The APHL Minute

News for Leaders in Public Health Laboratories

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Training Funds Threatened

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APHL Visits Restructured CDC

Positioning Labs Among Competing Priorities

In January, APHL’s Board of Directors met in Atlanta at CDC’s new Global Communications Center. During the three-day meeting, the board took a tour of the new infectious disease laboratories, handled internal association business, met with CDC Director Julie Gerberding and with officials and partners from the National Center for Infectious Disease (NCID), the Coordinating Center for Infectious Diseases (CCID), the National Center for Environmental Health (NCEH), the Office of Workforce and Career Development (OWCD), the Coordinating Office of Global Health (COGH) and the Coordinating Office for Terrorism Preparedness & Emergency Response (COTPER).

APHL President Kati Kelley and Executive Director Scott Becker discuss the key take-away points from the experience.

What was your impression of the new CDC?
Kelley: The visual is overwhelmingly strong when you enter the new CDC campus: modern beautiful buildings, striking landscaping and security unlike anything we have ever seen. No longer are we going to Building One and saying hello to the same guard we’ve always known. It’s a powerful visual reinforcement that this is the new CDC.

Becker: It really was striking to finally walk through and see it. It’s a brave new world. Everyone should visit; it helps clarify the complex changes at CDC.

Has the reorganization brought clarity to CDC?
Becker: The change is vast—with enormous impact on the states and on APHL.

Kelley: The board kept seeing again and again that things are still up in the air. Our partners are still uncertain about how the mechanics are going to work in the new system.

Becker: Touring the new facility, the visual is: “We’re done. We’re reorganized. We’re totally new.” The reality is: “We’re still working on this. Business practices are being developed.”

How has the reorganization affected the relationships between APHL and CDC?
Becker: When we met with Julie Gerberding, she said, “Welcome to your building.” She emphasized that APHL and its members are key partners—the public health laboratories are in the top five in terms of importance to CDC.

Kelley: The board was consistently impressed by our appointments. Senior-level officials came in person; they brought key staff with them; they spoke openly and directly; they emphasized the importance of the labs. Our working relationships are as strong as ever.

You will begin to hear talk from CDC about saving the ‘critical’ part of programs and we need to listen.

Becker: There are many new positions, and often there are new people filling them. APHL has spent a lot of time getting to know these new people, talking about the laboratory history and making connections. We’re beyond that now, having moved into the nuts and bolts of working through these changes together.

Did you discuss the ultimate effect of CDC’s budget constraints on public health laboratories?
Kelley: Yes. The board was very focused on discussing the implications of funding cuts and did a thorough job of relaying specific examples of how cuts play out at the state level.

Becker: The reverberations of this federal cut are spreading from CDC down to the state level; we’re just
beginning to get a measure of how severe they’re going to be.

Kelley: Funding ties are changing and APHL members will see downstreams as their grants come up for renewal. You will begin to hear talk from CDC about saving the “critical” part of programs and we need to listen. It is imperative that we begin to think critically, looking hard at programs…there will be cuts and at a time when state money is low. We must figure out how to manage the changes efficiently.

Did CDC convey consistent messages on what laboratories should do now?

Becker: Yes, state cooperative agreements must specifically reflect the CDC’s goals. Drawing these parallels shouldn’t be too hard—we just have never done it before. We easily identify with the preparedness goal; but now we must view our entire function through the prism of CDC goals, so when we talk about newborn screening, we need to reference the healthy child and infant goal. (For a complete list of goals, see www.cdc.gov/about/goals/default.htm.)

Kelley: Also be aware that your project officers at CDC will be talking about cuts. Be proactive. Meet with your programs and discuss how to maintain your work in a climate of cuts. Use your discussions with CDC staff to learn the new agency lingo; buzzwords have changed and you should learn them. In our new grant cycles, we need to reshape our goals and our language. This will help us translate into the new paradigm.

What is APHL doing to help?

Becker: APHL is both behind and in front of the scenes, speaking up, making needs known. This recent board meeting is an example of the valuable work the association can do—we were getting feedback from issues we raised in these meetings within hours.

Kelley: We can look at this fiscal situation with gloom and doom, or we can take the tack of efficiency and effectiveness. But sitting back and not engaging in the discussion is disastrous.

What is the status of APHL’s cooperative agreement?

Becker: The Division of Laboratory System is our tried and true friend and it is still there. Bob Martin is still in charge. It has been moved into NCID, but that is actually a better alignment than in years past. This mechanism remains stable. (Pause.) Now, the National Laboratory Training Network (NLTN) has been moved under the wing of the OWCD and funding is very unstable. We are aware of this and are, by no means, sitting by the side and waiting to see what happens.

Kelley: APHL has retained a consultant who will be studying the NLTN’s alignment within the broader context of laboratory training. We are also advocating strongly for the NLTN’s unique product.

Becker: We are reviewing business practices for training and education. We are studying emerging markets in environmental health and global settings. Just as the labs have to change to stay healthy in the current climate, so does the association.

What’s next?

Kelley: We’re going to Capitol Hill next month. Our key messages are on state and local terrorism preparedness, emerging infectious diseases and environmental health funding.

Becker: And the board is committed to meeting again at CDC. We saw the value immediately. Within a day of speaking to Julie Gerberding, reports were circulating at CDC. Specific issues raised by board members were being addressed. Within two days, I was invited to participate on a breakthrough group on informatics. Meetings like these are key to our success in working with the new CDC.
A Pivotal Moment for Public Health Funding Cut Threatens NLTN

Ask any laboratory director why continuing education is important and you’re likely to get an astonished response, the answer being so transparent to those in the field. Michael Kimberly, recently retired after serving for 38 years as the head of the Tennessee Department of Health Laboratory, had this to say:

“What you’re asking is ‘Why do you need training in West Nile virus? Why do you need training in rabies, SARS and bioterrorism?’ If you’re not up-to-date in those technologies, obviously you can’t do them. Two years ago who ever heard of avian influenza? There’ll be another one next month; there’ll be another one next year.”

In short, not only is ongoing training a requirement for various certification and licensure programs for laboratory scientists, it is a necessity to carry out testing for the most menacing bugs-of-the-moment using the most advanced technology available. It is at heart a matter of public health preparedness.

Given this context, talk of a significant funding cut for the National Laboratory Training Network (NLTN) is worrisome for laboratorians, especially in the public sector where affordable and relevant training opportunities are scarce. Scott Becker, APHL executive director, said it should be worrisome for health authorities and policymakers as well.

The NLTN—funded by the CDC and administered by APHL—is widely regarded as one of the nation’s premier laboratory training networks. Judy Delany, who directs CDC’s Training Services Division and oversees NLTN funding, said the network “is absolutely critical to CDC.” Last year the NLTN hosted more than 200 training events, with almost 30,000 enrollments. But it is unlikely that this volume of training can continue with only a third to half of the current NLTN budget, as some officials have suggested might be the new funding level in the 2007 fiscal year (FY), beginning July 1.

Day-to-Day Survival

Already, a recent CDC reorganization—in which the NLTN and the APHL cooperative agreement were moved to separate organizational units—caused some confusion about the location of NLTN funds within the CDC bureaucracy. Last July, the NLTN received only six months of funding, with the remainder promised at a later date and eventually delivered in December.

Uncertainty about when and how much funding would arrive was exacerbated by appropriations delays at the congressional level and jeopardized planning for training courses scheduled after December 1. Linette Granen, the NLTN’s communications and marketing manager, said, “We were at the point where January 31 was going to be our last day (of operation) . . . . This is the first time we’ve gotten to the point where our survival is threatened.”

An erosion of overall CDC funding is more bad news. The CDC experienced a loss of over $300 million in FY 2006 and is slated to lose almost $100 million in the president’s proposed FY 2007 budget. Betsy Szymczak, manager of the NLTN’s communications and marketing manager, said, “We were at the point where January 31 was going to be our last day (of operation) . . . . This is the first time we’ve gotten to the point where our survival is threatened.”

A Rare Commodity

In fact three things make the NLTN unique: a public health orientation, just-in-time training and accessibility.

The NLTN was created in 1989, at a time when political fashion, budget deficits and an agency-wide restructuring led CDC to dismantle its extensive and well-respected laboratory training division. At the same time, a terrifying new illness—HIV/AIDS—was reaching epidemic proportions and creating an urgent need for laboratorians trained to carry out what were then novel HIV testing protocols. A group of public health laboratorians, including Kimberly and most notably CDC’s Paul...
As the CDC’s external training arm, the NLTN is dedicated to improving laboratory practice of public health significance. And because the four regional NLTN offices are out in the marketplace—embedded in state public health laboratories—staff are well-positioned to assess public health-related training needs. Many courses are developed in consultation with laboratory training coordinators and the Public Health Series of hands-on workshops is designed solely for public health laboratorians.

While private training vendors are driven to deliver courses that will be profitable, the NLTN has always focused on delivering the courses and training tools that are needed. Many public health laboratories are mandated by the state or by CDC to perform certain tests that are rarely or never done in the private sector. Rabies is a good example. And the NLTN rabies workshop is the only rabies diagnostic workshop offered by anyone, anywhere in the US.

Even courses that are delivered to clinical laboratory workers—who comprise 85% of NLTN program participants—are on topics of public health importance. One example is specimen packaging and shipping, a crucial issue related to the transfer of specimens from one laboratory to another for confirmatory testing and other high-level analyses. (If a novel influenza virus or a suspected anthrax isolate is packaged incorrectly, the isolate may be useless for further testing and could pose a public safety threat.)

Other high-priority NLTN topics are parasitology, antimicrobial susceptibility testing, mycology, public health virology and molecular methods. CDC’s Delany calls the network “CDC-plus,” because of its ability to bring in the best and the brightest of CDC’s laboratory scientists, as well as world class experts from other federal and state agencies and the private sector.

Protecting the Public from Terrorism

Perhaps because of the NLTN’s close ties to the leading thinkers in the field, the network’s programming has always tended to be a bit ahead of the curve—so-called just-in-time training. Nowhere is this better demonstrated than in the areas of bioterrorism (BT) and chemical terrorism (CT) response.

Beginning as early as 1998, the NLTN began to offer awareness programs for public health and clinical laboratories (referred to as sentinel laboratories in the new emergency response lexicon). These programs were designed to alert laboratories to the very real possibility that microorganisms might be used for terrorism and were among the only proactive efforts to prepare the laboratory community for what occurred after the World Trade Center was destroyed in 2001.

Following the anthrax attacks that fall, a new stream of federal funding enabled the NLTN to expand its BT training.

Shortly after the NLTN became involved in BT training, chemical terrorism became a concern. NLTN staff recognized that a CT event would unfold quite differently from a BT event and would require a different laboratory response. Said Szymczak, “In a CT event, what will happen is that a significant number of people will report to a hospital emergency room with an illness that is probably going to be unexplained. If someone in the ER is astute enough to consider that it could be a CT event, the hospital is supposed to collect blood and urine and forward that to the public health laboratory for a toxic screen—highly sophisticated testing that is not going to be done in the hospital.” The NLTN, she said, was “very involved” in sending that message to various public health institutions and quickly developed a train-the-trainer program for chemical terrorism response.

Last July, the NLTN received only six months of funding, with the remainder promised at a later date and eventually delivered in December.

Betsy Szymczak, manager of the NLTN’s Boston office, said, “The next step was to do more than make people aware, but to show people what these (select agent) organisms look like.” Thus, the NLTN began hosting wet workshops with hands-on practice in select agent detection using look-alike agents.

But, as Szymczak pointed out, “the NLTN can’t train everybody in every lab in this country.” And the anthrax attacks made it clear that if another biological agent were released, it would in all likelihood be a sentinel laboratory—not a public health laboratory—that was going to see it first. (Every case of anthrax identified in 2001 involved an initial isolation of the organism in a hospital or other sentinel laboratory.) And so the next phase of training was development of a train-the-trainer package.

NLTN managers collaborated with CDC officials—and especially the managers of the new Laboratory Response Network (LRN)—to devise a training template, complete with all the materials state and local BT coordinators would need to host their own educational programs for the sentinel laboratories within their jurisdictions. Szymczak stressed that everything was based on a national standard: “The NLTN was very involved in making that connection from the federal level down to the states’ and through the states to local jurisdictions. Each public health laboratory could affix its own logo and contact information to the training materials and facilitate programs with no need to develop anything.

Continued on page 6
Forging Ahead with Cutting-Edge Training

A second example of in-time programming is molecular diagnostic training, what Granen calls “the wave of the future for laboratory testing.” Molecular testing—usually performed using a technique called polymerase chain reaction (PCR)—involves the isolation and replication of genetic material so that disease organisms can be more accurately identified. It offers the advantages of being highly specific to individual viruses or bacteria, quicker than standard culture tests and able to detect minute quantities of infectious agents—alive or dead.

Can’t Travel? No Problem

NLTN programs encompass everything from live multi-day, on-site seminars and workshops to self-study materials accessible via mail or computer. NLTN staff oversee all logistical arrangements for live programs, including renting buses on rare occasions when this is necessary to get participants to program sites.

The network has hosted training events in Alaska, Hawaii and other hard-to-reach locales where private training vendors are scarce and the cost of flying them to the training site is generally cost-prohibitive. Often events are held during local or regional professional conferences when students are already on-site. The NLTN has even collaborated with APHL on a tuberculosis training program for Mexican states along the southern US border as part of an effort to stem the flow of tuberculosis from Mexico.

Increasingly, the network has been diversifying its training modes to include more distance learning. Szymbczak said, “Our office is famous for doing the most low-tech distance learning possible. We invite a speaker and get a CDC bridge line so people can dial in and hear the talk. We also send a PowerPoint® presentation that they can view on their monitor. What astounds us is that there are many small labs in this country that can’t do more than that; all they have available is a phone and the ability to view a PowerPoint® presentation.”

The NLTN was set up to be cost-neutral and is celebrated within laboratory circles for its cost-effective programming. Shortly after it began operation, it was dubbed the miracle network because of the wealth of its offerings compared to the paucity of its fiscal resources.

Working Miracles with Limited Resources

CDC funding pays only salaries and office supplies, although it is sometimes boosted to underwrite the cost of particularly salient courses—on BT, food safety and the like—so that these will be sure to reach the intended audiences. Other than this dedicated funding, all operating revenue must be raised by the network. Granen said, “What we make on one course, we basically roll back into more courses and use to subsidize low-cost or free courses.”

Because the cost of high-level training can be substantial—on the order of $20,000 for a rabies wet workshop for 20 people—NLTN managers have learned to be creative in seeking corporate support. Olympus America, Inc., Nikon USA and Carl Zeiss, Inc., for example, have all loaned costly fluorescent microscopes to the network. Some sponsors have funded small receptions. “Our training is of such high quality that vendors are happy to work with us,” said Granen. “It’s a win-win situation because they get their name and their products exposed to people from all around the country in one venue.”

A January teleconference hosted by Szymbczak’s office, on the 2006 standards for antimicrobial susceptibility testing, drew 9,000 participants from 1,500 sites. The NLTN secured a grant from Ortho McNeil Pharmaceutical to cover costs, and, said, Szymbczak, “We didn’t charge a penny.”
Who Uses the NLTN?

About 15% of NLTN program slots are filled by public health labora-
torians and 85% by clinical laborato-
rians based in physician and hospital
laboratories, the US military, private
industry and other institutions.

Tommy Bruington, for example, is a
non-commissioned officer with
Charlie Company, 325 Brigade
Support Battalion of the US Army’s
25th Infantry Division based at
Schofield Barracks, Hawaii. He came
across the NLTN while doing online
research for training material to
prepare the laboratory section of a
medical support unit to deploy to
Iraq in support of Operation Iraqi
Freedom. Bruington wrote in an
email message to NLTN staff that
some of the soldiers under his
charge “haven’t worked in a lab for
several years and are a little behind
in their basic skills.” He was looking
for training materials “to bring these
soldiers and myself up to speed”
and he found them in the NLTN’s
free library. Bruington noted that
NLTN staff member Debbie Foster
supplied information on what mate-
rial could be copied and what was
copyrighted. “She even searched for
sources for me to purchase the
copyrighted material . . . (and
supplied) handwritten notes . . . to
assist me in their use!” He wrote
that it “would be a waste” for NLTN
offerings to be curtailed “for the
sake of ‘shaving the budget’.”

Jan Keithly is a senior research
scientist with the Wadsworth
Center, the public health laboratory
section of the New York State
Department of Health. Keithly has
been working with the NLTN for
several years to host wet workshops
on diagnostic parasitology and
molecular techniques for laborato-
rians throughout the northeast.
While the workshops are conducted
under the aegis of the Wadsworth
Center, the NLTN provides logistical
support, handles publicity, secures
continuing education credits for
program participants and has even
obtained microscopes from
Olympus. In return for this help,
Keithly has shared her teaching
materials with the NLTN for use by
others. If funding cuts curtailed NLTN
support for these kinds of state-run
programs, Keithly said, “It would be
a big loss for us. I consider the NLTN
as important as (the APHL/CDC)
Emerging Infectious Disease training
fellowships. I really do. The NLTN is
contributing something that’s just as
important as that.”

As an associate professor of microbi-
ology at Iowa’s Des Moines Univer-
sity medical center, Musau
Wakabongo used to borrow “a lot of
things” from the NLTN library: teaching
information, research methods and
more. Today, as the Laboratory Response
Network coordinator for California’s San
Bernadino County Public Health
Laboratory, Wakabongo has
attended two NLTN courses. The first,
a laboratory security workshop, was
held in Rancho Cucamonga, a 20-
minute drive from the public health
laboratory. “Four of us went from our
lab and earned 6 CE credits,” said
Wakabongo. The second, a train-the-
trainer workshop on BT agents, was
a hands-on wet lab, conferring 7 CE
credits. “Where else can we get this
kind of training?” Wakabongo asked.
She is now using NLTN materials as
the basis for her own BT workshops
for clinical laboratorians in San
Bernadino County. Wakabongo noted
that NLTN staff “just don’t give you
this material and leave you alone;
they will come and help you set up
and if you have questions you can
call and ask. It’s a very great help to
me as a new person in public health.”

Elliot Rank is director of scientific
affairs for BD Diagnostic Systems, a
Fortune 500 company that provides
tools and equipment to the health-
care industry. The NLTN, he said,
“promulgates an essential relation-
ship between hospital labs, commer-
cial labs and public health labs.” Most
recently Rank and some of the scien-
tists on his staff attended an NLTN BT
wet workshop. This kind of training,
he said, “helps in the (product)
design process” as it provides an
opportunity for his staff “to question
the authorities and experts in the
field and to understand the current
issues and problems laboratorians
are facing and the solutions people
have come up with.”

Funding Cuts Are a Nail in the
Coffin for Key Training Events

Precisely because the NLTN is already so
cost-effective, program staff are
pessimistic about the possibility of
continuing these kinds of programs if
CDC funding is slashed. “Because
public health has been traditionally
under-funded, the goal was to provide
training at no-cost or low-cost,” said
Szymczak. “And that no-cost, I think, is
very shortly going to be a thing of the
past. And that low-cost is probably
going to be at-cost.”

NLTN staff interviewed for this article
agree that price increases will inevitably
reduce the network’s reach. “I don’t
think we’re going to attract 1,500 sites
and 9,000 people when we charge,” said
Szymczak.

Granen added that a major cut in
funding would also mean fewer new
products and fewer courses overall.
“Audiences that CDC wants to reach
would be reduced,” she said. Even some-
thing as simple as purchasing new items
for the free lending library might be
discontinued.

The NLTN has already made several
changes to keep operating costs to a bare
NLTN training tools and events are tailored to develop skills for laboratory-based disease surveillance and emergency response. Courses address everything from reading a malaria smear to recognizing anthrax spores under a microscope to preparing specimens for newborn screening. Most programs offer continuing education credits. For more, go to www.nltn.org.

**NLTN Offerings**

NLTN training tools and events are tailored to develop skills for laboratory-based disease surveillance and emergency response. Courses address everything from reading a malaria smear to recognizing anthrax spores under a microscope to preparing specimens for newborn screening. Most programs offer continuing education credits. For more, go to www.nltn.org.

**Didactic Seminars**—Traditional workshops ranging in length from hours to multi-day, with on-site speakers in front of a live audience.

**Wet Workshops**—Hands-on workshops conducted in a laboratory setting, with live organisms or look-alikes. Topics include mycology, parasitology, BT agent detection, foodborne illness investigation, public health virology, rabies, molecular methods, and TB.

**Teleconferences**—Live telephone conferences for public health and/or general laboratory audiences. Conferences include a yearly update on standards for antimicrobial susceptibility testing and on seasonal and pandemic influenza. Teleconferences are archived for future reference.

**Online courses**—Currently include five BT course modules that can be completed at students’ convenience.

**Webinars**—Online courses offered at a prescribed time with live speakers and an opportunity for real-time interaction.

**Video Conferences**—Broadcasts of live presentations that are transmitted via satellite downlink or a networked video system.

**Workshops-in-a-Box**—Ready-to-go materials for workshops that can be facilitated at individual laboratory sites by on-site training staff. Materials—including slides, a script, handouts, pre- and post-tests, documentation and reference information—were originally packaged in a box, but are now being placed on CD ROM. Topics include packaging and shipping, foodborne illness, TB quality assurance, quality control principles, and handling and storing chemicals.

**CD ROMs and DVD**—Computer-based self-study programs available for a nominal shipping fee. There are five topics on CD-ROM and one—“Verification of Infectious Disease Molecular Assays”—on DVD. A DVD on newborn screening is in development.

**Lending Library**—Includes over 900 items—books, videos, CD-ROMs, etc—that can searched by topic. These are shipped free-of-charge to anyone with a US mailing address. (Borrowers pay return postage.) Some items offer CE credits.

**E-newsletter**—A free, quarterly electronic newsletter covering timely public health topics (in articles written by subject matter experts) and NLTN news. There are over 5,000 subscribers.

“... price increases will inevitably reduce the network’s reach. “I don’t think we’re going to attract 1,500 sites and 9,000 people when we charge,” said Szymczak.

Three of the NLTN’s seven regional offices were closed to redistribute staff from Texas to New York without having to redevelop a course.”

In the final analysis, it seems doubtful that the NLTN can sustain the level of cuts under consideration without risking its basic raison d’etre. Said Granen, “Low-cost, high-quality and public-health focused; that’s our mission and we may have to change it just to survive.”

If that happens, there will likely be adverse consequences for disease surveillance, emergency response and other public health functions that depend upon laboratory support. “There are stories of laboratories that haven’t been trained and do make fairly serious mistakes,” said Szymczak. “I have no reason to think that this would be any different.”

A well-functioning public health system depends upon skilled laboratory scientists. And, said Tennessee’s Kimberly, “If I don’t train ‘em and I don’t keep ‘em qualified, then I don’t have them, do I?”

minimum. The network has always collaborated with state and local public health agencies and regional laboratory professional associations to access experts and share expenses. In 2005, a whopping 70% of training events were co-sponsored.

three of the NLTN’s seven regional offices were closed to redistribute staff and centralize functions for greater efficiency. Small, specialized workshops are being phased out, said Granen, in favor of “things that fulfill everyone’s requirements so workshops can be transported...
Strategic Initiatives & Research

Electronic Lab Reporting: Informatics on the Move

Electronic exchange of data is a universal issue for public health laboratories at all capacity levels. Clinical, public health, environmental, veterinary diagnostic and water testing laboratories must all have the capability to exchange data to ensure the health of our populations. Due to a recent convergence of events, the need to develop electronic laboratory reporting (ELR) has climbed to the top of the national agenda. Michael Leavitt, secretary of HHS, is placing significant importance on the ability of medical systems to exchange data electronically and has announced his commitment to unleash the power of technology to improve the quality of health care, reduce mistakes and manage costs.

This became apparent in September 2005 when Secretary Leavitt announced the membership of the American Health Information Community (the Community)\(^1\). The Community, under the direction of the Office of the National Coordinator for Health Information Technology, is charged with providing overall guidance and coordination in an effort to meet the president’s request for electronic health records within the next ten years. The Community has formed subcommittees to focus on four specified breakthrough areas where technology can be applied to improve the nation’s health care infrastructure. APHL is pleased to learn that the electronic health record subcommittee is focusing its efforts on the exchange of laboratory data as the first-use case for an electronic health record adoption demonstration.

APHL is actively engaged in a number of projects that relate to electronic laboratory reporting:

- Secretary Leavitt’s office nominated Scott Becker, APHL’s executive director, to represent public health laboratories on the Biosurveillance Breakthrough Subcommittee, chaired by Julie Gerberding, director of CDC.
- APHL is working with its members to develop an information management electronic exchange protocols and will ease compatibility issues between public health partners’ systems.
- The APHL informatics and global health programs have partnered to understand and assess electronic data exchange and LIMS adoption on a global scale. Collaborating with CDC and the Office of the Global AIDS Coordinator, APHL is attempting to calculate the impact a lack of health information technology has in non-industrialized countries.

- In a meeting with Julie Gerberding, CDC director, APHL’s board of directors outlined the association’s key goals, including the need to increase the capacity for public health laboratories to interact via ELR. Gerberding agreed to investigate what CDC will require to transmit its lab results and data to strategic customers (such as public health laboratories) in a standardized and PHIN-compliant format. APHL hopes to pilot a transmission of standardized data between CDC and public health laboratories in the future.

The recognition of the important role laboratory data plays in disease surveillance and the worrisome specter of an avian influenza pandemic is accelerating interoperability of public health laboratories. The emergency funding plan recently approved by Congress contains money that could be used to close the gaps between the private sector, public health laboratories and the federal system, including CDC. Electronic laboratory reporting is another good opportunity to create an integrated national laboratory system; it will continue to be important for laboratory directors to monitor the guidance provided by HHS and CDC on the allocation of these funds.

1. www.hhs.gov/healthinformationtechnology.

Performance Standards Project Begins Development Phase

The public health laboratory performance standards project began its development phase in December 2005 with a two-day meeting of 30 subject matter experts. Project members include directors of state and local public health laboratories, scientists and staff from CDC’s Division of Laboratory Systems and National Public Health Performance Standards Program, members of academia and professional associations, and APHL staff. Other interested APHL members will serve as a review panel for the draft standards before they are piloted in late Summer 2006.

The development phase of this initiative follows the model set out by CDC’s National Public Health Performance Standards Program: detailed information on this program is available at www.cdc.gov/od/ocphp/nphpsp/. In order to devise optimal performance standards, the project builds off of the established framework of the 10 essential public health services\(^1\) and APHL’s explication of the 11 core functions of a state public health laboratory\(^2\). The performance standards will allow state public health laboratories to benchmark their current practices and chart quality improvement. For more information on the project, email James Ford, laboratory systems & standards manager, at james.ford@aphl.org.

1. www.cdc.gov/od/ocphp/nphpsp/EsentialPHServices.htm
2. www.aphl.org/docs/corefunct.pdf
The president submitted his $2.8 trillion budget request for fiscal year 2007 on February 06, 2006, including $698 billion (+$58 million) for Health and Human Services and $5.7 billion (-$92 million) for the CDC. Despite the overall reduction, there are funding increases. HIV/AIDS and TB Prevention is strengthened (+$86 million), although TB is reduced slightly (-$1 million). Public Health Informatics increases (+$38 million); Infectious Diseases Control goes up ($18 million) while Food Safety has a small reduction ($677,000). Global Health continues to receive significant pandemic influenza funding ($72 million), and state and local preparedness is level funded ($824 million).

Reductions in CDC funding include: the Public Health and Health Service block grant (-$99 million), Public Health Improvement and Leadership (-$75 million) and Environmental Health Laboratory (-$186,000).

Funding has again been eliminated (-$99 million) for the Health Professions Training Activities account at the Health Resources and Services Administration. The multi-agency President’s Emergency Plan for HIV/AIDS Relief receives $4 billion.

The Department of Homeland Security Science and Technology Directorate funding is reduced (-$494 million, down to $1 billion) as many research projects were completed.

The EPA increases (+$30 million) its pilot program for monitoring and surveillance of drinking water, WaterSentinel, and includes resources for the continuation of the Water Alliance for Threat Reduction (WATR). EPA funding increases (+$7 million) to expand its Standardized Analytical Methods (SAM) to include environmental sampling, and funding is again proposed (+$9.5 million) to administer an environmental laboratory preparedness and response capability.

The FDA will increase (+$19 million) for food defense, including additional (+$15 million) to Food Emergency Response Network (FERN) to expand the network to include 16 state laboratories, along with additional funding (+$2.75 million) for improved data reporting.

The overall reaction to the president’s budget request on Capitol Hill has been mixed, and it is premature to make any assessments on the final disposition of the proposed funding levels. Congress begins hearings on the budget request this week, and the annual federal appropriations process will commence shortly. APHL will continue to provide members regular updates throughout this process.

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New Offerings from NLTN

**Laboratory Learning Links**
Teleconference Series begins in June 2006

**Self-Study Options for Continuing Education**
Register online for self-study modules at www.nltn.org/courses

For more information on these or other options from NLTN, contact us at 800.536.NLTN (6586) www.nltn.org
OraSure Announces Plans for Over-the-Counter Rapid HIV Test

The FDA held its quarterly Blood Products Advisory Committee (BPAC) meeting in November. During the meeting, OraSure Technologies, Inc., announced its plans to seek over-the-counter (OTC) status for the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test for use with oral fluid specimens for home use. The FDA sought advice from the BPAC on issues that must be resolved prior to approval, specifically: validation of test accuracy; test interpretation; supplemental testing for confirmation of reactive results; management of psychological and social issues; availability of counseling; and medical follow-up based on the provision of information material instead of a trained test operator and counselor.

For the BPAC's to make sound recommendations to the FDA, presentations were given by various governmental and non-governmental partners on changes in CDC's HIV testing practices and counseling recommendations, quality system considerations for OTC HIV testing, psychological and social issues associated with HIV testing and OTC home use tests, and the Center for Devices and Radiological Health (CDRH) review practice for OTC in vitro diagnostic tests. Finally, the BPAC heard prepared open comments.

The BPAC discussed these issues and suggested studies that could provide the information required by the FDA for its decision. After the meeting, APHL, with guidance from its Infectious Diseases Committee, sent a letter to the FDA requesting that other questions and concerns be addressed prior to the agency's final decision on approval of an OTC indication.

APHL TB Steering Committee Discusses Implementation of TB Task Force Report

The APHL/CDC HIV Steering Committee, under direction of the APHL Board of Directors and Infectious Diseases Committee, is re-evaluating the HIV diagnostic testing algorithm. The steering committee will meet in March to further consider what changes need to occur and whether more than one algorithm will be required. Topics for discussion will include supplemental testing to confirm the presence of HIV-2, new screening assays, nucleic acid amplification testing for primary HIV infection, rapid HIV testing and the future of the Western blot.

The committee will also discuss validations of new HIV screening assays, how to handle the continuing emergencies and shortages of diagnostic reagents, and an HIV survey.

For information, contact Tony Tran, HIV, STD, TB program manager at anthony.tran@aphl.org.

HIV Diagnostic Testing Algorithm to Undergo Changes

APHL's TB Steering Committee, chaired by Nancy Warren, PhD, (PA), met in November to outline implementation methods for the recommendations in the TB Task Force report, The Future of TB Laboratory Services (see www.aphl.org/docs/TBTaskForceFINAL.pdf.) Committee members decided to address the report's first benchmark—assessing a TB laboratory's capabilities and capacities—by updating the 1995 Mycobacterium Tuberculosis: Assessing Your Laboratory Manual and creating an online repository of existing assessment tools. The updated version of the assessment document will emphasize a systems approach of active communication between laboratories to improve coordination of specimen and culture referral mechanisms, thus reducing delays in testing and reporting. A working group, led by David Warshauer, PhD, (WI) and Kenneth Jost (TX) and consisting of subject matter experts and partners in TB elimination, will be formed to revise the manual; special attention will be paid to new technologies, providing guidance and developing tools to assess the laboratory's role in the system of TB control. APHL, with assistance from the committee, will establish the online repository of available assessment tools.

The steering committee asked the former chair of the APHL TB Task Force, Eric Blank, DrPH, to formulate a plan of action to address the report's second benchmark—evaluating the true costs of TB laboratory services. Once created, a cost assessment tool will also help laboratories justify expenses to policy makers and funders.

The committee also discussed advocacy efforts to increase TB funding; build the relationship between APHL, the state TB laboratories, and the National TB Controllers Association (NTCA); and support meetings of interest, including the Northeastern TB Controllers meeting, other regional controllers' meetings, and a potential TB laboratory conference to be held jointly with NTCA.

HIV, STDs, TB
PulseNet Update

Influenza Update: Call for National Clinical Laboratory Organizations

APHL partnered with CDC’s Division of Public Health Partnerships and Influenza Branch to organize a conference call for national clinical laboratory organizations, “What Clinical Laboratories Need to Know About Their Role in Influenza Testing,” in January. The call inaugurated the CDC Laboratory Outreach and Communication System (LOCS), a new program designed to link the broad laboratory community on dynamic topics. The system will be the central source for laboratory professionals to obtain credible information, with a focus on education and routine and emergent issues. Thirty-seven representatives from various national clinical organizations participated in the inaugural call.

Lynette Brammer from CDC’s Influenza Branch described the comprehensive system used to monitor seasonal influenza in the US, which include laboratory and epidemiology reports, national surveillance networks and mortality reporting systems.

Dr. Niranjan Bhat, CDC Influenza Branch medical epidemiologist, reviewed the roles of state laboratories and CDC in a public health response. Bhat stressed the importance of involving public health agencies early in an emergency since they can advise on testing, initiate an investigation, control potential spread and interact with the media and public. State public health laboratories can better manage suspect H5N1 investigations due to capacity and training.

Dr. Peter Shult, director of the Communicable Disease Division and Emergency Laboratory Response for the Wisconsin State Laboratory of Hygiene, discussed the utility of rapid diagnostic tests for influenza. Shult reviewed the advantages of using rapid tests, as well as their performance limitations and biosafety concerns. With widespread rapid testing and diversion of testing from public health laboratories, loss of testing data, follow-up testing, and characterization of virus isolates can occur. Public health laboratories should be the clinical laboratories’ link to CDC and the best immediate source for consultation during outbreaks of influenza or other public health emergencies.

More information on the use of rapid tests for detecting influenza A viruses can be found at www.aphl.org/programs/infectious_diseases/pandemic_influenza.cfm and at www.fda.gov/cdrh/oivd/tips/rapidflu.html. Additional information about LOCS is available at www.phppo.cdc.gov/dls/LOCS/.

VA DCLS Receives Contract

In cooperation with Susan Maslanka, PhD, at CDC, APHL has awarded a one-year PulseNet research contract to the Virginia Division of Consolidated Laboratory Services (DCLS) to expand the range of pathogens that are monitored within the network. Under the direction of Denise Toney, PhD, the lab will develop, standardize and validate PFGE protocol(s) for Clostridium botulinum types A, B, and E and assist in establishing a PulseNet database for C. botulinum type A.

PT Survey: Passing Scores for E. coli, Shigella, Salmonella

With assistance from APHL, CDC continues to administer annual proficiency testing for the PulseNet USA
Emergency Preparedness

LRN Partners Discuss Flu, Water Safety, Surge Capacity

The Laboratory Response Network (LRN) Partners Working Group (see www.bt.cdc.gov/lrn/partners.asp) convened in February to discuss the recent release of the LRN assay for Influenza A/H5 (Asian lineage) virus, EPA’s Water Sentinel Initiative, network surge capacity assessment projects and the public health and research interface. Partners provided updates on ongoing initiatives, including the design and implementation of the all-hazards receipt facility prototypes and protocols, the capabilities of the Civil Support Teams and the activities of the Integrated Consortium of Laboratory Networks (ICLN). Highlights from the meeting include the following.

LRN H5 Procedure Release
On February 6, 2006, the LRN released its FDA-approved Influenza A/H5 (Asian lineage) Virus Real-time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) assay. The test provides preliminary results on suspected H5 influenza samples within four hours of sample receipt and subsequent testing at a designated LRN reference laboratory. All LRN labs are able to view the new procedures on the secure Web site. Reagents will only be supplied to qualifying labs. As of February 10, 2006, the LRN has received H5 reagent requests from 69 reference laboratories. CDC and APHL are developing guidelines for using the LRN assay in conjunction with the CDC Influenza Branch’s assay.

Deployment of LRN Results

Messenger, Version 2
The CDC released the LRN Results Messenger Version 2 (RMV2) in January, intending to complete installation in all domestic LRN reference laboratories by mid-year, beginning with BioWatch labs. Plans for the application include: bi-directional messaging, support for the LRN Chemical component, and utilization of end-user feedback to build the system.

NIH Regional Centers of Excellence
The NIH has established ten Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases throughout the US. The centers provide the NIH’s National Institute of Allergy and Infectious Diseases with focused research on bioterror agents and emerging infectious diseases. APHL will explore the potential role of these centers in public health laboratory response, and determine methods for collaboration among the centers and LRN reference laboratories.

Reference Lab Surge Capacity
APHL is working with RAND, a nonprofit institution, to further develop plans made by the association’s surge capacity subcommittee. RAND received a task order from HHS to create tools that increase the ability of local and state health departments to respond to bioterrorism and other public health emergencies. One component of this task order is to develop a tool to measure surge capacity of LRN reference level laboratories—work which dovetails with efforts of APHL’s surge capacity subcommittee. A similar effort to assess capacity of all the laboratory networks will be undertaken by the Homeland Security Institute; APHL will provide input into this assessment as well.

All-Hazards Receipt Facility Draft Protocol
An All-Hazards Receipt Facility Draft Protocol is under development by state and federal agencies, including EPA and DHS; it will assist receiving laboratories with screening (characterizing) unknown samples or specimens for radiation, explosives and hazardous chemicals prior to definitive analyses. Currently, this draft document is not recommended for implementation due to a lack of interpretive guidelines and both positive and negative controls for each test. However, these items should be available with the next release of the protocol.

Water Sentinel Initiative
The proposed Water Sentinel Initiative will develop a water surveillance system for dangerous contaminants by demonstrating a standardized, cost-effective approach. These efforts will help protect hundreds of thousands of miles of drinking water systems and provide an early chemical and biological terrorism warning mechanism. The Bush administration requested $44 million to fund the pilot program in five major cities. Lessons learned will be used in future state and local water system protection efforts. If Congress funds this initiative, EPA will be collaborating with CDC and the LRN to implement it.

For more information on the meeting or the LRN, contact Lena Lago, MPH, at lena.lago@aphl.org.

Program. The testing conducted in the fall of 2005 monitored laboratories certified for E. coli, Salmonella, and Shigella. As of February 15, 2006, all PulseNet USA laboratories passed each of their PT exercises. Laboratories certified for Listeria and Campylobacter will receive isolates in April for the next round of proficiency testing.

Training for BioNumerics Software
BioNumerics version 4.5 is now available for download from the Applied Maths, Inc website. All PulseNet laboratories should be prepared to switch to BioN v4.5 no later than June 1, 2006. Training on the new version of the software will be offered at no charge to all PulseNet USA participants via Web conference.
Environmental Health

PA’s Environmental Lab Sets National Precedents, Tackles Issues of Human Health, Air Quality

Due to pioneering research at the Pennsylvania Department of Environmental Protection Laboratory (DEPL), the state is the first to monitor hatchery trout for trace chemical contaminants of concern to high-risk populations. Consumption advisories have been issued as a result of the laboratory’s detection of polychlorinated biphenyls (PCBs), a substance once used in electrical insulating and heat exchange fluids. Although banned in the US in 1979, PCBs continue to be found in the environment, raising concerns. Exposure has been linked to cancer, liver disorders and certain reproductive effects. The DEPL’s analysis has helped determine the source of contaminants in the hatchery fish and gather the data needed for public health and public policy decisions. Other states are now following Pennsylvania’s lead: most recently, West Virginia.

After tests confirmed the presence of mercury and PCBs, the West Virginia Division of Natural Resources (DNR) placed locally-raised brown trout on the state’s consumption advisory list. The trout, raised in three hatcheries, were most likely contaminated by PCBs through their feed. The December 2005 advisory marks the first time any species of trout has been specifically listed by both the DNR and the state’s Bureau for Public Health and Department of Environmental Protection. Mike Shingleton, head of the DNR’s trout program, credits the Pennsylvania DEPL for the decision to test in West Virginia; they initiated testing after the Pennsylvania Fish and Boat Commission discovered PCBs in its own trout during the 1990s. In that instance, some of the PCBs were traced to feed containing high levels of fish oil from ocean-caught fish. By switching to a lower-fat feed and implementing some operational changes at the hatcheries, Pennsylvania was able to reduce levels of the contaminant.

In January, the DEPL also announced plans to use two mobile analytical laboratories to conduct air sampling in Towanda, PA, near large emissions sources like CraftMaster Manufacturing Inc., Osram Sylvania, and DuPont, to investigate malodors and respiratory problems reported by residents. The mobile labs employ a specialized instrument called an Aromascan, which mimics the human olfactory system by using a number of polymer sensors capable of altering their electrical resistance in the presence of different chemicals. The mobile units can perform the same types of analyses conducted at the State Environmental Laboratory in Harrisburg, PA. The DEPL will test for, among other things, formaldehyde, methanol, acid aldehyde and phenol, all known to be emitted from the CraftMaster Manufacturing Inc. plant. In addition, the units will test for ammonia, a common emission of Osram Sylvania. Initial tests will help establish a profile of chemicals emitted by each plant. This information can then be used to determine whether the plants are the source of the odors and chemicals detected in the surrounding community.

APHL Has Moved!

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Environmental Health Fellows: Laboratory Workforce Success Stories

The Environmental Health Fellowship was launched by APHL and CDC in 2003 to help meet ever-changing workforce needs. The fellowship program provides complete funding for state public health laboratories to hire a one- or two-year, full-time fellow, and covers stipend, travel allowance and health benefits. The program enables laboratories to initiate and/or enhance environmental health testing capabilities, such as human biomonitoring and chemical terrorism. Over the past two years, Alaska and Wisconsin have taken advantage of the benefits of this program.

Marina Blake, PhD, a fellow at the Alaska State Public Health Laboratory in Anchorage, remarked, “The learning opportunity afforded me this past year has been both a challenge and a joy. I feel that this opportunity has changed my life.” Blake obtained her PhD in chemistry from the St. Petersburg Institute of Technology in Russia. During her fellowship, Blake obtained experience in the applied field of clinical chemical analysis with training focused on inorganic elements in clinical specimens. Most of the analyses that she performed were carried out using inductively-couple argon plasma mass spectrometry (ICP-MS DRC II) and a Direct Mercury Analyzer (DMA-80).

Working in close collaboration with her mentor, David Verbrugge, PhD, Blake received training on instrument maintenance, internal standard calibration techniques, the implementation of a formal quality assurance program, and control charting practices. As a result, Blake can independently operate and maintain the Perkin-Elmer Elan ICP-MS DRC II and the Milestone DMA-80.

Blake and her colleagues at the Alaska laboratory investigated heavy metals and toxic elements in blood and urine and performed multi-element analysis and validation of over 1000 analytical batches. Her work contributed to the laboratory obtaining proficiency from the National Public Health Institute of Quebec (INSQP), as well as CLIA validation for CDC’s Toxic Elements in Urine procedure. Blake also applied ICP-MS DRC technology to measure trace elements in fish tissue digests, which ultimately allowed the Alaska laboratory to provide analytical services to the State Department of Environmental Conservation. Additionally, Blake participated in a proficiency training program for the Food Emergency Response Network (FERN), and received training for the detection of carbon monoxide in whole blood.

Upon the conclusion of her fellowship, Blake accepted a full-time position as a Chemist level 3 with the Alaska laboratory.

Blake is not the only environmental health fellow to make a significant impact on the state public health laboratory community. At the Wisconsin State Laboratory of Hygiene, fellow Kristie Ellickson, PhD, worked up an arsenic speciation method for the laboratory. The method is now used to analyze samples in the Kewaunee Marsh, an area marked by intense historic arsenic contamination that requires quarterly monitoring of surface and ground waters. Ellickson also helped bring methods for macrophage toxicity endpoints online. Additionally, Ellickson assisted in setting up a methyl mercury measurement apparatus, including a purge and trap set-up, detection gas line, and the distillation set-up.

Aside from gaining methods development and technical bench experience, Ellickson wrote her first grant application and was funded through the Wisconsin Joint Solicitation for Ground Water Research. Her project, "Arsenic Species (III, V) Distribution in Wisconsin Groundwaters: Field Measurements and Prediction Using Multivariate Analysis of Geochemical Data," was funded for two years at $25,140 each year. Ellickson also wrote her first institutional review board approval submission along with a group of colleagues at the Wisconsin laboratory: “Dose-Exposure Relationship for Arsenic Using Urine Biomonitoring and Groundwater Measurements: A Pilot Study.”

“This fellowship experience met my goals, I was able to write grant applications, be involved in IRB submissions, I was included in regional conference calls, and was very involved with laboratory personnel and laboratory method development,” says Ellickson. After returning from maternity leave, Ellickson would like to continue in the research field and incorporate more teaching and training experiences in her next position, which she hopes will either be with the Wisconsin State Laboratory of Hygiene or an academic institution.

Since 2003, only a handful of environmental fellowship applications have been received. In an effort to restructure the program, APHL is not currently accepting applications, but is interested in feedback from laboratories on how environmental health workforce needs can be better addressed. Applications for the shorter term EH Traineeship Program are accepted on a continual basis. For more information, visit www.aphl.org/training_and_fellowships/traineeships/. 

APHL
Fellowships

EID Fellows Contribute to Public Health Practice and Academics

Three fellows working in Virginia’s Division of Consolidated Laboratory Services presented their research at the Virginia branch meeting of the American Society for Microbiology in November. Angela Fritzinger presented “Characterization and Analysis of Norovirus Outbreaks in Virginia, 2001-2004” orally and as a poster. Heather Masri exhibited a poster, “Validation of a Microsphere-based Immunoassay for the Simultaneous Detection of Immunoglobulin M specific to West Nile and St. Louis Encephalitis Virus,” and Kari Belin presented “Development and Implementation of a Real Time PCR Assay to Detect Borrelia burgdorferi in Ixodes scapularis Ticks.” Masri and Belin also presented their work at a field epidemiology seminar in Charlottesville.

In September, Lisa Calhoun traveled to Guatemala to participate in a field study on sand flies and Leishmaniasis. Half of her time was spent in the field, collecting and dissecting sand flies at the CDC Leishmaniasis field station. The remainder of her time was spent in Guatemala City performing molecular work in a laboratory. Of the experience, Calhoun stated, “I learned a lot by being in Guatemala. My career goals have always centered on international health, and this trip has increased my desire to work on infectious disease in developing countries. It gave me a more in-depth perspective on how socioeconomic factors are related to disease transmission.” Back in the US, Calhoun continued her work on both Leishmaniasis and other projects. She presented a talk, “Combined Sewage Overflows and their Productivity for Culex quinquefasciatus, Major Vector of West Nile Virus in the Eastern United States,” at the Georgia Mosquito Control Association meeting and in her CDC host lab branch meeting.

APHL’s fellows also turned out at the December American Society for Tropical Medicine and Hygiene meeting in Washington, DC. Scott Shone presented the poster, “A Novel Real-Time PCR Assay for the Speciation of Medically-Important Ticks,” based on his research at the New Jersey Department of Health. From CDC’s Division of Parasitic Diseases, Caroline Grady gave an oral presentation, “Assessing Filarial Infection and Transmission in a Low Priority Area of Haiti.”

From the Michigan Department of Community Health, Peter Davidson gave two presentations on “National Tuberculosis Genotyping” at the October Southeast Regional Tuberculosis Controllers’ Conference in Louisville, Kentucky.

Julie Anderton gave a presentation, “Gene Expression Microarrays’ Clinical/Research Applications,” as part of a September course at Emory University. Jewell was also appointed as a research trainee at the Mayo Clinic and is participating in weekly coccidioidomycosis clinics at the Mayo Hospital in Phoenix.

From the Arizona Department of Health Services, Kelsea Jewell presented the poster, “Development of a Microsatellite Genotyping Assay for Clinical Coccidioides spp. Isolates in Arizona” at the Valley Fever Awareness Poster Session at the University of Arizona in November.

“The Doctor Goes Back to the Lab: Bringing Basic Science to the Bedside, a Two Day Course for the Inquiring Clinician.” Anderton works in the CDC’s Division of Bacterial and Mycotic Diseases.

Continued on page 22
**Workforce Development**

RWJF-Sponsored Workforce Initiative Update

The APHL Workforce Initiative Project, supported by a grant from the Robert Wood Johnson Foundation, is addressing the leadership crisis in the nation’s public health laboratory system by crafting a strategic action plan and discipline-specific workforce development initiatives. Phase I of the three-phase initiative, the refinement of the project charter, scope and methodology, was completed in November.

Phase II, an environmental scan and a root cause analysis of the leadership crisis, was completed in early January. The resulting document brief, *Developing Leaders for the Nation’s Public Health Laboratories: An Agenda for the Future*, identifies four focal areas requiring discussion and action: 1) The role of public health laboratories in the evolving health system; 2) Achieving excellence in laboratory leadership development; 3) Marketing, communication and partnerships; and, 4) Technology and best practices. Four task forces will tackle one focal area each, addressing recruitment, retention and succession planning.

Currently, the initiative is in Phase III, which is dedicated to developing solutions and an implementation plan. In January, an oversight team was established to provide guidance, feedback and perspective. Team members Katherine Kelley, Christine Bean, Eric Blank, Steve Hinrichs, Bruce Kleger, Donna Richter, and Paul Kimsey reviewed the initiative’s project charter, analyzed the role of oversight and discussed the proposed action plan and timelines. The oversight team then assigned other participants to the four task forces; the oversight team will also serve at this level.

A two-day meeting of the oversight team and the task forces will take place in February. In preparation, all participants will respond to a questionnaire that adheres to the four focal areas of the initiative. At the meeting, the group will finalize the project charter, review the questionnaire responses and break into task forces to develop the first draft of strategic goals for each of the four focal areas.

After this meeting, the oversight team will review and revise the resulting draft work. Task groups will continue to develop timeframes, resource requirements, goals and measures of success. A final strategy document with recommendations will be generated for presentation at the APHL annual meeting in June.

**Global Health**

Global AIDS Program Update

The CDC’s Global AIDS Program (GAP) awarded four cooperative agreements in the current fiscal year of the President’s Emergency Program for HIV/AIDS Relief (PEPFAR), forming a laboratory consortium to accomplish the program’s objectives. Because laboratory infrastructure in most affected countries is weak, the consortium, made up of APHL, the American Society for Microbiology, the American Society of Clinical Pathologists and the Clinical and Laboratory Standards Institute, will focus on training and technical assistance to support diagnosis and treatment of HIV/AIDS.

To achieve PEPFAR objectives, which currently outstrip the existing infrastructures not only of country laboratory systems, but also CDC and APHL, CDC is increasing resources in GAP and the laboratory consortium will enhance capabilities to support the rapid increase in treatment initiatives.

A first meeting of the consortium was held in Atlanta in January. The meeting was co-chaired by John Nkengasong, director of GAP/Atlanta Laboratories, and Tom Hearn, deputy director of CDC’s Division of Laboratory Systems. CDC presented information on current PEPFAR activities and the laboratory partners planned cooperative efforts and action plans.

There are 25 PEPFAR countries, fifteen of which are considered focus countries and receive annual awards of up to $60 million. Nearly 100 countries receive funding from CDC, NIH, the Department of Defense and the US Agency for International Development for HIV/AIDS activities.


Member News

Santa Clara County Public Health Laboratory

Tech Service in California’s High-Tech Corridor

"I have definitely focused my lab to prepare for the unexpected."

Director

Patricia Dadone, director of the Santa Clara County Public Health Laboratory, is a Californian through and through. It was while studying at the California State University at San Jose that Dadone recalled, “One of my professors said, ‘You know Patty, I think you would like public health more than you would like clinical lab practice.’” And that was exactly right. Dadone finished her degree, completed the state-required internship, obtained a California Public Health Microbiologist certificate, and went to work for public health laboratories in Los Angeles and Monterey counties. She then accepted a position as the operations manager for the Alameda County Public Health Laboratory and stayed for 11 years before accepting the directorship in Santa Clara County.

Applying for the position was a no-brainer, said Dadone. “When I was at San Jose State, I knew I wanted to be a PHL director and I knew I wanted to be a director in Santa Clara County.” Getting the job at the San Jose-based lab, Dadone said, “was like coming full circle.” She came onboard in October 1999 and has been there since.

Location

Santa Clara County is home to 1.8 million people, making it the fourth largest county in California. It is home to the nationally recognized high-tech “Silicon Valley” area, which plays a major role in the county’s health care dynamics. What was once an agricultural county, Santa Clara County is now a sprawling urban and industrialized area, and home to companies such as E-bay, Hewlett Packard, Google, IBM and other high-technology companies. With a diverse and somewhat affluent population, Dadone said, “There is a tremendous amount of international travel coming back and forth into the area by way of the San Jose International Airport.” Perhaps that is why the first case of SARS in California emerged there.

Facility

The 6,066 square-foot facility (3,580-sq. ft. of actual lab space) was built in the 1970s and has undergone three major renovations under Dadone’s leadership. Today the facility has a BSL-3 suite and a BSL-3 surge capacity room, areas that were renovated from existing BSL-2 space.

# Staff

The laboratory staff now numbers 13, (including a full-time courier which “makes us competitive with other laboratories in our area”) a major change from the 3.5 employees that were here when she came in October of 1999.

Revenue

Approximately 30% of the laboratory’s funding is through federal and state grants as well as revenue from services billed. The remaining 70% of the laboratory’s budget is through the county general fund.

If I’m not going to provide classic public health testing (STD etc.), I needed to look to the future, and the future is molecular and environmental testing."
**Distinguishing Characteristics**

- A LRN reference laboratory, providing BT testing services to five counties.
- High-volume molecular testing capability, encompassing tests for influenza, norovirus, West Nile virus, pertussis and others.
- One of the few labs in California that performs pulsed field gel electrophoresis (PFGE) testing.

**Highest Volume Testing**
The laboratory handles about 25,000 samples/year, including high volume work in the areas of virology, blood lead, Chlamydia and Gonorrhea testing. Additionally, bacterial water analysis is a fairly large volume test for the laboratory. The current goal is to be able to provide additional environmental testing by utilizing the laboratory's Atomic Absorption Spectrophotometer machine currently used for blood lead testing for children.

**Notable Success Stories**

- Re-inventing the lab. Between the time Dadone first toured the laboratory as an undergraduate at San Jose State and the time she became director, much of the facility's work had shifted elsewhere as the result of reorganization at the county level. "Knowing that I wasn't going to get back the work, I went back to the beginning. If I'm not going to provide classic public health testing (STD etc.), I needed to look to the future, and the future is molecular and environmental testing. So the tests that I looked to bring online were types of tests that offered PCR technology. We're very proud of our molecular capabilities."

- Surviving 9/11. "The day after 9/11 the laboratory was in the middle of a remodel. The staff were running possible anthrax samples on a single workbench that was held up by sawhorses. We had one single sink, one hood, one water bath and one counter. The staff processed (anthrax) samples with no delays. I have a phenomenal staff. They did what had to be done."

- Identifying, by PCR, a new influenza strain later identified as A/California/7/2004 (H3N2), which was added to the national vaccine in 2005.

- Computerizing the laboratory with M/LAB software from M/MGMT Systems.

- Offering the QuantiFERON-TB Gold® test for tuberculosis. QFT-G offers the possibility of detecting M. tuberculosis infection with greater specificity than has been possible previously with tests that used tuberculin PPD as the TB antigen. (MMWR, December 16, 2005, Vol. 54, No. RR-15).

**Biggest Challenges**

"Because the lab has gone through so many changes, trying to reacquaint the community with the services that we provide is a challenge. We need to get the community to recognize and understand that what this laboratory is offering is state-of-the-art."

**Goals**

"To have the best public health laboratory in California. Public health laboratories no longer need to be thought of as slow and antiquated. Today California's PHLs offer advance-testing services and it is my goal to make sure that I provide the best services, using the most current technology, and best practices for the community that I serve. If the lab does not provide the best to be offered, I'm not satisfied."

Laura Galli analyzes pulsed-field patterns.
In many ways Michigan is a state of surprises. Known as the home of Motown and the American auto industry, Michigan is popularly associated with the cities of Detroit and Grosse Point. But the state is also home to a number of American Indian tribes and the largest Arab community in the US. While three quarters of the state's 10 million residents are clustered in a few metropolitan areas, the remainder is scattered across a wide geographic area that includes some of the more rural and ruggedly beautiful sections of America. It takes as long to drive from Detroit, in the southeast corner of the state, to Washington, DC, as it does to drive from Detroit to the Upper Peninsula town of Calumet. Hunting and fishing are such an ingrained part of the state culture that the state public health laboratory routinely analyzes fish tissue for toxic chemicals, generating data that is used as the basis for fishing advisories.

The state is surprising in other ways as well. For 70 years the state of Michigan actively manufactured biological products; at various times turning out smallpox, rabies and anthrax vaccines. Although the state biologics facility was privatized in 1998—now BioPort Corporation®—the institutional culture that enabled such an operation to prosper is still in evidence. Frances (“Francie”) Pouch Downes, director of the Michigan public health laboratory, explained that “research was always part of the mandate here and they recruited people who were interested in it.”

Practicing Innovative Science
That interest is reflected in a public health laboratory history rich with innovations, such as the development of the Khan test for syphilis and the initial isolation of pathogenic E. coli (stemming from research on infantile diarrhea). This inquisitive, solution-focused approach to laboratory practice continues under Downes’ leadership today. The Michigan public health laboratory was among the first five state laboratories to acquire Level III test capabilities for chemical terrorism and is one of only two public health laboratories performing tuberculosis genotyping in the US.

Recently, the laboratory has been exploring ways to address contemporary health challenges ranging from obesity to a growing shortage of skilled laboratory scientists. Identifying a role for the public health laboratory in these non-traditional areas has placed Downes’ shop in the forefront of a trend—some might say paradigm shift—that takes laboratory scientists away from the bench and out into the community.

Exploring the Lab’s Role in the Obesity Crisis
Consider obesity. Michigan suffers the third highest obesity rate in the nation; 60% of state adults are either overweight or obese. The state public health laboratory is responding in two ways. Since 1992 it has provided doctoral-level scientists to serve as the CLIA directors of local public health laboratories that perform glucose monitoring, cholesterol screening and related tests. The state-level scientists provide quality assurance oversight and leadership to assure continued CLIA certification and a high caliber of service in support of public health prevention and awareness programs. Downes herself is the CLIA director not only for the state public health laboratory, but for the local public health laboratory serving the Grand Rapids area.

“The other thing we’re doing,” said Downes, “and I hope we’ll be getting into more, is helping to promote statewide best practices for testing of public health significance that is done in clinical labs.” Currently the state public health laboratory is training clinical laboratorians to calculate glomerular filtration rates (GFRs) using a formula that hinges on creatinine, a value that clinical laboratories routinely generate. Downes said the GFR is a good measure of the progression of kidney failure—often associated with obesity and with
obesity-related diabetes—and can be used to identify people at risk of needing future dialysis. The idea is to catch the disease progression early on when diet and exercise might prevent irreversible kidney damage. Downes emphasized that the state public health laboratory doesn’t do any of the testing involved. Rather, the state’s role is “to work with the clinical lab community to develop (the GFR) as a best practice.”

Helping Fend Off Drug-Resistant Bugs

Another topic that has propelled state scientists to work closely with the private sector is Staph. The Michigan public health laboratory detected the first case of vancomycin-resistant \( \text{Staphylococcus aureus} \) (VRSA) in the world and the state has been home to four of five VRSA cases reported in the US. “I like to think we have such good relations with our clinical labs that we found out about VRSA sooner [than other states],” said Downes, “but I’m beginning to think something else is going on because we’re isolating it at regular intervals and other states aren’t.”

To address the problem, the laboratory used a small pot of National Laboratory System grant money to develop a series of antibiograms—lists of the bacteria circulating within healthcare facilities and the drugs-of-choice to kill them. Even before laboratory tests reveal the exact strain of the bug infecting patients, clinicians can use the antibiogram as the basis for deciding the first round of treatment.

Recruiting Young Students

Workforce problems have been yet another stimulus for creative problem-solving and partnering. The Michigan laboratory has 146 full-time employees and about eight vacancies; four of them stemming from recent retirements. Two of the vacancies are at the doctoral level and, said Downes, “that’s where we’re finding it most challenging to recruit.” Facing not only a state, but a national shortage of laboratory scientists—and the closure of several laboratory training programs in Michigan—Downes and her staff realized some years ago that proactive measures were necessary to meet the laboratory’s future staffing needs.

Thus, in 2002 the state laboratory—based in Lansing—began working with nearby Michigan State University and other institutions with clinical laboratory education programs to develop a tool to interest high school students in laboratory science careers. The tool includes a model curriculum and teaching materials and has been distributed to thousands of high school teachers across the state.

For those students who pursue clinical laboratory science training and for practicing laboratory professionals, the Michigan public health laboratory offers mini-internships lasting anywhere from one day to two weeks. Students rotate through the various testing labs, attend meetings and, said Downes, “get a better perspective on how work the clinical labs do ties in with public health laboratory work and with disease control.”

Facing Down a State Recession

But some problems have proved more intractable than others, even for the forward-thinking staff at this laboratory.
The downsizing of the three big US motor companies, for example, has rippled through the state economy right to the doors of the public health laboratory. “We’re in a recession; we’ve been in a recession,” said Downes. With a state unemployment rate that exceeds the national average and recent news of massive Ford Motor Company layoffs, state funding is becoming less and less secure.

More than a third of the public health laboratory’s $21 million annual budget now comes from the state in the form of either general or restricted funds. While Downes noted that federal funding has been generous, she said, “The problem is that it’s extremely categorical.” Thus, Downes is looking for ways to up the roughly $4 million the laboratory collects annually in fees (much of it now coming from newborn screening).

Without additional funds, some vacancies may have to go unfilled and a much-needed expansion of the laboratory’s Hepatitis C testing program may have to wait.

Fortunately, Downes’ background reveals an adventurous streak that makes her particularly well-suited to provide vision and leadership in such a challenging environment. After earning a degree in medical technology, the Indiana native joined the Peace Corps, where she became interested in public health while working in a hospital laboratory in Niger. Two years later she returned to the US, earned a graduate degree from the University of North Carolina at Chapel Hill, worked for a few years as a scientist in the Michigan public health laboratory and then went back to Africa—this time with a husband and three young children. Upon her second homecoming, Downes resumed work at the Michigan laboratory and became its director in 1999.

Today, her interest in the African continent is satisfied through work with the APHL Global AIDS Project, which has enabled her to make several trips to Botswana for laboratory capacity assessment and training. The Michigan public health laboratory is also hosting a visiting scientist from the Ivory Coast.

Despite funding and staffing challenges, Downes has plenty of exciting developments to distract her, such as a new modular all-hazards laboratory and the beginning of some investigational work to carve out a role for the laboratory in the growing field of genomics. All in all, she said, “I love my job. I think I have the best job anywhere—ever. I have the best people to work with. I’m right in the middle of everything that happens in terms of health. I like living in Michigan. It’s a perfect fit.”

“Students rotate through the various testing labs, attend meetings and, said Downes, “get a better perspective on how the clinical labs do ties in with public health laboratory work and with disease control.””

The APHL Minute

Fellowships

Continued from page 16

in December in Honolulu, Hawaii. Lee works in the California Department of Health Services.


Gillian Genrich presented a poster at the 1st International Conference of the Journal of Travel Medicine and Infectious Disease in London in November. “Post-Mortem Diagnosis of Plasmodium falciparum in Four Travelers Using a Novel Immunohistochemical Assay Targeting Histidine-Rich Protein-2” was based on her work in CDC’s Division of Viral and Rickettsial Diseases.
Member News

New APHL Institutional Members
Since extending institutional membership to local public health and state environmental and agricultural laboratories in 2005, many new and 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
Corpus Christi-Nueces County (TX) Health Department Laboratory, Sandra Heatherley
Los Angeles County (CA) Public Health Laboratory, Sue Sabet, PhD
Placer County (CA) Public Health Laboratory, Sharlet Elms
San Mateo County (CA) Public Health Laboratory, Bruce Fujikawa, DrPH

Member Notes
Research conducted by the Marion County (IN) Public Health Laboratory was included in February's *Journal of Occupation and Environmental Hygiene*. The article, “Blood Lead Levels in NASCAR Nextel Cup Teams,” examined whether NASCAR drivers and team members had elevated blood lead levels due to exposure to exhaust emissions. APHL members Matthew Matusiak and Jyl Madlem are two of the article's authors.

Board of DirectorsMeets with Top CDC Officials, Tours New CDC Facility

APHL’s Board of Directors convened in January at CDC’s new Global Communications Center in Atlanta. The board met with CDC officials to explore how the agency’s reorganization will affect public health laboratories and the association. Throughout the meetings, the board emphasized the need to minimize the impact of funding shortages on state grant programs that support critical public health laboratory functions, while CDC representatives cited federal budget challenges as the cause for the funding cuts.

Representing APHL committees, board members met with center and division-level representatives to delve into programmatic issues. The group also met with Dr. Julie Gerberding, CDC director, to discuss the need for a laboratory ‘home’ in the reorganization. Workforce development issues and informatics were also addressed. Gerberding expressed her appreciation to APHL for its leadership in public health and its continuing patience with the CDC reorganization. The board also enjoyed tours of the new BSL-4 laboratories and the soon-to-be completed Director’s Emergency Operations Center.

In its official business meeting, the board approved the association’s overarching strategic plan for 2006-2009, devised a yearly calendar for governance activities, and received the annual audit report. At the meeting, board members also met with representatives of the HHS Office of the Inspector General, urging them to investigate reagent shortages, barriers preventing local, state and federal agencies from communicating and coordinating with each other, the various definitions of surge capacity, and the all-hazards approach to preparedness. Lastly, a proposed strategic partnership between the George Washington University Schools of Medicine and Public Health and APHL was discussed. The board moved forward the GW proposal, which will be developed further in the spring. The partnership would provide international laboratory training and assistance.

Later in January, the board also met by conference call and endorsed the laboratory director and laboratory manager competencies developed by the competency task force. They also approved a new policy to extend committee member terms to three years.

APHL Annual Business Meeting
Westin Hotel
Long Beach, CA

Sunday, June 4, 2006
1:30pm-4:30pm

This constitutes official notification to APHL members. The purpose of this meeting is to discuss items of strategic importance to APHL.

Awards Luncheon
This year all APHL honors and awards will be presented at a luncheon, rather than at the business meeting. Please mark this special event on your calendar!

Tuesday, June 6, 2006
12:00pm-1:30pm
Staff News

Charles Green has officially come aboard as senior accountant following a temporary appointment to the accounting department. A graduate of Florida International University, Green worked exclusively in accounting prior to accepting the position at APHL.

Jeremy Gillissen, JD, resigned his position as food safety program manager to pursue a career in civil rights law. APHL wishes him luck in his future endeavors.

Diane Johnson, MPH, recently resigned her position as global health program manager to pursue a position at the National Institutes of Health. Johnson has been resolute in managing the complexities of assisting countries from Haiti to Botswana in their efforts to improve laboratory services for HIV/AIDS prevention and treatment. APHL wishes Johnson the best in her new post.

Anne Ramos recently joined APHL as the new global health program coordinator following several weeks as a temporary employee. Ramos received her bachelor’s in political science from Texas Christian University in Fort Worth, TX, and speaks English, Spanish, French, Italian and Portuguese.

APHL Sustaining Member Program

The following corporations partner with APHL to support the nation's public health laboratory system.

Diamond Partners

- GEN-PROBE
- Applied Biosystems
- STARLIMS

Platinum Partners

- BD
- Bio-Rad
- Cepheid
- Smiths
- ChemWare

Gold Partners

- BD
- Bio-Rad

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The Association of Public Health Laboratories (APHL) is a national, non-profit dedicated to working with its members to strengthen public health laboratories. By promoting effective programs and public policy, APHL strives to provide public health laboratories with the resources and infrastructure needed to protect the health of US residents and to prevent and control disease globally.

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