The Problem: Outdated Laboratory Information Systems Hamper State Labs

In an emergency, time matters. That’s why staff at the Virginia Division of Consolidated Laboratory Services were frustrated when, at the height of the anthrax crisis last fall, they had to devote 240 person-hours to the development of an Access® database. Although state laboratorians were working overtime to test the more than 300 possible anthrax samples they received each day, the database was so important that it was allowed to “eat manpower.”

Without it, explained Wanda (Willie) Andrews, the lab’s assistant bureau director for analytical services, staff could not track thousands of potentially deadly samples through the public health system or answer basic questions from health and law enforcement personnel. Were preliminary test results reported back to submitters? How many samples tested positive? Were findings reported to forensics? Without some kind of a laboratory information management system (LIMS)—in this case an ad hoc, stand-alone database with limited capabilities—this kind of information would be unavailable.

The Solution: Partnering to Develop Lab Information Management Systems

The Association of Public Health Laboratories (APHL) has joined with a new nonprofit, the Public Health Informatics Institute (the Institute), to address the urgent need to update or acquire new public health laboratory information systems (LIMS). The two organizations launched this unprecedented collaboration at a meeting in Atlanta, October 23-25, attended by representatives from both groups and participating states.

The joint initiative aims to develop a comprehensive set of LIMS requirements that conforms to all applicable and published data and system standards. Public health laboratories can use the information to assess commercial and government software products. Currently, labs that wish to overhaul their information management systems must either develop their own list of requirements and work with a private software vendor or use the CDC’s LIMS software, LITS-Plus.
RESIDENT’S THOUGHTS

A little over a year ago, CDC announced that it would consider applications for biomonitoring planning grants from state consortia. While this was a novel idea at the time, the consortia concept has benefited participating states and is generating interest among others.

Originally CDC had expected to award grants for development of biomonitoring proposals to approximately 25 states, and that these states would then compete for one of five implementation grants. Because several consortia applied, CDC was able to fund 33 states, eight more than originally projected. Now several states with individual planning grants are considering creating consortia for the implementation phase.

As a member of a consortium, I have received several calls asking for advice on how to form one. While I am certainly no expert in this area, and the success of the Mountain States Consortium is yet to be determined, we (the Consortium) have overcome several hurdles in the initial organization process. I would like to share a few tips with others who might be considering a similar initiative.

The first problem we encountered was how to move funds between the funded state and other state members of the consortium. Resolution of this issue took six months of negotiations. We overcame this obstacle by placing grant funds in a category used to fund grants to public agencies and treating member states as recipient agencies.

Coordination of activities and communications among consortium members also posed problems. This was addressed by funding an independent scientific consulting group to travel to all of the member states and coordinate their planning activities. The consultant maintained a list serve, established and facilitated regular conference calls, wrote and distributed minutes of calls and meetings, and generally herded the member states together.

In addition, the consortium has held a series of planning meetings, one in each member state. At these meetings, group decisions are finalized, interim activities reviewed, work goals set, and tours held of the local state laboratory. These meetings have been instrumental in advancing the work of the consortium and have also created a regional identity among participants.

Many issues remain to be addressed by our consortium: IRB jurisdiction, state differences in indirect cost rates, regional data management, linkage to environmental health tracking grants where applicable, and others. Yet the consortium has developed a spirit of cooperation and compromise that will allow us to move forward to face these challenges.

To those who seek to form a consortium, I would say that it would be a gross understatement to describe the task as “difficult.” On the other hand, it can be highly rewarding.

Sincerely,

David E. Mills
Gone are the days when we sent information via paper. Now, it seems, information must flow electronically—either via email, downloadable via the Internet, or carried on voicemail. This is true for retrieving a phone message or transmitting important laboratory test results. Behold the pink message slip—read it, feel it, touch it, for it is on route to the Smithsonian!

Where will your laboratory be when electronic reporting and the paperless lab become the reality? Now that fiscal support is available through increased federal appropriations to state public health laboratories, we want to make sure that your laboratory isn’t left behind. This is why we have committed to a fast-track project to develop laboratory IT systems requirements, under the guidance of the APHL Management Information Systems Committee.

One of APHL’s strategic goals directs the association to improve the capability of public health laboratories to capture, process, and communicate laboratory information of public health significance. This objective has many implications for our work and calls for the development and promotion of effective laboratory information systems. About the same time we were thinking through how we might accomplish this task, we became familiar with the approach of the Public Health Informatics Institute, a program of the Robert Wood Johnson Foundation and the Center for Innovation in Health Information Systems. We often say, “Timing is everything.” How true in this case!

The founders of the Institute identified a pressing need to upgrade laboratory information systems (LIMS.) Virtually ignored in the past and of paramount significance in the area of public health informatics, this demand gave birth to a partnership between APHL and the Public Health Informatics Institute. A joint initiative now aims to develop a comprehensive set of LIMS requirements, one that will guide public health laboratories working to overhaul their information management programs in assessing software products. It represents true progress in the areas of communication and coordination; thus, we are extremely optimistic about its potential to improve the quality and speed of our responses to threats ranging from West Nile to bioterrorism.

Take a moment or two to learn more about this new project by reviewing the article beginning on page 1. But not too long—have a wonderful holiday season spending time with friends and family!

Sincerely,

Scott J. Becker
Unfortunately, the situation in Richmond was not unique. Connecticut State Lab Director Katherine Kelley, for example, was at the same time struggling with a LIMS that is a quarter century old. Since the system would not supply the reports she needed to produce, her staff had to create them by sheer brute force. At least three times each day they extracted raw data and organized it by hand: for 8:00 A.M. and 7:00 P.M. teleconferences with postal authorities and health and law enforcement personnel, for a report due to the public health communications office by 2:00 P.M., and for frequent news briefings given by the governor. “This process took an enormous amount of time and was fraught with problems,” said Kelley. At the time, she noted, the outdated system contained at least two test results for each of approximately 2,500 lab specimens related to ongoing anthrax investigations.

More recently, Stan Falk, director of quality assurance for the Arkansas Department of Health, reported difficulties keeping up with West Nile virus (WNV) data. “We’re on an old Wang® computer system that doesn’t interface with anything,” he said in an interview. Because it is impossible for other labs to electronically submit data to the state, all WNV case reports must be typed in manually. Then specific queries must be designed to import data from the Wang® system into an Access® database. Once in Access®, staff can run programs to provide summary data—such as the ages of individuals infected with the virus—that cannot be retrieved directly from the Wang®. Staff had to work with CDC officials to figure out how to get WNV data from Access® into the national Arbovirus Data Management System. “We have to always be cognizant of when test results are final so that we can run the queries against the Wang® and update all the other databases,” said Falk.

These scenarios illustrate a serious problem in the backbone of the nation’s disease surveillance infrastructure: dependence on a haphazard and mostly outdated collection of hardware and information software by the nation’s public health laboratories. As Ralph Timperi, director of the Massachusetts State Laboratory Institute explained, “The public health laboratories ... are often spoken of as a system, and are relied upon to provide testing services and data for policy and decision-making on issues that often affect national priorities and millions of our citizens. In many ways, this system is strong and responsive, but from an information technology (IT) perspective, it is weak.”

Years of under-funding have kept the laboratories from capitalizing on IT advances. Thus while cutting-edge data systems have radically transformed the modus operandi in other industries, many public health laboratories still carry out critical functions using paper and pencil. Lack of modern information management tools affects virtually all laboratory activities, from the routine—managing inventory, tracking quality assurance and maintaining data security—to the momentous—quickly sharing and analyzing data during infectious disease outbreaks. Falk said that if an emergency arises in Arkansas, “the way things stand right now, there is no way that individuals out in the field can get real-time lab results. No way.”

System upgrades, on the other hand, would significantly bolster laboratory capabilities, reduce costs for medical care providers, reduce illness and deaths from infectious diseases, and provide added protection for the public against the consequences of a biological, chemical, or radiological terror attack. Better technology would also enable public officials in different locations to access and report identical laboratory information, thus minimizing confusion and helping to maintain public confidence in times of crisis.

Although some states have allocated money to beef up their own LIMS, federal bioterrorism grants represent the first significant infusion of funds to address the problem on a national level. “While this initiative should be applauded,” said Timperi, “even greater levels of funding are needed due to the years of neglect and the extraordinary costs of IT systems, and these funds should be made available from state as well as federal sources.”

But funding is not the only obstacle. There is no off-the-shelf software product that public health labs can purchase to meet all of their information management needs. Even more fundamentally, “There has never been a consensus among public health laboratories on a set of LIMS requirements that can be provided to vendors,” noted APHL program manager Helen Regnery. “The partnership with the Public Health Informatics Institute is our first opportunity to make this a reality.”
According to Anita Renahan-White, project director for the Institute, the LIMS requirements document is on a fast track. She anticipates that it will be completed by spring, 2003, in order to provide labs with the guidance necessary to commit funding for bioterrorism. The document will include specifications on:

- Tracking specimens through the laboratory system.
- Coding test results and other data.
- Real-time data access and reporting from on- and off-site locations using security measures that comply with the Health Insurance Portability and Accountability Act.
- Interfacing with other databases, such as the National Electronic Disease Surveillance System (NEDSS).
- Client billing.
- Quality assurance (e.g., monitoring the results of control tests).

APHL members and staff are enthusiastic about prospects for the initiative. “Participating labs will benefit through direct assistance in the requirements development process, improvement of their informatics skills and potential cost savings through collaboration in software acquisition,” said Scott Becker, APHL executive director. Non-participating labs will benefit as well, since the requirements document will be available through the association.

Key contributors to the collaborative include APHL members Stan Falk and Charles McGee (AR), Donald Mayo and Deborah Roy (CT), Matthew Matusiak and David Czerny (IN), Jack Cameron and Dariush Shirazi (IA), Duane Boline and Bob Bostrom (KS), Jack Krueger (ME), Michelle Meigs (MA), Jenny Richard and Karen Greene (NY), Charles Brokopp (UT) and Jim Pearson and Willie Andrews (VA).

For further details, please contact Helen Regnery, NED SS project manager, 202.822.5227, hregnery@aphl.org.

### The Public Health Informatics Institute

The Public Health Informatics Institute was recently funded by The Robert Wood Johnson Foundation to build state and local public health agency capacity to use information tools to respond to bioterrorism and other public health threats. The new enterprise will offer a constellation of services and informatics education, including the LIMS requirements project, an information clearing house, a software exchange program and workshops on IT.

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Rare Cases of Mosquito-Transmitted Malaria Detected in Virginia

Do parts of the D.C. metropolitan area have higher rates of malaria-infected mosquitoes than some developing countries with endemic disease? As reported by The Washington Post, this scenario is highly unlikely, despite recent positive tests for Plasmodium vivax-210 circumsporozoite protein in at least five mosquito pools in Northern Virginia.

Mosquito testing was prompted in late August by diagnoses of P. vivax malaria in two teens residing within a mile of one another in Loudon County, Virginia. Neither had any known risk factors for the illness (international travel, needle sharing, blood transfusion or organ transplant) other than their proximity to Dulles International Airport, which receives non-stop international flights from countries in which the disease is endemic, and the presence of migrant workers in the area.

Analysis of mosquito pools was done using the newly available VecTest, a rapid assay that has been extensively tested by the Department of Defense to gauge its ability to detect malaria quickly in areas where US military personnel may be deployed. Robert Wirtz, chief of the Entomology Branch at CDC’s National Center for Infectious Diseases, reported that in about 40,000 assays in Africa, Southeast Asia, and Latin America, the VecTest demonstrated a sensitivity and specificity in the high 90s. Nevertheless, he said in a telephone interview that the Virginia results “seem very unlikely.”

The final chapter of this story will be determined by confirmatory polymerase chain reaction tests being run by CDC researchers (a difficult task since the VecTest consumes most of the organic material in the mosquito pools, leaving little for researchers to work with.)

Wirtz said that malaria “used to be a terrible problem in the US,” with somewhere on the order of 600,000 to one million infections in 1914. Even today, the US has about 1500 annual malaria cases and a few malaria deaths due to misdiagnosis or delayed diagnosis—although almost none the result of local mosquito transmission. Yet, even if the parasites are present in Virginia, they will almost certainly die as cold weather arrives and their mosquito hosts perish. Unlike West Nile virus, the only reservoir for human malaria is another human.

Wild Poliovirus Inventory
The U.S. national wild poliovirus inventory of all biomedical institutions/laboratories began in October 2002. Responses are due December 31, 2002.

Inventory forms will be mailed to academic institutions, biotechnology and pharmaceutical companies, and clinical, hospital and government facilities. Even if no wild poliovirus materials are retained, all institutions/laboratories must respond by December 31, 2002. Laboratories that retain poliovirus materials will be placed on the national inventory to be informed of global eradication progress and when to implement biosafety measures appropriate for the materials stored and procedures performed.

Additional information can be accessed at the Poliovirus Laboratory Containment Preparedness website at www.cdc.gov/od/nvpo/polio.
2002 Emerging Infectious Disease (EID) Fellows Begin Assignments

EID fellows from APHL’s ninth class have been placed in host laboratories around the country. Fellows are posted at 12 local and state public health laboratories, as well as CDC laboratories in Atlanta, Fort Collins, and Anchorage. APHL looks forward to working with these fellows, mentors and host laboratories as they pursue their training and research activities.

EID Fellow Accomplishments

Class VII Research Fellow Virginia Headley presented a poster on invasive disease epidemiology in Illinois at the June 2002 Illinois Department of Public Health annual immunization-communicable diseases meeting in Springfield, Illinois. Headley is in the second year of her fellowship at the Illinois Department of Public Health.

Class VI Research Fellow Sheila Abner presented the poster “Colorectal Explant Model to Evaluate Efficacy and Safety of Topical Microbicides for Preventing Sexual Transmission of HIV-1” at the 11th International Congress of Mucosal Immunology in Orlando, Florida in June. Results of Abner’s fellowship research lead to recent publications in the Journal of Experimental Medicine and the Journal of Infectious Diseases. Although her two-year fellowship ended in October, Abner will continue her work in CDC’s Tuberculosis Pathogenesis Lab and HIV Pathogenesis Lab through an amfAR (American Foundation for AIDS Research) grant she was awarded based on her fellowship research.

Sarah Levin presented the poster “Serotype Distribution of Haemophilus influenzae Carriage Isolates from a Rural Alaska Village Using Antisera- and PCR-Based Typing Methods” at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in San Diego in September. Levin is a Class VII training fellow at CDC’s Arctic Investigations Lab and the Alaska Department of Health and Social Services in Anchorage, Alaska.

Vladimir Chulanov’s abstract “Molecular epidemiology of Hepatitis A Virus in Russia Federation” was accepted for publication in the journal Infection, Genetics, and Evolution. Chulanov is an international EID fellow in CDC’s Division of Viral Hepatitis.
Environmental Health

CDC Shares Biomonitoring Expertise with States

Biomonitoring provides data about human exposure to environmental toxicants ranging from environmental tobacco smoke to pesticides to dioxin. This information, gleaned from samples of human blood, urine, saliva, and adipose or other tissue, is critical to health research, public health planning and emergency response.

Currently 33 states have received biomonitoring planning grants from the CDC, and implementation grants will be awarded next year. The CDC National Center for Environmental Health (NCEH) also recently sponsored a series of biomonitoring workshops, which laboratorians from 46 states attended. The series reviewed biomonitoring basics and policy implications for a number of important toxicants.

Cotinine
Cotinine is the primary metabolite of nicotine, and has been analyzed in human blood, saliva, urine, and hair using tandem mass spectrometry. CDC estimates about 3,000 lung cancer deaths are caused by environmental tobacco smoke (ETS) annually. Although ETS exposure has declined substantially over the past decade, significant exposure continues, especially among children in the home.

Volatile Organic Compounds (VOCs)
VOCs are found in personal products, chlorinated water, and paint. They are extracted from whole blood, using solid phase microextraction, gas chromatography and mass spectrometry. Tetrachloroethylene, also known as PCE, is used in dry cleaning and can impair the nervous system. Preliminary results of PCE biomonitoring show that blood tetrachloroethylene concentrations are high in New York study populations compared with past and present national data. Similarly elevated levels have been observed in World Trade Center study participants.

Persistent Organic Pollutants (POPs)
Because POPs are resistant to metabolic degradation and generally accumulate in adipose tissue, they are measurable in humans. POPs biomonitoring is useful for tracking pesticide exposure in humans, evaluating acute exposures, and identifying those pesticides to which humans are most commonly exposed. Automated solid phase extraction is used to reduce variation and inconsistencies, providing unattended operation and less sample handling. Automated high resolution gel permeation chromatography is also used to minimize analytical interferences by high molecular weight tissue components. Blood and urine are analyzed for organophosphate pesticide metabolites to allow determination of parent analytes, such as chlorpyrifos and parathion. Due to the chemical diversity of contemporary pesticides, a versatile methodology for biomonitoring must be used.

Dioxin is perhaps one of the most ubiquitous POPs now present in the environment. In fact, it is so pervasive that an extensive quality assurance program is necessary to avoid sample contamination when measuring dioxin. One study documented a significant excess exposure to dioxin among female children in Seveso, Italy, in the eight-year period following a factory explosion there, possibly indicating endocrine disruption by some of the explosion-generated POPs. Dioxin has also been detected in Vietnam War veterans and residents of Times Beach, Missouri.

Metals Analysis
The ICP-MS inductively coupled plasma mass spectrometry multielement urine panel examines twelve elements (Ba, Be, Cd, Co, Cs, Mo, Pb, Pt, Sb, Tl, U, W) in a half milliliter of urine, and can process 40 specimens in eight hours. Like most of the machines at the NCEH lab, it is expensive and complex to operate but provides high sensitivity and high sample throughput. Metals analysis has been used to measure human exposure to lead, mercury, arsenic, and other elements, and provided the data used by the Environmental Protection Agency to justify requirements for lead-free gasoline.
APHL in Uganda

APHL members Judith Wethers and Leonard LaFazia joined with speakers from CDC and the WHO/African Regional Office to conduct a workshop in cooperation with the Uganda Virus Research Institute (UVRI), November 4-8, 2002. The event marked the first such APHL initiative in the country of Uganda. Laboratorians from several African countries attended the workshop, “Serologic Diagnosis of HIV Infection: Evolving Roles of National Reference Laboratories,” which provided hands-on training in performance and troubleshooting of EIA and rapid tests for HIV.

Using a train-the-trainer approach, the workshop provided for the exchange of experiences and perspectives on HIV testing methods as well as troubleshooting strategies. Representatives from Zimbabwe presented their experiences in developing and implementing HIV testing and establishing national reference laboratories. Other speakers included Dr. Robert Downing of Uganda, who presented on HIV technologies and implementation of new assays, and Dr. John Ridderhof (CDC), who spoke on the core functions of a public health lab. Mr. LaFazia and Ms. Wethers presented overviews of quality assurance and quality control as well as lab safety. In the UVRI lab, the laboratorians performed DBS ELISA tests and several rapid tests for HIV. They also discussed specific solutions to the issues raised by country representatives. Conversations concerning preventive maintenance and information management gave attendees tools to take back to their home countries and share with associates.

Judging the workshop as a success, attendees recommended that it be held again to train additional staff who can, in turn, train others in their respective countries.
Infectious Disease

Diagnostic Testing for Poxviruses and Other Febrile Vesicular Rash Illnesses

The potential use of smallpox as an agent of bioterrorism is an issue of great national concern. As policy makers evaluate the merits of mass vaccination, clinicians, laboratorians, and other health officials are developing strategies for rapid detection and diagnosis of smallpox, smallpox look-alike diseases, and vaccine related adverse events.

This past October, the CDC, APHL, and the American Society for Microbiology co-sponsored a meeting in San Diego, California, to update and seek input from physicians, clinical and public health laboratorians, and epidemiologists on the status and use of laboratory diagnostics for febrile vesicular rash illnesses that may look like smallpox.

Participants discussed diagnostic approaches for poxviruses and other febrile rash illnesses, reported on progress in the development and validation of rapid diagnostic methods, and considered laboratory needs and requirements. The meeting was co-chaired by James LeDuc, with the National Center for Infectious Diseases (NCID), and Peter Estacio, with the Office of Public Health Preparedness, Department of Health and Human Services (HHS).

Febrile Vesicular Rash Algorithm: Concepts and Clinical Experience

CDC officials recognized the need for an algorithm to evaluate patients with febrile vesicular rash illness. The algorithm must have a high degree of specificity to detect the first case of smallpox while minimizing laboratory testing. The misdiagnosis of even one in one thousand varicella cases could result in one thousand false alarms for smallpox per year. The algorithm they developed offers a systematic approach to evaluate cases of febrile vesicular or pustular rash illness using the clinical features of smallpox to establish major and minor diagnostic criteria. Based on these criteria, clinicians can classify cases of rash illness into risk categories for smallpox.

Varicella is the rash illness most likely to be confused with smallpox. The differential diagnosis includes disseminated herpes zoster, enteroviral vesicular and papular exanthems, impetigo, drug eruptions, contact dermatitis, erythema multiforme, disseminated herpes simplex, scabies, insect bites, and molluscum contagiosum, syphilis, and rickettsialpox.

Since implementation of the algorithm in January 2002, CDC has received 19 calls concerning cases of rash illness. Using the algorithm criteria, none of the patients were designated as high risk, and there were no indications for variola testing. Four patients were considered to be at moderate risk. These included three cases of varicella in adults (one of whom died) and one case of erythema multiforme in a 15-year-old child. The remaining patients were all low risk and included nine cases of varicella (one death), disseminated VZV, disseminated herpes simplex virus (HSV)-2, Behcet's disease, Gianotti-Crosti syndrome, and contact dermatitis. Eleven diagnoses were laboratory confirmed.

The initial experience with the algorithm demonstrates two facts. First, it is important to rule in VZV since 75 percent of moderate-risk cases and 66 percent of low-risk cases were in patients with VZV. Second, the algorithm can limit variola testing by providing a standard approach to evaluation. Every laboratory should have a copy of the Febrile Rash Algorithm. See www.bt.cdc.gov/agent/smallpox/diagnosis/index.asp.

Complications of Smallpox Vaccination (Vaccinia)

Smallpox vaccine is generally safe and effective. However, because of the presence of live virus on the skin for up to two weeks, vaccination can prompt abnormal adverse reactions. Vincent Fulginiti, Professor Emeritus of the University of Arizona

See Smallpox, continued on page 17...
Newborn screening programs collect dried blood spots in every state for the approximately four million children born each year. Over 95 percent of newborns have leftover dried blood spots retained by state programs for some period of time. They offer a valuable, population-based source for public health surveillance and potential epidemiologic research. Yet the specimens are scattered among the states, thus limiting their utility.

In September, the Centers for Disease Control and Prevention (CDC), Office of Genomics and Disease Prevention, in collaboration with the Newborn Screening Branch in the National Center for Environmental Health and the Center on Birth Defects and Developmental Disabilities, hosted a meeting in Atlanta, Georgia, to assess the feasibility of establishing a bank for storage of leftover dried blood spots specimens and the logistical structure for controlled access to a multi-state or central dried blood spot bank.

In the end, few state participants agreed to the development of a virtual central clearing house coordinated by the CDC and facilitated by APHL, where blood spots would be stored by states, and researchers could gain access via requests for application. In fact, representative from each state emphasized that the states own the blood spots. Many participants cited legal restrictions that would prohibit them from sending blood spots to a central bank.

State representatives did agree that research should not be done on newborn spots unless there is a direct benefit to children in general. Several states argued that they could not release the spots for unknown purposes.

Participants, representing 12 states, also discussed funding for freezers to store blood spots at -20°C, legal consent and privacy requirements, and the merits and demerits of having federal control over a central blood spot bank. They outlined potential uses of dried blood spots banks for public health, reviewed the storage and use policies for leftover specimens for all 50 states, and explored alternative models for shared blood spot storage.

Jelili Ojodu, APHL program manager for newborn screening and genetics, presented the association’s draft statement on retention of specimens for newborn screening and genetics. The draft statement supports the development of national consensus policies, procedures, and standards for retaining residual dried blood spot samples following NBS analysis. It recommends that such policies and procedures recognize existing federal regulations for clinical testing, state laws, professional guidelines, and ethical and legal precedents. The draft also suggests national policies allow for the introduction of new newborn screening analytes and laboratory techniques. The draft position statement is under final review by the APHL Newborn Screening and Genetics in Public Health Committee and will soon be sent to the full membership for comments.

Future steps include:

1. Formation of a smaller working group from the meeting participants to develop a strategic plan on storage of blood spots.
2. Creation of a listserv by CDC, solely for issues pertaining to storage.
3. Additional input by APHL’s Newborn Screening and Genetics in Public Health Subcommittee on Quality Assurance and Quality Control.

For further information, contact Jelili Ojodu, program manager for newborn screening and genetics at 202.822.5227 x235 or jojodu@aphl.org.
The Chicago Office of the National Laboratory Training Network, in conjunction with Audionet International, presented the workshop “Bloodborne Pathogens/The New Needlestick Safety and Prevention Act” on September 12. The program, featuring Michelle Hill, MT(ASCP), was accessed by thirty-five sites nationwide. Altogether 220 laboratorians and other public health staff participated, representing 13 county or state public health facilities in 16 states.

The program was the first NLTN offering to use Audionet programming—Web-enhanced teleconferencing that blends Internet-delivered speaker visuals with traditional telephone-delivered audio. This new distance learning modality allows for an interchange between speakers and participants and also enables Internet polling. Participants must have access to a speakerphone and Internet browser to fully take part, although they may listen to the audio only via telephone.

Just over one-third of participants utilized the audio-conference modality only. More than half of the sites used audioconference in conjunction with the Internet. About 90% of participants reported that the teaching method was appropriate for learning, and 94% indicated that the program was worthwhile in terms of time and money invested. (Because the workshop was partially supported by an educational grant from Becton Dickinson, the site fee for the program was $50.)

The workshop will be archived and made available as a self-study course for continuing education credit. The Chicago NLTN office is planning four Audionet programs per year; two in the fall and two in the spring. “Rapid Influenza Test Kits: What You Should Know” will be co-sponsored by the Wisconsin State Laboratory of Hygiene and the University of Iowa Hygienic Laboratory, on November 20, 2002. For more information, contact the Chicago office at 312.793.3306 or visit the NLTN website at www.nltn.org.

New Secretary-Treasurer for APHL’s Board of Directors

Susan Neill, PhD, MBA has assumed the position of secretary-treasurer on the APHL board of directors, replacing Norm Crouch, the current president-elect. Dr. Neill will complete the final year of the term. She brings to the board a wide array of experiences and expertise. Dr. Neill serves as Bureau Chief of the Bureau of Laboratories within the Texas Department of Health. In this role, she heads the laboratory and coordinates the activities of five separate divisions.
The APHL Minute Page 13

Public Health Preparedness

Hostage Crisis in Moscow Theater: A Lesson for Chemical Terrorism Readiness?

In October, Muscovites were shaken by the terrorist takeover of a crowded theater. Terrorists, many with explosives strapped to their waists, were kept from detonating their deadly charges when law enforcement officials pumped a disabling gas into the theater’s air conditioning system. While hundreds of lives were saved, 116 hostages were killed by the unknown gas.

What if a terrorist were to release a disabling gas in a crowded American theater? In the immediate aftermath of the Moscow event, chemical weapons experts and physicians reviewed the symptoms of affected hostages and theorized that the gas carried one of three types of compounds: a nerve agent, an incapacitating agent or a narcotic. Each has a specific antidote, but they are not interchangeable. Each can rapidly induce coma, a diagnostic “black-box” that often can be resolved only through laboratory work-up.

Hospital emergency rooms and laboratories can answer certain questions to help coma victims. Are they suffering the effects of alcohol or drug intoxication, low oxygen or blood sugar levels, or meningitis? Our health care system is prepared for these known perils, but it is not prepared to identify military-grade chemical weapons, the kinds of chemicals that may already be in the hands of those who would do us harm.

There is no national pre-event plan to guide a public health laboratory director who might confront a mass-casualty chemical terrorism event. According to Dr. Richard Harris, Deputy Division Administrator at the Wyoming Department of Health Laboratory, “Public health labs need practical guidelines. In the earliest stages of a chemical event, we critically require a strategy for public health risk assessment of the threat, coordinated with rapid analytical techniques to provide support and information for first responders. As with the anthrax incidents, public health labs will be expected to provide technical guidance at the state level.”

APHL is working to address these needs. In September, the association awarded to RTI, Inc., of Research Triangle Park, NC, a contract for “assessment of state public health laboratory capability and capacity to respond to chemical terrorism.” The six-month project, funded through APHL’s cooperative agreement with the Centers for Disease Control and Prevention, was described in the September-October 2002 issue of The Minute.

For more information about the RTI contract and the assessment project, contact Sarah Lister, director of public health preparedness, 202.822.5227 x207, slister@aphl.org.

“We critically require a strategy for public health risk assessment of the threat, coordinated with rapid analytical techniques to provide support and information for first responders.”
Yvette J. Benjamin joined the APHL staff as global health director on November 18. Benjamin recently served as a technical officer at the World Health Organization. Highlights of her distinguished public health career include work as a senior associate at The Lewin Group, where she directed a project on the impact of grant-giving in communities of color. As a research associate at the National Academy of Sciences Institute of Medicine, she provided technical assistance and served as a lead on various studies conducted by the Division of Health Sciences Policy. Benjamin holds a master’s degree in public health administrative medicine and a bachelor of science and physician’s assistant certificate from The George Washington University. At APHL she will oversee implementation of the organization’s global health program.

Kimberly Davis joined APHL’s Chicago office as a new program assistant. She has a BS from DePaul University and 10 years of experience as an information specialist in the U.S. Air Force. She was also a Program Assistant at DePaul University. APHL anticipates that Davis will be a tremendous help as the scope of the Chicago office expands.

Eba On’gele joined APHL as a global health training specialist on December 2. On’gele comes to APHL from the University of Maryland College of Medicine where she has been working as a research fellow. Her credentials include fifteen years of teaching experience at the high school and college levels and over ten years of research experience in the biotechnological scientific field. On’gele holds a doctorate in molecular biology and a master’s of science from Howard University and a bachelor’s of science from Kenyatta University in Kenya. Her duties will include development of laboratory training courses and material for the global AIDS laboratory project.

Ernest Schoenfeld, MPH, DrPH, will join the APHL team as founding director of the National Center for Public Health Laboratory Leadership. At present, he serves as Senior Advisor to the Dean of the School of Public Health, University of North Carolina. In addition to his vast experience relating to the National Center, he brings an expertise in public health laboratories to APHL. In 1980 he spent a year at CDC’s Laboratory Management Consultation Office and soon after received his DrPH in Laboratory Practice. His dissertation was entitled “Safety Practices in the Public Health Laboratory.” Since 1972 Dr. Schoenfeld has served UNC in a variety of capacities, including two years as Associate Vice Chancellor for Health Affairs. From 1981-1989 he held an assistant professor position in the department of Parasitology and Laboratory Practice where he taught courses in laboratory management. We are extremely fortunate to welcome Dr. Schoenfeld, who will divide his time between his continuing responsibilities at UNC and those at APHL.

Lori Uscher joined the staff as communications/program assistant on November 7. This fall she completed her master’s degree at the London School of Economics, and while interning at the US Embassy in London she wrote her thesis on the strategic implications of AIDS/HIV. As an undergraduate at the University of Pennsylvania, she pursued many health-related writing opportunities and currently submits her work to globalenvision.org, a Mercy Corp website. Her duties include assisting Jody DeVoll with a wide-range of communications projects from web development to media outreach and providing logistical support for the National Laboratory System project.
Burton W. Wilcke, Jr., PhD, has been appointed chair of the Department of Biomedical Technologies, at the University of Vermont College of Nursing and Health Sciences.

Wilcke had been director of the Division of Health Surveillance at the Vermont Department of Health since 1995, where he was also laboratory director from 1988 to 1995. He joined the UVM faculty in 1990, and is an associate professor of biomedical technology. He served as interim department chair from July through December 2001.

“I’m honored to be working with such a wonderful team at UVM, preparing laboratory scientists and other health professionals to be ready for the challenges ahead,” says Wilcke, who is looking at development of a curriculum that addresses emerging global threats. “In today’s environment, we need to educate laboratory professionals who understand the principles of disease prevention and public health as well as they understand the ways to diagnose disease.”

As past president of the Association of Public Health Laboratories and current chair of its Leadership Development Task Force, Wilcke regularly presents to national audiences on public health issues. He was senior author for APHL on the Center for Disease Control Mortality and Morbidity Report issued in September on “Core Foundations and Capabilities of State Public Health Laboratories.” He also is leading the laboratory infrastructure development team in Zimbabwe as part of the CDC/APHL initiative to fight AIDS in South Africa.

“Dr. Wilcke is a proven leader in a critical area of societal need. He is an inspiring teacher, seasoned administrator, and brings new areas of inquiry to the college,” says Dean Betty Rambur, DNSc, RN. “I am delighted to have him join my administrative team.”

Wilcke begins his new role at an exciting time for the field, as well as for the newly consolidated College of Nursing and Health Sciences, where the department of biomedical technologies offers four undergraduate and two graduate programs. Louis Izzo, MS, CNMT, associate professor of biomedical technologies, who had been interim chair since December 2001, will now lead the Nuclear Medicine Technology program reestablished in the department.

Wilcke received his Ph.D. in Microbiology and Immunology at the Temple University School of Medicine in Philadelphia, and completed a postdoctoral fellowship in medical and public health microbiology at the California Department of Health. He and his family reside in South Burlington.
LIMS Postscript

Here are two additional perspectives on state laboratory information management systems:

Maine
"Maine is a beta test site for LITS-Plus," says Jack Krueger. "It’s doing the job." Although Krueger’s staff uncovered a few serious problems with the software, the CDC has worked diligently to resolve them. Nonetheless, the system is a work-in-progress. Krueger said he views the APHL-Institute project as a mechanism to introduce enhancements to LITS-Plus. (He also noted that, because the CDC has provided free user training, free technical support for installation, and free upgrades, LITS-Plus is a good option for states with limited funding.)

Massachusetts
The Massachusetts state laboratory developed its own LIMS with support from the Massachusetts IT Division. The initial components of the state-of-the-art system are now nearing production. Ralph Timperi, director, said he credits Massachusetts’ LIMS success to “a clear vision to support the mission of laboratory services.” Staff conducted a detailed needs assessment, sought buy-in from laboratory and client users, sought out a development team with laboratory experience and used CDC IT guidance to the fullest extent possible. Through the APHL-Institute project, Massachusetts will have an opportunity to share its system innovations and to assess the functionality of its LIMS against a common set of standards.

Timperi describes public health laboratories as “the nation’s flak jacket.” They may not prevent a terrorist attack,” he said, “but they can save lives.” Modern information management tools will make this task much easier.

...Fellowship, continued from page 7

Class VI Research Fellow Sandra Smole recently completed her two-year fellowship at the Massachusetts Department of Public Health State Laboratory Institute. Smole will be building on the research she started as an EID fellow in her new position as a state laboratory employee at her host laboratory. Congratulations Sandy!

APHL Fellows Head Overseas

APHL is now recruiting the 2003 class of EID fellows and host laboratories!

The deadline for submitting an application to host a fellow for the 2003 EID Laboratory Fellowship Program is March 3, 2003. The deadline for receipt of completed fellow applications is February 21, 2003. For more information, contact Heather Roney, fellowship program manager, at 202.822.5227 x 218, or hroney@aphl.org.

Class VII Training Fellow Maribeth Lovegrove returned to Haiti for the fourth time during her fellowship. Her project involves assessing filarial transmission in the communes of Hinche and Thomazeau. She attended the regional lymphatic filariasis program manager’s meeting in Port-au-Prince, Haiti, in September. Her work was mentioned by the manager of the national filariasis program as an example of operational research that is important to the national program. Lovegrove works in the Immunology Branch, Division of Parasitic Diseases, in Atlanta.

Class VII Training Fellow Andrea Crowell recently spent three week in Peru. She visited a laboratory of the Peruvian health organization Prisma, and helped to further their efforts to establish reliable diagnostic procedures for a trichomonas project. Crowell explained, “My time was divided between working at the Dos de Mayo Hospital in downtown Lima, where I was able to see how urban health care is carried out in a third world country, and visiting patients at home with other health care workers in rural Iquitos, a small jungle
city in the north of Peru... I worked closely with several Peruvian scientists and physicians, and scientists and medical students from the US, Canada, and England.” Crowell works in CDC’s Immunology Branch, Division of Parasitic Diseases, in Atlanta.

In conjunction with Guatemala’s Universidad de Valle and local Guatemalan public health ministries, Class VII Training Fellows Kalyani McCullough and Pritha Sen spent several weeks at CDC’s Guatemala field station MERTU (Medical Entomology Research and Training Unit). They participated in a week of fieldwork for the national Chagas surveillance project, which involved traveling to numerous villages in the mountainous region of Baja Vera Paz, meeting with locals to discuss the threats of Chagas disease and kissing bugs, and searching for the bugs in local homes. Following the fieldwork, they returned to the laboratory to dissect the bugs. Now back in the US, McCullough said, “I greatly valued the chance to see the disease in context and the insects in their natural environment. I have a much better understanding of the challenges facing Chagas control programs. The MERTU staff was extraordinarily knowledgeable and helpful.” Both McCullough and Sen work in CDC’s Entomology Branch, Division of Parasitic Diseases, in Atlanta.

Jeff Librant, Iowa EID Fellow, trains International visiting scientist, Momodou Njie, from Gambia, in current Mycobacterium tuberculosis techniques.

...Smallpox, continued from page 10

College of Medicine, noted that expected reactions include fever, malaise, and myalgia; local soreness; regional lymphadenopathy; and intense erythema at the vaccination site with considerable edema. True adverse events following vaccination, he said, range from non-infectious rashes and allergic or toxic eruptions to bacterial and viral superinfections, including post-vaccination encephalitis. One of the most common complications is accidental inoculation, that is, transfer of virus from the vaccination site to other areas of the body.

In many cases, diagnosis is obvious as lesions are identical to those caused by the original vaccination. Ocular lesions, however, can be confused with herpes and other eye infections. Laboratory diagnostics may be necessary to confirm the presence of vaccinia or to differentiate viral from bacterial infections. A new Web site, www.bt.cdc.gov/training/smallpoxvaccine/reactions, provides information on smallpox vaccine, vaccine administration, and the spectrum of vaccination reactions.

Febrile Rash Algorithm: Diagnostic Lessons Learned

Segaran Pillai, with the Florida Bureau of Laboratories, discussed a recent case in Florida in which the rash algorithm was misused, resulting in unnecessary testing and transport of specimens to the CDC. Despite the absence of both major and minor criteria for smallpox, the patient was treated as a suspect case. Pillai recommends that the febrile rash algorithm be distributed to infection control and dermatology staff. DFA and real-time PCR for VZV should also be available in every state public health laboratory.

Inger Damon, Chief, Poxvirus Section, CDC related the case of a research laboratory worker with a papular/vesicular rash on the extremities, sparing the face, and other systemic symptoms that fit the moderate risk designation of the febrile rash algorithm. Test results of an orthopoxvirus IgM assay were positive on day four of the rash. Negative-stain electron microscopy using material reconstituted from a touch preparation was...
unrevealing. PCR assay results were conflicting. Real-time PCR was vaccinia negative and variola negative by one set of tests; CDC laboratory results were non-variola orthopox positive and variola negative. Standard PCR assays showed definitively that the patient was infected by a vaccinia strain.

This case yielded several lessons:
- Diagnostics must be well validated and have known performance characteristics.
- There is a need for rapid diagnostic capability for diseases that look like smallpox.
- Specimen-collection procedures need to be optimized, and collection materials and information must be readily available.
- Multiple diagnostic methods may be necessary to confirm a diagnosis.
- A strong interface among clinicians, epidemiologists, and laboratorians is needed to maximize patient care and ensure the safety of health professionals.

Diagnostic Testing for the LRN
The current CDC poxvirus diagnostic strategy is based on multiple confirmatory tests:
- Culture—the gold standard for sensitivity and a critical source for extensive analysis. (Time to culture depends on the amount of material in the specimen.)
- Histopathology/immunohistochemistry.
- Electron microscopy—a technique that yields sensitivity as high as 95% for variola and 75% for vaccinia.
- Serology—IgM capture (8 hours), neutralization antibodies (48-96 hours)/acute and convalescent titers, and IgG ELISA (6 hours)/acute and convalescent titers.
- Antigen detection—antigen capture assay, IFA/DFA, beads-based assays
- Polymerase chain reaction (PCR) methods.

CDC’s PCR methods for orthopoxvirus diagnosis are based on multiple confirmatory tests.
- Single-gene PCR with confirmation by restriction fragment-length polymorphism (RFLP) requires about 8 hours for a species-specific result and <6 hours for a generic result. Sensitivity depends on clinical specimen collection. Specificity is 99%.
- Real-time PCR (in development) can yield species-specific and generic results in 3-4 hours.
- Species-specific and strain-specific results of E-PCR/RFLP take >24 hours.

Laboratory Response Network (LRN) labs will not be able to implement the same extensive battery of tests used by CDC for orthopox testing since the culture must be done in a BSL-4 laboratory. Moreover, electron microscopy expertise is limited.

Katherine Kelley, director of the Connecticut Department of Public Health Laboratory, reported that the APHL-CDC-Department of Defense-HHS process for the implementation of laboratory diagnostics for smallpox and smallpox-like rash illness is moving forward in several areas.

VZV diagnostics
- LRN labs are implementing commercially available DFA assays.
- A total of 450 US laboratories currently perform VZV DFA, and collaboration with clinical labs is progressing.
- Standardized real-time PCR protocols are being validated, with deployment to LRN laboratories planned for October-November 2002.

Orthopoxvirus electron microscopy
- Minimal expertise in negative-stain EM has been documented throughout the US, and protocols for this technique are under review.
- A limited number of LRN laboratories with on-site EM capacity have been identified.
- Assessment of potential EM capacity available to LRN laboratories through partnerships with clinical/research institutions has begun.

Orthopoxvirus PCR assays
- The initial focus for candidate tests has been on variola-specific assays.
- There is a need for orthopox-generic/vaccinia-specific tests.
- A two-stage E9L real-time PCR orthopox assay has been selected for deployment to qualified LRN laboratories. Protocols are being revised.
- Experts have proposed that a non-variola...
orthopox assay be used by all LRN laboratories with real-time PCR capability (vaccinia adverse events), and that a variola-specific assay be deployed to LRN labs that meet safety and facility criteria. The non-variola orthopox component of the assay is currently being validated on multiple real-time PCR platforms. Reagents are in production and deployment is anticipated by year’s end.

- A real-time HA PCR assay is being optimized as an additional variola-specific assay.
- Validation and training issues for variola-specific assays will need to address World Health Organization (WHO) restrictions.

Future orthopoxvirus PCR assays
- Orthopox-“generic” assays are in development.
- The performance characteristics of additional variola-specific assays are being evaluated by CDC, DoD, state public health laboratories, and academic and research laboratories.
- Evaluation panels must be performed at CDC due to WHO restrictions on the distribution of variola and genetic material.
- Mechanisms to facilitate assay evaluations from partners at CDC are underway.

Diagnosis of the first cases will need to be confirmed at CDC by many diagnostic strategies with independent sources of error. Subsequently, minimum criteria to confirm cases in surge-capacity laboratories will be established based on performance data from available assays.

Many of these presentations will soon be posted on the CDC Web site.
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Due to APHL’s partnership with CDC and ACS, these services are **FREE** for state laboratories for one year. Contact Jennifer Liebreich at 202.822.5227 x236 for more information.

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