APHL Helps Speed Deployment of Lab Tests During Public Health Crises

Regulatory Burdens Still Frustrate Labs

When crises loom, public health laboratories now have more leeway to deploy newly developed diagnostic tests to safeguard public health. Thanks to an effort spearheaded by APHL, laboratory tests for novel new pathogens, such as monkey pox and SARS, can be temporarily performed to prevent or respond to infectious outbreaks even when it is not possible to comply with all of the requirements of the Clinical Laboratory Improvement Amendments (CLIA)—the principal federal legislation that regulates testing in clinical laboratories, those that perform human medical tests.

The temporary exemption from CLIA rules—detailed in new CLIA surveyor guidelines released by the Centers for Medicare & Medicaid Services (CMS) in January—is the product of a collaborative effort by APHL and partners at the CDC and CMS to resolve an increasingly common conundrum with serious public health implications. Dean Willis, an APHL member who helped draft a policy statement last summer calling for ways to streamline the transfer of new testing technology, said in seeking the exemption APHL was “trying to head off a train wreck before it happened.”

Crossing CLIA’s Regulatory Hurdles

Under normal circumstances CLIA mandates that diagnostic tests pass two regulatory hurdles; one related to initial test performance, the other to ongoing quality control. Each time a CLIA-certified laboratory brings a new test on-line it must demonstrate that:

• The new test performs as well in its unique setting as in the laboratory where the test was developed.
• With routine usage, the test continues to meet high quality standards—such as producing few false-positive and false-negative results.

To verify test performance, however, laboratories must have adequate control materials. Depending on what the particular assay or test system is designed to detect, these materials might include anything from human blood samples or other specimens known to be infected with the microbe of interest to samples of a biological product the microbe produces to actual genetic material from the targeted pathogen. If the microbe is widespread and many individuals are infected, control materials are relatively easy to come by. However, if few human cases are documented—as is typical with emerging infectious diseases and cases of targeted biological terrorism—control materials are likely to be scarce.

Mitigating Regulatory Problems, continued on page 4
PRESIDENT'S THOUGHTS

PulseNet Vital to Public Health Laboratories

PulseNet, a hallmark of CDC's National Center for Infectious Disease, exemplifies the essential role our public health laboratories play in protecting the public's health. This highly successful network, designed to identify and investigate local, state, national and international outbreaks of food borne infectious disease, depends upon the continuous generation of reliable analytical data by our public health laboratories. This is a laboratory function that is purely public health.

In contrast to diagnostic testing for patient care, the role of our public health laboratories in PulseNet is strictly population-based surveillance. Our laboratories are responsible for providing the critical data needed to detect possible outbreaks that may require public intervention for control and public policy development for prevention. Due to this work, it has become possible to detect outbreaks of infectious disease much earlier, allowing rapid implementation of effective prevention and control measures that markedly reduce widespread illness, untimely death, and excessive costs attributable to medical treatment and loss of productive work time. This is a remarkable state and national system.

While reliable, standardized data from our public health laboratories are central to the success of PulseNet, other key factors are equally important. Collaborative partnerships, real-time analysis, effective communication and immediate case investigation are all essential. Clinical laboratories serve the physicians that see the patients from which isolates of infectious agents are obtained. Veterinary laboratories serve veterinarians and isolate microbes that may also involve human patients. These are the collaborative sentinel laboratories that provide the microbial isolates that make the analytical surveillance work of our public health laboratories possible.

For this surveillance work to be useful in detecting outbreaks early, our public health laboratories must be able to conduct these analyses daily, in real-time. In addition, the data generated by our laboratories must be communicated in a manner that is useful to our second group of collaborative partners, the infectious disease epidemiologists. Real-time data, presented so as to reveal trends and clusters of genetically related organisms suggestive of a common source outbreak, is what epidemiologists need to focus their case investigation. Finally, and of critical importance, the data generated by our public health laboratories must be investigated in immediately.

The key factors that determine PulseNet success may be obvious, but they are not easily achieved. While the network now includes all of our state public health laboratories, the level of intra-state development varies considerably. While all of our laboratories have the technical capability to analyze isolates for genetic relatedness, there remains a serious deficiency in the capacity of some states, not only for laboratory analyses in real-time, but also for epidemiological investigation of cases in real-time. There remains a serious lack of resources for laboratory and epidemiology staff. Since the laboratory work required for PulseNet is for prevention and not treatment, a diagnostic testing fee cannot cover the cost. Instead, because the activity is purely for public health, it must be funded as public health by state and federal resources.

PulseNet has proven effective in detecting outbreaks of food borne illness. It also has future potential in the areas of invasive infectious disease and bioterrorism investigation. Because of its extraordinary public health utility, our states and the nation will be served well by providing the resources needed to bring all of our laboratory and epidemiology programs up to a level of maximum effectiveness. To be all it can be will require that PulseNet functions every day in every state to detect and investigate an ever increasing number of infectious disease outbreaks that threaten the public's health.

Sincerely,

Norman A. Crouch
Executive Director’s Note

Crisis Planning Essential to Weathering Potential Storm

Have you ever wondered if those preparedness plans will ever be put to use? As leaders of laboratories that deal with new and emerging threats almost daily, I imagine that you would nod your head.

In the past few years, APHL has invested considerable time, effort, and resources to develop preparedness plans covering a range of scenarios. We have a plan for an emergency in our immediate facility, another for a national or regional crisis, and still another for a national crisis in which our members are involved, for example, the anthrax attacks, ricin-tainted letters. The fourth and final plan for business continuity is now under development. When completed, it will ensure that we can provide the core services now expected by our members, even in times of crisis. This plan provides for backup servers, offsite data storage and alternate work stations for our staff.

I’ve always hoped that we would never have to implement any of these plans, but that changed a few weeks ago. Let me explain. Late in the day on February 5, we learned that the FDA had obtained a court order authorizing U.S. Marshals to seize materials used in neonatal screening at the PerkinElmer facility in Norton, OH. Over the course of the next few days, word began to filter in from state laboratories that a lengthy delay in product delivery would severely impact certain, highly critical newborn screening assays. Some labs reported mere days’ worth of reagents and other materials.

Quickly we realized that we had a national crisis on our hands, and it wasn’t in the area we would have expected it. Public health laboratories, and APHL for that matter, have become better prepared for bioterrorism, other manmade threats and emerging infectious diseases—but a crisis in newborn screening?

Unlike the anthrax crisis, the SARS outbreak or recent events with ricin, there was no public outcry and barely a ripple of media coverage in response to the PerkinElmer seizure. Despite the lack of publicity, we knew that this was a national public health laboratory emergency of a regulatory nature which had never been encountered before. The chairman of the APHL newborn screening and genetics committee, Dr Ken Pass likened this experience to a natural disaster—it came on quickly, could have devastating and even deadly effects, and its path was unpredictable.

As we go to press, APHL’s newborn screening committee is meeting to tackle new issues such as a reliable supply chain, communication vehicles to connect newborn screening laboratory personnel, and quality assurance across the newborn screening system.

I’m pleased to report that our planning helped us through the storm. Although I never took our national member crisis plan off my bookshelf, we put it into place quickly. Fact collection and verification was job number one. Next we identified roles for key staff and members, kept each other informed, and communicated what we did know to the membership. We gathered and reported out offers of assistance from member states, the private sector and other suppliers. Mostly we worked furiously behind the scenes to ensure that the voice of our members was heard. Time was the critical factor. We were called on for technical assistance and had 15 minutes to gather the technical team, which we did in 10 minutes. When asked to provide written input ASAP, we did it within an hour; and when we were contacted by the press, we made ourselves available. At each step of the way, we assessed where we were, and finally, when a resolution was at hand, we concluded with a “lessons learned” session.

Unfortunately, newborn screening, for all of its inherent value, is yet one more unknown public health program. We estimate that state public health laboratories account for approximately 97% of the newborn screening done in the U.S.—which means that APHL members have touched the lives of virtually every American born in the past 40 years.

Newborn screening is an awesome responsibility and one we take very seriously. Just like preparedness planning. You never know when it will be put into action.

Public health laboratories: Analysis, Action, Answers.

Sincerely,

Scott J. Becker, MS
Until early this year, laboratorians had few options when control materials were unavailable. They could either forego testing in the midst of an emergency or, as Willis’ lab in the Florida Bureau of Laboratories did when SARS was a threat, carry on while making a good faith effort to verify test performance and hope that CLIA inspectors understand the urgency of the situation.

New Guidelines Offer Alternate Methods
Now these good faith efforts have official sanction. The new CLIA surveyor guidelines list several alternate mechanisms that laboratories can temporarily employ to ensure accurate test results when control and calibration materials are in short supply. For example, alternate quality control methods [listed in section §493.1256(h) and posted at www.cms.hhs.gov/clia/apcsork1.pdf] include:

- Splitting specimens for testing by another established method or in another laboratory.
- Using previously tested specimens (both positive and negative specimens that have been tested in duplicate) as surrogate controls.
- Testing multiple specimen types (e.g., saliva, urine, blood) from the same patient.
- Performing serial dilutions of positive specimens to confirm positive reactions.
- Providing additional supervisory review of results prior to release.

SARS, in particular, highlighted problems with the previous CLIA requirements. The SARS diagnostic test developed by the CDC detects human antibodies to the virus and, therefore, requires antibody-containing blood specimens as a control. But very few U.S. residents were infected with the disease. Most SARS-positive blood specimens were collected in Asia and were not readily available to American laboratories.

At the same time, Jan Nicholson, the associate director for laboratory sciences at CDC’s National Center for Infectious Disease, explained that because the test was created with limited access to clinical specimens, “when we deployed those assays, we couldn’t tell (laboratories) very much about the performance of the test. We didn’t have that luxury at the time.”

Thus laboratories were missing both the base performance specifications and the control materials needed to comply with CLIA regulations. Yet Nicholson averred, “It was in the public health interest to deploy those assays when we did.” Indeed, Jane Getchell, chair of APHL’s Infectious Disease Committee and director of the Delaware state laboratory, said her lab was under pressure from the press, from public health authorities and from physicians to deliver test results quickly despite the problems with the testing technology and with CLIA compliance. “It was really frustrating,” she said.

Nancy Anderson, a senior CDC health scientist who helped draft the CLIA exemption language together with staff from APHL and CMS, acknowledged that it was “obvious that it was not always possible to meet the regulations when there was an emergency and new testing was being conducted.” The new guideline, she said, is “definitely a good thing.”

Still a Tangle of Regulations
But despite this important step forward, public health laboratories are still struggling to work in an environment of multiplying and sometimes overlapping state and federal regulations. A wrinkle in the SARS story, for example, involves the U.S. Food and Drug Administration (FDA). Because the CDC could not provide definitive performance specifications for the test, the FDA could not approve it for routine use. Steve Gutman, director of the agency’s Division of In Vitro Diagnostics, said “you couldn’t pretend (the SARS test) was a pedigreed test.” However, he said the agency recognizes that emerging and biothreat pathogens pose regulatory challenges. “Osama bin Laden isn’t inclined to work with us on clinical trials,” he noted. But, he said, “the questions that we ask to underpin our regulatory program are actually the questions that anyone in their right mind would want to ask before using the test.”

In the case of SARS, Gutman said, the FDA had “fairly reasonable assurance” that the test measures what it intends to measure. Outstanding questions related to how the test affects people included its cross-reaction with any non-SARS nucleic acids or antibodies, yielding false positives, its possible failure to pick up all true positives, or when in the course of disease a positive result is rendered.
Under these conditions (and given the dire circumstances) the FDA was willing to grant an investigational device exemption, which, explained Gutman, “allowed broad access to the assay, but in an informed and controlled manner.” The test was labeled so that users understood the nature of what was known about it. It was largely deployed in public health labs, which have high quality standards. And it was deployed under strict institutional review board (IRB) oversight, with informed patient consent whenever possible.

In practice, though, some of these measures proved problematic. Nicholson noted that test deployment was delayed while the CDC sought the imprimatur of its internal IRB. “They thought (the test) was research. We had to convince them that no, it’s not,” she said. Even after the CDC gained IRB approval, several state laboratories were required by state law to go through an independent IRB review process before using a non-FDA-approved diagnostic device.

Getchell noted separately that “the whole informed consent process was just a real incredible mess.” Physicians, she said, didn’t know where to get informed consent forms and often failed to give them to patients. Her lab’s experience with the West Nile virus test—which was also put into use under experimental conditions—was “a whole lot easier,” Getchell recalled, since no IRB involvement was required. Nonetheless, test deployment was delayed again because of government oversight as the U.S. Department of Agriculture required laboratories to obtain permits before they could import West Nile virus samples from CDC labs.

**Select Agent Rules—An Endless Process**

Perhaps the most onerous—and costly—new regulations for public health laboratories are the federal select agent rules. Enacted in the wake of the 2001 anthrax attacks, the rules require laboratories that handle high-consequence organisms—i.e., select agents such as anthrax, ricin, or smallpox—to implement strict security measures, undergo inspections, and limit access to select agents to identified staff members who have undergone background checks through the Federal Bureau of Investigation (FBI).

Willis said that one staff member devoted at least half of his work hours over a period of 18 to 24 months to bring the Florida public health laboratory into compliance with the law. Getchell reported that one staff person worked virtually full time for four months on select agent certification for the relatively smaller Delaware state laboratory.

And the process is literally never-ending. “Every time a new agent comes down the pike, and every time somebody leaves or somebody new comes on board, you’ve got to submit an amended form,” said Getchell. (For example, until recently public health laboratories anticipated no need to acquire highly pathogenic avian influenza virus, which is on the USDA select agent list. If laboratories need virus samples in the future, they will have to modify their select agent applications—a process that can take weeks to complete.)

While Willis acknowledged that many of the select agent precautions are “a good idea,” he said that they become unnecessarily burdensome when the rules are applied to what should be considered normal work. For example, the Florida public health laboratory routinely tests for Brucella, a bacterium that is passed from animals to humans and is endemic in Florida because of the state’s large agricultural base. Willis’s lab has historically received one to two Brucella isolates each month for confirmatory testing. “Now,” he said, “we have to do a lot more because it’s on that (select agent) list.” The referring hospital must transfer or destroy the suspected isolate within seven days. And the state public health laboratory must create a paper trail documenting where the isolate originated and how it was disposed of. Yet, said Willis, “It’s not a BT (bioterrorism) event.”

Moreover, because Brucella infects animals as well as humans, Brucella testing is also regulated by the USDA. Even if a lab is approved by the CDC select agent program to handle Brucella, it must still obtain a USDA-Veterinary Services import permit for animal pathogens to get appropriate test reagents and controls. “Everybody wants to have control,” Willis said. “We have to figure out where the lines are drawn in the sand.”

**Standards for Legally Admissible Evidence: Frye, Daubert, Other?**

Finally, although public health laboratories have always
had to deal with criminal law in a limited fashion, criminal considerations have become much more prominent in the post-9/11 world. Today, every time a laboratorian tests an unknown white powder, she must be mindful of federal and state rules defining legally admissible scientific evidence.

The two major sets of rules in use are Frye and Daubert, named after plaintiffs in two federal court cases. The Frye standard (established in 1923 and adopted by Alaska, Arizona, California, Colorado, Florida, Illinois, Kansas, Maryland, Mississippi, Missouri, Nebraska, New York, Pennsylvania, and Washington) merely dictates that the method of scientific analysis be “sufficiently established to have gained general acceptance in the particular field in which it belongs.” The Daubert standard (established in 1993 and adopted by the federal government and Connecticut, Indiana, Kentucky, Louisiana, Massachusetts, New Mexico, Oklahoma, South Dakota, Texas, and West Virginia) sets more stringent and specific criteria. It stipulates that an applicable technique be rigorously validated, preferably by more than one laboratory, that it be published in a peer reviewed journal, that its potential error rate be defined and that it be explicable in a court of law.

But not all jurisdictions use Daubert or Frye. The U.S. military and a handful of states (Arkansas, Delaware, Georgia, Iowa, Minnesota, Montana, North Carolina, Oregon, Utah, Vermont, and Wyoming) have separate criteria. For cases potentially involving state and federal jurisdiction, in which the legal venue is unclear, laboratories may have to meet multiple standards of admissibility, suggesting that validation testing and performance criteria always meet the highest legal standard.

Pending Legislation Could Reduce Regulatory Burden

Fortunately, as illustrated by the new CLIA exemption, federal officials do seem aware of the increasingly complex environment in which laboratories must function. If enacted, the Project Bioshield Act (Title II of S.15) could drastically reduce regulatory burdens in times of crisis. The bill grants certain federal officials the power to temporarily authorize the use of an experimental device to “detect, diagnose, treat, or prevent” illness during public health emergencies when alternatives are unavailable. Although introduced in March 2003, it has not yet been scheduled for floor debate in the Senate.

Asked if he had any message for laboratorians, the FDA’s Gutman said, “What folks need to do is to talk to us. They’d be surprised at how strong our mutual scientific bridge is. And surprised at the flexible regulatory tools we have that may be applied.”

In the meantime, Getchell said, “I don’t expect (regulations) to go away. I’ve been in the laboratory business a long time and I remember when CLIA first came into being and many of us thought that it was unnecessary. Hindsight would tell me in fact that it has been very valuable and I would expect the same for these new regulations.”

But she implored, “Help us to work through them all. Quite frankly, figuring out what we’re supposed to do to comply is a struggle.”

Emergency Preparedness

Secretary’s Council on Public Health Preparedness Meeting

APHL staff Scott Becker, Doug Drabkowski, Chris Mangal and Jennifer Liebreich attended the Secretary’s Council on Public Health Preparedness meeting on January 22-23, 2004, in Washington, DC.

On October 22, 2001, under the authorization of the Public Health Service Act, the Secretary of Health and Human Services (HHS) established the Secretary’s Council on Public Health Preparedness. The purpose of the council is to advise the HHS Secretary on necessary actions for the proper preparation and response to public health emergencies. The council typically addresses issues such as:

- Public health infrastructure, to better enable federal, state and local response to a public health emergency, specifically, a bio-terrorism event
- Comprehensive contingency plans to respond to a public health emergency, specifically, a bio-terrorism event
- Public health preparedness at the federal, state and local levels

D.A. Henderson, MD, MPH, chairman of the council, welcomed the participants to the two-day meeting. The agenda was centered upon pending bioterrorism legislation, modeling initiatives, research and development progress at NIH, BioSense, state and local preparedness programs, Laboratory Response Network activi-
ties and education and training programs at the state and local levels.

BioShield Legislation
Stewart Simonson, Esq., Special Counsel to the Secretary, Office of the Assistant Secretary for Public Health Emergency Preparedness (OASPHEP), and Phillip Russell, MD, Acting Director, Office of Research and Development Coordination, OASPHEP, provided an update on the BioShield legislation. Though Congress has not approved the bill, Simonson said that he is hopeful that in late spring it will pass. Project BioShield contains several major initiatives, including an approximately $6 billion incentive for drug companies to develop otherwise unprofitable medicines, vaccines and countermeasures to combat biological weapons. According to Simonson, this funding has been approved by Congress and is considered separate from other BioShield legislation. Under debate on Capitol Hill are portions of the plan that allow the executive branch to use unlicensed drugs in the event of a biological terrorist attack and loosen restrictions on drug procurement and hiring at the National Institutes of Health (NIH).

Research and Development at NIH
Anthony Fauci, MD, Director, National Institute of Allergy and Infectious Diseases (NIAID), provided an update on biodefense research and development activities at NIH. Funding in this area has continuously increased since 2001; in fiscal year 2004, NIH received $1.625 billion for biodefense research. Biodefense research priorities include basic research, therapeutics, genomics, diagnostics, development of new vaccines, and expansion of research capacity. In order to further research capabilities, NIAID released a broad agency announcement for grant applications and contract proposals for the establishment of regional and national biocontainment laboratories. To date, the agency has approved two national biocontainment laboratories, Boston University and University of Texas Medical Branch at Galveston, and nine regional laboratories across the country.

Laboratory Response Network (LRN)
Richard Kellogg, MS, Laboratory Response Network Coordinator, Bioterrorism Preparedness and Response Program at CDC, provided an update on LRN activities. In 1999, CDC, APHL and the FBI founded this network of laboratories to respond quickly to biological terrorism events. Since then, the network has responded to emerging infectious diseases, like SARS, and more recently chemical terrorism events. David Ashley, PhD, Chief, Emergency Response and Air Toxics Branch, Division of Laboratory Sciences at CDC, summarized the integration of chemical terrorism planning into the LRN. In addition to describing successes and challenges, Kellogg and Ashley provided an overview of funding and other response activities in support of the public health preparedness goals.

Council member, Mary Gilchrist, PhD, Director of the University of Iowa Hygienic Laboratory, stressed the need for protocols on the testing of environmental samples. Council members discussed the current lack of evaluation on handheld devices; in response, Ashley stated that the National Center for Environmental Health (NCEH) has a report on the evaluation of handheld devices and will share it with various federal agencies. The council also requested a report on NCEH’s interaction with poison control centers and first responders.

Emergency Preparedness Education and Training Activities
Lily Engstrom, MS, Director, Office of State and Local Preparedness, OASPHEP, discussed the need for laboratory workforce development. She emphasized that continued training of the existing workforce is critical and advised the council to address workforce shortages in all levels of the public health laboratory. Engstrom and other education professionals discussed minimizing redundancies in emergency preparedness training activities. She raised a number of issues to the council, including the need to identify gaps in workforce development and the role of the Academic Centers for Public Health Preparedness. Engstrom asked the council for guidance on whether to engage professional associations, such as the Council of State and Territorial Epidemiologists (CSTE) and APHL, in the efforts to address training gaps.

At the public discussion forum, APHL’s Executive Director Scott Becker called on the federal government...
to increase resources for environmental microbiology testing at CDC. He also emphasized the importance of addressing terrorism preparedness from an all-hazards perspective; policymakers need to improve resources for chemical, biological and radiological terrorism planning. Becker called for capital improvement funding for public health laboratories. These dollars would go towards construction of new facilities and renovations of existing structures.

APHL continues to track the BioShield Act and will inform members of any legislative action. For more information on APHL’s public affairs and policy program, please contact Peter Kyriacopoulos, director of public policy, at pkkyriacopoulos@aphl.org. For information on the Laboratory Response Network and emergency preparedness program activities, please contact Chris Mangal, emergency preparedness and response program manager, at cmangal@aphl.org.

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**CDC’s 8th National Symposium on Biosafety**

The American Biological Safety Association (ABSA) sponsored the 8th National Symposium on Biosafety, January 24-28, 2004, in Atlanta, GA, entitled *Biosafety and Biosecurity: A New Era in Laboratory Science*. Approximately 450 federal, state and local public health laboratorians discussed crisis communication skills, biosecurity considerations, threat vulnerability and risk assessment strategies, and security issues for high containment facilities. Program highlights are listed below.

**Biodefense Research Efforts**

Janet Nicholson, PhD, Associate Director for Laboratory Science of CDC’s National Center for Infectious Diseases, moderated an emerging issues session. Ernest Takafuji, MD, MPH, Director of the Office of Biodefense Research Affairs in the Division of Microbiology and Infectious Diseases at the National Institutes of Health (NIH), surveyed NIH’s efforts to establish the Centers of Excellence in Biodefense Research and Emerging Infections. He also discussed the planned construction of biosafety level 3 and 4 facilities that support continued research efforts. The National Institute of Allergy and Infectious Diseases (NIAID) has accelerated its biodefense research activities since the fall of 2001, resulting in a steady expansion of biodefense research infrastructure capabilities in the US.

**Biosafety in State Public Health Laboratories**

Norman Crouch, PhD, Director, Minnesota Public Health Laboratory and APHL President delivered a presentation on biosafety in the state public health laboratory. Crouch outlined the role of public health laboratories in detecting and investigating bioterrorism agents and other emerging infectious diseases. He emphasized that an all-hazards approach is essential for preparedness since public health laboratories routinely process unidentified specimens that could be infectious, toxic, or radioactive. Crouch also reviewed lab safety requirements and the accompanying challenges in ensuring that proper levels of biosafety and biosecurity are maintained in the public laboratory.

**Laboratory Response Network**

Michael J. Miller, PhD, Chief, Laboratory Response Branch, Bioterrorism Preparedness and Response Program at CDC, provided an overview of the Laboratory Response Network (LRN) and held it up as a model for preparedness. In 1999, CDC, APHL and the FBI aligned this network of laboratories to respond quickly to biological and chemical terrorism events. Currently the LRN includes state and local public health, veterinary, food, military and international laboratories. Miller also provided a list of CDC/LRN contacts for each state and discussed the APHL-proposed integration model of the LRN.

**Revising Biosafety in Microbiological and Biomedical Laboratories (BMBL)**

CDC and NIH have initiated a collaborative project to revise the 4th Edition of BMBL. The planned publication date of the 5th Edition is April 2005. Emmett Barkley, PhD, Director of Laboratory Safety, Howard Hughes Medical Institute, reviewed the history of the BMBL and described the process for updating the revised edition. Proposed changes include a chapter on biosafety, an emphasis on risk assessment and agent summary statements. The agent summary statements will focus on organisms that are known to have caused laboratory-acquired infections. A public workshop will be held at NIH in late March 2004.

**Select Agent Regulation and Inspection Process**

Shanna Nesby-O’Dell, DVM, MPH, Chief, External Activities Program, CDC Office of Health and Safety, moderated a session on the impact of the Select Agent regulation. Mark Hemphill, MS, Chief of Policy at
CDC’s Select Agent Program, discussed the requirements for the possession, use and transfer of select agents and toxins (42 CFR Part 73). Hemphill provided a legislative history of regulation of biological agents and toxins and outlined the general requirements of the Select Agent Rule, including exemptions and exclusions.

James Blaine, PhD, Chief of Operations at Constella Health Sciences, provided an overview of the CDC Select Agent Program inspection process and informed participants of an upcoming workshop entitled, How to Prepare your Laboratory for a Select Agent Inspection. It will be held May 23, 2004, at the American Society for Microbiology (ASM) general meeting. Because participants noted the lack of coordination between the Animal and Plant Inspection Service (APHIS) at the USDA and the Select Agent Program at CDC, Hemphill and Blaine assured them that the two agencies are working to coordinate and prevent duplicate efforts.

APHL staff will continue to monitor the Select Agent Rule and provide guidance to members. For more information on APHL’s Emergency Preparedness and Response program, please contact Ms. Chris Mangal, program manager for emergency preparedness and response, at cmangal@aphl.org.

**GLOBAL HEALTH**

APHL Gears Up for PEPFAR

In the developing world, and particularly in Africa, AIDS threatens peace and stability as it wipes out entire generations, orphans whole communities and cripples nations. According to UNAIDS an estimated three million people died from AIDS last year, and it is expected that at least another 68 million will die in the next two decades.

In his 2003 State of the Union Address, President Bush announced an Emergency Plan for AIDS Relief (PEPFAR). The plan provides $15 billion, including nearly $10 billion in new funding, to fight the HIV/AIDS pandemic over five years, focusing on 14 of the hardest-hit countries in Africa and the Caribbean. Specifically, the initiative is intended to prevent 7 million new infections, treat 2 million HIV-infected people, and provide care for 10 million HIV-infected individuals and AIDS orphans.

To meet these goals, CDC has partnered with APHL to assist in strengthening laboratory services in Africa related to routine testing, surveillance, and care and treatment of the HIV-infected. Specifically APHL will procure laboratory equipment, provide consultation and training on HIV testing, TB, sexually transmitted and opportunistic infections, and offer training in quality assurance and laboratory management.

APHL members and global health staff have already begun working with counterparts in Rwanda, Botswana, Haiti, Cote d’Ivoire, Ethiopia and Mozambique and anticipate collaborating with CDC on activities in Guyana, Kenya, Namibia, Nigeria, South Africa, Tanzania, Uganda and Zambia over the next couple of years. Member participation in these activities will be vital to the success of laboratory-related programs. If you are interested in more information or would like to participate in this exciting initiative, please send inquiries to globalhealth@aphl.org.

**FOOD SAFETY**

Food Security Takes Center Stage in Washington

President Bush released his ninth Homeland Security Presidential Directive, “Defense of United States Agriculture and Food,” in February. Among other tasks, it calls upon the leaders of various federal departments to develop comprehensive surveillance and monitoring systems for animal, plant, and wildlife disease, food, public health, and water quality. It also directs the development of nationwide laboratory networks for food, veterinary, plant health and water quality that integrate existing federal and state laboratories and utilize standardized diagnostic protocols and procedures.

The same week, the President released the fiscal year 2005 (FY 2005) budget for the Food and Drug Administration (FDA). The budget included a large increase of $65 million, earmarked for strengthening the FDA’s role in a new, interdepartmental program for the defense of the nation’s food supply. The FY 2005 request would add 15 FDA-funded state laboratories to the 10 FDA laboratories planned for FY 2004. While the funding for the 10 laboratories has not yet been announced, it is expected that public health laboratories will be eligible to compete for those funds. Estab-
Establishment of a joint FDA-USDA Food Safety Inspection Service (FSIS) Food Emergency Response Network (FERN) of laboratories would cost $35 million. Once completed, FERN would encompass a nationwide network of federal and state laboratories capable of analyzing thousands of food samples for biological, chemical and radiological threat agents.

**FERN**

In recent months, representatives from state laboratories and key federal agencies have met to discuss the structure of FERN. Officials from the Departments of Agriculture, Commerce, Defense, HHS, Homeland Security, EPA and the FBI took part in discussions. State laboratory participants included Nick Cirino (Wadsworth, NY) Marion Aller (Florida Dept. of Agriculture), William Krueger (Minnesota Dept. of Agriculture) and Jim Pearson (Division of Consolidated Laboratory Services, VA).

Currently, the FERN structure includes a steering committee, an operations unit, and regional coordination centers (RCCs) in Georgia and Maryland. The RCCs will coordinate state and local laboratories in different regions of the country. FERN is now represented at the APHL/CDC LRN working group by steering committee co-chairs, Patrick McCaskey, executive assistant for laboratory operations at the USDA's FSIS, and John Marzilli, deputy associate commissioner for regulatory affairs in the FDA's Office of Regulatory Affairs.

FERN sub-committees serve in an advisory capacity, providing recommendations to the steering committee. FERN sub-committees include: Method Development/Validation; Surveillance (national food safety monitoring program); Training; Electronic Communication; and Proficiency Testing. State laboratory volunteers are sought for the sub-committees.

**Data Coordination**

The Booz Allen Hamilton Electronic Laboratory Exchange Network (eLEXNET) team met with representatives from FDA, CDC, EPA, USDA, state governments, APHL and other professional associations in January to discuss ideas for the National Laboratory Directory (LabDIR). The directory would allow a user to search laboratories by state and by capabilities. Bill Krueger noted this type of tool would help food safety and security officials to identify laboratories that can perform testing for non-traditional analytes (select agents). Public health laboratories are encouraged to join www.elexnet.com to keep abreast of food security activities.

To volunteer for a FERN sub-committee, or for more information on the food safety program, please contact Jennifer Liebreich, director of environmental health, at jliebreich@aphl.org.

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### Infectious Disease

**APHL Presents New HIV, STD, TB Programs**

Conscious of the growing need for association and laboratory coordination in the areas of HIV, STDs, and TB, the National Center for HIV, STD, and TB Prevention (NCHSTP) provided APHL with funding for a position in this field with the goal of improving communication and fostering connection between CDC and public health laboratories. In this role, Anthony Tran, MPH, MT(ASCP), joined APHL in September 2003, focusing on the TB Task Force report and HIV testing issues.

**TB Task Force Report**

In response to the Institute of Medicine's May 2000 report, *Ending Neglect, The Elimination of Tuberculosis in the United States,* and the growing awareness of challenges to the TB laboratory infrastructure, APHL and CDC commissioned a task force to address critical TB laboratory issues. The primary goal of the task force has been to improve tuberculosis control by promoting the optimal use of laboratory services and effective information and tracking. In addition to recommending a systems approach for TB control that involves clinicians, laboratories and TB controllers, three laboratory benchmarks are proposed: assessment of available laboratory services, assessment of the true costs of TB laboratory services, and development of jurisdictional strategic plans to address needs identified through the assessments. Several models for TB service networks are described. The APHL Board of Directors approved the draft report, "The Future of TB Laboratory Services, A Framework for Integration, Collaboration and Leadership," at the end of 2003.

At the recent meeting of the Advisory Council for the Elimination of TB (ACET) in Atlanta, GA, Eric Blank, director of the Missouri public health laboratory, pre-
The APHL Minute Page 11

The 2004 PulseNet Update Meeting will be held April 27-30 at the Holiday Inn on the Bay in San Diego, CA. The theme this year is “PulseNet: Getting Connected,” and the agenda will highlight issues related to laboratory interactions with epidemiologists and other PulseNet stakeholders. Two pre-conference BioNumerics training sessions will be offered at the hotel on April 26-27 for an additional fee. Each PulseNet laboratory sent at least one person to the 2003 meeting, and we hope to reach that milestone again in 2004.

Contact Shari Rolando at srolando@aphl.org or 202.822.5227, ext. 205, for more information, or visit the APHL Web site for the appropriate forms.

**Certification Process Improvements**

In response to member concerns about delays in PulseNet Certification, APHL obtained funds from CDC to support a PulseNet QA/QC contractor in November, 2002. In the first 12 months of her contract, Christine Steward evaluated all outstanding E. coli, Salmonella, and Listeria certification submissions from participating PulseNet laboratories and provided constructive feedback to laboratories in need of assistance. Through Steward’s efforts, the number of laboratories certified by PulseNet greatly increased in 2003: 34 laboratories are certified for E. coli, 28 laboratories are certified for Salmonella and 14 laboratories are certified for Listeria subtyping. A second APHL contractor, Deb Sheehan, has analyzed the Shigella certifications, all of which were completed by January 20, 2004. In total, 138 certification results have been completed since July 2003. As a result of these efforts to improve the Certification process, all newly submitted certification sets should be analyzed and returned to the laboratory within 4 weeks.

**Proposed In-House PulseNet Certification**

APHL QA/QC contractor Christine Steward has proposed changes to the PulseNet certification program that would allow participating laboratories with one CDC-certified staff member to set up a program for in-house gel certification of additional staff members. CDC would establish a minimum set of QA/QC requirements and an evaluation program involving the PulseNet Area Laboratories. Details on this new certification option will be distributed via the PulseNet Web board in the spring of 2004 and at the PulseNet Update Meeting in April 2004.

**Proficiency Testing - Round 3**

All laboratories eligible for the fall mailing of the third round of PulseNet proficiency testing (PT) received passing scores of 85 points or higher. Isolates of E. coli, Salmonella and Listeria were sent to 21, 19, and 7 labs, respectively. Additionally, in response to concerns raised by participants, laboratories received a CDC-generated TIF image for each organism. Analysis of this image will help reduce score differences that can arise from different levels of experience with PFGE. Please continue to send comments about the PulseNet Proficiency Testing Program to Shari Rolando or Chris-

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**PulseNet**

2004 PulseNet Update Meeting

The 2004 PulseNet Update Meeting will be held April 27-30 at the Holiday Inn on the Bay in San Diego, CA. The theme this year is “PulseNet: Getting Connected,” and the agenda will highlight issues related to laboratory interactions with epidemiologists and other PulseNet stakeholders. Two pre-conference BioNumerics training sessions will be offered at the hotel on April 26-27 for an additional fee. Each PulseNet laboratory sent at least one person to the 2003 meeting, and we hope to reach that milestone again in 2004. Contact Shari Rolando at srolando@aphl.org or 202.822.5227, ext. 205, for more information, or visit the APHL Web site for the appropriate forms.
tine Steward. Laboratories that are eligible for the spring mailing of the third round of PT received their test isolates and TIF image in February.

**Shigella National Database Now Online**

As of December 29, 2003, the Shigella National PulseNet Database can be accessed online. This is a much-needed improvement to PulseNet, as many of our laboratories have been subtyping Shigella isolates for some time. APHL mailed scripts for the new Shigella database to all participating laboratories in late December 2003. Any laboratories that need assistance in converting local databases to a compatible format with the national database can contact CDC or APHL.

**National Database in SQL Format**

Also on December 29, 2003, the entire PulseNet National Database was converted to a SQL format. The change to the SQL format marks a move to a common method of storing relational data. This change will allow better connectivity with other public health databases, such as PulseNet International hubs and the Laboratory Response Network (LRN), and will provide more administrative functions for the PulseNet database team at CDC. Few changes will be noticed from the client interfaces in the participating public health laboratories, although comparisons, searches, and other functions should be faster. CDC staff hosted a national net conference in late December to explain the new log-on procedure and to provide details about the new Shigella scripts distributed by APHL.

**BioNet Collaboration**

BioNet represents collaboration between the LRN (through CDC’s Bioterrorism Preparedness and Response Program) and PulseNet (through CDC’s Foodborne and Diarrheal Diseases Branch) that is designed to enhance CDC’s capability to determine rapidly any possible links between disease agents during a terrorist attack. At the heart of this collaboration is the idea that the LRN and PulseNet should be able to exchange data on similar samples received for confirmatory testing and genomic sub-typing. The BioNet investigational effort will combine the rapid identification capacity of the LRN with the “fingerprinting” capabilities of PulseNet. Appropriate methods to share this data will be developed; special consideration will be given for the security requirements of both networks. The transition of the PulseNet E. coli National Database to SQL server format was the first step in the BioNet collaboration.

**PulseNet Latin America Planning Meeting**

Public health professionals from 14 Central and South American countries gathered in Buenos Aires, Argentina, on December 1-2, 2003, to discuss the formation of PulseNet Latin America. The meeting was hosted and facilitated by the Pan-American Health Organization. Presenters from CDC, APHL and the Minnesota Department of Health described the successes of PulseNet USA as well the activities of PulseNet hubs in Canada, Europe and the Asia Pacific region. Meeting participants formed work groups to identify and discuss the benefits of and obstacles to forming PulseNet Latin America, and to develop solutions to some of those obstacles. Immediate future steps include lobbying for funds and technical support and the establishment of a training course in PFGE and BioNumerics to be held in Buenos Aires in June 2004.

**Area Laboratories Provide Support**

CDC has designated seven state public health laboratories as PulseNet Area Laboratories. These laboratories are in Massachusetts, Virginia, Michigan, Minnesota, Texas, Utah and Washington. All PulseNet participating laboratories can call upon their designated Area Laboratory for assistance with troubleshooting gels, reagent or equipment problems, cluster identification and investigation, software utilization, surge capacity or special subtyping requests, and training assistance. CDC acts as an Area Laboratory for states in the southeast, but all states are welcome to call CDC with PulseNet concerns. To facilitate communication and relationship building within each PulseNet Area and between CDC and the public health laboratories, APHL coordinates quarterly conference calls in each Area. Topics of discussion during these calls include introduction of new staff members, current clusters, outbreak investigations, Web Board matches, isolate referral from clinical laboratories, equipment and troubleshooting issues, software improvements and concerns, workload and prioritization issues, certification and proficiency questions, pattern submissions and the PulseNet National Database.

Please direct any questions to Shari Rolando, APHL’s program manager for PulseNet, at srolando@aphl.org or 202.822.5227 ext. 205.
**Plan Effective Crisis Communication**

“... the major public health challenges since 9/11 were not just clinical, epidemiological, technical issues. The major challenges were communication. In fact, as we move into the 21st century, communication may well become the central science of public health practice.”
Edward Baker, MD, MPH, Assistant Surgeon General

Risk communication was the focus of a workshop that took place during the fourth leadership forum of the National Center for Public Health Laboratory Leadership held January 15 in San Antonio, Texas. Laboratory leaders from the southwestern United States and Alberta, Canada, participated in the workshop, supported by Widmeyer Communications and facilitated by expert Dr. Vincent Covello, director of the Center for Risk Communications.

Drawing on his experience working with the Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), and the City of New York, Covello noted the substantial differences in risk perception between scientists and the general public. He pointed out that public health laboratory leaders must understand the needs, expectations, and priorities of their audience. Only when these are identified and addressed can a risk communications strategy be developed.

Covello emphasized that risk communication is a science-based discipline supported by solid research and practice. Notwithstanding, public health laboratory professionals should not assume that they can only communicate factual information. In a crisis situation, it is critical to address concerns, establish trust, alleviate fear and anger, and encourage participation.

To arrive at a well-tailored, researched and thoroughly prepared plan for risk communication, preparation is fundamental. Covello urged that the following be researched and organized in advance of a crisis:

**Identify and Assess.** Consider a wide range of potential threats and the inherent consequences to public health. Develop risk scenarios and assign probability and impact ratings with a description of possible consequences.

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**Profile and Interact with Communities.** Identify the target audience. Research their concerns, how they perceive risk, and whom they trust. Cooperation between an entity and its community increases understanding and credibility.

**Identify partners.** Partnerships should be based on the partners’ common purpose of response before, during, and after a crisis. Each should play a specific role during a crisis assigned based on respective strengths and capabilities.

The National Center will continue to sponsor risk communication workshops. For more information on the content of this workshop or on future programming, please contact Rachel Collins, National Center Program Manager, at rcollins@aphl.org

*This article was written in collaboration with Dr. Vincent Covello and Tim Tinker of Widmeyer Communications.*

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**Center Advisory Board Tests the Waters with OARS Leadership Program**

Center Advisory Board and Staff traveled to Miami in February to participate in the OARS Program, a team building exercise. The Advisory Board evaluated the program, as an exercise for laboratory director orientation. The OARS program mixes classroom and experiential training to build teamwork in a professional environment.

*Above, Ernest Schoenfeld, Center founding director, leads his team into the water. At left, Rachel Collins, Center program manager, rows with her team against the backdrop of the coast.*
Several EID fellows attended and presented at the 52nd annual meeting of the American Society of Tropical Medicine and Hygiene (ASTMH), December 3-7, 2003, in Philadelphia, PA.

Emily Butler, a Class VIII training fellow in CDC’s Division of Viral and Rickettsial Diseases laboratory, presented a poster, “An immunohistochemical staining method for the diagnosis of scrub typhus from formalin-fixed, paraffin-embedded biopsies.”

Class IX Research Fellow Katie Kurkjian, from the Division of Parasitic Diseases at CDC, gave a presentation “Immunologic Profiling for Diagnosis of Visceral Leishmaniasis in Bangladesh.” The presentation was based on data collected by former Class VIII EID Training Fellow, Louise Vaz. Kurkjian also received the Pfizer Centennial Travel Award in Basic Science Tropical Disease Research. Valued at $3000, the award will fund her travel to Bangladesh for laboratory and field data collection.

Susan Wilson, a Class VIII training fellow from the Division of Parasitic Diseases, CDC, gave an oral presentation, “Effects of a Lymphedema Management Program in Leogane, Haiti on the Histopathology of Filarial Lymphedema.”

William Glover, a Class VIII training fellow at the North Carolina state laboratory, collaborated on an abstract, “Genetic Diversity of Salmonella Enterica Serotype Typhi and Salmonella Enterica Serotype Paratyphi A from Nepal.”

Michelle Crum, Megan Pearce, April Price, Renée Ned, Ann Schmitz and Abigail Viall also attended the conference.

Class IX Training Fellow Abigail Viall, from the Division of Parasitic Diseases at CDC, spent three weeks in Haiti working on a noncompliance project. The project is focused upon the mass drug administration effort of the Lymphatic Filariasis eradication campaign within the population of Leogane, Haiti, and its surrounding rural areas. Viall aims to reveal why 18% of Leogane’s residents consistently refuse the drugs. In Haiti, she helped train healthcare workers to effectively interview the noncompliant individuals; these local workers will now use an interview template created by Viall to encourage honest and detailed responses and will record the answers uniformly. Viall regards her work abroad as “a real eye-opening experience...one I’m grateful to have had, and which would not have been possible without my fellowship.”

APHL conducted a site visit of the San Francisco Department of Public Health. Fellowship program staff toured the laboratory and meet with the current training fellow, Ann Mintie and her mentor, Sally Liska.

Class VIII Research Fellow Shannon Manning, from the Michigan Department of Community Health in Lansing, wrote a textbook, “Escherichia coli infections,” targeting upper level high school students. The textbook is currently in press at Chelsea House Publishers in Philadelphia, PA.


CDC provided funding for all current EID fellows to attend the 2004 International Conference on Emerging Infectious Diseases (ICEID) in Atlanta, GA.
NLTN Sponsors Rabies Course in San Antonio

The fourth National Laboratory Training Network (NLTN) Rabies Public Health Series Course, “Laboratory Methods for Detecting Rabies Virus,” was held January 5 – 8, 2004, at St. Philip’s College in San Antonio, Texas. Attended by twenty-six participants from twenty-three different states, this workshop provided an intensive, hands-on learning experience for public health laboratorians.

Sponsors and Instructors

Alongside the NLTN, several different agencies, organizations and companies participated in the facilitation and presentation of this workshop, including CDC/NCID Division of Viral and Rickettsial Diseases, Department of Defense Veterinary Laboratory, the Army Medical Department Center and School, the Texas Department of Health, Chemicon International, Nikon Instrument Group, Olympus International and Zeiss Incorporated. Texas Department of Health Bureau of Laboratories personnel, led by Dr. Pushker Raj, were responsible for preparing, teaching and facilitating the laboratory sessions. Faculty from CDC included Dr. Charles Rupprecht, Lillian Orciari, and Michael Niezgoda. Other faculty were Jim Powell (WI), Robert Rudd (NY), Letha Zuckero (TX) and Patrick Hunt (TX). Generous support from Chemicon International included the provision of laboratory reagents.

The Rabies Work Begins

An opening reception on Sunday evening, sponsored by Chemicon International, was held at the hotel on San Antonio’s Riverwalk. The following morning, Dr. Susan Neill, Chief, TDH Bureau of Laboratories, opened the workshop by welcoming the participants to Texas. During the next four days, students attended lectures and participated in hands-on laboratory sessions, with focus upon the use of fluorescent microscopes, implementation of the new standardized protocol for rabies testing, preparation of FA slides, cell culture procedures, necropsy techniques, microwave and acetone fixation, bat identification and monoclonal antibody typing.

The format, location and events outside of the sessions allowed for free exchange of information and networking among students and faculty. In course evaluations, participants reported that the experience had inspired them to make changes in their home laboratory’s practices. Many also noted that the instructors were knowledgeable and well prepared and that the workshop was excellent. Acknowledging the broad experience afforded by the intensive week’s work, one student concluded that he had gained insight into the part he plays in “the whole scheme of testing for rabies in public health.”

APHL Launches Environmental Health Fellowship and Traineeship Program

APHL and DLS/NCEH are pleased to provide an opportunity for state public health laboratories to enhance environmental health laboratory testing capabilities through a new Environmental Health Traineeship and Fellowship Program. The traineeship program provides short-term (2-6 week), specialized training in environmental health technology and testing methods for current laboratory staff. The selected staff will train at another state health department, NCEH/CDC, or other state or federal agencies, such as ATSDR, EPA, NIEHS or NIOSH. The fellowship program provides an opportunity for the recruitment and placement of a pre- or post-doctoral fellow for 1-2 year assignments to address specific environmental health technology needs.

For more information or application materials for these programs, please contact Heather Roney, fellowship program manager, at hroney@aphl.org.

This meeting, co-sponsored by APHL, was held February 28 - March 3, 2004. We were thrilled to offer this exciting opportunity to our fellows!
Molecular Diagnostic Techniques for the Public Health Laboratory
Responding to the urgent need for training, the NLTN held the first “Molecular Diagnostic Techniques for the Public Health Laboratory” Public Health Series course in Richmond, CA, on October 20-24, 2003. Facilitated by the staff of the Richmond, CA NLTN office, the course attracted thirty public health laboratorians from as many states. The lecture and laboratory sessions focused on molecular techniques specific to public health laboratories.

Thirteen commercial supporters provided test kits and equipment for the hands-on portion of the workshop. Participants considered this networking opportunity a great benefit; one participant noted “[I] finally had a chance to talk to others in public health also doing molecular work.” The response was so positive that the NLTN is offering another Molecular Diagnostics course the week of August 16, 2004, in Richmond, CA.

Distance Learning + NLTN = Success
The success of two recent National Laboratory Training Network (NLTN) audioconferences has been remarkable, even for an organization that has presented such programs for years. According to Betsy Szymczak, Manager, NLTN Boston office, “Through a synergistic collaboration with the Public Health Training Network (PHTN) and CDC’s Microsoft Live Meeting System, we have been able to market and deliver two major teleconferences within the past six weeks. What’s most amazing is that all of the marketing and post-course processes were paperless!” Nonetheless, site registration still required the faxing of forms, not a small job with 1,500 sites registered.

The first audioconference on December 16, 2003, “Influenza, RSV and SARS: What Every Laboratory Should Know,” was presented as a joint effort of the NLTN Boston office and the Wisconsin State Laboratory of Hygiene. Speakers for this training program were Carol Kirk and Peter A. Shult, PhD, from the Wisconsin laboratory. Over 3,000 participated, representing 49 states and 54 state, county, and city public health laboratories. The program is currently archived as a Web cast on the NLTN Web site, www.nltn.org.

Janet Fick Hindler, MCLS, MT(ASCP), F(AAM) spoke at the What’s New in the 2004 NCCLS Standards for Antimicrobial Susceptibility Testing? teleconference, presented twice in January. Experience with previous technical problems prompted staff at the NLTN Boston office to secure an unrestricted educational grant from Ortho-McNeil Pharmaceutical to duplicate and distribute a CD-Rom containing handouts, a lab procedure and references. This audioconference had 1,034 U.S. sites registered, with over 6,500 individual participants, plus 25 Canadian sites and 12 others from “six of the seven continents,” according to Szymczak. Much appreciation goes to Leslie McDonald (CDC) for facilitating the international participation.

Distance learning provides customers with training at their convenience. The NLTN’s distance learning selec-
tions run the gamut from satellite conferences, audioconferences, Audionet programs, Web casts, videoconferences and computer-assisted, self-study to the low-tech option of workshops-in-a-box. These recent teleconferences, which reached over 10,000 participants, represent a significant step toward the implementation of distance learning as a viable methodology for presenting quality continuing education to a large segment of the laboratory community.

Recent Board Activity
The APHL Board of Directors met in conjunction with the Council of Chairs meeting in San Antonio, TX, in January 2004. The board’s agenda included a heavy allotment of global-related activity as the staff prepares to determine APHL’s role in the President’s Emergency Plan for AIDS Relief (PEPFAR) and the board continues to nurture its relationship with the Lyon office of the World Health Organization (WHO). Dr. Philippe Dubois of the WHO met with the board to discuss the development of a Memorandum of Understanding.

Mike Miller from CDC’s Bioterrorism Preparedness and Response Program discussed recent changes in the Future’s Initiative, challenges with the Laboratory Response Network (LRN), and Biowatch. Dr. Bob Martin gave a brief summary of CDC’s Public Health Practice Program Office Division of Laboratory Systems events.

The board also adopted a plan submitted by APHL’s Environmental Health Committee to work with Agilent Technologies and PerkinElmer to obtain bulk discounts for members on Chem-T consumables.

Council of Chairs Meeting
The Council of Chairs met in January 2004, to discuss member issues. The first day focused on the Membership and Recognition Committee’s proposal for a new APHL membership structure. Scott Zimmerman, chair of the committee, presented the plan which was endorsed by the committee and will be presented to the full membership at the 2004 annual meeting in September.

Tom and Casey Milne presented their findings on the local laboratory survey. Bob Kingon led a strategic planning exercise for the new Cooperative Agreement with CDC. Kingon also reviewed the findings of over 60 interviews conducted at CDC, an APHL staff retreat and a survey for committee members, all of which will lend to writing the new Cooperative Agreement.

On Sunday, the council addressed association-wide issues, including the strengthening of relationships with federal agencies and problems with the Food Emergency Response Network, environmental sampling, clinical linkages, LRN expansion and genetics beyond newborn screening. The group also discussed the effect of changes made per the Governance Task Force recommendations and agreed to keep them in place.

If you would like a copy of the minutes from either meeting, please contact Shawna A. Webster, swebster@aphl.org or 202.822.5227 ext. 225.

Board Endorses Proposed Membership Structure
Final Approval Set for 2004 Annual Meeting
APHL’s board of directors has made it a priority over the years to ensure that member service and governance have grown in accordance with our membership numbers. In keeping with this policy, the board directed the Membership and Recognition Committee to evaluate membership satisfaction and to assess whether the current membership structure serves the needs of the member.

Over the past year, the committee evaluated APHL’s current structure by studying the results of the membership satisfaction survey, the recommendations of the Governance Task Force and the resolutions of the 2003 leadership meeting. The committee ultimately concluded that the membership structure could be refined to enhance member relationships, clarify governance roles, and encourage future, controlled growth of the association. In response to this report, the Board of Directors charged the committee to devise a new membership structure that addressed these areas properly.

Proposed Membership Structure
The Membership and Recognition Committee has proposed a more institution-based membership structure that is designed to mirror the strategic initiatives of the...
association and clarify the meaning behind the name "Association of Public Health Laboratories." The committee believes that the proposed structure encompasses the diverse scope of the public health laboratory field while still maintaining a clear focus upon the core membership of the association.

**New Membership Categories**
The membership categories have been reshuffled to unify types of members. This unification will allow the association to develop targeted member benefits for specific categories, will ease communication between similar institutions and will clarify the composition of the membership base to interested legislators, funders and media.

The core membership category will be called **Public Health Institutional** and will be comprised of all state and local public health laboratories. A second category, **Associate Institutional**, will encompass other state governmental laboratories, such as environmental or agricultural facilities. In addition to the lab director, all laboratories represented by the Public Health Institutional and Associate Institutional categories will be granted three **Delegate** members. An **Individual** category will accommodate public health laboratory scientists, international members, CDC employees and students. The current categories of **Emeritus**, **Honorary** and **Corporate** would remain unchanged in the structure.

**Further Recommendations from the Committee**

**Expand Board of Directors**
The committee recommends that the Board of Directors officially augment the size of the board by two, voting, member-at-large positions. This will bring the number of board members to nine.

Based upon recommendations of the Governance Task Force, these two new positions should be filled by one Public Health Institutional-Local member and by one Associate Institutional member. The new board members would be nominated by the respective membership categories. The nominations would go through the current Nominating Committee process and ultimately the relevant categories would elect the two new board members.

**Voting**
The voting structure is unchanged. Even though state and local laboratories have been grouped together as like public health institutions, the state laboratory remains the voting member. Public Health Institutional-Local and Associate Institutional members would be allowed to vote only for their respective board representative.

**Institutional Delegates**
In addition to the member-representative, all Public Health Institutional and Associate Institutional members would be allocated three delegate members; all delegate members must be current employees of the laboratory. Each laboratory would also have the right to purchase more delegate slots, at $100 apiece. Delegate slots are unlimited.

**Rights and Benefits**
Rights and benefits for the categories would remain largely the same. As before, all Public Health and Associate Institutional members would be able hold appointed office, serve on committees and speak from the floor of a general member meeting. Public Health Institutional-Local members and Associate Institutional members would now be able to hold elected office in the form of the two additional seats in the expanded Board of Directors. State public health laboratories would still be the voting members; however, other institutional members would now be able to vote for their representation on the Board of Directors. Rights and benefits for the remaining categories have not been altered in any way.

**Dues**
The dues structure for all institutional members would be population-based; however, the Public Health Institutional-Local members and the Associate Institutional members would pay on a smaller scale than the state public health laboratories to more accurately reflect the benefits provided to these membership categories. Three free delegate memberships are included in the institutional dues and additional delegates could be pur-
chased for $100 apiece. The dues structure for other categories would remain the same.

**Procedural Process for Proposed Changes**
The Board of Directors has endorsed the following proposal. It has also been presented to and discussed by other APHL leaders at the 2004 Council of Chairs meeting. APHL’s Full members will vote on the future of this proposal at the annual meeting in September 2004. If approved, the association will begin implementation in July 2005.

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**Member News in Brief**

**Graves Retires from MS Lab**
Dr. Joe Graves, Director, Mississippi state public health laboratory, announced his retirement January 30, 2004, after 30 years of service. Graves was the director of the laboratory for ten years; the State Department of Health has yet to name a successor. Graves currently serves on two APHL committees and plans to remain active as an Emeritus member. He will teach in the Department of Biological Sciences at Mississippi College in Clinton, MS.

**Former OH Lab Director Croft Dies**
Dr. Charles C. Croft, 89, formerly of Columbus, OH, passed away January 27, 2004, in Tulsa, O.K. Croft received a Doctor of Science degree in 1949 from Johns Hopkins School of Hygiene and Public Health. He served the Ohio public health laboratory for 32 years, retiring in 1981. Services were held on January 30 in Broken Arrow, O.K. Contributions in his memory may be made to the World Health Organization.

**Rutledge Receives DE Award**
Debra Rutledge, an APHL member from the Delaware public health laboratory, was one of three recipients of the 2003 Delaware Award for Excellence. The award recognizes state employees who have made outstanding contributions to public service. The state pays tribute to them with a celebratory luncheon, a plaque, a $2000 gift and a place in the Employee Hall of Fame. In an address at the award luncheon, Governor Ruth Ann Minner said, “We recognize the efforts of those state employees whose dedication and commitment to service are exemplified by their exceptional accomplishments.” Rutledge was selected for her accomplishments as a microbiology laboratory manager and her proactive approach to the training needs and issues surrounding the bioterrorism scare.
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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 U.S. residents and to prevent and control disease globally.

This publication was supported by Cooperative Agreement Number 303019 and 319522 from the Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC or imply an endorsement by APHL officers, members, staff or management.

To submit an article for consideration, contact Emily Mumford via email, emumford@aphl.org.

STAFF NEWS

Mitchell Berger, JD, MPH, APHL’s program manager for food safety, tendered his resignation January 16. Berger will continue to work with APHL as an independent contractor until mid-June to coordinate the Food Safety Capacity Follow Up Survey Project. APHL wishes Berger well in his endeavors.

Patricia Blevins, MPH, joined the APHL staff on February 9 as the new emerging infectious diseases program manager. Blevins is a former EID Fellow with the New York State Public Health Department, where she prepared samples during the anthrax crisis in 2001. Before the EID position, Blevins worked as a consultant with the New York State Department of Health Environmental Laboratory Approval Program (ELAP), an accreditation system for critical agent testing of environmental samples.

Peter Kyriacopoulos, joined APHL as the director of public policy on February 16. Kyriacopoulos has a unique combination of experience with state government and policy at both the executive office and agency department levels. Most recently, he served as the assistant director of government relations for the American Association of State Highway and Transportation Officials (AASHTO), working as the key contact for congressional staff, state transportation departments, governors’ offices and federal agencies on transportation-related issues. Previously, he represented state government interests at the federal level in a policy role in the Maryland governor’s office.

Eba On’gele, APHL’s global health training specialist, left the association in January. APHL thanks On’gele for her many contributions and wishes her well.

Pandora Ray joined APHL staff in February as the new staff associate for the National Center for Public Health Laboratory Leadership. Ray has extensive work experience in the private-sector healthcare arena, having served as vice president of operations with Premera Blue Cross in Seattle, WA, and as vice president of Humana, Inc. in Louisville, KY. Ray will focus initially on the development of a core curriculum in leadership and management training for the public health laboratory leader, as well as the development of a conceptual model of the public health laboratory for the 21st century.