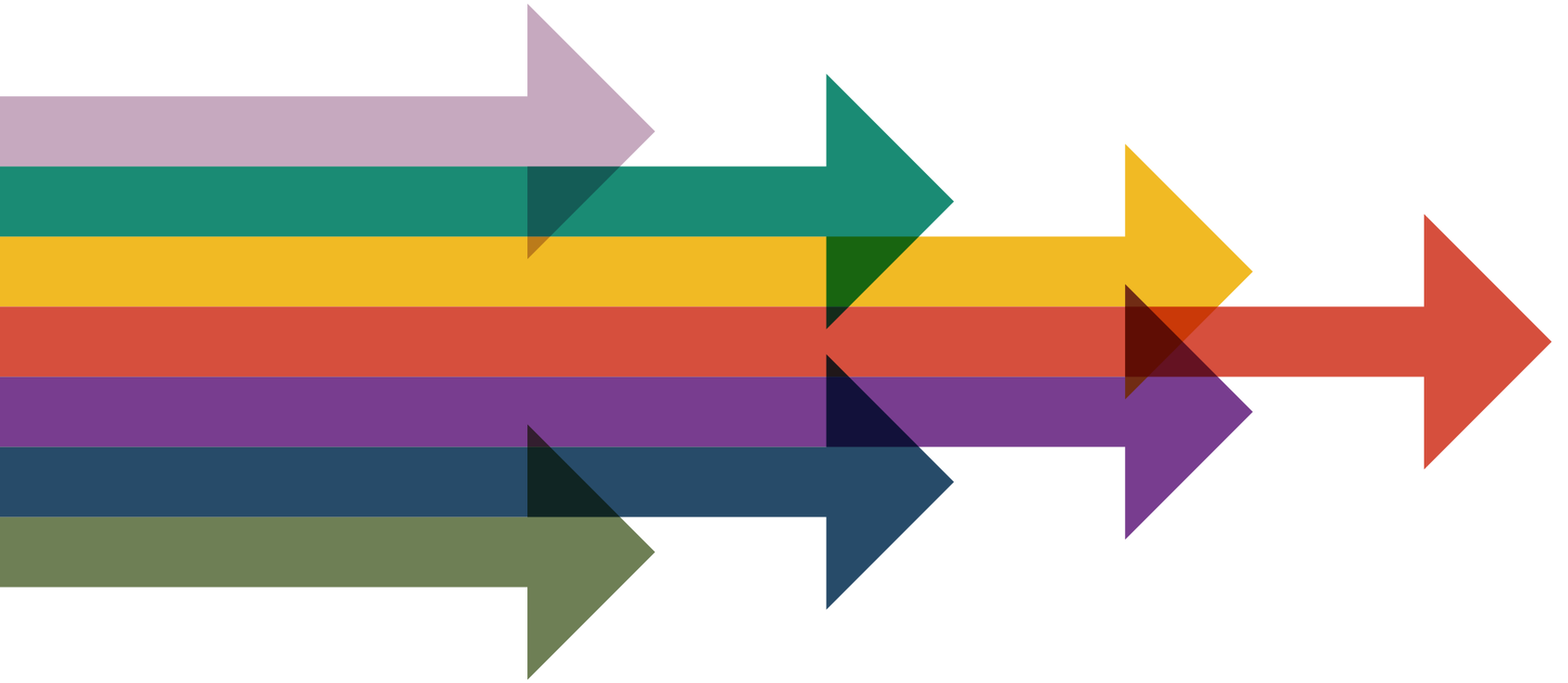
LAB MATTERS
analysis|answers|action
Winter 2024 Issue 4



Achieving Global Laboratory Coordination: What's the Way Forward?

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ASSOCIATION OF PUBLIC HEALTH LABORATORIES

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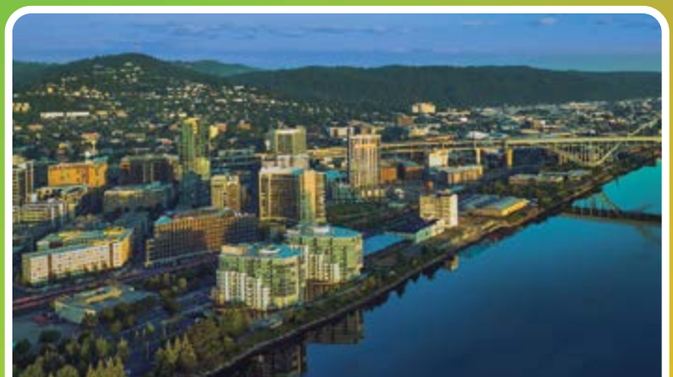

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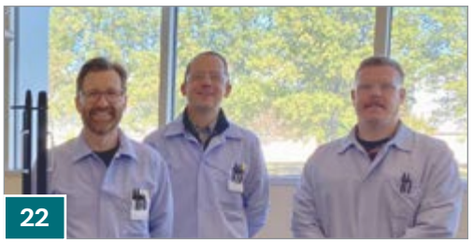

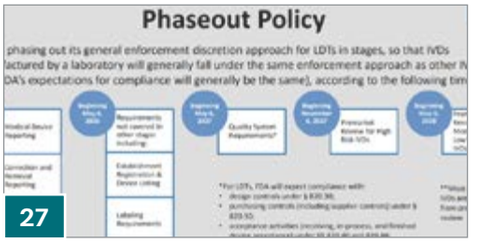

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The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne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

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Maintaining the Status Quo in Changing Times

Q&A with APHL President Megan Crumpler and CEO Scott Becker

We have just come through a very turbulent election process and, in some places, people are still figuring things out. How does the turbulence around politics affect public health laboratories?

Scott Becker: Political turbulence doesn't change APHL's work as much as you would think. It doesn't change who we talk to, as much as it changes how we talk about the issues affecting our members. The work of our members continues—specimens keep coming, babies keep being born and, as we've seen in the last six months, the infectious diseases don't stop. As a non-partisan organization, maintaining a good dialogue with all Congressional policy makers and with the new Administration will continue.

Megan Crumpler: National politics do affect state and local laboratories. For example, much of our grant funding flow in California comes from the US Centers for Disease Control and Prevention (CDC) through our state government, and then it flows down to us. It's the funding for surveillance work for hospital-acquired infections, for antibiotic-resistant gonorrhea and other surveillance activities that come from the federal level—which could be in jeopardy if there are any changes or reductions in funding.

Becker: When we talk about public health and politics at the national and local level, they are inextricably linked because we serve the public. And while the focus has been on the Executive Branch election, the reality is that Congress holds the purse strings for public health, and that's where we place a lot of our focus for policy. Although public health is often seen as a left-leaning field, it isn't. APHL and its members serve all the people all of the time.

Crumpler: Back during the pandemic, our public health emergency funding was supported by the Republican administration and Congressional leadership because it was a huge issue. We really gained a lot of momentum for reaching more communities with diagnostics, surveillance and technology innovations for our laboratories. We have come so far forward from where we were four years ago, even two years ago, and right now we're hoping we will be able to maintain what we have built.

Becker: We know that a change will be coming because of the end of pandemic funding, and we have been talking with policy makers about the public health fiscal cliff for quite some time. What we don't know is what levels might exist in the future and unfortunately, we won't know for quite a while. The government is funded on a continuing resolution through December 20, and then there will probably be another one that will take us through the inauguration.

So how do you allow your staff to process what's going on in the world, and still keep their eye on the public health laboratory mission?

Crumpler: Without a doubt, it can certainly be distracting, and it definitely raises stress levels in the laboratory, regardless of the position. I think we can honestly say that we are exhausted by the process.

Becker: Agreed!

Crumpler: And so, we just try to keep focusing on our staff and what their needs are. Many laboratories are in the process of building or remodeling their facilities and technology, so we're trying to generate and keep excitement about coming attractions. I routinely talk to interested folks about what we're doing and let them know that there is a future in the laboratory for them, and that we are very proud of the work that we do.

Becker: The push to share public health laboratory stories is definitely there, and we are getting much better about not only sharing the results and data, but also the "why" of what we do. Creating the narrative about the impact of the work of the public health laboratories will also articulate the benefit of expanding this work and the certain harm that would

occur to people and businesses if that work does not continue to be funded.

Crumpler: People are genuinely interested in what we do as well as why we do it—the stories that our laboratory staffers share with county leadership every month, as well as presenting at national conferences and producing publications for the interested public generate a lot of interest. When we can link our work to state funding sources, there is a greater opportunity for that state funding source to remain in the budget because the story is a tangible link to the work that is being performed. It's not just funding that disappears within the walls of the laboratory…it influences our communities.

Becker: And those communities are not just here, they are around the world. APHL is privileged to have offices in 10 countries, as well as a presence in many other countries to assist with laboratory strengthening. The association works with many global partners as well to put those foundations in place to establish a global community of public health laboratory and professionals for the next outbreak, which, as we know, is only a plane ride away.

In that global laboratory system, do you see United States public health laboratories as leading a country down a specific path to establish a system, or empowering countries and partners with the knowledge to strengthen their public health laboratory systems?

Becker: The US does some things well, and I also think our laboratory system does things very well. But when it comes to a global presence, there's no such thing as an ideal archetype. You know I am very fond of saying, "If you've seen one public health laboratory, you've seen one public health laboratory." Virtually any public health system in the US faces some sort of resource constraints, and the processes of what is prioritized can be handled a thousand different ways. For international public health systems, that reality is no different.

Crumpler: APHL's twinning program is a great example of a process where all involved take away some new processes that they hadn't thought of before. Anytime you walk into another laboratory, you're going to learn something from them because they have their own procedures and policies that work within their own facilities. And even though APHL is taking the lead in facilitating those twinning relationships, the actual exercise is for the benefit of all parties. It's not just APHL members going in and helping these other laboratories—it's a two-way sharing experience.

"When we talk about public health and politics at the national and local level, they are inextricably linked because we serve the public. … Although public health is often seen as a left-leaning field, it isn't. APHL and its members serve all the people all of the time."

Becker: The term that comes to my mind is "glocalization" which is defined as the practice of conducting business according to both local and global considerations. Within APHL, we don't represent public health laboratories outside the US. That is a conscious decision because we cannot support those laboratories in the same way as we support those within the US. That's why we choose to contribute globally on laboratory system strengthening through workforce technology and training, practices, protocols and other ways.

Crumpler: That is a really great point, Scott, and really defines what we do. For example, at the request of CDC, the HIV, Viral Hepatitis and STI Subcommittee created a training course on rapid plasma reagin testing for syphilis. Since it is an online course, it can be used for both domestic and international laboratory staff. It is currently available in the APHL Learning Center, along with many other courses and webinars.

Becker: And that work will continue, no matter the politics. We are the steady hand, and we will adjust no matter what happens. ■

Trailblazing to Support Public Health Laboratory Science Careers

By **Rudolph Nowak**, MPH, senior specialist, Marketing and Communications, **Susan Baughman**, senior specialist, Quality Systems and Analytics and **Somaye Sarvazade**, senior specialist, Quality Systems and Analytics

When APHL kicked their Career Pathways in Public Health Laboratory Science program into overdrive with additional funding from the American Rescue Plan in 2021, the goal was to create a pathway for early-career scientists to strengthen the workforce at public health laboratories. The plan included ramping up an internship program and building upon the existing fellowship program. Since 2021, the pathway has become a well-established trailhead and continues to expand. Josh Rowland, director of Experiential Learning, is pleased that there has been a fellow or intern in nearly every state.

"We are making progress on getting someone in every APHL member laboratory but will always need more mentors and host laboratories, including academic and non-member laboratories," Rowland said.

Taking the First Steps

The internship program, started in 2023, has placed 141 interns at 39 laboratories in 22 states since its inception. Darrell Gibson, Jr., an internship program participant who is now a fellow at the Florida Department of Health Bureau of Public Health Laboratories-Tampa, was

Tomi Ekibolaji

excited about the opportunity so close to home.

"I chose this (internship) because it was so close to where I live. I had just finished another job where I worked at a hospital, so it was good timing," Gibson said.

Gibson's moving on to a fellowship position also means he will be staying at the same laboratory, although he does have a new mentor.

Tomi Ekibolaji completed her internship at the Houston Public Health Laboratory then applied and was accepted into the fellowship program at the same laboratory.

"I've had the benefit of ongoing mentorship. My mentors have provided consistent guidance, making the transition seamless," Ekibolaji said.

Gibson agreed. "The transition has been very easy," he said. "We had several fellows who bestowed upon us knowledge and advice they had learned from their experiences. If I ever need any assistance, we have people who have already been in that position."

Realizing the Goal

Rowland believes the internship and fellowship programs have been a success.

"It is great to see interns like Darrell and Tomi transitioning to fellowship positions," he said. "We feel that by doing so, there is a higher likelihood of them staying on the public health laboratory career path."

Since the additional funding, the fellowship program has had 260 fellows fellows at 74 laboratories in 41 states. Erika Roloff—a former fellow and, since June, an employee at the District of Columbia Department of Forensic Sciences Public Health Laboratory

Darrell Gibson, Jr., shown here working in the laboratory during his internship, transitioned from intern to fellow at the Florida Department of Health Bureau of Public Health Laboratories—Tampa.

Erika Roloff stands in front of Hologic's Panther Fusion, an instrument she learned to use during her fellowship at her host laboratory and current place of employment, the Washington, DC Department of Forensic Sciences Laboratory.

Colleen Donohoe

Division—said that her fellowship gave her the freedom to ask a lot of questions and learn more about the variety of work happening at the laboratory.

"Something that's nice about the fellowship is that it gave me a project for my portfolio," she said. "You're working towards and completing a project. At the end of the fellowship, I have this finished product to present," Roloff said.

Roloff added she knew she was qualified to interview for her current position since she was confident that she could demonstrate the skills that she learned in achieving a finished product.

"I didn't know that this was a path that was available to me when I applied for the fellowship. I realized that this was a good fit between my professional interests and the skill sets that I worked so hard in grad school to learn. I came to the realization that I really want to stay here and be here," Roloff said.

Like Roloff, Colleen Donohoe, who recently finished her fellowship, was hired by the New Jersey Division of Health Public Health and Environmental Laboratories, her host laboratory.

"It wasn't necessarily the goal when I started, but when my mentor encouraged me to pursue my MPH concentrating in epidemiology and biostatistics, I knew I had a unique opportunity to take what I was learning and apply it every day at work," Donohoe said.

During her fellowship, Donohoe had been involved in many different aspects of the New Jersey population-based state surveillance study, which included recruitment, field collections, sample receiving, data management, data visualization and analysis.

"I had little practical public health experience before this fellowship, so I could never have imagined how far this fellowship would advance my professional skills in data management and analysis," Donohoe added. And the experience she gained was rewarded when her mentor encouraged her to apply for a job opening within the same program. Now her mentor is her supervisor.

"We are grateful that the host laboratories and mentors have provided such great experiences for our interns and fellows," Rowland said. "They have played a key role in the success of the programs. We love to see fellows and interns getting jobs in public health laboratories. This is the ultimate goal." ■

Empowering Laboratories and Mentors: The Multifaceted Benefits of the APHL Internship Program

By **Camille Danielson**, MS, director, Environmental Chemistry Program, Wisconsin State Laboratory of Hygiene; **Royce Riessen**, MBA, specialist, Environmental Health; **Cherie Estrada**, senior specialist, Internship Program; and **Mariane Wolfe**, MS, MLS(ASCP)CM, manager, Internship Program

Do you have projects that you can't seem to find the time for? Does your laboratory have staff that want to give supervision a try, and they just need a little nudge? Would you like to save money? The Public Health Laboratory Internship Program: an APHL-CDC Initiative may be the answer.

Since its launch in 2023, the Internship Program has been a huge benefit to many laboratories and mentors. A host laboratory can save significant funds by utilizing the extra workforce support of interns. Over a 15-month period, the Wisconsin State Laboratory of Hygiene (WSLH) estimates that it saved over $350,000 by utilizing 44 interns instead of student workers or seasonal project positions. This includes 13 additional student positions they would not have hired otherwise due to lack of funding. Offering mentors the opportunity to shape future public health professionals, the program builds a reserve of skilled students who can transition into permanent laboratory roles or expand their education in public health fields.

An added benefit of interns is the savings on less tangible costs by easing staff workload. Once interns had a handle on their established project, staff were freed up to focus on mission-critical work. A bonus: the presence of interns allowed staff to take vacations in the summer, something that was not always possible in past busy seasons. For this reason, many employees reported a better work-life balance due to the additional help.

Intern Success Story:

Mia Peck filters National Atmospheric Deposition Program rainwater samples to remove particulate matter before testing. (Photo by Jan Klawitter/WI State Lab of Hygiene, UW-Madison)

Mia Peck was a WSLH intern in the first cohort in Summer 2023. She has since extended multiple times and worked with a variety of mentors in more than four areas of the environmental laboratories. These included the inorganics laboratory, quality assurance group, sample receiving, shipping, trace elements clean laboratory (TECL) and the National Atmospheric Deposition Program laboratory. Her experiences have included: PowerPoint development, chemical inventory, sample preparation, kit building, shipping, reagent preparation and pipette verification. She said helping in many areas and with a variety of mentors has been a "fantastic opportunity." Mia was most excited about learning clean laboratory technique and working in the WSLH TECL.

Building Opportunities for Interns…

APHL's initial screening of applicants streamlines recruitment and saves time for the laboratory compared to traditional student hiring. The structured application and review process—as well as the competitive stipend—attracts higher-quality candidates and improves retention. Many interns extend their internship at the request of their mentor, an advantage for the laboratory since the students are pre-trained and can continue to help with essential tasks. To date, WSLH has invited 14 interns to extend their time, and the results have been beneficial for everyone. Another distinction is that the APHL and CDC affiliations boost the laboratory's appeal beyond a typical summer job; instant name recognition for potential employers in the laboratory science field is an impressive addition to any resume and can lead to other opportunities for interns.

The objective of the program is for interns from a variety of backgrounds to receive valuable training and hands-on experience while learning directly from a professional in the public health laboratory field. Mentors provide career guidance and insight on what majors can fit into professional roles, opening career pathways that most students are not traditionally exposed to in college studies. At WSLH, the required APHL learning modules are used to further increase opportunities for laboratory staff to enhance the intern experience. Each training topic is covered in a group setting with experts from both the clinical and non-clinical parts of the laboratory facilitating. For example, the safety module was covered by a chemist on the non-clinical side and a microbiologist from the clinical laboratories (both

"Fostering growth and expanding the breadth of knowledge for students has been rewarding for the team. I'm a big advocate for the program. The relationships we have developed with the interns, watching the interns grow and learn, but also the mentors, and lab staff having an opportunity to take on more responsibility while guiding the interns' training was equally as rewarding."

— Mentor Kathleen Dax-Klister, supervisor, Customer Service, Receiving & Data Management, WSLH

members of the Safety Team). Not only did the interns learn from some of the subject matter experts, but they were also introduced to two perspectives while getting to know their fellow interns better.

...and Mentors

The internship program also gives non-supervisory staff a chance to develop leadership, mentoring and time-management skills. This provides an opportunity to supervise without a full commitment to such a role. Mentors can further develop their abilities by providing constructive feedback, specialized training and guidance. Mentoring also fosters a collaborative environment beyond the scope of the program, where interns rotate among sections and work with others to address the short-term needs of the laboratory. Many laboratory staff were impressed with the curiosity and enthusiasm that the interns brought with them each day. The exposure to someone excited about the field of public health helps to strengthen the passion for the laboratory's mission.

Mentorship and providing hands-on laboratory experience are the keys to sustaining the public health workforce and preparing students for future professional roles. Everyone has something to offer through their unique characteristics and personal experience, and more mentors are needed to support the program's growth. Take a chance on an intern—you just might be mentoring your next colleague! ■

Since the beginning of the internship program, there have been:

22

Wisconsin Mentors

and

65

Wisconsin Internships

Interns have come from a variety of academic backgrounds:

Intern Degree Areas	
Atmospheric & Oceanic Sciences	Genetics
Biochemistry	Global Health
Biology	Horticulture
Biomedical Science	Informatics
Biotechnology Program	Microbiology
Cell Biology	Molecular Biology
Chemistry	Neurobiology
Computer Science	Public Health
Engineering Mechanics	Soil and Waste Resources
Environmental Engineering	STEM Education
Environmental Science	Tropical Medicine

Fellows Lead Public Health Initiatives in Montana

By **Kenlie Fite**, DrPH(c), MPH, CPCLC, lead specialist, Leadership and **Ashley Smith**, MS, lead specialist, Fellowships

The Public Health Laboratory Fellowship Program: an APHL-CDC Initiative is shaping the future of public health laboratory science by empowering future leaders. Enrico Di Castro Young and Geneka Glover, current fellows at the Montana Department of Livestock Veterinary Diagnostic Laboratory, are making significant strides in Montana, spearheading projects that highlight the importance of veterinary and zoonotic disease surveillance.

Di Castro Young's project led to a breakthrough in Montana by creating a much-needed opportunity to stand up testing for highly pathogenic avian influenza (HPAI) in domestic household animals in the state. While HPAI testing is common in avian populations, Di Castro Young's work explored the occurrence of this zoonotic disease in domestic animals, specifically cats. Testing revealed a higher-than-expected incidence of HPAI in domestic cats, with positive cases in counties where no previous cases in avian populations had been reported. This novel discovery required significant coordination between various parties including animal producers, pet owners, veterinarians, laboratory personnel, the US Department of Agriculture (USDA), the State Veterinarian's Office and the Montana Department of Public Health and Human Services. Di Castro Young's data was quickly shared with the USDA National Veterinary Services Laboratory, who integrated the findings into the national surveillance project. The cross-laboratory communication also sparked action in other states, prompting them to begin testing for HPAI in domestic cats. The early identification of HPAI spillover into domestic animals was crucial in shaping national responses to this zoonotic disease outbreak and underlines the importance of veterinary diagnostics in public health.

Enrico Di Castro Young demonstrates the proper technique for conducting fellowship project work within a biosafety cabinet.

Geneka Glover displays the proper personal protective equipment necessary to engage in hands-on fellowship project work.

Meanwhile, Glover has been focused on another pressing issue in Montana: the identification and prevalence of tick-borne diseases. Before her fellowship, tick-borne disease testing in the state was minimal. Glover's project changed that landscape when testing identified high seroprevalence of Rocky Mountain spotted fever and canine ehrlichiosis. The surprisingly high seroprevalence of canine ehrlichiosis uncovered by Glover's project raised concerns about the potential impact on animal health due to the associated high morbidity in domestic dogs—and sparked new questions about the spread of arboviruses and their tick vectors affecting both humans and animals within Montana. In response to this discovery, the laboratory is collaborating with the state's Department of Public Health and Human Services to develop public messaging and guidelines to mitigate tick-borne disease transmission risks.

Both fellows have also benefited from cross-training within the laboratory. Working across departments has allowed them to become proficient in a variety of techniques, from virus isolation and bacterial culture to microagglutination and rabies DFA testing. This interdisciplinary training deepens their expertise and equips them with transferrable skills that are crucial for future careers in public health laboratory science.

For both fellows, the fellowship has provided invaluable experience, not only in laboratory techniques but also in collaboration and public health communication.

Their fellowship projects illuminate the importance of surveillance, early detection and coordination in preventing the spread of diseases from animals to humans, reinforcing the One Health approach that is vital to safeguarding public health.

Through their fellowship experiences, Di Castro Young and Glover are making lasting contributions to Montana's public health infrastructure, demonstrating how the fellowship empowers future leaders in public health laboratory science." ■

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Reducing Risks for the Most Vulnerable: Enhancing Newborn Screening Through Interoperability

By **Juan Vasquez**, MHA, project coordinator, NBS Interoperability Implementation Project, Ruvos

Newborn screening (NBS) saves the lives of thousands of newborn infants each year in the United States. NBS is a vital part of our public health system, testing over four million infants annually for genetic, congenital, metabolic and other conditions that can have profound and life-threatening impacts which—if detected in time—may be treatable.

NBS programs work tirelessly to ensure that no infant is deprived of this lifesaving service, but challenges persist. Most programs compare their screening records, held on a laboratory information management system (LIMS), with birth records from the state vital statistics system, in order to identify infants that have yet to be screened. Because these systems cannot directly share data, reconciling records is an onerous and time-consuming manual process, risking errors or delays that could profoundly impact a baby's life.

According to the US Health Resources and Services Administration (HRSA), "newborn screening systems that can effectively, efficiently and securely exchange information are more likely to provide timely and accurate screening, leading to early diagnosis, intervention and treatment. Manual data entry and not having access to other state databases may lead to inaccurate or missing data, which could result in delays in screening or reporting results." This reality has led HRSA to promote modernization efforts that establish interoperability between NBS LIMS and vital statistics databases.

Recently, a HRSA-supported interoperability project brought together the Florida Department of Health's NBS Program and Ruvos, an innovative data solutions partner committed to revolutionizing newborn screening through advanced technology and modernization strategies.

The project started with a readiness assessment led by Ruvos to evaluate current capabilities, identify strengths and opportunities for interoperability, and provide a roadmap to reach modernization goals. The key achievement of the project was the creation of an application that automates data matching between NBS LIMS and the state vital statistics database. As a result, 100% of NBS LIMS and vital statistics birth records were matched and reconciled.

Positive outcomes were immediate and noteworthy.

- Data validation work that previously took several days now took minutes. Rather than validating each individual record, the application allows all records to be processed in a single run, pinpointing any discrepancies, which can then be addressed much more quickly. This results in a significant reduction in reporting time.
- Improved data quality greatly facilitates the work of follow-up teams.
- Home birth newborns that had not been screened were identified, as were newborns that had been screened but did not have vital statistics records. There was improved identification of out-of-state and non-reported births.

This project may serve as a useful case study for other jurisdictions contemplating data modernization efforts.

Some key considerations:

- **Data quality improvement:** Implement rigorous data validation and quality efforts to ensure accuracy and reliability.
- **Workflow and process optimization:** Identify and optimize critical workflows to enhance efficiency and effectiveness.
- **Data exchange and interoperability:** Utilize HL7 standards and other methods to enable smooth data integration and exchange.
- **Technical modernization:** Upgrade systems and infrastructure to support modern reporting solutions, data analytics, and visualization.
- **Technical partnership:** Identify collaborators with proven technical expertise and data modernization experience to assist with collaborative assessment, strategic roadmap development and project delivery.

For more information about this project and our approach to newborn screening modernization, contact us at hello@ruvos.com. ■

Ruvos is an APHL Diamond Level Sustaining Member.

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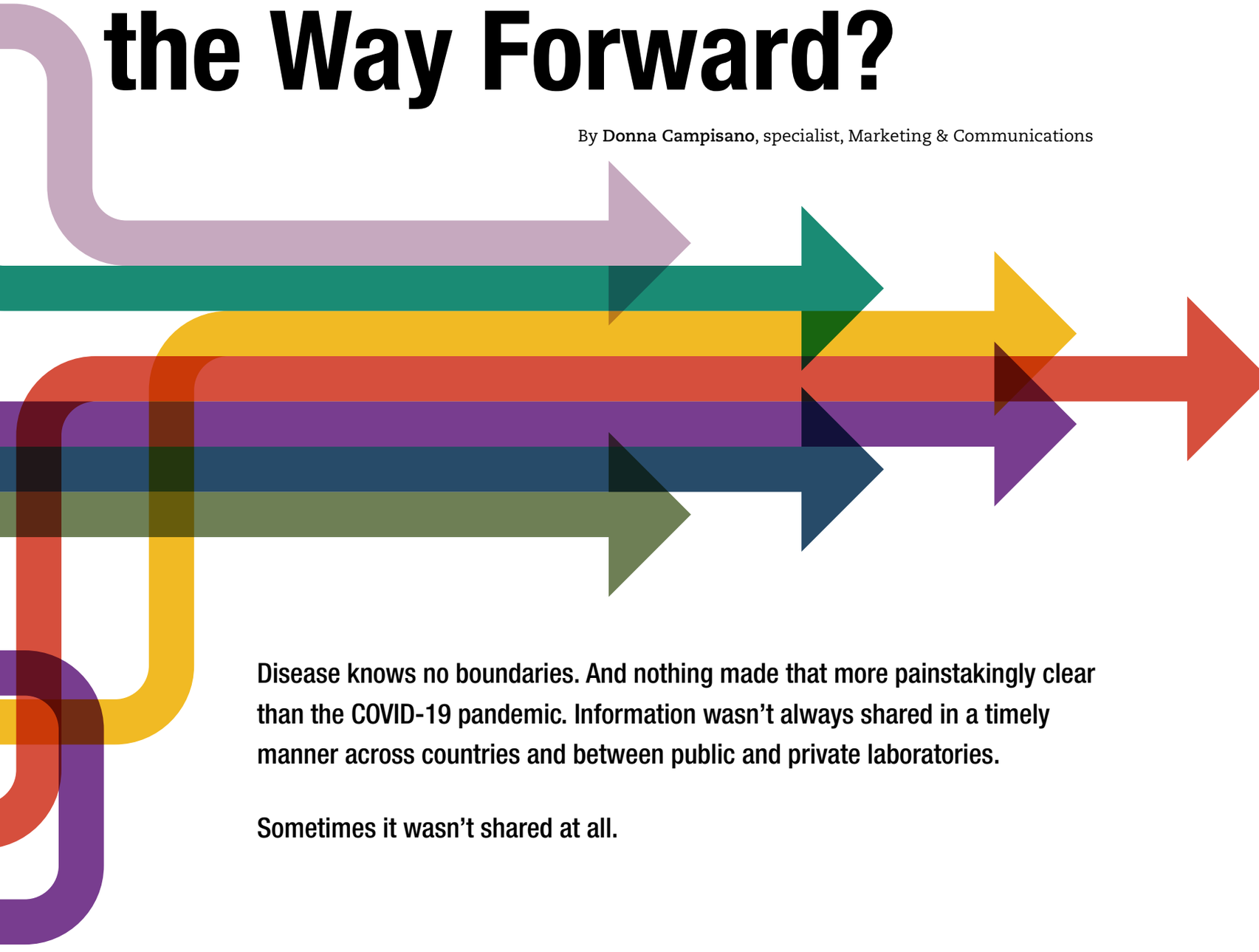
Achieving Global Laboratory Coordination: What's the Way Forward?

By **Donna Campisano**, specialist, Marketing & Communications



Disease knows no boundaries. And nothing made that more painstakingly clear than the COVID-19 pandemic. Information wasn't always shared in a timely manner across countries and between public and private laboratories.

Sometimes it wasn't shared at all.

"COVID-19 really forced us to solidify some otherwise loose coordination that was in place," said Lucy Maryogo-Robinson, MPH, director of APHL's Global Health program. "But now, thanks to the stress test that was COVID-19 around the world, we've been able to really improve that."

Where We Are Today

COVID-19 may have shone the brightest light on the lack of laboratory coordination around the world, but there were flickers of problems before.

Consider Africa and the Ebola outbreak of 2014. Not every country on the continent had the capacity to test for Ebola, and when they did, they didn't always have laboratories equipped to process the tests. Sending those tests to places that could properly analyze them—like the US Centers for Disease Control and Prevention (CDC)—was extraordinarily expensive, further handicapping the sharing of information.

Fast forward to 2024, and things look different, Maryogo-Robinson said.

"We now have, for example, the Africa Centres for Disease Control, and that group, which was stood up only four years before COVID-19, serves as a coordinating body to help facilitate response," she said. "Countries now have a sense of who has what capability/capacity and who has what resources that they can broker. They also can follow that up with workforce development, so laboratory staff can implement testing that they had never done before. A lot of this infrastructure and coordination didn't, unfortunately, exist pre-pandemic."

And if coordination was challenging before COVID-19, so was global collaboration.

"COVID-19 highlighted the need for sharing information on both sequencing data and logistical issues—like source availability for supplies and reagents," commented Kayla Laserson, ScD, director of CDC's Global Health Center. "Strong coordination encompasses a strong community of practice among public health laboratory scientists to share the application of emerging technologies, best practices and lessons learned. We [CDC] support an open culture of sharing data and solving public health problems within a national public health system and the global community."

Coordination Challenges

Despite the progress, there's still an urgent need for improvement, even here in the US, say experts.

"We need to have a better approach to how we engage laboratories, how we resource those laboratories and how we form stronger public/private partnerships," said Chris N. Mangal, MPH head of APHL's Public Health Preparedness and Response program.

And it all starts, she said, with sustained funding.

"In the US especially, one of the things we see is that there's a lot of money thrown at public health and at laboratories, either in the middle of a major issue or after the major issue," Mangal said. "We saw it with anthrax, H1N1 and certainly with COVID. The amount of funding that came through for the COVID response was unprecedented. But what happens is once that public health emergency is over and the threat is at the back of everyone's mind, those funds essentially go away. We don't have that sustained approach to how we resource laboratory coordination, both domestically and globally."

One of the places where that funding is essential is in workforce recruitment and retainment. Spending time and resources training people only to have them turn around and offboard isn't a good business model for any industry or organization.

"A lot of that has to do with salaries and the total compensation of what laboratory professionals are offered,"

"In the US especially, one of the things we see is that there's a lot of money thrown at public health and at laboratories, either in the middle of a major issue or after the major issue. . . . [O]nce that public health emergency is over . . . those funds essentially go away. We don't have that sustained approach to how we resource laboratory coordination, both domestically and globally."

— Chris N. Mangal, MPH

Mangal said. “Funding the workforce is a challenge we face.”

A focus also needs to be placed on workforce development—and not just technical training on new instruments and techniques, which is undoubtably important, but also on essential skills like communication, leadership, emergency response and advocacy.

“We’ve moved beyond just training in a method or platform,” Mangal noted. “We’re also looking at micro credentialling and how to partner with academic institutions to strengthen laboratorians skillsets and knowledge base.”

“More opportunities for laboratory scientists to pursue professional development, leadership growth and placement among cross-disciplinary leadership positions will strengthen the entire system,” added Laserson, who noted the need for laboratory scientists to be proficient in a plethora of skills, from biosecurity to quality management to laboratory governance. “Adequate support staff for ancillary laboratory management and operations are also needed to allow laboratory scientists to participate in a global community of knowledge to build skills for professional development and outreach.”

Maryogo-Robinson echoes those thoughts while also pointing out the need for adequate funding in infrastructure development.

“If we’re rolling out Ebola testing, for example, here within the US, there’s training that would happen across the country,” she pointed out. “There are standard operating procedures that are pulled together. There is a mechanism for communication and reporting. Operating a laboratory response network efficiently takes time, money and resources, which may be difficult to access in some countries.”

> **“It takes a concerted effort and a culture of integration to ensure that problems are addressed with all perspectives accounted for … Every opportunity to see your work from a different perspective benefits the entire health system.”**
>
> **— Lucy Maryogo-Robinson, MPH**

Bringing together bands of highly trained scientists from multiple disciplines can be challenging, acknowledged Laserson, but necessary for the exchange of ideas and insights that naturally strengthen public health endeavors.

“It takes a concerted effort and a culture of integration to ensure that problems are addressed with all perspectives accounted for—laboratory, epidemiology, clinical, veterinary/animal health, data science, response, etc.,” she said. “Every opportunity to see your work from a different perspective benefits the entire health system.”

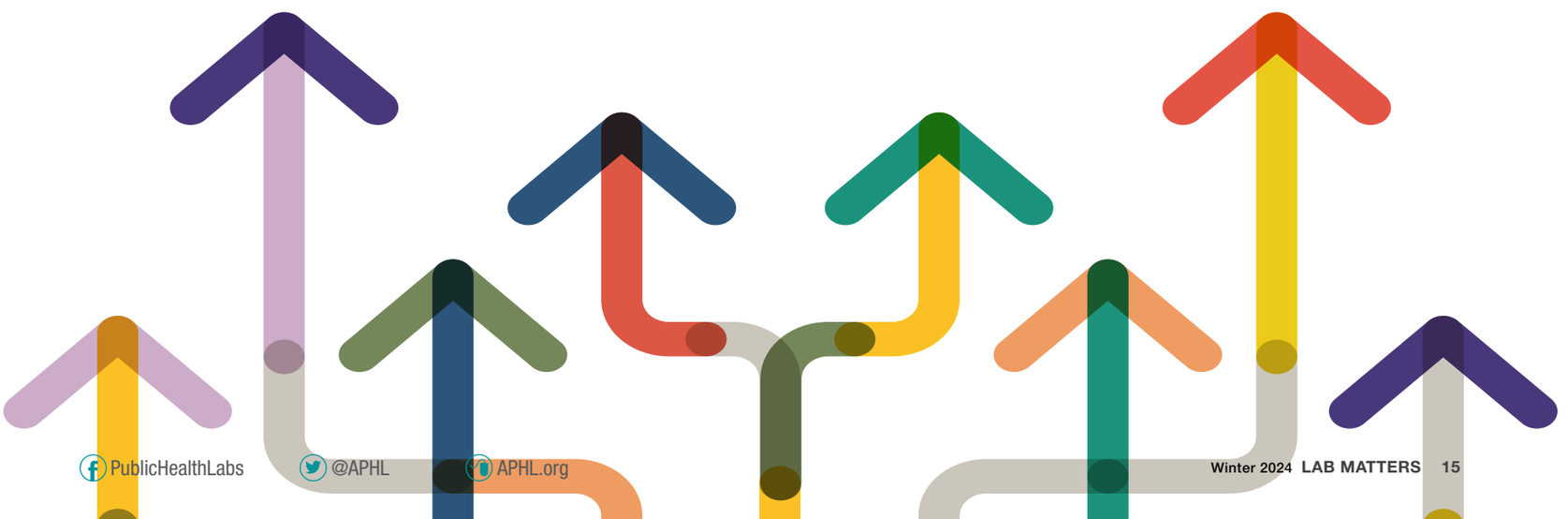
Another key to global laboratory coordination is policy—how, when and where countries need to sound an alarm on public threats. And thankfully, that policy is becoming clearer.

“The steps it takes to officially declare an outbreak of concern are better understood now,” Maryogo-Robinson said. “Countries are much more aware of how to go about doing it—there’s more clarity. There’s been a lot more education about what constitutes a public health emergency.”

She used mpox as an example. Not too long ago, one African country declared an outbreak. Shortly thereafter, Africa CDC declared it a public health emergency of continental security, and soon after that, the World Health Organization (WHO) declared it a public health emergency of international concern.

Yet even when laboratories have people and policy, they don’t always have products—another roadblock to global laboratory coordination. Supply chain disruptions can make it difficult for laboratories everywhere to acquire assays, sequencers, reagents and other necessary components of laboratory work. And without supplies, surveillance stands still.

“It can be very difficult for global laboratories to get all the supplies they need at any given time,” said Sara Vetter, PhD, D(ABMM), laboratory director at the Minnesota Department of Health. “Sometimes things get stuck through customs, and that’s a really hard issue to work through. Sometimes it’s just that a product isn’t available.”



> **“At CDC, we always say, ‘A disease threat anywhere is a disease threat everywhere,’ so we are truly only as strong as our weakest link in the public health system—and that system is global.”**
>
> — Kayla Laserson, ScD

What’s the remedy? Enlisting the help of APHL and other partners to develop relationships with manufacturers and convince them that there’s a need in a region is a start, said Vetter, who noted that APHL can help laboratories develop the language they need to communicate with manufacturers about the importance of their mission.

“That’s good for the manufacturers, who can see there’s a market for something, and it’s good for the laboratories and for public health in general,” she added.

The Road Forward

Global laboratory coordination is closer than ever, but silos still exist. More investment in training, infrastructure, data and technology sharing will be key.

“At CDC, we always say, ‘A disease threat anywhere is a disease threat everywhere,’ so we are truly only as strong as our weakest link in the public health system—and that system is global,” said Laserson. “Equitable access to technologies and training, along with a culture of continual quality/learning/improvement and supportive leadership, will yield high quality testing in any laboratory in the world.”

Focusing on a One Health lens will also be essential.

“Oftentimes, our investments are going into human health and we’re underappreciating the importance of how animal health and environmental health impacts it,” Maryogo-Robinson said. “And we often don’t get the full view. We know one affects the other, and we need better communication between them. There’s still a gap there today but acknowledging that we need that kind of dialogue is moving in the right direction.” ■

Share your laboratories’ success stories!

Help us reveal what the public health community stands to lose without dedicated and long-term support. Share your story with APHL by scanning the QR code or visiting bit.ly/Lab-Informatics.

*The **Innovations in Informatics: Laboratory Success Stories** series from APHL showcases innovations and enhancements in informatics, made possible by recent funding opportunities related to COVID-19, data modernization and public health infrastructure. It highlights the critical need for ongoing, targeted and sustainable informatics funding, while celebrating the progress that has been made.*

Become a Public Health Laboratory Ambassador

APHL | CAREER PATHWAYS in Public Health Laboratory Science
An APHL-CDC Initiative

Public Health Laboratory Ambassadors develop the laboratory workforce by promoting public health laboratory careers to students. The Association of Public Health Laboratories (APHL) is seeking people who are passionate about the future of public health laboratory science to serve as ambassadors.

Ambassadors receive benefits such as:

- Resources to support participation in outreach events
- A supportive community to share ideas and experiences
- Practice speaking about public health laboratory careers in a public setting

... **and much more!**

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Public Health Laboratory Ambassadors can participate in many different types of outreach events.

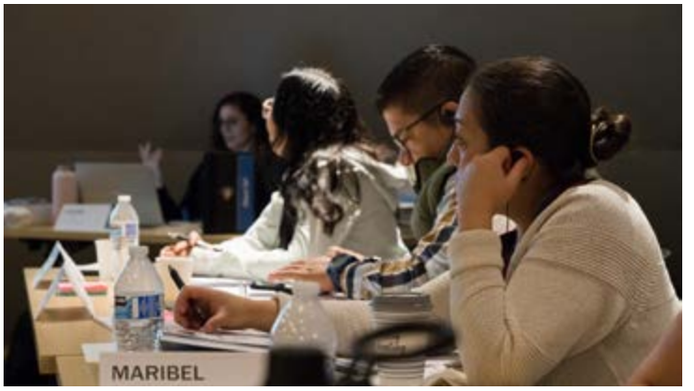
Some examples may include, but are not limited to:

- Classroom presentations
- Guest speaker commitments
- College career fairs
- Conference exhibit booths
- Science fairs (e.g., competition judge)
- STEM festivals
- STEM community nights
- Laboratory tours
- Remote (virtual) career readiness activities
- Q&A panels

Discover valuable tools and resources at **www.aphl.org/academic-partnerships**

APHL and Partners Host LRN Conventional Methods Training Course for InDRE Laboratorians

By **Tyler Wolford**, manager, Emergency Preparedness and Response



LRN Conventional Methods Trainees listening to lectures. Photo: Tyler Wolford.

The Laboratory Response Network (LRN) is a collaborative effort involving APHL, the US Centers for Disease Control and Prevention (CDC), Federal Bureau of Investigation (FBI) and US Department of Defense (DoD). This integrated network unites state and local public health laboratories, federal agencies, military institutions and international laboratories to respond to biological, chemical and radiological threats.

At the core of the LRN is the LRN for Biological Threats Preparedness (LRN-B), which is critical in preparing for and rapidly responding to biological threats, such as anthrax, and emerging infectious diseases like Ebola. In addition to its domestic efforts, the LRN works closely with international laboratories, offering support and fostering collaboration with countries like Canada and Mexico. These partnerships are vital to enhancing global preparedness by sharing knowledge, expertise and assisting with strategic planning.

In September 2024, APHL, CDC and the Arizona State Public Health Laboratory facilitated a modified LRN Conventional Methods Training Course in Phoenix, AZ for six laboratorians at the Institute of Epidemiological Diagnosis and Reference (InDRE) in Mexico City, Mexico. The goal of this course was to maintain capacity within LRN-B Reference Laboratories to effectively respond to actual or suspected biological threat events by increasing the participants' skills and confidence in test performance and result interpretation using conventional methods, facilitate the dissemination of the information and skills learned in the course to others and provide a forum that will foster a professional working relationship between the course participants and instructors.

The training encompassed traditional microbiological detection methods like culturing, microscopy, gram staining and biochemical testing. This intermediate-level course trains microbiologists in the laboratory identification procedures for *Bacillus anthracis*, *Brucella* spp., *Francisella tularensis*, *Yersinia pestis* and *Burkholderia* spp. These organisms have been identified as possible biological threat agents using several criteria, including the past weaponization of these organisms and the small infectious doses required to produce illness. Additionally, this course included training on Time-resolved Fluorescence, a screening assay for the detection of *Ricinus communis* toxin.

At the end of the course, participants were able to:

1. Use LRN-B Reference Laboratory protocols to perform all conventional microbiology tests for identifying biological threat agents.
2. Interpret test results to determine identification of organisms.
3. Identify the appropriate confirmatory test for each organism.
4. Explain the principles of the conventional tests used to identify these organisms.
5. Demonstrate the ability to work safely with biological threats agents under a biological safety cabinet at Biosafety Level 3.
6. Identify potential hazards associated with biological threat agents.

APHL would like to recognize the contributions of the following individuals. Thank you for your invaluable efforts.

Arizona State Public Health Laboratory
Dr. Victor Waddell
Dr. Kathryn Fitzpatrick
Dr. Joseph Manfrida
Drew Francis
Rachel Wrobel
Ksenia Poujlivaia
John Dulany
Teriani Johnson

Interpreters
Houda El Idrissi
Ernest Niño-Murcia
Irma Cornejo
Linda Galicia

Instructors
Dr. Philip Lee
Amanda Moore
Dr. Michael Perry
Erin Swaney

InDRE
Maribel González Villa
Mireya Mederos Michel
Daniel José Regalado Santiago
America del Pilar Mandujano Martínez
Blanca Estela González Martínez
Nancy Martínez Velázquez

Facilitators
Patricia Blevins
Rana Rahmat

This training opportunity enhanced preparedness and response capabilities for InDRE and laid the groundwork for implementation of LRN-B testing. ■

Introducing the **Human & Animal Food Laboratory Professionals Curriculum Framework**

The Laboratory Curriculum Framework is a competency-based curriculum framework — a career-spanning, visual schematic — for human and animal food laboratory professionals. The framework is being used for:

- Training development
  courses and other learning events
- Cataloging existing training
- Career development
- Competency assessment

The goal of this framework is to foster a competent workforce trained to a consistent standard. While this framework was originally created for analysts working in human and animal food laboratories, many competencies and training materials have a broader reach.

Learn more and start using the framework and evaluation tools at **www.aphl.org/HAFL-Framework**

Framework Levels

The framework spans four professional levels (entry, mid, expert and director), and depicts the content areas in which laboratory professionals must possess competencies (i.e., knowledge, skills, abilities, behaviors and attributes) in order to successfully perform their job functions.

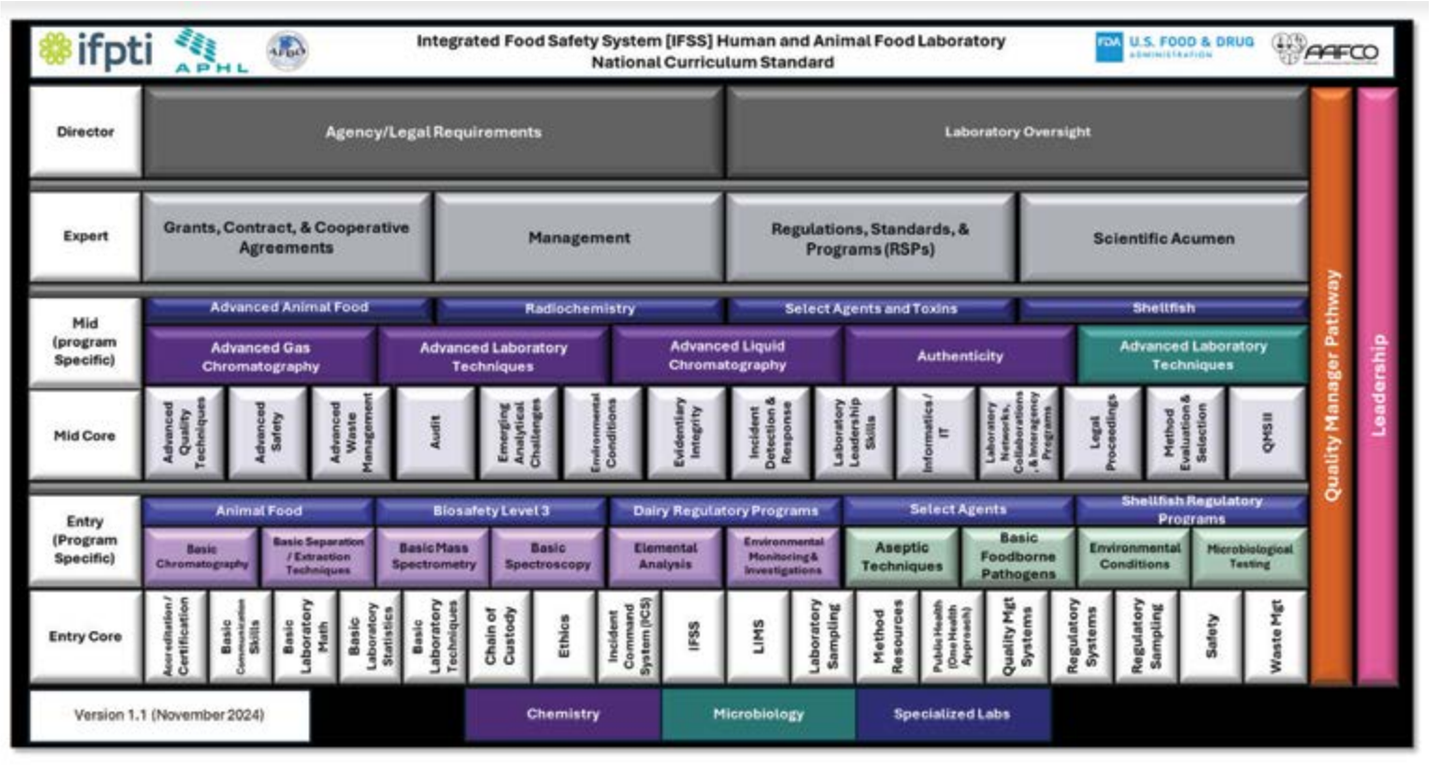
Building Analyst Competency

The framework outlines the competencies that laboratorians should possess in various stages of their career and in various disciplines (Microbiology, Chemistry, Specialized Testing). You can use these competencies to determine where you or your supervisee have knowledge gaps and identify learning resources to gain these competencies.

Competencies List: **www.ifpti.org/ncs-lab-competencies**
Interactive Framework: **www.ifpti.org/ifss-lab**

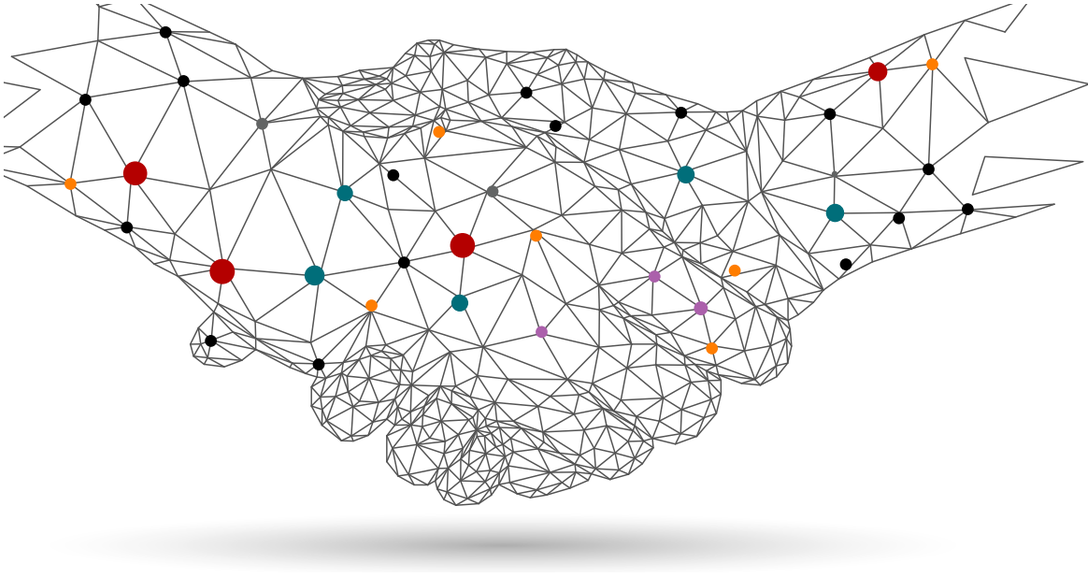
Training Available

Competency-based training courses are currently in development to complement the curriculum framework. These courses can be found on APHL's Learning Portal at **learn.aphl.org/learn**.



Strengthening the Nation's Laboratory Response System

By **Chris N Mangal**, MPH, director, Public Health Preparedness and Response



Responses to public health threats rely on timely and accurate data to identify the cause as well as assess ongoing disease prevalence, transmission routes and effectiveness of interventions designed to reduce morbidity and mortality. Whether the threat is chemical in nature—as seen with lead chromate in cinnamon applesauce—or biological—as demonstrated by the evolving mpox virus over the last two years—laboratories must be ready to respond. To ensure an effective response—where public and private systems work together—national laboratory coordination is critical. In the wake of the COVID-19 pandemic, APHL has spearheaded several efforts designed to strengthen the nation's laboratory response system and called attention to the urgent need for a coordinated national laboratory response system.

A Robust Network…

Chief among APHL's efforts is the collaboration with the US Centers for Disease Control and Prevention (CDC) to bolster the Laboratory Response Network (LRN). Formed in 1999 by CDC in partnership with APHL and the Federal Bureau of Investigation (FBI), the LRN was initially designed to ensure an effective laboratory response to bioterrorism. Today, the LRN is an integrated network of local, state and federal public health, hospital-based, food testing, veterinary, environmental testing and international laboratories providing laboratory diagnostics and capacity for biological and chemical threats other public health emergencies. The LRN is looking to integrate radiological testing as well.

The linking of state and local public health laboratories, veterinary, agricultural, military and water and food testing laboratories is vital and unprecedented. As a founding member of the LRN, APHL works closely with CDC to ensure LRN laboratories are ready to respond to threats. For instance, APHL partners with the American Society for Microbiology (ASM) to develop and issue LRN Sentinel Level Clinical Laboratory Protocols, a suite of standardized, practical methods and techniques to rule out microorganisms suspected as agents of bioterrorism or emerging infectious disease threat, or to refer specimens to public health laboratories for confirmation. Similarly, APHL partners with CDC and the College of American Pathologists (CAP) to issue the Laboratory Preparedness Exercise to approximately 1,300 laboratories twice a year. In these exercises, CAP sends live organisms that either exhibit characteristics of bioterrorism agents or demonstrate epidemiologic importance. Participating laboratories are expected to respond following the LRN Sentinel Level Clinical Laboratory Protocols if a bioterrorism agent is suspected. APHL's collaboration with CDC, CAP and ASM ensures that private and public laboratories have the protocols to prepare for a threat and then the option of an exercise to test that readiness.

APHL is also a key partner to the CDC Division of Laboratory System's Memorandum of Understanding (MOU), which articulates the roles of various organizations to collaborate on enhancing laboratory testing surge capacity outside of CDC and public health laboratories before and during public health emergencies.

…Leads to Strong Partnerships…

In addition to efforts to strengthen the LRN, APHL has a vital objective to bolster strategic system partnerships, including using APHL's elevated voice to strengthen laboratory coordination at a national level. To address this objective, APHL engaged diverse members via the National Laboratory Coordination Strategic Implementation Group. With the support of a consultant, Raphael Barishansky, DrPH, these members identified laboratory networks charged with responding to various threats and engaged partners via key informant interviews and focus groups. Based on these discussions, APHL issued a report, *Strengthening National Laboratory Coordination A Vision for a National Laboratory System*. This report highlights the importance of much-needed national laboratory coordination to ensure that both private and public laboratories are well positioned to respond to the next threat.

Key findings from these discussions highlighted the need for:

1. Flexibility and staffing to better pivot from routine day-to-day operations to response activities

2. Formalized external partnerships and relationships
3. Centralized coordination to provide support for all types of laboratories during responses, with many participants applauding APHL for its coordinating role in several responses
4. A national strategy for laboratory emergency response, including a national laboratory system
5. Sustained funding for both private and public laboratories.

APHL's members and partners also delved into the critical elements for a coordinated national laboratory system, which included:

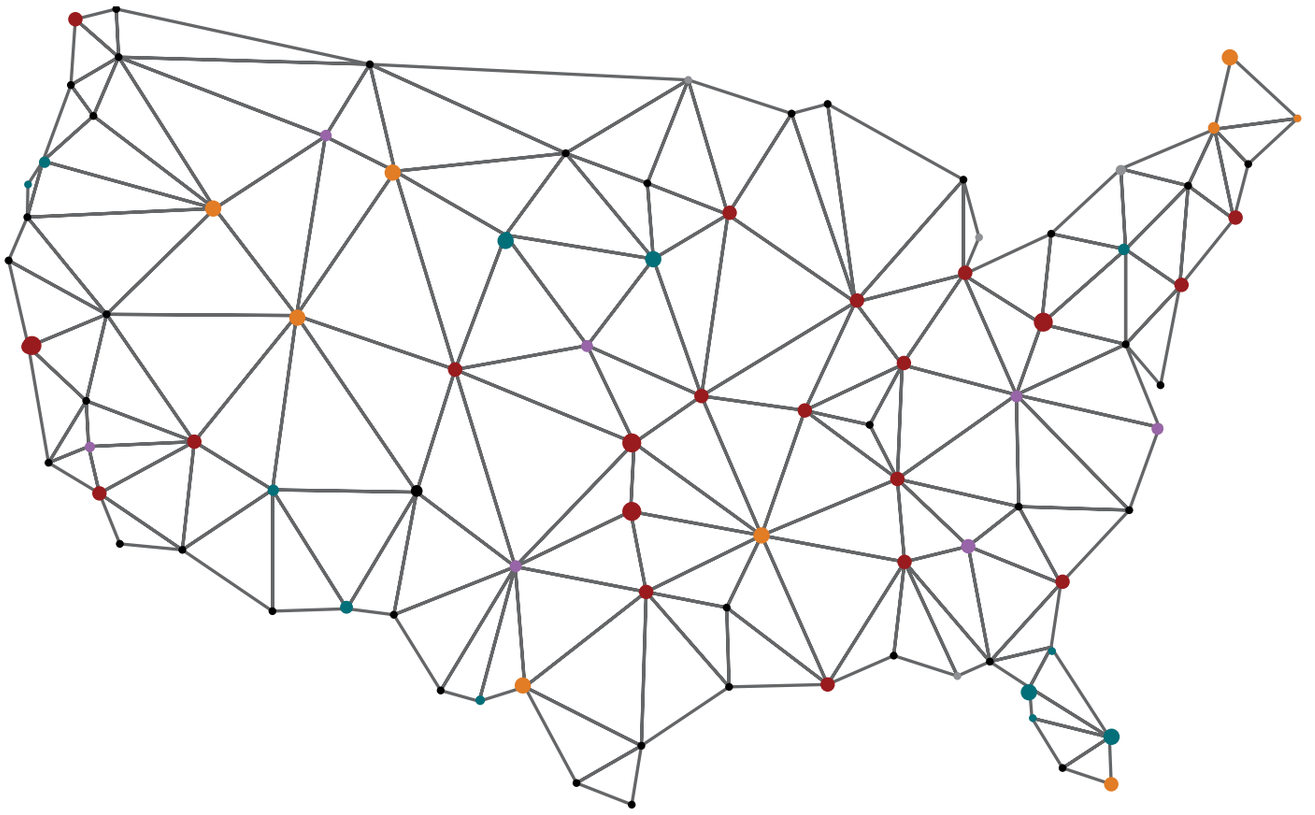
- Sustainable funding for both public and private laboratories
- Diverse workforce and an established pipeline for a highly skilled workforce
- Communication platform(s) to quickly share information with laboratories and partners
- Strong laboratory and epidemiological partnerships
- Identification of specific roles and responsibilities of each type of laboratory and other partners
- Surge planning that engages private sector
- Robust supply chain
- Scalable and flexible technologies that can easily pivot to respond to a range of threats
- Modern electronic system for test ordering, data collection, analysis and reporting
- Quality management system(s)
- Investment in research and development, with a focus on innovation.

In addition to the findings described above, participants noted that a gap analysis utilizing a scenario-based approach (e.g., previous emergency events) could be helpful in analyzing what worked, as well as opportunities for improvement in national laboratory coordination.

…Which Leads to Resilient Response Systems

APHL has also taken steps to formulate a strategy to prepare for and respond to biological emergencies. The strategy, articulated in The Testing Playbook for Biological Emergencies, provides US decision makers at the federal, state and local level with a clear, evidence-based guide for making rapid and effective decisions regarding the development, implementation and scale-up of diagnostic testing at every stage in an infectious disease emergency. The laybook is divided into six sequential phases of a biological emergency and outlines steps for achieving effective outbreak testing as early as possible and throughout a disease emergency. The playbook is the work of national public health experts, led by APHL and the Pandemic Center at the Brown University School of Public Health.

While there is progress in coordinating how the US responds to emerging infectious diseases, there remains a need to create a well-coordinated national laboratory response system, managed by a lead federal agency such as CDC. The system would certainly go beyond infectious diseases and encompass a network of private and public laboratories positioned to respond to public health threats. Many components of the existing CDC-managed LRN can provide the framework for a broader and effective national laboratory response system. ■



Closing the Radiochemistry Workforce Gap: Expanding Laboratory Readiness for Routine and Emergency Analysis

By **Royce Riessen**, MBA, specialist, Environmental Health and **Sarah Wright**, MS, manager, Environmental Laboratories

Dr. Dustin May (center), Environmental Laboratory Manager at the University of Iowa State Hygienic Laboratory, with lab analysts **Robert Walters** (left) and **Brandon Duve** (right) beside their new gas-flow proportional counter, set to be used for alpha/beta counting in next summer's session of the radiochemistry graduate certificate program.

Radiochemistry is a vital yet often overlooked area of public health that detects and quantifies radioactive materials in the environment and in people. These contaminants originate from both natural sources, such as radon and uranium, and man-made isotopes used in nuclear energy, medicine, and industrial applications.The demand to monitor for radiological contaminants may also expand in the future as carbon-free nuclear energy sources are chosen to meet carbon reduction goals. Radioactive contaminants all either emit alpha, beta or gamma radiation, which, respectively, increasingly differ in mass, energy and how deeply they penetrate people and objects. Lifetime cancer risks rise as radiation exposures rise, and high exposures during extreme events can cause acute radiation syndrome, leading to nausea, vomiting and possibly death. State and local public health and environmental laboratories are critical for providing accurate radiation testing to assess these risks in both routine monitoring and emergency situations.

One example of a radiation emergency response occurred in May 2019 at the Harborview Medical Center Research and Training Building in Seattle, WA. A sealed radioactive cesium-137 source typically used for sterilization in medical research was compromised during its decommissioning. The breach released cesium chloride powder, which contaminated the loading dock and multiple buildings, and exposed 13 individuals to the radioactive material. Although no immediate health effects were reported, the radiochemistry group at the Washington State Public Health Laboratories (WA PHL) was brought on to analyze over 2,500 air filter and surface wipe samples over the two-year cleanup process to ensure cesium was no longer detectable. This thorough investigation, which quantified gamma and beta radiation using gamma spectrometers and gas flow proportional counters, demonstrated that the contamination primarily affected surfaces and posed no long-term health risk.

WA PHL did this emergency work in addition to the 1,500 routine monitoring samples they do annually to ensure its residents are not exposed to unacceptable radiation levels. Sources across the state include the Hanford Reservation, a decommissioned nuclear production complex originally created to make plutonium for the US Government's World War II Manhattan Project; the Columbia Generating Station, the state's only nuclear power plant; Naval Base Kitsap, one of a handful of nationwide military sites housing US nuclear weapons; and various medical and research facilities that handle radioactive materials. Samples, most of which are analyzed for gross alpha, gross beta and gamma radiation, are primarily air filters, but other diverse matrices such as soil, vegetation, groundwater, surface water, agricultural products, milk, fish, game and surface wipes are also tested.

This diverse work demands a unique blend of radiochemistry expertise along with a committed and adaptable workforce. Yet, according to the 2023 APHL All-Hazards Laboratory Preparedness Survey, 91% (20/22) of the state public health laboratories with the responsibility to perform this testing in 2023 reported the need for additional radiochemists to meet their jurisdiction's public health needs. This one year of statistics, however, is representative of a decades-long shortage of trained radiochemists. To help address this, a new CDC-supported radiochemistry graduate certificate program has been developed by the University of Iowa in partnership with APHL.

The program's goal is to equip students with the background, theory, practical

20

state laboratories reported a need for additional radiochemists to meet work needs in 2023.

Reference:
Littell, V. H. (2024, September 12). Expanding the Radiobioassay Emergency Response Capabilities of the LRN-R [Webinar]. APHL. https://learn.aphl.org/learn/course/399/session/73/laboratory-response-network-101-part-ii-live

knowledge and hands-on training required to address the routine and emerging radiochemistry challenges that state laboratories, like WA PHL, continually face. In September, the first cohort of 12 students from 12 state public health and environmental laboratories went back to school for a year of online and in-person classes. The student experience is further supported by a mentorship program, APHL's new radiochemistry community of practice and travel scholarships to conferences and peer laboratories.

APHL also offers internship and fellowship opportunities to further support early-career scientists entering the field. These programs aim to attract more radiochemistry scientists to state laboratories, increase their retention rate and expand their expertise to ensure state laboratories have the capability and capacity to test for radiochemical threats to our nation's public health and security. For more information on these or other radiochemistry resources or opportunities, please contact eh@aphl.org.

"I wish I had this [University of Iowa radiochemistry graduate certificate program] opportunity when I first started. By having a member of my team get this scholarship opportunity, it will enable us to continue with our mission to protect public health and grow and develop the next generation of radiochemists using the knowledge and experience learned from this exciting educational opportunity."

— Sarah Martinez, manager, Radiochemistry Group, Texas Department of State Health Services Laboratory

Jimi Adisa

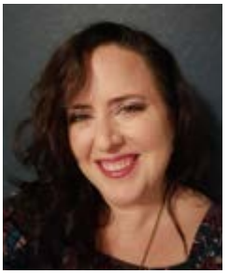
Chemist, Pennsylvania Department of Environmental Protection Bureau of Laboratories

Undergraduate degree: Chemistry

Justin Archuleta

Radiochemist Operational, New Mexico Department of Health Scientific Laboratory

Undergraduate degree: Chemistry



Madeleine Blumenthal, MA

Chemist III, Texas Public Health Laboratory Division

Undergraduate degree: Chemistry

Jenelle Hansen

Chemist, Kansas Health and Environment Laboratories

Undergraduate degree: Geology

Mark Kanow, PhD

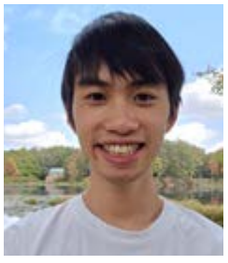
Lab Scientist, Minnesota Department of Health

Undergraduate degree: Biochemistry/Molecular Biology and Chemistry

Virginia Littell, MS

Chemist 3, Washington State Public Health Laboratory

Undergraduate degree: Earth and Space Sciences



Hosea Mak, MPH, MS

Chemist 1, New Jersey Department of Health

Undergraduate degree: Chemistry

Ashton McCuin

Radiochemistry Unit Coordinator, Vermont Department of Health Laboratory

Undergraduate degree: Chemistry

Michael Populin

Chemist II, Wisconsin State Laboratory of Hygiene

Undergraduate degree: Biochemistry

Saluta Sanders

Senior Chemist, Glen F. Baker Public Health Laboratory (AR)

Undergraduate degree: Chemistry

McKenzie Scheffler, MPH, MS

Scientist,Michigan Department of Health and Human Services

Undergraduate degree: Biology

Alex Wang

Research Scientist I, California Department of Public Health Radiochemistry Unit

Undergraduate degree: Pharmaceutical Chemistry

Twelve public health laboratory scientists make up the first cohort of the University of Iowa radiochemistry grauate certificate program.

No Boundaries: An Introduction to International Biomonitoring Initiatives

By **Julianne Nassif**, MS, senior director, Environmental Health

Scientists around the world rely on human biomonitoring to measure chemical body burdens and understand sources and routes of chemical exposure to individuals, communities and populations. Biomonitoring investigations are resource-intensive activities requiring highly skilled analytical, epidemiological and toxicology personnel; sophisticated instrumentation; and extensive participant recruitment activities. As analytical technology evolved and expertise expanded, an increased volume of biomonitoring data is being generated and reported. Several biomonitoring networks and partnerships have been implemented globally, leveraging the expertise, capability and capacity of colleagues to meet jurisdictional public health and research needs.

Starting Local…

Within the US, the Division of Laboratory Sciences within the US Centers for Disease Control and Prevention's (CDC) National Center for Environmental Health (NCEH) partners with the National Health and Nutrition Survey to collect clinical specimens and capture demographic and exposure information from a nationally representative US population. NCEH publishes the *National Report on Human Exposure to Environmental Chemicals* and updates analyte-specific tables periodically. These statistically derived reference ranges are frequently used for comparative purposes when no health-based values are available.

The National Biomonitoring Network is a collaborative effort of APHL and NCEH, which aims to increase capability and capacity in the states to conduct high-quality biomonitoring investigations for public health practice. State programs engage in biomonitoring for statewide surveillance, emergency response and/or community investigations. The data are used to inform and evaluate public health policy and interventions aimed at reducing exposures and improving health.

The National Institute of Environmental Health Sciences (NIEHS) coordinates the Human Health Exposure Analysis Resource (HHEAR) a collaboration of academic, federal and state partners with advanced analytical and data analysis capabilities available to researchers.

These US-based efforts regularly collaborate with European, Asian and Canadian biomonitoring projects in three priority areas: harmonization of laboratory measures, contributions to repositories of health-based reference ranges and standardization of minimum information requirements.

…and Going Global

Several domestic and international laboratories have partnered to demonstrate testing proficiency through analysis of common quality assessment panels, proficiency testing challenges and analysis of split samples. These efforts demonstrate the initial successes of the harmonization scheme and highlight areas of opportunity for improvement through shared training and protocols.

The International Society of Exposure Sciences (ISES) brings together scientists engaged in analytical chemistry, toxicology, modeling and statistical analysis to share ideas. ISES is also home to the international working group on human biomonitoring (i-HBM). The working group aims to promote comparability across international programs and borders through consensus publications and amplification of data harmonization principles. This large and active workgroup has collaborated on important technical issues by raising the collective voice of the group and amplifying the work of the individual members.

The Canadian Health Measures Survey developed and maintains an open access database of published health-based reference ranges to which public health professionals and researchers can refer when considering program and/or policy development. It serves as a repository of ranges that were determined in various ways. They should be reviewed critically to ensure the methodology for deriving the standards meets current needs. A peer-reviewed publication, *Interpreting Biomonitoring Data: Introducing the International Human Biomonitoring (i-HBM) Working Group's Health-based Guidance Value (HB2GV) Dashboard*, was published in 2023.[1]

European scientists from the Partnership for the Assessment of Risks from Chemicals (PARC), a follow-up to the groundbreaking work of the 28-nation Human Biomonitoring for the European Union (HBM4EU), aims to improve knowledge about chemicals to protect human health and the environment. A first step in standardizing collection of biomonitoring demographic and exposure information is a draft manuscript initiated by PARC with substantive input from numerous collaborators in the US, Canada and Asia, *Guidance on Minimum Information Required for Designing and Reporting Human Biomonitoring Studies*[4].

These are a few examples of efforts to harmonize laboratory measurements to enable comparison of biomonitoring data across geographic boundaries and to improve consistency in the way exposure information is gathered and interpreted. ■

References

1. Nakayama SF, St-Amand A, Pollock T, Apel P, Bamai YA, Barr DB, et al. Interpreting Biomonitoring Data: Introducing the International Human Biomonitoring (i-HBM) Working Group's Health-based Guidance Value (HB2GV) Dashboard. *Int J Hyg Environ Health.* 2023 Jan; 247:114046. Available from www.ncbi.nlm.nih.gov/pmc/articles/PMC10103580/
2. Kolossa-Gehring M, Schoeters G, Castaño A, Barouki R, Haines D, Polcher A, et al. Special Issue Editorial: Key Results of the European Human Biomonitoring Initiative (HBM4EU). *Int J Hyg Environ Health.* 2023 Aug; 253:114197. Available from pubmed.ncbi.nlm.nih.gov/37291032/
3. Various authors. Special Issue on Human Biomonitoring Networks. *International Journal of Hygiene and Environmental Health.* Available from www.sciencedirect.com/special-issue/10VXCV96ZMZ
4. Zayed et al. Guidance on Minimum Information Required for Designing and Reporting Human Biomonitoring Studies. Draft manuscript, 2024.

Unified Response to *Cronobacter*: A Public Health Collaboration Success Story

By **Allison Gennety**, specialist, Food Safety

Bacterial contamination in food provides a constant reminder of the critical role public health laboratories have in protecting the safety of the nation's food supply. However, foodborne illness is not always caused by the typical enteric pathogens, such as *Salmonella* or *Listeria*. *Cronobacter* species are bacterial pathogens that can be found throughout the environment, from soil to kitchen sinks, and sometimes find their way into food. An opportunistic pathogen, *Cronobacter*, is particularly dangerous to children under 12 months, and infections can lead to meningitis and sepsis. In 2022, an incident occurred that brought national attention to *Cronobacter* contamination in powdered infant formula, after which a US Food and Drug Administration (FDA) investigation resulted in a large voluntary recall of formula from one manufacturer's plant.

A Position Statement is Submitted

Due to this high-profile event, the Council of State and Territorial Epidemiologists (CSTE) worked with various partners, including public health laboratories, to write a position statement to add *Cronobacter* to the list of Nationally Notifiable Conditions. This position statement is an important step forward in strengthening the ability of public health professionals to detect and control *Cronobacter* contamination events.

Additional work is necessary to raise awareness of this pathogen and facilitate actions to better help with testing and surveillance of *Cronobacter* illnesses.

With support from APHL and CSTE, a collaborative workgroup was born out of the position statement with the goal of creating guidance documents on how to handle *Cronobacter* cases and included key partners and subject matter experts from the US Centers for Disease Control and Prevention (CDC), FDA, clinical and public health laboratories and epidemiologists. The guidance documents provide a framework for public health to work within and include information on sample collection, transportation time, where to send isolates and the use of whole genome sequencing to aid in *Cronobacter* surveillance. This multidisciplinary collaboration ensured that the new guidance, which was released to the public in June, is practical for a range of public health settings, from laboratory to epidemiologists, while also including the latest information on *Cronobacter* control and testing.

A Framework for Future Unified Health Collaborations

The development of these guidance documents is a testament to the power of coordinated action by public health. The joint efforts of these public health partners create a foundation to improve the detection and surveillance of *Cronobacter* and strengthens public health preparedness and response as a whole. The success of this group shows the importance of cross-agency collaboration for addressing emerging food safety threats and can serve as a blueprint for future projects. By working together, a unified health response can continue to protect vulnerable populations and food safety. ■

Creating National Repositories for Managing AMR Data

By **Reshma Kakkar**, manager, Global Health Informatics; **Rufus Nyaga**, deputy director, Kenya; **Ephrem Mekonnen**, specialist, Informatics, Ethiopia; **Kasimona Sichela**, lead, Informatics, Zambia; and **Fredrick Mwasekaga**, senior technical manager, Tanzania

This poem was presented at the Global Health Security Conference, held in Australia in June 2024, where attendees were advised they could not use PowerPoint slides for their presentations:

There once was an antibiogram
That said all on my own I am
I can tell you more about susceptibility
And resistance trends are my specialty
But without good reporting, I am in a jam

There's data data everywhere
But for standards, not many have a care
Labs doing manual data entry
Often duplicating and a lot of reentry
But good AMR data, now that is rare

Along comes APHL's practical approach
To support these labs, with no reproach
How about a national AMR data repository
That doesn't care what systems labs use and is free!
And for missing standards can serve as a coach

LIMS, WHONET, Excel are all welcome
Web portals, APIs will all find a home
Reporting becomes a piece of cake
One point of integration is all it will take
AMR repository can help, and then some!

Let's take the case of Ethiopia
Using the LIMS for AMR seemed like a utopia
But WHONET now, each lab used consistently
To enter AMR data and conduct analyses
So why not have WHONET be the source here

16 sentinel sites there are
With separate WHONET instances, each afar
Emailing files to the national lab monthly
Some on time, and some, quite tardy
Opportunities to harmonize! And not a high bar

The AMR repository was set up centrally
OpenLDR is what it is called colloquially
Each lab just used its own WHONET
To automatically push data, no need to get
Data centralization, therefore, becomes key

Now we look at Zambia
Unlimited LIMS licenses, what a great idea
Virology, parasitology, micro—you name it
The LIMS handled it all, no doubt about it
But GLASS reporting was still a dilemma

The lab data repository was well established
With reporting of data to it, labs were habituated
Now where to fit WHONET in
So GLASS reporting can effectively begin
This needed to be ruminated

What if we approach the problem differently
Labs don't have to change what they do daily
The repository generates an Excel file
Send speedily to the labs, no waiting a while
And Baclink imports the file to WHONET immediately!

Kenya, not to be left behind
Centralizing lab data has been on everyone's mind
Since the start of the pandemic
When testing volume at borders was epic
And results reporting had labs in a bind

Kenya too set up a data repository
Initially COVID lab data was all it was meant to be
But as the Ministry realized its value
For AMR reporting this was the clue
And soon these data had their own residency

All roads can lead to Rome
In OpenLDR, AMR can have a home
WHONET and GLASS reporting can be done
With standards and data centralization, it doesn't have to take eons
And data modernization doesn't become a tome

Zambia now has labs totaling 30
With AMR reporting capability
Twenty-three nationally in Kenya
Six and growing in Ethiopia
Solutions based on opportunity ■

GLOSSARY

AMR ..... Antimicrobial Resistance
GLASS ..... WHO Global Antimicrobial Resistance and Use Surveillance System
LIMS ..... Laboratory Information Management System
OpenLDR ..... Open Laboratory Data Repository

DIGITAL EXTRA

Read APHL's recent success story about its informatics team in Zambia and how the team helped develop a solution for handling and streamlining AMR data management.

The LDT Final Rule: What Public Health Laboratories Need to Know

By **Mandi Cosser**, MPH, manager, Public Policy and Regulatory Affairs

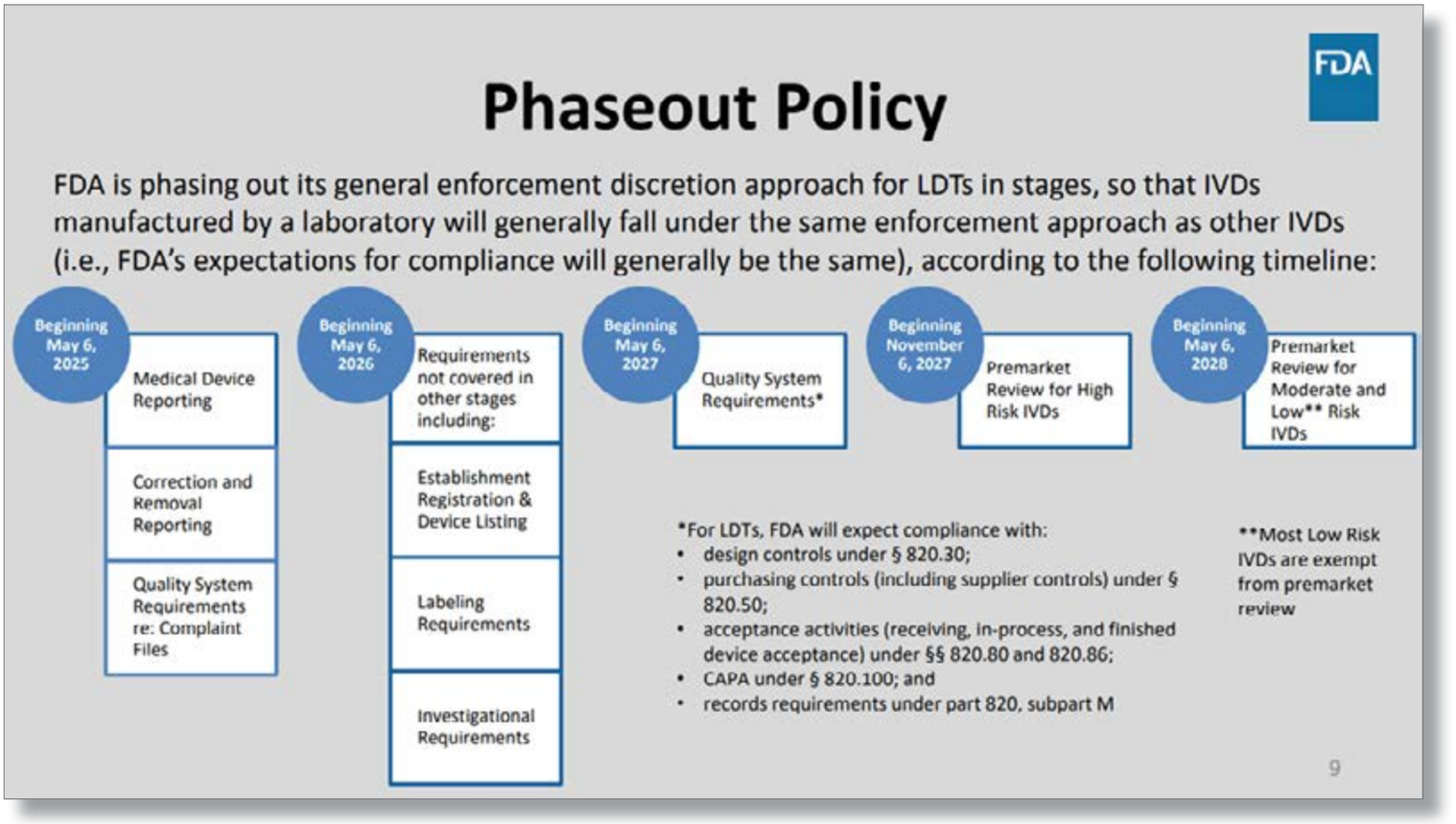


Figure 1. Enforcement Discretion Phaseout Policy

On May 6, 2024, the US Food and Drug Administration (FDA) published the Final Rule: Medical Devices; Laboratory Developed Tests (LDTs). The rule made it explicit that in vitro diagnostic devices (IVDs) are medical devices subject to regulation under the Food, Drug and Cosmetic Act, including when the manufacturer of the test is a laboratory. These IVDs include LDTs developed and used in-house at public health laboratories. This means public health laboratories are considered manufacturers when they implement an LDT.

APHL is taking multiple actions to support members in implementing the requirements of the Final Rule. The APHL Board of Directors approved the formation of the LDT Task Force, which will advise APHL where clarification and support is needed. Comprised of APHL members and staff representing program areas affected by the Final Rule, the Task Force will suggest and prioritize materials for development to assist with member compliance, identify where clarification is needed from FDA, and contribute to APHL's comments on future FDA draft guidance. This is an important function of the group as FDA will continue to provide information on meeting Final Rule requirements and will be looking for examples for their documents. APHL will inform FDA of member feedback, sharing specific examples that can be used in future FDA materials.

APHL has developed a specific mailbox, LDTquestions@aphl.org, for member requests for information.

Enforcement Discretion and LDTs

For many years, FDA had chosen to exercise enforcement discretion for LDTs and not require public health laboratories to submit packages to FDA for review and approval prior to marketing (offering) the test. The agency maintains they have always had the authority to regulate LDTs, but they had generally chosen not to. The era of general enforcement discretion for LDTs ends with the release of the Final Rule.

APHL understands public health laboratories utilize LDTs for many reasons—to promote health equity, prevent the spread of disease, conduct surveillance, develop disease treatment and prevention guidelines and respond to public health emergencies—and that members implement them to meet

population, specimen type and testing volume needs. APHL communicated this information via public comment to the FDA in December 2023 and was pleased to see many of the suggestions reflected in the Final Rule. Of significant importance to public health laboratories is the targeted enforcement discretion for certain types of tests, an improvement from the restrictive Proposed Rule language and a benefit to public health.

FDA will give targeted enforcement discretion with respect to premarket review requirements for LDTs implemented before May 6, 2024. This means the LDTs public health laboratories had in use by that date will not be subjected to the full FDA review process (also known as a premarket submission, which includes 510(k) and De Novo packages) if they are not modified or are modified in limited ways. Additionally, FDA has acknowledged that modifications to FDA-authorized tests are sometimes needed, such as to add specimen types. Under the Final Rule, there will be targeted enforcement discretion for limited modifications to another manufacturer's FDA-authorized 510(k) or De Novo test. Both the legacy LDTs and the modified FDA-authorized tests will still need to meet certain Quality System requirements:

- By May 6, 2025: Medical Device reporting, Correction and Removal reporting and Quality System (Complaint Files) requirements
- By May 6, 2026: Establishment Registration and Device Listing, Labeling and Investigational Use requirements
- By May 6, 2027: Quality System (Records) requirements for both types of tests and additional requirements for tests that are LDTs due to modifications to an FDA-approved test (Design Controls, Purchasing Controls, Acceptance Activities, and Corrective and Preventive Actions)

FDA will allow modifications to the legacy LDTs and FDA-approved tests if they do not:

- Change the indications for use of the IVD,
- Alter the operating principle of the IVD (for example, changes in critical reaction components),
- Include significantly different technology in the IVD (e.g., addition of artificial intelligence or machine learning to the test algorithm, a change from targeted sequencing to whole genome sequencing, a change from immunoassay to mass spectrometry, or a change from manual to automated procedures) or
- Adversely change the performance or safety specifications of the IVD.[1]

New LDTs marketed after May 6, 2024, and those that do not fall under one of the enforcement discretion policies, will be subject to the Enforcement Discretion Phaseout Policy (**Figure 1**), a four-year, five-stage transition that eases laboratories into meeting Quality System and premarket review requirements.

Public health surveillance tests, defined as those used strictly for surveillance and where the results are not returned to the patient or provider, are not affected by the Phaseout Policy.

Less pertinent to public health laboratories, FDA is allowing targeted enforcement discretion for LDTs for unmet needs when the laboratory and ordering provider are in the same healthcare system (such as hospital laboratories and most academic medical centers). FDA believes risk is mitigated in these situations because there is communication between the laboratory and the provider, and liability may be shared. Targeted enforcement discretion is also given for LDTs approved by the New York State Clinical Laboratory Evaluation Program. The other enforcement discretion policies are less pertinent to the majority of public health laboratories.

The FDA has many resources to help laboratorians understand these requirements, such as this overview and many recorded webinars, including a May 14 webinar specifically on the LDT Final Rule. They also intend to publish additional guidance documents, such as those on validation requirements and acceptable modifications.

Questions from APHL members are encouraged and welcomed at the LDTquestions@aphl.org mailbox. Recurring themes are developed into frequently asked questions (FAQs) and published on the new member resources LDT webpage along with other important information, such as key facts with APHL interpretation, resources for implementing LDTs and a recorded APHL webinar.

APHL continues to advocate for a pathway for public health laboratories to conduct their unique and vital work and is here to support you during this transition. Please do not hesitate to contact us at LDTquestions@aphl.org. ■

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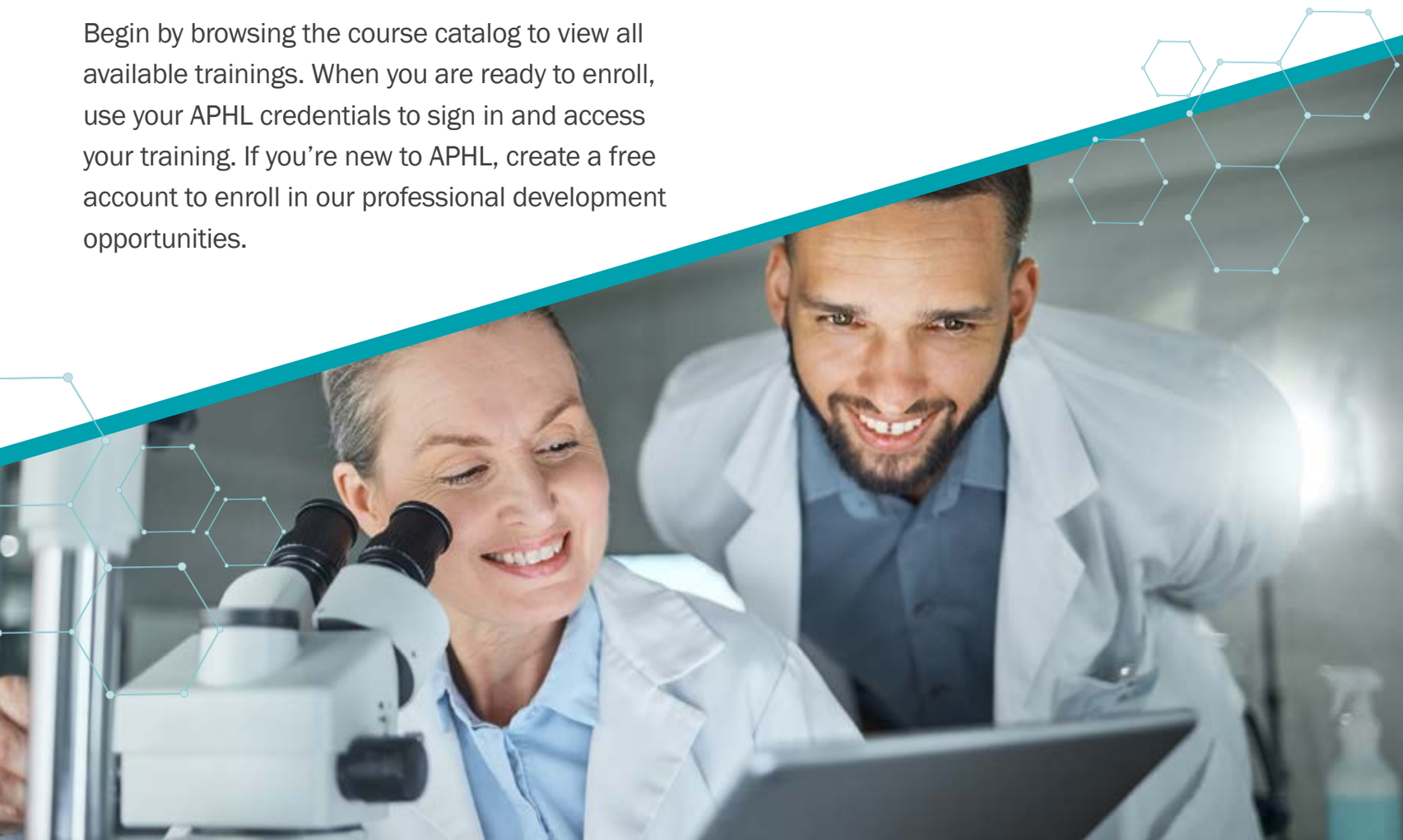

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