of existing pharmaceutical stockpiles and—if need be—to make informed decisions about the use of more extreme measures, such as quarantine.

“If [public health laboratories] were not able to carry out our functions for testing, really no disease or case investigations could take place,” said Bean. “What that would mean is that it would be quite difficult to limit the spread of disease from person to person. Disease control [authorities] would not be able to make the decision about whether someone could go back to work or not or go back to school or not. Really, without the results from the laboratory, then no more work can be done to try to stop the spread of disease.”

Surveillance Networks Require Constant Maintenance

The whole chain of surveillance, however, depends upon the clinical specimens or isolates that are forwarded to public health laboratories by their carefully nurtured networks of frontline laboratories and rapid testing sites. And

Find a Place at the Table

Pandemic Influenza Planning

All states and several federal agencies are now involved in pandemic influenza planning. Jane Getchell, APHL president-elect and chair of the association’s Infectious Diseases Committee, noted that an APHL policy statement outlining the public health laboratory role in pandemic influenza preparedness and response was expedited by her committee precisely “to emphasize why the laboratory needs to be included in these plans.”

In South Dakota, inclusion has not been a problem. “We tend to be all-inclusive,” said Mike Smith, director of the state public health laboratory. Smith said the South Dakota pandemic plan was begun “as soon as the word pandemic began to be used.” The plan is still being tweaked. A core group of state officials meets every two weeks to review new information coming from the federal government and to adapt it to fit state circumstances. Smith has served on the committee since its inception. Moreover, his microbiology section supervisor and bioterrorism coordinator provide much needed input and attend meetings when their expertise is needed.

Without public health laboratory involvement, said Smith, the pandemic plan “would miss almost that entire [laboratory] universe.” He pointed out that the lab not only contributes to the content of the plan—explaining, for example, its ability to do PCR testing and to train local laboratorians—but also plays a critical role communicating the plan to clinical laboratories throughout the state. “If you’re talking to med techs out there, you have to speak their language,” said Smith. “We can do that education to our colleagues in hospitals and clinics so that they’re aware that the state of South Dakota has a plan and this is [their] part; this is what we expect.”

The laboratory component of pandemic influenza response, said Smith, is “huge.” He advises his colleagues, “If the laboratory has not been invited to the table, just walk into that room and sit down.”


To learn more about the public health lab role in an influenza pandemic, visit www.aphl.org/docs/influenza_q_a.pdf.
those specimens are forwarded on a purely voluntary basis. Said Shult, “We’re really at the mercy of these surveillance participants.”

To keep the specimens coming, the Wisconsin public health laboratory pays for the specimen collection kits as well as a private specimen courier system. It also pays Kirk to coordinate outreach, training and information-sharing activities to maintain the proficiency and the goodwill of these frontline laboratories. All of these public health activities are ultimately funded in whole or in part through federal grants for bioterrorism (BT) preparedness or epidemiology and laboratory capacity building.

The money is well spent. Shult noted that the network infrastructure will be “instrumental” in tracking flu activity if a pandemic strain emerges. “People are used to working with us and understand the importance of being part of the network and that they would play an important role.” He also noted that the network is set up to contribute to surveillance for any infectious disease of public health significance. “We’ve tried not to make the distinction between BT and influenza,” he said. “It is a multi-use network. And I’ll say unashamedly that we feel our network is one of the better networks out there.”

And yet, even in Wisconsin, Shult stressed, “That is a very, very fragile network. If we keep on top of it and continue to foster it, we’ll be fine. But if we skip a beat—if we didn’t provide them the free shipping, if we didn’t continue to give them training that they need, if we didn’t give them summary reports—that network will come apart pretty quick. My worst nightmare is that something will happen to Carol.”

In Delaware the statewide laboratory network is already showing signs of strain. For the past five years, the state’s physicians had become accustomed to same-day turn-around for rapid influenza testing performed by the Delaware public health laboratory. But no more.

“We don’t have the funds to buy the reagents for that this year,” said Getchell. An immediate consequence as been a drop in the number of influenza specimens coming in. “Physicians just liked the quick turn-around,” Getchell said, and now are less motivated to go to the trouble of sending specimens, even though all of laboratory’s flu testing is performed free-of-charge.

This is an alarming development in a state with more chickens than people, a state that is a potential paradise for avian influenza and strategically located on the high-traffic corridor between DC and New York. Should a pandemic occur, Getchell said, “As long as we can identify the early cases, that’s really the critical part. That’s why capturing a large number of people in our surveillance program is really important and why all the submissions from our docs out there is something we’ll sorely miss.”

The situation in Delaware highlights the importance of adequate public health laboratory funding. Shult said, “I don’t see any one else taking up the banner if we don’t do it. We’re the only one [charged] by mission to do this.” Quite simply, said Kirk, “If funding collapsed and state public health laboratory surveillance were not done, you won’t have national data either. Nobody will know what types or subtypes of influenza are circulating. You wouldn’t even know for sure that it is influenza.”

New APHL Institutional Members

Since extending institutional membership to local public health, environmental and agricultural laboratories in 2005, many long-time APHL members are now enjoying the benefits of institutional membership. APHL welcomes the following laboratories as its newest institutional members.

Public Health Institutional—
Local Members
Seattle–King County, WA Public Health Laboratory, Paul Swenson, PhD
Sutter County, CA Health Department, Public Health Laboratory, Greg Costa
Santa Clara County, CA Public Health Laboratory, Patricia Dadone

Associate Institutional Members
New York State Department of Agriculture & Markets Food Laboratory, Daniel Rice
The Emergency Preparedness & Response (EPR) Committee met in December to address the priorities assigned by the Board of Directors as well as new preparedness initiatives. The committee’s liaison to the board, Susan Neill, PhD, MBA provided an update on recent board activities. Neill mentioned that the board narrowed the priorities of all committees to provide a more focused approach toward addressing laboratory issues.

Scott Becker, MS, APHL’s executive director, addressed initiatives on membership expansion and workforce development. Chris Mangal, MPH, emergency preparedness and response program manager, and Lena Lago, MPH, laboratory response network program manager, briefed the committee on staff project activities. The committee also discussed the recently released Trust for America’s Health’s (TFAH) “Report on Preparedness” and the need to develop performance indicators for state and local preparedness.

Jim Pearson, DrPH, BCLD, MPH, APHL’s terrorism preparedness liaison, provided an update via teleconference on the all-hazards preparedness issues. Pearson mentioned that EPA is in the process of establishing a program office for the eLRN, which is a network that will provide standard methods for the analysis of environmental samples for chemical agents. At this time, there is no funding to provide support to the states. Pearson also discussed the progress on the development of a screening protocol for use in the all-hazards receipt facilities.

### Developing Performance Measures in Light of Reduced Preparedness Funding

A subcommittee of the EPR Committee was tasked with collaborating with CDC and the Department of Homeland Security (DHS) to refine and develop performance measures and target capabilities for public health laboratories. Subcommittee members reviewed the performance measures for laboratories in the draft CDC Bioterrorism Preparedness Cooperative Agreement and provided feedback to CDC. Alison Johnson, MPA, director, Division of State and Local Readiness, CDC’s Coordinating Office for Terrorism Preparedness and Emergency Response, participated in the discussion, addressing the new DHS and the Department of Health and Human Services’ (HHS) risk-based approach to preparedness funding. Johnson noted that a baseline funding level, which each state would receive, will be established. Additional funding will be based on other factors, currently under review at HHS. Committee members stressed the importance of sustainability and mentioned that further cuts will threaten their ability to adequately respond to a potential threat. Committee members also expressed their concern about reductions in the CDC preparedness and epidemiology laboratory capacity funding. The committee will continue to work with CDC’s Coordinating Office for Terrorism Preparedness and Emergency Response to refine the performance measures and the target capabilities for public health laboratory preparedness. APHL will continue its advocacy efforts with Congressional staff to ensure that adequate funding is available to maintain a robust public health laboratory infrastructure.

### Sentinel Clinical Laboratories and Preparedness

The committee chair, Norman Crouch, PhD, presented the newly-approved sentinel clinical laboratory definition. Previously, committee members had reviewed the draft document, providing comments to improve it. The committee then continued an earlier discussion on training and proficiency testing exercises for sentinel laboratories. There were numerous concerns about existing proficiency testing exercises for sentinel laboratories and the need to develop better drills to test the Laboratory Response Network (LRN) construct.

### Surge Capacity for State and Local Public Health Laboratories

The EPR Committee has made surge capacity a priority, recognizing that the demand for laboratory analyses has increased steadily with the proliferation...
Defining Sentinel Clinical Laboratories: The Inclusive Definition

The Laboratory Response Network (LRN) is organized as a three-tiered pyramid, with thousands of sentinel laboratories at the base of the pyramid. Since the inception of the LRN, sentinel laboratories have played a key role in the nation’s preparedness efforts. These sentinel laboratories perform initial screening of clinical specimens for potential pathogens. When the sentinel laboratories cannot rule out the presence of an agent of bioterrorism, they refer specimens and isolates to a state or local LRN reference-level public health laboratory. In the broadest sense, all laboratories capable of analyzing or referring specimens or samples that may contain microbial agents or biological toxins function as sentinels in the LRN. These include environmental, food, veterinary, agriculture, public health and clinical laboratories.

State and local public health laboratories work closely with all types of sentinel laboratories. In an effort to formally recognize the role of clinical laboratories that handle human specimens in the LRN, APHL collaborated with the American Society for Microbiology (ASM) and the Bioterrorism Preparedness and Response Program at CDC to develop a definition of sentinel clinical laboratories. The Joint Leadership Council of the LRN approved the vetted definition and it is now awaiting final clearance at CDC.

Recognition of sentinel laboratories is an integral part of the LRN and is the responsibility of each state and local LRN reference-level public health laboratory in partnership with the CDC. For the successful operation of the LRN and to facilitate sentinel and reference level linkages, each state and local LRN reference-level public health laboratory:

- Identifies all of the clinical laboratories in their jurisdiction to determine if each has the characteristics that define a sentinel clinical laboratory;
- Provides each sentinel clinical laboratory with training in the use of the LRN sentinel protocols to rule-out possible bioterrorism agents;
- Trains each sentinel clinical laboratory in the use of appropriate specimen packaging, transport and chain-of-custody procedure; and
- Establishes with each sentinel clinical laboratory an effective electronic system for timely communication of emergency alerts and critical information, and plans exercises with each to evaluate the effectiveness of the network.

APHL, ASM and CDC determined that it was essential to develop a definition that included the varying levels of clinical sentinel laboratories. As such, the group identified characteristics of two broad levels of clinical sentinel laboratories: advanced and basic. Advanced laboratories function at the local front line and have the most capability. Laboratories with less analytical capability that also might handle specimens containing agents of bioterrorism or emerging infectious disease are referred to as basic sentinel clinical laboratories.

Both advanced and basic sentinel clinical laboratories have the following characteristics:

- The laboratory is certified by the Centers for Medicare & Medicaid Services (CMS) as a high complexity laboratory performing the specialty of microbiology.
- The laboratory is inspected successfully by CLIA or an agency that has been given deemed status by CMS.
- The laboratory has policies and procedures for direct referral of suspicious specimens or isolates to the nearest LRN reference laboratory within its state.

In addition to the characteristics outlined above, advanced sentinel clinical laboratories must have a Class II or higher certified biological safety cabinet, comply with biosafety level II (BSL-2) practices and have additional safety requirements in place, participate in training and demonstrate competency in the sentinel level clinical microbiology laboratory guidelines. There are more specific characteristics of advanced sentinel clinical laboratories, which will be further outlined in the approved definition.

Sentinel laboratories are on the front line for detecting public health threats caused by agents of bioterrorism or newly emerging infectious diseases. While this definition only addresses the role of sentinel clinical laboratories testing human specimens, it is an important step towards formally recognizing these laboratories in the LRN. A certificate of recognition is in development and will be shared with all state and local reference level public health laboratories. These laboratories can customize the certificate and award it to designated sentinel clinical laboratories. For more information on this definition or the certificate, contact Chris Mangal at cmangal@aphl.org.

### APHL Is Moving!

Effective February 1, 2006, Our New Address Is

8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910

Check [www.aphl.org](http://www.aphl.org) for telephone numbers.
Continuity of Operations Plans

Committee members discussed developing a checklist containing the essential elements for a continuity of operations plan (COOP). Recent natural disasters, such as Hurricane Katrina, highlighted the need for better planning and coordination at all levels of government. The public health laboratory is a key component of each state emergency preparedness and response system. It is imperative that these laboratories have a continuity of operations plan in place to ensure that essential testing, such as tuberculosis screening, newborn screening, and drinking water testing, can be conducted by other qualified public health laboratories identified in their plan. The committee will engage other APHL committees and members in this activity so that a comprehensive checklist can be developed and shared with all state and local public health laboratories.

All-Hazards Preparedness, Safety in the Laboratory

The group discussed current gaps in environmental sampling and testing. Lauren DiSano, MHS, APHL environmental health program manager, reported on the activities of the Environmental Health Committee and their efforts to address these gaps. DiSano provided an update on the EPA Homeland Security Advisory Committee (HSAC) and mentioned that APHL provided written and verbal statements to the HSAC on the gaps in methods, analytical standards, proficiency testing and certification for the analysis of environmental samples for chemical agents, including chemical warfare agents. APHL’s Environmental Health Committee continues to emphasize the need for the federal government to address these testing gaps. In a recent article in the Environmental Council of States (ECOS), DiSano again called attention to these deficiencies.

APHL, through the Environmental Health Committee, also provided comments to EPA on the recently-released draft document, “Environmental Sampling, Analysis and Results (ESAR) Data Standards.” ESAR is a collection of 14 standards that are based on business processes used to collect and analyze environmental data. APHL’s statement commended the EPA for attempting to move towards a single format for electronic data exchange.

The EPR Committee discussed a number of other key laboratory preparedness issues, such as preparedness funding and advocacy efforts, need for training guidance on Class III biosafety cabinets and glove boxes, and the need for a repository of best practices. The committee continues to address all of the board priorities as well as other elements critical to public health laboratory preparedness. For more information on the Emergency Preparedness and Response Committee and APHL preparedness activities, contact Chris Mangal, cmangal@aphl.org.

New York State Public Health Laboratory

Convenes Preparedness Conference

More than 50 participants attended the second Northeast Public Health Laboratory Preparedness Conference in November 2005 in Albany, NY. The one-day meeting provided an opportunity for state and local public health laboratory, FBI, EPA, FDA and local law enforcement representatives to discuss the critical issues surrounding preparedness and to showcase best practices. Issues discussed included building surge capacity, laboratory outreach and pandemic influenza preparedness. Some highlights of the conference:

Regional Centers of Excellence

Dr. Lawrence Sturman, director of the Wadsworth Center, New York’s State Public Health Laboratory, opened the meeting with remarks on the integral role public health laboratories play, in collaboration with industry and academia, in the development of diagnostics, vaccines and therapies. He provided a brief synopsis of the NIH-funded Regional Centers of Excellence (RCE): who participates, their goals and emergency response plans. The primary goal of the RCE is to streamline emergency response by identifying and combining complementary resources among institutions.

Connectivity with Sentinel Laboratories

Expanding on the theme of collaboration and partnerships, APHL’s Scott Becker and Chris Mangal explained the important role sentinel laboratories play in preparedness. Sentinel laboratories provide fundamental support to state and local public health laboratories and the Laboratory Response Network (LRN) by referring suspicious specimens or isolates for further analysis. (See page 10 for a detailed description of the identifying characteristics and LRN role of a sentinel laboratory.)
Environmental Health

Biomonitoring in the States: Recent Activities

Over the past three years, APHL has worked closely with CDC’s National Center for Environmental Health’s Division of Laboratory Sciences to launch the State Public Health Laboratory Biomonitoring Planning and Implementation Grant Program to help build biomonitoring capacity across the nation. This program distributed five million dollars to 25 applicants, several of which represented multi-state consortia. In January 2003, APHL, in partnership with CDC, held a fifty-state biomonitoring meeting to provide an opportunity for state and national biomonitoring programs to discuss activities.

Although the CDC grants afforded most states the necessary funding to plan biomonitoring programs, additional resources are crucial for those states to implement and sustain these plans. Finding money for states without biomonitoring programs is even more critical. From 2003 to 2005, just three grantees received funds to begin implementing biomonitoring plans: New York, New Hampshire, and the Rocky Mountain Biomonitoring Consortium (RMBC) which is comprised of state public health laboratories in Arizona, Colorado, Montana, New Mexico, Utah and Wyoming. The amount of federal funding available to these states continues to significantly decline with each new fiscal year; altogether, those three grantees received less than three million dollars. However, despite this limited funding, those state public health laboratories are moving forward, building state laboratory biomonitoring capability and capacity through unique and innovative research studies.

The Arizona state public health laboratory is actively engaged in a regional arsenic study being conducted by the RMBC states. The Arizona laboratory performed a detailed geographic and environmental analysis to identify the best areas to sample for the regional arsenic study. In early November, sample collection for the study began. So far, community response to this arsenic study has been overwhelmingly positive. Citizens have willingly provided urine specimens to the laboratory for biomonitoring analysis, understanding that the lab will also carry out analyses on drinking water quality, an issue of local concern. In testing both human clinical and environmental drinking water specimens, the laboratory intends to determine the correlation, if any, between the arsenic content in the drinking water and the arsenic levels in the urine samples.

In New Mexico, recent biomonitoring efforts have focused on thiodyglycol extraction. Thiodyglycol is an important primary metabolite of sulfur mustard, a chemical warfare agent. The New Mexico laboratory is currently performing thiodyglycol extraction on fifty samples collected in Wyoming, another RMBC member. First responders in clinics throughout Wyoming collected the clinical samples, which were then shipped, via the Wyoming lab, to the New Mexico state public health laboratory for analysis. Fifty samples have already been extracted, and 55 additional extractions will be necessary in order to achieve reliable baseline data for the study. Through studies such as this, the New Mexico laboratory has been able to promote the concept of “full-use” by demonstrating how chemical terrorism and biomonitoring programs can be integrated successfully in the state public health laboratory setting. In addition to the thiodyglycol study, the New Mexico laboratory is developing methods for LC/MS/MS or GC/MS/MS analysis of organophosphates.

The Montana state public health laboratory is also busy with the regional arsenic study: specifically, with the exploration of different sampling methods for detection and quantification of arsenic levels.

Pandemic Influenza Preparedness

Kirsten St. George from the clinical virology program at the Wadsworth Center, lectured on issues, challenges and logistics related to pandemic influenza preparedness. St. George expressed concern about laboratory testing in a pandemic, stating that there is no clear algorithm for identifying avian influenza. She outlined components state and local entities should consider when planning for a pandemic, including surge capacity equipment, staff training, specimen transport and reporting.

Testing the Biohazard Detection System

A presentation on the Massachusetts Bioterrorism Response Laboratory’s Biohazard Detection System (BDS) was provided by Cheryl Gauthier. Massachusetts was the first state to test its United States Postal Service BDS Multi-agency Incident Response Plan with a simulated, positive BDS alert. The comprehensive exercise tested the specific role of more than 165 participants and 24 agencies. Every aspect of the response plan—from the alert, notification, transport and sample processing—was meticulously scrutinized to ensure any problems were clearly identified. The drill proved to be valuable by fostering relationships between the first responders and the department of public health, and by establishing a real-time BDS timeline for Massachusetts.

Other topics discussed at the conference were the BioWatch initiative in New York City, recent activities of the New York City, recent activities of the New York State chemical terrorism laboratory, building environmental laboratory capacity, and food testing for biological and chemical agents. The conference provided an excellent opportunity for participants to discuss lessons learned from real events, as well as drills and exercises.

For more on the conference or the LRN, contact Lena Lago at llago@aphl.org or 202.822.5227 ext. 216.
in both urine and drinking water samples. Once the laboratory succeeds in identifying the most effective sampling methods, the information will be used to streamline future analyses.

Beyond practicing the laboratory biomonitoring, Montana has invested significant energy in outreach activities. The laboratory is currently exploring the possibility of acquiring interns and establishing partnerships with environmental public health tracking programs to link into additional resources for building laboratory biomonitoring capacity.

In Utah, the state public health laboratory is validating methods for the analysis of arsenic and selenium. As defined by their role in the RMBC regional arsenic study, Utah, like Arizona, identified a city with high arsenic levels, and will collect 50 specimens of urine and drinking water for analysis.

Besides participation in the regional arsenic study, the Utah laboratory has begun investigating the feasibility of using newborn screening bloodspot specimens as a source of data for future biomonitoring studies. As part of this effort, the laboratory has already collected bloodspot specimens from several different states and is developing a method for detecting and measuring mercury levels present in the bloodspots.

The New York state public health laboratory at the Wadsworth Center just completed analysis on two thousand samples of blood and urine obtained through the New York City Health and Nutrition Examination Survey (NYC HANES). To perform these analyses, the laboratory utilized an ICP/MS method for lead, mercury and cadmium, and received assistance on sample analysis from the New York City public health laboratory.

The laboratory also partnered with CDC in the development and validation of a method for analyses of serum cotinine levels. Two thousand serum specimens obtained through the NYC HANES were analyzed using a LC/MS/MS cotinine method. Coordination with the New York Bureau of Tobacco Control, the New York state public health laboratory is assisting with the analysis of self-administered saliva samples from a recent survey of 2000 adults. By extending their biomonitoring expertise, the laboratory has acquired supplemental funds from the Bureau of Tobacco Control to bolster their program.

Aside from cotinine and metals analyses, the New York laboratory continues to improve the method for measuring PBDE in serum and plasma, primarily through a study of local game fishermen. Still other biomonitoring methods under development in the state include analysis of PAH metabolite using high-resolution GC/MS and methods pertaining to the measurement of perfluorinated compounds in human samples. Like Utah, New York has also begun to research the feasibility of conducting biomonitoring studies using newborn screening bloodspots as specimens.

New Hampshire has biomonitoring studies underway involving four chemicals: arsenic (speciated) in urine; mercury (total, inorganic and organic) in blood to research the relationship between blood/mercury and freshwater fish consumption; phthalates in urine; and PBDEs in human breast milk and serum. So far, method development and proficiency have been achieved for analysis of total arsenic in urine samples, and laboratory staff received training in arsenic speciation from CDC in September. The arsenic study, begun this fall, involves sampling drinking water sources and urine samples, and participant interviews regarding dietary histories and water consumption information. Studies such as this illustrate the often overlooked link existing between public health laboratories and epidemiology.

In an excellent example of establishing partnerships between state public health laboratories and academia, the New Hampshire laboratory has formed an effective partnership with the University of New Hampshire’s Department of Animal and Nutritional Sciences. The university is assisting in the biomonitoring studies related to PBDEs and phthalates, and will be involved in the sample collection and survey process, while the New Hampshire laboratory will be responsible for conducting method development and sample analyses.
Bioterrorism, Chemical Terrorism Lab Preparedness Surveys Launched

On November 9, 2005, APHL launched the annual bioterrorism and chemical terrorism laboratory preparedness surveys. APHL has been collecting annual data on public health laboratory capacity for bioterrorism response for the past three years and data on chemical terrorism response for the past two. Data obtained from these surveys have proved critical in demonstrating the essential value of the preparedness funding in building laboratory capacity. Additionally, data have been used to develop educational tools, such as issue briefs and presentations, factoids used in media campaigns, and by APHL members when looking for comparator data. Past issue briefs were shared with each state public health laboratory, Laboratory Response Network (LRN) partners, and federal and state policymakers. These documents continue to provide an accurate synopsis of state public health laboratory bioterrorism and chemical terrorism capacity and capability.

The 2005 surveys include new sections that pertain to all-hazards laboratory concepts such as screening. APHL strongly encouraged bioterrorism and chemical terrorism staff members in the laboratory to work in concert with one another to complete the all-hazards laboratory preparedness sections of the two surveys. While completion of the bioterrorism and chemical terrorism surveys is entirely optional, full participation on behalf of each state public health laboratory is widely encouraged to ensure that resulting recommendations regarding laboratory needs will be based upon data that is both comprehensive and nationally representative. In the past, APHL has achieved either full or near 100 percent participation, a trend that will hopefully continue. Results from the surveys will be published in issue briefs and made available to APHL members, LRN partners, federal and state policymakers, and the general public in early 2006.

For additional information related to the bioterrorism survey, contact Chris Mangal at cmangal@aphl.org. For additional information related to the chemical terrorism survey, contact Lauren DiSano at ldisano@aphl.org.

Dues Increase for Local, Associate Institutional Members

Dues for Local Public Health and Associate Institutional Laboratory members will transition on July 1, 2006, from the one-year, introductory rate of $500 to the following, population-based rates. The Board of Directors approved these new rates in January 2005. Please use the schedules below to develop your budget for the next fiscal year. For more information, contact Anna Dillingham, membership manager, adillingham@aphl.org.

### Local Public Health Laboratories

**Representation**
1 member-representative, 3 delegates

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<th>Population</th>
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Additional delegate members may be added by the member-representative for $100 apiece.

### Associate Institutional Members

**Representation**
1 member-representative, 3 delegates

State governmental laboratories, such as environmental or agricultural facilities

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<th>Population</th>
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Additional delegate members may be added by the member-representative for $100 apiece.

Global Health

APHL Collaborates to Open Lab in Mozambique

The opening of the Mavaleine Hospital in Maputo, Mozambique, was celebrated on December 5 with a ribbon-cutting ceremony. Located in the capital city, Malavene Hospital is one of eight provincial laboratories in Mozambique that will soon be equipped to provide diagnostic testing services to support antiretroviral therapy. APHL is supporting this effort by managing three reagent rental contracts that provide instruments and reagents for CD4, hematology and biochemistry testing. In addition to the instruments and reagents, the three contracted vendors are providing other laboratory equipment such as safety cabinets, autoclaves and general supplies.

APHL has worked with the CDC Global AIDS Program (GAP) Office in Maputo and Ilesh Jani, MD, PhD, chief of the immunology laboratory at the Mozambique Instituto Nacional de Saúde (National Institute of Health), to determine appropriate equipment and materials to be purchased for the testing sites. Columbia University School of Public Health International Center for AIDS Care and Treatment Programs (ICAP) has partnered to renovate laboratory areas. Following a major renovation of that lab space, instruments were delivered, set up and calibrated. Some of these items include a flow cytometer, hematology analyzer and chemistry analyzer. Six new microscopes, two safety cabinets and numerous other items have also been delivered. The new laboratory space is well constructed and provides the laboratory technicians with a first-class space in which to work safely and efficiently.

The technicians are currently undergoing training on the new instruments. Because their formal university training does not include use of computers, the technicians must receive such training.
before they can operate some of the Windows-based instrumentation.

Ideally, computer training for the technicians would have been accomplished before instruments arrive to avoid delays in testing start-up. However, this was not possible at Mavalene. As a result, technicians must be trained on computers without sacrificing too much laboratory productivity. According to a plan that APHL has provided, the Mavalene lab's two full-time technicians receive computer training two hours a day for two to four weeks. A CD-ROM self-teaching program is also available: known as the "International Computer Driver's License," the CD-ROM is used in many countries with great success. APHL will provide funding for both modes of training.

APHL is also working to build a sustainable infrastructure to ensure that the newly-equipped laboratory and its technicians can produce timely and accurate test results and information. Facing this ultimate challenge, APHL tries to take steps to assure lasting effects such as: provide training in writing standard operating procedures, establish quality control practices and organize ongoing training. APHL looks forward to continued success with projects in Mozambique.

For more information on APHL global health activities in Mozambique, contact globalhealth@aphl.org.
2005 Newborn Screening and Genetics Testing Symposium

The 2005 Newborn Screening and Genetics Testing Symposium held in October was the largest-ever gathering in the history of newborn screening and genetics testing meetings: more than 391 participants represented 47 states and 14 countries. The participants came from diverse fields, from laboratorians to nurses, state health officials to vendors. The symposium addressed state and national issues including quality assurance/quality control, follow-up care, reports from state newborn screening programs, new technology, policy and ethical issues.

A workshop on quality assurance and quality control in newborn screening featured speakers from state public health laboratories and was well received by over 160 participants. Designed for laboratorians to share their own experiences in quality assurance, the program consisted of three discussion sessions covering pre-analytic, analytic and post-analytic activities.

Another workshop addressed some of the issues currently impacting newborn screening follow-up. The first part of the workshop featured a review of two Health Resources and Services Administration (HRSA)-funded projects of national significance to newborn screening programs and a question-and-answer session focusing on challenges of interpreting some MS/MS screening results. It also included a discussion of a Performance Evaluation and Assessment Scheme (PEAS) that will soon be available for program use as a self-assessment tool for newborn screening system quality assurance. The second part of the workshop featured discussions of follow-up practices and the barriers to short- and long-term follow-up. Coleen Boyle, PhD, director, National Center for Birth Defects and Developmental Disability, closed this workshop with an interactive discussion of follow-up challenges faced by programs. Information obtained in this discussion will be reviewed by the Follow-up and Treatment Subcommittee of the Secretary of Health and Human Services’ Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children.

The next newborn screening and genetic testing symposium will be held May 7-10, 2007, in Minneapolis, MN. For more information, contact Jelili Ojodu, newborn screening and genetics program manager, 202.822.5227 x235 or jojodu@aphl.org.

Newborn Screening and Genetics in Public Health Committee

APHL’s Newborn Screening and Genetics in Public Health (NBSGPH) Committee met in October, focusing on committee priorities assigned by the Board of Directors. These priorities include:

**Contingency Planning**
A subcommittee of the NBSGPH Committee is working in collaboration with the Newborn Screening Quality Assurance Program (NSQAP) at CDC and APHL’s Quality Assurance/Quality Control Subcommittee to develop a framework model/guidance document for preparedness and contingency planning. The main objective is to provide risk mitigation strategies for state newborn screening programs.

**Training and Education**
The NBSGPH Committee, in collaboration with NSQAP and National Newborn Screening and Genetics Resource Center, will continue to promote and offer tandem mass spectrometry intensive workshops for state newborn screening laboratorians. The committee also plans to collaborate with the National Laboratory Training Network to develop courses in molecular genetics for newborn screening laboratorians. The committee will coordinate Web conferences on newborn screening quality assurance and quality control practices.

William Becker, DO, MPH, medical director, Ohio Department of Health Laboratory and NBSGPH Committee chair, led a planning discussion on the next newborn screening and genetic testing symposium. The 2007 Newborn Screening and Genetic Testing Symposium will be held in Minneapolis, MN, May 7-10.

**Policy Statements**
Participants also discussed the development of a newborn screening policy statement on contingency planning in state newborn screening programs.

Currently there are five policy statements on newborn screening issues, including residual newborn screening specimens and newborn screening follow-up. The committee plans to revisit some of the policy statements with approaching sunset dates during this fiscal year.

**Advocacy**
The committee also discussed the development of an advocacy plan to promote the CDC NSQAP. In light of expanded screening in states and the continuous need for the highest level of quality proficiency program in the country, it will be necessary for the committee to be proactive in advocating for the NSQAP.

For more information, contact Jelili Ojodu, newborn screening and genetics program manager, at jojodu@aphl.org, 202.822.5227 x235.
APHL Honors Newborn Screening Professionals

In recognition of his leadership, vision, and contributions to newborn screening, Scott Becker, executive director, presented the 2005 APHL On the Front Line Award to Neil Buist, MB, ChB, professor emeritus, Oregon Health and Science University. APHL’s On the Front Line award honors an individual or organization outside of the association’s membership who makes significant contributions to APHL, its membership and mission. Over the course of his fifty-year career, Buist has been instrumental in promoting universal newborn screening nationwide and continues to be a strong voice for expanded screening for many disorders.

Earlier in the year, APHL’s Presidential Award was given to Michele Lloyd-Puryear, MD, PhD, chief, Genetic Services Branch, Maternal and Child Health Bureau, HRSA, honoring outstanding leadership and dedication to improving the lives of newborns and children across the nation.

Workforce Development

Center Launches Workforce Development Strategic Planning Initiative

The National Center for Public Health Laboratory Leadership (the Center) has been awarded a one-year planning grant from the Robert Wood Johnson Foundation to further its work to address the leadership crisis in the nation’s public health system. The grant will fund the development of a strategic plan and model framework that can be used to craft discipline-specific workforce development initiatives.

To date, the Center has designed the work process and organizational structure for the project. An oversight group composed of public health laboratory directors and APHL staff will have the primary responsibility for activity coordination; workgroups will evaluate issues that emerge from a “re-scan” of the status of public health leadership. The intent is to validate previous work and to integrate new information. Areas of address will likely include:

- Training and education of current and future laboratorians.
- Technology support.
- Marketing the public health laboratory for increased visibility and appeal to potential leaders.
- Monitoring of workforce status.
- Identification and dissemination of best practices in laboratory science and leadership.

The Center is recruiting workgroup participants from laboratory management, academia, foundations, associations and federal agencies with a stake in the future public health laboratory workforce. Sessions will convene in January and February to conduct preliminary work for the development of action plans that address the crisis systematically. The output from these sessions will be shared at the APHL annual meeting in June, 2006.

Periodic updates on the initiative will be made to the oversight group, the Robert Wood Johnson Foundation and the APHL membership.

APHL Congratulates 2nd Team of Leadership Scholars

The fourteenth group of leadership scholars graduated from the National Public Health Leadership Institute (PHLI) in early November. APHL congratulates the team of Mary Celotti, MS (VT), Frances Downes, DrPH (MI), Romesh Gautam, PhD (WA), and Paul Kimsey, PhD (CA) for their commitment and effort. At graduation, Celotti and Downes presented the team’s report on developing a national consensus process for evidence-based programs to assure newborn health. They noted, “While newborn screening is nationally recognized as a successful public health prevention program, the reality is that the scope of services is so variable from state to state that there are actually 50 separate programs.”

The team will outline their proposed consensus process in a white paper to be published in a peer-reviewed journal. The paper will also serve as an APHL policy statement. The APHL Newborn Screening Committee will assume responsibility for advancing the consensus process.

Team members cited the value of the institute in improving their communication, listening and negotiation skills and by providing a deeper understanding of political, technical, financing and administrative issues.

APHL Welcomes New Team

APHL is fielding a third PHLI team this year. Jack DeBoy, DrPH, MPH (MD), Patrick Luedtke, MD (UT), Nancy Warren, PhD (PA) and Mike Wichman, PhD (IA) will concentrate on retention, recruitment and succession planning strategies, a topic that complements APHL’s focus on workforce development. We wish them a productive and rewarding experience.
**Fellowships and Training**

**Life after Fellowship**
Environmental Health Fellow Marina Blake recently accepted a full-time Chemist level III position at the Alaska Public Health Laboratory. Marina affirms that her fellowship experience in Alaska “has been both a challenge and a joy. I not only learned valuable information that will be utilized and expanded upon throughout my career, but gained dear friends that made the learning experience a pleasure. I feel that this opportunity has changed my life.”

Research Fellow Mary Kate Yost-Daljev accepted a permanent senior scientist position at her host laboratory, the Virginia Division of Consolidated Laboratory Services (DCLS). Yost-Daljev spent her fellowship term conducting *Bordetella pertussis* research at DCLS and is looking forward to joining the laboratory as a full-time employee.

David Sue, a research fellow in CDC’s Division of Bacterial and Mycotic Diseases, was awarded an NIH-sponsored FIRST (Fellowship in Research and Science Teaching), three-year, post-doctoral fellowship at Emory University. The goal of the fellowship is to “combine a traditional mentored postdoctoral research experience with an experience to develop teaching skills through innovative programs that involve mentored assignments at a Minority Serving Institution (MSI).” FIRST fellows are assigned both research and teaching mentors, participate in a semester-long “How to Teach” course, and are required to teach a course at one of the minority serving institutions in the Atlanta-area. Sue will be joining a laboratory group focused on Group A Streptococcus and *Bacillus anthracis* research.

**Fellow Accomplishments**
Research Fellow James Amburgey participated in research that resulted in two new pathogen detection methods that can concentrate 10 to 100L water samples containing pathogens down to a few milliliters or less with high efficiency. Amburgey confirms that “both methods, which initially started as ideas on paper near the beginning of [his] fellowship, have now been developed, optimized and put into use, even implemented in several outbreak investigations and transferred to other laboratories. The ultrafilter method is under consideration for use by the EPA and bioterrorism group at CDC.” Amburgey recently published a paper in *Applied and Environmental Microbiology*, “Development of a Rapid Method for Simultaneous Recovery of Diverse Pathogens in Drinking Water by Ultrafiltration with Sodium Polyphosphate and Surfactants.”

Class XI EID Training Fellow Bradley Changstrom assists with mosquito trapping as part of his fellowship training at the University of Iowa Hygienic Laboratory.

Microbes in Drinking Water by Ultrafiltration with Sodium Polyphosphate and Surfactants.”

2006 EID Fellowship Deadlines
APHL is now accepting applications for the 2006 EID Fellowship Program! The application deadline for local, state and federal public health laboratories interested in hosting a fellow for the 2006 EID Laboratory Fellowship Program is March 1, 2006. The application and instructions can be found at www.aphl.org/hostlabapplication. The application deadline for prospective fellows is February 17, 2006. For more, contact Heather Roney, 202.822.5227 ext. 301, or fellowships@aphl.org.

Class X Training Fellows, Amanda Tiffany and Yashicka Blount, from the Division of HIV and AIDS Prevention at CDC, spent three months in Gaborone, Botswana, working on a HIV prevention study. The study, which started in September, examines the safety and efficacy of Tenofovir Disoproxil Fumarate (TDF) in preventing HIV transmission in young, heterosexual adults. While working at the HIV Prevention Research Laboratory, BOTUSA (Botswana-USA collaboration), the fellows participated in laboratory capacity building, trained field laboratory staff on equipment use, testing and quality controls, assisted with equipment procurement and set-up, and wrote standard operating procedures for the laboratory. The majority of the fellows’ time was spent training laboratory staff and study clinicians to run study-specific assays with the goal of passing proficiency tests. Blount explains that she “felt especially proud of [the staff] when they passed each of the proficiency tests and were shown to be ready to work on the trial.”

Annual Meeting in Fort Lauderdale, Florida, in November.

Training Fellow Gillian Genrich presented her poster, “Post-mortem diagnosis of Plasmodium falciparum in four travelers using a novel immunohistochemical assay targeting histidine rich protein-2,” at the 1st International Conference on Travel Medicine and Infectious Disease in London at the Royal College of Surgeons, in November.

Electronic Resources
The NLTN introduced CD-ROM self-study modules in 1997 with “DNA: The Foundation of Molecular Technology.” Three years later in 2000, a second module, “DNA: Molecular Technology Techniques,” was released. To date, more than 300 copies of these modules have been distributed to the laboratory community, providing a firm base to build knowledge on molecular diagnostic testing. The NLTN hopes to expand its distribution with plans to update these modules into an online course. Additionally, “Verification of Infectious Disease Molecular Assays,” a case-based approach to CLIA compliance for molecular testing assays, is now available on DVD and online.

Focus on Public Health Workforce Development
The NLTN’s Public Health Series courses—multi-day, hands-on workshops for public health laboratory personnel on a variety of infectious disease subjects—have historically provided some molecular testing training. In 2003, the course, “Molecular Diagnostic Techniques for the Public Health Laboratory,” made its debut with 31 attendees from public health laboratories. Due to an overwhelming response, it was offered again in 2004 for 27 attendees; it will be taught again in 2007. In addition to this course, the NLTN has organized four Public Health Focus multi-day, hands-on courses on both norovirus detection by polymerase chain reaction (PCR) and influenza detection and typing within the past year. These courses have trained 67 public health laboratory staff.

Clinical Laboratory Training
Over the past few years, the NLTN has also reached out to the general laboratory community with molecular diagnostic training opportunities. Together with the Wadsworth Center in New York, the NLTN has offered each year a hands-on course developed at Cold Spring Harbor Laboratory on molecular techniques, featuring thirteen laboratory experiments and guest lecturers. Since 2003, this course has attracted 44 participants. Additionally, in the past year, 900 participants have taken courses and teleconferences on molecular testing quality assurance, general molecular diagnostic testing procedures, mycobacteriology testing using molecular techniques, and detecting norovirus by PCR. All of the NLTN offices, in co-sponsorship with CDC’s Division of Parasitic Diseases, continue to facilitate courses that include molecular components on identification of parasites.

Additional Resources for Laboratorians
An additional molecular technology resource is the NLTN library, which contains sixty different items on the topic of molecular diagnostic testing; it can be accessed at www.nltn.org. The NLTN staff has also pulled together a comprehensive list of training opportunities outside of its own umbrella on a variety of subjects, including basic molecular technology testing, PCR, sequencing, variable-number tandem repeats applications, and microarrays. This list may be accessed at www.bttrain.org/molecular. If you are interested in any of the courses or resources mentioned in this article, email nltnmarketingmgr@nltn.org.
Eric Blank has been with the Missouri state public health laboratory since 1985; all but two years as its head. During that time he has seen the emergence of the public health laboratory as a major emergency response entity and the role of the public health laboratory director make a "180 degree turn" from an internally-focused job.

Blank, who plans to retire within the next three years, has given some thought to the future of the laboratory that has been his professional home for two decades. Next summer his staff will be moving about two miles across Jefferson City to a brand new building with 80,000 square feet of usable space, more than twice that now available. The laboratory will be upgraded from a BSL-2+ facility to a solid BSL-3, and the setting will change from a downtown location to an overview of the Missouri River.

The new laboratory, said Blank, "is on-budget and on-schedule." In fact the design and construction have progressed so well that state officials call it one of the smoothest running projects in the state, despite its complexity and $30 million budget (raised via state bonds). Assuming no major upheavals in the next seven or eight months, a full complement of almost 100 staff members will be on-site for the building’s christening. (There is currently only one vacancy: a chemist position that Blank is "holding back" because of fiscal constraints.)

Once the move is complete—coincidentally during the laboratory’s centennial anniversary—Blank has a full agenda for his last two-and-a-half years as laboratory director.

Of course the laboratory’s primary mission—supporting the public health programs that serve Missouri’s 5.2 million residents—will remain unchanged, with most resources directed toward newborn screening (including MS/MS testing) for 75,000 infants a year and toward STD tests. (St. Louis has the highest rate of syphilis in the country.)

Maintaining emergency readiness will also be a focus. The public health laboratory faced its first major catastrophe under Blank’s leadership in 1993, when the Missouri River overflowed its banks and inundated most of Jefferson City, including the laboratory. “We got into the emergency response mode perhaps a little bit earlier than most folks because we had to deal with it,” he said.

As you lose your senior staff to retirement, you have fewer and fewer individuals who are ready—or have had enough experience to even understand if they are ready—to move into management positions.

"I don’t want to limit ourselves in terms of how we think . . . .”

But in addition to assuring quality service in core areas, Blank wants to set the laboratory on a forward-looking path that goes beyond the traditional. "I don’t want to necessarily limit ourselves in terms of how we think about [the laboratory’s future]. I think we can maybe be a little more innovative in the testing services and assistance we can provide to the department." He noted, for example, that Missouri has a serious obesity problem and the public health laboratory needs to consider what can be done to address obesity-related illness from a laboratory perspective—such as quality assurance for Type II diabetes testing. “We have not gone into those waters yet,” said Blank, noting that a full-time state training coordinator is building the groundwork for enhanced public-private collaboration through an outreach program to clinical laboratories.

Blank also wants to make the best use of the new laboratory’s training and conference facilities, something not now available to his staff. “We want to use those to extend our outreach,” he said.

The laboratory’s chemistry section is moving away from environmental testing toward biomonitoring, and that trend is likely to continue. Blank explained that it’s easier than “fighting another state agency for resources for water testing” and satisfies a real need for studies of possible human exposure to a number of environmental toxicants. Missouri-based agribusinesses, concentrated in the state’s northern plains, place workers and communities at risk for exposure to high levels of agricultural pesticides. Lead smelting—the state’s “number one” mining activity—produces industrial tailings containing a number of heavy metals and other toxicants. And the underlying geology of the state—with central Missourians using groundwater and southern residents using surface water—predisposes Missourians to a mix of potential sources of water contamination.

Supplemental bioterrorism grant money supports a chemical terrorism (CT) Level 2 chemistry suite that has been used to
develop additional capabilities to detect heavy metals in tissue, thus demonstrating the dual-use of CT funding for emergency preparedness and improving services for ongoing public health concerns.

Finally, Blank looks forward to increasing the laboratory’s involvement in professional development and global health activities: perhaps serving as a host site for an APHL fellow and/or participating in a twinning project with a foreign laboratory.

But while positioning the laboratory to capitalize on these opportunities, Blank is also striving to prepare the laboratory for two significant challenges: limited fiscal resources and limited human resources.

The Missouri public health laboratory has a budget of roughly $10.8 million. Forty percent of that budget comes from general state revenue, 30 percent from federal grants and the remaining 30 percent, Blank said, “we earn.” But the largest of those funding streams may be cut in the next fiscal year. Blank explained that “demand [on the state treasury] exceeds revenue.” And with a governor opposed to tax increases, the likely alternative will be a reduction in funding. Blank is exploring options to increase earned income—mostly from Medicaid reimbursement and fee-for-service work—to at least partially offset any state budget cuts.

The second challenge—staffing—is one that the Missouri laboratory has been focused on for years. Blank said that once new staff members come onboard, “they stay; they tend to spend their careers here.” But finding those people is becoming more and more difficult, especially with a worsening national shortage of laboratorians. The Jefferson City area, explained Blank, does not provide “access to as large a pool of qualified candidates as a larger metropolitan area or [a site] near a university.” Moreover, it is hard to attract outsiders to a “mid-America, small town.”

So far, the laboratory has been blessed with low turnover. But with an aging workforce, the situation is likely to change. “We feel very acutely the shortage of qualified people at the entry level,” said Blank. “It took us well over a year to finally fill four or five vacancies for positions created with BT funding, and we were working very hard. The problem is magnified as you go up the organizational chain-of-command. As you lose your senior staff to retirement, you have fewer and fewer individuals who are ready—or have had enough experience to even understand if they are ready—to move into management positions.”

Blank, who serves on the board of APHL’s National Center for Public Health Laboratory Leadership, has long encouraged unit managers to take on mentoring responsibilities. One of their job expectations, he said, is to identify junior staff members who have the interest and potential for advancement. The goal is to develop a pool of potential future managers. Blank said, “we can provide them an opportunity to take the training courses supervisors need to take and to dip their toe in the [managerial] water and see if they like it.”

He noted that it takes a different skill set to be a good manager than to be a good laboratorian, and that skill set has changed “tremendously” in the past twenty years. Blank said that the job is much more policy-oriented now and therefore subject to greater public and political pressures. That may lead to higher rates of turnover among public health laboratory directors nationwide; rates that are more comparable to those of other senior health department managers today than to lab directors in the past.

“Our previous lab director was here 30, 35 years,” said Blank. “I think that era is over. I think we’re chopping off 10 to 15 years in future tenures. I’m very concerned where my replacement is going to come from and where others’ [replacements] are going to come from.”

And yet Blank recognizes the necessity of having managers who are more externally focused. “If you don’t want to be treated like a black box, you can’t sit in your little black box. You have to get out and talk to people. You have to be out there working with the constituents and with the policy people at the departmental levels. You have to speak their language. If you don’t, it can hurt the laboratory.” The upside is that the public health laboratory is now considered “more of an equal partner with the health agency.”

Blank acknowledges that he and the Missouri lab have “grown along with...
Pennsylvania Environmental Laboratory
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It’s almost like a living, breathing kind of organism...

Director
Roger Carlson has always taken a holistic approach to public health. “My academic background is environmental health science,” he said. “But again my technical background is a microbiologist. I’ve always been interested in environmental applications of microbiology throughout my academic and working careers.” Thus it made sense for Carlson to settle for 25 years in Kansas, serving as the director of the laboratory for the Kansas Department of Health and Environment. At the end of that time, in December 2000, a new opportunity tempted him to move. “What attracted me to Pennsylvania,” he explained, “was a plan that I thought was very forward-thinking, in which all state analytical laboratories were going to co-locate in a centers for excellence.” Although the political situation did not allow that vision to pan out, Carlson, now the director of the state laboratory for the Pennsylvania Department of Environmental Protection, is finding other ways to make those linkages in a state that considers environmental quality a high priority.

Location
Just last year the laboratory relocated to the edge of the Harrisburg metropolitan area. “Two characteristics were important to us in choosing a location,” said Carlson. “We insisted that the new laboratory be within five miles of the programs that we serve . . . to keep that interaction close. And we wanted to be near major interstate highways so that we could rapidly receive materials, supplies and so forth.”

Facility
The laboratory is in a five-year-old, 110,000-square-foot building that was completely restructured to meet the needs of a modern analytical laboratory, while simultaneously meeting the stringent requirements necessary to earn a gold Leadership in Energy & Environmental Design (LEED) award from the US Green Building Council (www.usgbc.org). Carlson said such a feat was not easy “because we use a lot of energy,” with single-pass air on three floors and over 100 chemical fume hoods. The facility has two gas fire generators that can provide full back-up power and whose waste heat is captured and redirected for either heating or cooling, as needed. Carlson said, “It’s almost like a living, breathing kind of organism, the kind of inter-linked systems we have here to make it as energy efficient as possible. We even have waterless urinals.” The commonwealth of Pennsylvania, he said, has elected to build energy efficiency into all new or renovated government buildings. “It’s a major issue and it just makes sense from a renewable, sustainable kind of philosophy. These are challenges that we must undertake and they can be incorporated into the economics of state government and should be.”

# Staff
91, primarily chemists, microbiologists, laboratory technicians and administrative personnel.

Revenue
“We never have enough,” said Carlson, whose $8 million annual budget comes entirely from fees from either analytical work or from a laboratory certification program that regulates all commonwealth labs reporting analytic data to the state in relation to Pennsylvania environmental statutes. The certification program has historically focused on water testing but has just been expanded to include hazardous wastes and other discharges, which will increase the number of laboratories that need to be certified from 126 to almost 1,000. Still, with no general revenue from the state, Carlson said, “we have no flexibility” to do testing of public health significance when there is no apparent payer. “That’s the dilemma that we face. We’re not comfortable with that.”

This is not your grandmother’s laboratory, and so the credentials candidates need to have when we have a vacancy have changed within the past 20 years. That’s frankly one of the most important things we can do to ensure the future of our laboratory. Any laboratory is only as good as the quality of staff that it employs.

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Distinguishing Characteristics
In addition to its sophisticated energy conservation systems, the laboratory is notable for having perhaps more mobile capabilities than any other state environmental laboratory in the nation. One mobile laboratory is focused on organic chemical analysis, one on inorganic chemical analysis, one on emergency response and yet another on the immediate detection of analytes without the need to collect samples. “We can shoot a beam across a landfill, for example, or search for fugitive methane sources. We even have an aroma-scan with which we can detect odors, remember odors and even track down the source of an odor. All of the instruments are ruggedized (some originally designed for the space program) and many are exchangeable among vehicles. “People who operate these are sort of the cowboys of laboratory analytical staff. They work all hours and live on the road and it takes a special cadre of laboratory scientist to be successful. They work very closely with our regional offices throughout the commonwealth. Once they are launched, they will not fail. They will not come back until they get the answer.”

Highest Volume Testing
The laboratory handles about 80,000 environmental samples/year, ranging from air to hazardous wastes to animals. Acid mine drainage is a “big issue” in Pennsylvania and the laboratory does a fair amount of water quality monitoring to help mitigate the problem. Pennsylvania is also the only state in the nation that monitors trout produced in state hatcheries for PCBs and other contaminants. Altogether, the laboratory produces roughly 700,000 quality-assured analytical results annually.

Notable Success Stories
▶ Designing and building a new laboratory. “We worked very hard over four or five years to accomplish that. We didn’t have the luxury of closing down our laboratory for 30 days [to relocate equipment]; we wanted to maintain productivity during that moving process. We’re pretty proud of that.”
▶ Updating the academic and training requirements for chemists and microbiologists. “This is not your grandmother’s laboratory, and so the credentials candidates need to have when we have a vacancy have changed within the past 20 years. That’s frankly one of the most important things we can do to ensure the future of our laboratory. Any laboratory is only as good as the quality of staff that it employs.”

Biggest Challenges
“One of the biggest challenges for any state lab director is to exist in this plane between the programmatic and political arenas that operate immediately above you and the scientific and administrative arenas that are your responsibility. I feel sort of like a gymnast sometimes on the balance beam. If you don’t manage that role well you won’t serve your laboratory as well as you should and you won’t serve the programs that use your data as well as you should. . . . That’s the toughest thing that we do for sure.”

# Vacancies
“It’s unusual for us to have more than a 4 to 5% vacancy level at any one time. To try to recruit the best and the brightest, which is our goal, is never easy, but we seem to be reasonably successful.”

Goals
▶ Achieve more fiscal flexibility. “It would be really great if the time comes that we could have some state general revenue in our budget. That would give us some breathing room.”
▶ Introduce new assays into the laboratory based on the molecular technologies clinical laboratories use to track the source of infectious disease microbes. “Those technologies are now being applied to environmental source tracking. So, for example, when you have a source of fecal pollution you can tell whether it came from humans—from an undiscovered sewage outfall—or from geese or deer or whatever. [Acquiring that capability] obviously takes funding and staff, but we’re pressing hard.”

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Staff News

Crystal Jones, MBA, resigned her position as human resources manager in November 2005. APHL wishes her luck in her future endeavors.

Michelle Meigs joined APHL as the new informatics program manager in November 2005. Meigs comes to APHL from the Massachusetts State Laboratory Institute, where she held various positions in an eight-year tenure. Most recently she served as laboratory supervisor of the STD and Pertussis testing laboratory where she developed and implemented a custom IT system for the laboratory.

Kris Peters joined APHL in December 2005 as the new program assistant for workforce and informatics. Peters brings extensive administrative experience from several local organizations, most recently, BETAH Associates, Inc.

Katherine Pollenz resigned her position as fellowship program coordinator in December 2005 to pursue her master’s in public health at Boston University in the fall. In January she will take a job teaching English in Costa Rica until her studies begin. APHL wishes her the best.

Danniele Smallwood came aboard as the new operations program assistant in late November 2005. Before coming to APHL, Smallwood held a dual role of front desk receptionist and administrative assistant at BETAH Associates, Inc. At APHL she will assist all areas of operations including accounting, communications, cooperative agreements, development, human resources and policy.

Erika Sykes joined APHL in December as the new information systems manager. Sykes comes from the American Fisheries Society where she helped implement IMIS. Sykes will serve as the netFORUM database guru, and will manage upgrades and customizations, maintain data integrity and assist APHL staff with complicated queries.

Kim Watkins was recently promoted to General Ledger Accountant. Over the past four years Watkins has taken on increasing responsibilities, including those of the general ledger position. APHL extends its congratulations to Watkins.

APHL Sustaining Member Program

The following corporations partner with APHL to support the nation’s public health laboratory systems.