

# LAB MATTERS

analysis|answers|action

Spring 2019 Issue 2

## The Promise and Challenge of Newborn Screening in 2019

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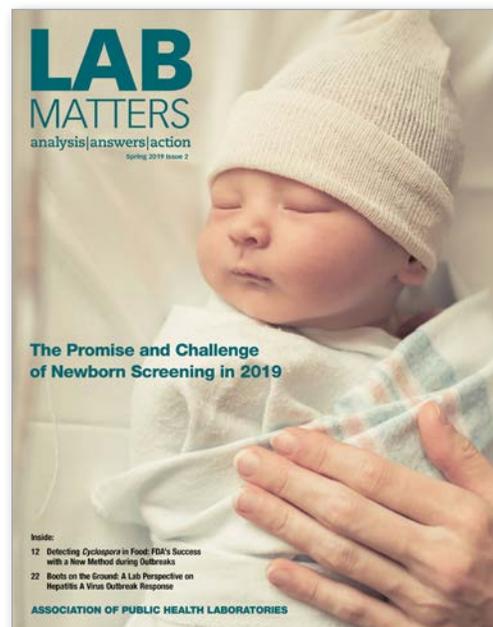
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### The Promise and Challenge of Newborn Screening in 2019

NBS is a public health success story, ongoing for 56 years. On the one hand, new treatment and laboratory testing options open up the possibility of expanded screening panels. On the other hand, testing laboratories and follow-up providers are generally under-resourced and straining to keep pace with growing workloads. But scientists are working diligently to improve the accuracy and precision of existing tests and to bring on new disorders, even as they continue the high-stakes work of screening tens of thousands of infants a year.

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The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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## Evolution and Transition



**“I am excited to see what future advancements there will be in informatics and data analytics and their applications in infectious disease, newborn screening and environmental science.”**

*Joanne Bartkus, President, APHL*

When I started as director of Minnesota's public health laboratory in 2007, I had little working knowledge of newborn screening. Fortunately, I had a team of knowledgeable (and patient) staff, and the exceptional resources provided by APHL to help me develop a working knowledge of the myriad disorders, tests and treatments, and to better appreciate both the successes and challenges of newborn screening. Having just attended the 2019 Newborn Screening and Genetic Testing Symposium April 7-10, I realize how far things have come in the past 11 years, and how much I have yet to learn.

The feature article in this issue of *Lab Matters* describes the changing nature of newborn screening and the challenge of bringing on testing for increasingly complex disorders. Because some of the disorders may not cause symptoms until the child is older, or maybe not at all, it will be increasingly important for newborn screening programs to collect and analyze data to improve their ability to predict which children may go on to develop disease and which may not. In addition, the increasing use of molecular methods, including DNA sequencing, as second or third tier tests will require that programs develop or enhance their bioinformatics capability. At the symposium, CDC presented their efforts surrounding data analytics for newborn screening, including creation of data analytic tools, providing training for newborn screening staff, and funding for bioinformatics fellows to work in newborn screening programs.

The priority that I chose to emphasize for my year as APHL president was “data science” (aka data analytics). In choosing that priority, I was hoping to underscore the need for informatics and analytic capabilities beyond that which we have developed for whole genome sequencing. Therefore, I am particularly gratified to see CDC's emphasis on developing data analytics and bioinformatics in newborn screening. And now that environmental laboratories are also acquiring high-resolution mass spectrometers that generate large data files, we can utilize the sequencing infrastructure that we have developed to deal with those massive files. As we continue to develop our bioinformatics capabilities while implementing whole genome sequencing for an increasing number of microbial pathogens, I am excited to see what future advancements there will be in informatics and data analytics and their applications in infectious disease, newborn screening and environmental science.

I write this message as my year as APHL president is coming to an end. I feel like I am just starting to get the hang of it. Still, I look forward to handing the reins over to our very capable president-elect, Grace Kubin, at APHL 2019 and to supporting her next year as the past-president.

See you in St. Louis! ■

## Spring has Sprung, and So has APHL

It's spring in DC and there's so much to report on! No, I'm not talking about the Mueller report...I'm talking all things APHL.

These past few months we held a series of meetings ranging from the Newborn Screening and Genetic Testing Symposium, the Public Health Laboratory Training Conference, three PulseNet/OutbreakNet Regional Meetings and the 11th National Conference on Laboratory Aspects of Tuberculosis. These gatherings, not including the various committees that met, have put us in touch with a vast number of members. How vast you ask? By my count, we had over 850 members and partners come together—all engaged in the work of their laboratories AND the association.

Let's look at the Newborn Screening Symposium as an example. We had 562 people gathered in Chicago, representing 24 countries—Australia, Austria, Belgium, Brazil, Canada, China, Costa Rica, Denmark, Finland, France, Germany, Greece, India, Japan, Lebanon, Mexico, Netherland, New Zealand, Qatar, Spain, Turkey, UAE, United Kingdom and Vietnam—along with representatives from 45 states across the US. We had over 25 companies exhibiting and highlighting the latest in technologies and support for the newborn screening system. Lastly, we announced to the cheering crowd that, as of 2020, the symposium would become an annual event. Be sure to dig into our lead article in this issue of *Lab Matters* because there is so much going on in this dynamic field, led by many of APHL's members and partners.

Meetings and events are not the only thing we have been busy doing. We have worked with our close partner and allies at the Council of State and Territorial

Epidemiologists, NAPHSIS and HIMSS to launch an advocacy campaign called Data: Elemental to Health. The goal is to seek funding of \$1 billion over 10 years to modernize the public health surveillance enterprise so that we can transform disease surveillance and save lives. More, better, faster data yielded by secure, interoperable systems will allow public health professionals and policymakers to make better decisions and get ahead of chronic, emerging and urgent threats. This campaign fits nicely in the overall APHL strategic initiatives related to improving the informatics infrastructure and ways to engage with non-traditional partners in all things “data science.”

Spring is also a time of anticipation. I'm excited and am getting ready for APHL 2019 which is fast approaching. Plan to attend and mix and meet with your 600+ colleagues, choose from over 35 plenary and breakouts, eight roundtables and four Innovate! Sessions. You can also view 117 posters, listen to 30 speed-dating presentations and visit 77 booths representing 66 companies. Also, if you are one of the first 500 people at the Kati Kelley lecture, you will receive a copy of *What the Eyes Don't See* by Dr. Mona Hanna-Attisha, this year's lecturer. Won't you meet me in St. Louis?

With spring turning soon to summer, it is also a time of leadership transition at APHL. I am grateful for the leadership and guidance of Dr. Joanne Bartkus. She has been a strong voice for our members and for the association. I am appreciative of all Joanne has done this year and look forward to working closely with incoming president Dr. Grace Kubin in the coming year. ■



**“More, better, faster data yielded by secure, interoperable systems will allow public health professionals and policymakers to make better decisions and get ahead of chronic, emerging and urgent threats.”**

*Scott Becker, Executive Director, APHL*

# The Promise and Challenge of Newborn Screening in 2019

by Nancy Maddox, MPH, writer

**When Stella Turnbull was born in 2007, she showed all the signs of a healthy baby. At one month of age, however, everything changed. “I went to give her a bath,” said her mother, Sarah Turnbull, “and her head, her arm, her legs were all very floppy.” On the advice of Stella’s pediatrician, Sarah and her husband rushed the baby “that very night” to the emergency department at Mayo Clinic in Rochester, Minnesota—a five-hour drive from their home in Iowa.**

Over the next week, the parents learned that their daughter has spinal muscular atrophy (SMA), a rare genetic disorder that has left Stella, now age 12, dependent on a trach tube for breathing, a gastrointestinal tube for feeding and 24-hour care. When the family finally left Mayo Clinic after Stella’s diagnosis, the parents were told, “Just take her home and love her, because there’s nothing we can do.”

Fast forward to 2019, and the outlook for infants with SMA is dramatically different. The US Food and Drug Administration (FDA) approved the first drug to treat the disorder, Spinraza®, in 2016. And FDA is expected to approve a potentially curative gene therapy this year. But both interventions work best when delivered soon after birth, while infants are pre-symptomatic and their motor neurons fully functional; although Spinraza® has given Stella some movement in her legs and neck, and potentially stopped her disease progression, neither Spinraza® nor gene therapy can replace the motor neurons that have died. “Her independence,” said Sarah, “is limited to finger movements to operate her power chair.”

Heartbreaking stories like Stella’s epitomize the strongest case for newborn screening (NBS): to detect congenital disorders at birth, so effective treatments can be implemented before dire health consequences set in.

Just last year, SMA was added to the federal government’s list of disorders recommended for inclusion in state NBS programs—the Recommended Uniform Screening Panel (RUSP) maintained by the US Department of Health and Human Services. Six states currently conduct routine NBS for SMA. And Stella’s own state, Iowa, will begin a pilot SMA screening program sometime this year.

NBS is a public health success story, ongoing for 56 years. Today, the field is full of both promise and challenge. On the one hand, new treatment and laboratory testing options open up the possibility of expanded screening panels. Already, the RUSP has grown from an initial 29 core conditions in 2006 to 35 today, and fragile X syndrome and Duchenne muscular dystrophy are expected to be next up for consideration.

On the other hand, however, testing laboratories and follow-up providers are generally under-resourced and straining to keep pace with growing workloads. In the laboratory, there is pressure to simultaneously enhance quality, reduce test turn-around-time and rigorously evaluate new high-throughput screening methods. In providers’ offices, there is the need to care for increasing numbers of patients with conditions whose progression and management may be poorly understood.





**Heartbreaking stories like Stella's epitomize the strongest case for newborn screening (NBS): to detect congenital disorders at birth, so effective treatments can be implemented before dire health consequences set in.**

Stella Turnbull with mom Sarah. Photo: Sarah Turnbull

**“The easy disorders have already been done”**

Currently, virtually all of the four million or so babies born in the United States each year receive NBS within the first 24 to 48 hours of life. Since 97% of this screening is the responsibility of state public health laboratories (PHLs), PHL scientists have spearheaded the implementation of new screening technologies and generally embraced the expansion of screening panels. But as NBS candidate disorders become rarer and rarer, their diagnosis less clear-cut, and their treatments less effective, NBS advocates have grappled with what Michele Caggana, ScD, FACMG, calls the “push and pull of adding new conditions.”

Caggana, who heads the NBS Program and the Genetic Testing Quality Assurance Program at New York’s Wadsworth Center—the state PHL—said, “New York has always been an early adopter” of NBS candidate conditions, just last year adding SMA, mucopolysaccharidosis Type I (MPS-I) and guanidinoacetate methyltransferase deficiency to its screening panel. Yet, she said, “We have to be thoughtful about how we do NBS expansion. The low hanging fruit, the easy

disorders, have already been done.”

One unresolved issue, said Patrick Hopkins, the semi-retired former NBS chief at the Missouri State Public Health Laboratory, is the “growing challenge of deciding on what we’re screening for, such as newborn disorders, childhood disorders and late onset disorders. Often we cannot safely sort out the difference between these on the screening test, and if we could, where would we draw the line?”

Pompe disease, for example, has a classic infantile form, requiring immediate intervention, and later onset forms (about 72% of cases) in which serious symptoms may be delayed until adulthood. Babies with either of these variants will screen positive for Pompe, as well as babies with a less-urgent, non-classic infantile form and babies with pseudo-deficiency, who have biochemical Pompe disease markers, but will never go on to develop the disease. Follow-up providers must determine the appropriate diagnosis and counsel families based on limited clinical guidance, since there is little medical experience with Pompe, especially over the long term.

Molecular testing raises similar issues. Now used for discrete NBS applications—mostly second or third tier testing—it is expected to become more prominent in the NBS laboratory.

Said Caggana, “What we’re seeing with molecular [technology]—the ability to multiplex and look at several different genes at once—harkens back to when mass spectrometry came on the scene [in the early 2000s].... It really pushed the field.”

Yet molecular testing comes with its own challenges, including the need for added infrastructure (including new instrumentation, a dedicated “clean” room and space to accommodate a unidirectional flow of testing), highly specialized staff training and capacity to analyze massive amounts of genetic data.

Moreover, Caggana noted that “no one’s assessed molecular [findings] on a broad stroke of the population of healthy babies” to inform data analysis and interpretation of novel gene variants.

Kimberly Noble Piper, RN, CPH, CPHG, genetics coordinator for the Iowa Department of Public Health (IDPH) said molecular screening “comes with a



Babies Saved Here: Patrick Hopkins and Mark Temple in the Missouri LSD Testing Laboratory. Photo: MO PHL

whole lot of ethical considerations.” She explained, “When you test the genome, you’re going to find mutations that may not mean anything, and we won’t know what’s significant and what’s not. And how do you tell the family that; that you found a variant and you don’t know what that means, maybe nothing?”

Equivocal and false-positive findings come at a cost.

Neena Champaigne, MD, FACMG, FAAP, director of the metabolic treatment program at South Carolina’s Greenwood Genetic Center, diagnoses and follows patients with metabolic NBS disorders from birth onward. False-positives and findings of unknown clinical significance, she said “cause us a lot of concern.”

Among the consequences are:

- “Running the risk of inundating providers,” who may then develop a lack of urgency “because they now have so many infants with abnormal results and they don’t know how to sift through them and triage them.”
- Placing unnecessary psycho-social burdens on families. Champaigne said, “I personally have seen families who have medicalized their children even after it’s proven that they don’t have a NBS condition; they have a hyper-awareness for that child, more doctor visits, which can have ramifications for years.”
- Compromising medical specialists who are already “stretched thin,” and must then follow individuals who may never develop symptoms. Champaigne, for example, is one of only two biochemical geneticists serving the entire state of South Carolina, plus the nearby border regions of Georgia and North Carolina. Some states, she said, “don’t even have a biochemical geneticist.” Although her training is in pediatrics, of necessity, Champaigne has followed some patients well into adulthood.

### “External pressures to meet challenging timelines”

NBS programs are working diligently to address these challenges; to improve the accuracy and precision of existing tests



**“I personally have seen families who have medicalized their children even after it’s proven that they don’t have a NBS condition; they have a hyper-awareness for that child, more doctor visits, which can have ramifications for years.”**

*Neena Champaigne, MD, FACMG, FAAP*

and to bring on new disorders, even as they continue the high-stakes work of screening tens of thousands of infants a year—in some states a six- or seven-day-a-week job.

Hopkins oversaw one of the first Pompe disease screening programs in the world, demonstrating proof-of-concept for Pompe NBS. To do so, his team adapted and validated a brand-new methodology called digital microfluidics fluorometry. A statewide hiring freeze at the time meant that no additional help was available in a laboratory already screening 93,000 NBS specimens/year for over 60 other disorders.

An early success, said Hopkins, was detecting a child with infantile Pompe on the second day of pilot screening. And data from the first six months of population-wide screening revealed about twice as many Pompe cases as predicted in the scientific literature. These outcomes bolstered the case for adding Pompe to the RUSP in 2013.

Caggana is working with colleagues to create a forum for sharing molecular

test data to reduce ambiguous findings. “If we see a [genetic] variant twice in New York and the baby is, and remains, asymptomatic,” she said, “it’s more likely to be identified in asymptomatic infants across the country.”

Wadsworth is also working to enhance long-term follow-up, so, Caggana said, data “can feed back to [the laboratory] to help us modify the testing algorithm so we don’t catch the babies who will never develop disease.”

Wadsworth scientists are in the midst of refining the laboratory’s screening algorithm for cystic fibrosis (CF) to reduce the number of false-positive results—an example that showcases the complexity of modern-day NBS. In the first phase of analysis, specimens are winnowed via a biochemical test to measure levels of the CF marker, immunoreactive trypsinogen (IRT). Those with IRT levels among the top 5% of specimens screened in the past ten days then advance to molecular testing.

New York is transitioning from a two-tier genetic screening protocol—a 39-mutation CF panel, followed by CFTR gene sequencing for specimens meeting certain criteria—to an enhanced process: “We’ll take a bioinformatic look to interrogate all the [CFTR gene] variants we’ve seen in babies in New York,” said Caggana. “If a baby has one variant, we’ll look at the rest of the gene.” Infants with two CF variants are reported as screen-positive and those with one as “single variant detected.”

Although this multi-step process increases test turn-around-time, it also increases specificity. “We’re able to reduce the number of families impacted and the downstream number of babies who have to undergo [a diagnostic] sweat test,” said Caggana. “That makes the longer time palatable.”

Further complicating the work of NBS scientists, said Hopkins, are “external pressures to meet challenging timelines and quality in a very sensitive and oftentimes emotional area of laboratory testing.”

Earlier this year, Sanofi US—which manufactures enzyme replacement therapies for a group of NBS conditions known as lysosomal storage disorders (LSDs)—lobbied the Iowa legislature and

got bills introduced that would essentially require the state to screen for all LSDs on the RUSP by 2020—an impossible feat. (By way of comparison, Wadsworth screened tens of thousands of infants for Pompe, a LSD, during its pilot program, before the disorder was added to routine NBS.)

Piper, who participated in an analysis of the bill, said the health department concluded that there was “no way we could add these conditions to our panel by next January.” She said, “We don’t have the physical capacity and infrastructure to screen for LSDs on a population level. We would require additional equipment, more electrical resources, more data resources. It would take a capital outlay that is not insignificant.”

Declining to appropriate the funding, the legislature backed down. As of early spring, it seems likely the final bill will instead ask IDPH to review every new condition added to the RUSP—which it already does—and then submit a report to the governor’s office.

“We dodged a bullet,” said Piper.

Most states—all except, FL, KS, NY, PA and DC—fund their NBS programs at least in part through fees, ranging from \$30/infant in Louisiana to \$162.98/infant in Rhode Island. But increasing these fees is rarely easy. After Missouri added screening for Pompe disease and other select LSDs in 2013 (an effort costing a few hundred thousand dollars), it took two years to raise the statutory cap on NBS fees so the state could charge an extra \$20/baby—an adjustment requiring the approval of both the state legislature and governor.

Given budgetary constraints, NBS laboratories continually work to increase efficiency. New York’s Wadsworth Center has implemented “lean” methods to streamline its processes. Recent improvements include using state health department systems to enhance electronic communications with hospital newborn coordinators, and tweaking laboratory systems to assure more timely data entry.

### “We save two babies every three days”

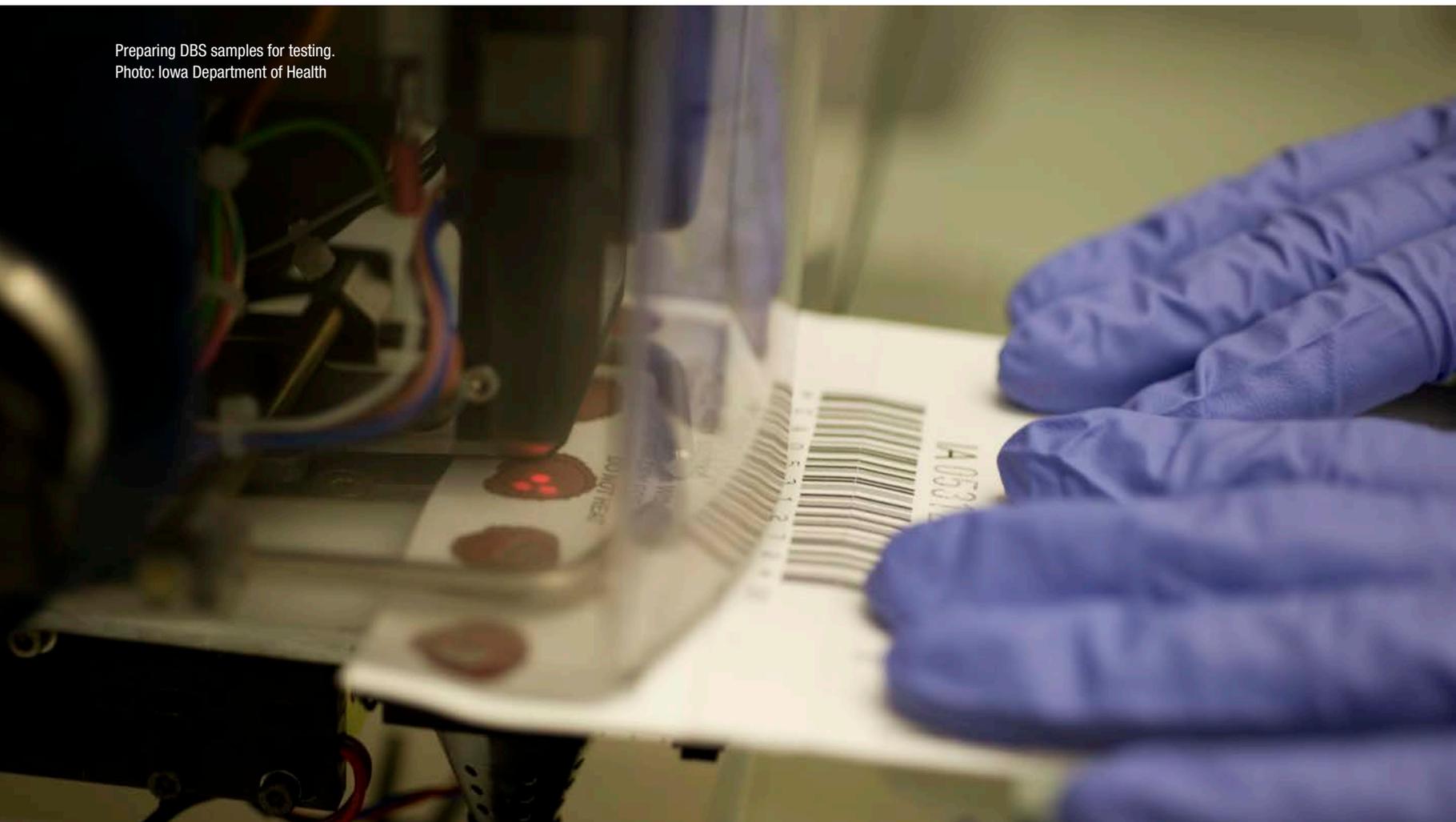
What does the future hold for NBS?

The experts cited in this article predict continued expansion of the NBS panel due to advances in gene therapies that will target more candidate disorders and a greater willingness to screen for conditions whose symptoms can only be attenuated through early intervention.

The growing NBS panel, in turn, will require growing the nation’s pipeline of NBS laboratory scientists—for example, through efforts like the APHL NBS fellowship program—and follow-up providers. Currently, Champaigne said, there is one biochemical geneticist for every 2.2 million US residents, and new professionals are added at the rate of only 15 every two years—not enough to replace those retiring from this demanding specialty.

On a technical level, multiplexing, whereby several different disorders can be tested simultaneously from the same NBS dried blood spot, is likely to expand, via platforms like mass spectrometry.

Preparing DBS samples for testing.  
Photo: Iowa Department of Health





Madison (left) and Mackenzie Braddock.  
Photo: Victoria Braddock

“There’s only so much blood on a card,” said Caggana, “so we have to depend on using the same specimen.”

At the same time, a push to decrease false-positives will likely mean more second and third tier screens. And, because of limited capacity and funding, more state NBS laboratories may opt to outsource this work.

In place of disease-specific screening, Caggana foresees “analyzing a collection of data more broadly across each baby,” based on results from next generation sequencing or metabolomic methods, like mass spectrometry, which capture data on metabolites associated with many different cellular processes.

Finally, data management—APHL’s top federal priority for this fiscal year—will loom large. Within the laboratory, there will be a need to analyze the massive datasets produced by newer technologies. And outside the laboratory, there will be a need to better manage and share follow-up data, especially across states.

## UPPING THE ANTE FOR BABIES: APHL PUSHES TO RENEW, IMPROVE THE NBS SAVES LIVES ACT

The US Centers for Disease Control and Prevention play a crucial role supporting state NBS programs via work to improve current screening tests, translational research to adapt new technologies for use in NBS, scientific training and technical assistance programs and its NBS Quality Assurance Program (NSQAP), which produces about a million (non-regulatory) blinded dried blood spot quality assurance samples to give screening laboratories an external check on their testing. A significant portion of this work—and especially the NSQAP—is funded through the NBS Saves Lives Act, enacted in 2009 and up for renewal this year. APHL and partners are asking Congress to reauthorize the act for a third five-year term (FY20-FY24) at an increased funding level of \$29,650,000.

Peter Kyriacopoulos, APHL’s public policy director, explained that “more funding is needed so we can maintain the highest possible level of quality in laboratory testing and deliver the most accurate screening results.”

Other requested updates to the act include:

- Expanding the authority of the US Health Resources Services & Administration to support public, educational programming around NBS.
- Commissioning a National Academy of Medicine report on the modernization of NBS, including a review of barriers that keep states from adding new conditions to their NBS panels and a review of infrastructure needs to improve timeliness of diagnosis for infants who screen positive for a NBS disorder. ■

As Champaigne explains, “We won’t know what we don’t know until we start [screening for new disorders]. We have to be mindful that we’re going to have some results that are indeterminate and will require long-term follow-up, and we should make some attempt to collect this information in an organized and meaningful way so we can learn how to improve test precision, as well as disease management further down the line.”

Overall, said Caggana, “NBS is definitely at an interesting time, with a lot of change over the last few years” and a lot of change in progress.

In the midst of this flux, children like Madison Braddock, age 7, are a reminder of why NBS matters so much. Madison, one of Champaigne’s South Carolina patients, was diagnosed at two weeks of age with glutaric aciduria, Type 1—added

to the state’s NBS panel in late 2004. Her mother, Victoria, said, “She didn’t have any abnormal signs at all.”

Without the early alert provided by NBS, Victoria said, “Definitely over the next couple of months of infancy she could have had a metabolic stroke that could lead to cerebral palsy, low muscle tone and ultimately death, without the proper medical formula.” Instead, she is a happy child whose main disease complication is “a feeding tube in her tummy” to deliver her formula.

And therein lie the rewards of the work: “We save two babies [from death or disability] every three days here in Missouri,” said Hopkins. “How cool is that?” ■

# A Non-Conventional Matrix: Potential Use of Dried Blood Spots for Biomonitoring

by **Jennifer Liebreich**, MPH, senior specialist, Environmental Health

Limited information exists about the extent of human exposure to many environmental chemicals, and the potential toxic health effects of these chemicals in humans are largely unknown. Dried blood spots (DBS) could provide biomonitoring data for populations from whom collecting blood is difficult such as children. Children are recognized as being more susceptible to the effects of potentially harmful environmental chemicals. This article provides an overview of the potential use of DBS for biomonitoring based on a chapter on the topic.

## Addressing Sample Collection and Sample Sensitivity Concerns

In population-based studies, biomonitoring data can be useful to establish background levels of select environmental chemicals and can help identify population groups most highly exposed. The **US Centers for Disease Control and Prevention's (CDC's) National Health and Nutrition Examination Survey (NHANES)** is considered the gold standard of biomonitoring population-based surveillance in the US. However, even in NHANES, biomonitoring data for infants and young children are limited because of age restrictions around collection of blood, making DBS look like an attractive alternative. However, NHANES is not a proponent of including DBS because of technical issues related to difficulty in standardizing collection of capillary blood.

Biomonitoring generally requires measuring chemicals at trace concentrations (parts per billion or lower) so biomonitoring with DBS must use analytical methods providing adequate sensitivity and selectivity at such concentrations, which is challenging and



A scientist sorts through DBS punches. Photo: Iowa Department of Public Health

**Biomonitoring directly measures the actual concentration of environmental chemicals or their metabolites in human biospecimens, and, when used in combination with indirect measures of exposure like questionnaires, biomonitoring data can provide useful information about differences in exposure across geography, race/ethnicity, and socioeconomic status. Blood and urine are most commonly used for biomonitoring.**

costly. Additional challenges relate to standardization of collection of capillary blood vs venipuncture, and presence of other endogenous and exogenous chemical substances on the DBS. Further analytical considerations for biomonitoring using DBS include limited sample volume; contributions from the filter paper; extraction of biological material from the filter paper; stability; and comparison of data between DBS and serum, plasma or whole blood. DBS offer

the promise of making biomonitoring available to a wide range of populations but also represent substantial analytical challenges for both method development and quantitation of analytes (chemicals).

While there are concerns with using DBS for biomonitoring of endogenous chemical substances, it has been recently noted that DBS can serve as a good matrix for chemicals such as nerve agents and opioids.

<sup>1</sup> Calafat, A. M. and Kato, K. In *Dried Blood Spots: Applications and Techniques*, Li, W.; Lee, M. S. Eds.; John Wiley & Sons: Hoboken, NJ, 2014; Chapter 10.

<sup>2</sup> Seymour C<sup>1</sup>, Shaner RL<sup>2</sup>, Feyereisen MC<sup>2</sup>, Wharton RE<sup>2</sup>, Kaplan P<sup>3</sup>, Hamelin EI<sup>1</sup>, Johnson RC<sup>2</sup>. Determination of Fentanyl Analog Exposure Using Dried Blood Spots with LC-MS-MS. *J Anal Toxicol*. 2018 Nov 20.

<sup>3</sup> Shaner RL<sup>1</sup>, Coleman RM<sup>1</sup>, Schulze N<sup>2</sup>, Platanitis K<sup>2</sup>, Brown AA<sup>2</sup>, Seymour C<sup>2</sup>, Kaplan P<sup>2</sup>, Perez J<sup>1</sup>, Hamelin EI<sup>1</sup>, Johnson RC<sup>1</sup>. Investigation of dried blood sampling with liquid chromatography tandem mass spectrometry to confirm human exposure to nerve agents. *Anal Chim Acta*. 2018 Nov 29;1033:100-107.

### Storing Samples and Data for Future Use

Residual DBS are a potentially valuable resource for research, but the cost of storage, retrieval and preparation of DBS for biomonitoring can be substantial. The lack of storage guidelines for residual DBS around physical conditions like temperature and humidity, in combination with issues around privacy and consent, currently limit the use of residual DBS for biomonitoring.

Looking to the future, DBS and other non-conventional matrices such as amniotic fluid, meconium, cord blood, placenta and umbilical cord have the potential to be matrices for assessing exposure to select environmental chemicals. Newly emerging analytical approaches offer the possibility of analyzing DBS spiked with pharmaceutical compounds with minimal sample preparation and

extraction steps. These quantitative methods, already applicable in the pharmaceutical field for analyzing whole blood, offer exciting promise for the analysis of DBS for biomonitoring purposes.

High-quality analytical methods already permit the determination of target environmental chemicals in DBS. However, limited data exist on the suitability of DBS for biomonitoring purposes, particularly for chemicals with widespread commercial and industrial use. As validated protocols are developed for the collection, handling, shipping and storage of DBS to preserve the integrity of both DBS and the target analytes, they will help assure valid generation and interpretation of biomonitoring data. Further research will provide critical data to determine the suitability of DBS for epidemiologic studies to assess exposures to environmental chemicals.

Since 1999, NHANES has included an ongoing exposure assessment of the US population to select environmental chemicals. CDC's **Updated Tables, January 2019** presents nationally representative and cumulative biomonitoring data gathered from 1999 through 2016, including all the data from each previous *National Report on Human Exposure to Environmental Chemicals*. ■



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# Detecting *Cyclospora* in Food: FDA's Success with a New Method during Outbreaks

by Robyn Randolph, senior specialist, Food Laboratory Accreditation

Protecting our food supply and preventing human illness is a core mission for the **US Food and Drug Administration (FDA)**. In summer 2018, FDA led several investigations into multistate outbreaks of Cyclosporiasis, an intestinal illness caused by the parasite *Cyclospora cayetanensis* that sickened hundreds of people. Luckily, a newly-developed FDA food testing method allowed investigators to identify the pathogen in food or food articles, and remove implicated product from shelves quickly.

## Public Health Significance

*C. cayetanensis* is not a newly emerging threat, as outbreaks have been associated with the parasite for years. However, both sporadic case reports and outbreaks of Cyclosporiasis are increasing based on surveillance data from the **US Centers for Disease Control and Prevention (CDC)**. These increases could be due to improvements in surveillance methods, better diagnostic testing methods for human illness, or actual increases in illness due to yet-unknown factors. Whatever the reason for the reported increase in Cyclosporiasis cases, FDA's development of a new *Cyclospora* food testing method was timely given last year's large-scale outbreaks. Having a method to confirm the parasite's presence in food commodities helps identify potentially contaminated products and hasten their removal from commerce.

## Validation of the New Method

FDA has not been able to detect *Cyclospora* in food since the early 2000s, as the previous detection method relied on supplies that are no longer commercially available. Following large, multi-state Cyclosporiasis outbreaks in 2013, FDA's Center for Food Safety and Applied Nutrition (CFSAN) created the Foodborne Parasitology Research Program to develop a new detection method. The Parasitology Program worked to adapt and improve a real-time polymerase chain reaction (PCR)

method for detection of *C. cayetanensis* in fresh produce such as leafy greens and berries. The Parasitology Program conducted a multi-laboratory validation to ensure the method's accuracy and reproducibility. The **method was published** in 2017 in FDA's Microbiological Methods & Bacteriological Analytical Manual (BAM)<sup>1</sup>, which lists the FDA's preferred methods for pathogen detection. All seven FDA Office of Regulatory Affairs (ORA) Human and Animal Food (HAF) laboratories can conduct the *Cyclospora* analysis, with an ongoing expansion to state laboratories.

## *Cyclospora* Outbreaks in Summer 2018

Summer 2018 was a busy season with two large multi-state outbreaks attributed to *C. cayetanensis*.

In June 2018, FDA<sup>2</sup> and CDC<sup>3</sup> worked together on a Cyclosporiasis multi-state

outbreak in four states. As of September 2018, the CDC had been notified of 250 laboratory-confirmed cases of Cyclosporiasis from four states. Epidemiologic evidence pointed to pre-packaged vegetable trays. Unfortunately, traceback analysis was unable to determine the specific component of the vegetable tray that was responsible for the contamination.

In July 2018, an even larger outbreak surfaced, with 511 laboratory-confirmed cases<sup>4</sup> from 15 states and New York City. Cases reported consuming salads from a major fast-food chain. FDA<sup>5</sup> was able to utilize the newly developed method to confirm the presence of *C. cayetanensis* in an unopened package of salad mix (romaine and carrots) distributed to the chain restaurants. Although a single source of contamination was not identified, FDA worked with the chain to stop selling salads in 14 states; the



**FDA was able to utilize the newly developed method to confirm the presence of *C. cayetanensis* in an unopened package of salad mix (romaine and carrots) distributed to the chain restaurants.**



**In FY 2018, FDA sampled fresh herbs, specifically basil, parsley and cilantro. FDA ORA laboratories tested these domestic and imported products for *Salmonella* and Shiga toxin-producing *E. coli* (STEC). FDA also added the newly developed *Cyclospora* method to this sampling assignment, as past Cyclosporiasis outbreaks were linked to imported produce, including basil and cilantro.**

company has since reported that it has changed suppliers of its salad mix in the affected states.

While the two outbreaks do not seem to be related, the scope of these outbreaks show the timeliness of FDA's new method for confirming the parasite's presence and contributing to food recalls.

### FDA Sampling Assignment

FDA routinely conducts sampling assignments that assess microbial contamination in targeted food commodities in response to previous outbreaks and environmental signals. For a specified time period, FDA collects and tests a selected group(s) of foods, both domestic and imported, to better characterize microbial risk.

In FY 2018, FDA sampled fresh herbs, specifically basil, parsley and cilantro. FDA ORA laboratories tested these domestic and imported products for *Salmonella* and Shiga toxin-producing *E. coli* (STEC). FDA also added the newly developed *Cyclospora* method to this sampling assignment, as past Cyclosporiasis outbreaks were linked to imported produce, including basil and cilantro.

In August 2018, FDA reported<sup>6</sup> two samples of imported cilantro that were positive for *C. cayetanensis*. The imported shipments associated with the positive sample were refused entry into the US. Additionally, FDA confirmed the presence of the parasite in a domestically produced cilantro sample. FDA initiated an investigation into the domestic producer, and another sample taken from the farm was positive. FDA worked with state officials and the producer to initiate a voluntary recall and worked on corrective actions with the farm to reduce further contamination.

This was the first confirmed evidence of *Cyclospora* in domestic produce. FDA was able to remove the contaminated product from the food supply, possibly preventing human illness. FDA plans to train staff and deploy the *Cyclospora* detection method to additional laboratories in the coming year. With more laboratories able to perform investigative and surveillance testing for this parasite, and with federal and state regulatory partners willing to take action on the results of this fully validated test, the US food supply will be that much safer. ■

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## Addressing Punch Conservation with Digital Microfluidics

By **Candice Brannen**, PhD, senior director of laboratory products, Baebies

As public health newborn screening (NBS) programs expand to test for more conditions, we've heard that there is growing concern that the standard volume of dried blood spots (DBSs) collected from each newborn may not be sufficient to perform all screening tests. The current standard newborn card contains five DBSs. In order to accommodate additional tests, NBS programs can change the standard practice for collection of more blood spots or require new tests to utilize technology that conserves existing sample volume.

Changing the standard practice may not be a good option. By requiring collection of additional blood spots, the risk of inadequate and unsatisfactory samples may increase. The increased risk may be avoided by adopting technology that enables more tests to be performed from the current standard 3.2 mm punch of a DBS.

Digital microfluidics fluorometry (DMF) technology enables the precise manipulation of discrete droplets and can support multiple assay formats including enzymatic biochemical reactions, immunoassays, and molecular analyses. This technology is uniquely positioned to address this issue of punch conservation.

To perform tests from a standard 3.2mm DBS punch, 100 uL of solution is added to extract assay analytes into solution. Since each DMF assay only requires 0.1 uL of DBS extract, nearly 1,000 discrete reactions could be performed using the DBS extract from one punch. In addition, standard cartridges can be readily modified to accept more samples or more assays per cartridge. With DMF, the miniaturized assay format conserves sample usage, reduces reagent costs and minimizes the installation footprint.



Baebies team member Jon Washburn (right) training newborn screening staff on SEEKER® in Qatar

**Baebies' DMF technology is protected by more than a hundred patents and is utilized by SEEKER®, the first FDA-cleared test for lysosomal storage disorders (LSDs)—Pompe, MPS I, Gaucher, and Fabry. SEEKER® is currently used for LSD NBS in six US states and in Qatar. Since DMF technology supports a variety of assay formats, Baebies is actively expanding our assay pipeline in order to offer more tests.**

Sample volume doesn't have to limit the expansion of NBS. DMF technology, while not the only solution, is a great start. Baebies looks forward to continued partnerships with public health NBS programs to provide testing as we carry out our mission—to save lives and make lives better for children everywhere.

*Baebies is a gold level sustaining member of APHL. ■*

# Rhode Island Leverages Agency Partnerships to Identify Contaminated Leachate

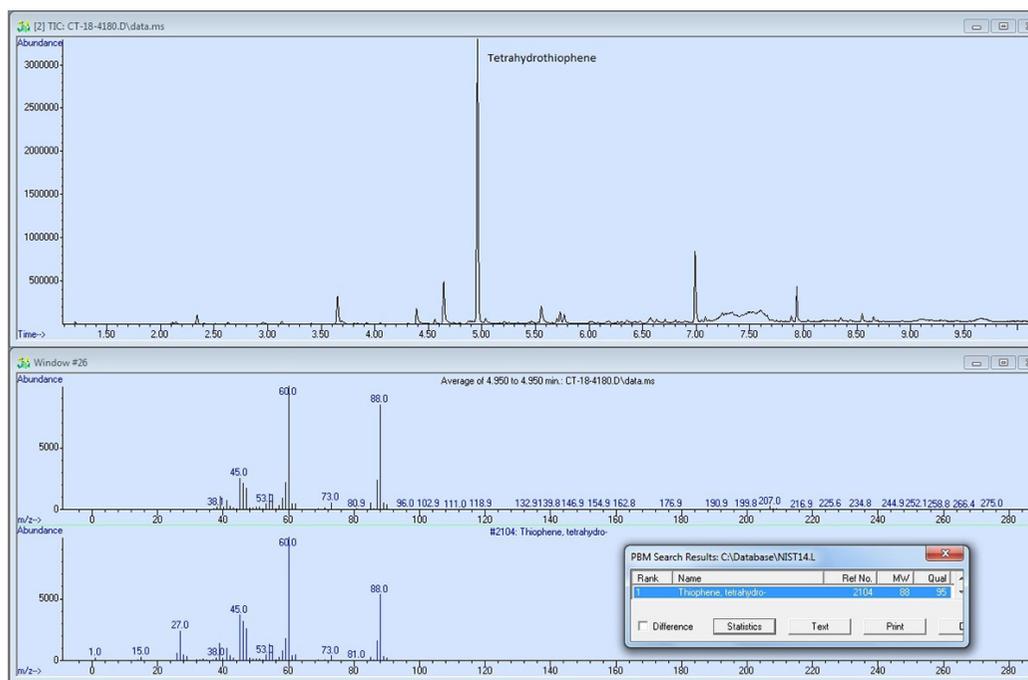
By **Louis Marchetti**, PhD, CT coordinator, Rhode Island Department of Health State Health Laboratory

To further the working relationship between the first responder community and state agencies, Rhode Island's Chemical Threat (RI CT) laboratory has expanded its sample submission criteria to include requests for analysis of non-clinical samples. RI CT partners with CDC through its participation in the Laboratory Response Network for Chemical Threats (LRN-C). Chemical Threat laboratories, such as RI CT, may leverage this testing capacity to support emergency response stakeholders such as local law enforcement, hazmat teams, and other governmental partners that contact the laboratory for assistance. Utilizing the LRN-C infrastructure, requests for presumptive identification of unknown materials may be submitted directly to the CT laboratory by emergency response stakeholders.

## An Odoriferous Problem

Recently, Rhode Island's Department of Environmental Management (RIDEM) was contacted to investigate a complaint, made by several individuals, of a natural gas odor emanating from a Providence home. The homeowner had recently switched from oil to gas heating, which resulted in the installation of a new underground line from the street to the house. The local energy company was contacted to assist with air and soil probing to determine if a natural gas leak could be identified, but, despite the strong odor emanating from the property, results of all field screening analyses were negative.

At this time, a liquid discharge pooling around the base of the piping of the regulator supplying the home with gas was observed. A sample of the water runoff from the piping was collected and submitted to the Rhode Island State Health Laboratory (RISHL), and the CT Coordinator was asked to assist in the investigation. With a few minor alterations to the LRN-C's VOC method, the CT laboratory was able to presumptively identify, through library matching, the presence of



Chromatogram of tetrahydrothiophene with library match

tetrahydrothiophene—a common odorant for natural gas—and pyridine within the sample.

## A Quick Response

RIDEM was immediately notified of the results, and the energy provider was alerted of the possibility that contaminated leachate material was coming from the ground. As a result, a section of the yard of the home in question was excavated within the hour. It was determined that an old pipe connected to a gas main no longer in use was cut below the soil grade and capped with a rubber stopper that did not properly fit. Due to recent rain storms, groundwater was entering the main line that ran upgradient of the house. It was pushing the residual gas through the pipe and discharging into the property, thus contaminating the soil and resulting in the odor which triggered the investigation. The energy provider has since removed the pipe, and follow-up testing results came back negative for additional contamination. It was determined that because the old gas main was no longer under pressure, the gas company could not detect natural

## NATURAL GAS ODORANTS

Since natural gas is combustible and odorless, the government requires it be odorized as a safety measure. Odorants may smell like rotten eggs, kerosene, lighter fluid and skunk, and often vary regionally. While some compounds are used by themselves (such as tetrahydrothiophene), most odorants consist of a mixture of compounds including:

- dimethyl sulfide
- isopropyl mercaptan
- methyl ethyl sulfide
- normal propyl mercaptan
- secondary butyl mercaptan
- tertiary butyl mercaptan
- tetrahydrothiophene.

gas vapors under the ground near the release. The gas company had been out at the site on and off for over two weeks attempting to identify a gas release. Jim Ball of the Department of Environmental Management Office of Emergency Response indicated that, due to the coordinated efforts of the two agencies, the life safety hazard and toxic exposure to the public was eliminated in a much more expedient fashion. ■

# Pacific Rim Consortium Meets, Establishes Strategic Priorities

By **Tina Su**, MPH, manager, Quality Systems

With beautiful Pearl City off in the distance, the Pacific Rim Consortium members convened their first in-person meeting at the Hawaii Public Health Laboratory March 5-6, 2019. Though the group had met several times via teleconference, they wanted face-to-face time to learn more about each laboratory and discuss topics such as shared services, continuity of operations and future collaborative opportunities.

Participants from Alaska, California, Guam, Hawaii, Los Angeles County and Washington presented overviews of their respective public health laboratories, created a network mission statement and participated in strategic planning to determine the focus of Consortium activities over the next one to three years. They conducted an exercise to determine which projects to prioritize and their respective determinants of success. Through consensus and active discussions, they landed on continuity of operations, best practices, purchasing power, training, funding and shared services.

Paul Kimsey, the director of the California Department of Public Health Laboratory and the chair of the Consortium reflected on the meeting's outcomes: "Our first face-to-face meeting of the Pacific Rim Consortium in Hawaii was a great example of public health laboratories coming together for their mutual benefit and to ensure laboratory services for their respective states and territories. In the next one to three years, I'm hopeful that the consortium will develop a regional memorandum of understanding (MOU) and a continuity of operations agreement, and I am looking forward to a closer working relationship with our consortium partners." ■



The Pacific Rim Consortium convened an in-person meeting in March 2019 at the Hawaii Public Health Laboratory

## MISSION STATEMENT

The Pacific Rim Consortium is a network of public health laboratories established for cooperation and support for mutual benefit of members through a collective voice for technical assistance, training, shared services, mutual support in emergencies, and best practices.

It includes the following members:

- Alaska Division of Public Health Laboratory
- California Department of Public Health Laboratory
- Guam Department of Public Health & Social Services
- Hawaii State Laboratories Division
- Los Angeles County Public Health Laboratory
- Oregon State Public Health Laboratory
- Washington Public Health Laboratories

**“In the next one to three years, I’m hopeful that the consortium will develop a regional memorandum of understanding (MOU) and a continuity of operations agreement.”**

*Paul Kimsey*

# APHL Closes Productive Decade of Work in Sierra Leone

by **Sherrie Staley**, MPH, manager, Global Health; **Palmira Mangae**, specialist, Global Health; and **Lucy Maryogo-Robinson**, MPH, director, Global Health

In January of 2019, APHL officially handed over its Sierra Leone portfolio to the country's Ministry of Health after a decade of involvement, including four years helping to develop the nation's lab system during the worst Ebola outbreak in history. With that outbreak ended, Sierra Leone has emerged a stronger country committed to continued growth and development, including that of its laboratory system.

APHL has always sought to strengthen the laboratory system in Sierra Leone. It is with this vision in mind that our subsidiary opened with a staff of four in January 2016 to respond to the Ebola crisis. APHL began work in Sierra Leone many years before this, however, with a focus on supporting HIV Ante Natal Clinic (ANC) surveys. Over the course of the last four years, our PEPFAR work expanded as did our Global Health Security Agenda initiatives.

Between 2015 and January 2019, APHL worked closely with the Sierra Leone Ministry of Health, the Centers for Disease Control and Prevention, and other key stakeholders. During our tenure, some of our key accomplishments include:

1. Completing the renovation of the Central Public Health Laboratory (CPHRL) to include storage and external quality assurance (EQA) facilities, resulting in a more secure and safe environment for laboratory testing
2. Providing training and mentorship of 26 university science graduates on Ebola epidemiology, diagnosis and related data management, health and safety. These graduates, known as the Public Health Laboratory Response Team (or RRTs) received additional training on epidemic-prone diseases (HIV early infant diagnosis (EID) & viral load, measles, rubella, rotavirus) and enteric bacterial diseases. These high caliber laboratory scientists have provided sustainable testing, service

delivery and outbreak preparedness from 2015 to the present.

3. Supporting laboratories throughout the country, specifically CPHRL, Princess Christian Maternity Hospital, Ola Doring Children's Hospital and Jenner Wright Laboratories. APHL support to these sites included:

- Activation of clinical diagnostic labs for hematology and clinical chemistry
- Application of the laboratories to an accredited international EQA program
- Procurement of laboratory equipment and consumables
- Development of quality manuals and written standard operating procedures such as the national laboratory rapid response manual, national testing algorithm, national policy and health and safety manual, and the national laboratory reporting tools
- Supported the development of a national priority plan and the national laboratory strategic plan

- Sponsored high level and extended workshops in quality management systems, laboratory validation protocols, and equipment management in the laboratory
- 4. Supported microbiology activation at Ola Doring and Princess Christian Hospital laboratories. At baseline (May 2017) the laboratory scored zero stars on the SLIPTA checklist. But as of December 2018, the score on the same checklist was two stars. Today, the microbiology laboratory is a referral facility for bacteriology culture analyses and supports outbreak responses for epidemic prone diseases such as cholera and meningitis.
- 5. Provided onsite and remote continuous mentorship in microbiology and tuberculosis testing at CPHRL and TB Reference Lab.

A robust laboratory system underpins every strong health system. It has been APHL's honor and privilege to contribute to the health of Sierra Leone's people by strengthening its laboratories. ■



The APHL team with representatives from the Ministry of Health and CDC Sierra Leone at the Handover Ceremony

# Sierra Leone's Antimicrobial Resistance Surveillance Strengthens with Microbiology and Bacteriology Lab Activations

by Lucy Atieno, PhD, QMS consultant, Global Health

To support the Sierra Leone Ministry of Health and Sanitation (MoHS) in a bid to set up a functional microbiology laboratory and address the priority of antimicrobial resistance surveillance, APHL installed a microbiology unit at two adjacent referral hospitals in May 2017: the Ola During Children's Hospital (ODCH) and Princess Christian Maternity Hospital (PCMH). The clinical setup of these facilities ensured that sample availability would not pose any challenges.



The Microbiology laboratory at ODCH before workstation set up



The Microbiology lab at ODCH after workstation set up.

## Creating the Laboratories

The project began with clearing, cleaning and redesigning the provided workspace to make sure the minimum specifications for a microbiology and, especially, bacteriology laboratory were met. APHL ensured the facility had the key supplies and equipment to provide necessary testing services.

A training program was created for relevant staff that included standard procedures for optimal lab operability. When APHL started at this facility, there were no ongoing culture or quality management system (QMS) activities; this was primarily due to lack of relevant training and/or practical experience of staff working in bacteriology.

## Accomplishments

Over a period of nearly two years, the ODCH/PCMH microbiology laboratory has acted as a training hub for both MoHS staff and medical laboratory science (MLS) students from the College of Medicine and Allied Health Sciences (COMAHS). The training covered theoretical seminars and QMS activities.

**Table 1: Current Status of Testing at ODCH/PCMH Microbiology Laboratory (February 2018)**

Examination Procedure (s)	Current Status
Urinalysis and Urine Culture	Urine Microscopy, Biochemistry and Culture tests available and running. Cultures can be done for Urinary <i>Enterobacteriaceae</i> .
Stool Microscopy and Culture	Stool Microscopy and culture tests available and running. Cultures can be done for all Pathogenic <i>Enterobacteriaceae</i> , <i>Campylobacteriaceae</i> and <i>Vibrionaceae</i>
CSF Culture/Gram Stain, Cell Counts and India Ink Preparations	Culture, Cell Counts and Gram Stain are currently available. Organisms that can be isolated include: Group B Streptococci, <i>E. coli</i> and other coliforms, <i>Haemophilus influenzae</i> , <i>Neisseria meningitidis</i> and <i>Streptococcus pneumoniae</i> .
Urogenital Swab Cultures/Wet Preparations and Gram Stain	Culture, Wet preparations and Gram Stain is currently available. Organisms that can be isolated include: <i>Neisseria gonorrhoeae</i> , <i>Beta Haemolytic Streptococcus</i> Group and <i>Staphylococcus aureus</i> .
Respiratory Samples for Culture and Gram Stain	Culture and Gram Stain is currently available. Bacteria that can be isolated include: Group A Streptococcus, <i>Pseudomonas aeruginosa</i> , <i>Haemophilus influenzae</i> , <i>Streptococcus pneumoniae</i> and <i>Staphylococcus aureus</i> .
Pus Samples for Culture and Gram Stain	Culture and Gram Stain is currently available. Bacteria that can be isolated include: <i>Staphylococcus aureus</i> , <i>Serratia marcescens</i> , <i>Enterococcus</i> species, <i>Streptococcus pyogenes</i> , <i>Streptococcus pneumoniae</i> , <i>Enterobacteriaceae</i> and <i>Pseudomonas</i> species
Effusions (Synovial Fluids, Pleural Fluids, Pericardial Fluids Ascitic Fluids and Hydrocele Fluids)	Culture, Cell Count, wet preparations and Gram Stain is currently available. Bacteria that can be isolated include: <i>Staphylococcus aureus</i> , <i>Serratia marcescens</i> , <i>Enterococcus</i> species, <i>Streptococcus pyogenes</i> and <i>Streptococcus pneumoniae</i> .
Blood Culture	Test currently <b>NOT</b> available.

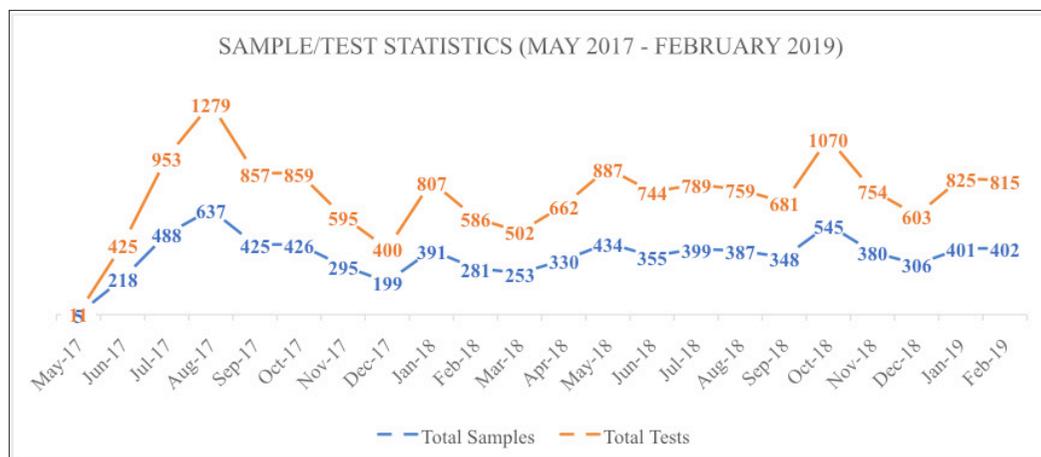


Figure 1: Expansion of Scope of Testing



Figure 2: Illustration of audit scores based on the SLIPTA Checklist showing the laboratory's improvement on QMS.

Under the technical aspects of the project, the following have been achieved:

- Implementation of media preparation
- Implementation of culture techniques (see Table 1)
- Implementation of outbreak response activities
- Initiation of research activities
- Expansion of the scope of testing, which has seen statistics move from an average of 90 tests per month (verbal information, data not available) to the current average of 700 tests per month.

Under QMS, the following have been realized:

- Full documentation and validation of the QMS procedures, including Quality, Biosafety, Laboratory User, Training, Media/Reagents Preparation Manuals and Examination Procedures

- In May 2017 the laboratory had a baseline score of 31/265 (11.7%) on the Stepwise Laboratory Quality Improvement Process towards Accreditation (SLIPTA) checklist and a rating of No Star. As of December 2018, the laboratory scored 173/265 (65.3%, Figure 4) for a rating of Two Stars. This represented a 53.6% increase in under two years

**Impact**

1. A MoHS Antimicrobial Resistance Surveillance Program is currently running in this facility. This will ensure that resistance patterns of common isolates are determined so that Empirical Treatment Regimes are based on available data. Also, extended spectrum β-lactamase (ESBL) strains can now be identified based on Cefotaxime resistance; this is significant resistance and considered is a high priority infection control alert.

2. The ODCH/PCMH microbiology laboratory is currently used as a referral facility for bacteriology culture analyses and antimicrobial sensitivity testing. In addition, the laboratory supports outbreak responses for epidemic prone diseases such as cholera and meningitis.
3. The facility currently supports the practical training of MLS students.
4. Clinical research can now be carried out at this facility. ■

# Building TB Testing Capacity in Sierra Leone

By **Shirematee Baboolal**, PhD, consultant

In Sierra Leone, tuberculosis exacts a heavy burden. In 2018 alone, there were more than 17,000 notified cases of the disease in a country with a population of less than 8 million.

Since 2016, APHL has engaged with the country's Ministry of Health and Sanitation to provide technical assistance to the National TB Reference Laboratory (NTRL) to build its TB testing capacity for culture and drug sensitivity testing (DST). Initially this capacity was limited. In 2016 the NTRL was still a new entity with uncompleted facilities. Formed in 2014 under the country's National Tuberculosis Program, it performed only acid fast bacilli smear microscopy using the Ziehl-Neelson stain and GeneXpert MTB/RIF. There was no facility available for TB culture.

APHL began by modifying several small rooms in the NTRL facility to perform concentration of samples, solid culture and line probe assay (LPA) (first line). It leverage equipment available for LPA and borrowed other equipment from the Central Public Reference Laboratory to train staff in molecular LPA.

The following year, APHL introduced quality management systems (QMS) with a baseline assessment using the WHO/

AFRO SLIPTA checklist. At baseline, the NTRL scored 57/275 points, which was equivalent to zero stars under the rating system. APHL trained NTRL staff to build and sustain QMS in a step-wise manner focusing on documentation, practice and competency building. Though several key areas remain to be addressed, a SLIPTA audit in March 2019 showed significant improvement with a score of 214/275, equivalent to a three star rating.

With support from **The Global Fund**, a modular laboratory was purchased with all equipment and supplies for conducting solid and liquid culture as well as DST for first- and second-line drugs. This facility was installed and commissioned in February 2019. Training was conducted on liquid culture and DST utilizing the BD MGIT™ TB System.

The laboratory can now conduct both phenotypic culture and DST for several drugs, including Streptomycin, Isoniazid (0.1µg and 0.4µg), Rifampicin, Ethambutol and Pyrazinamide, as well as LPA for first and second line drugs. Second line drugs for phenotypic testing will be added to the test algorithm soon. ■



Dr. Baboolal training staff in the new laboratory at NTRL

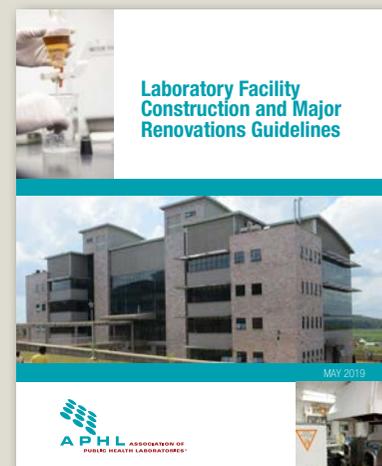
## APHL PUBLISHES GUIDE TO LAB FACILITY CONSTRUCTION, RENOVATION

By **Palmira Mangae**, specialist, Global Health

As part of its commitment to continuously improve the public health laboratory system, APHL has published new **Laboratory Facility Construction and Major Renovations Guidelines**. Developed in collaboration with HDR, Global Health Committee members and consultants, this multifaceted resource will help public health laboratory leaders and stakeholders think comprehensively about their facility's needs, functions and sustainability.

The guide provides an overview of core activities in the laboratory design process based on lessons learned and best practices in laboratory development and renovation. The information helps laboratory teams walk through the design process so that their construction project is a success—not only in design, but operationally.

For more information, please contact [Palmira Mangae](#)



# Developing Laboratory Leaders:

## APHL Joins with Global Partners to Address a Growing Need

By **Jocelyn Isadore** MPH, consultant, Global Health; **Burton Wilcke, Jr.**, PhD, associate professor emeritus, University of Vermont; and **Shannon Emery**, MSPH, manager, Global Health

Across the globe, health laboratories play an essential role in human and animal disease detection, diagnosis, and control and the detection and control of environmental and agricultural pathogens, chemicals and residues. Laboratories from all sectors depend on effective leaders and collaborative systems for their success. However, advanced leadership learning opportunities designed specifically for laboratorians are not readily available, especially in low- and middle-income countries. To address this critical gap, six health organizations have united for the first time to define competencies for laboratory leadership and create a global leadership plan.

The Global Laboratory Leadership Programme (GLLP) is a multi-year collaboration between APHL, the US Centers for Disease Control and Prevention (CDC), the European Centre for Disease Prevention and Control, the Food and Agriculture Organization of the United Nations, the World Organisation for Animal Health and the World Health Organization. Each partner has extensive experience in laboratory strengthening within their respective mandates and together they provide a unique multi-sectoral perspective to improving laboratory systems. The GLLP will provide competency-based course materials and an implementation guide for a comprehensive laboratory leadership program.

### First Steps

The partners have successfully developed a **Laboratory Leadership Competency Framework**, the first framework focused specifically on leadership competencies for laboratory scientists. It provides a three-level structure that allows step-wise progress towards the expert level of a competency. The framework can be used at the individual or institutional level as a:



The Global Laboratory Leadership Programme Partnership. Representatives from the Association of Public Health Laboratories (APHL), the Centers for Disease Control and Prevention (CDC), the European Centre for Disease Prevention and Control (ECDC), the Food and Agriculture Organization of the United Nations (FAO), the World Organisation for Animal Health (OIE) and the World Health Organization (WHO) meet in Paris, France in January.

- Standardized reference for laboratory workforce development applicable across national and/or regional health laboratory systems
- Foundation for laboratory leadership curricula and programs
- Guidance for writing standardized job descriptions
- Guidance to develop a tool for self-assessment, observer assessment or a combination of both to identify individual or group needs and guide staff development planning
- Guidance for individuals to assess their current level of knowledge, skills and abilities, identify areas in need of improvement and plan for achieving higher levels of proficiency

### Future Products

This framework will provide the foundation for the second product of the GLLP, a learning program designed to foster and mentor current and emerging

laboratory leaders to build, strengthen and sustain national laboratory systems. The learning program is flexible and may be adapted to individual country needs. Since its intent is to include all sectors and disciplines of the laboratory system in the same program, it will reinforce collaboration, communication and coordination under the One Health approach.

The GLLP partnership has successfully taken the first step to addressing gaps in laboratory leadership through the development of the Laboratory Leadership Competency Framework and all partners are committed to creating the GLLP learning package. According to CDC Division of Global Health Protection Laboratory Team Lead Dr. Leonard Peruski, “The promise and power of the GLLP is because of this collaboration. The expertise and experience provided by each of these organizations is complementary and fosters the use of best practices—a true ‘win-win’ for developing laboratory leaders to meet global needs.” ■

# Boots on the Ground: A Lab Perspective on Hepatitis A Virus Outbreak Response

by **Nicholas Ancona**, specialist, HIV, Hepatitis, STD & TB Programs

Hepatitis A virus (HAV) is the causative agent of a self-limiting vaccine-preventable liver disease. Since March 2017, outbreaks of HAV have been detected in 18 states nationwide with reported associations with individuals who use drugs, persons experiencing homelessness, and in MSM (men who have sex with men) communities. State and local public health laboratories have been engaged in epidemiological and laboratory response efforts aimed at combatting these outbreaks in conjunction with the CDC Division of Viral Hepatitis (DVH). In recognition of both Hepatitis Awareness Month (May) and **Hepatitis Testing Day** (May 19), Tracy Basler, molecular scientist, Public Health Services Laboratory, County of San Diego Health & Human Services Agency and Marty Soehnlén, PhD, MPH, director of infectious disease, Michigan Department of Health & Human Services Bureau of Laboratories spoke to APHL about their experiences with Hepatitis A virus (HAV) outbreak response efforts and ongoing work.

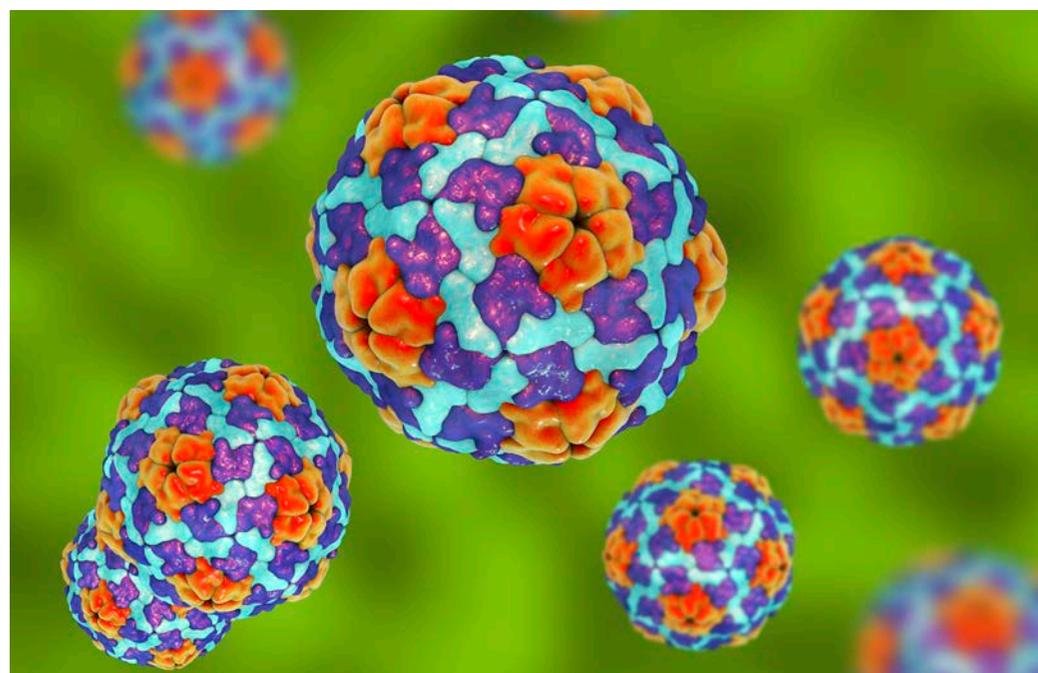
## Advice for Public Health Laboratories Current Responding to HAV Outbreaks

Basler suggested that laboratories use the outbreak response as an opportunity to assess existing capabilities and develop realistic goals. San Diego County identified the need to increase technological capacity during the outbreak response and worked with partners to implement a PCR screening assay to supplement existing serologic testing at external laboratories. She emphasized the importance of community partnerships and leveraging those in a way that would ultimately enhance laboratory capabilities. During the outbreak response, Basler and her colleagues built partnerships with multiple entities such as universities, non-profits and other public health laboratories. With the help of these organizations, San Diego County improved their communication with submitters and strengthened their bioinformatics infrastructure.

Soehnlén stressed the importance of working with partners to identify methods to streamline PCR and genotyping workflows so large volumes of samples do not overwhelm existing laboratory capabilities. Laboratorians may be interested in inquiring about serologic testing capacity at local hospitals as well as reaching out to CDC DVH with questions about the utility and application of molecular sequencing options. Since HAV is highly virulent and can spread rapidly across state lines, she suggested that laboratories prepare for an influx of a large number of samples and identify mechanisms to address staffing and ensure continuity of day-to-day laboratory operations.

## Value of Interjurisdictional Collaborations for Public Health Laboratorians

Basler was new to public health and was brought in during the outbreak. She was pleased to report how supportive and welcoming public health colleagues



Hepatitis A

**Since March 2017, outbreaks of HAV have been detected in 18 states nationwide with reported associations with individuals who use drugs, persons experiencing homelessness, and in MSM (men who have sex with men) communities. State and local public health laboratories have engaged in epidemiological and laboratory response efforts aimed at combatting these outbreaks in conjunction with the CDC Division of Viral Hepatitis (DVH).**

within her laboratory and in external jurisdictions were as she navigated a new world. In fact, San Diego already had a connection to Michigan. Basler's supervisor, Syreeta Steele, PhD, had worked extensively with Soehnlén who was Steele's coach through the APHL **Emerging Leaders Program**. Basler and Soehnlén, along with the California Department of Public Health's Viral and Rickettsial Diseases Laboratory (CDPH VRD), held bi-weekly calls during the outbreak response. These calls were beneficial as they navigated challenges associated with assay development and bioinformatics capabilities.

Soehnlén echoed Basler's response about the benefit of her connections with the County of San Diego as well as CDPH VRD.

She also noted that she found the **APHL Microbiology Discussion Community of Practice** site to be particularly useful. Through this community of practice, she built strong connections with public health laboratorians in New York and Kentucky, in addition to those in California.

Although Basler's and Soehnlén's professional and personal relationship proved to be an invaluable asset in the fight against HAV in their respective jurisdictions, the dedication and hard work of the staff they work beside cannot go unnoticed. They both emphasized the value of their staff. ■



Michigan Department of Health and Human Services HAV Team (from l to r): Diana Riner, Julie Day, Kevin Rodeman, Laura Mosher, Bruce Robeson



San Diego County Public Health Laboratory HAV Team (from l to r): Brett Austin, Jovan Shepherd, Tracy Basler, and Syreeta Steele

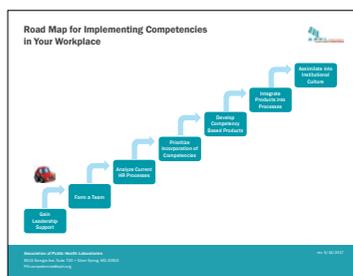
# Build a Competency-Based Lab



## Laboratory Competency Implementation Toolbox

Resources, tools and examples for behavior-based lab competencies

- ✓ Management
- ✓ Performance
- ✓ Retention
- ✓ Recruitment



**Competency Guidelines for Public Health Laboratory Professionals**  
Laboratory Professions are Challenged  
By Workforce Shortages and Retention of Qualified Professionals 1-3

**Checklist for Implementation of Laboratory Competencies**

- Leadership Support**
  - Establish leadership on Laboratory Competencies and the value of their work
  - Secure support and commitment
- Team Buy-In**
  - Ensure how competencies can be applied to address current pain points
  - Engage and engage a full champion
- Develop Job Profiles**
  - Establish processes for developing position descriptions, career ladders, learning performance and testing needs
  - Identify gaps need in needed equipment
- Practice of Competency**
  - Identify on what areas efforts can be most impactful and are easily achievable
  - Encourage and engage staff!
- Measure Competency**
  - Use Laboratory Competencies to develop position descriptions, career ladders, performance assessments, and/or testing needs assessments
  - Use APHL Competency Tools and Resources
- Assess the Impact on Culture**
  - Identify how processes such as position descriptions, career ladders or performance or testing assessments
  - Establish a pathway to support for additional products
  - Disseminate the use of Laboratory Competencies into human resource and regulatory processes
  - Ensure effectiveness and make as needed

**76% | 83% | 73%**

**Checklist for Implementation of Laboratory Competencies**

**Career Ladder Editable Template**

**Standard Qualifications**

Standard	Job	Job Description	Job Function	Job Title
1.1	1.1.1	1.1.1.1	1.1.1.1.1	1.1.1.1.1.1
1.2	1.2.1	1.2.1.1	1.2.1.1.1	1.2.1.1.1.1
1.3	1.3.1	1.3.1.1	1.3.1.1.1	1.3.1.1.1.1
1.4	1.4.1	1.4.1.1	1.4.1.1.1	1.4.1.1.1.1

[www.aphl.org/CompetencyTools](http://www.aphl.org/CompetencyTools)

To check out other APHL toolkits, visit [www.aphl.org/toolkits](http://www.aphl.org/toolkits)

## Looking For *Legionella*

By Jill Sakai, writer

Kara Levinson had only been in New Hampshire for a few weeks when a phone call last August set the course for her new position.

Two recent visitors to the beachside tourist town of Hampton, New Hampshire, had just been diagnosed with Legionnaire's disease. Within a week, two more reports had been linked to the same town.

As a [US Centers for Disease Control and Prevention \(CDC\)](#) Laboratory Leadership Service Fellow newly based at the New Hampshire Public Health Laboratories, Levinson suddenly found herself at the heart of New Hampshire's first *Legionella* outbreak investigation in decades.

The New Hampshire lab rushed to pull together a team of health officials, environmental scientists and epidemiologists and reached out for federal assistance. As the laboratory lead, Levinson became immersed in planning and testing while simultaneously navigating a multifaceted response involving numerous labs and public officials on the ground in Hampton. With no recent outbreak experience to guide the investigation, the team managed issues as they arose and successfully pinpointed a town hotel as the source of the outbreak.

"It was an outbreak that taught us a lot. We're a relatively small state and we have a relatively small population, and Legionellosis is not something we deal with routinely," Levinson said.

With reported cases on the rise around the country, other states may find themselves in a similar position. [Reported Legionellosis cases to the CDC](#) increased nearly five and a half times from 2000 to 2017. Whether the bacterium is becoming more prevalent in the environment is not clear, but growing awareness, increased testing and advances in test sensitivity may be increasing detection of the pathogen. Together, these changes are bringing questions about *Legionella*



*Legionella pneumophila* growing on specialized microbiological media (BYCE). Photo: CDC

**“A huge component of *Legionella* investigations is the environmental sampling, and a lot of states, including us, are considering expanding our testing capabilities to include both clinical and environmental testing.”**

*Kara Levinson*

surveillance, testing and response to the forefront for public health labs across the country.

### Put to the Test

Since the 2017 directive from the Centers for Medicare and Medicaid Services (CMS) that requires healthcare facilities to reduce the risk of *Legionella* transmission through building water systems, Nancy Hall has seen greater awareness and more testing demand. Hall is the environmental microbiology manager at the State Hygienic Laboratory in Iowa, where a *Legionella* outbreak early in her 40-year

career launched her expertise in the organism. But testing is often not the right first step, she said.

The organism is ubiquitous in the environment, so “more likely than not, the labs will find it,” she noted. “But just because you find it doesn’t mean it’s going to cause illness.” A better place to start, she said, is education.

Essentially all *Legionella* outbreaks are preventable through proper maintenance of water systems. Hall directs people to [the CDC toolkit](#), which provides information and resources

about developing a water management program. “I think public health labs need to educate the health care community,” she said. “The first thing they should do is not test, but to focus their efforts on developing and implementing that water management plan.”

Even public health labs that aren’t involved in routine environmental testing can play a key role in helping facilities know what questions to ask and in connecting them with resources to find the expertise they need.

But when suspected or reported cases emerge, it’s important to know whose role it is to conduct and interpret environmental tests as part of an investigation, Levinson said.

The Hampton investigation has led the New Hampshire team to reexamine its approach. “Prior to the outbreak, we offered clinical testing,” Levinson said. “But a huge component of *Legionella* investigations is the environmental sampling, and a lot of states, including us, are considering expanding our testing capabilities to include both clinical and environmental testing.” They’re also thinking about moving beyond culture and antibody-based methods to add molecular methodology and DNA sequencing.

### Connecting the Dots

More advanced testing capabilities have been key in New York City, said Scott Hughes, associate director of the NYC Department of Health and Mental Hygiene. During a large outbreak in the Bronx in 2015, the NYC lab worked with the state’s Wadsworth Center and CDC to implement improved methodology, including polymerase chain reaction (PCR) to screen environmental samples for *Legionella* DNA. That allowed the response team to quickly triage samples and reduce the need for slow and finicky bacterial cultures.

They also used pulsed-field gel electrophoresis and whole-genome sequencing to compare strains from environmental and clinical samples, much like is often done in foodborne illness outbreaks. “We’re really doing the same thing, linking *Legionella* patients to the environmental source,” Hughes said. In that way, they were able to identify the specific cooling tower responsible for the outbreak and begin remediation efforts. They’ve continued to use these approaches with good results in subsequent outbreaks.

Of course, such methods rely on having clinical isolates to analyze—and unfortunately, that remains a challenge, Hughes said. Hospitals often use rapid urinary antigen tests to diagnose *Legionella* infections and determine a course of treatment for the patient. Far fewer clinics routinely collect or culture respiratory samples. We’re “continuing to educate hospital facilities about how important it is that we receive isolates, especially during cluster investigations,” Hughes said.

Another challenge is being prepared for more frequent outbreaks, he added. Given the complexity of working with *Legionella*, he recommends having testing expertise in place before you need it. “In 2015 we were unprepared for a large outbreak,” he said. Now, “the agency as a whole is looking much more closely for potential outbreaks and clusters.”

### The Value of Collaboration

For some labs, that preparation may mean developing in-house testing expertise, such as certification through the [Environmental \*Legionella\* Isolation Techniques Evaluation \(ELITE\)](#) program. For others, it may involve strategic partnerships.

Levinson suggests a regional approach to decision-making. “We’re learning not every state has to reinvent the wheel and offer everything themselves,” she said. Instead, they are evaluating their needs and resources and talking to neighboring states to balance local and regional capabilities.

Hughes agreed that region-specific collaborations are crucial in both surveillance and response efforts. Since New York City and State passed laws in 2015 mandating regular cooling tower checks, for example, the NYC lab works closely with the Bureau of Water and Sewer Operations.

Those partnerships are built on strong lines of communication among a range of health and environmental stakeholders at local, regional and national levels. They can also include non-traditional public health partners such as city officials, utilities and emergency responders, all of whom Levinson found invaluable during the Hampton outbreak.

Public health labs sit at the nexus of all of these moving parts. “The most critical role of the PHL is helping guide and provide explanations of how to interpret the laboratory tests,” said Levinson. “What they can—and can’t—tell you is really critical to how you communicate risk to the public.”

Part of that includes understanding the baseline local ecology of the organism well enough to be able to identify changes that might signal an outbreak. In one ambitious project, Hall and the Iowa lab are sequencing years of archived *Legionella* samples to learn more about strain variation and trends over time.

As people live longer and water infrastructure ages, climates shift and test methods evolve, outbreak investigations are likely to become even more complex, Levinson said. “Everyone has to come together with their representative expertise from the environmental site, the epidemiology side, as well as the laboratory side, to be able to put the pieces together and make decisions that ultimately protect the public’s health.” ■

# MeVA Assay Aids Public Health Labs in Fight Against Measles

by **Alisa Bochnowski**, senior specialist, Respiratory Diseases

Almost 20 years after measles was declared eradicated, outbreaks of the virus continue to plague the United States. International travel to areas where the virus remains endemic coupled with communities with low vaccination rates have led to hundreds of infections over the last decade and, subsequently, additional testing assistance from public health laboratories. With the number of confirmed cases currently surpassing pre-eradication declaration levels—and still rising—a new assay has given public health laboratories a new tool in the fight against the spread of the disease.

## Rash or Reaction?

Measles vaccination of vaccine naïve individuals is an important part of curbing an outbreak; however, approximately 5% of individuals vaccinated with a measles-containing vaccine develop clinically indistinguishable symptoms from measles infection (e.g., fever, rash). The routinely used measles virus reverse transcription PCR (RT-qPCR) assay (MeV) cannot distinguish between wild-type infection and vaccine reaction, and sequencing, which could delineate between wild-type and vaccine associated rash, can take up to 72 hours to yield results. To assist in the rapid differentiation between the two, **CDC developed the Measles Virus genotype A RT-qPCR (MeVA)** based on the detection of genotype A nucleoprotein regions that are unique to the vaccine. This assay was adopted by the Vaccine Preventable Disease Reference Centers in 2018 and used for testing during outbreaks in New York, Washington and Texas.

The reference center in Minnesota recently employed the MeVA assay in the case of a child from Minnesota that received the MMR vaccine and then traveled internationally. After returning home to Minnesota, the child began

exhibiting symptoms that raised the suspicion of measles three weeks post-vaccination. Because of the recent travel and the vaccination history, the clinician wanted to rule out wild-type measles infection. At the Minnesota Department of Health, they first ran the MeV assay, which resulted in a late positive (Ct score ~38). Attempts to genotype this specimen would likely have been indeterminate since the sensitivity of the genotyping assay decreases in specimens with Ct scores higher than 34 and genotyping would have pushed the result reporting back 24-72 hours. Minnesota was able to run the MeVA assay, which was indeterminate, and combined with early lab data and epidemiological case investigation make a determination to treat the rash as unrelated to either measles or the vaccine.

## Speeding Results for Treatment

Not only does the MeVA assay cut down on time to diagnosis, it can also spare patients from unnecessary medical treatments and the public from panic. During a 2017 outbreak of measles in Washington, the delay in genotyping confirmation resulted in two pregnant women being given IVIG after exposure to individuals who ended up having vaccine-associated rashes, not wild-type cases. Had MeVA been available, these pregnant women would not have been treated with IVIG. In another instance in Washington, a person with a vaccine-associated rash was reported to the media as a suspect measles case due to concern about multiple exposure sites. The public health system had to mitigate public concern and respond to this case for several days before the rash was confirmed as vaccine related. During the current outbreak of measles in Washington and Oregon, the MeVA assay is being used to differentiate between wild-type and vaccine associated rashes saving individuals from



## DID YOU KNOW?

**You can request MeVA testing when submitting specimens to the reference centers for testing. By directly requesting MeVA and supplying patient vaccination history you can help identify the correct diagnostic method and expedite testing. Please contact [infectious.diseases@aphl.org](mailto:infectious.diseases@aphl.org) for more information.**

unnecessary medical treatments and the public from unwarranted concern.

Sociopolitical trends coupled with a high incidence of disease abroad indicate that measles will continue to be an ongoing public health issue in the United States. Every measles outbreak affects the entire public health infrastructure, but the availability of the MeVA assay provides a new tool to help public health officials and clinicians make informed decisions and to appropriately allocate resources during outbreaks. ■

# APHL Makes Progress on Electronic Lab Reporting for Animal Rabies

by Rachel Shepherd, specialist, Informatics

Reliable and timely methods for data exchange are critical for the surveillance of animal rabies disease. Currently, most laboratories that APHL works with either are not reporting or are sporadically reporting rabies data manually in a variety of ways. Typically, the [US Centers for Disease Control and Prevention \(CDC\)](#) receives rabies data from laboratories on an annual basis, making surveillance nearly impossible.

In order to facilitate more timely rabies reporting, APHL is collaborating with the US Centers for Disease Control and Prevention (CDC) Poxvirus and Rabies Branch (PRB) and reporting entities (REs) including public health, agriculture and academic laboratories to accelerate the adoption of standardized Health-Level Seven (HL7) ELR 2.5.1 results to improve the overall national picture of rabies disease trends.

APHL's technical assistance team for electronic lab reporting (ELR) of rabies—consisting of technical architects and terminologists and funded by the CDC—works with the laboratory to electronically report animal rabies data using a standardized vocabulary and message format. Not only does this automation ease the reporting burden for laboratorians, it ensures the timely and accurate flow of information to CDC. Reporting happens in near real-time, providing a comprehensive snapshot of rabies trends.

To achieve this, APHL works alongside the laboratory informatics team, state epidemiologists and state veterinarians to build and validate messages. The ELR does not take the place of or supersede existing mechanisms for reporting to state epidemiologists; rather it works alongside a laboratory's existing system.

For most laboratories, especially those who have already upgraded to 2.5.1 HL7, this project is quite manageable, as the



Digital illustration of Rabies virus

**APHL's technical assistance team for electronic lab reporting (ELR) of rabies—consisting of technical architects and terminologists and funded by the CDC—works with the laboratory to electronically report animal rabies data using a standardized vocabulary and message format.**

rabies message uses the same format as PHLIP 2.5.1. If laboratories are working with APHL on other technical assistance, rabies messaging could easily be treated as a tack-on project.

Right now, three laboratories are in full production and actively reporting, and nine others are in the onboarding and validation process. APHL is striving to get the majority of states electronically reporting their animal rabies data by the end of the year. ■

To find out how your laboratory can electronically report Animal Rabies data, please contact Rachel Shepherd at [Rachel.shepherd@aphl.org](mailto:Rachel.shepherd@aphl.org), or 240-485-2796.

## Ensuring Readiness for Rabies in Puerto Rico

by Sean Page, associate specialist, Public Health Preparedness and Response

In late 2018, APHL was awarded a two-year, \$15.1 million cooperative agreement by the US Centers for Disease Control and Prevention (CDC) to provide technical assistance for response to public health crises in three jurisdictions—Puerto Rico (PR), US Virgin Islands (USVI) and Houston—impacted by hurricanes. The Center for State, Tribal, Local and Territorial Support (CSTLTS) Office of Insular Affairs manages this cooperative agreement with APHL and coordinates across CDC to provide leadership for crisis response in the impacted jurisdictions.

Key activities for APHL encompass human capacity building in the jurisdictions – to date, APHL has hired over 30 local staff to support Puerto Rico and four local staff to support USVI. The range of these activities include procurement of equipment, reagents, vaccines and other supplies, training of staff and travel support. To accomplish these activities, APHL is using a modified approach, which facilitates expedited delivery of much needed goods and services.

APHL engaged in discussions with PR Department of Health State Epidemiologist, Dr. Carmen Deseda, and other key personnel to gather information on rabies needs on the island. Rabies is an immediate threat for the residents of PR due to large populations of stray dogs and mongooses. Given the urgent need for rabies treatment in PR, APHL collaborated across CDC and externally to procure over 1,000 vials of rabies vaccines and over 700 vials of human rabies immunoglobulin (HRIG).

### Finding a Cost-Effective Procurement Process

In order to expedite the procurement of vaccines and HRIG, APHL turned to local vendors in Puerto Rico for a fast solution. As APHL researched and obtained quotes, however, it discovered that pricing of vaccines and HRIG were much higher at the local level than what was originally budgeted.

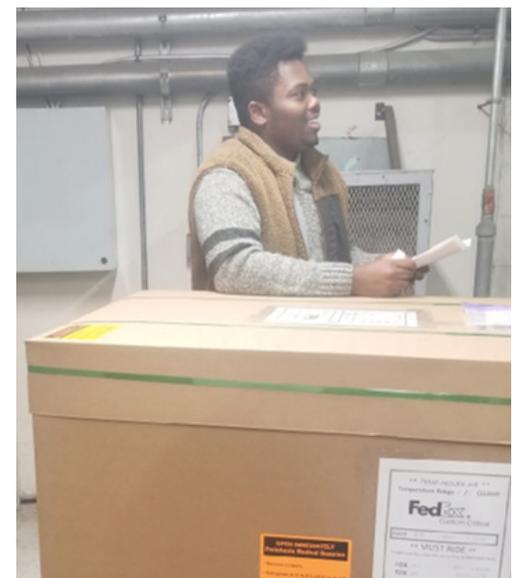


**Rabies is an immediate threat for the residents of PR due to large populations of stray dogs and mongooses. Given the urgent need for rabies treatment in PR, APHL collaborated across CDC and externally to procure over 1,000 vials of rabies vaccines and over 700 vials of human rabies immunoglobulin (HRIG).**

APHL turned to vaccine producers with offices on the mainland US to identify more cost-effective products. With much persistence and collaboration, APHL procured the vast amount of vaccines and HRIG. Additionally, APHL collaborated with FedEx and Worldwide Diagnostics to ensure cold chain was maintained during shipment.

FedEx and Worldwide Diagnostics worked to ensure both shipments cleared the PR customs process in an expedited manner. In addition, APHL coordinated with the PR Department of Health and CDC staff in Puerto Rico to confirm the vaccines and HRIG reached the OCASET Pharmacy. The partners also confirmed the shipment's temperature of 2°C–8°C was maintained.

This procurement story demonstrates the importance of public-private partnerships to support readiness and response to major public health threats, such as rabies. ■



Sean Page along with PHPR staff organized a FedEx shipment of rabies vaccines from APHL

# Public Health System Recovery in Full Swing: Hurricane Response in Puerto Rico and the US Virgin Islands

by **Jill Sutton**, associate specialist, Crisis Response

Following back-to-back hurricanes in 2017, public health laboratories and other programs within the Puerto Rico Department of Health (PRDH) and the US Virgin Islands Department of Health (USVIDOH) entered into response and recovery mode. Nearly 19 months later, both jurisdictions are continuing to restore public health infrastructure that is vital for detecting and responding to health threats.

With the help of external partners such as APHL, the US Centers for Disease Control and Prevention (CDC) and other non-governmental organizations, both jurisdictions' public health laboratories have been able to:

1. Implement a temporary specimen transport system to restore specimen testing capacity.
2. Address procurement needs to replace or repair equipment, reagents and other supplies needed to ensure public health operations and services have the capacity to support local public health needs.
3. Assess and respond to critical health infrastructure damage.
4. Scale up staffing to support gaps in workforce needed to maintain laboratory operations and services.

## Repairing the Critical Infrastructure Needed to Support Quality Laboratory Systems

PRDH recognized that in order to mitigate the impact of future public health emergencies—especially hurricanes—their laboratory network must scale up their capabilities and capacity to support both immediate and long-term public health testing needs. With coordination and collaboration from external partners, PRDH prioritized implementing whole genome sequencing (WGS) within the bacteriology/molecular laboratory to improve testing capacity for infectious diseases. However, prior to implementing



The PRDOH Bacteriology Molecular Lab minor repairs completion marks the beginning of genomic sequencing for outbreak identification and for the detection of bacterial special pathogens in Puerto Rico



this technology, structural damage that occurred to the lab in San Juan had to be addressed. Repairs on the molecular laboratory began in January 2019 and are expected to be complete by the end of May 2019.

Another priority project to further support catastrophic readiness is the implementation of a laboratory quality management system. This project has been initiated across all PRDH laboratories to harmonize and strengthen key operations such as biosafety and biosecurity, information management, equipment maintenance, procurement tracking and continual workforce training.

## USVIDOH – Health Information Management and Exchange to Address Data Access and Exchange

Ensuring rapid and secure exchange of laboratory data is a priority at the USVIDOH. During a disaster situation, lives depend on the ability to use public health laboratory data to inform public health decisions. With support from APHL and CDC, the USVIDOH public health laboratory plans to enhance their current laboratory information management

system (LIMS) and move from off-site hosting to on-site. The purpose of transitioning to an on-site hosting environment is to eliminate potential issues with internet infrastructure should it be interrupted during a natural disaster. With the infrastructure in place to support data storage on-site, access to laboratory data during a public health crisis will not be delayed.

After the 2017 hurricanes, patients and healthcare providers had limited access to medical records. In addition to enhancing their existing LIMS system, USVIDOH is prioritizing the development and implementation of a universal repository for health data that not only public health officials and laboratorians will have access to, but also healthcare providers and patients. Access to information such as vaccination records, health screenings, laboratory results and treatment status of a patient's pre-existing condition can drastically improve the medical response and minimize the operational impact in USVI. ■

# The Future of Biosafety and Biosecurity in the Public Health Laboratory

by **Michael Marsico**, senior specialist, Biosafety and Biosecurity

In 2015, 64 state, local and territorial public health laboratories (PHLs) were part of the three-year, \$24 million **US Centers for Disease Control and Prevention (CDC) Epidemiology and Laboratory Capacity Domestic Ebola Supplemental for Enhanced Laboratory Biosafety and Biosecurity Capacity cooperative agreement (ELC Ebola Biosafety Agreement)**. The agreement was designed to enhance PHL biosafety capacity and improve coordination and outreach with clinical laboratories. With assistance from APHL over the span of the agreement, PHLs were able to not only enhance their internal biosafety programs, but also provide biosafety guidance to clinical laboratories.

For jurisdictions that requested an extension of the three-year funding, CDC approved this requested and laboratories continued their efforts through March 2019. With the CDC ELC Cooperative Agreement ending this year, laboratories are vulnerable to losing their biosafety officers and the biosafety capacity achieved since 2015. These laboratories rely heavily on federal funding to sustain their biosafety activities, especially training and outreach activities to clinical labs. Four laboratories look towards the future.



Bryan Burk

## **Biosafety Officer William Bryan Burk Utah Public Health Laboratory**

### **What is one key accomplishment in biosafety and biosecurity you are proud to share?**

“I’ve produced a weekly newsletter that has vitalized communication between our facility and the sentinel clinical labs we serve. By being in a position to propagate a message of biosafety to my clinical laboratory partners, I promote the significance of risk awareness and the importance of implementing mitigation to the betterment of public health overall. I would like to note the training and onboarding provided to me by UPHL, APHL, CDC, the Laboratory Response Network and Sean Kaufman’s program have given me an understanding and insight that 35+ years of laboratory bench experience never even touched. With the biosafety program, a light has been cast upon an aspect of the profession long kept in the dark. I now have a clearer, focused perspective about the risk, consequence and mitigation of biological hazards.”

### **What is the future plan for biosafety for your public health laboratory?**

“I am fortunate to have leadership that values my input and outreach, and my efforts have helped to bridge the gap

between the state PHL and sentinel clinical laboratories. Our budget was adjusted to accommodate a BSO position going forward. I’m recognized for an impact on safety awareness in this lab and across Utah’s hospital laboratories and that is expressed in a promising future for the position.”

## **Former Deputy Laboratory Director Michael Stevenson, PhD Idaho Bureau of Laboratories (IBL)**

### **What gap(s) do you believe still need to be addressed in regards to biosafety and biosecurity?**

“There is still a gap in having Division 6.2 Infectious Substances properly packaged and shipped according to Department of Transportation regulations. We continue to see specimens sent to our state PHL that are not properly packaged—this is more noticeable in samples sent by veterinarians of animal heads or bats for rabies testing. We recognize that outreach is needed for vets to learn how to properly package and ship Division 6.2 Infectious Substances.”

### **What is the future plan for biosafety for your public health laboratory?**

“We have been fortunate to have Hospital Preparedness Program funding for these workshops over the past several years. With the loss of the ELC Ebola Biosafety



Michael Stevenson



Andy Cannons

Agreement, we plan to ask for funding for a partial full-time equivalent personnel from the Public Health and Emergency Preparedness cooperative agreement. Regardless of funding, we will continue outreach with sentinel labs in the form of workshops and other training opportunities.”

**Laboratory Director  
Andrew Cannons, PhD, HCLD/CC  
(ABB) and Biosafety Outreach Officer  
Edgar Kopp**

Florida Department of Health Bureau of  
Public Health Laboratories (BPHL) – Tampa

**What gap(s) do you believe still need to  
be addressed in regards to biosafety and  
biosecurity?**

“Clinical labs have to test a large number of specimens as quickly and cheaply as possible. Due to space, time and/or monetary constraints, errors can occur even when staff are aware of the potential biosafety gaps in their testing procedures. This has led to continued *Brucella* exposures across Florida. Biosafety cabinets (BSCs) are not used when they should be for specimen and culture observation and manipulation. Basic biosafety practices, such as capping tubes and working in a BSC when vortex mixing a solution containing bacterial cultures, are sometimes not followed. This is especially unfortunate when that culture contained a low inhalation infectious dose bacterium such as *Brucella*, with vortex mixing noted in the biosafety literature as being a major aerosol generating activity.”



Ed Kopp

**What is the future plan for biosafety for  
your public health laboratory?**

“BPHL will maintain its culture of safety as well as possible in the years following the ending of the ELC Biosafety funding. Training, biosafety risk assessments, exercises and other biosafety initiatives will be continued as required to meet Select Agent regulations, OSHA requirements and other legal obligations while trying as much as possible to do more beyond that. BPHL is working with the Florida legislature to establish permanent biosafety outreach officer positions to continue the biosafety work it began under ELC Biosafety funding well into the future.”

**Biosafety Officer Kristin Long, PhD  
North Carolina State Laboratory of Public  
Health (NCSLPH)**

**What is one key accomplishment in  
biosafety and biosecurity you are proud  
to share?**

“Providing increased biosafety support to our public health partners throughout North Carolina. We created a Biosafety section on the state laboratory website that includes links to document templates, free training opportunities and biosafety guidance resources. In addition, we designed fillable templates for both a BSL2 Biosafety Plan and a Biorisk Assessment and Mitigation Worksheet offered through the website. We have worked alongside our Communicable Diseases group and presented biosafety information at numerous public health meetings and venues as well as collaborating with them and the CDC to investigate a unique lab associated infection that occurred in an academic

laboratory in the state in 2018. occurred in an academic laboratory in the state.

“In the past year, NCSLPH provided two very exciting and successful opportunities for public health partners in North Carolina. A workshop titled ‘Fostering a Culture of Biosafety’, facilitated by Eagleson Institute was designed to provide valuable training to host clinical laboratories and local health departments. Recently, NCSLPH joined with APHL to host a forum to discuss the effectiveness of biosafety outreach programs between public health and clinical laboratories and the ongoing biosafety needs of clinical laboratories in NC.” ■



Kristin Long

At the national level, APHL will continue its efforts to support public health and private clinical laboratories with strengthening biosafety and biosecurity. More information on APHL's initiatives is available at: [www.aphl.org/biosafety](http://www.aphl.org/biosafety). To share your stories or request assistance, contact APHL at [biosafety@aphl.org](mailto:biosafety@aphl.org).

# Celebrating 20 Years of the Laboratory Response Network: Partnering in Preparedness and Response

by Tyler Wolford, MS, manager, Emergency Preparedness and Response

In 2019, the **Laboratory Response Network (LRN)** will celebrate two decades of laboratory preparedness and response for biological, chemical, radiological and emerging threats. The nationwide, all-hazards network has come far since 1999, when public health laboratory scientists were largely classically-trained microbiologists and chemists. In the years since its creation, the LRN has played an instrumental role in improving the public health infrastructure by helping to boost laboratory capacity. Laboratories are better equipped, their staff levels are increasing, and laboratories are employing advanced technologies. Improving capability and capacity is only a piece of the puzzle. LRN laboratories also build and sustain partnerships with clinical laboratories, first responders, the Federal Bureau of Investigation (FBI), **US Centers for Disease Control and Prevention (CDC)**, Department of Defense and others, which are critical to respond to evolving public health threats.

## LRN in Action

The LRN has successfully responded to a variety of domestic and international threats since 1999. In the beginning, laboratories focused on just a few biological threat agents. Over the years, LRN has evolved to respond to chemical and radiological threats, as well as emerging infectious diseases such as Ebola. LRN is transforming into a multipurpose tool with a focus on new technologies and laboratory efficiency initiatives that improve the capacity and capability to respond to new threats. In addition, the core infrastructure of LRN is being leveraged for expanding and improving coverage in high-risk population areas. Via these changes, LRN will continue to maintain strategic partnerships and provide efficient, accurate testing across the network.

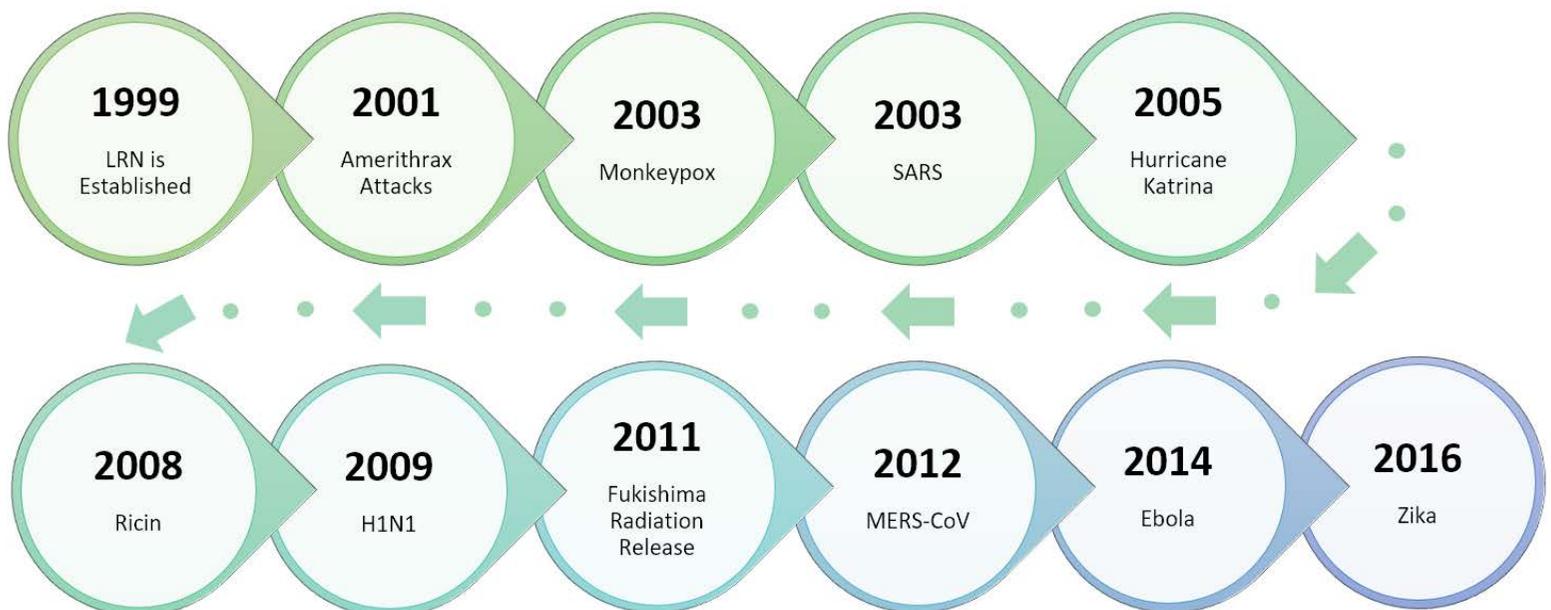
## Unique Networks within the LRN

The state of Texas has ten LRN member laboratories at the Reference level who provide testing coverage for over 28

million residents. The partnerships among the Texas LRN laboratories and organizations such as the Texas State Chemist, the Brooke Army Medical Center, and FBI makes for a strong network able to respond to a variety of biological and chemical threats. Although members stay in constant contact through conference calls and email, the Texas Department of State Health Services convenes these laboratories once a year to discuss preparedness and response efforts. Opportunities like this facilitate partnership building among the Texas LRN laboratories and are crucial in the success of preparedness and response efforts in Texas.

The Minnesota Laboratory System (MLS) is a statewide network of laboratories established in 2001 by the Minnesota Department of Health Public Health Laboratory to facilitate communication and coordination. MLS consists of more than 70 public health and clinical laboratories, as well as veterinary and agriculture laboratories which serve as sentinel laboratories in LRN. In addition to

Laboratory Response Network (LRN) responses to biological, chemical, radiological, and emerging infectious disease threats since 1999.



## 2019 PREPAREDNESS SUMMIT

For the 20th anniversary, APHL and CDC are leading an initiative to highlight the role and success of the LRN, especially as it pertains to partnerships in biological, chemical, radiological and emerging threat detection and response. The 2019 Preparedness Summit in St. Louis, MO, co-sponsored by APHL, provided a forum for public health and emergency preparedness professionals to network, share current information on preparedness collaborations and emerging technologies, share model practices, and discuss solutions to ongoing challenges. At this year's Summit, APHL hosted three LRN sessions covering everything from laboratory testing capacity and capabilities to partnerships with clinical laboratories, FBI, National Guard Bureau Civil Support Teams and other first responders. ■

providing a laboratory network essential for statewide emergency preparedness and response, MLS also plays a key role in detecting emerging infectious disease outbreaks.

The Florida Bureau of Public Health Laboratories (BPHL), with LRN member laboratories in Jacksonville, Tampa, and Miami, utilized their network of laboratories to respond to the Zika virus outbreak in 2016. Florida was the first state to report local transmission of Zika virus. However, by this time, the Florida BPHL had already implemented laboratory testing capabilities and worked with the health department on mitigation programs to combat the virus spreading. Within six months Florida was declared Zika free. Communication among the laboratories in Florida contributed to the successful coordination of efforts to eliminate the threat of Zika in the state.

Part of LRN's success over the last 20 years' in being well equipped to respond to threats, lie in strong partnerships. By maintaining partnerships across multiple sectors, the LRN can continue to meet new, challenging demands, as threats continue to evolve. ■

# Using MicrobeNet to Enhance Biothreat Agent Detection

by **Robert Nickla**, RBP, M(ASCP), LRN coordinator, Oregon State Public Health Laboratory and **Samuel Abrams**, MPH, PMP, specialist, Public Health Preparedness and Response

The **US Centers for Disease Control and Prevention** (CDC) curates and provides a free online database containing a variety of identification information for pathogens that are not commonly encountered in laboratory diagnostic testing. Known as **MicrobeNet**, the database was established by CDC in 2013 to assist public health laboratories (PHLs) and sentinel clinical laboratories with diagnostic capabilities and species identifications, and is updated monthly. MicrobeNet is a robust and powerful online tool that can provide laboratorians the capability option to search for species identification assistance based on genetic sequence (16s ribosomal), phenotype biochemical profiles, or by real time protein classification profiles, the latter of which is generated by matrix-assisted laser desorption/ionization – time of flight mass spectrometry (MALDI-TOF MS) technology.

## MicrobeNet as a Resource

MicrobeNet provides a unique, expansive resource that many laboratorians are now learning about. In addition to having an easily searchable database, individuals are able to submit their MALDI-TOF MS system read files to compare against MicrobeNet. In instances where PHL MALDI-TOF MS software libraries return an inconclusive match, the protein profile can be submitted online to MicrobeNet and compared against the CDC's libraries. Within a few moments the user will be provided the best matches for their sample, which may help with specific identification of a potential biothreat pathogen. MicrobeNet is intended for use by PHLs, clinical laboratories and research laboratories worldwide.

## Why Use MicrobeNet?

Among the countless number of samples processed monthly, both PHLs and clinical laboratories may encounter rare or emerging pathogens, and routinely encounter potential biothreat agents. MALDI-TOF instruments are becoming common in the microbiology laboratory and although laboratories continue to implement the use of MALDI-TOF MS technology for specimen identification, the software libraries used for identification are often limited in their capability and adding additional libraries can be cost prohibitive or not yet available. Typically, a laboratory only utilizes the MALDI-TOF library that is provided from their instrumentation manufacturer. MicrobeNet consists of the manufacturers' database, but also offers an increased database that is comprised of a merged library of the manufacturers' entries plus the entries that CDC has added to their own connected library. The enhanced MicrobeNet library provides a free resource that is fast, expansive and highly accurate, allowing a laboratorian to further speciate their sample and determine whether a biothreat agent or near-neighbor is likely contained within the sample. This enhanced library detection assistance can provide an increase in accuracy identification matching results, and can help decrease the amount of time a clinical laboratory spends handling and testing a potentially significant pathogen, such as a biothreat agent rule-out. The increased identification efficiency leads towards safer laboratories with fewer exposure potentials, and ultimately better patient outcomes with faster and more accurate results. ■

### DIGITAL EXTRA:

[Read about how the State Hygienic Laboratory at the University of Iowa uses MicrobeNet.](#)

## The Laboratory District: Protecting the Nation's Capital

by Nancy Maddox, MPH, writer

Washington, DC—part local/state jurisdiction, part federal city, part tourist magnet—is “very different now than it was 20 years ago,” says Anthony Tran, DrPH, MPH, D(ABMM), head of the **District of Columbia (DC) Public Health Laboratory**. A new crop of businesses, new ballpark, changing neighborhoods and Michelin-starred restaurants give the area a “Manhattan-esque” vibe says Tran, a former Midtown Manhattanite himself. But just as the city has changed, so too has its public health laboratory, now housed in a cutting-edge, 6.5-year-old building near L’Enfant Plaza.

Unlike most public health laboratories (PHLs), the DC laboratory is not part of its jurisdiction’s health agency. Instead, it is a division of the laboratory-focused DC Department of Forensic Sciences, which also includes the Forensic Science Laboratory and Crime Scene Sciences Division.

In recent years, DC PHL has done everything from testing a raccoon that attacked a US park ranger (it was positive for rabies) to processing “near-record numbers” of unknown white powders to analyzing an unusual sheen on the Potomac River (caused by turbine oil). But its bread-and-butter work is disease surveillance, controlled substances testing and diagnostic and reference testing on behalf of the DC Department of Health (DC Health) and area clinics and hospitals.

### Facility

In 2012, the laboratory moved into a brand-new glass, steel and concrete building across the street from the **Centers for Disease Control and Prevention’s** (CDC’s) DC office and just blocks away from the US Capitol, White House, FBI headquarters and dozens of other high-profile federal landmarks. The facility is a 15-minute walk from the District Wharf—a \$2 billion revitalization of DC’s Southwest Waterfront—and from the acclaimed Arena Stage theater, where the laboratory hosts large-scale events.



The staff of the DC Public Health Laboratory. Photo: DC PHL

The 351,000-square-foot building boasts two BSL-3 suites and a Leadership in Energy and Environmental Design (LEED) platinum certification—the highest level possible. It sports such ecofriendly components as a green roof, waterless urinals and a system of external glass panels that auto-adjust to regulate the building’s sun exposure and internal temperature. A multi-tiered security system includes outdoor barricades (concealed in benches and planters), 24-hour camera surveillance, iris scans, electronic badges and physical door locks.

The PHL occupies 33,539 square feet of the eight-story building, taking up the fourth floor and parts of the second floor.

### Director

Tran was born in Washington, DC, and raised in nearby Montgomery County, Maryland. He earned a BS in medical technology from the University of Maryland School of Medicine and went to work for the National Institutes of Health testing specimens from patients enrolled in clinical research studies. After gaining an MPH from University of Maryland College Park, Tran became APHL’s HIV/STD/TB Program manager and also worked in the association’s global health areas for over seven years. Tran left APHL to continue his education at the University of California, Berkeley, where he earned a DrPH. Following graduation, Tran secured a coveted American Society for Microbiology Committee on Postdoctoral Education Programs

fellowship, based at the University of North Carolina–Chapel Hill Hospitals. At the conclusion of his fellowship, he became a diplomate of the American Board of Medical Microbiology and took a position at the New York City PHL, where he oversaw laboratory operations and provided technical input into all scientific areas. In 2016, Tran returned to Washington to fill the newly vacated director’s post at DC PHL.

### Staff

The laboratory has 34.5 FTEs, including a scientific staff of 10 chemists and 17 medical technologists. It also supports a laboratory/epidemiology coordinator who splits her time between the PHL and the DC Health, and employs three contract chemists and two contract medical technologists.

### Revenue

The laboratory’s \$5.6 million annual budget comes from a combination of city funds (60.2%) and federal grants (39.8%).

### Testing

Owing to its physical and organizational position, the laboratory has a unique and broad portfolio encompassing “all the PHL stuff an urban jurisdiction requires.” That means no dairy testing, but ability to check for contamination at public spray parks in summertime. The laboratory participates in the PulseNet foodborne disease surveillance network, Antimicrobial Resistance Laboratory Network, Laboratory Response Network (LRN) for biological pathogens (Tier 1 capabilities), LRN for chemical agents (Level 2), CaliciNet, OutbreakNet Enhanced, FluNet and ArboNet. Among other things, it has ability to confirm infection with Ebola virus and other emerging pathogens, to measure trace elements in environmental samples, to identify pathogens in foods and to analyze law enforcement seizures for novel street drugs.



The LEED platinum certified facility at 401 E Street, SW. Photo: DC PHL

## Success Stories

- Developing a “sequencing core” that processes and tests biological samples on behalf of other laboratory units and provides the data back to them. Over the course of 2018, DC PHL “went from no PulseNet WGS and one sequencer to PulseNet WGS certified and four sequencers.” In addition, staff are “taking the manual work out of next generation sequencing (NGS)” and applying NGS technologies to novel areas; for example, using automated nucleic extraction and library preparation and developing CLIA-approved field protocols to enable NGS at point-of-care sites
- Achieving surveillance of nearly all heroin and most other synthetic opioids and cannabinoid drugs seized by DC law enforcement personnel in undercover buys or arrests—perhaps the only US jurisdiction to do so. Laboratory drug testing—supported by a cooperative agreement from CDC—is independent of any legal proceedings and has so far identified roughly half a dozen opioid analogues and half a dozen synthetic cannabinoids previously unseen in DC.
- Providing technical expertise to DC government leaders. Despite its national and global prominence, the DC government is small enough that “we’re able to interact intimately with other agencies,” said Tran. A recent collaboration with the DC Office of the Attorney General led to the SAFE

DC Act, which completely revamps the city’s controlled substance’s list. Said Luke Short, PhD, chief of the PHL’s chemistry section, “As you find new, opioid analogues and synthetic cannabinoids on the street, if they’re not in the law, you can’t arrest anyone for possessing or selling them.” Instead of enumerating such analogues drug-by-drug, the SAFE DC Act creates a taxonomy of controlled substances, based on the class of chemical compounds in the drugs. “DC is pioneering a whole new approach to dealing with controlled substances,” said Short.

- Working with the DC medical examiner on quick-turnaround “STAT” requests. As Tran explained, “STAT requests might seem unusual for someone who is no longer living. But here, if the medical examiner, upon autopsy, finds signs of anything potentially highly contagious, they will request a STAT test to quickly identify the cause of demise. A couple weeks ago, we had such a request, and the cause of death was identified as meningitis, which is highly contagious and can pose a severe public health threat, if that is what killed the person.”
- Ramping up the city’s influenza surveillance program, which increased its scope by 700% between 2017 and 2018, in terms of specimens analyzed. “In 2019, we will double that,” said Tran.

- Instituting an internal career ladder and a merit pay system that boosts salaries beyond the city’s periodic cost-of-living increases and mandatory, step-level increases based on years of service. Said Tran, “Our salaries have to be competitive with the federal government and with area hospitals.”

## Challenges

- The laboratory’s “rarely say no” ethos and limited staff mean leaders must “be innovative and think outside-the-box” to meet their commitments. At present, a major strategy is to “move toward robotics and automation to reduce the burden on staff” said Tran.
- Being part of a stand-alone, laboratory-based department means the PHL has to “work a little harder to assure optimal coordination with the [city] health department.” Tran said, “We want folks to know we’re here and available for them.”
- Although there are well over a million people present in DC at any time, day or night, the PHL is sometimes stymied by funding algorithms based solely on the size of its residential population (about 700,000 people).
- The complex interplay between the DC and federal governments sometimes creates extra challenges. “If there is a Legionnaires’ disease outbreak at the NASA facility across the street,” said Tran, “DC Health would be responsible for responding to that outbreak, even though it’s a federal property.”

## Goals

- Provide city agencies with “the best available laboratory expertise to recognize and respond to emerging health and safety threats.”
- Continue building the laboratory’s next generation sequencing testing capabilities.
- Re-establish the laboratory’s STD, HIV and TB testing program.
- Employ the PHL’s state-of-the-art facility as a demonstration laboratory for other PHLs. ■

# Fellowship Programs Prepare for Incoming Fellows and Celebrate Successes of Past Fellows

by **Heather Roney**, MA, manager, Fellowship Programs

The **Antimicrobial Resistance (AR) Laboratory Fellowship** is completing recruitment for the 2019 cohort. Fellows will be placed in the regional laboratories of the AR Lab Network, the National TB Center and up to three state public health laboratories. Fellows will be expected to start in summer 2019.

2017 AR Fellows Kelsey Florek and Marisabel Etter were offered and accepted full-time positions at their host laboratories. Dr. Florek was hired as a bioinformatician at the Wisconsin State Laboratory of Hygiene, building on the great work she completed during her fellowship to strengthen sequencing capability and capacity. Dr. Etter will work as a public health microbiologist in the Vaccine Preventable Diseases and Herpes Viruses section at the Microbial Diseases

Laboratory of the California Department of Public Health, where she will continue to advance her knowledge of public health laboratory science in pursuit of a leadership position within public health.

The **Bioinformatics Fellowship** has completed recruitment for the 2019 cohort. Selected fellows will be matched with state and local public health laboratories and the CDC.

2018 Bioinformatics Fellow Curtis Kapsak accepted a position at a consulting firm working as a bioinformatician in the CDC Enteric Diseases Laboratory Branch. His fellowship at the Colorado Department of Public Health and Environment prepared him for this position where he will continue to work in public health. ■



Former APHL fellows were a huge presence as both students and faculty at the January AMD Academy Intermediate Bioinformatics Training for microbiologists. (From l-r:) former Bioinformatics Fellows Logan Fink, Kevin Libuit and Sean Wang; former Emerging Infectious Diseases Laboratory Fellow Jade Mowry; and former AR Fellows Victoria Stone and Jennifer Dale

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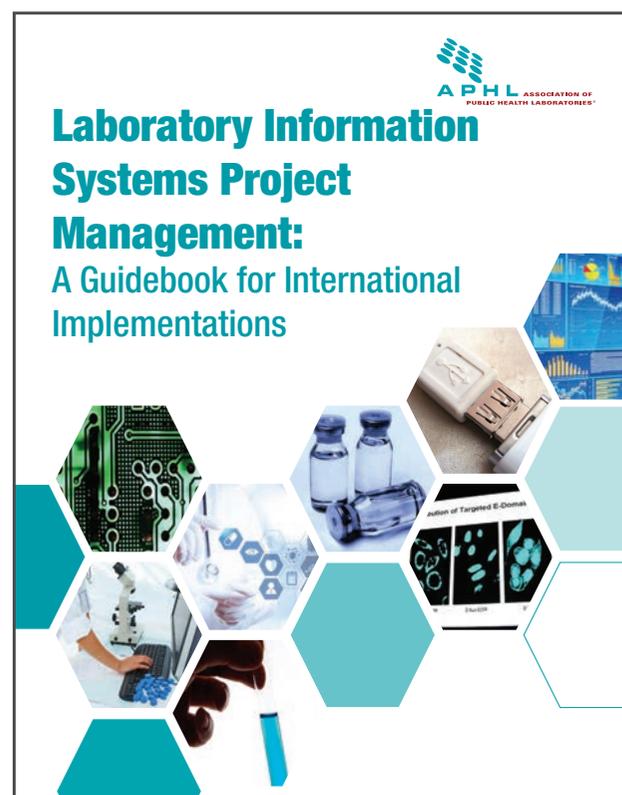
# Laboratory Information Systems (LIS) Guidebook



The world's medical care and public health systems could not provide the improved patient care we now have and prevent disease outbreaks without Laboratory Information Systems (LIS).

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- LIS increases the capabilities and capacities of diagnostic and public health laboratories.



**The Guide has something for everyone! Novices who are considering LIS in their laboratory will find a starting place and a complete implementation road-map to follow, while more experienced implementers who have questions on specific topics or are looking for a strategic approach to a problem will find the support they need.**

For more information or to get a copy of the guidebook, contact us!

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