Also in this issue:

23  A New Lab for Sierra Leone
24  Q&A With Renown Expert Dr. May Chu
35  Top 5 Ways to Go Green this Year
The **T-SPOT. TB** Test

**Comprehensive TB testing coverage for high risk groups such as healthcare workers, immunosuppressed, TB contacts, and TB suspects.**

**Benefits of the T-SPOT. TB Test:**

- Reliable in immunosuppressed patients*
- Results not affected by BCG vaccine*
- “One and Done”; no second visit required
- Utilizes standard collection tubes

TB testing available through Oxford Diagnostic Laboratories.

**TB Screening Just Got Easier.**

[www.TSPOT.com](http://www.TSPOT.com)
WIPEOUT: WHAT WILL IT TAKE TO END TB? 12

Recent advances in technology have led to the development of a TB test that can deliver results in less than two hours—a drastic improvement from previous testing methods that can take several weeks. The good news: this advanced technology makes TB elimination a future possibility. The bad news: as the economy continues to threaten public health laboratory budgets, an increasing number of labs lack the resources to make TB elimination a reality.

Can You “Guess This Pathogen?”

Hints: Rare member of the filovirus family. Often misdiagnosed as malaria or typhoid fever. Its cousin is Ebola. It has an incubation of 5-10 days with a sudden onset of symptoms. Around the 5th day of symptoms, a rash may appear on the trunk. To get the answer:

Visit www.aphl.org, click on “About APHL” and “Publications”
Safe food is not a luxury. It is a necessity.

Food testing laws are changing. The resources to address them are here.

We are Thermo Fisher Scientific. Connecting methods-based consulting with the most comprehensive lineup of food safety technologies in the world.

Learn more: thermofisher.com/foodsafety
Change is underway within America’s food safety surveillance system. Under the new Food Safety Modernization Act, some of the problems identified in the highly-publicized foodborne outbreaks of recent years will be addressed. Consumers, producers and outbreak responders have been frustrated by the investigations, advocating for better infrastructure, communications, procedures and funding. These new laws are an important beginning, even as we scramble to understand how it will all play out. Some changes have gained shape and are well underway; others are still murky.

ACCREDITATION

In a boon to state labs, the new laws aim to halt unnecessary duplicative testing, allowing labs and the FDA to have a more equal partnership during food outbreaks. Until now, labs had to submit the suspect samples to the FDA, which then had to re-test to confirm the state’s data—a burdensome process when action is required. Under the new laws, the FDA will be able to accept state data for regulatory purposes. However, the FDA must first ensure that appropriate sampling and analytical testing methodology is in place. Within 30 months, the FDA will create a list of approved accrediting bodies (such as ISO) and accrediting agencies (such as A2LA). The law encourages the FDA to increase the number of eligible domestic laboratories and to examine the qualification of foreign facilities.

APHL members have been working with FDA partners, preparing for these changes. Within the Partnership for Food Protection, APHL members Robyn Atkinson and Andy Cannons are co-chairing a Laboratory Task Group to implement the accreditation requirements. Several other APHL members, including some from the agricultural sector, are also on this committee. Atkinson is also drafting a position statement for APHL’s Food Safety Committee on how public health laboratories, or other food testing labs that are not fully accredited, can still submit data for regulatory action. Still in draft form, the statement will likely suggest three potential courses for a lab: 1) become accredited, 2) refer food testing that needs FDA acceptance to a state governmental laboratory that is accredited or 3) collect adequate quality management system records to submit full data packages along with any results that need FDA acceptance. The Food Safety Committee and the Accreditation Work Group will work closely together on this effort.

INTEGRATED FOOD SAFETY CENTERS OF EXCELLENCE + ICLN

These are the murkier areas of the new law that are, nevertheless, pretty interesting. HHS and CDC will designate five Integrated Food Safety Centers of Excellence at selected state health departments to help the response efforts for foodborne illness outbreaks. These health departments must partner with an institution of higher learning that has demonstrated expertise with the food production chain, as well as leadership during outbreak investigations. This is unfunded. Another notable inclusion in the law was the Integrated Consortium of Laboratory Networks (ICLN). This consortium had not previously been codified into law, existing mostly in word, not deed. No longer; now the ICLN is tasked with assembling agreements, methods and data for regulatory purposes, perhaps kicking this very good idea off to a strong start.

FERN

Although not specified, current reporting requirements indicate that Congress may add funding to the current $10 million FDA provides for external Food Emergency Response Network (FERN) activities. (USDA/FSIS also has a separate pool of money for FERN labs.) There is some measured hope that FERN funding will increase to solidify the rapid growth and potential in this sector.

LOOKING AHEAD

Will the Food Safety Modernization Act prove to be the next major, durable funding source for PHLs—akin to the Bioterrorism/Chemical terrorism initiatives of the past decade? It is difficult to answer this question at present; but suffice it to say, APHL and its many partners will continue working diligently to interpret the potential of these new laws and inform members of requirements and opportunities as they become known.

It will be interesting to see where we are 30 months from now, both in regards to food laboratory accreditation and food safety funding. With such significant APHL member involvement at all levels of this process, I expect the growing pains to be manageable and the improvements in our national “food safety net” profound and highly visible.
In early 2010, APHL partnered with the Laboratory Response Network (LRN) Program Office, the CDC’s Public Health Informatics and Technology Program Office (PHITPO) and three state public health laboratories in a unique LRN Laboratory Information Management Systems Integration (LIMSi) pilot project. The Idaho, Virginia and Massachusetts state laboratories modified their LIMS—implementing the necessary message structure for all LRN biothreat agents—to support the direct electronic exchange of secure data with CDC, thereby eliminating the need for the LRN Results Messenger and its attendant double data entry.

The state public health laboratories worked with the CDC LIMSi and LRN Results Messenger/Viewer Developer Teams to ensure that data could be transmitted to CDC from the laboratory securely and according to vocabulary and messaging standards. Achievement of this milestone ensures that LRN reference laboratories no longer need to perform double data entry, which strengthens the laboratories’ capability to support rapid emergency response and data dissemination.

The aggressive LIMSi schedule culminated in presentations at the 2010 LRN National Meeting in San Diego in October. The successes of the Virginia Division of Consolidated Laboratory Services, Idaho Bureau of Laboratories and the William A. Hinton State Laboratory Institute, Massachusetts Department of Public Health were highlighted in a plenary session on data exchange, and during a more informal roundtable session titled LRN LIMSi Integration: Tools and Resources for Successful Interoperability. In both sessions, consultants and staff from all three of the laboratories shared their experiences and findings with the LRN audience. The success of the three pilot laboratories resulted in a second phase of LIMSi projects, which began in February 2011, engaging several additional laboratories in configuring their LIMS and standing up related IT infrastructure according to LIMSi specifications.

THESE ARE THEIR STORIES…

Idaho Bureau of Laboratories: Staff at the Idaho Bureau of Laboratories demonstrated great success in meeting each of the milestones of the LIMSi project. Thanks to support from the CDC LIMSi Team and their aid in developing documents with significant terminology and code translations for configuration and messaging processes, the lab was able to “go electronic” in October 2010. Keys to success for this project included a flexible LIMS and integration engine coupled with a team atmosphere and fantastic communication between all participants.

Virginia Division of Consolidated Laboratory Services (DCLS): Samples received at the Virginia DCLS can be tested for all chemical and biological threats per LRN protocols, and utilize the same orderable test within LIMS. As such, the DCLS utilized an “all hazards” approach to recording samples in their LIMS, including allowing for the segregation of high security samples, thus limiting access to scientists with proper clearance. The implementation of LIMSi at DCLS involved the development of new messaging capabilities and required the expertise of various members of the laboratory, including LRN-trained scientists, DCLS information technology support staff, in-house StarLIMS trained developers, business analysts, HL7 and messaging specialists and a certified project manager. The successful implementation of this project and a subsequent proficiency exercise in September 2010 revealed that manual data entry into LRN Results Messenger took longer to complete, while the LIMSi messaging was nearly instantaneous. DCLS reports benefiting from participating in the LIMSi pilot project for many reasons, chief among them the time saving advantages of replacing manual data entry as well as fostering enhanced relationships between IT and LRN scientists, establishing contacts at partner states and at CDC, and by helping to shape this project in its infancy.

William A. Hinton State Laboratory Institute, Massachusetts Department of Public Health: Participation in the LRN LIMSi pilot project enabled the William A. Hinton State Laboratory Institute, Massachusetts Department of Public Health to enhance its existing IT infrastructure by incorporating the LRN biothreat agents and molecular components.
In recent years, public health laboratory leaders have emphasized the importance of forming high-quality relationships with the clinical laboratory and first responder communities. To support these ties, APHL's Public Health Preparedness and Response (PHPR) Committee has prioritized outreach efforts to public health and safety communities. This committee provides guidance to the APHL staff who have developed and delivered several trainings to the Laboratory Response Network (LRN) biological and chemical preparedness laboratories, Civil Support Teams (CSTs) and sentinel clinical laboratory communities. These courses provide guidance to laboratorians on chain-of-custody, sentinel clinical laboratory outreach and the capabilities of the National Guard Bureau CSTs. To reach a broad audience, APHL relies heavily on web-based platforms to deliver the training quickly and efficiently.

In October 2010, a successful APHL, CDC Laboratory Response Network (LRN) and FBI joint Chain-of-Custody presentation reached 572 participants at 172 sites in all 50 states, and District of Columbia and Puerto Rico. The training delivered a basic overview of the chain-of-custody process, provided the FBI’s perspective on investigations, evidence collection and importance of maintaining chain-of-custody, and demonstrated case studies and helpful hints for laboratories. Participants also had a significant amount of time for questions and answers with a panel of experts. Overall, the feedback for the training has been very positive and APHL will work with other response networks to adapt the training for new audiences.

In January, APHL teamed up with National Guard Bureau CST leadership, CDC LRN Program Office, State Hygienic Laboratory at the University of Iowa and the Iowa Branch 71st CST to develop a webinar connecting the CST and LRN laboratories. The goals of the training were to provide further guidance on the use of the recently released document “The Role of Civil Support Teams in Support of the Laboratory Response Network,” outline the unique capabilities of the LRN reference laboratories and CSTs, and demonstrate a real-life example of these partnerships in action.

APHL is also working with the American Society for Microbiology (ASM) to provide two trainings bridging the LRN reference and sentinel clinical laboratory levels. These co-sponsored trainings are scheduled for the spring and fall of this year. The first training is for LRN reference laboratories and will provide guidance on using tools such as the Laboratory Preparedness Exercise to better connect with sentinel clinical laboratories. The next training is for both the reference and sentinel laboratory communities and will focus on how to expand current relationships, as well as address technical questions.

These activities contribute to meeting key milestones—such as workforce training and network and community building—in APHL’s strategic plan. APHL will continue working to provide members with timely and informative learning opportunities.

APHL has released a new brochure, “partners in Preparedness and Response.” For more information, email Tony Barkey at Anthony.barkey@aphl.org.
F
ollowing the ambitious path of the Human Genome Project, a parallel concept of mapping the human “exposome” has emerged. Its goal: revealing the role of environmental exposures in disease development. Environmental factors represent the “missing” piece to understanding disease epidemiology; recent endeavors in exposure science may hold the critical key to unraveling the underlying causes of disease.

Conceptualized in 2005 by Christopher P. Wild, director of the WHO’s International Agency for Research in Cancer and a molecular epidemiologist, an exposome is defined as “the comprehensive measurement of all lifetime environmental exposure events—external and internal—from conception to death as a unit of importance for understanding the environmental causes of disease.”

Centered on the body’s internal chemical environment, the exposome accounts for both direct measures of traditional environmental exposure factors (i.e., metals, chemical metabolites and pesticides) and biomarkers of other factors related to environmental health (i.e., stress, diet and behavior) to characterize an individual’s unique environmental exposure profile over time. The exposome aims to account for all environmental exposures in relation to public health-related outcomes (i.e., cancer, coronary heart disease and type-2 diabetes).

The ideal, top-down approach involves the measurement of high priority analytes in human specimens (biomonitoring). Some scientists hope to leverage existing cohort studies to identify important agents and sources of exposure via a combination of biomonitoring, genomic, proteomic and metabolomic methods. The main challenge is that the exposome is highly variable and complex, with exposure evolving throughout an individual’s lifetime and across populations due to diverse genetic and personal factors.

To address these hurdles, The National Academies Standing Committee on Use of Emerging Science for Environmental Health Decisions recommends research should be targeted in the areas of the advancement of biomarker technology, improvements on bioinformatics tools, standardization of study design and reporting of exposome data. Investments by the National Institute of Health’s Genes, Environment and Health Initiative, sponsored by the NIEHS, already yielded innovative technologies to determine how environmental exposures—including diet, stress and drug use—contribute to disease. These technologies range from sensors for chemicals in the environment to panels of biomarkers aimed at measuring cellular, molecular and physiological response to environmental stressors.

Public health and environmental laboratories are strategically positioned to contribute to the practical application of the exposome via biomonitoring and environmental monitoring, respectively. Moving toward a more predictive and personalized public health system, the exposome may represent a better way to assess chronic disease risk, similar to high cholesterol in adults or phenylalanine in children with Phenylketonuria. The translation of this nascent concept into an applied science yields new promise for determining the impact of environmental exposure on human disease. For more information or journal articles related to this topic, contact Dr. Megan Latshaw, APHL’s director of environmental health, at megan.latshaw@aphl.org.

ENVIRONMENTAL LABS READY TO RESPOND
by Jennifer Pierson, MPH, senior specialist, environmental health

Environmental and public health labs work behind the scenes to prepare for and respond to emergencies. While many events are not large-scale and end up being benign, the laboratory’s “rule-out” role is still imperative. Much of this work goes unnoticed; and soon, it seems it will also be unfunded.

Several members shared stories of such activities—both real and simulated.

PREPARING

In Delaware, the public health laboratory’s analytical chemists work closely with the local Civil Support Team (CST). Part of the National Guard, the CST acts as a first responder when requested by the governor. The chemists brought the CST into the laboratory, conducting joint training and validation exercises. The chemists then participated in joint exercises and hands-on work in the CST mobile unit. Such cooperation provides education and builds relationships, improving Delaware’s ability to respond to large-scale events.

RESPONDING

Hospitals and poison control centers may play a key role in detecting chemical exposure events, but often are not well trained to recognize the signs. The Connecticut Public Health Laboratory helps raise awareness and train health professionals to detect chemical incidents. In the spring of 2007, this work paid off when the local hospital called the laboratory about a poisoning. The doctor on-call recognized the symptoms of an emergent patient as being consistent with arsenic exposure. Due to the laboratory’s outreach efforts, the hospital knew the Connecticut lab was capable of testing for arsenic; the lab determined that the patient had ingested a material containing 42% pure arsenic. The doctor was able to treat the patient successfully.

The State Hygienic Lab in Iowa also has strong relationships through outreach with local hospitals. After doctors were unable to identify a strange rash on a patient, they called the laboratory. After some testing, the laboratory identified the source of the rash as a homemade pepper spray, and the patient was treated.

During a large fire in Philadelphia, the Pennsylvania Department of Environmental Protection (PA DEP) needed drinking water and runoff samples analyzed to ensure they did not contain harmful chemicals. Fortunately, the state laboratory tested the samples at the same time as a commercial laboratory. Otherwise, officials may not have known about the presence of benzoic acid—a skin irritant that is toxic if ingested. Consistent with public laboratories’ missions, the PA DEP did more than due diligence to ensure the health of the public.

Preparedness is not a constant state but instead a dynamic state that must constantly be maintained or expanded. Environmental laboratories resolve public health threats routinely, providing invaluable services to the people affected. To share stories like these, contact jennifer.pierson@aphl.org.

Helping families to be better patients.

For ten years, Lab Tests Online has been helping families to better understand their laboratory tests so that they can speak with their doctors more effectively about the care they are receiving. We want to thank our Sponsors and Partners from the lab community for their support in making Lab Tests Online available to over 24 million visitors in 2010.

Contact 2labtestsonline@aacc.org to become a sponsor and join our 10th-year celebration at AACC in Atlanta.

www.labtestsonline.org
Over the years, the laboratorians and epidemiologists participating in PulseNet regional meetings have expanded their focus from merely sharing experiences with PFGE testing and surveillance to fostering the alliances required for effective foodborne illness investigations. This change reflects the increasing scope and quantity of work that laboratorians at state, local and federal agencies perform routinely, as well as the introduction of new federal initiatives that complement the PulseNet network.

MEETINGS IN WI, RI, GA, TX

In 2010, APHL and regional PulseNet Area Laboratory Coordinators organized two-and-a-half day meetings in Wisconsin, Rhode Island, Georgia and Texas. In total, 183 representatives from 26 states, localities and relevant federal agencies attended the four regional meetings, including laboratorians, epidemiologists, sanitarians, agricultural and food protection representatives, as well as federal partners from CDC, USDA and FDA. Environmental health and food protection representatives learned current PulseNet news, explained their role in outbreak investigations, and participated in a workshop about the Council to Improve Foodborne Outbreak Response’s (CIFOR) Guidelines for Foodborne Outbreak Response. The meetings allowed many colleagues from state and local governments to meet for the first time.

REGION-SPECIFIC TOPICS

Each regional meeting had a slightly different focus, but many of the same issues and concerns were discussed, including funding, workload and communication. Region-specific topics included updates to regional surveillance projects, creation of regional websites and discussions on seasonal PFGE pattern trends. Representatives from New York City and Wisconsin presented their experiences with the Outbreak Sentinel Site (OSS) project, and Tennessee participants described a project sponsored by CIFOR aimed at integrating laboratory and epidemiologic data through an open source software.

New federal initiatives were highlighted, such as EHS-Net, a network for environmental health specialists led by the CDC’s National Center for Environmental Health. A current EHS-Net project is the development of a National Voluntary Environmental Assessment Information System (NVEAIS) to identify environmental factors that may cause foodborne illnesses and outbreaks. [See www.cdc.gov/nceh/ehs/EHSNet/nveais.htm for more information.] Participants also described experiences with the Foodborne Emergency Response Network (FERN), discussing how PulseNet and FERN laboratories could work together during national foodborne emergencies. Other federal initiatives raised were the FDA-sponsored Rapid Response Teams and the USDA Microbiological Data Program.

FOCUS ON RESPONSE GUIDELINES

With the involvement of the Council of State and Territorial Epidemiologists (CSTE) and CIFOR, a day of each meeting was focused on the Guidelines to Improve Foodborne Outbreak Response and a new toolkit for public health professionals. The CIFOR toolkit is designed to help an agency assess its foodborne outbreak response activities and determine how to implement the new CIFOR guidelines throughout the health department. Tim Monson from the Wisconsin state laboratory said, “The CIFOR workshop and toolkit covered priority focus areas such as planning and preparation, surveillance and outbreak detection, investigation of clusters and outbreaks and control measures... With many of the key players in foodborne disease response and surveillance present, we were able to effectively develop and outline steps to implement changes in the priority area of communications, which is part of the planning and preparation focus area.”

The regional meetings foster new energy, build professional ties and expose the shared vision of the local, state and federal participants—all of which contributes to improving the nation’s food safety. For more information, contact Kristy Kubota, senior specialist for PulseNet, at kristy.kubota@aphl.org.

---

2011 PULSENET REGIONAL MEETINGS

April 27 – 29: Mid-Atlantic meeting | Richmond, Virginia
October 12 – 14: North Central meeting | Sioux Falls, South Dakota
LABORATORY TRAINING FROM THE EXPERTS

GRANT WRITING TELECONFERENCE SERIES

The Grant Writing Practicum Series covers the components typically requested in federal government proposals with emphasis on time saving techniques. Those new to grant writing receive an overview of the process; those already experienced learn new ways to look at RFP requirements.

- Grant Writing Mantra: Be Prepared!
- Why Our Department is the Best: How to Write an Organizational Background
- Condensing a Year’s Work Into Mere Pages: Planning and Writing the Work Plan
- Proving Excellence: The Evaluation, Monitoring or Quality Section
- What Does Our Program Really Cost?: Budgeting Strategies

To register for these and other courses, visit www.aphl.org/courses/LM1

APHL 2011 ANNUAL AWARDS

Recognizing the Unsung Heroes of Public Health

APHL’s annual awards program recognizes commitment, innovation and talent in the field of laboratory science. The Membership and Recognition Committee invites you to recognize your colleagues by submitting a nomination for one these awards, presented at APHL’s Annual Meeting, June 5–8, Omaha, NE.

- Lifetime Achievement Award
- Gold Standard Award for Public Health Laboratory Excellence
- Emerging Leader Award
- On the Front Line Award
- Champion of the Public Health Laboratory Award
- Thomas E. Maxson Education, Training and Workforce Development Award
- Healthiest Laboratory Award

Nomination deadline: Friday, April 1, 2011
www.aphl.org/awards
The importance of neonatal screening as a public health program is recognized in the United States and abroad. Each year, thousands of newborns with severe genetic and congenital conditions are identified in the US at state newborn screening laboratories. However, approximately 97% of the world’s children are born outside of the US and Canada, so there is a lot to be learned from interactions and discussions among international newborn screening systems. APHL and the Newborn Screening Quality Assurance Program at CDC recognize the value of mutual efforts to expand and optimize neonatal screening programs and maximize the coverage of screened infants worldwide, thus improving their health.

To highlight future global partnerships in newborn screening, APHL signed a Letter of Intent with the International Society for Neonatal Screening (ISNS) to work collaboratively on international newborn screening issues in 2008. Since then, ISNS has co-sponsored the Newborn Screening and Genetic Testing Symposium, using the meeting to highlight ISNS activities and international newborn screening programs.

In 2009, APHL in collaboration with the Newborn Screening Quality Assurance Program (NSQAP) at CDC and the Global Sickle Cell Alliance began work on a newborn screening initiative in Nigeria. The initiative’s goal is to reduce morbidity and mortality related to newborn screening conditions, using sickle cell disease (SCD) as a model. In partnership with the Commissioners of Health in Oyo, Anabara and Kaduna States, and equipment donation from Perkinelmer Inc., the newborn screening initiative will kick-off in April 2011. Nigeria accounts for 75% of all sickle cell births in Africa and ranks first among sickle cell endemic countries in the world, with approximately 24% of Nigerians carrying the trait. More than 150,000 babies are born in Nigeria with sickle cell disease every year. In comparison, about 1,500 newborns are born with SCD in the United States.

In 2010, APHL and NSQAP, in partnership with the Sickle Cell Foundation of Ghana, launched some collaborative activities related to newborn screening for hemoglobinopathies. These initiatives included laboratory staff training on newborn screening quality assurance and quality control, as well as population newborn screening at CDC in Atlanta and the Georgia Public Health Laboratory. Subsequent collaborations led to the development of a Memorandum of Understanding (MOU) with additional partners in Ghana. The MOU outlines a collaborative newborn screening project with laboratory support for sickle cell disease and other hemoglobinopathies, organized by a group of partners that includes the Ghana Ministry of Health, the Sickle Cell Foundation of Ghana, Komfo Anokye Teaching Hospital, Noguchi Memorial Institute for Medical Research, APHL and the NSQAP.

In 1995, a research project piloting a newborn screening program for SCD was implemented in Kumasi, Ghana. Based on its success, this newborn screening program will expand in the near future to cover the Ashanti region of Ghana and then countrywide in 2014. Data from the pilot program indicated that approximately 2% of the newborns in Ghana are affected with SCD, which translates to more than 11,000 babies per year.

APHL has also developed a partnership with the Ministries of Health in Tanzania for a newborn screening initiative at the Muhimbili University of Health and Allied Sciences, and is working with the NSQAP and the Ministry of Health in Brazil to develop laboratory “twinning” initiatives that will help foster knowledge and information-sharing among international newborn screening programs and American state public health laboratories.
In 2010, APHL’s newborn screening and genetics program became an independent department, staffed by Jelili Ojodu, Elizabeth Jones and Asha Farrah. APHL Executive Director Scott Becker believes this structural change positions newborn screening more appropriately for “greater visibility and a move to the forefront of the public health issues that the organization addresses.” The department goals are consistent with APHL’s broader objectives, handling issues surrounding education and outreach, workforce training, technology and information exchange, partnership formation, and the provision of resources and news to members.

HELPING STATES IMPLEMENT NEW TESTING

In October 2010, in Atlanta, GA, the newly-formed department co-sponsored its first meeting, on Severe Combined Immunodeficiency (SCID) with the CDC, National Newborn Screening and Genetics Resource Center, and Health Resources and Services Administration. SCID, which is characterized by defects in cellular and humoral immunity, was recently added to the recommended uniform newborn screening panel—currently, only Wisconsin, Massachusetts, California, New York, Louisiana and Puerto Rico screen for the disorder. The meeting, designed to help state newborn screening programs implement the new test, assembled 196 people from 48 states and three countries, including pediatricians, immunologists, laboratorians and parent advocacy groups. Participants discussed the importance of adding SCID to the panel, the TREC assay and methodology, implementation challenges, alternate technology for testing, and treatment and clinical management. A participant noted that “the meeting will help prepare the labs with issues and challenges surrounding SCID testing including funding, legislative approval, staffing and new methodologies.”

ENSURING NECESSARY TRAINING

In November, to help address technology and workforce training gaps, APHL co-sponsored a Laboratory Health Information Technology Meeting on Standardizing and Automating Newborn Screening Messages in Bethesda, MD. Laboratorians, vendors and government professionals discussed health information exchange through HL7 messaging and standardization of electronic data transfer in health care settings. Additionally, in order to address workforce issues, the department will continue working with the CDC to develop hands-on molecular and tandem mass spectrometry training courses for members.

EXPANDING INTO PUBLIC HEALTH GENETICS

The department will expand APHL’s activities further into the field of public health genetics. The field has a natural connection to newborn screening, but there is an enormous, additional potential for genetics to inform other areas of public health. Staff are working closely with a Genetics Taskforce comprised of members and affiliates to develop a whitepaper that addresses genetics beyond newborn screening. “It is our hope that the taskforce will help us become a leader in understanding the interactions between genes and the environment to help find better ways to improve health and prevent disease,” said Farrah, associate specialist.

SHARING NBS INFORMATION

Also interested in education and outreach, the department will work closely with the Health Resources and Services Administration, the Genetic Alliance, and several other partners, to develop the Newborn Screening Clearinghouse. The clearinghouse will serve as an information exchange resource for stakeholders in the newborn screening system.

PROVIDING GUIDANCE ON POLICY ISSUES

As newborn screening evolves, it will be increasingly important for the Newborn Screening and Genetics Department to address policy issues, including storage and use of residual dried blood spots, parental consent for screening, and the disclosing of carrier status or other information gained peripherally through screening.

EXPANDING TO DEVELOPING COUNTRIES

APHL and the CDC’s Newborn Screening and Molecular Biology Branch share a mutual interest in optimizing neonatal screening programs and extending coverage globally. To that end, APHL and CDC have been working with the Ministries of Health in developing nations to explore the feasibility of newborn screening. These efforts are currently underway in Ghana, Nigeria, Tanzania and Brazil (see page 10).
Winter 2011
LAB MATTERS 13

WIPEOUT
WHAT WILL IT TAKE TO END TB?
by Nancy Maddox, writer

Something extraordinary happened in 2009: the rate of reported new tuberculosis (TB) cases in the United States dropped 11.4%, the greatest annual decrease ever recorded in 56 years of national TB surveillance. The decrease was of such magnitude and significance that in public health circles it quickly acquired its own acronym—DIRT—meaning “decline in reported TB.”

Not only was the DIRT of historic proportions, it was somewhat of a surprise. Ken Castro, MD, director of CDC’s Division of TB Elimination, said the plunge in incidence went “beyond our expectations.”

TB—an infectious and potentially deadly disease that attacks the respiratory system—can only be diagnosed by laboratory testing and only reliably treated after additional testing to determine which anti-TB drugs will target the infecting organism. Thanks in part to laboratory-based disease surveillance and other public health activities, the overall rate of TB has been creeping downward since the mid-1990s. But an 11% drop was a jolt.

Health authorities considered the possibility that underreporting or underdiagnosis of TB was responsible for the DIRT. But after a CDC investigation, Castro said, the decline “doesn’t seem to be the result of underreporting or anything that we could put our finger on other than it coincided with the economic disaster faced by our country.”

The timing is suspect since many foreign-born residents—who have a rate of TB 11 times higher than US-born persons at 18.6 cases/100,000 versus 1.7/100,000—left the country after the US economy soured and some would-be immigrants likely did not come. At the same time, US immigration officials instituted more stringent pre-immigration TB screening protocols.

Whatever the reason, health officials both welcome the DIRT and caution against undue optimism.

The ultimate public health goal, as reflected in the name of Castro’s CDC division, is not to reduce the burden of TB, but to eliminate it—a much more formidable task that depends on a robust infrastructure for TB testing and other services. Said Castro, paraphrasing a statement made famous by Dr. William Brown during the campaign to eliminate syphilis in the 1960s, “As you approach the eradication of the disease, you are more likely to eradicate the program than the disease.” This axiom—dubbed Brown’s Law—alludes to the complacency and diversion of resources that has stalled many initially successful disease control programs, including that for syphilis. So far, only smallpox, a once rampant illness with high rates of disfigurement and death, has been officially eradicated after an intensive, sustained worldwide campaign. With TB, success has bred its own challenges.

Said Castro, paraphrasing a statement made famous by Dr. William Brown during the campaign to eliminate syphilis in the 1960s, “As you approach the eradication of the disease, you are more likely to eradicate the program than the disease.”

Even as TB incidence declines, the number of patients showing up as ‘TB suspects’ does not decline. “People forget about that because they’re just looking at the [confirmed] cases,” said Michael Iademarco, MD, MPH, a pulmonary physician-scientist who is chief of the laboratory branch in CDC’s TB division. “The number of TB suspects,” he said, “is driven by the number of patients with pulmonary disorders mimicking TB, so the demand for TB testing is constant.”
In fact, said Iademarco, as TB becomes more rare, “we have to increase the number of suspects to find the needle in the haystack. And I don’t think that’s something that’s commonly appreciated.”

Ironically, worries about declining funding for TB testing, case management and patient contact investigations have been prompted by the same economic downturn presumed to underlie the DIRT. And, in an unlucky twist of fate, budget cuts are coming at a time when new laboratory technology puts TB elimination in closer reach than ever before by drastically shortening delays in diagnosis and treatment.

TB OR NOT TB: THAT IS THE QUESTION

By far the most common method of TB diagnosis is acid-fast bacillus (AFB) smear microscopy, in which a patient’s sputum specimen is treated with staining reagents and examined under a microscope to detect rod-shaped bacteria or bacilli. This method is rapid, inexpensive and identifies the most contagious patients. But it has serious limitations.

Smear microscopy identifies just 45% to 80% of TB cases. It also has poor positive predictive value (a measure of confidence in a positive result), since it does not distinguish between Mycobacterium tuberculosis and nontuberculous bacilli that are also acid fast.

Because of these shortcomings, AFB smear-positive specimens and AFB smear-negative specimens from patients with known TB risk factors must undergo confirmatory testing. Culture—in which M. tuberculosis is grown in a Petri dish or culture tube—is the gold standard confirmatory test and is required to isolate bacteria for drug-susceptibility testing and for genotyping to characterize TB strains.

The problem is M. tuberculosis is a notoriously slow-growing organism. It can take two to four weeks for the mycobacteria to grow in culture, and laboratorians cannot rule out the possibility of M. tuberculosis growth until at least six weeks have elapsed. Once the organism is isolated and confirmed as M. tuberculosis, additional testing to gauge drug resistance can take up to four weeks longer. Thus, physicians and patients with drug resistant infections can wait anywhere from three to ten weeks before learning the appropriate course of treatment and definitively breaking the chain of transmission.

Said Castro, “Because you’re dealing with a slow-growing bug, you need to beat it. One way to beat it is by reading its DNA before it has time to replicate.”

The MTB/RIF assay (see page 15) has generated much excitement in the international public health community. Last December, the World Health Organization (WHO) endorsed the assay, saying it could “revolutionize TB care and control” and enable a three-fold increase in the diagnosis of patients with drug-resistant TB.

NEW TECHNOLOGIES FOR TB

In 1995, the FDA approved the first DNA test to diagnose TB directly from sputum specimens, a nucleic acid amplification (NAA) test produced by Gen-Probe for use with AFB smear-positive respiratory specimens. Four years later, the agency approved an enhanced Gen-Probe NAA test for use with AFB smear-negative specimens from patients suspected to have TB.

NAA testing is more reliable than smear microscopy and more rapid than culture, taking just hours to generate results. CDC has recommended its use since 1996. The most recent guidance—based on input from a panel of experts convened by APHL and CDC—was released in early 2009 and recommends NAA testing “on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet been established and for whom the test result would alter case management or TB control activities.”

A second testing milestone was the September 2009 launch of CDC’s Molecular Detection of Drug Resistance program, a laboratory service that accepts TB isolates from public health laboratories (PHLs) and other submitters and provides preliminary susceptibility data for eight first- and second-line anti-TB drugs, based on examination of genetic mutations associated with drug resistance. Results are confirmed in parallel with culture-based susceptibility tests.

The program sidebar, pg 17, has so far, examined isolates for about 150 patients, comprising half of all multidrug-resistant TB (MDR TB) cases reported nationally during that time. It advertises a turn-around-time of four days, but often delivers results sooner. The real delay comes at the front end, since submitting laboratories must still isolate M. tuberculosis in culture in order to submit the necessary isolates.

The latest technological innovation—Cepheid’s GeneXpert MTB/RIF assay—bridges this gap. It not only provides positive or negative results for M. tuberculosis from sputum
specimens within two hours, but simultaneously detects mutations associated with resistance to rifampin, one of the most important anti-TB drugs. In many settings, especially internationally, rifampin-resistance is considered a surrogate marker for multidrug resistance.

The MTB/RIF assay has generated much excitement in the international public health community. Last December, the World Health Organization (WHO) endorsed the assay, saying it could “revolutionize TB care and control” and enable a three-fold increase in the diagnosis of patients with drug-resistant TB.

PROMISE DEFERRED

Where it has been instituted, molecular TB testing has been a boon to laboratories, healthcare providers and TB controllers. The Florida Department of Health Bureau of Laboratories (FBL) was an early adopter, implementing the first NAA test kit for TB within one month of FDA approval. In 2009, the Florida PHL network tested roughly 24,000 clinical specimens for the disease, and the FBL performed more NAA tests for TB than any other PHL.

Overall, though, Max Salfinger, MD, a TB expert and Florida state laboratory director, said implementation of the 15-year-old technology has been “too slow.” In fact, most US PHLs have not yet been able to fully implement CDC’s 2009 NAA test guidelines.

Even though early TB diagnosis and treatment would likely generate overall savings for state TB control programs, the expense to individual laboratories is considerable.

One reason is cost. Even though early TB diagnosis and treatment would likely generate overall savings for state TB control programs, the expense to individual laboratories is considerable. Operating costs associated with Gen-Probe's NAA assay, for example, can exceed $100 per test (depending on testing volume), placing it beyond the reach of many PHLs at a time when most states face budget deficits.

Kelly Wroblewski, MPH, MT(ASCP), director of APHL’s infectious disease program, said PHLs are generally worried about maintaining existing services, given the current economy. Adding new technology, she said, “is difficult and involves huge training components.” [See pg. 17 sidebar for information about a one-time CDC grant that is aimed at helping labs ramp up TB NAA testing.]

But there are other barriers. Chief among these is lack of commercial availability of Cepheid’s highly touted MTB/RIF NAA assay. The assay is in use in the European Union and at least seven other countries—Australia, Brazil, Columbia, Korea, Mexico, Panama and Venezuela—but awaits US FDA approval for domestic use.

Because TB prevalence is so low in the US, and the prevalence of MDR TB even lower, the pre-market clinical evaluations required for FDA approval pose greater challenges here than in high-prevalence settings. (When a disease is rare, the major determinant of positive predictive value is disease prevalence in the screened population.)

Sally Hojvat, PhD, director of FDA’s Division of Microbiology Devices, said, “FDA realizes that, in the interest of public health, there is a definite need for such a test to be available in the US, and we will work diligently with our sister agency, the CDC, and the company to enable this to occur as quickly as possible, with the important caveat that the safety and efficacy of the test is demonstrated in the US population.”

Russel Enns, PhD, Cepheid’s chief regulatory officer, said the company anticipates product approval and availability in the US in 2013. In the meantime, CDC officials are hoping to collaborate with the FDA to secure an investigational device exemption (IDE) that would enable laboratories to use the assay with appropriate mitigation procedures and quality controls.
"We ought to assertively try to use it in the US and not just wait for the next two years of data collection for it to happen," said Castro. "The IDE would enable the use of this promising diagnostic device while collecting additional key information to confirm safety and validate performance."

At least one PHL, the San Francisco Department of Public Health Laboratory (SFDPHL), has performed an extensive in-house validation of the MTB/RIF NAA assay and is already using it. Mark Pandori, PhD, HCLD(ABB), the lab’s director, said SFDPHL scientists tested 120 specimens of varying degrees of positivity, including specimens containing non-tubercular mycobacteria, and found the Cepheid assay to be as sensitive as the Gen-Probe NAA assay for smear-negative, culture-positive specimens—"the real challenging specimens."

The SFDPHL implemented the assay in April 2010. Last year, the laboratory tested 2,385 sputum specimens and confirmed 98 TB cases, including 17 drug-resistant cases and 3 multidrug-resistant cases.

With the MTB/RIF NAA assay, Pandori said, molecular testing is "no longer a major issue; we can turn it around in two hours or less with very little impact on the labor situation."

Because of the tremendous difference in the time to diagnosis—two hours versus several weeks—Pandori said, "If you believe we have an honest obligation to eliminate TB, then you have to embrace molecular technology."

Low-incidence states, however, face extra challenges. When the number of specimens submitted for testing drops below a certain threshold, it becomes increasingly difficult for laboratorians to maintain technical proficiency, and the cost per test increases.

Andrea Labik, ScD, head of the West Virginia state PHL, said her lab was "on the verge of getting rid of TB testing altogether" about a decade ago precisely because of low specimen volume. Laboratory staff and the state TB control officer embarked on an outreach campaign to "drum up business" from hospitals that had been sending their suspect specimens elsewhere for testing.

The campaign worked. Last year, the laboratory received 1,308 clinical specimens and identified 48 TB cases using Gen-Probe's molecular assay. However, specimen volume—roughly two dozen per week—is still insufficient to enable scientists to maintain proficiency in drug susceptibility testing. Thus, the West Virginia lab sends TB isolates across state lines to the Pennsylvania Bureau of Laboratories for drug-resistance testing.

Other low-incidence states have devised similar arrangements to maximize efficiencies and assure prompt, reliable testing.

Although California vies for position as the highest incidence state in the country, TB specimens are divvied up among the state PHL, three dozen or so local PHLs and a few large commercial labs. Ed Desmond, PhD, D(ABMM), who oversees mycobacterial disease testing at the state laboratory, said his staff tests about 2,000 specimens per year.

Some of those specimens are sent for testing through an innovative program devised to support California’s rural, local PHLs. Those labs, said Desmond, have highly qualified staff, but find it uneconomical to invest in the expensive instrumentation needed to keep up with the standard of practice when they receive so few specimens from patients suspected to have TB.

Under the program, ten rural PHLs perform smear microscopy onsite and simultaneously inoculate a broth culture with a portion of the specimen, which is sent to the state PHL’s Microbial Diseases Laboratory for incubation. Positive cultures undergo rapid drug susceptibility testing, including molecular testing. If physicians have reason to suspect drug resistance when the specimen is collected, the local PHL also sends sputum sediment for rapid molecular testing using a “home-brew” molecular beacon assay (developed in-house) or DNA sequencing.

This model provides for rapid availability of smear results locally, as well as access to state-of-the-art methods.

"COMPLACENCY IS UNACCEPTABLE"

With molecular assays, innovative testing models for low-incidence jurisdictions and other advances—including some in the pipeline—Desmond said he believes TB elimination is an achievable goal: “It’s not rocket science. It’s a matter of having the resources.”
But, he quickly added, “Do I believe we’re going to have the resources? I have my hopes, but maybe I’ve been around too long; I’m somewhat skeptical.”

Historically, at least, the resources have not always been available. CDC’s Castro cited “very sad evidence” of past TB funding cuts.

**TB elimination in the US cannot occur in isolation from the rest of the world. Both CDC and APHL have adopted a global perspective of TB control.**

Between 1985 and 1992, he said, the US experienced an “unprecedented” resurgence of TB following a perfect public health storm: rising rates of HIV infection, leaving those co-infected with TB especially prone to disease progression; emergence of MDR TB at a time when drug resistance testing was uncommon; lax infection control practices in institutional settings; and, importantly, a deteriorated infrastructure for TB services after the elimination of categorical federal TB funding in 1972 and subsequent state funding cuts.

“We were very ill-prepared to respond,” said Castro. By 1992, TB case rates had risen 20%.

This history perhaps explains Castro’s interest in ‘Brown’s Law’ and the aftereffects of the DIRT in 2009. “We’ve learned painfully in our past that the moment you let your guard down, it comes back to haunt you,” he said. “Complacency is unacceptable with TB.”

National TB statistics for 2010 are not yet available, but Desmond said, “I will predict for you rather than an 11% drop, we’re going to go back to the [2% to 4%] figures we were seeing before [2009], and we’re not going to be too pleased with that. This is not the point at which we should be saying TB is going to go away and we don’t need to worry about it.”

**INTERNATIONAL INFECTION RATES REINFORCE NEED FOR TB CONTROL PROGRAMS**

Overall, 11,540 TB cases were reported in the US in 2009, but there were 9.4 million new cases worldwide. The WHO estimates that one-third of the global population is infected with *M. tuberculosis*.

The health officials interviewed for this article agree that TB elimination in the US cannot occur in isolation from the rest of the world, especially since the highest pockets of domestic TB are in foreign-born populations. Thus, both CDC and APHL have adopted a global perspective of TB control.

APHL is a member of the Partners’ Committee of the Global Laboratory Initiative, an independent, expert advisory group to the WHO Stop TB Program. In addition, the association:

- Coordinated the efforts of an expert workgroup to develop an exhaust cabinet that provides a safe working environment for the thousands of technicians in developing countries who prepare sputum specimens for smear microscopy—the most widely used means of diagnosing TB in developing countries.
- Implemented advanced laboratory information systems in the national TB laboratories of Kenya, Botswana and Mozambique, with more laboratories to be added. The systems connect to automated testing equipment, making it possible to test more specimens and to report results more quickly to TB clinics using text messaging services.

CDC’s Iademarco said, “I am impressed with APHL’s new strategic plan because it defines our collective mission as shaping national and global health objectives and promoting policies, programs and technologies to assure continuous improvement in the quality of laboratory practice and health outcomes. We stand behind this mission, and I think it is essential to eliminate tuberculosis.”

Despite unpredictable challenges ahead, one thing is certain in the realm of TB control. Said Castro, “TB is an infectious disease only diagnosed by finding the organism in those who have it. And therefore, the lab is at the heart of this. The ability to diagnose TB depends on having good labs.”

---

**UPGRADING TB TESTING TECHNOLOGY**

In October, APHL and CDC requested applications for a series of sub-grants intended to expand Nucleic Acid Amplification Testing (NAAT) for TB in public health laboratories. Fifty-five of the 64 eligible state, local and territorial public health laboratories applied for and were awarded a portion of the funds. The awards are intended to implement, expand or improve access to NAAT for the identification of *Mycobacterium tuberculosis* complex or the molecular detection of drug resistance in *M. tuberculosis* in their jurisdiction.

Over the next several months, APHL will administer the funds which total nearly $2.5 million. Laboratories will use the influx of resources in a variety of ways including implementing testing in areas where it wasn’t previously available; upgrading technology currently in use; expanding the number of patients to whom testing is offered; educating health care providers on appropriate use and interpretation of the test(s); and expanding courier services to improve current turnaround-times.

Along with their applications for the funds, laboratories were asked to submit data on the current use of TB NAAT in their jurisdictions and will be required to submit the equivalent data at the end of their project period. APHL and CDC will work together to analyze the pre- and post-project data in an effort to determine the impact that the funding had on improving access to the latest in TB testing technology across the United States.
In November 2010, a diverse group of 75 Milwaukee area professionals gathered for an unprecedented event: the assessment of a local public health laboratory system through APHL’s Laboratory System Improvement Program (L-SIP).

To date, 24 states have conducted the L-SIP assessment. Assessing a local public health laboratory system required a revision of the L-SIP Performance Measurement Tool and the development of a formal definition of a local public health laboratory system.

LAYING THE GROUNDWORK

“It was really a convergence of so many things that put us in a spot to do this,” said Steve Gradus, PhD, City of Milwaukee Health Department (MHD) laboratory director. Support from administration, a departmental objective toward outreach, the availability of funding to hire a consultant familiar with the inner workings of the department and public health community, assistance and encouragement from APHL and participation on the APHL L-SIP Steering Committee, Gradus said, all contributed to the decision to initiate the L-SIP process. Consultant Amy Murphy’s observation of Minnesota’s assessment was also a significant help.

Participants represented nearly 35 state and local organizations, including the Wisconsin State Laboratory of Hygiene, suburban health departments, area hospitals, regulatory and non-profit agencies, universities, first responders, the medical examiner’s office and the crime lab—to name a few. The city’s laboratory is co-located with the health department and operates in tandem with other public health professionals; these relationships result in rapid and relevant response and strong community ties.

The Milwaukee laboratory is co-located with the health department and operates in tandem with other public health professionals; these relationships result in rapid and relevant response and strong community ties.

Ensuring that the “right people” participated was one of the planners’ most crucial tasks, said Gradus. The invitation list was crafted carefully to secure individuals’ participation and assure redundancy when needed.

Participants evaluated the lab system’s effectiveness in one of the 10 Essential Services of Public Health. (See www.cdc.gov/nphpsp/essentialServices.html.) Following this group exercise, participants were divided into three groups based on areas of expertise; each group spent the day evaluating three of the nine remaining Essential Services. Through facilitator-guided discussion, the groups identified the lab system’s strengths and weaknesses and defined next steps to improve system performance.

After hearing an overview of the process, participants evaluated the lab system’s effectiveness in one of the 10 Essential Services of Public Health. (See www.cdc.gov/nphpsp/essentialServices.html.) Following this group exercise, participants were divided into three groups based on areas of expertise; each group spent the day evaluating three of the nine remaining Essential Services. Through facilitator-guided discussion, the groups identified the lab system’s strengths and weaknesses and defined next steps to improve system performance.

“Bringing all of us from many different agencies to have this discussion was very valuable,” one participant wrote. Many others agreed. (See Figures A & B at page 19.)

Although a significant component, the discussion generated by the assessment is just the beginning of Milwaukee’s L-SIP process. A detailed report of assessment findings is being compiled and will be posted on the lab’s L-SIP webpages. Results will be used as a basis for strategic planning to develop and implement improvement tactics. With the help of a grant from APHL, strategic planning (including formation of a steering committee and work groups) is expected to take place during the first half of 2011. Over the course of the next several years, the Milwaukee Health Department hopes to have the opportunity to reassess the local PHL system once designated improvement efforts are underway.
In late 2010, applicants submitted 13 proposals for the second round of "Innovations in Quality Public Health Laboratory Practice" grants. The grant program supports selected and innovative projects that help define and assess quality public health laboratory practice, systems and services. A team of members and APHL and CDC staff evaluated each proposal against criteria such as the degree to which the proposed project related to one of the research questions, how the project could be used by other public health laboratories, appropriateness of the methodology, goals and objectives, description of measurable objectives and degree of collaboration with others. The awards went to...

**INNOVATIONS IN QUALITY PUBLIC HEALTH LABORATORY PRACTICE**

*Karen Breckenridge, MBA, MT(ASCP), director, quality systems*

In late 2010, applicants submitted 13 proposals for the second round of "Innovations in Quality Public Health Laboratory Practice" grants. The grant program supports selected and innovative projects that help define and assess quality public health laboratory practice, systems and services. A team of members and APHL and CDC staff evaluated each proposal against criteria such as the degree to which the proposed project related to one of the research questions, how the project could be used by other public health laboratories, appropriateness of the methodology, goals and objectives, description of measurable objectives and degree of collaboration with others. The awards went to...

**TEXAS DEPARTMENT OF STATE HEALTH SERVICES’ LABORATORY SECTION**

Public Health Performance Measures Project – Laboratory Role in Blood Lead Screening Program

**WISCONSIN STATE LABORATORY OF HYGIENE**

Enhancing Statewide Surveillance for Rotavirus

**ARIZONA DEPARTMENT OF HEALTH SERVICES–BUREAU OF STATE LABORATORY SERVICES**

Development of a Crosswalk of Regulations and Guidance Documents Affecting State Environmental Laboratories

**WISCONSIN STATE LABORATORY OF HYGIENE**

A Method for Creating LIMS Specifications Based Upon the APHL LIMS Requirements

**MICHIGAN DEPARTMENT OF COMMUNITY–BUREAU OF LABORATORIES**

Legislative Policy and Communication Skills Workshop

**CITY OF MILWAUKEE HEALTH DEPARTMENT–PUBLIC HEALTH LABORATORIES**

Strategic Planning for Implementing Process Improvement Activities Identified by Participation in a Pilot of the L-SIP Assessment in a Local Laboratory System

To learn more about these projects, attend the breakout session on Innovation Grants and/or the poster sessions at the APHL Annual Meeting on June 5, 2011. Session and posters will include summaries of some of the completed projects from spring 2010, as well as those still in-progress. General information on the grant program can be found at www.aphl.org/aphlprograms/research/Pages/innovations.aspx.
Within 10 years, many public health laboratory scientists will retire, leaving more than 250,000 vacancies in the field. Simultaneously, terrorist threats and emerging infectious diseases will require laboratories to add frontline response activities to their ongoing responsibilities. Unfortunately, the public health field lacks a sufficient number of leaders just when it needs them most.

In response, APHL created the National Center for Public Health Laboratory Leadership’s (NCPHLL) Emerging Leaders Program (ELP), a 12-month leadership development program designed to recruit future leaders in public health. The program invites current public health laboratory (PHL) managers to collaborate to advance one of the following goals:

- Develop leadership capability within the existing workforce,
- Encourage networking among scientific professionals,
- Strategically market PHL careers to qualified scientists and management personnel.

Now in its third year, the ELP cohort classes have made significant headway and are eager to share their success.

PREPARING LABORATORIANS TO TAKE THE REINS

In January 2008, the first cohort of the ELP met in Tampa, FL, and identified workforce training as a critical need. The goal was to develop a solid base of qualified and motivated staff to fill the future shortage of laboratory leaders.

“Most laboratory staff come from a medical background or other hard science background and really have a limited understanding of the public health system as a whole, and about management and running a business,” said participant Steve Marshall, MS, epidemiologist/assistant researcher, Wisconsin State Laboratory of Hygiene.

Veteran lab directors worked with CDC to create the “Laboratory Management Curriculum,” a series of courses on the public health system and laboratory management. Designed to expand over time, “the modules provide background on how to manage a lab as a strategic thinker, a skill that’s being lost every day as more and more of our managers retire,” said Marshall.

Public Health 101, the first module in the series, is a four-hour interactive course that educates staff about the history of public health laboratories and the role of the laboratorian in the greater context of the public health community. The course has been administered at state public health laboratories in Texas, Utah, Florida and New Mexico.

“So often, we are isolated in the lab and never get to experience how our work impacts our communities; and this training provided that link,” said Dawni Allen, manager, container preparation group, Texas Department of State Health Services.

DEVELOPING A NEW GENERATION OF LEADERS

In 2009, a new group of laboratorians, Cohort II, set out to address the limited and waning workforce. The group collaborated with “Labs are Vital” to develop content for LabScienceCareers.com, which educates youth (ages 16-19) about careers in science, particularly in public health laboratories. The group researched and posted content on public health salaries, degree programs, job descriptions and links to public health-related organizations. Members of this cohort also posted “field stories” from lab staff and interactive videos to offer a glimpse into the daily life of a laboratorian. Ongoing efforts will include marketing the site and tracking its progress.

“Laboratorians tend to work behind the scenes; it is our hope that we laid the groundwork to help bring this exciting career field into the spotlight. Ultimately, and with continued work, we hope that our project will help remedy the shrinking public health laboratory workforce,” said Denise Bolton, microbiologist IV, New Hampshire Public Health Laboratories.

NEXT STEPS

A third cohort is building an employee retention plan for state public health laboratories with plans to roll it out this summer. The success of the ELP program is expected to grow as more courses and projects are added. By targeting staff currently in the workforce, while simultaneously reaching out to a younger generation, the cohorts are promoting PHL careers at every stage.

Check out all the emerging leader cohort members at http://www.aphl.org/profdev/lablead/projects/Pages/emerging.aspx.
The Cooperative Republic of Guyana, formerly British Guiana, is located on the northern coast of South America and is the lone English-speaking country on this continent. Approximately 90% of Guyana’s 770,000 population live on the coastal plane. A major cause of death for age group 15-44 is HIV/AIDS. As such, there have been considerable investments in improving HIV prevention, treatment and care. In 2008, the National Public Health Reference Laboratory (NPHRL) in Georgetown, Guyana, and the North Carolina State Laboratory of Public Health (NCSLPH) in Raleigh, NC, entered into a twinning relationship facilitated by APHL and CDC and funded via the US President’s Emergency Plan for AIDS Relief (PEPFAR). PEPFAR, which is driven by a shared responsibility among donor and partner nations and others, is the largest US government initiative to help save lives of those suffering from HIV/AIDS around the world. Read about the goals of PEPFAR at http://www.pepfar.gov/countries.

The primary goal of the NPHRL-NCSLPH twinning partnership is to strengthen laboratory capacity at the NPHRL in Guyana. In November 2008, staff from the North Carolina state lab conducted their first site visit of the NPHRL, regional and private laboratories. Following this visit, the twinning partners crafted their scope of work focusing on mentoring, quality assurance, biosafety, technical assistance for implementing new methods and development of a national laboratory system. Since 2008, the NCSLPH staff, Leslie Wolf, PhD (laboratory director), and Royden Saah, MS, (bioterrorism and emerging pathogens coordinator) have provided ongoing mentorship to lab director Colin Roach, MBBS, and his team at the NPHRL. Staff from the NCSLPH provided training on biosafety at the NPHRL and hosted their staff. APHL facilitated NPHRL staff travel and participation in educational activities, such as molecular biology and management training, in the US and Guyana. In March 2010, North Carolina’s Wolf and Saah conducted a follow-up visit, developing a comprehensive assessment of the NPHRL, which provided key recommendations for enhancing laboratory security, quality assurance practices, and laboratory procedures and staff policies.

The two laboratories will continue to collaborate in areas of mentorship, quality assurance, facilities management and implementation of new technologies.

December 2010, APHL facilitated a week-long series of strategic planning sessions with the Guyana Ministry of Health’s National Public Health Reference Laboratory (NPHRL) and its key partners. Participants reviewed the National Strategic Plan for Medical Laboratories, and in a second meeting, crafted a strategic plan specific to the NPHRL. Approximately 30 partners contributed: the Ministry of Health, Georgetown Public Hospital Corporation, Regional Laboratories, Supply Chain Management Systems, Bureau of Standards, CDC, APHL and the North Carolina State Laboratory of Public Health. By the end of the sessions, the group produced a revised draft National Strategic Plan for Medical Laboratories. Presentations from key partners, included: –Barbara Allen, MD, medical officer, CDC Guyana, noted the important role laboratories play in any country to assist with diagnosis, guide appropriate treatment and provide information on the progression of disease.

–Gayathri Warnasuriya, PhD, CDC senior technical laboratory advisor, emphasized CDC’s support and the importance of strengthening the national laboratory network to ensure sufficient capacity.

–Royden Saah, MS, bioterrorism and emerging pathogen unit coordinator at the North Carolina state laboratory, discussed strategic planning within his unit, and the twinning partnership between Guyana and his laboratory.

–Chris Mangal, MPH, director of public health preparedness and response, APHL, provided an overview of the association and its global health activities.

–Eric Blank, DrPH, APHL principal consultant, provided an overview of strategic planning and his expectations for the process.

The MOH will reconvene the participants early this year to finalize the plan and develop a specific implementation (operational) plan. APHL will provide support for a Laboratory Information Management System assessment/implementation and collaborate with CDC and North Carolina to provide quality assurance training and ongoing laboratory support to the NPHRL.
“Gbosa! Gbosa! Gbosa!” Fists pumped; cheers filled the room. This fervor did not emanate from spectators of a sports game on cable TV, but from participants at the end of the fourth annual GWU-APHL International Institute for Public Health Laboratory Management professional development seminar. Dr. Adedeji Adebayo, the head of Nigeria’s Public Health Laboratory, explained, “Gbosa’ is a coinage among activists and students here in Nigeria to show deep appreciation for a job successfully accomplished—synonymous with “hurray” in English but with a deeper sense of acknowledgement.”

This purposeful energy pervaded the two-week course, held in October 2010 at the George Washington University (GWU) in Washington, DC, as 25 senior level public health laboratory professionals representing Barbados, Botswana, Cambodia, Cameroon, Ethiopia, Ghana, Mozambique, Namibia, Nigeria, Sierra Leone, Vietnam and the United States worked together to deepen their understanding of various aspects of public health laboratory management. Twenty-six subject matter experts from organizations including GWU, APHL, US-CDC Global AIDS Program, Clinical Laboratory Standards Institute, the Elizabeth Glaser Pediatric AIDS Foundation and the World Health Organization taught sessions on topics including laboratory accreditation, supply chain management, strategic planning development and implementation, quality management systems and geographic information systems. APHL members and GWU faculty formed the teaching core of the seminar, advancing their shared vision of “a healthier world through quality laboratory practice.” The curriculum included a day at one of the DC, Maryland or Delaware public health laboratories where participants studied laboratory practices and conducted a mock inspection.

The seminar is a part of the institutional partnership between GWU and APHL. In the coming years, the institute leadership intends to expand into laboratory systems-strengthening projects in partner countries.

GWU-APHL INSTITUTE BRINGS TOGETHER GLOBAL LAB LEADERS

by Pamela Hu, specialist, global health

1. Institute class member William Mills-Pappoe from Ghana
2. APHL President Pat Luedtke pictured with GWU mascot George at the GWU-APHL Institute Meeting
3. Dr. Guy-Michel Gershy-Damet (WHO-AFRO)
4. Class member Thi Dzung Dang from Vietnam
5. Dr. Buth Sokhal and Dr. Sokunna from Cambodia, with Dr. Alpha Diallo, Global Health Committee Liaison
6. Dr. John Nkengasong (CDC-ILB GAP Chief)
A civil war in Sierra Leone from 1991-2002 led to the destruction of the country’s health infrastructure and forced many of its skilled professionals into exile. The laboratory system left in place was characterized by weak leadership, poor organization, and inadequate legal and regulatory systems, resulting in unregulated growth of the private sector and the entry of unskilled personnel into the workforce.

Now Sierra Leone is faced with the task of rebuilding its health infrastructure, including its laboratory system, and recognizes the need for policies and plans to address these challenges.

The Sierra Leone Ministry of Health and Sanitation (MOHS), through PEPFAR and CDC, requested that APHL provide assistance in development of a national laboratory policy and strategic plan. Under the leadership of Sahr Gevao (the MOHS laboratory services manager), a Laboratory Technical Working Group comprised of laboratory specialists and ministry representatives began to develop these plans. With technical support from APHL consultants Dr. Isatta Wurie and Dr. Jack Nyamongo, the working group met 12 times over the course of a year and formulated a draft policy that was presented at a stakeholders’ meeting in November. After additional input from the developing partners and international laboratory experts, the finalized draft was presented to senior leadership at MOHS and is now awaiting parliamentary endorsement. Work on the strategic plan is still underway.

As part of the implementation process, APHL—along with WHO, UNICEF and CDC—has provided assistance in establishing a Central Public Health Reference Laboratory (CPHRL), expected to open this month, February 2011. CPHRL will be the pinnacle of the national laboratory network and offer technical support in training and quality management to the rest of the nation’s laboratories. APHL also coordinated training for CPHRL staff on quality management systems and complex testing methods at both the CDC laboratories in Atlanta, GA, and the African Center for Integrated Laboratory Training in South Africa. APHL will continue to report on laboratory system strengthening efforts in Sierra Leone, as well as the upcoming opening of the Central Public Health Reference Laboratory.

The Central Public Health Reference Laboratory is scheduled to open February 2011 in a newly-renovated space. The building was previously used to store antiretroviral drugs (ARVs) for HIV/AIDS treatment, with only a few rooms available for lab testing. With APHL’s support, the ARVs were moved to a proper storage facility to free up space for the new full-fledged laboratory.

REBUILDING SIERRA LEONE’S DAMAGED LABORATORY SYSTEM
by Dr. Jackton Nyamongo, APHL consultant, and Dr. Marie-Claire Rowlinson, senior specialist, global health

Far Right: Plaque on outside of ARV storage building to show supporting partners.

Near Right: Newly renovated building for storage of Antiretrovirals (ARVs) at Lakka (near Freetown) Sierra Leone. Renovation included improvements to the roof, drainage system and shelving for inside the building. The renovation was supported by APHL, CDC, Global Fund and WHO.
Q1: WHAT ARE YOUR MAIN PRIORITIES FOR LS3PO IN THE NEXT YEAR OR TWO?

One of the things I’m really excited about is the chance to lead the conversation with laboratory scientists about what the vision of laboratory services should be like in 2020. With healthcare reform coming up, one of the requirements is the electronic medical records and the electronic laboratory reporting and the meaningful use of such data. We have to begin to incorporate the technologies that are coming down the line. One of the things that I feel very strongly about is that we need to link the dialogue between clinical laboratorians, the state public health laboratories, and entities like CDC to be more connected as one under electronic medical records. So as we look to the future, we need to prepare now to get ready for that. It’s not a 2-year vision, but it’s really the marching orders for this decade.

Q2: HAS THERE BEEN A MAJOR OUTBREAK EVENT IN YOUR CAREER THAT STANDS OUT AS A TEACHABLE MOMENT?

The anthrax letters and SARS. We appreciated the difficulties in translation of laboratory practice tests within the confines of the laboratory and its application—intended or not for patient diagnosis and environmental testing. But the diversity of what you apply diagnostic tests for was not appreciated. And I think in the years since, we’ve worked very hard to correct that. The success is that it’s motivated us to have, from the lab side, conversations with environmental health folks and also with the investigation arm, such as the FBI, to realize we weren’t talking the same language. Communication-wise, we have improved that greatly in the last 10 years—in part because of what was learned from that experience.

Q3: CAN YOU SHARE A NOTABLE EXPERIENCE FROM YOUR TIME AT THE WORLD HEALTH ORGANIZATION THAT HAD A BIG IMPRESSION ON YOU?

There were quite a few, but the most recent one that was very important for me was related to the international health regulations (IHR). One of my jobs was to help prepare 194 countries to be prepared to respond to public health events of international concern, on the laboratory side.

And one of the things that was very impressive to me was that during the 2009 H1N1 pandemic outbreak, I saw the words of the IHR’s mission literally spring to life. The orderliness of how the response went and how countries reported events to WHO was by far a much more measured, accurate and elegant process compared to the SARS outbreak where things were confused. For me, to have witnessed the jumping to life of the IHR and how all the countries used the tools was quite impressive.
Q4: WHAT MUST PUBLIC HEALTH LABORATORIES DO TO BE EFFECTIVE IN DOMESTIC AND INTERNATIONAL SURVEILLANCE?

Communicate... share information... build trust and confidence. These are all human qualities supported by some electronic tools. There must be an atmosphere of collaboration and sharing with partners. Some of our regulations and some of the restrictions that we put ourselves into preclude good cooperation. It’s a two-way street. It’s not ‘you do it for us, and we don’t do it for you.’

Q5: YOU HAVE A LONG HISTORY WITH THE LABORATORY RESPONSE NETWORK (LRN). HOW HAS THE LRN EVOLVED, IN YOUR OPINION, AND HOW CAN APHL BETTER COMMUNICATE THE SUCCESS OF THIS UNPRECEDENTED NETWORK?

The LRN has developed very well. It’s built a workforce that is able to rapidly perform tests that rule in or rule out select agents, because they’re trained well. It’s also been recognized by authorities as something that you should commit to, and it’s allowed the state laboratories to have access to funds. It helped labs gain capabilities that brought them up to fairly modern standards, which they may not have done as quickly or at all without LRN. I do see that LRN is maturing, and the capabilities they have need to address how to identify and triage unknowns.

One of the fears for me would be loss of funds and commitment to LRN, because in public health, ‘no news is good news,’ so when you’re able to control and prevent outbreaks, it tends to be that the funds get pulled because nothing has happened. So, the message we need to get out is that ‘nothing has happened because of the commitment and the work that’s been done.’ APHL needs to share that message with congressional representatives and other political entities that oversee funding for LRN—ask the question “What if there was no LRN, where would we have been?” and relate that back to 10 years ago.

Q6: WHAT DO YOU CONSIDER TO BE THE MOST SIGNIFICANT EMERGING GLOBAL HEALTH THREATS?

Anti-microbial resistance is huge. I think cholera is something we underestimate. Certainly, the spread of diseases that are not vaccine-preventable, without treatment, such as dengue. I think it’s important not to forgot that we are always at the peril of some new agent emerging, and we need to be prepared to sort that out as quickly as possible.

Q7: WHAT DO YOU SEE AS THE CURRENT AND FUTURE TOP PRIORITIES FOR PUBLIC HEALTH IN THE US?

Workforce development, and leadership and management. I would say that’s really important globally. We lose that battle every day because clinicians, doctors and everybody expects the laboratory to be there; they don’t feel that they need to invest in laboratory capacity and improvement. And this is how outbreaks and disasters happen, when there’s lack of capacity, lack of good surveillance, lack of good public health metrics. In order to have that, the workforce has to be trained and empowered to be much more interactive with clinicians and others to bring the results to their attention and to help them interpret tests.
what’s your story?

APHL FELLOWS IMPACT LABORATORY SCIENCE AND RESEARCH
by Heather Roney, manager, fellowship programs

EID LABORATORY FELLOWS
Several APHL fellows presented their work at the November American Society of Tropical Medicine and Hygiene’s (ASTMH) meeting in Atlanta:

- **Dawn Roellig**: “Detection and persistence of host DNA in blood meals from Triatoma infestans using a novel molecular method”
- **Charissa Fritzen**: “Babesia spp. in White-Tailed Deer and Eastern Cottontail Rabbits in Tennessee” and “Infection Rates of Common Tick borne Pathogens in Lone Star ticks (*Amblyomma americanum*) and American Dog ticks (*Dermacentor variabilis*) from Kentucky”
- **Amma Semenya**: “The impact of schistosomiasis and malaria on the pathology of disease and the immune response in non-human primate models” and “The impact of schistosomiasis on malaria infection and anti-malarial immune responses in a non-human primate model” for the Young Investigators Award.

Semenya also received the 2010 ASTMH Pfizer Centennial Travel Award; with it, she will go to Kenya to conduct studies in children with schistosomiasis co-infections to understand the immunological effects in humans.

The November 2010 *Journal of Clinical Microbiology* includes the article “Rapid detection of Multidrug Resistant Tuberculosis using real-time PCR and High Resolution Melt analysis” by Melissa Ramirez. At the November meeting of the Virginia Branch of the American Society for Microbiology, Kristen Kreisel gave a presentation: “Pyrosequencing Analysis for the Detection of Antiviral Drug Resistance in Strains of Influenza A in the Commonwealth: April 2009 to January 2010.” Lauren Turner also spoke, presenting “Evaluation of a real-time PCR assay for the identification of Bordetella species in Virginia.”

Two EID fellows helped prepare successful proposals for the APHL/CDC TB Nucleic Acid Amplification Testing Expansion Grants. Lauren Turner took the lead on the Virginia Division of Consolidated Laboratory Service’s proposal to support the evaluation of new amplified technologies for susceptibility testing and a more cost-effective test for *Mycobacterium tuberculosis* detection. John Feltner helped with the Hawaii Department of Health’s proposal to fund a TB pyrosequencing project.

Erin Rottinghaus spent October and November in Botswana collecting specimens for her fellowship project. “I was stationed in Francistown, Botswana, at the Nyangabgwe Hospital. We were working with BOTUSA (Botswana-USA), a partnership between the CDC and the government of Botswana that was established to stop the spread of TB and HIV/AIDS in southern Africa. We collected dried blood spots and plasma from patient specimens that had been processed for CD4 testing at the Nyangabgwe HIV Reference Laboratory in Francistown. The purpose of the study is to test two new types of filter paper used for DBS collection that have never been used for HIV drug resistance genotyping.”

LATEST ON THE ENVIRONMENTAL HEALTH FELLOWS
Thelma Garcia, PhD, environmental health fellow at the California Department of Toxic Substances Control, is collecting and preparing milk and blood samples as part of a California human biomonitoring research project study. Concurrently, she is working on the analysis of method development using test samples for setting up automated systems for the extraction and cleanup of samples. These systems included a Gillson autosampler and Rapidtrace Solid-phase extraction setup. In between these two projects, Garcia helped with the extraction of fish samples mainly for learning techniques. At present, she is gaining experience analyzing the fish samples using a Thermo DFS HR-GCMS.

Justin P. Miller-Schulze, PhD, environmental health fellow at the Wisconsin State Laboratory of Hygiene and University of Wisconsin-Madison, is working on a project looking at the chemical transformation of mercury in the exhaust plumes of coal-fired power plants. Mercury is a significant public health concern in the US and around the world due to numerous adverse health effects, including the impairment of neurological development of fetuses, infants and children. Miller-Schulze is investigating elemental mercury (Hg0), which has a relatively long atmospheric lifetime, as it is resistant to oxidation. Current models may underestimate levels of Hg0 since divalent mercury may be reduced to elemental mercury in the exhaust plumes of coal-fired power plants; this study will look at the effect of different environmental factors (temperature, sunlight, humidity and reactive gases such as sulfur dioxide and ozone) on this reactivity.

HOST A 2011 EID FELLOW IN YOUR LAB
Applications to host one or more of the 2011 EID Laboratory Fellows are due on March 1. Go online to www.aphl.org/fellowships/hostapp for forms and instructions, or contact Heather Roney at 240.485.2778 or heather.roney@aphl.org.
MEMBERS AND PARTNERS ON THE MOVE

Dr. Garry L. McKee, PhD, MPH, director of the Oklahoma Public Health Laboratory, retired on January 31, 2011. McKee has a total of 40 years of service in public health, with 22 years as a lab director. McKee also served as the director and cabinet secretary of the Wyoming Department of Health and as a Lt. Commander in the US Public Health Service Reserve. He was a consultant to the Pan American Health Organization on the development of laboratory training in Mexico and Guatemala and served as a member of the National Public Health Anti-Terrorism Preparedness Task Force with ASTHO.

Dr. Eric Blank, DrPH, APHL’s former president, 1998-1999, joined APHL as senior director, public health systems, on January 3, 2011. In this role, he will provide strategic direction as it relates to informatics, institutional research, quality systems and global health. Most recently, Blank was an APHL global health consultant. He served as director of the Missouri State Public Health Laboratory for 20 years. Blank earned both an MPH and a DrPH in parasitology and laboratory practice from the University of North Carolina at Chapel Hill.

Dr. Jane Getchell, DrPH, APHL’s former president, 2006-2007, joined APHL in the capacity of senior director, public health programs, on January 29, 2011. She will apply her more than 20 years of laboratory experience to further the infectious diseases, food safety, public health preparedness, environmental health, and newborn screening and genetics programs. Previously, Getchell served as director of the Delaware Public Health Laboratory and the associate director of the University of Iowa Hygienic Laboratory. She earned both her MPH and DrPH in public health laboratory practice from the University of North Carolina at Chapel Hill.

Mimi Lachica has joined APHL’s board as the new Local Institutional Member Representative. Lachica has been with the City of Long Beach Public Health Laboratory for 23 years, spending the last five as laboratory director. Lachica obtained her master’s degree in health science with an emphasis in laboratory management at California State University in Los Angeles. She served as president of the California Public Health Laboratory Directors (CAPHLD) in 2008, and currently sits on the California State University Long Beach’s Health Care Advisory Board.

Jim Pearson, APHL member and director of the Virginia Division of Consolidated Laborator Services, co-authored an article in this month’s edition of Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. The article, “Planning for Exercises of Chemical, Biological, Radiological and Nuclear (CBRN) Forensic Capabilities,” addresses the deficiencies of forensic components in exercises conducted to increase preparedness and response capabilities to CBRN terrorist attacks. It also provides guidance for planning and executing exercises at local, state, federal and international levels that test the effectiveness of forensic capabilities for CBRN threats.

GOVERNANCE UPDATE
JANUARY 2011, BOARD MEETING, CDC, ATLANTA

In January, the APHL Board of Directors held its Annual Winter Meeting at CDC, giving the board an opportunity to exchange dialogue with several CDC officials on public health issues and member engagement: Dr. Judith Monroe (Office of State, Tribal, Local and Territorial Support) and Dr. May Chu (Director of Laboratory Science Policy & Practice Program Office). For more information, contact tiffany.adams@aphl.org or 240.485.2721.
North Carolina begins in the Atlantic Ocean, with a string of low-lying islands that attract beachgoers from throughout the mid-Atlantic region; so much so that OBX—shorthand for the famed Outer Banks—is a common sight on bumper stickers on out-of-state cars traveling along nearby I-95.

From this beginning, the state stretches out into a broad coastal plain with fertile soils that have supported tobacco, soybean and cotton farming for more than 200 years. In the western reaches of the state, the Appalachian Mountains rise up to 6,700 feet, the highest point east of the Mississippi River. And in the piedmont region between the mountains and the plain lie the urban centers: the Raleigh-Durham-Chapel Hill triangle, Winston-Salem, Greensboro and Charlotte.

The North Carolina State Laboratory of Public Health (SLPH) is strategically located in historic, downtown Raleigh, a stone’s throw from the state capitol. Director Leslie Wolf, PhD, says the organization is “basically a full service public health laboratory,” performing a wide range of clinical and environmental tests on behalf of North Carolina’s 9.5 million residents.

With wide swaths of rural areas and a number of large-scale turkey and hog farms, zoonotic infections are a concern here. “We keep influenza in mind,” said Wolf. The state has one of the highest rates of Rocky Mountain spotted fever in the country.

VALUE-ADDED SERVICES BENEFIT WOMEN, CHILDREN

Yet while the laboratory performs all of the traditional public health tests, it also provides what retailers refer to as value-added services.

For example, the SLPH screens roughly 120,000 newborns each year for more than 30 disorders (all of the nationally recommended disorders, except SCID). But when infants are diagnosed with PKU or tyrosinemia, it continues to measure their phenylalanine or tyrosine levels as long as they submit samples. When infants are diagnosed with hemoglobinopathies, the laboratory performs family studies so biological parents know the risks associated with future pregnancies.

Similarly, while virtually all state public health laboratories perform testing to identify children with elevated blood lead levels, the SLPH partners with the investigative unit that works to identify the source of lead in the child’s environment, and another SLPH unit tests the suspect environmental samples.

The SLPH is one of a handful of state public health laboratories that perform routine cancer cytology to support health department clinics. Yet even here, it goes above and beyond the minimum service, reflexing indeterminate Pap specimens to a human papillomavirus (HPV) assay to identify women with any of the 13 high-risk HPV genotypes associated with progression to cervical cancer. “Those results go back to the health care provider,” said Wolf, “and it helps them make better decisions about how to follow up with these patients.”

The SLPH’s Environmental Science unit analyzes well water and Grade A milk for chemical or biological contaminants, certifies other laboratories performing drinking water and milk testing, and tests a range of environmental samples for radionuclides.

By far the laboratory’s largest unit is virology/serology, which performs classical serological and molecular methods to analyze routine samples submitted by local health departments—mostly for HIV, syphilis and chlamydia/gonorrhea, the lab’s highest volume tests.

The SLPH is one of few public health laboratories with both a full-time mycologist and a full-time parasitologist. “So far able to maintain that,” said Wolf.

RECESSION’S TOLL

Unfortunately, maintaining services is an increasing worry. Over the past 50 years, North Carolina has transitioned from mostly tobacco, textile and furniture production to a mixed economy, with emphasis on engineering, biotechnology and finance. In the recent recession, all of those sectors took a hit. This fiscal year, the state of North Carolina projects a $3.7 billion budget shortfall, and that deficit has impacted the SLPH on several fronts.

Although the laboratory receives only about $1 million in direct state appropriations—4.5% of its $23 million annual budget—it depends on fees from state agencies and Medicaid clients. Last year, the lab’s Medicaid receipts totaled $12 million, accounting for just
over half its budget. Wolf expects this figure to drop, in light of a 4% reduction in Medicaid reimbursement rates beginning March 2010 (on top of an earlier 9% reduction). Federal grant funding, which makes up 20% of the SLPH budget, has also fallen.

Wolf said, “This is going to be the first time we can remember that the state lab will actually have a budget shortfall—to the tune of $2 million.”

Intermittent state hiring freezes over the past two years have come at an especially bad time for the SLPH, since many of its scientists have reached the point of retiring. Of 217 laboratory positions, 24 are either vacant or will soon be vacant as a result of pending retirements. “It is a problem,” said Wolf. “We have one lab that is only 50% staffed.”

Wolf is hopeful the state’s fiscal situation will not delay a planned move next year to a brand new facility, the lab’s third dedicated home since its founding in 1905. The $52 million building is about six miles from the current location and offers close proximity to other state labs, the state emergency operations center and interstate highways. When completed, it will have more usable space because of a flexible, open design, and will also boast a central accessioning bay, enhanced security features, a better parking situation, a centralized data entry area and many energy-saving innovations.

**This is going to be the first time we can remember that the state lab will actually have a budget shortfall—to the tune of $2 million,” said lab director Wolf.**

“It’s going to cost money to move into the new lab and to operate it, and we need legislative approval for that,” said Wolf. “And we won’t know that until July. We remain optimistic.”

In the meantime, Wolf and her staff are making do with what they have. Those challenges, however, are tempered by the satisfaction that comes from rewarding work.

**A LAB LEADER IS BORN**

After earning a bachelor’s degree in microbiology from the University of Kentucky and a PhD in immunology from the University of Colorado Health Sciences Center, Wolf said she was “bitten by the public health bug” in 1997, when she became an APHL/CDC Emerging Infectious Disease post-doctoral research fellow in the lab she now heads.

“During that two-year [internship] I had a wonderful time learning microbiology and starting the PulseNet lab,” she said. “And I liked it so much, [then-director Lou Turner, DrPH, MPH] allowed me to stay, and I became the first public health scientist we had here at the state lab.”

After three years in that position, Wolf was promoted to assistant director, and, in July 2005, became acting director when Turner left to become interim state preparedness coordinator for public health. When Turner was later tapped as deputy section chief for epidemiology, Wolf became the permanent SLPH director. She was awarded the APHL Emerging Leader award in 2008.

“I love the mission of our laboratory,” said Wolf. “We’re really looking out for people’s health, even if they don’t know it.”

**“WE KNOW THE VALUE OF A CLOSE RELATIONSHIP”**

To maximize the laboratory’s effectiveness carrying out its health-critical mission, Wolf and her staff have built up a strong network of partnerships. Laboratory staff meet two to three times yearly with state communicable disease officials to discuss emerging problems and testing issues. The SLPH brings together representatives from the state’s larger microbiology labs three times yearly to discuss topics of mutual concern, such as the response to the 2009 Influenza A H1N1 pandemic. “Because we have these relationships, we were able to convene conference calls really quickly as the guidance was changing so rapidly in those early weeks [of the pandemic],” said Wolf.

Last year, the laboratory was awarded a grant from APHL and the Association of Schools of Public Health to launch its Pathways to Public Health program, which provided public health microbiology internships to four students from North Carolina State University. Wolf sees the program as one way to address the chronic shortage of laboratory scientists in the US and hopes to continue it even without the student stipend provided by the one-time grant.

Laboratory partnerships extend even abroad, as the SLPH is paired with the national public health reference laboratory in Georgetown, Guyana, through APHL’s “twinning” program (see page 21). “We’re working to help them develop their technologies, quality assurance and safety plans,” said Wolf.

At the same time, laboratory improvements continue at home. First on the priority list is making “the best case” to state leaders for a prompt move into the new lab building. “It’s a better investment of our money to move there than to maintain two facilities,” said Wolf.

A final goal is the development of an annual report to document laboratory successes. “I say we’re one of the state’s best kept secrets,” averred Wolf. Soon, a secret no more.
IT’S ALL HAPPENING AT THE ZOO—
THE KALAMAZOO COUNTY HEALTH AND COMMUNITY SERVICES LABORATORY
by Nancy Maddox, writer

LOCATION
With just under a quarter million residents, Kalamazoo County is the largest urban area in southwestern Michigan. It is located roughly halfway between Detroit and Chicago and bisected by the Kalamazoo River. Kalamazoo City—the county’s most populous jurisdiction—dates to the early 1830s and is known today for its microbreweries, colleges (notably including Western Michigan University) and vibrant outdoor festivals. Variously referred to as “The Zoo” or “Mall City,” Kalamazoo is home to the first outdoor pedestrian shopping mall in the United States and prides itself on being a livable, sustainable community.

FACILITY
The Kalamazoo County Health and Community Services (KCHCS) Laboratory is just a few miles northeast of Kalamazoo City. It occupies almost 5,000 square feet of a one-time dormitory complex on the campus of now defunct Nazareth College. The building is leased by the county from the Congregation of St. Joseph, which still occupies buildings on campus. The laboratory itself has taken over the former dormitory kitchen—a logical location given an existing network of exhaust ducts, now retrofitted to vent laboratory hoods. It has dedicated areas for water testing, clinical testing, PCR testing, microbiology, BSL-2 testing, specimen processing, phlebotomy, visitor reception and administrative activities. Elsewhere in the complex are the county’s area agency on aging, community action agency, maternal and child health division, clinical services division, environmental health program and other KCHCS offices, as well the parks foundation programs, Michigan State University (MSU) extension program and 72 senior housing units. The laboratory boasts high ceilings and a full bank of windows overlooking the campus’s pastoral setting.

MANAGER
Aaron Hoogenboom is a Michigan native, born and raised in Kalamazoo. Although he once aspired to be a physician, he discovered a love for the laboratory while studying biology at MSU. Hoogenboom went on to earn a second bachelor’s degree in medical technology and was certified as a medical technologist (MT) through the American Society of Clinical Pathology in 1995. He worked as an MT first in Port Huron, just north of Detroit, and then at the POH Regional Medical Center in Pontiac, MI (where he also served as laboratory outreach supervisor), before taking a job as a laboratory scientist at the KCHCS Laboratory in late 2006. Two years later he was promoted to laboratory manager, which includes duties as technical consultant for Region 3 of the Michigan Regional Lab System. “I’ve come full circle,” said Hoogenboom, “starting in Kalamazoo and now ending up in Kalamazoo.”

STAFF
The laboratory employs seven staff members: three full-time laboratory scientists, two medical laboratory technicians, one secretary/public health technician and the laboratory manager. After a period of staff turnover, Hoogenboom said, “We’ve gone two years with no vacancies; we’ve found our rhythm and that’s great.” The current staff, he said, is made up of experienced, dedicated people, with several having a tenure of more than ten years with the county.

REVENUE
The laboratory’s annual $675,000 budget comes from state grants (30%), fees (35-38%) and county general fund dollars (32-35%). Although the laboratory has suffered no state or county budget cuts as a result of government deficits, it has experienced a loss.
of revenue due to decreased testing, especially water testing. Said Hoogenboom, "When the housing industry failed, a lot of construction stopped, which meant that new wells weren’t being drilled and houses weren’t selling, so there was no need for realtors to have wells assessed. We saw a big effect on testing that we bill for.” At the same time, the county’s downsized environmental health division submitted fewer surface water samples for testing. Fortunately, said Hoogenboom, the revenue situation is “recovering a little bit.” He said last year was the first year “in quite a while” that the demand for services increased somewhat, going up a couple percentage points from 2009.

**TESTING**

Last year, about half of the lab’s work was clinical testing (54%) and about half environmental testing (46%), much of it for county agencies and clinics co-located in the former dormitory. In fact, said Hoogenboom, the laboratory strives to deliver test results to county providers while patients remain on-site in the building. Its single highest-volume work is STD testing, mostly for chlamydia/gonorrhea. Other clinical work includes wet preps for trichomonas, norovirus testing, pregnancy testing and testing for foodborne pathogens. On the environmental side, the laboratory tests well water, public swimming pool water and surface water from the county’s numerous lakes, streams and creeks, as well as from beaches on nearby Lake Michigan.

Since 2003, the laboratory has been a Level B member of the Laboratory Response Network, performing rule-out testing for a number of select agents on behalf of sentinel laboratories throughout southwestern Michigan.

**NOTABLE SUCCESSES**

- Implementing a new laboratory information management system, STARLIMS, has been both a challenge and a success for the laboratory. The initial installation is virtually complete and enables electronic communication with the state public health laboratory in Lansing.
- Last year, the laboratory was involved in 11 separate norovirus outbreak investigations in six different counties. Positive specimens were forwarded to the state public health laboratory for typing, and a study is ongoing to track the various outbreak strains.
- In 2007, the laboratory made a preliminary finding of *E. coli* O157 in frozen beef patty samples. The finding led to a nationwide product recall, following a recommendation from the FDA.
- The laboratory is accredited by the US Centers for Medicare and Medicaid Services to provide clinical testing under the Clinical Laboratory Improvement Amendments and also maintains certifications from the Michigan Department of Community Health and the Michigan Department of Environmental Quality.

In a period of economic stagnation, the laboratory’s primary challenge is “to maintain quality testing with the ever-present threat of decreased funding.” Hoogenboom said, “Every year, it seems the state budget shortfall grows a little bit. It keeps edging up, so we need to find ways to keep our costs down.”

**GOAL**

“With an uncertain economic picture, we definitely want to maintain the quality testing that we do for our community... We’ve also got to remain flexible and open to new ideas and new technology,” said Hoogenboom.
Recently, we have had one public health outbreak after another that has caused our labs to break into a full-out sprint in an effort to accommodate the testing that must be done to adequately answer fundamental questions like: is it what we think it is, where did it start, and what caused the outbreak?

When the call comes down that there is a suspected outbreak or threat, one of the lab sections must prioritize and possibly postpone routine testing and immediately begin testing on the suspected samples. The key to a quick response is for labs to be as flexible as possible, and to continue routine testing while taking on the increased samples due to an event. But how can we do this when we have a laboratory bench only designed and set up to perform routine testing?

One approach is to reduce the amount of traditional, fixed floor mounted benching in order to accommodate more moveable tables and carts. By replacing the last five to six feet of built-in bench with moveable tables, the flexibility of that bench dramatically increases. Tables are designed to accommodate changes in benchtop equipment, or be completely removed to make room for large floor-mounted analyzers or sample carts.

Older labs are designed by test or science and are usually sized for that test. New labs are more generic and open, allowing the benches adjoining the area that’s experiencing the “event” to be used to stage samples, etc.

“Moveable tables in the laboratory have allowed us to add a substantial amount of new equipment to our lab without disrupting existing testing.”

–Victor Waddell, director, Arizona State Laboratory of Public Health

HDR designed a new lab for the University of Iowa laboratory in Ankeny, Iowa, using an open lab design concept. “When we were notified that the Skunk and Des Moines rivers as well as the Cedar and Iowa Rivers were causing significant flooding in central and eastern Iowa, we knew that we needed to identify space to process and analyze samples. Due to the new, open laboratory design, our staff had more flexible space to prepare sampling kits to assess flood impact.

–Michael Wichman, associate director, environmental health, State Hygienic Laboratory at the University of Iowa

In analytical labs, we are seeing an increased use of overhead service carries (OSC). The OSC is suspended from the ceiling directly above the area on the floor where casework would sit. Since the work in these labs is very equipment-driven, we eliminate the traditional casework and mount the equipment on tables or moveable racks. This allows infinite flexibility to change out and service equipment without the casework being an impediment. The OSC requires some upfront construction time but affords years of future flexibility.

Flexibility to accommodate change starts with challenging the preconceived means and methods to perform testing. And just like Olympic athletes who are called upon only once every four years to perform beyond expectations, laboratorians must be given the tools to enable them to perform above and beyond when called upon to solve the unknown. Creating a flexible lab environment helps to facilitate smooth transitions when needed to accommodate increased testing demand, new methods development, and empower the laboratorians to discover, develop and deliver.
BOOK REVIEW
INSIDE THE OUTBREAKS: CASE NOTES OF THE EPIDEMIC INTELLIGENCE SERVICE

Summarized from reader reviews

In his book *Inside the Outbreaks: Case Notes of the Epidemic Intelligence Service*, author Mark Pendergast tells the fascinating history of the Epidemic Intelligence Service (EIS), a group of “shoe-string epidemiologists” who travel the globe investigating the causes of major infectious disease outbreaks. Founded in 1951 as a CDC training program for physicians, the EIS has since grown into a larger organization that works to safeguard the public’s health. The EIS has battled polio, cholera and smallpox successfully, and in recent years, has begun to tackle modern day epidemics like obesity and smoking.

*Inside the Outbreaks* is divided into three chronological sections that describe EIS activities from its founding to the present day. Short chapters in each section focus on specific epidemics, the political climates that influenced the investigations and the reporting of the investigations. Quotes from field officers are woven throughout the text, drawing readers into detailed accounts of some of the most widespread infectious diseases of our time.

The biggest criticism of the book is that it aims to cover too much: the author depicts nearly 50 years of EIS history at rapid speed. The scope of outbreaks covered is enormous, ranging from anthrax in the US, to chemical exposures in India to contaminated bread in Africa. In his attempt to cover so many cases, Pendergast loses some of the essence of the stories, some say.

Nonetheless, the book provides an exciting account of the work of a government branch that often goes unnoticed. It will be enjoyable for anyone interested in the history of medicine or public health, and especially those working in the field of epidemiology. The book may also spark interest in public health careers, as it does an excellent job of depicting the meaningful work of epidemiologists.
WHAT’S NEW ONLINE?

LABORATORY LEADERSHIP SITE OFFERS MORE
APHL has launched an updated laboratory leadership site with fresh content, including links to laboratory websites and APHL partner organizations, and new training resources. It also features hot topics and trends in laboratory leadership, such as going green, successful budget management, and tips for building a new laboratory. Explore the site at http://www.aphl.org/profdev/lablead.

LAB PROFILES AVAILABLE ONLINE
Want to learn more about APHL member laboratories? Now you can access member profiles of all the laboratories that have been profiled in Lab Matters, as a PDF online. Profiles offer an in-depth look at each facility’s unique challenges, success stories, programs, goals and more. Check them out at http://www.aphl.org/AboutAPHL/aboutphls/Pages/MemberLabs.aspx

SUBSCRIBE TO THE APHL BLOG
You can now subscribe to APHL’s blog, LabLog, via email. Go to http://blog.aphl.org and enter your email address in the box on the sidebar. You will then get a confirmation email with a link to finalize your subscription. When new content is posted to the blog, you will receive it directly in your inbox!

SEARCHING MADE SIMPLE
Find information on APHL.org faster! APHL has added a site map and site feedback link to the page footer and corrected problems with the search function. Visit the site and search for yourself! Please contact matthias.martin@aphl.org with any questions or issues regarding search.

NEW VIDEO ONLINE: A NEWBORN SCREENING STORY
by Laura Siegel, associate specialist, communications

Mr. Adams is the father of a 24-year-old son with Phenylketonuria (PKU), whose life would have been dramatically different without newborn screening services. In a compelling 11-minute video, Adams discusses learning about his son’s PKU diagnosis, dealing with the realities of the disorder, and the challenges of living on the PKU diet. Prior to his son’s diagnosis, John had no knowledge of newborn screening. But he has now become a strong advocate for educating the next generation of parents about the importance of newborn screening tests. “If your newborn has one of these disorders, you need to know about it right away, and you need to deal with it. And everybody that travels life needs to know about it too,” said Adams. Each year, state and territorial public health laboratories test over 97 percent of the four million babies born in the US for genetic and inherited disorders. Because of their efforts, approximately 3,000 babies with genetic disorders are identified annually.

Check out the video and share it with others to show the impact of newborn screening!

View the video online at: http://vimeo.com/19501628.
TOP 5 WAYS TO GO GREEN THIS YEAR

1. **Provide staff incentives for mass transit or carpooling.**

2. **Reduce or recycle chemical solvents used in the analytical process, and buy green products.**

3. **Replace lab canopy hoods with smaller, variable air volume (VAV) fume hoods.**

4. **Use energy-efficient T-5 and halogen lamps for indirect lighting and T-8 lamps for direct lighting.**

5. **Upgrade heating, ventilation, and HVAC systems to make them more energy efficient.**

WHEN IN DOUBT, ASK ARIZONA

The Arizona Public Health Laboratory is a prime example of a lab that has implemented significant “lab greening” initiatives. Some of their projects have included reducing the lab’s temperature range, changing night and day temperature settings and reducing the number of exhaust fans running in the laboratory. The lab has seen savings of about 50-60% on utility bills as a result of the initiatives. Future plans include adding an evaporative cooler system to help reduce the amount of energy needed to cool outside air before it enters the HVAC system.

On the left side of the building are 3 “chiller units.” The lab had previously been using between 1 and 1.5 chillers in the summer to cool the building, and have since reduced this to 0.5-1, dramatically reducing utility costs.
Carving out five weeks of life after elective foot surgery to sit and read books, watch daytime television or surf the web may sound like a vacation to some. To me... well, for someone who finds it darn near impossible to stay still... this enforced, completely-off-my-feet recovery has been a significant challenge.

Did you know that you can buy anything on the internet? In addition to a few online purchases, I’ve been working my way through a stack of books (recommendations are always welcome), and I’ve discovered that there are some silly things on TV and some decent things. One program that caught my attention is an ABC News endeavor called Be the Change, Save a Life (http://saveone.net/). For one year, ABC News will focus on global health issues that impact the poorest populations of the world (think malaria, HIV/AIDS, tropical diseases, malnutrition, maternal and child health) and on innovative efforts made by governments, corporations and communities to effect positive change.

Even for someone who felt relatively well-educated on global health aid projects, it has been impressive to learn more about the breadth and variety of work undertaken by our partners. If you have time, read about some of the ongoing humanitarian projects to provide clean water, eradicate polio, combat TB, nourish children or keep infants warm.

The TB pieces are particularly relevant. There’s one (found online at http://bit.ly/hTmjz4) that makes an excellent counterpart to the feature story in this issue of Lab Matters, providing the valuable “other side” to our more domestic approach. Just as we labor to tamp down TB in the US, the fight is waged in other parts of the world on a more elemental level as communities struggle with sham “doctors,” inadequate access to medication and an overwhelming need. Interestingly, this article also focuses on the potential of Cepheid’s GeneXpert MTB/RIF NAA test. In this case, rather than struggling with validation in a low prevalence population, a researcher in India is trying to determine if affected children can produce a large enough sample to employ this technology successfully. While Americans may perform a careful cost/benefit analysis before adding the test to our labs, scientists abroad are certain of the benefit—after all, WHO estimates that one-third of the world’s population has TB. Labs in poverty-stricken settings, instead, strain to scrape the funds together and ensure the systems are in place to support the technology.

Systems-building is where APHL has found its home in the global health community. APHL members understand that a public health lab cannot exist for long in isolation. To be successful, labs must be more than a functional shell of a facility: also necessary are a well-trained staff, supplies, laboratory leadership, laboratory information management systems, data transmission, strong ties to the Ministry of Health and health workers and more. These are the “systems” pieces that transform laboratory test data from being of use to only one patient to informing and empowering a public health prevention and support program.

Here in the US, we are close enough to TB eradication that we can talk about it without sounding absurd. But we know eradication can’t happen until we’ve reduced the global burden: currently the infection rate of foreign-born US residents is 11 times higher than domestic-born. Until the rest of the world is able to worry about validating new tests due to low prevalence, this disease will remain a threat.

By the time this issue of Lab Matters goes to print, I will be up and running. I will return to my regular life energetically and with a refreshed ability to help focus APHL’s considerable collective skills on the public health issues of our age.
experience
[ constant contamination control ]

**CO₂ Incubators**

Closed Loop HEPA Filtration
Creates an ISO Class 5 cleanroom inside the growth chamber. Air and gas pass through 99.99% HEPA filters to create Class 100 air. Filters are kept out of the growth chamber ensuring a contaminate free work zone. The chamber is maintained at positive pressure to prevent potential contaminates from entering the growth chamber.

Help Celebrate 40 Years with a Free Accessory
www.nuaire.com/40years

---

**Your Source for Biosafety**

The American Biological Safety Association (ABSA) was founded in 1984 to promote biosafety as a scientific discipline and serve the growing biosafety and biosecurity needs of scientists, laboratorians, health care workers, and biosafety professionals throughout the world.

**ABSA Activities and Resources**

- Biosafety Conference, Courses, and Seminars
- **Biosafety Publications** – Including **Anthology of Biosafety** Series
- **Animal Biosafety Training Video** – www.absa.org/resanimal.html
- **Credentialed Biosafety Professionals** – Registered Biosafety Professional (RBP) and Certified Biological Safety Professional (CBSP)
- **ListServe, Training Tools, Risk Group Table**, and more…

Go to www.absa.org
APHL Sustaining Member Program
The following corporations partner with APHL to support the nation’s public health laboratory system.

Diamond Partners

Platinum Partners

Gold Partners

Abbott
life
HDR
CUBA
GEN-PROBE
PerkinElmer
QIAGEN

BD
BIO-RAD
DiaSorin
APOLLOLIMS

LABS VITAL