Innovation—the theme for APHL’s 2016 annual report—is defined by Wikipedia as “better solutions” to meet new or existing needs. That jives perfectly with our own thinking about what APHL and its member laboratories strive to achieve every day.

In 2016, APHL’s “better solutions” ran the gamut from advanced molecular detection pilot projects to a help desk for the association’s informatics customers. APHL also (among other things):

- Developed the first laboratory guidance for testing cannabis, a legal medicinal in over two dozen states.
- Championed the use of coliphages as a better water quality indicator than E. coli.
- Developed a system for simultaneous influenza and Streptococcus whole genome sequencing (WGS) and electronic data-streaming—a necessary measure to deal with the unwieldy volume of data WGS produces.
- Began two new fellowship programs for PhD and master’s levels students—one focused on antibiotic resistance and the other on infectious diseases.
- Celebrated the launch of the Antibiotic Resistance Laboratory Network, specializing in the detection of “superbugs” and other drug-resistant pathogens.

In addition to these groundbreaking innovations, APHL strengthened its relationship with key partners. The association finalized an agency-wide MOU with the US Environmental Protection Agency and was awarded:

- A CDC cooperative agreement to help strengthen laboratory systems in resource-limited countries under the aegis of the Global Health Security Agenda.
- $4 million from the US Health Resources Services Administration (HRSA) to support states implementing newborn screening for Pompe disease, X-linked adrenoleukodystrophy or Mucopolysaccharidosis I (the latest disorders added to HRSA’s recommended screening panel).

Of course, APHL was also active in the biggest public health event of the year—the response to a massive Zika virus epidemic in the Western Hemisphere. The association served as a liaison among emergency responders and helped lead intensive advocacy efforts to secure federal funding for critical public health activities.

Finally, ever attentive to the bottom line, APHL documented the value of past investments in public health: a $70 savings for every dollar spent on the national PulseNet foodborne disease surveillance network and anywhere from $7 to $100 generated by every dollar invested in US public health laboratories.

In a dynamic world of evolving health threats, and in the wake of a historic election, we recognize the many challenges and opportunities ahead. Never has APHL’s work been more important. We look forward to working with our members and partners to continue to advance our collective vision of “a healthier world through quality laboratory practice.”

A. Christian Whelen, PhD, D(ABMM)
President

Scott J. Becker, MS
Executive Director
SCIENCE + INNOVATION = THE FUTURE OF PUBLIC HEALTH

It is an exciting time in the field of public health. Important scientific innovations have finally matured to the point where they can be applied successfully in governmental laboratories, where efficiency, rigor and quality are mandatory.

APHL is at the forefront of efforts to adapt and integrate the most promising technologies—such as whole genome sequencing and other molecular techniques for detection and characterization of infectious pathogens—into public health practice. With CDC support, the association is coordinating several advanced molecular detection (AMD) pilot projects, addressing microbes of public health significance such as *Mycobacterium tuberculosis* and organisms responsible for unexplained respiratory disease outbreaks (URDOs).

“We know we can sequence pathogens’ genomes,” says Kelly Wroblewski, MPH, APHL’s infectious disease program director. “What we’re trying to do is examine the practical, innovative applications of the technology for optimal public health impact.”

Goals include:

- Faster detection of Hepatitis C outbreaks.
- Better linkage of *Legionella pneumophila* bacteria collected from human specimens and environmental sources, such as rooftop cooling towers.
- Deeper understanding of circulating influenza viruses to inform vaccine strain selection.
- Development of a multiplex assay capable of testing for hundreds of possible URDO pathogens on a single microfluidic chip.

Yet, “the most innovative thing we’re doing,” said Wroblewski, is “expanding bioinformatics capabilities” for faster analysis of the millions of gigabytes of data AMD technologies produce. For example, one APHL project team is evaluating use of a whole genome multi-locus sequence typing database for parallel sequencing and analysis of archived *L. pneumophila* isolates. The goal is to determine the recent evolutionary history and spread of this problematic microbe.

## GETTING THE MOST FROM MOLECULAR DATA

A separate bioinformatics project involves the association’s own APHL Informatics Messaging System (AIMS) platform. In 2016, AIMS passed a CDC security audit and gained new tools for manipulating molecular data: Tableau® Desktop (for individual analysts) and Tableau® Online (for storing and sharing data in the cloud). Among other things, AIMS users will be able to compare complex microbial genomes to look for drug-resistance mutations and other markers of interest.

Elizabeth Nazarian, Yan Zhu, MLS, Lisa Mingle, PhD, and Kara Mitchell, PhD, MS, discuss testing data during the *Legionella* South Bronx investigation at the Wadsworth Center, NY.
INCREASING CONFIDENCE IN TEST DATA

Evaluating laboratory technology and providing guidance on testing processes—from specimen collection to results reporting—are core APHL activities to enhance worker safety and reduce the possibility of errors. Important APHL projects in 2016 focused on clinical, environmental health, newborn screening and biothreat testing programs.

• **MALDI-TOF:** In 2015, APHL assessed the safety of MALDI-TOF testing, which identifies microbes based on the size of their ionized protein molecules, as compared with those in an electronic library provided by the test manufacturer. In 2016, the association recruited eight member laboratories—public health laboratories in NY City, NY state, MI, MN, IA, FL, NC and TX—to examine the accuracy of the technology, which is proliferating in both public health and clinical laboratories owing to its low cost and high speed. Follow-up studies are likely to improve the libraries and thus reduce the risk of misidentifying infectious agents.

• **Cannabis:** Although more than two dozen states allow adult use of cannabis for medical reasons (and several allow adult recreational use), there is no federal guidance for laboratory testing to gauge the quality, potency or purity of cannabis products, which may be contaminated with metals, pesticides, mold, pathogenic bacteria or other substances. To fill the information void, APHL established a community of practice, comprising laboratory scientists, toxicologists and other experts. In May 2016, this group released the first US Guidance for State Medical Cannabis Testing Programs, which details sampling and testing protocols, target analytes and action levels and other essential information for testing laboratories.

• **Newborn Screening:** Newborn screening is one of the most consequential activities laboratories perform, and misleading or confusing screening data can delay the diagnosis of serious congenital disorders. An ongoing APHL project is reducing the possibility of misdiagnosis by documenting factors that might influence the interpretation of dried blood spot screening results, such as infant blood transfusion, the presence of certain infant medications, or underlying infant disorders that could disrupt analyte detection. Subject matter experts serving on APHL’s Newborn Screening Quality Assurance/Quality Control Subcommittee are validating a slate of interferences nominated by newborn screening experts.

• **Biomonitoring:** As environmental toxicants proliferate, it has become increasingly important to determine human exposure by measuring the chemicals or their metabolites in blood, urine or other clinical specimens. This is the science of biomonitoring, which APHL has long championed. In 2016, APHL and CDC convened the first meeting of the National Biomonitoring Network steering committee to direct and guide implementation of the network of governmental laboratories. To accomplish these goals, the steering committee established workgroups to develop biomonitoring best practice and guidance documents related to study design and to harmonize analytical methods to assure the quality and comparability of laboratory data network-wide.

Courtney Demontigny extracts an environmental unknown sample from an LRN proficiency test at the Minnesota Department of Health
• **Biothreat Agents**: APHL, in collaboration with CDC, updated the *Clinical Laboratory Preparedness and Response Guide*, which describes the tools and standards necessary for identifying and handling patient specimens potentially containing biothreat agents—the most dangerous pathogens that come into governmental laboratories. The guide was informed by over 100 subject matter experts and aligns with American Society of Microbiology (ASM) testing protocols.

• **Enteric Pathogens**: New APHL guidelines, developed in collaboration with ASM, address a nagging problem unique to the Molecular Age: infectious disease tests that can be performed directly on patient specimens (e.g., stool), without the need to isolate and grow microbes in culture. So-called culture-independent diagnostic tests have the unintended side effect of eliminating microbial isolates for reference-level public health laboratory testing—a particular problem in the national PulseNet network of laboratories. To ensure the continuation of enteric surveillance, the interim APHL/ASM guidelines list specific recommendations regarding the handling and referral of patient foodborne disease specimens in clinical laboratories.

“What we’re trying to do is examine the practical, innovative applications of the technology for optimal public health impact.” —KELLY WROBLEWSKI, MPH

Analyst Amy Lovelace of the New York State Department of Agriculture & Markets Food Laboratory transfers purified genomic DNA from a variety of food samples into storage tubes using the Maxwell® 16 Instrument PCR analysis, screening the DNA for *Salmonella* and *E. Coli O157:H7*
The 2014-15 West African Ebola epidemic underscored a 21st Century reality: public health threats can quickly escalate to become national security threats. Although Ebola never gained a serious foothold in the United States, The Dallas Morning News reported that having even three Ebola patients in Dallas County released “pure, unharnessed panic.”

Even before the Ebola outbreak ended in Africa, Zika virus was emerging in the Americas. The mosquito-borne pathogen—a zoonotic microbe at the center of epidemics throughout the Americas and linked to serious neurological birth defects—posed a more imminent US threat than Ebola: by July 2016, Puerto Rico was in the midst of a Zika epidemic and active transmission was documented in Florida. Yet, Congress still had not acted on a February 22 White House request for emergency Zika funding.

As a key player with decades of public policy experience, APHL worked diligently to assure a clear-headed government response. The association organized more than 70 meetings specific to Zika, including multiple White House meetings and conference calls. In addition, after the US Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for CDC’s Trioplex Real-time RT-PCR Assay (which differentiates among Zika, dengue and chikungunya viruses), APHL pressed for an EUA amendment authorizing the use of the most prevalent viral RNA extraction equipment in US public health laboratories.

In late September, after a lapse of more than eight months, Congress appropriated $1.1 billion for the response. In addition, CDC collected the data needed to enable FDA to amend its Trioplex EUA, so that the alternate extraction equipment could be used (thus, negating the need for time-consuming manual RNA extraction).

The intense effort by APHL and partners positioned the US public health system to respond quickly, should Zika become a greater threat in future mosquito seasons. It led to new APHL contacts with the House Speaker’s Office, House leadership offices and Congressional offices of the high-risk Gulf of Mexico states. And it prompted the creation of a broad-based coalition of partners, focusing on maternal and child health.

Although Zika was the most high-profile public health threat of 2016, APHL was involved in numerous other policy initiatives that will impact drinking water quality, the time needed to resolve foodborne disease outbreaks, containment of infectious diseases abroad and other public health concerns.
APHL wrote to the US Environmental Protection Agency (EPA), endorsing its use of coliphages—viruses that infect only coliform bacteria (e.g., *E. coli*)—as a recreational water quality indicator with considerable public health benefits. Although regulatory coliphage testing is somewhat novel, coliphages may better represent the presence of viruses in lakes, rivers and beach water, which are more likely than bacteria to make swimmers sick. The association also partnered with the Water Environment Federation to create a webinar on the topic, reaching over 450 people worldwide.

**COUNTING COLIPHAGES TO KEEP SWIMMERS HEALTHY**

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**APHL’s work with the EPA Water Security Division morphed into a formal relationship across the entire agency, as a memorandum-of-understanding (MOU) reached final form. The MOU facilitates collaboration between APHL and EPA to enhance environmental public health through laboratory-related activities, from air quality testing to method validation studies.**

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**CELEBRATING PULSENET—AMERICA’S FOODBORNE DISEASE DETECTION NETWORK**

PulseNet—the US laboratory network crucial to solving foodborne disease outbreaks—prevents an estimated 270,000 illnesses/year, from *Salmonella*, *E. coli* 0157 and *Listeria monocytogenes* alone, according to an economic study supported by APHL to celebrate the network’s 20th anniversary. This disease prevention translates into an estimated savings of $507 million/year in averted medical costs and lost productivity. Stated differently, PulseNet saves $70 for every dollar governments invest in the network, which was cofounded by CDC and APHL in 1996.
STRENGTHENING FOOD SAFETY STATUTES AND SUPPORTING ISO ACCREDITATION

• APHL published a compendium and evaluation of state reportable disease laws for major foodborne pathogens, including Salmonella, Listeria, Cryptosporidium and five others. The analysis shows that, as of June 2015, 43 states mandated that hospital and other clinical laboratories submit some form of outbreak specimens for at least three of the eight pathogens to state public health laboratories to inform epidemiological surveillance. Already, both New York City and Los Angeles (LA) County have referenced the document when updating their isolate submission requirements for foodborne pathogens. And, following LA’s lead, the California legislature strengthened foodborne reportable disease requirements statewide.

• In 2012, FDA awarded a cooperative agreement to APHL, the Association of Food and Drug Officials, and the Association of American Feed Control Officials to support governmental food and feed testing laboratories seeking external accreditation to ISO standards. In 2016, APHL developed an issue brief for policy makers and potential funders detailing the benefits of ISO accreditation. Chief among these are more valid, reliable and defensible test data.

• APHL developed a white paper detailing the rigorous guidelines laboratories must follow so FDA can take regulatory action—such as recalls of tainted foods or animal feeds—based on state and local laboratory data (thus, negating the need to re-collect the data at the federal level). The paper includes a lengthy checklist to assist laboratories in submitting data packages to FDA, regardless of the laboratory’s ISO accreditation status.

DELIVERING NEWBORN SCREENING DATA TO CONGRESS

When Congress mandated that the Government Accountability Office (GAO) report on the timeliness of newborn screening activities across the US, GAO turned to just one data source: APHL’s Newborn Screening Technical assistance and Evaluation Program (NewSTEPs), the only federally funded program that collects such comprehensive and detailed information. Among the findings: a higher proportion of newborn screening laboratories open seven days a week report out screening results within four days of specimen receipt than do laboratories open only five or six days per week.

CONTAINING OUTBREAKS ABROAD

APHL has supported the Global Health Security Agenda (GHSA) since the initiative began in early 2014, with the goal of helping nations adopt the World Health Organization’s International Health Regulations (IHR)—developed to stop the global spread of infectious pathogens. In September 2016, APHL was awarded a five-year CDC/GHSA cooperative agreement with over $8 million in Year 1 funding to accelerate progress toward meeting laboratory goals. Support for the creation of a strategic plan to guide development of Tanzania’s public health laboratory system is just one example of APHL’s GHSA work.
Alexander Kim of the Maryland Public Health Laboratory’s Molecular Diagnostics Unit/Biosafety Level 3 laboratory trains to handle Ebola specimens wearing personal protective equipment for BSL-3 plus infectious agent PCR testing.
APHL’s value can be measured by real-world outcomes. In 2016, the biggest test of the year was Zika virus. In the United States, Puerto Rico recorded more than 30,000 locally acquired cases, and travel-associated cases were confirmed in all 50 states, plus the District of Columbia. Both Florida and Texas documented active local transmission. Early in 2016, APHL mobilized 16 staff members to track developments and serve as liaisons among public health laboratories, CDC, FDA and other partners, such as test manufacturers and the Canada Public Health Laboratory Network Zika workgroup. In addition to assuring an efficient and timely flow of information, APHL:

• Issued a risk assessment template to laboratories implementing CDC’s Trioplex assay, which requires a Biosafety Level 3 test environment. The Trioplex assay itself was deployed through the US Laboratory Response Network, cofounded by CDC, APHL and the Federal Bureau of Investigation.
• Reviewed laboratory testing guidance documents drafted by CDC.
• Clarified FDA requirements for facilities using their own laboratory-developed Zika assays.
• Hosted a training webinar on implementation of the Zika MAC-ELISA test. Because of the complexity of this serology antibody test, CDC required laboratory staff to complete the webinar before being authorized to receive the assay.

• Engaged commercial and clinical laboratories to assess their needs and connect them with public health laboratories, as appropriate.
• Conducted special outreach to obstetricians and other clinicians to apprise them of public health laboratory capabilities and special considerations when interpreting complex Zika test data.

Thanks to the collective efforts of public health partners, Zika virus was contained as the 2016 mosquito season drew to a close. Should the virus return in 2017, APHL will resume its central coordinating role.
**EASING IMPLEMENTATION OF NEW TEST PROGRAMS**

- **Antibiotic Resistance Testing:** Unfortunately, Zika virus was not the only novel pathogen to rear its head in recent years. Some of the most concerning new microbes share one trait: a growing immunity to modern medicines. Relatively common illnesses like gonorrhea and yeast infections are suddenly potentially scary. And a new class of superbugs, typified by carbapenem-resistant Enterobacteriaceae (CRE), is indifferent to most existing antibiotics, with correspondingly high mortality rates for infected patients.

Thanks to a federal infusion of $160 million, CDC launched its Antibiotic Resistance (AR) Laboratory Network in 2016, with instrumental support from APHL. The two partners had been strategizing for years to develop a plan for assuring adequate laboratory capacity to detect, monitor and characterize drug-resistant microbes. The solution was the selection of seven state public health laboratories—in MD, MN, NY, TN, TX, WA and WI—to serve their geographic regions. Network members participated in specialized training for AR testing for CRE, Candida spp., Streptococcus pneumoniae and other priority pathogens. In addition, public health laboratories in all 50 states were funded to develop whole genome sequencing capability for confirmatory CRE testing.

- **Next Generation Sequencing:** Next generation sequencing technologies replicate and assemble millions of strands of RNA or DNA into proper order for scientific analysis, revealing relationships among microbes and markers for virulence, transmissibility and other critical attributes. Yet, to capitalize on the promise of the technology, laboratories must navigate a maze of options and technical hurdles. Which sequencer has the right price, capacity and read length to meet laboratory needs? What ancillary equipment—like thermostyclers or ultrasonicators—are necessary? APHL’s *Next Generation Sequencing Implementation Guide*, released October 2016, helps laboratories answer these and other questions, so they can optimize their testing programs. The living document includes a detailed appendix addressing whole genome sequencing in PulseNet food safety laboratories.

- **Newborn Screening:** The US Health Resources and Services Administration (HRSA) awarded APHL $4 million to support states implementing newborn screening for Pompe disease, X-linked adrenoleukodystrophy and/or Mucopolysaccharidosis I—treatable genetic disorders recently added to HRSA’s Recommended Uniform Screening Panel. APHL encourages states to adopt creative strategies to expand their newborn screening programs, such as relying on expert newborn screening laboratories to provide training or to conduct confirmatory testing utilizing DNA sequencing technologies.

In addition, APHL developed and released a guidance document to inform newborn screening, diagnosis and follow-up practices for sickle cell anemia and other hemoglobinopathies. Although, US newborn screening programs have decades of experience with these disorders, hemoglobinopathy screening programs are just beginning in many countries. The guidance details best practices for laboratories and those responsible for short-term follow-up of infants with positive screens.
Thanks to a federal infusion of $160 million, CDC launched its Antibiotic Resistance (AR) Laboratory Network in 2016, with instrumental support from APHL.

- **HIV Testing in Zimbabwe**: In 2014, the UNAIDS program launched an ambitious 90-90-90 campaign, with a target of assuring that by 2020, 90% of people living with HIV know their HIV status, 90% of people diagnosed with HIV receive antiretroviral therapy, and 90% of those on therapy attain viral suppression. In resource-limited countries like Zimbabwe, this is a big challenge. APHL is trying to make it easy. With CDC funding, the association purchased necessary laboratory equipment and oversaw its installation in six high-volume testing sites in Zimbabwe. APHL is also providing viral load testing reagents and training for these sites, with plans to scale up further. As APHL Global Health Program Director Lucy Maryogo-Robinson, MPH, notes, “Treatment prolongs life, but it is also prevention.”

**SKILL-BUILDING AT THE CUTTING EDGE OF SCIENCE**

The underpinning of all laboratory practice is qualified personnel. Yet, there are few resources for aspiring and practicing laboratorians to attain the highly specialized skills employed in governmental laboratories everyday—expertise in quality management systems, mastery of assays for emerging toxicants and microbes, familiarity with epidemiological concepts and facility with sensitive, cutting-edge technology.

This is where APHL excels.

The association periodically surveys the public health laboratory workforce to document salaries, training needs and demographic trends—such as the ongoing retirement of a generational cohort of experienced professionals. Beginning in 2017, this data will be supplemented with additional information collected via a new online tool focusing on member laboratories’ informatics staffing, training and infrastructure needs.

Through its training programs and the APHL/CDC National Laboratory Training Network (NLTN), APHL offers seminars, conferences, hands-on workshops and webinars addressing a broad range of topics from antibiograms to Zika and laboratory accreditation to whole genome sequencing. In 2016, APHL delivered 40 webinars to over 16,000 attendees from the US and 12 other countries. Webinars served attendees from clinical, academic, veterinary, hospital and private laboratories as well as from public health laboratories. The NLTN produced 80 educational programs serving nearly 8,000 participants. Programs included hands-on laboratory workshops, Public Health Series webinars, seminars and on-demand educational services.

Rapid HIV dried tube specimen production at the Zimbabwe National Microbiology Reference Laboratory. Pictured left to right: Charles Chiku (NMRL), Staford Mupandasekwa (NMRL) and Goodridge Mguni (APHL)
Other standout 2016 training and peer-to-peer learning activities include:

- A webinar on per- and polyfluoroalkyl substances (PFASs). PFASs were developed as fire suppressants and water repellents, but persist in the environment and are increasingly contaminating drinking water, especially around military installations. The US Environmental Protection Agency issued a new health advisory limit for exposure to these unregulated substances in April 2016. The PFAS webinar was created with the Water Environment Federation and The Private Well Class and has reached over 250 viewers.

- Workshops on the interpretation of newborn screening results (e.g., complex tandem mass spectrometry data) and short-term follow-up for infants with positive screens.

- The APHL Newborn Screening and Genetic Testing Symposium, the largest newborn screening meeting in the world. The 2016 scientific conference addressed prospective newborn screening conditions, molecular testing, birth defects registries, screening for special populations, quality improvement and a host of other subjects.

- Quality Improvement Forum conference calls—a no-cost, high-value activity that provides a vehicle for the sharing of quality improvement practices.

- Two Laboratory Response Network courses on conventional test methods for biothreat agents such as anthrax and mustard gas.

- Bionumerics training for analysis of next generation sequencing data.

- A hands-on, wet bench workshop for next generation sequencing of enteric pathogens.

Five new courses are being developed by APHL, CDC and Deloitte to help laboratorians of varying skill levels attain core informatics competencies. The first in the series—*The Life of a Specimen*—will be released in 2017.

Also in 2016, APHL’s communities of practice continued to meet and share ideas for best practices. Communities include laboratory outreach to clinical laboratories, short-term, newborn screening follow-up and cannabis testing, among others.
NURTURING FUTURE LABORATORY LEADERS

Growing the next generation of laboratory leaders has been a special APHL project for many years.

In 2016, the association added two new fellowship programs for PhD and master’s-level scientists considering public health laboratory careers: the Antimicrobial Resistance Fellowship and the Infectious Disease Laboratory Fellowship. To maximize the value of the fellowship experience, APHL is creating a standardized curriculum for individuals in all five of its fellowship programs—also including programs in bioinformatics, newborn screening and environmental health. The curriculum—covering ethics, laboratory research, leadership, management, communications, emergency response and biosafety—will align with a comprehensive catalog of public health laboratory competencies developed through an effort of CDC and APHL and the public health laboratory professionals. It was published last year in CDC’s Morbidity and Mortality Weekly Reports.

APHL’s National Center for Public Health Laboratory Leadership oversees some of the association’s most rewarding work. In 2016, the Center graduated its 8th cohort of emerging leaders—mid-level public health laboratory scientist-managers who receive intensive leadership training and carry out workforce-related projects. Cohort 8 developed and beta tested a laboratory competency assessment tool and added materials for educators to the association’s www.thatssick.org website for adolescents and teachers. The Center also recruited 14 emerging leaders for Cohort 9, coming from local, state and federal governmental laboratories, and recruited its second global Emerging Leader Program (ELP) cohort in Uganda. In an innovative move, the Center is pairing domestic ELP graduates with current participants in the domestic and international programs to “leverage leadership skills using coaching as a vehicle,” per the Center’s director, Pandora Ray, MPH.

Finally, perhaps the most fun APHL event of the year—“Lab Jedi: The Force Behind Public Health,” a Star Wars-themed science day program for middle school students held at the New Mexico Scientific Laboratory Division in conjunction with the APHL annual meeting. Its mission: to increase interest in laboratory careers by showing students how to extract their own DNA from skin cells and build a rudimentary spectrometer.
Pathogens move in real time. And so must laboratory data.

Over the past decade, APHL has provided on-site technical support to virtually every state public health laboratory in the country to institute electronic data exchange systems. Today, its informatics services are in demand as never before. In the first eight months of 2016 alone, the APHL Informatics Messaging System (AIMS) cloud-based platform handled over 2.7 million messages. AIMS now supports 80 trading partners and enables cross-jurisdictional data exchange in 13 states. And the system continues to grow.

To support the increased demand from traditional partners and new clients—including state and local health agencies, commercial laboratories and non-governmental public health organizations—APHL expanded its informatics team from six to 10 full-time staff and added an informatics help desk for more efficient response to informatics queries, including hands-on implementation assistance when needed. At the same time, the association expanded its cadre of contract staff, so it can ramp up support dynamically as projects require.

Notable AIMS projects in 2016 addressed priority pathogens.

- **Foodborne Pathogens**: APHL developed IT infrastructure and data pipelines for foodborne pathogens being monitored by CDC’s Emerging Infections Program Foodborne Diseases Active Surveillance Network, also known as FoodNet.

- **Rabies**: APHL developed a messaging format, vocabulary and pipeline for transmission of rabies data for wild and domestic animals. All of the data sent to the AIMS rabies portal is accessible to CDC rabies epidemiologists.

- **Flu and Strep**: APHL developed pipelines for the transmission of whole genome sequencing data for influenza and *Streptococcus pneumoniae*, two important wintertime microbes. To ensure reasonably fast transmission of the petabytes of extremely large datasets produced by whole genome sequencing, APHL devised an innovative system to continuously stream data into the cloud even as pathogens are being sequenced. Three APHL-supported influenza centers—in the CA, NY and WI state public health laboratories—are making use of the flu pipeline as part of CDC’s Sequence First Initiative, which aims to collect genetic influenza data earlier in the flu season to better inform vaccine strain selection and assess how well the current vaccine matches circulating influenza strains. Virtually 100% of the public health laboratory data used to inform the nation’s influenza vaccine now flows through AIMS.

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BOLSTERING THE SYSTEMS THAT PROMOTE QUALITY

Quality testing cannot be separated from the laboratory system that supports it. In addition to data pipelines, this undergirding system encompasses everything from the physical laboratory infrastructure to workplace safety protocols to mechanisms to ensure the quality and timeliness of the testing specimens themselves.

• **Biosafety:** Protecting the laboratory workforce is a priority in all governmental laboratories. It has also been a priority at APHL, which expanded its role as a biosafety/biosecurity expert in 2016. A few noteworthy activities include (1) developing laboratory risk management tools; (2) providing input to inform revisions to the laboratory biosafety bible, *Biosafety in Microbiological and Biomedical Laboratories*; (3) convening a biosafety partners forum involving over 15 organizations; and (4) convening regional biosafety workshops for laboratorians in the Northeast and Mid-Atlantic and in Hawaii and the US-affiliated Pacific Islands.

• **Newborn Screening Timeliness:** The most severe congenital disorders can ruin a life in a matter of days. Thus, part of the value of newborn screening lies in its timeliness: presumptive positive screening results must reach providers in time to intervene before the disorder causes lifelong morbidity or even death. The NewSTEPS 360 program, a partnership between APHL and the Colorado School of Public Health, aims to assure that all presumptive positive results for time-critical conditions are communicated to a child’s primary care provider no later than the fifth day of life. NewSTEPS 360 provides direct assistance to 28 states, up from 20 in 2015. It has also begun working with birthing hospitals to speed the transfer of newborn bloodspot specimens and the delivery of data to newborn screening laboratories.

• **Food and Feed Laboratory Accreditation:** Accreditation to the ISO/IEC 17025:2005 standard is a recognized imprimatur for laboratory quality, ensuring the integrity and accuracy of analytical data. Backed by funding from the US Food and Drug Administration, APHL is helping US food and animal feed laboratories achieve this distinction. In 2016, APHL co-hosted the 2nd Governmental Food and Feed Laboratories Accreditation Meeting, which provides presentations, discussions and exercises focusing on continuous quality improvement and brings laboratory scientists together with the officials who enforce federal food and feed safety regulations.

• **Systems-building in Africa:** The 2015 West African Ebola epidemic is over... for now. But instead of exiting Africa, APHL is doubling down in two of the hardest hit countries—Guinea and Sierra Leone—to upgrade laboratory systems and prevent future outbreaks. Sample APHL activities (involving multiple partners) include overseeing laboratory repairs and renovations, developing laboratory quality manuals, delivering courses on Ebola epidemiology and maintaining APHL in-country senior laboratory advisors to support the two national Ministries of Health.

APHL was also busy in other parts of the African continent. In 2016, the association instituted in Mozambique what may well be the first electronic laboratory results reporting system in Africa. The software application enables direct reporting of HIV patients’ viral load test results to clinics that may be 50 miles or more from the testing laboratory—a challenging distance in a country with few paved roads. The rapid, electronic receipt of test data reduces transcription errors and can hasten the onset of treatment by several weeks. The tool is now being piloted in other African countries.

Just one more of APHL’s many global activities is an ongoing project in Ethiopia, Kenya, Tanzania and Uganda to train local engineers to certify laboratory biosafety cabinets.

APHL Annual Meeting attendees learn more about the NewSTEPS 360 program
“BIG PICTURE” TOOLS FOR LABORATORY LEADERS

Ensuring laboratory quality means attention to matters both small and large. Here are three APHL projects that focused on big picture issues in 2016.

• **Vision 2020:** In 2010, APHL launched its Vision 2020 initiative to identify the overarching factors expected to drive changes, and challenges, in governmental laboratory practice through the year 2020. Last year, APHL revisited and updated those “drivers” so they can be better understood and planned for. The revised list includes the advent of point-of-care diagnostics that bypass the laboratory, an uncertain workforce pipeline and several others.

• **Return on Investment:** Every dollar invested in US public health laboratories generates anywhere from $7 to $100 in return, according to an APHL project begun to appraise public health laboratory efficiency. The finding confirms the value of the nation’s governmental laboratories for its beneficiaries—the US public—and for the policy makers who allocate funding.

• **Nationwide Test Directory:** In September 2016, APHL had a soft launch of its Public Health Laboratory System Database, which in the future will populate a nationwide test directory that enables laboratory leaders to compare their test menus to those in other jurisdictions, to identify laboratories offering specific services, and to gauge national testing capacity for individual analytes.

**QUALITY SYSTEMS AT APHL**

APHL’s commitment to quality is demonstrated by efforts to evaluate its own impact.

• **APHL Evaluation:** APHL has a comprehensive plan to gauge progress toward its vision of “a healthier world through quality laboratory systems.” As of late 2016, evaluators had conducted more than 20 interviews, focus groups and meetings to assess the impact of individual APHL programs and the association’s collective impact on population health.

• **Biochemical Genetic Testing:** Impact evaluations of APHL’s live and recorded webinars on quality practices in biochemical genetic testing found that 81% of respondents improved their knowledge of federal requirements for biochemical genetic testing, and 75% implemented recommendations discussed in the webinars.

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Drs. Daniel Garcia (CDC) Romesh Gautom (WA PHL), Mayank Dwivedi and Nidhi Sood (Gujarat Laboratory) discuss molecular workflow during a site visit to the Gujarat Medical College Laboratory in Ahmedabad, India.
2016 FINANCIALS
(unaudited figures)

**Domestic Programs**
- Infectious Diseases: $7,758,494
- Informatics: 5,449,176
- Food Safety: 3,041,494
- Newborn Screening: 2,985,858
- Lab Strengthening/Leadership: 2,276,242
- Member Services: 1,557,177
- Public Health Preparedness: 1,547,815
- Workshops: 1,508,076
- Leadership Development: 967,622
- Environmental Health: 754,460
- Conferences: 748,688
- APHL Consulting: 633,735
- Laboratory Systems and Standards: 579,851
- Administration: (310,968)
- **Domestic Programs Total**: $29,497,720

**Global Programs**
- Angola: $1,202,720
- Botswana: 15,398
- DRC: 181,586
- Ethiopia: 840
- Ghana: 4,971
- Guinea: 604
- Kazakhstan: 878,953
- Kenya: 836,953
- Mozambique: 40,766
- Namibia: 71,045
- Nigeria: 2,781,844
- Other Global Health: 51,326
- Program Management: 1,962,476
- Sierra Leone: 151,468
- South Sudan: 143,646
- Swaziland: 380,946
- Tanzania: 130,814
- Ukraine: 129,853
- Vietnam: 121,270
- Zambia: 626,564
- Zimbabwe: 4,478,843
- **Global Programs Total**: $14,251,851

**Total Expenses**: $43,749,571 (unaudited figures)

**Total Revenue**: $43,936,064 (unaudited figures)
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