LAB MATTERS

Summer 2009, Issue 3

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ON THE BRINK

H1N1 DRAINS LABS HIT BY CUTS
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ON THE BRINK: H1N1 DRAINS LABS HIT BY CUTS

With the benefit of significant advance work, the public health laboratory community rose to the occasion during the H1N1 outbreak, even though state and federal cutbacks have drained critical surge capacity from a system already weakened by long-term workforce shortages.
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LEADING THE CHANGE

by Susan Neill, PhD, MBA, APHL president, director, Laboratory Services Section, Texas Department of State Health Services

It is a privilege to serve as president of this phenomenal organization. APHL does a tremendous job representing the public health laboratory network, and I have no doubt it will continue to do so as we face what I think will be a challenging year for us. Our immediate past president, Frances Downes, has been a tireless advocate for our labs, leading us all through a sea of shifting national priorities. I am honored to follow her as president.

Labs are up against change on every front. In the mix of a recession and new national leadership, the nature of our work is up for debate: What are our national health priorities? Why should prevention play a bigger role? What is public health testing? Who should pay for it? APHL’s role in this scenario is not to respond to these fundamental questions, but to guide the best solutions through each level of the health reform discussion.

Meanwhile, as the national health debate begins, our laboratories work steadily through daily testing (including H1N1 flu sample submissions), meet community needs, maintain severely underfunded programs and find solutions to other shortfalls. As the year progresses, I expect a number of our major concerns to enter the national discussion, including:

**FLU**

We must prepare for the fall flu season. Even now, the flu numbers are not decreasing. The number of specimens entering the lab is under control, but we continue to identify new cases, and deaths from H1N1 are increasing. As we prepare for the height of flu season, we need to follow the old adage: hope for the best but prepare for the worst.

**FOOD SAFETY**

Headlines reveal what laboratorians already know—the US continues to have widespread outbreaks of foodborne illness. Our food network, PulseNet, is exceptional, and we must continue to improve it. A better, faster food network will lead to far fewer incidents of foodborne illnesses. Food safety testing is an important part of prevention and should be a component of national health reform. This is a big issue.

**ELECTRONIC REPORTING**

We must work for universal data operability. The H1N1 flu crisis is the perfect example of how critical electronic reporting is to public health surveillance. Without the ability to share our tests results on a national scale either quickly or accurately, we have no way to understand the scope or progress of disease transmission.

**NATIONAL LABORATORY SYSTEM**

We are a country with a tremendous collection of labs—national, local, hospital, reference and physicians’ office labs—all conducting testing of public health import. But we are not interconnected, as we should be. How do we connect?

**QUALITY SYSTEMS**

Our quality systems should be improving continually. At a time when states are making cutbacks, making it hard to focus on laboratory improvements, we should focus on our quality systems more than ever. Quality systems allow us to cut costs and improve services, and there are models that we can look to for guidance. (Minnesota’s Mayo Clinic is a health system that offers superior services at lower costs.)

Public health should have a major role in national health reform, targeting prevention in the wider population. Many of our nation’s crippling health costs can be avoided through strong education and prevention programs. Health is not just about treating the sick, and I think we will begin to see a stronger laboratory emphasis on prevention. APHL is in a strong position to guide our labs through these changes.
In 2008, APHL’s global health program worked with Miami Dade College (MDC) and its medical technology faculty to develop and teach an intensive, three-month course in medical laboratory science for 12 biologists from Mozambique. The program was a resounding success, leading APHL and MDC to formalize the relationship through a Memorandum of Agreement in February 2009.

MDC will continue to provide assistance to the Mozambique students, three of whom are in Miami June-August 2009 for a hands-on training in clinical chemistry and hematology. In Mozambique in March, MDC faculty taught a one-week course in the basic principles of quality assurance and quality control. Aimed at bench-level technologists and recent medical technology school graduates, the training was met with great enthusiasm; another course is planned for the fall of 2009.

MDC has a large Haitian student and alumni population, so the APHL/MDC collaboration is a good fit for laboratory improvement projects in Haiti as well. APHL will work with MDC to provide assistance with training, curriculum development and standardization for the medical technology programs.

EXPANDING SUCCESSFUL GLOBAL HEALTH PARTNERSHIPS

by Marie-Claire Rowlinson, PhD, global health program manager, and Anne Ramos, global health coordinator

Aimed at bench-level technologists and recent medical technology school graduates, the training was met with great enthusiasm; another course is planned for the fall of 2009.
LIMS IMPLEMENTATION IN BOTSWANA: LABS PUSH PAST PAPER IN PURSUIT OF AN ELECTRONIC SYSTEM

by Ava Onalaja, MS, MPH, global health program manager, and Michelle Meigs, informatics program manager

APHL’s global health and informatics programs are assisting the implementation of a Laboratory Information Management System (LIMS) in Botswana through intra-departmental work with CDC-Botswana (BOTUSA) and the Botswana Ministry of Health (MOH). APHL played a central role, ensuring that the key stakeholders were involved to make informed decisions.

Facilitated discussions with BOTUSA and MOH clinical services were instrumental in gaining buy-in for this effort to streamline the organization, storage and dissemination of laboratory data.

APHL performed comprehensive assessments of several laboratories to document the laboratory processes and the infrastructure required to support a LIMS. Following recommendations from BOTUSA and key MOH personnel, four laboratories were chosen as pilot sites to implement the new LIMS.

These assessments and recommendations formed the basis of the detailed requirements that were set forth in a global request for system proposals. APHL issued a Request For Proposal and five vendors were selected to participate, leading to a LIMS chosen by a consensus of MOH and BOTUSA.

The pilot sites are expected to be up and running in the next five months. The goal for phase two is to integrate the selected LIMS system with the Patient Information Management System currently in use by hospitals and clinics throughout the country.

This is the fifth country in which APHL has facilitated effective implementation of LIMS in resource-limited settings.
The Michigan Department of Community Health (MDCH) announced plans recently to develop a population-based biobank that could lead to advanced medical breakthroughs—such as improved newborn screening, faster identification of genetic disorders and earlier diagnoses of chronic diseases—by making leftover newborn blood samples more available for research.

“The Michigan BioTrust for Health is an initiative that will help create a healthier Michigan,” said MDCH Director Janet Olszewski. “The access researchers will have to residual dried blood samples will help further medical and public health research and it could lead to groundbreaking medical discoveries.”

The BioTrust’s roots are planted in the state’s newborn screening program, which began in 1965 in the MDCH Bureau of Laboratories. Newborn screening is a successful public health program that has prevented disabilities and saved the lives of more than 4,000 Michigan babies by screening for 49 disorders at birth. A comprehensive system, it provides screening and follow-up to ensure appropriate medical management for affected children and monitor long-term outcomes. Once screening is complete in the state laboratory, leftover dried blood spot samples are stripped of all identifying information and stored in the Michigan Neonatal Biobank in a temperature-controlled facility.

In the early 1980s, Michigan was required to keep dried blood samples for 21.5 years. Now they are stored indefinitely. As scientific interest in the use of biobanks increased, the MDCH laboratory began to explore the usefulness of residual samples, take steps to better preserve them and formalize policies for their use that are acceptable to the public. MDCH, with support from community-based volunteers, the MSU Center for Ethics in the Humanities and Life Sciences and the UM Center for Public Health and Community Genomics, has explored public opinion through focus groups and a random statewide telephone poll of more than 3,000 Michigan adults. A substantial majority of residents supports the idea of using leftover newborn screening samples for research on childhood conditions, adult-onset diseases and potentially harmful environmental substances. In addition, a community-values advisory board will guide MDCH in the development of BioTrust policies.

Other partners in the BioTrust are Wayne State University, the University of Michigan, Michigan State University and the Van Andel Institute (VAI) in Grand Rapids.

“Measuring the relative abundance of thousands of expressed genes from universally collected neonatal blood spots may open new avenues of research into perinatal markers and determinants of disease development,” said James Resau, PhD, director of the Division of Quantitative Sciences at VAI, the company that provides the database and software system that will track the four million blood spots and their related data.

For more information, visit www.michigan.gov/newbornscreening.
ONE EXERCISE, FOUR STATES AND A NEW UNDERSTANDING OF SURGE CAPACITY
by Anthony Barkey, MPH, emergency preparedness and response program manager, and Sikha Singh, MHS, Laboratory Response Network program manager

In a continuing effort to assess emergency preparedness and response capabilities, select LRN member labs participated recently in a surge capacity exercise. Over the course of five days, the labs responded to a mock surge event and then processed and evaluated unknown samples. The goal of the exercise, which was conducted by the state public health laboratories in Minnesota, Florida, North Carolina and Michigan, was to measure surge capacity and to improve the decision-making environment that exists during an event.

The labs met the demands that would occur during a surge and, in the process, were able to evaluate the implications of their decisions. The exercises identified strengths, weaknesses, opportunities and potential safety concerns, as well as created a knowledge base to help labs plan improvements. Overall these exercises help labs gauge specific capabilities in detection, communications and information sharing, both locally and within the laboratory network.

The recent influenza pandemic validated the predictive utility of the surge capacity exercises, confirming that the bottlenecks calculated during the exercise, such as extraction, were indeed the limiting steps in the sample processing and identification pipeline during the peak of the outbreak. J. Royden Saah, MS, bioterrorism laboratory coordinator for the North Carolina State Laboratory of Public Health, said, “The North Carolina State Laboratory of Public Health was able to immediately implement measures to counter the pinch points in our process discovered during the surge exercise in March. The addition of phone lines, coordinating a phone bank for laboratory-specific communication and separating some data entry were crucial to maximizing our staff’s capacity.”

Tools such as the RAND Surge Capacity and the CDC Lab Capacity model offer laboratories a much needed resource in preparedness efforts. Even the best-laid plans can fail during a real event, but not having plans in place can slow down the initial response, limit the initial capacity or, worse, result in preventable casualties.

WORKING WITH YOUR CIVIL SUPPORT TEAM THE IOWA WAY
by Bonnie Rubin, CLS, MBA, MHA, the University Hygienic Laboratory team, and Anthony Barkey, MPH, emergency preparedness and response program manager

The terrorist attack of 9/11 and the subsequent threats from anthrax-laced letters were stark demonstrations of the need to establish partnerships that assure rapid and effective emergency responses. One such critical alliance in Iowa teams the state’s public health and environmental laboratory—the University Hygienic Laboratory (UHL)—and Iowa’s 71st Civil Support Team (CST).

In early 2003, Bonnie Rubin, the lab’s current assistant director, was hired as UHL’s emergency response coordinator. Her top priority was to identify potential partners in the state for collaborative responses to incidents involving weapons of mass destruction (WMD). The 71st CST was a logical choice because it shares a mission with the UHL—to respond to and identify unknown substances that are potential WMDs.

The first step in forging the alliance was to meet with the unit’s commander and chief scientific officer to discuss ways to collaborate. An obvious opportunity was in the training of the state’s HazMat teams to collect, field test and ship unknown substances. CST and UHL jointly created a “just-in-time” DVD and corresponding training program for the HazMat teams. One major accomplishment that continues today is that HazMat teams simultaneously collect samples for both the CST and UHL so that the two can coordinate test findings.

“This is one of the most important partnerships that a state public health laboratory should establish,” said Rubin. “CST is really an advocate for public health laboratories with the Department of Defense; likewise, we advocate for CST with our partners at APHL and CDC.”

Staff also have an opportunity to gain understanding of the other agency’s capabilities and protocols. Every other year, a joint training session is conducted so that UHL’s staff learn how the CST mobile laboratory is used and the CST team works in UHL’s BSL-3 laboratory. This training aids in coordinating testing methods and reduces the time needed to identify and report unknowns.

“Our collaboration assisted in the development of operating procedures to ensure a synchronous assessment of mobile laboratory operations and intelligence using Laboratory Response Network protocols,” said Jeff Largent, of the 71st CST.

Since Beverly Pennell stepped into the role of UHL emergency response coordinator in 2007, she has continued the close partnership with the 71st through joint exercises and first responder training. Current discussions focus on developing a training curriculum for CST scientific officers that could be used nationwide, detailing good laboratory practice, testing theory and methodology.

Like all good partnerships, the CST/UHL alliance is a dynamic one. It is successful because both parties understand the importance of working together continually with one common goal: protecting Iowans.
LRN: A DECADE OF ACCOMPLISHMENTS
by Sikha Singh, MHS, Laboratory Response Network program manager

In 1999, CDC, in partnership with the FBI and APHL, launched the Laboratory Response Network (LRN). Its mission: to develop, maintain and strengthen an integrated national and international network of laboratories that can respond quickly to needs for rapid testing, timely notification and secure reporting of results associated with acts of biological or chemical terrorism and other high priority public health emergencies.

MISSION IN ACTION
LRN partners have been at the forefront of preparedness for the past 10 years:

• Bioterrorism Preparedness:
  • Detected Bacillus anthracis in a timely manner during the anthrax attacks in 2001.
  • Warned the government and public health community early of a potential bioterror event through the BioWatch Program, which detects the release of pathogens into the air.

• Chemical Terrorism Preparedness:
  • Developed new analyses to detect chemical warfare agents.
  • Expanded the LRN to include surge capacity laboratories to detect chemical agents, which are capable of analyzing more than 500 patient samples in less than one week.

• Public Health Emergency Response:
  • Deployed rapid tests for detection of Severe Acute Respiratory Syndrome.
  • Deployed rapidly an FDA-approved assay for detection of H5N1 for use in patient care.

ACHIEVEMENTS
• Partnerships with all states, multiple local laboratories and numerous federal agencies and partners
• Extensive hands-on training
• Standardized assays and reagents
• Data messaging
• Proficiency testing
• Uniformity and quality control
• Working groups that solicit member contribution and feedback on quality improvements

GOALS
• Increased and sustained funding
• Enhanced competency
• Fully-equipped laboratories

More than 160 federal, state and local labs in 50 states and abroad.
National labs—CDC, military perform definitive testing.
Reference labs, which are highly specialized and capable of identifying threat agents such as B. anthracis and C. botulinum.
Several years ago, the CDC’s National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) launched the Program Collaboration and Service Integration (PCSI) initiative, identifying it as a major strategic priority. Under the PCSI premise, public health programs in HIV/AIDS, hepatitis, STD, and tuberculosis would integrate their service delivery for every patient, creating a simultaneous health impact across the four disease areas. It is logical to link these four programs due to the high level of co-infection and many shared risk factors of the diseases.

Philadelphia is an example of PCSI in action. The Philadelphia Department of Health offers STD testing at local HIV care sites and STD clinics. Those sites also offer Hepatitis A and B vaccinations, as well as Hepatitis C screening; additionally, HIV care sites offer TB screening. The health department’s TB clinics offer HIV testing.

About a year ago, NCHHSTP leaders approached APHL to identify barriers to service integration within the laboratory. APHL’s Infectious Disease Committee, as well as the HIV, TB, and STD sub-committees, explored the lab process to find potential problems. The committees did not identify any significant issues in the analytical phase of testing, but did find barriers in both the pre- and post-analytical phases, mainly in the test ordering and reporting processes. Several communication complications with point-of-care testing were also identified. Insufficient communication between public health programs and labs is not a new finding, but it is clear that making the effort to work together may lead to an improved public health outcome. During lean economic times, this sharing and stretching of resources is of even greater importance.

In upcoming months, APHL will work with public health programs and labs to name the top barriers to service integration; with a focus on program-laboratory communication in the pre- and post-analytical phases of testing and on developing potential solutions. 

During lean economic times, this sharing and stretching of resources is of even greater importance.

For more information on the PCSI initiative, visit www.cdc.gov/nchhstp/programintegration/Default.htm.

This figure illustrates the pre-analytical, analytical and post-analytical phases of integrated laboratory testing. Red text indicates potential difficulties. Blue text indicates opportunities to improve public health impact.
IMPLEMENTING CDC’S UPDATED GUIDELINES ON NAAT IN TB

by David M. Warshauer, PhD, D(ABMM), deputy director, communicable diseases, Wisconsin State Laboratory of Hygiene, and Kelly E. Wroblewski, MPH, MT(ASCP), APHL program manager for HIV, TB, STD and Hepatitis

In January 2009, CDC published updated guidelines for the use of nucleic acid amplification (NAA) tests in the diagnosis of tuberculosis.1 The major departure from the guidelines issued in 20002 is a new recommendation that NAA testing become the standard practice in the United States for the initial diagnosis of tuberculosis (TB), rather than just being a reasonable approach.

The current guidelines state, “NAA testing should be performed 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.”

In response to this change, laboratories need to institute appropriate utilization protocols to assure that NAA testing is only being performed on specimens from patients suspected to have TB. The guidelines state that NAA testing should not be routinely ordered when clinical suspicion of TB is low (i.e. “rule out” testing). It is therefore imperative that a clear definition of a “TB suspect” is established within the testing algorithm.

In Wisconsin, where NAA testing is supported by state funds, a TB suspect is defined as a patient who: has signs and symptoms of pulmonary TB; is currently in isolation; and has been reported to the local public health or TB control program as a suspect TB case. If the patient does not reach this level of suspicion, fee-exempt NAA testing is not provided. It is the responsibility of all parties—health care providers, health care facilities, infection control, TB control programs, local public health and laboratories—to monitor appropriate test utilization. The laboratory alone cannot be the gatekeeper.

Culture is still the gold standard for laboratory confirmation of TB and is required for isolating bacteria for drug-susceptibility testing and genotyping. However, used appropriately, NAA testing has the potential to shorten the time needed to diagnose TB from 1-2 weeks to 1-2 days. For this reason public health laboratories are responsible for assuring that NAA testing is available to patients in their jurisdiction in an efficient and cost-effective manner. To do this, there must be collaboration among the public health laboratory, TB control program, local public health, clinical laboratories and health care providers.

Several approaches can be taken to accomplish this goal depending upon the situation in the jurisdiction. One option is that the public health laboratory works with its clinical laboratory network to assure that testing is available in the private sector. If testing is performed in the clinical laboratories, the public health laboratory, working with TB control and local public health officials, must assure that testing and reporting of results are timely and accurate.

Another option is to provide NAA testing in the public health laboratory system. The New York and Florida Fast Track Programs are examples of cost-effective systems that provide timely NAA testing for private sector laboratories lacking a high-enough volume to make it economically feasible to host NAA testing.3 Again, this approach requires collaboration with the clinical laboratories for appropriate test utilization, specimen collection and transport. In some jurisdictions, a combination of NAA testing in the public and private sector may be necessary to provide diagnostic services to the population.

It is the responsibility of all parties—health care providers, health care facilities, infection control, TB control programs, local public health and laboratories—to monitor appropriate test utilization. The laboratory alone cannot be the gatekeeper.

The Thomas E. Maxson Education, Training and Workforce Development Award needs your help.

This award was established in 1998 in memory of Dr. Thomas Maxson, a long-time supporter of continuing education and workforce development in the public health laboratory community. Each year this award is given to an APHL member who has made significant contributions to public health laboratory practice by creating, delivering or developing continuing education opportunities, programs, policies or practices for the laboratory community. However, unlike other APHL awards, the Thomas E. Maxson Award depends on the continuing generosity of APHL members to maintain it. If you would like to help maintain this award, visit www.aphl.org/maxson to donate or send a check to:

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CDC LAUNCHES CALICINET: A LABORATORY SURVEILLANCE SYSTEM FOR NOROVIRUSES

by Kara Watarida, temporary PulseNet program coordinator, and Kristy Kubota, PulseNet program manager

On June 12, 2009, the CDC published a Morbidity and Mortality Weekly Report that focused on surveillance of US foodborne disease outbreaks in 2006. Norovirus was the most common cause of outbreaks (with a confirmed etiology), accounting for 54% of all foodborne outbreaks and more than 11,000 cases nationwide.

To improve the detection of norovirus clusters, Jan Vinjé, PhD, head of the CDC’s National Calicivirus Laboratory, and his staff have developed a new electronic network for Calicivirus surveillance, named CaliciNet. CaliciNet went live in March 2009, allowing states to upload norovirus sequences to CDC and share data with laboratories across the nation. CaliciNet uses reverse transcription-polymerase chain reaction and a software application, BioNumerics, to analyze and upload genetic sequences or “fingerprints” to a database located at CDC. Similar to PulseNet, this laboratory network links state and local public health laboratories and regulatory agencies to identify regional and national clusters of noroviruses quickly and help epidemiologists investigate outbreaks.

To date, Vinjé and his staff have trained 44 laboratorians from 37 states, including some from FDA and Canadian laboratories. Vinjé expects training for all states to be completed by 2017.
In May 2009, the APHL laboratory system and standards program sponsored a national teleconference for member laboratories to discuss the benefits of public-private laboratory partnerships. Representatives from Michigan, Mississippi and Nebraska shared examples of established partnerships and model practices.

Trish Somsel, DrPH, director of the Division of Infectious Diseases at the Michigan Public Health Laboratory, reported that Michigan laboratory stakeholders wanted to improve communication on reportable disease and actionable results, enhance “standards of practice” in testing sites and increase the visibility of public health and public health laboratories. The public health laboratory partnered with commercial laboratories to offer a daily courier service for local health departments and regional laboratories at a nominal cost, provide on-site training for local health department clinics and develop public health rotations for interested university students. This public-private partnership enables the Michigan public health community to tackle the challenges associated with daily laboratory activities.

Regina Derstine, MT(ASCP), laboratory state training coordinator at the Mississippi State Department of Health, described the public health laboratory’s coordination of the delivery of emergency preparedness training, products and services for hospital, military, reference and veterinary laboratories. She emphasized the importance of collaboration with other partners during public health emergencies. Derstine said, “The continued functionality of this communication network depends on regular updates to sentinel labs. Without training and knowledge resources from other valuable partners like [APHL] and the National Laboratory Training Network, the Mississippi laboratory response network could not have reached its current capacity to respond to a public health emergency, nor could it meet the challenges of the future.”

Julie Miller, BS, program manager from the Nebraska Newborn Screening and Genetics Program, spoke of the importance of communication among the newborn screening laboratories, health care providers, the state follow-up program and the newborn’s family to ensure that any positive results are confirmed and treated accordingly. The program’s goal is to complete the screening process within the first days of life because effects for the screened conditions may emerge within that time period. She recognized the importance of the private partners involved in the newborn screening process in Nebraska. Miller said, “No newborn screening program can succeed without partnering with private health care providers. When the newborn screening system has a centralized public health entity responsible for administering the newborn screening system, it can be most effective with that input of these important stakeholders.” The immediate benefits of partnering with a private laboratory included: significant expansion of the required newborn screening panel using relatively new technology adapted for newborn screening (tandem mass spectrometry or MS/MS), maintenance of high quality testing by a laboratory with extensive experience with this technology, reduction of charges to the hospitals and patients for testing services and access to an enhanced data system for follow-up and tracking. Over time, the capacity for quality assurance monitoring and reporting has significantly expanded as a result of this partnership, and more conditions can be added easily to the newborn screening panel.

After the presentations, call participants were invited to share additional examples from their states. Paula Snippes, MT(ASCP), the laboratory program advisor for the Minnesota Public Health Laboratory, identified some examples of public-private partnerships occurring in her state. She spoke of several activities that have played a part in strengthening the laboratory network, including the creation of a database of sentinel and basic laboratories, the establishment of a listserv in 2004 that allows laboratories to communicate with each other, the enhancement of the state public health laboratory website and the availability of educational resources and regional conferences. She stressed that the dedication of all involved parties is instrumental to fostering and maintaining successful partnerships.

These public-private partnership activities help improve laboratory efficiency, laboratory testing, communication and connectivity. Through the growing network of public and private laboratories, public health needs can be addressed more efficiently. Ultimately, these blossoming collaborations will lead to a stronger National Laboratory System.

APHL, along with CDC, is committed to strengthening the National Laboratory System through a strategic planning process currently underway. For more information on public-private partnerships, visit APHL’s Public-Private Partnerships website at www.aphl.org/aphlprograms/lss/projects/publicprivate/pages/default.aspx.
Fellows and their research were well represented at several recent national meetings. At APHL’s annual meeting in Anchorage, AK, in May, three fellows presented posters:

- **Sara McNamara:** “Molecular and Epidemiologic Characterization of Clostridium difficile Infection in Michigan”
- **Modupe Osinubi:** “Rabies diagnosis in dogs from Zaria, Northern Nigeria using a Direct Rapid Immunohistochemistry Test (dRIT)”
- **Tam Van:** “Surveillance of Influenza Antiviral Resistance in Wisconsin from 2006-2009” (first author) and “Building a State Public/Private Clinical Laboratory Network: Moving Beyond Bioterrorism” (co-authored with former fellow Nicole Broekema)

Many fellows also presented posters at the American Society for Microbiology meeting in Philadelphia, PA, in May:

- **Baha Abdalhamid:** “Cost Effectiveness of Using the QuantiFERON-TB Gold Test as a Follow-up Assay to Evaluate Healthcare Workers for Latent Tuberculosis Who Had a Positive Tuberculin Skin Test during Pre-employment Screening”
- **Kelly Fitzpatrick:** “Evaluation of Bulk Soil Sample Extraction Methods for Inhibition and Efficiency of DNA Extraction”
- **Lisa Mingle:** “Brucella Speciation using Pyrosequencing Technology”
- **Elizabeth Perez:** “Control of Escherichia coli Biofilm Formation on Urinary Catheters Using a Genetically Engineered Bacteriophage”
- **Ailyn Perez-Osorio:** “Stratified Growth Rate, rpoS and rhlR Expression Levels in Pseudomonas aeruginosa Biofilms”
- **Rebecca Terilli:** “Analysis of Botulinum Neurotoxin G using Endopep-MS and Proteomics,” also presented at the American Society for Mass Spectrometry meeting in June
- **Samantha Wirth:** “Application of reference laboratory resources to identify novel bacteria from clinical specimens: a /Psychrobacter/ species isolated from blood”
- **Abel Wu:** “Neisseria gonorrhoea with mosaic penA genes and reduced susceptibility to oral cephalosporins”

In June, **Shelly Krebs** gave a presentation, “Investigations into a Whole Inactivated HIV vaccine and Low Cost Methods for Laboratory Monitoring of HIV Treatment,” at the Oregon Health and Science University National Primate Center in Portland.

**Jenish Patel** presented a poster and gave a talk, “Impact of NADPH Oxidase Inhibition on Influenza A Virus-induced Inflammation,” at the American Association for Immunologists annual meeting in Seattle, WA, in May.

The June 2009 [American Society of Tropical Medicine and Hygiene](http://www.asts.org) printed the article, “Identification of Flea Blood Meals Using Multiplexed Real-Time Polymerase Chain Reaction Targeting Mitochondrial Gene Fragments,” by **Michael Woods**.

**Libo Dong** co-authored “Serum Cross-Reactive Antibody Response to a Novel Influenza A (H1N1) Virus after Vaccination with Seasonal Influenza Vaccine” in the May 22 [CDC Morbidity and Mortality Weekly Report](http://www.cdc.gov/mmwr). At the XVIII International HIV Drug Resistance Workshop: Basic Principles and Clinical Implications in Fort Myers, FL, in June, **Jing Zhang** presented the poster, “Monitoring of HIV-1 Drug Resistance Mutation Development from Patients under Antiretroviral Therapy from Shandong Province, China.”

**Christine Graham** gave an oral presentation, “The Role of Host Immunity in Interepizootic Maintenance of Yersinia Pestis,” at the International Conference on Diseases in Nature Communicable to Man in Fort Worth, TX, in June.
EID FELLOWS RESPOND TO THE INFLUENZA PANDEMIC

by Heather Roney, fellowship program manager

APHL's EID fellows were instrumental in the response to the recent H1N1 influenza pandemic. In local, state and CDC laboratories, fellows helped the host labs meet the steep demands of the outbreak. From volunteering with the Diagnostics Lab Team at CDC to staffing the Incident Command Call Center at the Tennessee Department of Health, fellows were on the front line of the response efforts. They assisted with the clinical testing of hundreds of samples and advised local health departments and health care providers on how and when to submit specimens. Fellow Scott Spear summarized the experience: “Being an EID fellow in an influenza lab during an influenza pandemic provided an amazing learning opportunity that is not likely to be repeated again in my career.”

Top: Former EID Fellow Elizabeth Perez presents her research at the May American Society for Microbiology meeting in Philadelphia, PA. Photo courtesy of Perez. Bottom: International EID Fellow Modupe Osinubi presents her research at APHL’s annual meeting in Anchorage, AK.

STRENGTHEN YOUR SKILLS

APHL offers a range of high-quality continuing education programs to strengthen the skills of laboratorians and promote excellence in laboratory practice. You can register for a series of teleconferences at a discounted rate:

• Mycobacterium Tuberculosis Series
• Enterococcus Series
• Mycology Series
• Infectious Disease Series
• CLSI-APHL Series

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But underscoring the substantial element of uncertainty surrounding emerging pathogens, the novel human influenza A now circulating—swine-origin H1N1—is a different bug altogether from the avian-origin H5N1 subtype thought most likely to trigger a pandemic.

Pete Shult, PhD, an influenza expert who oversees communicable disease testing at the Wisconsin State Laboratory of Hygiene (WSLH), said, “What had been driving all of our planning had been an event such as H5.... We all thought, to be frank, the key event would arise somewhere in Eurasia and we’d have some weeks, at least some days to weeks, to brace ourselves for the first cases in North America.”

Instead, the novel H1N1 was already in the US when an unidentified respiratory illness began making headlines in Mexico.

Two California children who fell ill in March were eventually diagnosed with novel H1N1, followed by about half a dozen people in Texas, which had its first laboratory confirmation of the virus in late April.

“Within a week, a week and a half of the first reports,” said Shult, “we began to see our first cases (in Wisconsin) and we’ve been off to the races ever since.”

The initial outbreak posed a number of challenges to public health authorities, beginning with its abrupt onset and the unexpected viral characterization.

The only diagnostic test for swine-origin H1N1 was an in-house CDC assay, not cleared by the FDA for widespread use.

The public health laboratories (PHLs) charged with influenza surveillance and outbreak response had varying testing capabilities. Not all were equipped with a critical diagnostic platform, the Applied Biosystems ABI 7500 FAST Dx. And many were grappling with the effects of repeated budget cuts and personnel shortages.

But the public health community had one huge advantage: timing.

Said Shult, if H1N1 had emerged a year ago, “we would have been in a bad place. In fact, we had been planning. We just had to redirect our plans. We were in a good position.”

Health authorities have been anticipating an influenza pandemic for many years. On June 11, it officially arrived when the World Health Organization raised its pandemic alert to the highest level, Phase 6.
The deputy director of CDC’s influenza division, Dan Jernigan, MD, MPH, echoed that thought, saying, “The timing could not have been any luckier.”

With the benefit of significant advance work, the public health laboratory community rose to the occasion. “We had people volunteer to do whatever they could in this situation,” said Victor Waddell, PhD, chief of the Arizona Bureau of State Laboratory Services.

Sara T. Beatrice, PhD, assistant commissioner of the New York City Public Health Laboratory, said the response is “a great example of how people in public health in general really step forward when the need is there and do what it takes.”

A number of highly placed laboratory officials, however—including more than half a dozen experts interviewed for this article—also note that the peak public health laboratory response was unsustainable; state and federal cutbacks have drained critical surge capacity from a system already weakened by long-term workforce shortages.

Said Waddell, “It’s hard to explain to the public that if people just worked their normal nine-to-five hours, the system probably would’ve crashed and burned.”

Rosemary Humes, MS, MT(ASCP) SM, a senior APHL advisor who served as go-between for federal officials and state and local public health laboratories, said “If we also had a big outbreak like the 2006 E. coli outbreak in spinach, there’s no way state labs could have effectively responded to that and H1N1 at the same time.”

As it is, public health laboratories are wondering how they will pay for the H1N1 response, which cost the Texas lab more than $600,000—so far.

Now perhaps nearing the end of the first wave of the US pandemic, laboratory officials reflected on the public health response to the crisis and outlined possible scenarios for the fall flu season. “This outbreak response,” said Shult, “should be considered a model to help us for planning as we go into next autumn.”

‘WE’RE GRATEFUL TO THE VIRUS FOR WAITING’

Planning for pandemic influenza has been ongoing at least since 2004, the year human cases of the highly pathogenic avian-origin H5N1 influenza virus were detected in the Far East. In 2005, the Bush administration issued the “National Strategy for Pandemic Influenza,” followed by an implementation plan in 2006.

Working closely with CDC subject matter experts, APHL provided input to a laboratory-specific appendix to the national plan and to laboratory elements in CDC’s pandemic operations plan.

Just last year, APHL and the Canadian Public Health Laboratory Network hosted an influenza preparedness summit and entered into a memorandum-of-understanding for cross-border collaboration during a flu pandemic.

In conjunction with these national activities, federal funding has enabled every state to develop and exercise its own pandemic response plan.

Said CDC’s Jernigan, “I’ve never been a part of something that was as deeply tested and planned ahead of time.”

From a laboratory perspective, though, three activities stand out: 1) development of the Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel (rRT-PCR Flu Panel), 2) a CDC arrangement with the American Type Culture Collection (ATCC) to manufacture reagents for the panel and distribute test kits to CDC-qualified laboratories and 3) training to enable state and local public health laboratory scientists to use the test panel.

Without these pieces in place before the detection of H1N1 in the US, Shult said, “We wouldn’t have been able to deal with this.”

The rRT-PCR Flu Panel, also known as the IVD five-target assay, can identify influenza A and B and can subtype influenza A as human H1, H3 or H5. It was designed for seasonal flu surveillance, with a focus on detecting novel viruses, including avian-origin H5N1.

The panel was developed largely by Stephen Lindstrom, PhD, a scientist in CDC’s influenza division. State public health laboratories in California, Iowa, Massachusetts, Virginia, Washington and Wisconsin conducted the clinical evaluations needed to secure FDA 510(k) clearance for the assay as a human diagnostic test.

The FDA cleared the panel September 30, 2008—barely six months before the H1N1 outbreak. And just last fall, the CDC contracted with ATCC to produce the FDA-approved reagents.

Reflecting on the chain of events, Jernigan said, “We’re very grateful to the virus for waiting.”

In mid-April, just as the H1N1 outbreak was beginning to emerge, the APHL/CDC National Laboratory Training Network (NLTN) hosted two courses for 37 scientists on influenza detection and subtyping using the CDC assay. (Another 42 scientists attended an earlier NLTN training in May 2008.)

The first US diagnosis of novel H1N1 came as a fluke. A 10-year-old boy with a fever and cough presented at the Naval Health Research Center in San Diego on March 30. Given his mild symptoms, physicians could have treated the child without bothering to test him for influenza. But the Naval Research Center is one of four sites participating in a clinical trial for another CDC flu test, this one intended for rapid, point-of-care use.

The 30-minute test confirmed influenza infection, but could not identify the subtype.

The boy’s specimen eventually reached Shult at the Wisconsin public health laboratory, which provided consultation and test confirmation to an in-state laboratory serving as a reference lab for the ongoing clinical trial. Shult’s communicable disease laboratory classified the specimen as a true unsubtypable and sent it on to the CDC.

On April 15, CDC scientists identified the virus as...
swine-origin H1N1—an unusual finding, but certainly not alarming.

Just two days later, however, the scientists had in hand a second specimen—from a nine-year-old girl also treated at the Naval Research Center—that proved to harbor an identical virus.

That was jarring.

Jernigan’s team blast-sequenced the virus against the CDC’s entire inventory of known swine-origin influenza genotypes. The scientists came up empty-handed. No match.

In the meantime, more suspect cases were identified. It took six days to solve the epidemiologic mystery: on April 23, CDC identified the novel H1N1 virus—then confirmed in two Texas teenagers as well—as the same bug wreaking havoc across the border in Mexico.

That same day, APHL convened the first in a series of conference calls with federal officials and public health laboratory leaders from the 50 states. The message: ramp up laboratory-based influenza surveillance.

The US government declared the outbreak a “public health emergency” April 26.

By April 27, 40 US cases were confirmed.

‘A REMARKABLE FEAT’

In Texas, Health Commissioner David Lakey, MD, realized that his state was suddenly on the frontlines of a possible pandemic.

He said, “There was an assumption in pandemic response plans that (an influenza outbreak) would start somewhere else in the world. We thought by the time it reached us we would have good information to make public health decisions; information about disease severity, ease of transmission, etc. We didn’t have any of that information.”

Answers to the most pressing questions invariably relied on laboratory data.

Fortunately, as Jernigan noted, the virus had waited until after the CDC and partners began disseminating the technology and training for the agency’s standardized, FDA-cleared influenza assay.

Said Lindstrom, “We were lucky that we were able to work with the states and APHL to be in a position to mobilize and to act so quickly and so effectively.”

But even the CDC five-target assay could not confirm the new strain of H1N1. On April 27, the CDC had the only lab in the US—and one of only two or three in the world—capable of making that determination. That meant public health laboratories across the country were sending all unsubtypable Influenza A specimens directly to Lindstrom and his colleagues in the CDC Influenza Division. They received thousands in a matter of days.

Now the scientists had two pressing tasks: to test the flood of suspect specimens and to get a swine flu test out the door ASAP.

In fact, Lindstrom was already at work modifying the CDC’s swine flu panel to make sure it would reliably pick up the new virus and meet the requirements of an FDA emergency use authorization (EUA).

The EUA, issued the day after the government declared an emergency, allowed the CDC to distribute an rRT-PCR Swine Flu Panel diagnostic test to public health laboratories meeting strict criteria. Every test recipient had to:

• Be certified in accord with the Clinical Laboratory Improvement Amendments as a high complexity testing site.
• Have the designated testing platform, the ABI 7500 Fast with approved software (Dx).
• Have personnel trained by CDC or its designee to perform CDC’s rRT-PCR Flu Panel, on which the modified swine flu panel was based.

Once the swine flu panel was finalized, it had to be mass-produced for deployment to qualified public health laboratories. This, said Lindstrom, “entailed a lot of work. We had to make test kits and reagents and perform quality control testing on those to make sure they would perform appropriately.”

In what many laboratory insiders have called “a remarkable feat,” CDC rolled the first swine flu test kits out the door May 1, enabling public health laboratories in the US and abroad to perform their own confirmatory testing.

The agency also made the novel H1N1 genome and testing protocol immediately available to researchers, vaccine manufacturers, antiviral drug manufacturers and test manufacturers worldwide.

Said Lindstrom, “None of that would have been possible without the preparation and training in place. It really, really took the burden off of us.”

‘IT WAS A LITTLE HAIRY’

While CDC scientists had now cleared two major hurdles, state and local public health laboratories were still revving up. Not all of the labs were starting from an optimal position.

Jernigan said, “When you think of preparedness, you often think of an exercise that people go through. For laboratories, it’s more about improving infrastructure, staffing and staff training.”

Historically, government funding to maintain the public health laboratory infrastructure has been irregular and often inadequate. In fiscal year 2006 (FY06), for example, the federal government disseminated $225 million to states for pandemic influenza preparedness through the Public Health Emergency Preparedness Grant, although public health laboratories received few of these dollars. No funds were allocated in FY08.

The emergency supplemental appropriations bill signed June 24 includes $260 million of immediately available funding for state and local pandemic influenza preparedness activities. APHL worked closely with CDC on the distribution of this funding.

Unfortunately,
only a portion of $65 million will be spent on laboratories.

This supplemental funding assumes added importance given that public health laboratories were substantially left out of the federal stimulus package enacted in February. APHL Public Policy Director Peter Kyriacopoulos said there is a “glimmer of possibility” that laboratories may receive a small amount of stimulus funds for electronic messaging from the US Department of Health and Human Services. [The National Institutes of Health, by comparison, received $10 billion in stimulus funding.]

While federal funding has yo-yoed, worldwide recession has led states and localities to pare their own support for public health laboratories. Fiscal downsizing cost the Washington, DC and 50 state labs about 185 staff positions in the first quarter of this year, on top of significant losses last year.

Even after staffing reductions, at least half a dozen state labs, including those in Arizona and California, have been subject to mandatory staff furlough days this year.

Needless to say, the extra effort needed to respond to the H1N1 crisis strained the understaffed, under-funded and often ill-equipped laboratories.

In March, 36 state public health laboratories were using or were eligible to use the CDC’s five-target influenza assay, having both the required ABI platform and trained staff. These labs were in a relatively good position to implement the swine flu panel, needing only to validate the test in-house; a process that could take anywhere from a few days to a week.

But there were glitches. Susan Neill, PhD, MBA, director of the Texas Laboratory Services Section, said, “When we started (testing), we had one instrument we could run the test on. The first thing that happened was it broke.”

The Texas laboratory temporarily diverted specimens to a local public health laboratory in San Antonio, while the instrument was repaired. Neill also received FDA approval to use an older ABI platform and secured two loaner instruments from Applied Biosystems.

Adequate emergency preparedness, said Neill, demands “more than one instrument.”

A second group of 30-odd laboratories had at least one scientist who had just finished an NLTN influenza training course. Most of these labs were in the process of either upgrading an older ABI 7500 FAST or purchasing a new one.

In New York City, a hotspot for novel H1N1 activity, the city public health laboratory was using a manual

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“It has been my experience throughout all disasters...that there are always opportunities to improve your response. I think learning the most appropriate utilization of the laboratory for public health instead of clinical work was a major lesson.”

— David Lakey, MD, Texas Health Commissioner

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**H1N1 Timeline**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sept. 16-17, 2008</td>
<td>APHL, CPHLN host Laboratory Pandemic Influenza Summit</td>
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<tr>
<td>FALL 2008</td>
<td>CDC finalizes contract with ATCC to manufacture reagents for influenza testing.</td>
</tr>
<tr>
<td>March 28, 2009</td>
<td>9-year-old Southern California girl (Patient B) falls ill with cough, fever</td>
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<tr>
<td>March 30, 2009</td>
<td>10-year-old Southern California boy (Patient A) visits outpatient clinic with flu-like symptoms</td>
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<tr>
<td>April 7-9, 2009</td>
<td>18 public health laboratory scientists attend NLTN training course on rRT-PCR Flu Panel testing.</td>
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<tr>
<td>April 12, 2009</td>
<td>WSLH confirms Patient A sample as “unsubtypable” and ships it to CDC.</td>
</tr>
<tr>
<td>April 14-16, 2009</td>
<td>Another 18 public health laboratory scientists attend NLTN training course on rRT-PCR Flu Panel testing.</td>
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<tr>
<td>April 15, 2009</td>
<td>CDC confirms swine-origin H1N1 virus (novel H1N1) in Patient A specimen.</td>
</tr>
<tr>
<td>April 17, 2009</td>
<td>CDC confirms novel H1N1 in Patient B specimen.</td>
</tr>
<tr>
<td>April 23, 2009</td>
<td>CDC confirms novel H1N1 in Mexican flu specimens. APHL convenes first in a series of conference calls with state public health laboratories.</td>
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<tr>
<td>April 26, 2009</td>
<td>US government declares “public health emergency.”</td>
</tr>
<tr>
<td>April 27, 2009</td>
<td>FDA issues emergency use authorization for an rRT-PCR Swine Flu Panel diagnostic test based on CDC’s rRT-PCR Flu Panel. CDC confirms 40 cases of novel H1N1.</td>
</tr>
<tr>
<td>May 1, 2009</td>
<td>CDC begins disseminating test kits for new swine flu panel to public health laboratories in the US and abroad.</td>
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<tr>
<td>Early June, 2009</td>
<td>All state public health laboratories have equipment for novel H1N1 testing.</td>
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</table>
testing system while awaiting a software upgrade for its ABI 7500 FAST and authorization from state authorities to use the swine flu panel. “Once the authorization was sent to us,” said Beatrice, “we had to train the flu staff in the midst of surge and then we had to train the surge staff... We were required to do validation, training, testing and upgrade the instrument simultaneously. It was a little hairy.”

Finally, half a dozen public health labs had no ABI 7500 FAST and no immediate plans to acquire one due to budget constraints.

Arizona’s Waddell had been trying for some time to find $72,000 to purchase the instrument, but was stymied by the simultaneous cuts in his state funding and federal grants. In fact, Waddell had wanted to participate in the CDC validation study of the original five-target assay, but without the ABI 7500 FAST his lab was ineligible.

As the H1N1 outbreak was unfolding, he said, “First thought I had was, ‘We better be able to get our hands on this instrument or we’re gonna be one of the only states that can’t do this testing.’”

Given Arizona’s proximity to the source of the outbreak and the rapid spread of illness in the US, Waddell was able to impress his interim health director with the urgency of the situation. The health agency allocated funds to place a purchase order for the instrument to be manufactured—the Arizona laboratory was going to happen.

Despite such difficulties, by early June, every state and the District of Columbia had at least one public health laboratory with the swine flu assay up and running.

Once instrumentation issues were resolved, however, the bottlenecks for many laboratories became the front and back ends: specimen accessioning and processing and results reporting.

This was no surprise.

Last fall CDC contracted with Booz Allen Hamilton to map out all the steps involved in influenza PCR testing and to model how long it would take to go through those steps in about 20 representative state labs. The analysis showed that pre- and post-analytic work—all of the staff-intensive activities that take place before and after testing—were common limiting factors.

At one point, the Texas lab, for example, had 82 people working on outbreak response. Just 23 were actually performing testing, with the remainder assigned support tasks.

In New York City, Beatrice said, “The things that are always challenging for us have to do with appropriate collection, transport and documentation of specimens. So if the samples are the absolutely correct samples that are collected appropriately, stored at the right temperature and transported at the right temperature and all of the paperwork is complete and accurate, then the accessioning and processing go smoothly.”

In this case, with city hospitals overwhelmed at times, almost 40% of the H1N1 specimen submissions had problems. “That meant a great deal of one-on-one effort to reach out to hospitals and solve the problems.”

In Arizona, a general shortage of viral transport media prompted the state laboratory to mass produce media in-house using its own quality control program. “We found ourselves becoming more of a distribution site,” said Waddell.

As one of the laboratories participating in the APHL modeling study, the WSLH had the benefit of a preview of probable chokepoints.

Shult said the modeling analysis, which he received in February, identified two or three critical shortfalls: “We didn’t have enough PCR equipment, didn’t have enough people to do pre- and post-analytic work. We would need to have staff work longer hours and probably go to a seven-day workweek.”

Going into the crisis, he said, “We kinda knew what the gaps would be and we had started to take steps to address these.... Modeling helped to brace us for what was going to happen.”
THE CHALLENGE WAS NOT HAVING A WELL-DEFINED DISEASE

Given the public health laboratories’ limited testing capacity, a critical question facing every major health agency was how much testing to perform. Said Humes, “Early in the introduction of a new influenza strain, PHLs have to do diagnostic testing because no one else has the capability. But once you know the disease is established in the population, diagnostic needs change and PHLs can switch to surveillance testing.”

The goal of influenza surveillance is not to identify every outbreak case, but rather to gather sufficient information to monitor genetic changes in the pathogen and changes in the epidemiology of the disease to inform public health interventions. While national authorities may offer specimen triage guidelines, in practice every state makes this determination for itself based on past experience and current exigencies.

Wisconsin, for example, experienced a significant H1N1 outbreak in the Milwaukee area and has had the highest case count in the country so far, with 4,273 cases reported to the CDC by June 25, compared to 1,492 cases in California and 65 in Georgia.

Shult said, “If you’re too restrictive (in choosing which specimens to test), you’re not going to judge the full impact of the disease accurately. If you’re too liberal, you run the risk of becoming quickly overwhelmed. Our state’s health department took the approach that we’re going to be more liberal.”

Texas also took a liberal approach, at least initially. Lakey said, “The challenge for us was not having a well-defined disease... We knew there was ongoing replication (in Texas). Then we found out about Mexico’s high fatality rate.”

There was also the sheer size of the state to consider. With 254 counties, Lakey said, “Just because you have cases in one part of the state doesn’t mean you will find them in another part.”

By casting a broad net, however, the Austin branch of the state public health laboratory was quickly swamped with hundreds of specimens, about 90% of which tested negative for H1N1.

“It has been my experience throughout all disasters,” said Lakey, “that there are always opportunities to improve your response. I think learning the most appropriate utilization of the laboratory for public health instead of clinical work was a major lesson.”

The state revised its specimen submission policy several times, making it progressively more restrictive. As of mid-June, the state laboratory in Austin had tested more than 9,000 suspect specimens, with the positivity rate running about 16%.

On the other side of the country, Beatrice was working within a system tested and honed in some of the country’s worst disasters.

She said, “I truly believe our pandemic response did work. There was a great deal of attention to asking, ‘What is the most important public health question that needs to be answered and how do we go about doing that in a way that honors everyone’s resources: the PHL, clinicians, epidemiologists?’ And so if the question was, ‘Is swine flu here?’ or ‘Was there community transmission?’ the most logical process was in place instead of everyone sending in samples.”

Said Beatrice, “The lesson we learned in 2001 around anthrax was if every possible sample is allowed to flow into the lab, then when the highly important samples come in they can get stuck at the back of the queue and the critical answers can be delayed. That didn’t happen here.”

By mid-June, the New York City public health laboratory had received about 1,700 suspect specimens. Nearly 60% were confirmed as novel H1N1 and an additional 5% were seasonal flu.

LIMITS OF ALL-OUT LABORATORY EFFORT

Looking back on the outbreak, laboratory leaders marveled at the timeliness of CDC support and the dedication of their own staffs.

They mentioned other federal help as well. The Centers for Medicare and Medicaid Services, for example, delayed its routine regulatory surveys and suspended influenza proficiency testing in state labs during the crisis. The US Department of Homeland Security not only permitted BioWatch staff working in public health laboratories to shift to H1N1 response, but also paid them overtime.

But even with this support, none disputed the limits of the all-out laboratory effort.

APHL’s Humes said, “You can only have people work so many 16-hour days. At some point, you have to give them time off or mistakes will start to happen. You have to have the capability to rotate people.”

In Texas, the incident command center set up to coordinate response activities had a work schedule of five 12-hour days. Neill said, “They went through five rotations of staff and we still had the same laboratory staff working.”

Eventually, staff burnout led Neill to bring in 25
temporary workers. But she cautions against this approach as a routine strategy. "If testing needs exceed capacity, people and resources have to be planned and put in place ahead of time; not just hire temps three weeks into the situation," she said.

In Arizona, staffing constraints put Waddell in an impossible situation. Near the height of the crisis, his pregnant wife went into labor, facing what was expected to be a tricky delivery. At the same time, the laboratory was in crisis mode with no managerial staff to spare. Fortunately, one of his assistant bureau chiefs returned from vacation just in time to cover for him. Daughter Lily was born May 6.

One innovation that would have tremendously eased the burden on public health laboratories is standardized electronic messaging.

For several years, APHL and partners have been working on a project to equip all state labs with multi-directional data exchange capabilities with CDC labs and local partners. So far, however, only four state labs have the ability to send electronic influenza test results to the CDC, and 11 are scheduled to be live by the fall 2009 flu season.

In those states, the ABI 7500 FAST communicates directly with a laboratory’s in-house information management system, which, in turn, sends approved influenza data to the CDC, automatically populating data fields in the CDC’s own information systems. The possibility of transcription error is eliminated because there is no transcription at either end and data are transmitted in near-real-time.

The laboratories without this capability use more time- and labor-intensive means of communication: fax, phone, e-mail and a web-based portal requiring manual data entry.

Patina Zarcone, MPH, who oversees the project at APHL, said $100 million is needed to develop public health laboratories’ IT infrastructure and implement electronic messaging nationwide.

In the meantime, the Houston public health laboratory, for example, has 13,000 sets of test results that have yet to be entered into the lab’s computer system.

A second, much-needed resource is a national reagent stockpile. Since 2002, APHL has advocated for inclusion of reagents in CDC’s Strategic National Stockpile, a reserve of pharmaceutical and medical supplies maintained for use during a public health emergency.

Although a full-blown shortage of the commercial reagents needed to support PCR testing never quite materialized during this first wave of the H1N1 outbreak, reagents were sufficiently scarce that the CDC sequestered a supply for distribution to public health laboratories in the US and internationally.

Perhaps the most pressing laboratory need, however, is predictable and adequate long-term funding. With current resources, Humes said, “If we had had sustained levels of infection throughout the next few months, it would have compromised every state lab’s ability to deliver routine public health services.”

Although the novel H1N1 outbreak is now officially a pandemic, that designation has little impact on the US response, which has already peaked for the time being. With the onset of summer, the incidence of infection has slowed, but remains unusually high for this time of year, especially in Boston, New York City, Seattle, Chicago and a few other large metropolitan areas.

Shult, who lectures extensively on the epidemiology of influenza, explained that we may be nearing the end of the initial wave of disease, at least in the US, but cannot rule out a second or even a third wave to come.

What will happen when influenza season officially resumes in the fall?

“We can’t predict right now,” said Shult. “But we can come up with a small universe of possible outcomes.”

The virus may weaken and simply die out in the Southern hemisphere, which is now in its flu season, but Shult concedes this is unlikely.

It may undergo antigenic drift and become less virulent or more virulent, less transmissible or more transmissible.

Or it could re-assort its genetic material with other seasonal or novel viruses and pick up more pathogenic elements, maybe even gain antiviral resistance. Egypt, for example, is known to have H5N1 in its poultry population and has had dozens of recent cases of both human H5N1 and H1N1, two viruses that would be dangerous to mix.

The current novel H1N1 has an attack rate of about 18%; meaning about 18 of every 100 people exposed to the virus become ill. A few genetic changes could be sufficient to boost the rate into the 20s or 30s, on a par with past viruses of major concern.

“Probably what will happen,” said Shult, “is somewhere between the best- and worst-case scenarios. However, you sorta have to plan for the worst.”

Regardless of what happens, novel H1N1 will continue to complicate influenza surveillance.

“If it does nothing different, it’s still added to the current group of seasonal viruses,” said Shult. “Swine H1N1 and human H1 and H3 and influenza B have different profiles of severity of illness and antiviral susceptibility. It still has an impact on the lab, because you need to know which virus you’re dealing with.”

For public health laboratories already struggling to make do with scarce resources, this is bad news.

In congressional testimony in May, Daniel Sosin, MD, MPH, FACP, acting director of CDC’s Coordinating Office for Terrorism Preparedness and Emergency Response, said, “With stronger laboratory capacity in states, we could accelerate the detection and study of new viruses such as the 2009-H1N1 virus, helping us better understand and respond to emerging health threats.”

But instead of enhancing laboratory capacity, the US is not even treading water.

Said Waddell, “Until you fail nobody’s going to take notice. But we don’t want to fail. That’s not what we do.”

“Maybe,” he said, “H1N1 will be a wake-up call to the federal government to put some money into the labs before it’s too late.”
A severe shortage of qualified Public Health Laboratory (PHL) directors underscored the importance of determining PHL workforce development needs in California. LabAspire, the California Department of Public Health (CDPH) Laboratory Director Training Program, conducted a descriptive online survey of all 38 PHLs in May 2007 to assess the magnitude of workforce shortages, external and internal recruitment needs, training and communication practices and professional networking and partnership information. Data were collected from 36 PHLs. Results highlighted staff recruitment and training needs at all levels, especially in the director and public health microbiologist (PHM) levels, and the importance of increasing local laboratory training support. Based on these findings, LabAspire recruitment focused on strengthening four critical levels: (1) undergraduate and graduates for California PHM Certification; (2) undergraduates, graduates and working professionals into MPH, DrPH and PhD programs; (3) doctoral candidates into post-doctoral training programs; and (4) recruitment of doctoral fellows with two years of PHL work experience to enter assistant PHL director training positions.

The survey showed the number of public health laboratory employees, additional staffing needs and projected staffing needs within the next three years.

<table>
<thead>
<tr>
<th>JOB TITLE</th>
<th>NUMBER OF EMPLOYED STAFF (FTES)</th>
<th>NUMBER OF STAFF NEEDED (FTES)</th>
<th>NUMBER OF STAFF NEEDED IN 3 YEARS (FTES)</th>
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<td>Laboratory Manager</td>
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<tr>
<td>Supervisor Microbiologist II</td>
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<td>Total</td>
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Members approved several bylaw changes at APHL’s annual meeting in May, including the addition of a new position on the Board of Directors for a Local Institutional Member Representative. The recommendation to add a second local representative came from APHL’s Governance Task Force, chaired by board member Yvonne Hale Salfinger, director of Florida’s agricultural laboratory.

The task force surveyed most local and associate institutional members. Many local members made particular note of an inequity in representation on the board: the four officer positions (President, President-Elect, Past President and Secretary Treasurer) and the three Member At Large positions can be held only by State Institutional members. Thus the board has one Associate Institutional position, seven State Institutional positions (to represent 56 state-level members) and one local member representative (to serve more than 40 local-level members). As APHL’s membership department reaches out to more local labs, it is likely that their numbers will soon equal or surpass the state member category. The addition of another local leader will help address this gap. The new position will be added to the 2010 slate.

The membership also approved the Governance Task Force recommendation to allow any member who has completed at least one full board term, including local and associate institutional member representatives, the right to run for an officer position. This change should help resolve a recurring problem in recruiting new leaders. Since board members should be familiar with APHL’s work, the nominations committee usually selects Member At Large candidates from active committee members. President-Elect candidates are then selected from members with previous board experience.

Of the 56 state-level members eligible for seven of the board positions, not all are involved actively enough to meet these criteria and some are unable to commit the additional time required for board service. This selection process has resulted in a small supply of potential board members. The bylaws change will allow APHL to add slowly to its potential leadership base.
COLORADO PUBLIC HEALTH LABORATORY:
PROVIDING ENVIRONMENTAL AND PUBLIC HEALTH PROTECTIONS WITH A DOSE OF PRAGMATISM

by Emily Mumford, writer

Known for the rugged beauty of the Rocky Mountains, Colorado showcases its natural splendor with more than 22 million acres of state and federal parkland. Outdoor enthusiasts from around the world travel to Colorado to hike, ski, fish and explore the relatively untouched natural beauty.

Part of the state public health laboratory’s mandate is to protect this natural legacy through chemical and microbiological testing of waterways to monitor pollutants, as well as to offer testing for outdoor and recreation associated diseases, such as plague, Colorado tick fever, rabies, hantavirus and Rocky Mountain spotted fever.

The state laboratory is located in east Denver in an area known as Lowry. In 1994, Lowry Air Force Base was decommissioned and parcels were sold cheaply to encourage re-development. The state bought the lab’s building for $1 and then gutted and remodeled, opening the new facility in 1996. The area’s redevelopment has been successful, said Laboratory Director Dave Butcher, MBA, MT(ASCP)SM.

ROOM TO GROW
The public health laboratory building has 64,000 finished square feet with another 16,000 square feet of unfinished space available for expansion. Although the facility is relatively new, said Butcher, “it was designed before 2001 and we were lacking adequate BSL-3 capacity.” After a retrofit, the state lab has three BSL-3 spaces and a state-of-the-art radiochemistry area. The laboratory has a whole body radiation counter that can detect contamination in the lungs of radiation workers. This part of the laboratory can also measure radiation from potentially harmful environmental samples, such as radium, radon or plutonium.

ENCOUNTERING CHALLENGES
After 34 years in Denver, Butcher is definitely at home there, but he grew up in Parkersburg, WV. At West Virginia University, Butcher was drawn to engineering but, when he learned that jobs were relatively scarce in the field, he joined the med tech program. After graduation, Butcher moved to Denver to work in a hospital. He later spent 14 years at Kaiser Permanente, ending up as the administrative laboratory director. He earned an MBA from the University of Colorado and then nine years ago, brought his clinical laboratory and management expertise to the public health laboratory.

When Butcher became lab director, the facility was brand new. But he quickly discovered that there were some significant infrastructural challenges on his desk. “We did not have new equipment,” he said. “The organic chem lab had to be rebuilt from scratch. A key person had just left, the equipment was 20 years old and much of it was out of service.” Using know-how gained from years in a clinical lab, Butcher opted to lease the necessary equipment. “It was a bit controversial,” he said, “but we used reagent leases to acquire some new equipment. The rest was acquired with CDC grant funds. Our toxicology lab was also very outdated. Then we sent some talented staff for training and now we are fully certified again in radiochemistry, inorganic and organic chemistry.”

Decisions like these have been a fact of life for the Colorado laboratory. An unusual funding situation has them receiving absolutely no state money—until now. The lab operates annually on about $11 million, drawn from grants (33%) and fees (67%). However, the state’s general fund has just approved $900,000 for flu surveillance and public health tracking, starting in July 2009. This money will constitute 1% of the lab’s budget and is the first state funding received since 2001.

It took Butcher two years to earn this money and involved working with the governor’s office, the health department; and giving countless tours of the facility to legislators and others. Ultimately the legislature voted unanimously in support of the laboratory funding.

Butcher is very happy about the success, but is simultaneously trying to balance recession-related shortfalls. The lab has a staff of 79, but there are currently 10 vacancies. The state has had a hiring freeze for more than a year. Butcher has been able to hold the jobs open, but may not be able to do so indefinitely.

STAFFING SHORTAGES
Like other laboratories, Colorado has been cross-training staff and working short. “To some degree, we needed to do that anyway,” said Butcher, “to bring ourselves in line with private sector labs... but the situation has been terrible for morale.”

Staffing has been hit hardest in its fiscal area, “the purchasing, budgeting, financial staff,” said Butcher. “We cannot get any waivers to replace the staff who...”
left and it is increasingly hard to fill requests.” The lab has also lost a few scientific personnel. The hiring freeze may be lifted soon, but the state has been struggling to pass its budget.

Funding is always the battle. “The fight is never over,” said Butcher. “The lab is always fielding questions on ‘Why? Why not outsource to another state or a private lab?’ We must always defend our position and educate the decision-makers on what we do and why it’s important. So far we have not been directed to cut anything, but all the balls are up in the air.”

A LONG HISTORY
Despite this struggle, the lab has a long history in Colorado. Founded in 1895 by the State Board of Health, its main purpose was to stem the tide of diphtheria. By 1923, the laboratory was also testing for syphilis, typhoid, venereal diseases, tuberculosis and rabies; records also note that the laboratory could analyze water supplies for drinking and culinary purposes and conduct food and drug tests.

MEETING CURRENT NEEDS
Today, of course, the Colorado laboratory tests for a full range of public health and environmental concerns. Its public health microbiology section tests for pathogens that cause foodborne illness, such as shigellosis, salmonellosis and E. coli 0157. This section can identify outbreak-associated illnesses, such as Hepatitis A in restaurant workers, pneumonia in nursing homes, measles and mumps in college populations, along with STDs and HIV. The environmental microbiology section tests Colorado’s water, food and dairy supplies to keep consumers safe from contaminants; and a chemistry section tests water for pesticides, herbicides, toxic metals and other organic and inorganic pollutants.

A strong molecular science and virology program, run by Dr. Hugh McGuire and lead scientists Justin Nucci and Dr. Kim Keene, underpins the flu surveillance in the state. “With swine flu, Colorado was one of the first states to get the assay for H1N1 up and running, activating the state’s flu plan,” said Butcher. “[McGuire and Nucci] were staying late and working weekends to make it happen. This section is also capable of identifying West Nile virus, bioterrorism agents and other infectious agents.

Colorado’s public health laboratory is responsible for DUI/toxicology testing of blood and urine for drugs of abuse, as well as blood alcohol. It also maintains the alcohol breath devices and trains police in their proper usage. Last year the lab ran 6,000 blood alcohol tests, 4,000 blood drug analyses and 19,000 urine analyses for drugs of abuse. “Lab staff go to court to testify,” said Butcher. “It makes it difficult to run the lab tests and meet turnaround expectations when staff are pulled out to attend court sessions.” Tests can detect marijuana, cocaine (crack), methamphetamine (speed), morphine, heroin (snow), LSD and other illicit drugs including abused prescriptions and over-the-counter medications.

As the lab’s relationship with law enforcement suggests, its services have been built around the unique needs of the state. The lab’s biggest partner is the health department, located about four miles away from Lowry. Butcher regrets the distance between the lab and the health department and works to eliminate the idea that the lab is “something different.” He said, “We aren’t always seen as integral since we’re separated. I am always working to build relationships with the health department to make sure they don’t send testing somewhere else. We work closely with the epidemiology division and water quality control division—it’s a good relationship.” The lab also works with the National Guard Civil Support, the FBI and local county health agencies.

Looking ahead, Butcher sees a clear need for laboratory strategic planning to cut through the financial difficulties and shifting political theories. “We need to maintain the skills of our current workforce and our state of the art capability. It can be hard to motivate state employees to continue expanding and retraining. We are definitely impacted by hard-to-obtain funding and lack of performance-based pay. But we need to remain on the cutting edge so we can continue to address novel pathogens—like H1N1—with the same degree of proficiency.”

Keeping the laboratory linked into the national public health community is also vital. One of the lab’s pragmatic financial successes has been with its laboratory information management system (LIMS). “[previous] laboratory information system simply didn’t have the horsepower and we had data integrity problems,” said Butcher. “We had no funding, so we signed up for the LITS+ program through CDC and we still use it—very successfully. We are one of the PHLIP states that transfer data to CDC daily. We have all of the capability—and more—than other LIMS out there.”
HOUSTON’S PUBLIC HEALTH LABORATORY: A LOCAL LABORATORY WITH A WORLDLY VISION

by Emily Mumford, writer

STAFF
The Houston laboratory employs about 70 people: 23 of these staff have at least a master’s degree, including three MDs and four PhDs. “Not bad for a local lab, right?” asked Pottumarthy with a laugh.

Texas has suffered less from the national economic crisis, but, said Rajan, “We’re not immune from the recession.” The lab lost four positions due to city cutbacks. The positions were temporarily vacant during a lab reorganization. Unfortunately the city eliminated all positions vacant on a specific date, catching the lab in the crosshairs of its cost reductions. The lab is applying to recapture the positions.

The lab did receive an unexpected boon from the weakened economy. During the crush of swine flu testing, they hired temporary staff to help with sample processing and testing. “We were able to find some really highly qualified people,” said Pottumarthy.

LOCATION
Located 50 miles from the Gulf of Mexico, Houston is the fourth most populated city in the United States and a sprawling, multi-cultural place. Houston is a large international port, heart of the American energy industry, and home to NASA’s Johnson Space Center and many educational institutions.

Houston’s local laboratory conducts public health testing for the city’s 2.245 million residents and also serves as a reference lab to the greater Houston region, encompassing 6.33 million people.

DISTINGUISHING CHARACTERISTICS
“We seem to fall somewhere between local and state labs,” said Sudha Pottumarthy, MD, FRCPA, D(ABMM), acting laboratory director. This local laboratory has developed unusual testing depth in response to its large population base, proximity to Mexico and risk of hurricanes and other disasters.

The laboratory participates in many national programs, such as BioWatch and the CDC’s Childhood Lead Poisoning Prevention Program. It also performs specialized testing to support the state’s Clean Rivers Program, state dairy programs and potable water supplies. In the aftermath of Tropical Storm Allison in June 2001, the lab—operating on emergency power—continued testing programs, including water testing for the hospitals and for residents with private wells.

“We also have the PulseNet program, which is unusual for a local lab, but very valuable,” said Pottumarthy. During an outbreak over a two-week period, the lab identified six cases of typhoid salmonella, which were spread across four counties and involved no travel. Researchers ultimately traced the illness to oysters harvested from nearby Galveston Bay.

The PulseNet technology has proved its worth against other pathogens as well. An outbreak of E. coli 0157:H7 was traced back to a fair’s petting zoo. “It’s good to house these programs in a local lab,” said Pottumarthy.

LEADERSHIP
The overall leadership of the Houston laboratory is divided among the CLIA director, S. Vern Juchau, PhD; Pottumarthy, who serves both as acting director and manager of clinical services; and Odatt Rajan, PhD, manager for environmental services.

Pottumarthy’s education has been global: leaving her native India after medical school, she spent 10 years in New Zealand while completing a fellowship in clinical microbiology at the Royal College of Pathologists of Australasia. Then she moved to the US for a fellowship at the University of Washington in Seattle. After, Pottumarthy went to JMI Laboratories in Iowa, where she worked with Dr. Ron Jones. In 2006, Pottumarthy came to the Houston laboratory, becoming acting director in 2007.

She focused on microbiology due to its hands-on approach. “It tends to be less mechanized, which makes it more interesting to me,” she explained. Her laboratory counterpart in environmental sciences, Rajan, “is my exact opposite,” said Pottumarthy. “He loves the instrumentation.”

Rajan focused initially on teaching and research, but came to the lab in search of more interesting work. He finds particular fulfillment in environmental sciences due to the terrible pollution evident in developing countries. “It is satisfying to help control pollution here through environmental monitoring programs, like the Clean Rivers program and Neighborhood Protection Program,” he said.

FACILITY
Houston’s public health laboratory is part of the Texas Medical Center, which contains 47 health institutions—including 13 hospitals, two medical schools, four nursing schools and schools of dentistry, public health, pharmacy and more.

The 34,000 square foot lab is integrated into the city’s health department, inside of a three-story building with a basement. The laboratory has two BSL-3 spaces: one in a built-out area on the third floor for molecular bioterrorism work and another for microbiological bioterrorism work. The health department building is about 50 years old, resulting in some significant technical challenges. Pottumarthy explained, “Building Services help us a lot, but we have HVAC problems and can’t modulate the temperature efficiently inside the lab.”

A solution is pending as the city negotiates the purchase of a new public health lab within the Texas Medical Center. The new building is a 10-year old, 37,000 square foot building that was constructed as a laboratory. If all goes well, the Houston lab will move by the end of 2009. In addition to eliminating the HVAC problems, the lab will expand its BSL-3 space and centralize molecular testing.

TESTING
The lab runs about 650,000 tests annually. In recent months, swine flu has kept staff busy: as of mid-June, the lab had tested more than 6,000 samples and identified 804 local cases. Typically, however, the busiest area of the laboratory is in HIV and STD testing, with about 228,000 tests per year.

The Houston public health laboratory has fully functioning clinical, environmental and molecular sections. It is one of the 11 Laboratory Response Network labs...
in Texas, and in that role offers 17 counties and about 95 hospitals and private labs bioterrorism training and reference support. It serves as reference lab for area hospitals and private laboratories, performing high complexity tests.

The lab supports the health centers, providing critical blood counts and chemistries for maternity and family planning services; testing for HIV, STDs and TB; checking patients’ immune status to vaccine-preventable diseases; and overseeing point-of-care testing at STAT laboratories. “We can culture for influenza and send isolates to CDC for surveillance and vaccination purposes,” said Pottumarthy.

Its environmental section provides chemical analysis of water, soil, air and industrial waste samples in support of Environmental Health Initiatives and Programs mandated by the Federal Clean Water Act, Resource Conservation and Recovery Act and the state’s health programs. In addition to a robust lead poisoning prevention program, the environmental section houses a water and dairy section that can perform microbiological testing of potable water, milk and dairy samples.

**REVENUE**

The lab’s $3.4 million in annual funding comes from the city’s general fund. Federal and state grants help support TB testing, public health preparedness, lead testing, the HIV-STD program and Laboratory Response Network bioterrorism work.

The lab earns about $250,000 in revenue and hopes to boost that number. It recently gained permission to revamp its 14-year-old fee schedule and will now charge paying customers enough to cover test expenses. Under a new arrangement, this revenue will remain at the lab to buy equipment and supplies.

**SUCCESSES**

**Nucleic Acid Amplification Testing (NAAT).** The Houston public health laboratory is one of the first labs in Texas to introduce NAAT to identify acute HIV infection and help control the spread of the disease.

**BioWatch Award for Excellence.** In August 2007, the lab received a reward for teamwork and overall excellence in laboratory operations. Additionally, “we were the first lab in the nation to have a positive in the BioWatch program [Francisella, believed to be environmental], which helped set standards for the program,” said Pottumarthy.

**EPA Region 6 Laboratory Response Plan functional exercise.** The environmental section completed this exercise successfully, conducting organic testing on samples sent by Homeland Security and the EPA that mimicked an intentional contamination of the water distribution system.

**National Allergy Bureau accreditation for pollen and mold count.** The lab has a Burkhard machine housed above the building that collects pollen and mold samples for a 24-hour period. The media, hospitals and public have access to the results online, making this the second most visited part of the health department’s website.

**GOALS**

- Move into the laboratory’s new facility, ideally before the start of flu season.
- Enhance the lab’s food testing program to include bioterrorism agents, aiming for Food Emergency Response Network certification.
- Expand molecular testing approaches for TB, slow-growing bacteria and other bacterial and viral diseases.
- Expand environmental monitoring programs to include biomonitoring and prepare the laboratory for chemical threats or incidents.

But importantly, the lab will continue to prioritize community projects such as the upcoming Hip-Hop for HIV Awareness Intervention. The health department, along with a team of businesses, organizations and a radio station, aims to test 15,000 youth during a four-day social event culminating in a free concert for those tested. Activities like these align the Houston public health laboratory closely with its mission to maintain programs and services that are consistent with the health department’s goals.

**BIGGEST CHALLENGES**

*Balancing public expectations with a rational public health and epidemiological approach to testing.* Pottumarthy offered an example of a tragic death, in which a child was killed by rabies acquired in a bat bite: “It brought families from Houston to the lab with bats from their attics increasing the workload by 150%. It’s neither realistic nor necessary.”

*Juggling the silo-based funding of state and federal grant programs.* Pottumarthy said, “It would be beneficial to have balanced funding to allow continuity and growth of services.”

*Improving staff retention and training.* “We compete with the Texas Medical Center. We are often used as a training ground for young graduates to gain experience, earn certification and then move on,” said Pottumarthy.

*Maintaining the full capability of the environmental chemistry section.* Rajan noted the importance of keeping staff trained for potential chemical accidents, water supply contamination, and as a surge lab for chemical incidents or threats.
In early April, planning was nearing completion for the Influenza Public Health Laboratory Capacity Modeling plenary session to be held at APHL’s annual meeting, May 5-8, 2009, in Anchorage AK. However, due to the recent novel influenza A/H1N1 outbreak, all of the speakers canceled less than a week prior to the scheduled session. Although the annual meeting was to be held as planned, the plenary had not been re-planned due to APHL’s involvement in activities surrounding the influenza outbreak. While in Alaska, approximately a day and a half prior to the scheduled session, planning began for the Influenza Town Hall Session. The session proved to be a success and was enthusiastically attended by laboratory professionals who wanted timely and accurate information on the outbreak.

Richard Besser, MD, acting director of CDC, opened the session by thanking the participants for their efforts in the H1N1 outbreak. Dan Jernigan, MD, MPH, deputy director of CDC’s Influenza Division, then provided a national situational update. Eric Blank, DrPH, former director of the Missouri State Public Health Laboratory, gave a historical perspective of pandemic planning. Rosemary Humes, MS, MT (ASCP) SM, APHL’s senior advisor for scientific affairs, discussed APHL’s current activities in support of pandemic planning. Joseph Miller, PhD, CDC’s chief laboratory preparedness officer discussed the current novel influenza A/H1N1 (swine like) diagnostic assay. Brooke Schwartz and Greg Eichinger of Applied Biosystems talked about partnering with CDC to bring the ABI 7500 Fast Dx high throughput PCR platform through FDA clearance. They discussed the company’s commitment to public health laboratories, including sequestering instruments to improve public health laboratory capacity and providing 24-hour/7-day instrument support.

Almost 300 participants attended the 2009 APHL Annual Meeting and Third State Environmental Laboratory Conference. In addition to the Influenza Town Hall, sessions focused on infectious diseases, public health challenges in Alaska, workforce development, laboratory training management, all-hazard receipt facilities and exercises, environmental issues like water security and radiology, foodborne disease surveillance and LIMS.

Susan Neill, PhD, MBA, director, laboratory services section, Texas Department of State Health Services, Sara Beatrice, PhD, assistant commissioner, New York City Public Health Laboratory, and Dave Schnurr, PhD, research scientist, California Department of Public Health Laboratory (on behalf of Paul Kimsey, PhD), provided current public health laboratory perspectives. They also shared early lessons learned, including the success of maintaining their pandemic plan, the need to engage epidemiologists early in the outbreak to discuss testing algorithms, the importance of finding a way to rest staff and the need for a better electronic reporting system.

Clockwise from top right on this page: Norman Crouch, PhD, former assistant commissioner, Health Protection Bureau, Minnesota Department of Health, presented the Dr. Katherine Kelley Distinguished Lecture on “Public Health Laboratories of the Next Frontier: Surviving and Thriving.” Patricia Somsel, DrPH, Michigan Department of Community Health, moderated the Influenza Town Hall Meeting. Bernd Jilly, PhD, chief, Alaska Public Health Laboratories, presented “Unique Challenges of Leading Laboratories in Alaska” during the opening session.
Clockwise from top left on this page: Brian Hansen of Gen-Probe represents the sponsor by welcoming attendees to the Awards Luncheon; Frances Pouch Downes, DrPH, APHL president and director of Michigan’s public health laboratory, presents the Presidential Award to Thomas Hearn, PhD, deputy director of CDC’s NCPDCID; Patrick Luedtke, MD, MPH, APHL’s incoming president-elect and director of Utah’s public health laboratory, announces the winners of the Exhibit Hall Raffle, where conference attendees had the chance to win donated prizes by visiting the exhibit booths; Dave Carpenter, PhD, former director of Illinois’s public health laboratory, visits the Response Board, which highlighted the latest H1N1 outbreak developments and detailed APHL’s response; Eric Blank, DrPH, former director of Missouri’s Public Health Laboratory, honors Charles Sweet, DrPH, former director of Texas’s public health laboratory, winner of the Lifetime Achievement Award; Scott Becker, MS, APHL’s executive director, visits the PerkinElmer booth in the Exhibit Hall.

SUSTAINING MEMBERS AWARD TRAVEL SCHOLARSHIPS

by Linette Granen, MT(ASCP)CLDir(NCA), corporate relations manager

In the fall of 2008, public health laboratories knew that they were facing an inevitable cut in funding due to the economic downturn. Scott Becker, MS, APHL’s executive director, asked for help from the eight companies attending the Corporate Leadership Council Meeting in October in Austin, TX. He asked for corporate support in the form of travel scholarships for APHL members to attend the 2009 Annual Meeting.

Luminex Corporation responded by raffling off three Annual Meeting travel scholarships to attendees at the November 2008 Newborn Screening and Genetic Testing Symposium in San Antonio, TX. Subsequently, Applied Biosystems provided four travel scholarships, Gen-Probe provided two and PerkinElmer provided one. These 10 scholarships resulted in $25,000 in support.

Applied Biosystems, Gen-Probe, Luminex Corporation and PerkinElmer clearly demonstrated their unwavering support of the public health laboratory system and APHL. When a crisis arises, APHL member labs step up and respond. It is reassuring to know that APHL’s sustaining members will also.

APHL is grateful for the generous support of these companies, as well as the other corporate partners who assisted in making this Annual Meeting a success.

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CEREMONY HONORS MEMBERS, PARTNERS

Frances Pouch Downes, DrPH, 2008-2009 APHL president, and director, Public Health Laboratory, Michigan Department of Health, moderated APHL’s 5th Annual Awards Luncheon. The awards recognize dedication and excellence in the profession, outstanding leadership qualities and extraordinary support of laboratories serving the public’s health.

APHL SERVICE RECOGNITION

OUTGOING BOARD MEMBER

Victor Waddell, PhD
Member-at-Large (2006-2009)
Bureau Chief, Arizona Bureau of State Laboratory Services

OUTGOING COMMITTEE CHAIRS

Norman Crouch, PhD
Emeritus Director, Minnesota Public Health Laboratory

Jane Getchell, DrPH
Infectious Diseases Committee (2008-2009)
Laboratory Director, Delaware Public Health Laboratory

Gary Jones, BS
Informatics Committee (2006-2009)
Information Systems Manager, Minnesota Public Health Laboratory Division

Robert Rej, PhD
Knowledge Management Committee (2006-2009)
Director, Clinical Chemistry & Hematology, Wadsworth Center

PRESIDENTIAL AWARD

Thomas Hearn, PhD
Deputy Director, National Center for Preparedness, Detection, and Control of Infectious Diseases, CDC

GOLD STANDARD IN PUBLIC HEALTH LABORATORY EXCELLENCE AWARD

Stan Inhorn, MD
Emeritus Director, Wisconsin State Laboratory of Hygiene

EMERGING LEADER AWARD

Grace Kubin, PhD
Manager, Emergency Preparedness Branch, Laboratory Services Section, Texas Department of State Health Services

ON THE FRONT LINE AWARD

Allan Antley, BA
Retired Operations Liaison, Homeland Security Laboratory Response Center in the Office of Solid Waste and Emergency Response, Environmental Protection Agency

LIFETIME ACHIEVEMENT AWARD

Charles Sweet, DrPH
Emeritus Director, Texas Public Health Laboratory

APHL awards have been carefully designed to highlight some of the extraordinary achievements in laboratory science and creative approaches being made to solve today’s public health challenges.

APHL Board of Directors CALENDAR

Strategic Planning Retreat
August 8 & 9, 2009

Board, Council of Chairs & Corporate Leadership Council Meetings
September 30-October 2, 2009

CDC Meetings
early January 2010

Spring Meeting
mid-March 2010

Board & Council of Chairs at the Annual Meeting
June 4-5, 2010

Monthly board calls are held at 3:00 pm Eastern time on the fourth Thursday of each month. For more information, contact Shawna Webster, senior manager for membership & governance, at 240.485.2785 or shawna.webster@aphl.org.
2009-2010 APHL NATIONAL CONFERENCES

13TH ANNUAL PULSENET UPDATE MEETING AND 5TH NATIONAL MEETING FOR OUTBREAKNET
Snowbird (Salt Lake City), UT
September 22–25, 2009

2010 HIV DIAGNOSTICS CONFERENCE
Orlando, FL
March 24–26, 2010

2010 NEWBORN SCREENING AND GENETIC TESTING SYMPOSIUM
Orlando, FL
May 3–6, 2010

2010 APHL ANNUAL MEETING
Cincinnati, OH
June 6–9, 2010

Cincinnati, home to riverboats and the Great American Ball Park, will host the 2010 APHL Annual Meeting.
APHL offers institutional memberships to state and local public health laboratories, as well as state environmental and agricultural laboratories. Please join us in welcoming our newest APHL institutional member, listed below.

**Public Health Institutional-Local Member**

**Public Health Laboratory of East Texas,** Jeremy Jordan, MS

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Cathy Johnson joined APHL as a product manager for the Department of Continuing Education & Training in June. She has a bachelor’s degree in Medical Technology and a graduate degree in Instructional Systems Development from the University of Maryland system. Johnson most recently worked as an education manager with the Clinical and Laboratory Standards Institute.

Kristy Kubota, PulseNet program manager, and her husband welcomed the arrival of their son, Kane, on June 29.

Jennifer Beck Pierson, environmental health program manager, married Brock Pierson on May 23 in the bride’s hometown of Pittsburgh, PA.

Leigh Slayden joined APHL as director, marketing & member services. Her background includes 13 years in marketing and membership for organizations such as American Chemical Society, American College of Physicians and American Diabetes Association.

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**MISSISSIPPI LAB ANNOUNCES NEW DIRECTOR**

Daphne D. Ware, PhD, was appointed as the director of the Mississippi Health Laboratory in May. Ware previously served as clinical services director and as a clinical services technical consultant. She has a Bachelor of Science degree in biology from the University of Southern Mississippi and a Doctor of Philosophy degree in microbiology from the University of Mississippi Medical Center.

**ALABAMA DEPARTMENT OF PUBLIC HEALTH WELCOMES NEW LABORATORY DIRECTOR**

The Alabama Department of Public Health announced Sharon P. Massingale, PhD, as the next director of the Bureau of Clinical Laboratories (BCL). Massingale has been with BCL for more than nine years, most recently as the assistant laboratory director. In this capacity she played a critical role in several major initiatives, including the response to H1N1 influenza.

**UNIVERSITY OF NEBRASKA MEDICAL CENTER BUILDS NEW RESEARCH TOWER**

The University of Nebraska officially opened its latest research facility – the Durham Research Center II – in May. This building will serve as the new residence for the Nebraska Public Health Laboratories (NPRL). The University has provided facilities for the NPRL since 1997 in an arrangement that has saved the state millions of dollars.

**NEW ISDH COMMISSION CREATED**

Recently, the Commission of Laboratory Services was created within the Indiana State Department of Health (ISDH). ISDH Lab Director Judith Lovchik, PhD has been named assistant commissioner of the newly formed commission.

**NEW APHL INSTITUTIONAL MEMBER**

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**STAFF NOTES**

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MULTIPLEXING IN PHLS USING XMAP® TECHNOLOGY

by Chris Claxton, associate director, strategic marketing, and Greg Gosch, vice president, biosciences group, Luminex Molecular Diagnostics

EFFICIENCY. AUTOMATION. SPEED. SENSITIVITY. SPECIFICITY.
Several recent advancements in hardware and chemistry have created dramatic improvements in these areas. One such advancement is solution-based multiplexing. Luminex’s xMAP technology uses tiny microspheres suspended in solution to perform many different tests simultaneously on a single sample. The technology has been adopted in such diverse areas as pharmaceutical development for analyzing cytokine response, organ transplant testing for multiple human leukocyte antigens (HLA), clinical diagnostic detection of cancer markers and bioterror monitoring of dangerous pathogens. In all, over 6,500 xMAP-based instruments have been installed globally.

Recently, the technology has been applied to several areas of interest to public health labs. In particular, Luminex has developed reagent kits for detecting a broad spectrum of respiratory viruses, for analyzing multiple mutations in the CFTR gene and is about to launch an assay combining multiple immunoassays for newborn screening into a single test.

XTAG® RESPIRATORY VIRAL PANEL
In 2008, Luminex launched xTAG RVP, a multiplexed molecular test capable of detecting multiple viruses and subtypes simultaneously in a single patient sample. The assay was designed to provide clinicians with more information of higher quality as compared to most current lab testing methods, considerably reducing the doubt that occurs when a patient sample tests negative by less comprehensive methods.

In public health, xTAG RVP is being used for epidemiology, outbreak monitoring and surveillance programs. The broad spectrum of viral species covered enables labs to rule-in or rule-out suspected respiratory viral types and subtypes that might pose severe public health problems, as demonstrated in recent weeks.

3XMAP NEWBORN SCREENING
Luminex is entering the newborn screening arena with a multiplexed assay for congenital hypothyroidism (CH), congenital adrenal hyperplasia (CAH) and cystic fibrosis (CF). The assay tests for T4, TSH, 17-OHP and IRT 1&2. Luminex needs only a single punch spot from a newborn card to generate all of these results. The fully automated system will process over 700 samples per day, which with multiplexing provides a total of over 2,900 assays per system per day. Additionally, Luminex has an FDA-cleared assay for CFTR genotyping for use as a confirmatory test on IRT-positive samples as required by the laboratory’s testing algorithm.

CUSTOMER- BUILT ASSAYS
Luminex systems are open platforms, meaning that customers can also develop and validate their own assays for the system. xMAP has also been used in a variety of applications developed by the public health labs and CDC, such as Salmonella, Mycobacteria and West Nile virus. To date, there are over 2,500 publications from end users, demonstrating the open nature of the system. xMAP can be used for many different types of assays including sandwich immunoassays, nucleic acid mutation detection, enzyme activity and others. We invite you to visit the Luminex website for product information, a bibliography of publications and instructions on developing home-brew assays. The website is www.luminexcorp.com.

Multiplexing systems, like Luminex’s xMAP technology, allow labs to realize improvements in key performance criteria. As sample numbers and the number of diseases to be tested increase and demands to improve efficiency and customer satisfaction rise, please consider Luminex’s xMAP technology as a solution to help with these issues. We are excited about our new products and the opportunity to bring multiplexing’s efficiencies into more areas of public health.

Luminex Corporation develops, manufactures and markets proprietary biological testing technologies with applications throughout the diagnostic and life sciences industries. The company’s xMAP Technology is sold worldwide and is already in use in leading public health and clinical laboratories, as well as major pharmaceutical, diagnostic and biotechnology companies. Luminex is an APHL Platinum Level Sustaining Member.

Photo courtesy of Luminex.
DEFINING OUR PATH WITH STRATEGIC PLANNING

by Scott Becker, MS, executive director

As a new year begins for APHL, I want to thank Frances Downes for her 18-month tenure as president. She stepped up early when we needed her and, under her guidance, we saw enormous gains in our relationship with the Department of Homeland Security and the BioWatch program.

Also, as our labs shouldered an alarming influx of H1N1 samples, APHL received huge support for its flu initiative—in large part due to the work of our president. Francie dedicated countless hours to APHL during a time when labs all over the country—including her own—were struggling to make ends meet.

I would also like to welcome our new president, Susan Neill, director of the Texas public health laboratory. We are fortunate to have a president with such depth of APHL leadership experience: Susan has served on the Board of Directors for seven years, overseeing all of our major initiatives and participating in the evolution of APHL’s national impact. She enters the presidency at a critical time: not just because of the turmoil on the national stage, but because APHL is in the very early stages of creating our next strategic plan.

Our current strategic plan has been invaluable to the organization’s growth, creating a steady trajectory to follow throughout the twists and unknowns of outbreaks, funding shortfalls and change. We have stuck to the plan with enormous success—with necessary adjustments along the way.

We can’t plan or predict perfectly. But never before have we had a better example of the value of strategic planning than with the H1N1 influenza outbreak. The outbreak wasn’t quite what we had expected, but nonetheless the years of planning and preparation within our labs, APHL and CDC for an influenza pandemic paid off.

The H1N1 outbreak exposed the importance—the critical nature—of the laboratory role to others. In mid-June, with the public spotlight on our labs, APHL and ASTHO convened a day-and-a-half long meeting with state health officials, senior deputies and laboratory directors to discuss the role of the laboratory within the wider public health system. The first outcome of the meeting will be a guide for new state health officials on everything they need to know about the lab. Lab leaders should not be strangers to our health officials: we all share responsibility for the clear conveyance of what we do, how we do it, how it helps the health official and, conversely, what we need in exchange to make it all happen.

Because the lab was so central to the investigation of this novel flu, we were seen in a different light. Today there is much more awareness about the labs’ incredible scientific resources, right at the fingertips of our state and national leaders. In Indiana, for example, after the H1N1 outbreak, the state health official elevated the laboratory to an assistant commissioner level. In many places and ways, the lab role has been elevated, proving that our careful planning processes have been worth it.

We have more work to do. The H1N1 outbreak is still underway, and we have many adjustments to make in our response, especially as we look to this upcoming flu season. I am certain that as the new APHL strategic plan evolves and as the national health reform progresses, we will continue to advocate for all of our members—our state and local public health laboratories, our food safety labs, our
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