LAB MATTERS

Unstaffed Laboratories Threaten Public’s Health

Analysis | Answers | Action

Spring 2009, Issue 2

Association of Public Health Laboratories
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Tight state and federal budgets are having a negative impact on almost every aspect of laboratory work. We're engaged fully in efforts to reduce our overhead and streamline our services, but we are nearing the point when we will need to make some hard decisions about our direction.

As discouraged as we are, it's not all bad out there. Public health labs have been around for more than a hundred years. We are survivors of other challenging times. I have full confidence that our labs will survive this downturn and continue to provide essential services to our communities. Nobody else can do what we do and, frankly, the work is just too important to give up on.

We need to go back to what makes us unique. We need to explore our community ties and refine the services we provide. We need to re-invest in our sense of leadership. We need to do what it takes.

Over the years, APHL continues to find and refine its voice. Now is the time to amplify it so that our message can be heard clearly. It is important to take our place at the health care reform table, contributing our ideas, hammering out details, prioritizing, sharing our experience and perspective. This organization will be part of the solution. We are coming from a strong position: our input is sought and our contributions are heeded. As an organization, we have matured.

Nowhere is that more evident than in our recent work to develop uniform standards for laboratory testing, in the US and abroad. Through our mutually respectful relationships with federal partners, APHL has participated in and guided efforts to re-write the way laboratory testing is conducted. APHL's board is about to release new CIFOR guidelines for national foodborne outbreak response. HIV and STD testing draft guidelines are nearing completion and release. We are working with CDC to determine the best funding formula for TB testing. We helped develop and deploy a new test for influenza that identifies all common strains, including avian. Our members are widely represented on committees that set the course for major public health actions.

This work has made an impact and will continue to do so. We are also looking beyond our borders, recognizing public health as an international issue, and we are partnering strategically to effect positive change in the areas that need it most. Just look at APHL's annual report for proof of the permanent, sustainable and global changes we have made this year: www.aphl.org/AboutAPHL/publications/Documents/Annual_Report_2008.pdf.

APHL continues to blaze a path in the development of laboratory information systems and two-way electronic data exchange. We have reached thousands of laboratorians with our scientific and leadership training programs. As an organization, we have supported new biomonitoring initiatives that will supply important information on the human health effects of everyday chemicals.

As each of us struggles to make ends meet, do not forget the power of our collective voice, nor the import of the work we do in the national framework. The consensus we build and standards we develop will reap benefits for public health laboratory science for a long time to come.

As my term ends, I remain impressed by the resourcefulness of our membership, with the strength and promise of our organization and with the reach of our relationships throughout the public health spectrum. I have appreciated the opportunity to serve as APHL president and am humbled by your support in the past 18 months. I am convinced that our membership has the skill and spirit required to weather the current storm.
PREPAREDNESS AND BEYOND IN THE PUBLIC HEALTH LABORATORIES

by Jennifer Beck, MPH, environmental health program manager

Public health laboratories are normally found well outside of the media spotlight and, as a result, most Americans are unaware of the deep-seated value provided by the labs’ work.

As budgets constrict all over the country, funding for public health laboratories is declining; particularly for preparedness activities. When emergency preparedness is a hot topic—after the anthrax attacks, Hurricane Katrina and the radiation poisoning of Alexander Litvinenko—laboratories receive recognition and sometimes better funding. In 2002, post-anthrax, new funds became available to better prepare America for chemical threats (CT) and terrorist attacks. Since then, state public health laboratories have made great strides in CT preparedness, and beyond. Labs continue to help communities prepare for emergencies while simultaneously performing everyday tasks and making time for innovation in the field.

APHL recognizes the public health laboratories’ growing slate of responsibilities and wants to highlight some of the activities and successes in the field.

NEW YORK
At the New York State Department of Health laboratory in Albany, laboratorians use the equipment purchased for CT analyses to test for those chemical threats, but also for biomonitoring research. Laboratorians have many ongoing research projects and continue to be an asset to the state. In 2007, after the story broke that toys, jewelry and even cosmetics may contain lead, many public health laboratories, including the Albany lab, began testing products for lead, developing new methods to detect lead and even educating the public. When the New York legislature developed a bill to ban jewelry with high lead levels, the governor approached the laboratory for their expertise. Lab staff identified some technical flaws in the bill, such as incorrect information on the methods to analyze lead, and worked with the Governor’s office to make the corrections.

WISCONSIN
The Wisconsin State Laboratory of Hygiene is a leader in chemical threat preparedness and emergency response coordination. It collaborates with other state governmental agencies, including the Department of Agriculture, crime and veterinary laboratories, and is attempting to leverage funding for those laboratories through its partnership with the University of Wisconsin. Using equipment from the CT program, the Wisconsin Hygiene lab is able to assist university researchers with projects in need of laboratory analyses.

COLORADO
Colorado’s lab is one of the few public health laboratories with the capability to analyze radionuclides. In one event, a government research facility called the lab about a radiation exposure in which their laboratorians broke a vial containing weapons-grade plutonium. Not only were the laboratorians contaminated, but some of the plutonium was suspected to have washed into the sewage system. The Colorado laboratory is one of a few facilities able to analyze humans for radiation exposure and the only laboratory with a whole-body counter to measure gamma radiation. Colorado public health lab staff assisted in the analysis of urine from the exposed individuals and, although the samples were received more than a week later, were still able to detect low levels of radiation. They are also working with EPA to collect and analyze sewage samples, which will be a time-consuming process to ensure the sewage is clear of radiation.

The Colorado laboratory has also established strong relationships with area toxicologists and epidemiologists. Through these partnerships, the laboratory has helped solve several medical mysteries, ranging from a severe skin rash, nitrate and arsenic exposures and even a case of osteoporosis caused by elevated fluoride levels in drinking water.

UTAH
The Utah public health laboratory is making strides in biomonitoring. Using equipment from its CT program,
the lab initiated a new biomonitoring program to monitor environmental contaminants, such as lead and mercury, known to impact human health negatively. In one project, Utah laboratorians developed a new scientific method for a surveillance study of lead and mercury in newborns. This study, “Pilot study for utilization of dried blood spots for screening of lead, mercury, and cadmium,” has been published in the Journal of Exposure Science and Environmental Epidemiology (2009) 19, 298-316. Utah plans to use the surveillance data from this study to advocate for new legislation. In the future, every newborn will be tested for lead, mercury and other heavy metals.

ROCKY MOUNTAIN CONSORTIUM

Six state public health laboratories—in Arizona, Colorado, Montana, New Mexico, Utah and Wyoming—jointly formed the Rocky Mountain Biomonitoring Consortium. The consortium leveraged funds for biomonitoring projects to monitor chemicals in people. Laboratorians and epidemiologists from these states worked together to design biomonitoring studies with the new CT equipment and capabilities in mind. In one biomonitoring study, the laboratory staff researched arsenic and other heavy metals in urine samples from 5,000 individuals. They then compared the urine samples with drinking water arsenic levels and other dietary consumption data. Staff collected these samples from areas not previously represented in the CDC’s National Health and Nutrition Examination Survey. This allowed the laboratory to address new public health concerns while at the same time building and testing their capacity.

These member laboratories are leaders in new technologies to measure and detect chemicals in people and the environment. These advances were only possible due to the new funding sources in 2002, which are currently decreasing and at risk of disappearing altogether. It is necessary to continue to fund these important laboratory activities and advocate for the public health laboratories. APHL is committed to getting the word out to our nation’s health. To view the report, visit http://www.aphl.org/aphlprograms/ep/ahr/Documents/APHL_SurveyFinalEPR.pdf. For more information, contact Tony Barkey at anthony.barkey@aphl.org or Jennifer Beck at jennifer.beck@aphl.org.
The melting pot of this meeting allowed attendees to network with experts from federal, state and local government; members of the first responder community; and numerous vendors. Attendees recognized the value of learning others’ roles in emergency response efforts, and how each would respond and communicate.

Time magazine reporter Amanda Ripley delivered an intriguing keynote lecture on the findings from her recent book, The Unthinkable: Who Survives When Disaster Strikes—and Why. After interviews with hundreds of disaster survivors (including those of the recent emergency landing of US Air Flight 1549 in the Hudson River), Ripley painted a convincing portrait of the stages of denial, deliberation and decision-making in the minds of individuals who survived such unthink-
The APHL Laboratory Response Network (LRN) operational work group (OWG), created in 2007 and chaired by Maureen Sullivan, MPH, Bioterrorism Preparedness Laboratory Coordinator, Minnesota Public Health Laboratory Division, convened for its fourth in-person meeting in March 2009.

Addressing previous concerns, CDC representatives offered an efficient dissemination of policy changes and requested feedback on the development of a surge capacity model. The group also discussed the Office of Inspector General’s report, Public Health Laboratory Testing to Detect and Report Biological Threats, questioning specifically the testing measures and survey methodology therein. The group also noted that APHL's Emergency Preparedness and Response Committee is addressing the importance of working partnerships between LRN sentinel and reference laboratories.

The CDC representatives delivered presentations on three topics, and the group offered suggestions on the same:

- Role of the LRN technical advisors
- LRN surge capacity model
- Laboratory Information Management System (LIMS) integration project

In particular, the LRN surge capacity model garnered a great deal of interest from the OWG. Following a consensus on the necessity of the project, critiques from the group elucidated the strengths and limitations of the current model. Future iterations may broaden the repertoire of agent-specific epidemiological curves, include environmental parameters and accommodate the assessment of multiple threats. Rate-limiting steps and diverse diagnostic tests were also discussed, with the popular opinion being that these variables should also be considered in the model. The OWG agreed that individual labs should pilot test the model and identify further vulnerable aspects of the application.

These recommendations will be discussed further in the fifth meeting of the group, scheduled for June 2009. The operational work group serves as a customer voice, providing feedback to the CDC LRN Program Office on quality improvements needed for the network. LRN member laboratories are encouraged to provide feedback directly to LRN program staff and APHL’s LRN program manager, Sikha Singh. For more information on the OWG, contact Sikha Singh at sikha.singh@aphl.org.

The APHL Laboratory Response Network (LRN) celebrates 10 years of achievement.

The 2009 Public Health Preparedness Summit will be held in Atlanta, GA.

Many attendees voiced concern that efforts to maintain preparedness, whether programmatic or laboratory, were being eroded by diminished federal funding. APHL addressed those concerns in a staff presentation, “Leveraging Laboratory Assets in Public Health Preparedness,” presented by Chris Mangal, Jennifer Beck, Douglas McNamara and Anthony Barkey. Attendees, including federal, state and local public health laboratory officials, cited difficulties and responded to presenter questions regarding development, funding and progress in laboratory capacity at numerous jurisdictions across the US.

The 2009 Public Health Preparedness Summit will be held in Atlanta, GA.
Currently APHL participates in three WHO-funded twinning initiatives with Barbados, Ethiopia and Mozambique. Each project is funded for three years with seed money to initiate activities between the partner laboratories. Each twinned pair has a work plan that is tailored to the needs of the resource-limited national laboratory.

- The Barbados national public health laboratory is partnered with Utah’s public health laboratory with the aim of achieving ISO 15189 certification and ensuring safe food and water quality for the island. These objectives are important due to the impact of tourism in Barbados.
- The Ethiopian Health and Nutrition Research Institute is partnered with California’s public health laboratory. Their main objectives are to develop viral hemorrhagic fever and bacterial meningitis testing capabilities, as well as improve overall quality management systems.
- The Instituto Nacional de Saúde in Mozambique is partnered with the Michigan Public Health Laboratory. The objectives for this initiative are to develop Enterovirus isolation and identification testing capabilities.

Recently the WHO proposed a new Laboratory Twinning Initiative that includes APHL as the managing organization. The proposed twinning project will pair the San Diego County Public Health Laboratory with the Laboratorio Central de Salud Pública (LCSP) in Paraguay. With the support of the San Diego laboratory, LCSP will build strong, functional and auditable quality assurance and biosafety. These improvements will bring laboratory services to a level that fully meets international standards. APHL is waiting for final approvals from WHO of the project.

The CDC has now entered into the twinning arena with a project linking the National Public Health and Reference Laboratory (NPHRL) in Guyana and North Carolina’s public health laboratory. The partnership focuses on a mentorship of the new NPHRL laboratory director and the development of quality management systems and biosafety programs.

The upcoming 2009 APHL Annual Meeting in Anchorage, AK, will include a breakout session featuring the work these public health laboratories have done in the twinning projects. The session is scheduled for Friday, May 8 at 10:30 am.
The development and implementation of a national laboratory strategic plan provides a roadmap to navigate these issues. The plan is essential for the systematic pursuit of the strong national laboratory system critical to the achievement of national health goals and the Millennium Development Goals. APHL’s global health program is committed to supporting countries to develop and implement such plans by delivering national laboratory strategic planning trainings.

APHL has partnered with the CDC’s Global AIDS Program (GAP) and the African Center for International Laboratory Training to develop a short, introductory workshop that presents an overview of laboratory strategic planning. The training outlines the benefits that planning brings to national laboratory systems and health improvement. The workshop reviews the structure and fundamental elements of a comprehensive laboratory plan. Examples of key initiatives are provided to ensure a good understanding of the areas that must be addressed to achieve success; and success is defined not as the development of a consensus plan but as the implementation of a comprehensive plan whose outcomes are monitored and whose initiatives and objectives are continually updated to achieve priority health objectives. The plan must address the major issues of institutional and management framework; laboratory services; human resources; laboratory support services; laboratory quality systems; monitoring and evaluation of laboratory services; and policy, legal and regulatory frameworks.

This introductory workshop provides a sound overview for senior health and laboratory professionals who will participate in strategic planning and is also useful as a lead-in to more intensive APHL training programs for those involved in the organization of the planning process and writing of a draft plan. The brief seminar focuses on the pre-planning phase, the strategic planning meeting and how to integrate and implement the strategic plan into the laboratory operation. The inaugural training took place April 21 and 22, 2009, in Johannesburg, South Africa, and convened participants from more than 10 countries. This seminar was targeted for experienced senior public health professionals responsible for managing national public health laboratory systems. APHL consultants Eric Blank, DrPH, and Loris Hughes, PhD, co-facilitated the training with Ministry of Health laboratory leaders from Tanzania and Kenya and WHO-Afro representatives. APHL is excited about this collaboration and is eager to monitor the progress countries make toward the development of their plans.

2 See APHL website, www.aphl.org, for more information on the Laboratory Management Workshop, National Laboratory Strategic Planning Workshop and GWU-APHL Management of Public Health Laboratory Systems Professional Development
NEW TESTS EMERGING FOR SCID
by Jelili Ojodu, MPH, senior manager for newborn screening and genetics

Severe Combined Immunodeficiency (SCID), sometimes called “bubble boy disease,” is a group of inherited disorders that cause severe abnormalities of the immune system. These disorders lead to reduced or malfunctioning T- and B-lymphocytes, the specialized white blood cells made in the bone marrow to fight infection. When the immune system doesn’t function properly, it can be difficult or impossible for it to battle viruses, bacteria and fungi that cause infections.

There are several forms of SCID. The most common type is caused by a problem in a gene found on the X chromosome and affects only males. Females may be carriers of the condition, but because they also inherit a normal X chromosome, the abnormal X may be canceled out. SCID is fatal without treatment and is characterized by the lack of a functional cellular and humoral immune system. Almost all patients have absent or very low T-cell number and function. Successful treatment of SCID involves transplantation of hematopoietic stem cells from HLA-identical or haploidentical T-cell-depleted bone marrow.

During the past couple of years, there have been a number of newborn screening initiatives related to SCID in state public health laboratories. In January 2007, the Jeffrey Modell Foundation, Children’s Hospital of Wisconsin and the Wisconsin State Laboratory of Hygiene provided the initial financial support to establish a sensitive and cost-effective newborn screening test for SCID. The method for testing measures T-cell Receptor Excision Circles (TRECs) by real time PCR, using DNA extracted from newborn screening samples. Wisconsin began routine screening for SCID in January 2008.

In March 2008, CDC’s National Center for Environmental Health announced a funding opportunity: “Program to Expand State or Territorial Public Health Laboratory Capacity for Newborn Bloodspot Screening to Include Severe Combined Immune Deficiency (SCID).” Approximately $1 million was available to fund two awards. The purpose of the program is to conduct research to develop and evaluate newborn bloodspot screening tests for forms of SCID. Massachusetts and Wisconsin received the CDC grant in October 2008.

The New England Newborn Screening Program (NENSP), University of Massachusetts Medical School, had developed a multiplexed TREC assay targeting TRECs and RNaseP prior to receiving the grant to implement SCID newborn screening with multiplexed assays in an integrated program approach. NENSP is collaborating with the Massachusetts Department of Public Health, the Texas Department of Health, Jennifer Puck, MD, Department of Pediatrics and Institute for Human Genetics, University of California, San Francisco, and Ken Pass, PhD, Wadsworth Center, New York State Department of Health. The NENSP implemented a pilot program for SCID newborn screening in Massachusetts in November 2008.

SCID was nominated recently as a candidate for the “core” panel of recommended newborn screening conditions, and the Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children considered the evidence review in February 2009. The committee did not recommend SCID for the core panel, noting that only one state screens for SCID (Massachusetts screening for SCID is a pilot program not mandated), and the lack of quality control materials and a proficiency testing program were factors in the decision. Also, the current newborn screening program in Wisconsin and the pilot program at NENSP have not picked up a case of SCID yet. CDC plans to provide quality control materials for SCID by July 2009.

A diverse gathering of laboratory scientists, epidemiologists, information technology specialists, community activists and others attended CDC’s environmentally-focused Public Health Tracking (EPHT) Conference in February 2009. Also known as “trackers,” participants met to discuss the future of environmental public health and the development of the emerging EPHT Network. The conference was organized into four tracks:

- tracking at the intersection of national data standards and local health priorities,
- bridging the information technology and epidemiology divide,
- tracking for action and
- creating knowledgeable communities and individuals.

In an interesting keynote panel presentation on the global perspective of tracking, speakers from Canada, France and Western Australia shared biomonitoring and tracking initiatives ongoing in their countries. Presenters from the World Health Organization and the European Centre for Disease Prevention and Control also provided updates on tracking and biomonitoring projects. Throughout the conference, several states (Florida, Massachusetts, Maine, Missouri, New York, New Jersey and Wisconsin) provided participants with demonstrations of their not-yet-released EPHT web portals. These state portals are comprised of electronic records and statistics that are collected, organized and displayed based on standards. Networks include measures of health, exposures and hazards.

A breakout session on biomonitoring encouraged the integration of biomonitoring and tracking. Joy McVey, Division of Laboratory Sciences, National Center for Environmental Health, CDC, and Dr. Simani Price, Westat, presented on the importance of biomonitoring communication research in public health. Helen Flowers, New Mexico Department of Health, discussed how her state—a member of the Rocky Mountain Biomonitoring Consortium—used neonatal blood spots to detect the prevalence of lead and mercury. Another noteworthy breakout session was on the ability of EPHT to inform public health policy. Representatives from the National Conference of State Legislatures, Oregon Department of Health and Florida Department of Health described how state legislative involvement can play a role in creating a sustainable biomonitoring program.

More information on this conference, including session abstracts, poster abstracts and presentations, is available at www.cdc.gov/nceh/tracking.
NEW GUIDANCE AND COLLABORATIONS
IN FOOD SAFETY

by Shari Shea, MHS, MT (ASCP), director, infectious disease and food safety programs

NEW STEC TESTING GUIDELINES TO BE PUBLISHED AS MMWR R&R
Clinical laboratories are eager for guidance on the proper use of STEC diagnostic assays, as evidenced by traffic on the American Society for Microbiology’s (ASM) Division C listserv over the past months. A collaborative writing group, led by CDC and inclusive of APHL, ASM, clinicians and commercial laboratories, has finished a paper, “Recommendations for Diagnosis of Shiga toxin-producing Escherichia coli by clinical laboratories.” This paper will be published as an MMWR Recommendations and Report in July 2009 and is intended to educate clinical/commercial laboratories on the importance of detecting this pathogen and the purpose of public health surveillance. A section for clinicians is also included to assist with test selection and interpretation. APHL-affiliated authors include Trish Somsel (MI), John Besser (MN), Robyn Atkinson (TN) and Shari Shea (APHL).

A companion article that outlines standards for STEC testing and confirmation in the public health setting will be published by the end of the calendar year. Robyn Atkinson is leading this effort as the chair of APHL’s STEC workgroup and a member of the Food Safety Committee. In coming months, staff and members will complete the public health guidelines and promote the implementation of the clinical guidelines. A plenary session will be held at the APHL Annual Meeting in Anchorage, AK, and a sunrise session will take place at ASM’s General Meeting in Philadelphia, PA.

CIFOR GARNERS NATIONAL ATTENTION, RELEASES GUIDELINES DOCUMENT
Because of PulseNet and enhanced investigations of PFGE clusters, nationwide outbreaks of foodborne disease continue to be identified and publicized, catching the interest of everyone from parents and other consumers, to the President and members of Congress. Such attention naturally leads to calls for improving the national food safety system. The efforts of the Council to Improve Foodborne Outbreak Response (CIFOR) are mentioned favorably as important solutions in a report supported by the Robert Wood Johnson Foundation, “Stronger Partnerships for Safer Food: An Agenda for Strengthening State and Local Roles in the Nation’s Food Safety System.” The report was authored by Mike Taylor of The George Washington University School of Public Health and Health Services, in conjunction with the Association of Food and Drug Officials, the Association of State and Territorial Health Officials and the National Association of County and City Health Officials.

To support the efforts of CIFOR, CDC and FDA continue to finance projects and activities of the council (on which APHL has two official members) and its workgroups. The CDC Foundation provided additional funds. The first major product of CIFOR is a 120-page document, “Guidelines for Foodborne Outbreak Response.” Many local, state and federal government agencies work to solve foodborne disease outbreaks, and CIFOR intends this document to be a useful tool for epidemiologists, laboratorians, environmental health specialists and others involved in food-safety programs to coordinate the investigations among agencies.
specialists and others involved in food safety programs to coordinate the investigations among agencies. A roundtable session on the laboratory aspects of the CIFOR Guidelines will take place at the APHL Annual Meeting in Anchorage.

Any APHL member interested in involvement with a CIFOR work group should contact Mike Smith, APHL’s food safety program manager, at michael.smith@aphl.org.

**APHL REPRESENTED ON FDA’S NEW COORDINATING COUNCIL AND WORK GROUPS**

FDA has created a new Federal-State Food Protection Coordinating Committee, intended to serve as a strategic and technical committee to advise the agency on implementation strategies essential to building a national food protection system. Initially, this committee will work with FDA to provide oversight to four new working groups that formed as a result of the “Gateway to Food Protection” 50-state meeting held in St. Louis, MO, in June 2008. APHL staff and members are involved in both the Coordinating Committee and three of the four work groups.

Steps will be taken to ensure non-redundancy between Coordinating Committee efforts and CIFOR activities. Several members of CIFOR are involved in this new FDA initiative, including senior staff at FDA.

**LABORATORY ISSUES PROMINENT AT FOODNET VISION MEETING**

Many of the priorities set by FoodNet are focused on improving laboratory aspects of foodborne disease surveillance. At the Vision Meeting in Atlanta, GA, in early March, FoodNet participants outlined plans to improve *Campylobacter* speciation capabilities and to evaluate STEC EIA kits in comparison to PCR to examine reports of false positive results. Other laboratory-related topics included a sero-epidemiology study to investigate the incidence of *Salmonella* and *Campylobacter* infections in the US, a study using molecular methods to detect previously unidentified pathogens and efforts to improve submission of isolates from clinical laboratories to public health laboratories.

The Foodborne Diseases Active Surveillance Network (FoodNet) is the principal foodborne disease component of CDC’s Emerging Infections Program (EIP). FoodNet is a collaborative project of epidemiologists and laboratorians from CDC, 10 EIP sites, the USDA and the FDA. The project consists of active surveillance for foodborne diseases and related epidemiologic studies designed to help public health officials better understand the epidemiology of foodborne diseases in the United States. Major products include an atlas of food consumption in the US, updated estimates on the burden of foodborne illness in the US and an upcoming paper on the attribution of diseases to specific food commodities.

APHL staff and members are involved in FoodNet through the annual Vision Meeting, the STEC Laboratory Subcommittee and the development of innovative projects to improve collaborative foodborne investigation techniques.

Contact Mike Smith, APHL’s food safety program manager, at michael.smith@aphl.org for information about APHL’s food safety activities.

The official CIFOR logo was approved at the Council Meeting in Salt Lake City in March 2009. It will be used on new letterhead and to denote products that are created by CIFOR or deemed by the council to further the goals of CIFOR.
The CDC Influenza Division is developing a RT-PCR diagnostic test that will be able to test human specimens for multiple respiratory pathogens. With the new test, laboratories will be able to reduce the time it takes to identify various agents of disease by testing for multiple pathogens simultaneously.

To aid in the validation of this test, CDC is looking to build a specimen repository comprised of human respiratory specimens such as nasopharyngeal swabs and aspirates, oropharyngeal aspirates or washes, throat swabs, sputum, tracheal aspirates and/or bronchoalveolar lavage specimens. The pathogens included in this call for specimens range from influenza viruses and rhinoviruses, to *Haemophilus influenzae* and *Mycobacterium pneumoniae*, among many others.

Currently laboratories are asked to submit lists of available respiratory specimens to CDC, who will then select and pre-approve every specimen needed for the repository. APHL will compensate participating public health laboratories after CDC has received selected specimens. Participation in this project allows public health laboratories to provide a valuable resource to CDC while benefiting financially. APHL encourages public health laboratories to participate in this endeavor.

Over the past several months, the APHL/CDC HIV Steering Committee has proposed several new algorithms for laboratory and point-of-contact HIV testing. The culmination of the group’s work, HIV Testing Algorithms: A Status Report, is available at www.aphl.org/hiv/statusreport. The report does not make formal recommendations of any of the algorithms due to a large lack of available data on alternative HIV testing. The APHL/CDC HIV Steering Committee requests that public health laboratories using alternative HIV testing algorithms share any relevant data to help develop more definitive guidelines for HIV testing. If your laboratory is willing to share data or has questions about the status report, submit them to hiv.algorithm@aphl.org.

There are many challenges associated with implementing the proposed algorithms, ranging from structural (policy, law) to operational (staff training, developing quality assurance protocols). The ultimate goal is to have an increased number of individuals tested accurately and, if infected, linked into medical care as soon as possible.
PRIMING THE PIPELINE: ABB-APHL
PUBLIC HEALTH MICROBIOLOGY
CERTIFICATION PROGRAM

by Jack M. DeBoy, II, DrPH, MPH, director, Maryland Laboratories Administration

Last October APHL’s Workforce Development Committee chartered a Certification Task Force to work with the American Board of Bioanalysis (ABB) to establish examinations approved by the Centers for Medicare and Medicaid Services (CMS) in public health microbiology for:

- Doctoral-level scientists who wish to be certified as high-complexity clinical laboratory directors (HCLD).
- Qualified scientists who wish to be certified as technical supervisors in public health microbiology.

The project addresses a pressing need. APHL anticipates that during the next five years, as many as 15 state public health laboratory (PHL) directors will retire, leaving slots that states will be hard-pressed to fill in the face of a workforce shortage and a lack of scientist-managers with the board certification required by CMS for clinical laboratory directors. In fact, even though CMS has approved eight certification boards, none examine for the types of training and experience required to effectively direct a state PHL.

Under this joint effort—overseen on the APHL side by David Smalley, Certification Task Force chair and director, Tennessee Laboratory Services—APHL will recruit experts to help develop a content outline and to generate and validate examination questions. The association will also sponsor at least one question-writing workshop and convene a group of public health laboratory directors to meet with ABB staff to review questions for content application, clarity and accuracy of answers.

ABB will manage the examination question pool, provide standardized guidance on test question selection, administer and grade the examinations and notify examinees of test results. Both organizations will market the examinations, and APHL will provide a room so that the examination can be administered at its annual meeting.

Given sufficient member involvement, the first examination could be administered as early as this fall.

The Workforce Development Committee recommended a certification examination in public health microbiology for several reasons. First, a majority of PHL directors come from the ranks of microbiologists and an examination in public health microbiology will meet the need of this majority. Second, the examination fills a vacant niche in microbiology certification: it can be marketed to public health microbiologists who hold an acceptable doctoral degree but are still earning the required high-complexity testing or supervisory experience, as well as to public health microbiologists who lack a doctoral degree but otherwise meet ABB certification requirements for the specialty. And third, APHL can readily contribute to the development of the examination by drawing on its members’ expertise.

ABB was selected to partner with APHL both because of its flexibility and commitment to the project and because only ABB has a sufficient number of board-certified individuals to form an examination development team possessing broad education and experience in public health microbiology and public health laboratory practice.

If the effort proves successful, the Workforce Development Committee may consider additional examinations:

- HCLD-level certification in environmental chemistry
- HCLD-level certification in newborn screening
- Non-doctoral-level certification in environmental chemistry
- Non-doctoral-level certification in newborn screening.

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ELIGIBILITY CRITERIA

Eligibility criteria for the proposed public health microbiology board certification will be based on current CLIA rules and the general eligibility requirements already approved by CMS for ABB’s existing clinical microbiology board certification program for high-complexity clinical laboratory directors.

1. Meet the qualifications as a laboratory director of a laboratory performing high complexity testing under the CLIA ’88 regulations, Subpart M, Section 493.1443.

OR

2. Hold an earned doctoral degree from an accredited institution with a chemical, physical, biological or clinical laboratory science as the major subject and have completed successfully at least 32 semester hours in chemistry or the biological sciences acceptable to the Board.

AND

1. Have a minimum of four years of clinical laboratory training or experience on human specimens, or both, including at least two years of experience directing or supervising high complexity testing.

AND

2. Pass an ABB examination in general knowledge and in at least one of the following clinical laboratory disciplines or specialties: andrology, chemistry (including urinalysis, endocrinology and toxicology), diagnostic immunology, embryology, hematology (including flow cytometry), microbiology (including bacteriology, parasitology, virology and mycology), molecular diagnostics or public health microbiology.

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For more information, go to www.aphl.org/profdev/Documents/WDC_Cert_Proposal_Article.pdf to read an expanded version of this article. Direct questions to David Smalley, PhD, BCLD(ABB), at 615.262.6300 or David.Smalley@state.tn.us.
Radioactive slurry from Moab Tailings, a uranium mill waste pond in southeastern Utah, is believed to be leaching into the Colorado River. A hundred miles down US 191, Ute tribal members are worried about possible contamination from radioactive waste at the White Mesa Uranium Mill. As these cases suggest, the toxic legacy of Utah’s long mining history—and an estimated 5,000 abandoned uranium mines—will not go away anytime soon.

But what has disappeared is the state’s ability to perform radiation testing. The last of Utah’s radiation chemists was laid off February 2, when the state public health laboratory shut down its radiation chemistry unit, a victim of state and federal budget cuts.

The work is now being outsourced to labs in California, placing a critical public health service hundreds of miles away. Said laboratory director Patrick Luedtke, MD, MPH, “It means we’re not able to respond to environmental catastrophes that are naturally occurring or manmade.”

The closure has inevitable consequences beyond Utah. The Colorado River, for example, is the primary source of drinking water for millions of households in downstream Arizona and Southern California.

“We are part of that greater safety net in the US,” said Luedtke. “And that safety net has a lot of holes in it, because there are only 20 or so radiation labs in the entire US... And we just made another hole.”

With uranium mining on the verge of a comeback in Utah and radiological terrorism a continuing national concern, the timing could scarcely be worse. Alarming, Luedtke’s former chemist is but one of hundreds of state and local laboratory workers nationwide whose jobs have been lost or are now at risk owing to recessionary budget cuts. Based on a
Based on a member survey, APHL estimates about 430 state and local laboratory positions were either eliminated or left vacant in 2008 and another 250 or so will likely be eliminated or unfilled this year.

APHL is now trying out new ways to articulate the impact of laboratory testing on the population’s health. Kyriacopulos said, “We want to find ways to collaborate with all of the people who use the data the laboratory generates.” One effort is a survey to capture information about specific tests that might be eliminated.

The association has found that some jurisdictions are faring worse than others. For example, while state public health laboratories in Texas and New York so far remain unscathed by the recession, those in Utah, Michigan and California have been hit hard.

**UTAH: ‘ANOTHER HOLE IN THE SAFETY NET FOR THE WHOLE COUNTRY.’**

In Utah, Luedtke said, “Our real problems began last summer.” His laboratory not only suffered a major cut in federal bioterrorism funding (which also supports routine disease surveillance) but the state reversed its funding formula for state and local health departments from 60% state–40% local to 40% state–60% local. “That resulted in four people being riffed over the course of just a few weeks,” he said.

Overall, the Utah public health laboratory has lost 10 positions since the start of its fiscal year last July, and those losses now impact everything from the testing of drinking and swimming pool water to support for law enforcement investigations and the state medical examiner.

Consider the difference one person can make. In February, Luedtke let go the toxicologist responsible for virtually all blood alcohol testing in Utah. That duty was shifted to other forensic scientists, on top of their customary workloads, and immediately the turnaround time for DUI tests shot up 20%.

“If you look at the way the court system works,” said Luedtke, “when somebody is suspected of driving under the influence, they have to show up in court as part of the due process. And if we don’t have the test result back at their first court date—and we think we won’t—those people are going to go back out on the road. That’s a concern to us.”

At the same time, the turnaround time for routine cause-of-death tests has lengthened from 21 to 28 days and continues to drift upward, delaying the payment of life insurance benefits to survivors. “We’re potentially keeping someone in extremis if the deceased was the primary breadwinner,” said Luedtke.

Come August, the laboratory’s Level 2 chemical terrorism laboratory will drop to Level 3, meaning it will no longer meet funding and staffing requirements to test for agents like arsenic, ricin and toxic industrial chemicals. Instead, the laboratory will pack and ship suspect samples out of state—“another hole in the safety net for the whole country.”

**MICHIGAN: ‘THE HEMORRHAGE HAS TO STOP.’**

Frances Pouch Downes, DrPH, director of the Michigan Public Health Laboratory, is at ground zero of the US recession. Michigan’s economic struggles began with the recession of 2001 and have continued unabated. Now, with the meltdown of the state’s core automotive sector and a 12% unemployment rate—the highest in the nation—Downes expects the downturn here will be “deeper and longer” than in any other state.

The effect on the laboratory has been harsh. “In general, the ability of the lab to fulfill its mission gets increasingly more tenuous,” said Downes.

The laboratory lost 17 of 150 positions in the past six years, including five since January 2008. Infectious disease testing, which relies on state and federal support, has suffered a disproportionate share of cuts.

Among the most recent staff departures are an IT specialist working on the lab’s information management system and the program advisor heading up efforts to build a statewide clinical laboratory system.
A TB technician slot is now being held open. “We don’t have approval to fill it,” said Downes, “and there’s no guarantee we will in this environment.”

In the face of repeated budget cuts, Downes has been experimenting with several strategies to preserve as much testing as possible. More aggressive Medicaid billing has enabled the laboratory to switch a few technicians’ salaries from state funding to fee-for-service funding. This move allowed the lab to maintain its blood lead testing program and some STD testing despite a loss of general funds.

The lab has also reduced the volume of hazardous waste generated on-site to decrease disposal costs and instituted a robust cross-training program, so employees are able to perform multiple functions.

Staff work schedules and pay have been subject to any number of adjustments; some voluntary, some not.

“We’ve done the concessions,” said Downes. “No cost-of-living increases, and unpaid hours are not new to us at all. We have been doing that for years.”

From 2006 to 2008, the state instituted a mandatory program of “bank leave hours,” in which staff accrued unpaid hours that could be added to vacation leave or reimbursed as an equivalent contribution to employee 401(k) plans upon retirement. The program was discontinued after the Internal Revenue Service found it problematic.

Pay-for-performance incentives for executive staff have not been available for at least five years. Downes said, “I’ve got people in this executive management system who are not getting even routine salary increases that you would expect as they acquire experience.”

The state now has a voluntary work reduction program in place. “At first I didn’t approve those because of our workload and the vacancies we carried,” said Downes. “Now I’ve started to approve them because of the cost-savings. We’ve had to rethink that approach.”

Where innovation and sacrifice have reached their limit, the laboratory has been forced to pare services. The public health laboratory no longer performs routine species identification of non-TB mycobacteria; physicians must request the service if they suspect a novel pathogen.

The [Michigan] public health laboratory no longer performs routine species identification of non-TB mycobacteria; physicians must request the service if they suspect a novel pathogen.
We're abrogating some service contracts... We're taking a risk.

The loss of resources, said Downes, is “going to lead to, at least for me, a process of reevaluating what we’re doing. And if this continues, we’re going to have to eliminate services.”

She said, “I would rather do 10 things well as opposed to doing 12 things not as well. There’s only so much we can do. The hemorrhage has to stop.”

CALIFORNIA: ‘WE DON’T KNOW WHAT’S GOING ON.’

As a hub for sub-prime mortgage lenders, Southern California was at the leading edge of the global financial crisis. Today, the state has double-digit unemployment and an empty treasury.

The California State Public Health Laboratory (CSPHL), along with the rest of state government, has already shed student workers and “retired annuitants,” a category of employees who have retired from state service and returned to work on a part-time basis.

Since last fall, all California agencies have been subject to a two-day/month furlough, amounting to a 2-3% employee pay cut. At first, government offices were closed the first and third Fridays of each month, for all except emergency work. In March, Governor Arnold Schwarzenegger remanded that order and asked agencies to stagger employee furlough days to keep government doors open.

The biggest hit, though, is still pending. In January, the governor instituted mandatory, across-the-board lay-offs of the least senior 10% of the entire state workforce. CSPHL Director Paul Kimsey, PhD, explained that “the bottom 10% was calculated and those people received layoff letters; they were put on notice that they were declared surplus and a layoff process was initiated.”

However, because it takes about six months for authorities to work through all the civil service rules and regulations governing furloughs, those “surplus” workers are still on the job, and Kimsey said the governor’s office is now rethinking the layoffs.

“If you’re an employee and you’ve received one of those letters, you’re wondering what’s going on,” he said. “We don’t know what’s going on.”

The one certainty is that such a huge loss—amounting to dozens of employees from essential support staff to scientists with highly specialized training—would devastate the laboratory.

Because the least senior 10% of the public health laboratory workers are distributed unequally across laboratory units, some units would lose few employees, while others would lose as much as 75% of their staffs.

The Food and Drug Laboratory Branch microbiology section, for example, would likely be so understaffed that it would cease all food regulatory testing and nearly all work to support foodborne illness investigations and traceback investigations of food products with microbial contamination. Such a development would reverberate well beyond California, a state that is, after all, home to an agricultural corridor popularly known as “The Salad Bowl of the World” and that exports more produce and tree nuts than any other US jurisdiction.

[A California spinach farm was the source of the E. coli O157:H7 outbreak that killed three people and sickened hundreds across the US and into Canada in 2006.]

Other Food and Drug Laboratory Branch staff losses would hinder the analysis of foodstuffs for chemical contaminants, such as melamine, potentially delaying product recalls and endangering health.

In the CSPHL’s Environmental Health Laboratory, layoffs would disrupt the development of new analytical methods and halt research on nanoparticle emissions from laserjet printers, as well as measurement of formaldehyde and other volatile organic compounds off-gassed by building materials.

Other CSPHL branches would suffer similar consequences.

Given that the California budget bill enacted in February has already fallen out of balance, with plunging state revenue creating a new, multi-billion dollar shortfall, Kimsey said the likelihood of proposed layoffs taking effect is “still very unclear” as of early April.

CONCRETE LOSSES, QUESTIONABLE GAINS

The piecemeal dismantling of laboratory units is undoing years of effort and millions of dollars of government investment in sophisticated public health testing. Often, this substantial sacrifice does not even bring expected cost-savings.

Luedtke noted a domino effect. He said, “Some of these state-funded positions do work for other state agencies for free. Now the state will have to pay someone else to do the work, probably for more money than it cost us to do it.”

Government scientists also do fee-for-service work for private entities and other government jurisdictions. Overall, Luedtke reckons that for every $100,000 cut in state funds, the Utah public health laboratory foregoes an additional $30,000 to $50,000 in fee-for-service work that it will no longer be able to deliver. He estimates his total forfeited fee-for-service income at about $250,000.

In California, the proposed downsizing of the lab’s Food and Drug Laboratory Branch would leave it with insufficient staff to meet its obligations under three federal emergency preparedness grants, amounting to a potential loss of nearly a million dollars in annual federal funding. Elimination of the grant programs, in turn, would impact national emergency preparedness,
since California would no longer assume its role as a key member of the Food Emergency Response Network, coordinated by the USDA and FDA.

Proposed staff losses in California’s Environmental Health Laboratory would endanger a $3 million/year CDC grant supporting a new state biomonitoring program, a groundbreaking effort to monitor residents’ exposure to select pollutants.

Once gone, some programs will be hard to resurrect. Certain types of scientists are extremely difficult to recruit, especially in predominately rural states. Radiation chemists are so hard to find that Luedtke said, “We have a sense that radiation chemistry may be gone forever.”

Other types of scientists, such as water microbiologists, must undergo extensive training and achieve federal certification before they can assume senior positions.

But there are other obstacles as well. Michigan’s Downes explained, “The bigger challenge is administrative approval to reinstitute a position once it’s eliminated and removed from the organizational chart. Then it’s considered a new position. And having to justify a new position is much, much, much more difficult than filling a vacant position.”

The Colorado Department of Public Health and Environment’s Laboratory Services Division (CDPHE-LSD) is one of only two state public health laboratories receiving no state funding at all. Since 2002, the CDPHE-LSD has relied on user fees as its main source of income.

Said Director David Butcher, MBA, MT(ASCP)SM, “It worked as long as we could supplement it with adequate grant funds, because you can’t run a total fee-for-service shop.”

The problem, he said, is that it is often impossible to identify a willing payer for public health testing: “If a potentially rabid dog’s running loose, everybody wants to be sure they’re not exposed to it, but if you ask someone to pay a fee to test that dog, you don’t have as many people stepping forward.”

After winning department and governor support to petition the state legislature, Butcher has preliminary approval for a resumption of some state funding next year. If the funding comes through and a statewide hiring freeze is lifted, he will begin to refill 10 positions that he is holding vacant to balance his budget.

California’s Kimsey noted that the collective impact of state and local laboratory downsizing is akin to placing blinders on the health and safety officials tasked with crisis management. He said, “Inevitably, erroneous decisions will be made. There will be greater reliance then on federal laboratories, and states will have far less capacity to make public health decisions.”

As one example, Kimsey said, “If you look at the information authorities used during the investigation of Salmonella tainted peanut butter, that’s all local information. The federal government isn’t capable of providing that level of local and state data for national outbreaks.”

Without that rich collection of data—including the identification of specific patients known to be contaminated with the outbreak strain of Salmonella Saint-paul—Kimsey said the source of the outbreak “may not have been figured out.” If current trends continue, he said, “We’ll just have a higher level of disease burden and mortality and just not know why.”

The piecemeal dismantling of laboratory units is undoing years of effort and millions of dollars of government investment in sophisticated public health testing. Often, this substantial sacrifice does not even bring expected cost-savings.
In March 2009, Michigan was the seventeenth state to complete a state public health laboratory system assessment through APHL’s Laboratory System Improvement Program (L-SIP). Approximately 75 participants were involved, representing the Michigan Department of Community Health, State Police, Department of Environmental Quality, hospital personnel and other organizations. An independent consultant hired by the state facilitated the one-day assessment; staff from the Department of Community Health professional development and training unit, and from the local public health liaison office, assisted the consultant.

The goal of this assessment was to ensure that the public health laboratory system in Michigan is effective, seamless and comprehensive, while meeting quality standards. Two central documents inform the assessment tool: CDC’s 10 Essential Public Health Services¹ and APHL’s 11 Core Functions of State Public Health Laboratories.² Using the provided guidelines, participants discussed the strengths and weaknesses of the current system, including the extent to which laboratories were performing public health testing to serve the community’s needs.

It became clear that current economic conditions are taking a toll on the laboratory system. The negative effects of the economic downturn have trickled down from the laboratory to the general public. Patients must now pay a small fee for some laboratory tests that were previously free. The hospitals are under financial strain because they must continue to provide care, with or without reimbursement. It is important to note that financial strain was not one of the main points of discussion during other state assessments held in 2008.

Frances Pouch Downes, DrPH, the director of the Michigan Public Health Laboratory, deemed the assessment successful: “The assessment was valuable in getting stakeholders together to start the dialogue on system improvement. The tools were well designed to define the process of the day but also adaptable to local needs.” Participants were also positive, calling the event stimulating, enlightening, educational, interesting and engaging. The assessment provided participants with a better understanding and appreciation for the state public health laboratory system and the services it provides to the public.

The information gathered will be collated into a report that will be shared with participants and other stakeholders. Some key next steps for improvements in the state public health laboratory system have been identified. One recommendation was to convene an advisory body to assist with prioritization and help strategize improvement in other areas. Other suggestions for improvement included creating a directory of key contacts, writing formal memoranda of understanding and prioritizing projects and funding.

¹ See http://www.cdc.gov/od/ocphp/nphpsp/essentialphservices.htm
² See http://www.aphl.org/AboutAPHL/publications/Documents/Core_Functions_and_Capabilities_of_State_PHLs.pdf

For more information on L-SIP, visit www.aphl.org/lsip. If interested in convening a state assessment, contact Tina Su at 240.485.2729 or bertina.su@aphl.org.
APHL RELEASES LABORATORY PROGRAM ADVISOR JOB DESCRIPTION

by Tina Su, MPH, laboratory systems and standards program manager

In January 2009 the APHL Laboratory Systems and Standards Committee completed a description of the optimal duties for a laboratory program advisor (LPA) position. The job description is designed to help laboratory directors create or modify an LPA position that supports and strengthens the state public health laboratory system. LPA duties should be coordinated with the Laboratory Emergency Preparedness and State Training Coordinator program responsibilities.

To learn more, APHL interviewed Ellie Carter, MT(ASCP), MPH, an LPA from Indiana. Before taking the LPA role, Carter worked for two years as a clinical microbiologist. She then earned a master’s degree in public health and became a microbiologist in the Preparedness Division at the Indiana State Department of Health (ISDH) laboratory.

The ISDH laboratory director, Judith Lovchik, PhD, decided to create Carter’s position after learning about another state’s LPA at a panel presentation on the National Laboratory System at the 2007 APHL Annual Meeting. Lovchik and the ISDH preparedness division director designed the LPA position to help integrate the public health laboratory into the broader laboratory system that encompasses sentinel, veterinary and environmental laboratories.

In the LPA role, Carter focuses on outreach, connecting the public health laboratory to the sentinel laboratories. To build these connections, Carter surveys the labs regularly on subjects such as personnel contact information, types of testing conducted and laboratory preparedness. Also, because the laboratory is separated geographically from the rest of the ISDH, Carter interacts actively with the health department’s program staff to improve communication, especially with the Epidemiology Resource Center. She strives to initiate educational partnerships with the local Clinical Laboratory Science program, as well as the ISDH medical resident rotation. Stronger partnerships among the public health laboratory and laboratory partners continue to grow as a result of the regular communication.

Carter works with a National Laboratory Training Network (NLTN) special interest group that focuses on job responsibilities and standard practices for laboratory communication and outreach. She is also part of the coordinating team that is preparing Indiana for a state public health laboratory system assessment, as a part of APHL’s Laboratory System Improvement Program Spring 2009 cohort. During the assessment, stakeholders from around the state will assess the laboratory system and discuss next steps for improvement.

Carter takes great pride in developing the new LPA position. She also expressed satisfaction in the personal aspects of the job: “I am a people person and like to connect with others. I enjoy providing customer service and helping people out when they need it.” In uncharted territory, she attempts to understand and address the needs of the Indiana public health laboratory system. She credits the NLTN databases with helping initiate contact with other state public health laboratories to research the nature of their partnerships with other laboratories.

The ideal candidate for the LPA position has a good understanding of medical technology or microbiology, as well as of laboratory issues, such as staffing and testing. An LPA—or, absent that position, staff members sharing responsibility for the described tasks—can be very effective in meeting the goal of creating a stronger state public health laboratory system.
ENVIRONMENTAL FELLOWSHIPS OFF TO A GOOD START

by Jennifer Beck, MPH, environmental health program manager

July 2008 marked the inception of the new and improved Environmental Public Health (EPH) Laboratory Fellowship Program. The four fellows have all made great strides in their short time in the environmental health laboratory research program.

Suhash Harwani, PhD, set up a new laboratory to analyze human and wildlife serum specimens in the environmental chemistry laboratory at California’s EPA. Laboratorians will investigate a comprehensive list of contaminants, including persistent organic pesticides and brominated flame retardants. Harwani hopes to present some of his work at several conferences in the coming months, including the 11th Annual Workshop on Brominated Flame Retardants and the Northern California Regional Chapter of the Society of Environmental Toxicology and Chemistry Meeting.

Lindsay Pack is participating in research at the Arkansas Public Health Laboratory and has helped develop more efficient and greener methods to analyze cotinine, a metabolite of nicotine. Pack also received training on CDC chemical terrorism methods and instrumentation for these methods, and participated in several preparedness exercises. Her work on cotinine was recently presented during the Pittcon 2009 Conference.

Linda Su is conducting research on volatile organic compounds and cyanide in burn victims in the laboratory at the Texas State Department of Health Services. Su also attended the Texas Chemical Threat Meeting where CDC’s Chemical Emergency Response Team completed an exercise. Su will attend the APHL Annual Meeting in May 2009 to present some of her work in a poster.

Rana Zahedi, PhD, has been busy learning more about phthalates, chemicals commonly found in plastics. She has also been training to use one of the more advanced instruments, the API 5000, to analyze the phthalates as well as several other instruments in the laboratory. Zahedi will begin her research in the coming weeks when she completes her training.

FELLOWS TRAVEL AND PRESENT

by Heather Roney, MA, fellowship program manager

Currently Narry Tiao is spending several months in Peru working at the Peruvian University of Cayetano Heredia. She is helping diagnose norovirus using real-time reverse-transcriptase PCR of fecal samples from an infantile cohort group in Lima. Tiao notes, “All of the ‘exotic’ diseases that I learned about in graduate school I have seen and learned about firsthand here in Peru, and to see the detrimental effects they have on the community is eye-opening.”

From the University of Iowa Hygienic Laboratory, Jeremi Mullins presented the poster, “Influenza Surveillance: A Rapid Test Online Survey Compared to Sentinel Surveillance Sites,” at the annual Pan American Society for Clinical Virology Symposium in April.

Abel Wu gave an oral presentation at the Northern California American Society for Microbiology’s spring 2009 meeting. “Detection of Neisseria Gonorrhoeae Isolates with Mosaic penA Genes and Potential Cephalosporin Resistance in San Francisco, 2008” was based on his work at the San Francisco Public Health Laboratory.
MARYLAND’S PUBLIC HEALTH LABORATORY: RESPONDING TO COMMUNITY NEEDS

by Emily Mumford, writer

Like other public health laboratories, Maryland’s laboratory has grown over the years in direct response to the needs of its community. It was founded in 1898 with a $2,500 budget and one biologist. Today the public health and environmental chemistry lab has a $23 million budget and 250 employees—and a scope that encompasses every person in the state, from screening newborns to ensuring drinking water quality; from inspecting pharmacies to testing for dangerous communicable diseases.

Building laboratory services around specific state needs has created a unique institution. The lab founded its radiation program in the 1970s to support a large local nuclear power plant. Since 9/11, there has been an added emphasis on this program, and several grants have introduced new instrumentation, developing the lab’s relevance.

State radiation labs are becoming scarcer as budgets shrink and fewer laboratory scientists are trained to work in the field. Yet Maryland—which surrounds the District of Columbia on three sides—is called upon frequently to support the capital and its federal agencies in response to chemical, biological, radiological or nuclear threats and to participate in preparedness exercises. Their need for superior emergency response practices is well-proven: in 2001, the Maryland lab completed more than 3,000 tests for anthrax and in 2003 confirmed the presence of ricin in the Dirksen Senate Office Building.

Despite its advanced capabilities, the laboratory struggles with an aging facility. Designed in the 1960s, the current building opened in 1974. It is part of a larger state office complex and has 227,000 square feet and seven stories of laboratory space. Security risks worry the laboratory’s director, Jack DeBoy, DrPH. “There are three levels of an underground garage beneath the lab, and we’re connected through the lobby to other state offices,” he said. The facility also has continuing HVAC problems, no all-hazards receipt facility and inadequate BSL-3 space, challenging the staff’s safety and work quality.

Plans for a much-needed new facility began in 2002 and are proceeding. “We have not chosen a site,” said DeBoy, “but we’re researching a spot just a few blocks to the north of the Johns Hopkins School of Public Health.” Late this summer, the lab will release an RFP seeking an architectural design firm; this is not, however, the lab’s first foray into design—staff have already worked with two architects on two preliminary designs. “It’s been well worth the time and money,” said DeBoy. “We’ve managed to trim 50,000 square feet...
and $30 million from the initial plans."

The new facility will replace the lab’s current modular system with a flexible, open design that will maximize efficiency and actually downsize it to 198,000 square feet. It will have more than a dozen BSL-3 spaces and will eliminate the other building and staff security issues. DeBoy hopes it will be completed in 2013.

The lab will leave behind some of the quirks of its old facility, including a large incinerator used by the local Federal Reserve Board to burn worn-out currency retired from circulation. Routinely, armored trucks bring loads of cash for incineration. "It’s fair to say that the MD laboratory burns through money," joked DeBoy.

And yet money is rarely a light-hearted topic in the lab. The economic downturn, coupled with already tight budgets, has forced the lab to make some tough decisions on staffing. "For most laboratories, salaries are about 70% of our cost. Here, we haven’t had layoffs in years, but every new vacancy is scrutinized. We are currently about 10% understaffed," said DeBoy.

To make up for staff losses, DeBoy said, "We have been transferring scientists to other areas. We are cross-training. We are increasing our automation to make up for losses in manpower. We’re trying to keep our heads above water. Because, of course, the mission doesn’t shrink. All we can do is look at everything we can do to cut back and maintain some balance."

In 2008, the lab’s $22.93 million budget drew 79% from general funds, 16% from federal funds and 5% from special and reimbursable funds. Several million of the general funds are earned through programs like newborn screening. "The Maryland laboratory is extremely lucky to have such a high percentage from general funds, rather than fees. We do have to ensure that the General Assembly meets our needs, but we don’t have to compete with private laboratories," said DeBoy.

To ensure its relevancy to the state, the lab continues to work with other state agencies and stay on the cutting edge of laboratory practice. The lab has documented its rich history of scientific discovery, spanning more than 100 years and ranging among discoveries of new pathogens, development of new methods, enforcement of regulatory and safety measures and identification of novel information about disease.

Last year the lab performed nearly 11 million analytical tests. Approximately 10 million of those were in its newborn screening program, which tests babies for 53 hereditary disorders that are treatable if diagnosed upon birth.

The state’s environmental chemistry program is a good example of why federal funds are so critical to the lab, despite its state funding. "For many years, labs have been dependent on grants and federal funds to replace instrumentation, because it continues to get more expensive," explained DeBoy. "We recently purchased a LCLCMS and it cost more than $500,000. There is no way the state could have bought that for us. Without these funds, it would be difficult to avoid becoming second-tier labs."

DeBoy has learned the ins-and-outs of laboratory science and management through a career in university hospital and research laboratories, in military and state veterinary laboratories, and in state and federal public health laboratories. Fittingly, it all began in the same lab he now directs: his first job out of college, in 1969, was as a serologist in Maryland’s syphilis lab. "About four or five months later, I received a draft notice. About the same time, a notice on the lab’s bulletin board appeared, advertising the University of North Carolina and CDC public health laboratory practice program. The Army noticed my training and sent me to the Army Medical Laboratory in Fort Sam Houston," he said.

Later, DeBoy earned a master’s and a doctoral degree

—Jack DeBoy, DrPH, director

“We’re trying to keep our heads above water. Because, of course, the mission doesn’t shrink. All we can do is look at everything we can do to cut back and maintain some balance.”
in public health laboratory practice at UNC’s School of Public Health. After years afield, DeBoy returned to his hometown of Baltimore and the Maryland public health laboratory as a division chief. Moving through the administrative ranks, DeBoy became deputy director in 1998 and finally director in 2003.

As laboratory director, DeBoy feels a sense of responsibility to the community. “Our food, dairy and water labs go back to our founding, and they are totally state-funded. It is often hard for states to support programs like this because as funding for environmental microbiology goes up and down over the years, it can be difficult to maintain FDA certification,” he said. If the Maryland lab ever lost its certification, dairy farmers would be unable to sell milk outside of the state and the industry would effectively come “to a crashing halt.”

The lab monitors the state’s drinking water quality, as well as swimming pools, the Chesapeake Bay and beaches. Because of Baltimore’s large port, the lab may soon increase its food safety testing of imported food products. Currently Maryland is one of two labs in the nation that have an FDA grant to test for radionuclides in food.

Almost since its founding, the lab has been responsible for regulating the quality of prescription drugs. Currently state regulations require all practitioners who prescribe drugs to receive controlled dangerous substance (CDS) permits from the laboratory. Five pharmacists and supporting staff conduct inspections of pharmacies, nursing homes and doctors’ offices, and a new prescription drug monitoring program is under development. In 2008, due to the laboratory’s investigations, several pharmacists were convicted in a large-scale OxyContin fraud case involving millions of dollars.

Vast regulatory programs like this one led the laboratory to incorporate a laboratory information management system called StarLIMS. The final module is almost complete after a five-year process and $2 million of hardware and software. Six IT staff maintain the system, which contains separate software modules covering drug control, clinical testing, newborn screening and environmental chemistry. “Our StarLims is really helping the lab get CDS permits distributed on time,” said DeBoy, noting that permits are updated biannually, and are required to vend drugs legally.

“The LIMS and our improved customer service are going to save us money. But, also importantly, it is going to improve our quality systems,” predicted DeBoy. The lab is developing a myLIMS system for two-way data exchange of test requests, demographic data and test results among the newborn screening program, large birthing centers and county health departments. The technology will eliminate the current double-entry of the 11 million annual test requests.

The lab is also focusing on training—and retaining—its valuable personnel by offering a graduate tuition reimbursement program to employees seeking advancement in the laboratory field.

Continuing its diverse testing programs and sharpening the focus on technology and workforce development—plus the construction of a state-of-the-art laboratory facility—will keep laboratory staff busy and, hopefully, DeBoy said, “ensure we’re around for the next hundred years, too.”

Implementing new technologies and equipment continues to be a priority for the lab, and DeBoy hopes to expand the use of rapid molecular techniques from molecular biology and virology/immunology into the environmental and public health microbiology divisions.
OKLAHOMA’S AGRICULTURAL LABORATORY: PROVIDING A DIVERSE RANGE OF TESTING TO PROTECT CONSUMERS

by Emily Mumford, writer

LOCATION
Richly captured in the classic American musical, Oklahoma!, by Rodgers and Hammerstein, the state of Oklahoma is a microcosm of US complexity. Known for aviation technologies and oil and natural gas production, the state also has a healthy farm system that produces wheat, cattle, pecans, peanuts and peaches in notable quantities. The state’s economy has been booming in recent years. Oklahoma has also had a pivotal role in Native American history and today more than 39 tribes and nations are headquartered there.

The state’s agricultural laboratory, part of Oklahoma’s Department of Agriculture, Food and Forestry, is located in the heart of Oklahoma City, in the capitol complex. The laboratory is largely a regulatory agency, ensuring the safety and legitimacy of numerous agricultural products, including milk and dairy products, fertilizer, pesticides and seeds. Due to the diversity of its work, the lab works with numerous state and federal agencies, including USDA, FDA, EPA and state public health and animal diagnostic laboratories.

DIRECTOR
Laboratory Director Michael Talkington, DVM, grew up in Newcastle, OK, on a small farm. He married his high school sweetheart and they live in her childhood home. “I never went far from home,” he laughed. As Talkington grew up, small farms were disappearing into the big ones and ultimately, taking over the family’s farm was not a viable option for him. Becoming a veterinarian allowed Talkington to stay in the area he loved. After graduating—from Oklahoma State University, “not that other one”—he practiced veterinary medicine for nine years. Talkington began working for the state in the Animal Industry Services Division, working to eradicate Brucellosis in cattle and Pseudorabies in swine.

In 1999, Talkington came to the laboratory as acting director. In 2000, he was made director. “My training was very helpful in understanding the lab’s microbiology programs, and I counted on my excellent staff to catch me up on the chemistry side.”

Of the many challenges faced in this leadership role, perhaps the most recent has been overseeing the design and construction of a new laboratory facility. Staff began moving into the modern space in March 2009.

FACILITY
The new building is adjacent to its old space inside the department headquarters, juxtaposing the older granite building with a sleek, glass-encased design. “It makes the whole thing look better,” said Talkington. The three-story, 40,000 square foot lab incorporates as much glass inside as possible, helping staff give tours without passing through active lab space. Security measures have been modernized: the building is key-carded throughout, with individuals receiving entry permission where needed. The design also incorporates a first-ever BSL-3 lab which, Talkington says, will be in constant use—but ideally, never as a BSL-3 space. “We wanted to serve as a back-up to the state public health and animal diagnostic laboratories in case of an emergency and to increase the state’s surge capacity.” The state’s labs are working on agreements that will allow public health personnel to work at the agricultural lab’s facility, if necessary.

Talkington credits the Secretary of Agriculture, Terry Peach, with helping make the new lab a reality. “When he was elected, he came to us and asked what we needed.” After giving the secretary a tour, they asked for a new lab. Three years ago Peach helped pass a bond issue that funded the new building. “The timing worked perfectly for us,” said Talkington. As in other states, budgets are tight in Oklahoma today. Had the request come any later, “we might not have been so lucky,” said Talkington.

TESTING
Divided into seven focus areas, the laboratory focuses on animal health; feed, fertilizer and lime; food and dairy; pesticides; quality assurance; seeds; and water and inorganics.

The largest volume of testing occurs in the area of animal feed and fertilizer. The laboratory ensures label compliance, protecting consumers by regulating everything from bulk fertilizer and livestock feed to dog food.

Talkington notes that the lab’s pesticide program is also robust and that the technology there is transferable to the food safety program. “We are testing parts per billion in pesticides. By tweaking our methods, we’ve been able to help test for carcinogens in certain products imported from China,” he said. The lab recently tested seafood imported from China for pesticide content.

Food safety staff tests state-produced meat and dairy products, including cheese, milk and ice cream, for quality and safety. “We can also assist with foodborne outbreaks on a case-by-case basis,” said Talkington. The lab recently finished helping with the investigation of a large E. coli 0111 outbreak that sickened more than 340 people in Locust Grove, OK, in 2008.

The lab’s animal health section conducts serological and microbiological testing for disease diagnosis in large animals, searching for evidence of Brucellosis, Pseudorabies and Equine Infectious Anemia.
Other lab sections test ground and surface water to protect citizens from any contamination caused by agricultural industries, and regulate seeds according to federal and state laws.

DISTINGUISHING CHARACTERISTICS
"Our metrology lab is one of the best in the country," said Talkington. "We have Swiss robotics that can perform small mass measurements down to 1/1 milionth of a pound—only one other lab in the US shares the technology." While the measurement lab is not a high volume area, almost anything sold in Oklahoma is traceable back to the agricultural lab. Through its NVLAP accreditation process, the National Institute of Standards and Technology has recognized the metrology lab as meeting ISO 17025 standards.

The seed laboratory can identify the DNA of proprietary seeds. Talkington explained, "When someone comes up with something new, say, a roundup resistant soybean seed, they're the only ones allowed to sell it." The laboratory helps regulate a thriving seed industry.

Oklahoma’s agricultural lab has also been designated by EPA Region 6 as the state regulatory agency for pesticide testing under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The busy pesticide lab concentrates on the entire range of pesticide issues, from label compliance to appropriate usage to the effects on human health, "all the way down to flea collars," said Talkington.

SUCCESS STORY
"We report out a lot of things that don't become public because they’re caught early," said Talkington. "The lab feels most successful when it’s able to keep a low profile. "We're doing our best work when nobody knows what we're doing."

The lab also continues to add new technologies, despite financial limitations. Staff have been "proactive, seeking ways to add the right technology" at the right cost. The food safety lab can ribotype to identify bacteria sources. And they have just added PCR-DNA technology to support outbreak testing.

"We're not a high-profile research lab, and aren't funded that way, but I think our staff is using money wisely to accomplish goals and stay at the top of their practice," said Talkington.

BIGGEST CHALLENGES
The big challenges all come back to money.

Increasing costs. "Everything costs more now," said Talkington. "Reagents cost more. Waste disposal costs more. Our expenses are 30% higher than five years ago, but expectations remain the same." Even with a lean budget, the state expects the usual expanding array of lab services but has not been able to make allowances for method development and training.

Staff retention and training. "We are a training ground for private industry," said Talkington. "We hire young scientists out of college, train them for a couple of years and then say farewell as they leave for a job down the street that pays twice as much. We need to retain our best scientists and move them into leadership positions. Many of our supervisors are Boomers, like me, and we're looking to retire in the next several years."

GOALS
National accreditations. The lab plans to bring three sections—general chemistry, pesticides and inorganic—to A2LA or ISO 17025 standards. It will also maintain its FDA food accreditation and ISO 17025 standard in metrology.

Provide advanced training. A long-term goal, Talkington would like to help staff scientists earn advanced degrees through tuition reimbursements, but realizes that current budget cuts are pushing that goal further into the future.

The agricultural lab continues to forge ties with customers and partners to ensure it is on track to meet needs. A Commodity Group Panel convenes the agricultural community, including representatives of the lab, retail feed, cattleman, pork farmers and dairymen. The lab is also developing relationships with junior colleges to begin a steady internship program at the lab. And Talkington is very pleased with the growing relationship among the state laboratories and with APHL, saying "I think there are going to be a lot of positive changes in the lab community in the coming years."
MEMBER NOTES

APHL emeritus member Ronald Laessig, PhD, passed away peacefully at his home in Madison, WI, on March 29. Laessig was a longtime member of APHL, a respected clinical chemist and a giant in the field of environmental health, public health laboratory science and newborn screening.

STAFF NOTES

Kristy A. Kubota, PulseNet program manager, has co-authored an article published in the Clinical Infectious Diseases journal. The report explores and differentiates the genotypes of Francisella tularensis through molecular epidemiologic analysis.

Doug McNamara, research analyst, was married in March, in College Park, MD.

Marie-Claire Rowlinson, global health program manager, was married in Los Angeles, CA, in April.

Sikha Singh joined APHL in March as the program manager, Laboratory Response Network. She most recently served as a research specialist at Johns Hopkins Institute for Genetic Medicine. Singh earned a Bachelor of Science in Biology from Temple University and a Master of Health Science with a concentration in Molecular Microbiology from Johns Hopkins.
AN ELECTRONIC FINAL REPORT
by David Trottier, Public Health Sales, LabWare Inc.

One of the more complex functional areas within a public health LIMS is the Final Report. Incorporating business rules, rendering patient information, tracking report status and permanently retaining reports all contribute to a very challenging reporting requirement.

A huge differentiator for a LIMS solution would be to offer a Final Report that is out of the box. A public health lab could in effect change the logo and address on the Final Report and be in a position to go into production.

In addition, public health customers would need the ability to extend or change the Final Report functionality through the use of data driven configuration tools.

The following are examples of public health specific requirements incorporated into a Final Report solution.

1. Samples or tests must be released and the demographic data entered before a Final Report is generated. A business rule indicates if certain tests are reportable while others are still pending.
2. A combination of Submitter (hospital) and Practitioner (physician) identifies the reporting method (courier, mail, online, fax). This feature allows multiple reporting methods for practitioners who work at several hospitals.
3. The Final Report is automatically rendered as a PDF and saved as an electronic document. An algorithm is used to prevent external modification of the PDF file.
4. The Final Report is assigned a status of either “PRELIMINARY, FINAL, or AMENDED.” All are associated with the sample and can be viewed on-line from within LIMS.
5. Generation of Final Reports can be scheduled (once per day, every hour, etc.) or rendered manually. Manual report generation can be restricted to an individual sample, submitter or facility.
6. A user with proper security can at anytime preview a Final Report.
7. Final Reports can be viewed online via the web. A web solution provides access to LIMS without requiring vendor specific software resident on the client.
8. Individuals can be specified to receive a copy of the Final Report. A cover page with the cc’d contact information is automatically attached to the front of the report.
9. A Report is included to display a summary of samples ready to report. Samples listed can be restricted to an individual submitter and/or by lab section.
10. A Report is included to display a summary of samples that have been reported. Samples can be restricted to an individual submitter, by data range and/or by lab section.

LabWare is recognized as the global leader of Laboratory Information Management Systems (LIMS) and is a platinum level member of APHL. The company’s flagship product, LabWare LIMS, is used extensively in public health in North America and around the world. LabWare LIMS offers a very modern and highly configurable LIMS architecture that allows organizations to spend less time installing and configuring the system, and more time applying it to their specific information management needs. For more information, visit the LabWare website, www.labware.com.
FIND THE TRACTION IN YOUR LAB
by Scott Becker, MS, executive director

Times are hard. To put it mildly, our member laboratories have had better years. And bluntly? Labs have not been “stimulated.” I am not going to gloss over that fact. I am also not going to ignore the frustration, disappointment and fear most of us feel. There have been times recently when it seems like everything we have worked for is slipping away in the night, quietly and unnoticed by others.

But I am going to be pragmatic. I don’t see any other proactive way to get out of the current ditch we’re in. Rather than spinning our wheels, let’s get out of the vehicle to look for something that can provide traction.

So what’s next? We keep our eyes open and continue to make our case. Who knows, with a potential for a reformed health system, there may be other funding streams that reach the labs. Funding may be an entirely different formula than we’ve seen in the past. We need to be open to differences.

Each lab needs to decide independently what core public health services it provides and skew towards them. Every lab will make its own decisions, based on its community ties, on its unique funding streams, on its current strengths and weaknesses. This is a local conversation, not a national one, and I encourage all of you to begin it. Be prepared; know what is essential to your lab.

We have seen the value of partnership time and time again. If any lesson should be learned from the past decade, it’s the value of teamwork. Share responsibility and cooperate to achieve a common goal. Look at what you have, collectively. Re-examine the way you do things. Search for overlap and shared functions, and consider novel solutions.

By definition, public health labs are flexible. We respond to our community’s needs. This ability to bend has always been our strength. And while creative thinking is not going to solve all of our problems, it is one of the most cost-effective tools in the arsenal.

We also need to remember our part in the greater public health system. APHL has joined with ASTHO, our sister ASTHO affiliates, APHA, NACCHO and others to advance the conversation on health reform. Our group is advancing a two-pronged public health argument, beginning with pragmatism: prevent illness in the first place. Provide people with positive opportunities for health (high-quality food, exercise, education) and protect people from obvious dangers (environmental hazards, contaminated food, dangerous worksites). Part two of the argument is a clear set of healthcare principles that incorporate population-based programs and services. All Americans deserve to have access to services that will keep them healthy.

There are things that we simply cannot change. But there is plenty we can do. As an organization, we will continue to advocate for the work of our labs and, collectively, we will find the best way to get back on the road to a stronger American health system.
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- Hill Day fact sheets
- Workforce Survey Report
- Laboratory System Improvement Program summary
- PulseNet fact sheet
- Policy success stories, which highlight vignettes from seven member labs
- Research Agenda
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