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Winter 2021 Issue 1



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Public health laboratories have been collecting and distributing data for decades, focused on the best practice of accessing the minimum patient data necessary to do the job required. But when the COVID-19 pandemic arrived in the US in 2020, public health laboratories began amassing data in unprecedented quantities. While the public health system has worked constantly to improve cybersecurity and data privacy protocols, there are many layers of protection that public health laboratories must engage in to ensure data accuracy, as well as to secure data for multiple uses.

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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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The Work Continues



Bill Whitmar, MS
President, APHL

"We have been at the table since Day One of the transition, talking to transition team members of the Department of Homeland Security, the Office of Science and Technology Policy, and the COVID-19 Advisory Council, providing subject matter expertise in public health laboratory science and practice."

As we write this message, it's Inauguration Day. We have witnessed history and we have lived history, all within the space of 14 days. There is cause for celebration on so many levels. But there is also cause for concern. Because even with a change in US administrations, natural disasters still happen. A pandemic is still in full swing. Babies are still being born. And an opioid crisis persists. So the work of the public health laboratory continues.

But let's take a "hot minute" to regroup.

We've been working through our day-to-day activities, but the past few years have felt different. Public health measures have been politicized on a level that we had never seen, and science itself has been questioned in ways that we never anticipated. For example, in summer 2020 we advised that focus needed to move from diagnostic testing to also consider and plan for genomic sequencing and serologic surveillance. As subject matter experts in infectious diseases, we know how an epidemic or pandemic works, and a return to surveillance is a natural next step in response. Many of our members began sequencing activities in early fall (some as early as March) and into the winter, but for the US public health system we had to strike a fine balance between operating under emergency response conditions and implementing surveillance systems–not an easy ask in the best of times.

APHL has been working closely with the Biden administration to bring them up to speed on public health laboratory activities. We have been at the table since Day One of the transition, talking to transition team members of the Department of Homeland Security, the Office of Science and Technology Policy, and the COVID-19 Advisory Council, providing subject matter expertise in public health laboratory science and practice. The administration is laser-focused on strengthening and building public health infrastructure through the American Rescue Plan, which will include a $50 billion boost in pandemic testing, sequencing and surveillance capacity.

Another positive development is that we have opportunities to be heard by the new administration—and when we say "to be heard," we mean hearing from folks on the ground. The White House wants to understand the real-world impacts of their policy decisions. We have been in contact with the Centers for Disease Control and Prevention Director Rochelle Walensky, MD, MPH, and Carole Johnson, the White House testing coordinator, as well as the White House supply coordinator and White House vaccine coordinator. Along with the Council of State and Territorial Epidemiologists, National Association of County and City Health Officials, Association of State and Territorial Health Officials, and other leading public health groups, APHL's Executive Committee will be meeting with the White House COVID Response team on a weekly basis to provide critical updates and discuss new plans.

We will also be working with the administration following its recommitment to the World Health Organization. As we well know, viruses do not care about borders or political affiliations. But we also know that we have got work to do to re-establish trust in the global public health community and the public at large. We will be working to create structures within government and outside of government that we will be able to count on for the next large-scale national event or pandemic.

"We have been telling the truth and telling the facts as we see them, and we have tried to improve the situation as much as we could."

We have begun to add in sequencing from our current role of diagnostics and surveillance, especially with the appearance of new variants. For all intents and purposes, we believe SARS-CoV-2 will be with us for the near future, so transitioning to long-term endemic testing will also become a priority. As we glean more information from the data, testing will improve with innovations in diagnostics. To help us learn more, the association has just launched "On the Horizon," a series of webinars that hope to raise awareness of new technologies, as well as initiating internal discussions about using these technologies effectively, field validation, reporting for point-of-care and home use devices, and guidance and training, among other topics.

Lastly, as you know, we have seen the dire consequences of inconsistent public health messaging. From masks to testing to vaccines, it is our fervent hope that the practices of the past can be set aside and the protection of the public can be made paramount. We have been telling the truth and telling the facts as we see them, and we have tried to improve the situation as much as we could. History is important for us, and the fact is that the history of public health funding has been on a roller coaster. COVID-19 has taught the public about the critical need for a consistent, sustained public health infrastructure and steady funding for public health programs everywhere. Much like preparing for a major snowstorm, foundations for preparedness matter. ■



Scott Becker, MS
Chief Executive Officer, APHL



Securing Public Health Data in the Age of COVID-19

By **Melanie Padgett Powers**, writer

> **"COVID-19 has shone a spotlight on the importance of information flow and maintaining privacy."**
>
> *Adam Greene, JD*

Public health laboratories have been collecting and distributing data for decades, focused on the best practice of accessing the minimum patient data necessary to do the job required. As technology has become more and more sophisticated, federal and state governments and the public health system have worked to improve cybersecurity and data privacy protocols. But there are gaps between what the Health Insurance Portability and Accountability Act (HIPAA) protects versus state privacy laws and even how state health departments interpret various privacy laws.

When the COVID-19 pandemic arrived in the US in 2020, it both underscored the gaps and exacerbated the challenges as public health laboratories began amassing data in unprecedented quantities. And, for the first time, the federal government required public health data be sent to it. In addition, more people began to question where people's health information was being stored and who could see it, particularly COVID-19 test results and vaccination records.

"COVID-19 has shone a spotlight on the importance of information flow and maintaining privacy," says Adam Greene, JD, partner at Davis Wright Tremaine LLP and outside counsel for APHL. "It has highlighted, for some, the limits of HIPAA and the fact that it doesn't reach throughout the health care system. It's brought new attention to a longstanding issue."

When it comes to medical privacy, public health laboratories may be bound by HIPAA's privacy protections, depending on whether they electronically conduct any administrative transactions with health plans, Greene explains. However, a HIPAA public health exception allows HIPAA-covered entities, including HIPAA-covered laboratories, to disclose patient health information to public health authorities without patient authorization in the interest of public health, such as preventing and controlling disease like in the case of COVID-19. Public health laboratories generally are covered under state privacy laws, which vary widely across the country.

"Each of the public health labs have to also worry about whatever their state data privacy laws require," says APHL General Counsel Troy Willitt, JD, MPA. "HIPAA sets the floor, and states can certainly build on top of that, and a number of states have done just that. How those data need to be handled once they're at the public health lab will depend on a variety of things, not the least of which is what the law requires."

This patchwork of laws can be confusing, but public health laboratories cannot always rely solely on the HIPAA public health exemption. "It's more nuanced than that," Willitt says. For instance, in some public health departments different divisions are responsible for HIPAA versus non-HIPAA compliant components. In those cases, "it depends on the division that gets the data in order to figure out how they have to treat it."

Public health laboratories should consider data privacy as a part of layers of data security that work together, says Michelle Meigs, MBA, APHL director of informatics. "You need the systems in place to help



> **"Each of the public health labs have to also worry about whatever their state data privacy laws require. HIPAA sets the floor, and states can certainly build on top of that, and a number of states have done just that. How those data need to be handled once they're at the public health lab will depend on a variety of things, not the least of which is what the law requires."**
>
> *Troy Willitt, JD, MPA*

safeguard patient data," she explains, "and then you need the processes in the laboratory, you need the policies at the state, but you also have to make sure you're complying with regulations, whether they be state or federal."

Federalization of Public Health Data

All of this became even more complicated when COVID-19 hit US shores. The Coronavirus Aid, Relief, and Economic Security (CARES) Act in March 2020 required, for the first time, federalization of public health data. The law requires "every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19" to report those results to the US Department of Health and Human Services (HHS), specifically the US Centers for Disease Control and Prevention (CDC).

APHL responded quickly to the requirement, modifying its existing APHL Informatics Messaging Services (AIMS) platform—which allows public health agencies to securely share data electronically—so agencies could send required COVID-19 test results to CDC.

However, CDC wants not only data on positive COVID-19 tests but also negative and indeterminant test results. "There is a lot of information being collected, and all data has to be reported," Meigs says. "So in the end, it is just sheer volume and it's crazy."

Public health laboratories must first report each COVID-19 test result, along with certain patient information, to their state public health department. Then the laboratories must de-identify the data before sending it to CDC.

To add to the workload, public health laboratories may receive too little or too much patient information from health care providers. Too little information requires public health laboratory professionals to track down the information required to be reported. Too much information—which may also be sent via unsecure email or fax—brings up data privacy issues. These challenges became more pronounced as COVID-19 testing ramped up and the pandemic worsened last fall and winter.

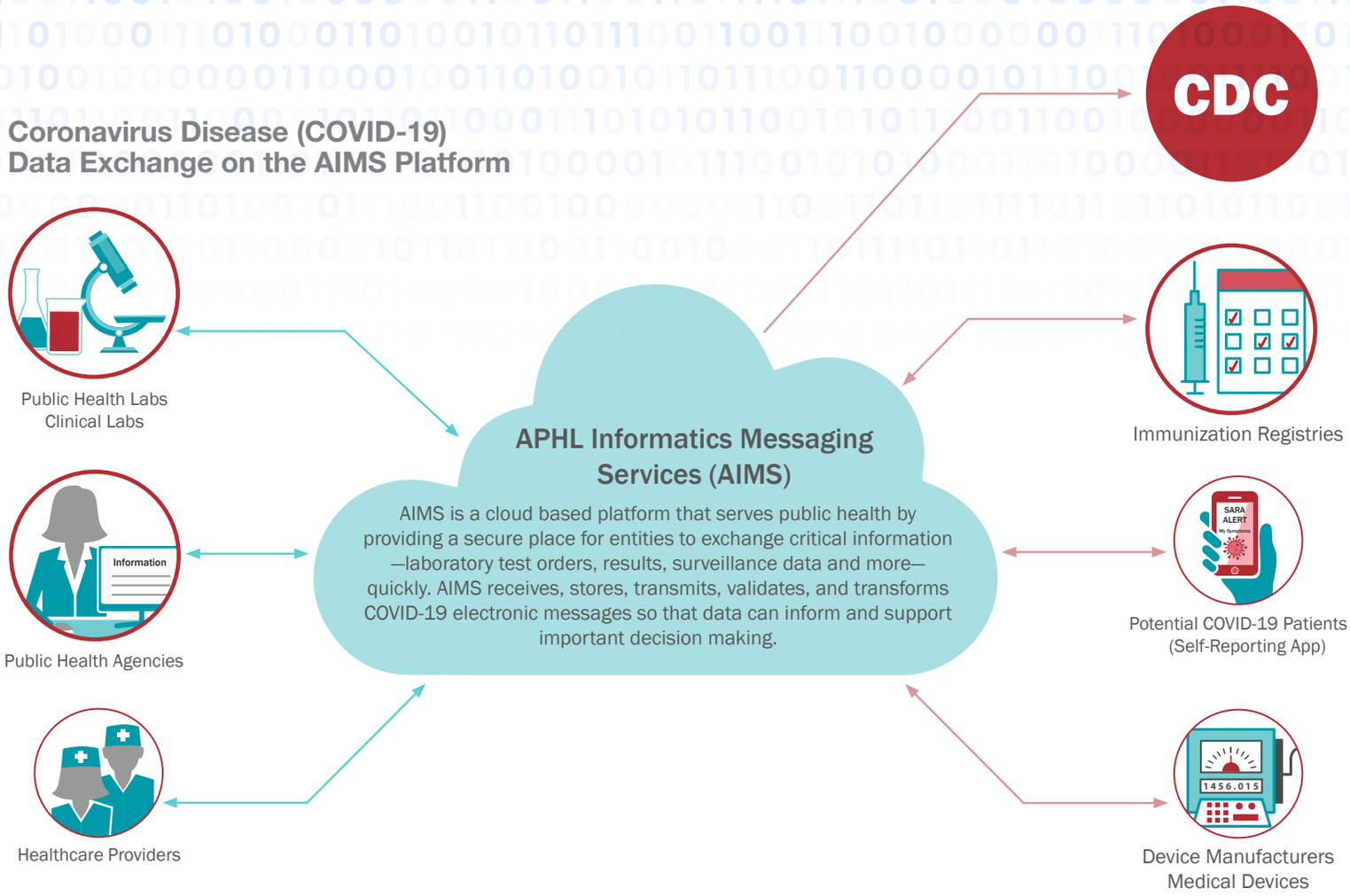
Expansion of Concerns

In 2021, data privacy and security concerns will likely reach beyond public health laboratory testing, as states develop vaccination rollout plans and as at-home testing expands. Already, the public has been worried about sharing personal data through COVID-19 contact tracing apps. Addressing one such concern, the American Civil Liberties Union has called upon states to ensure police and immigration enforcement do not have access to contact tracing or any personal health information.

A June 2020 Amnesty International report cited Norway, Bahrain and Kuwait as having some of the most invasive contact tracing apps. Norway halted its app's use after Amnesty pointed out the app violated privacy by using GPS to share real-time user location information with a government database.

During the pandemic, Google and Apple teamed up to create the Exposure Notifications System for mobile devices, which uses less-invasive proximity tracking via Bluetooth. This allows people to opt in to receive notifications when they have been near another mobile user who has since tested positive for COVID-19. While each state has a unique app, notifications can occur across states due to the use of a national server hosted by

Coronavirus Disease (COVID-19) Data Exchange on the AIMS Platform



APHL responded quickly to the requirement, modifying its existing APHL Informatics Messaging Services (AIMS) platform—which allows public health agencies to securely share data electronically—so agencies could send required COVID-19 test results to CDC.

APHL. Personal information and identities are not shared.

Americans are also expressing concern about who will have access to the vaccination records CDC is requesting from state and local public health departments. CDC is requesting names, birthdates, addresses and ethnicities of people who have been vaccinated against COVID-19, according to a December 7, 2020, *Healthline* article. New York Gov. Andrew Cuomo has said his state will not provide the data because he is not comfortable with the possibility that the US Immigration and Customs Enforcement will use it to find undocumented immigrants.

CDC does track other vaccination rates, such as how many people got an annual flu shot or how many incoming kindergartners have had the measles, mumps and rubella vaccine. However, that information is typically de-identified before sending it to CDC.

Personal information is shared with CDC for reportable illnesses such as tuberculosis, syphilis, and hepatitis A and B. However, the public may not even know about this process because of those diseases' relatively smaller numbers. In the case of COVID-19, by February 2021, more than 28 million people in the US had contracted the disease and over 500,000 had died.

Because of the widespread threat of COVID-19, debates have begun on whether individuals will soon need to show proof of vaccination to board a plane or train. Will employers require proof of vaccination for work?

> **"Some individuals are, rightly or wrongly, very concerned about the idea of big government databases that contain their sensitive information, including their health information."**
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> *Adam Greene, JD*

> **"It's not just making sure that the hardware is there, but you need staff who understand what data elements are needed, what data elements would be useful.**
>
> *Troy Willitt, JD, MPA*

"There are people who are ready and willing to provide to the Transportation Security Administration evidence of vaccination or a negative test result, but there are other people that feel very strongly that this is not the business of the federal government and may want to get on a plane without providing that evidence," Greene says. "There are strong differences of opinion on what information should be disclosed to the government entities and public health authorities and under what circumstances."

At-home Testing Data Challenges

Related to data privacy are the data collection challenges of at-home COVID-19 testing. President Joe Biden has endorsed making COVID-19 testing free for all Americans and creating a national strategy using rapid and at-home tests. If the number of tests increases substantially, Meigs says CDC may stop requiring negative and indeterminate test results because of the sheer volume of data. "CDC and others, I think, will probably say, 'Enough is enough; we don't need millions upon millions of negatives flooding our system.'" However, the federal government will likely still want national-level testing data of some sort to show test coverage.

Individuals are not mandated to report at-home test findings, so reporting will depend on where the test was done and if it needed to be sent to a laboratory. Prescription-based tests or those marketed and run by private laboratories will likely get reported, as opposed to a test that is completely over-the-counter.

At-home testing could also reduce the testing burden on public health laboratories, Meigs says. This may allow laboratories to get back to some of their regular functions and not focus primarily on COVID-19 testing.



AIMS PLATFORM ADAPTS TO NEW CHALLENGES

In 2008, APHL developed the original APHL Informatics Messaging Services (AIMS) platform, which has become instrumental during the COVID-19 pandemic. The secure AIMS platform—which became cloud-based in 2014—is the "highway" that allows public health laboratories and departments to safely transmit public health data.

In March 2020, as COVID-19 expanded throughout the US, APHL quickly modified the AIMS platform to respond to the federal requirement for state public health laboratories to share all COVID-19 test results with CDC. AIMS allowed laboratories to quickly and securely adhere to the new requirement.

APHL keeps on top of recommended cybersecurity protocols to protect AIMS and the data flowing through it. The information itself is stored in the cloud, meaning in an offsite server by a third-party cloud service provider. APHL staff cannot get to that server. In fact, they don't even know its exact address, as part of the cybersecurity measures. In addition, both the cloud service provider and APHL go through regular security and compliance audits that adhere to the Federal Information Security and Management Act.

What's Next?

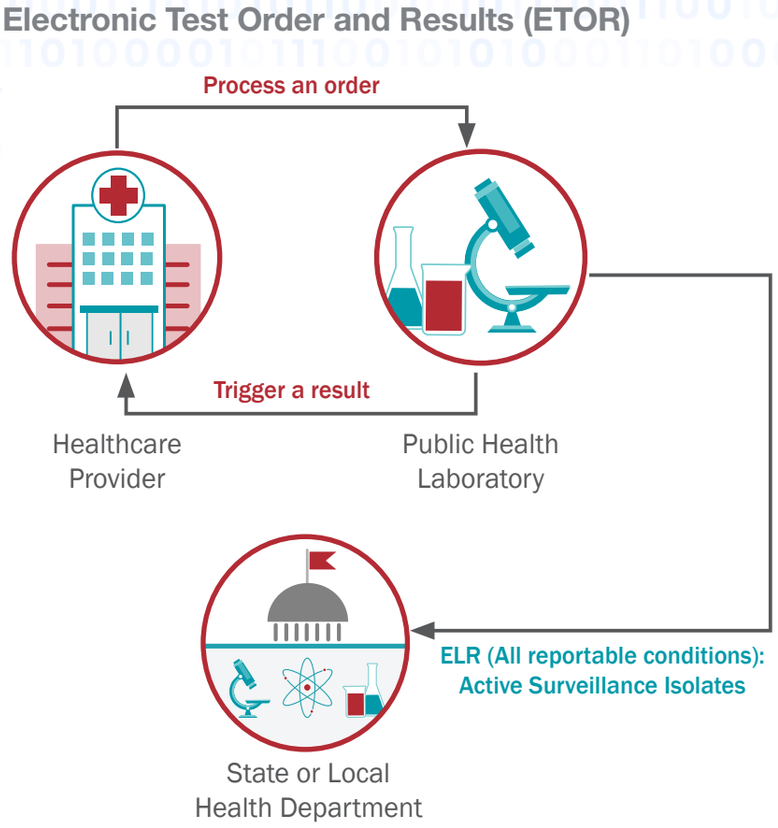
Federal health data collection has been swung wide open, with the government now requiring large amounts of personal health information. And Meigs doesn't see the door closing anytime soon. "They're going to want as much data as possible, so that they feel like they're prepared for the next pandemic. But I don't know how they're going to use it all, and I think that's the point."

Greene adds, "With CDC and the federal government involved in the response, there's definitely been a push for more direct reporting to the federal government rather than the more traditional reporting to the states and the states potentially reporting information to the federal government."

That raises a lot of questions, he says, such as whether some states will be more

adamant about maintaining their public health role over the federal government and whether the federal government needs all the data it is requesting. "Some individuals are, rightly or wrongly, very concerned about the idea of big government databases that contain their sensitive information, including their health information," Greene says.

Public health has been underfunded for years, but if state and federal governments want all this data, they must ensure the infrastructure is built to support it, Willitt says. "It's not just making sure that the hardware is there, but you need staff who understand what data elements are needed, what data elements would be useful. [Laboratory staff] can make very nuanced decisions about what should be collected and how it should be collected—rather than relying on a centralized IT department that is several layers removed and has an abstract understanding of what's needed, but not really understanding the public health necessity behind it." ■



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International Biomonitoring Network:
Collaborating to Keep Pace in a Rapidly Evolving Field

by **Annie St-Amand**, MSc, section head, National Biomonitoring Program, Health Canada

Human biomonitoring provides valuable data on the status of a population's exposure to potentially harmful chemicals and is an important tool to inform policy and decision making.

Several countries around the world have in place, or are in the process of developing, national-level human biomonitoring programs to establish baseline population exposure data and to monitor exposures over time. These programs are valuable for informing policy decisions but require large investments of time and resources to develop the necessary complex infrastructures and analytical methods. Strengthening links between programs and increasing global harmonization of approaches will allow programs to better leverage expertise, maximize efficiencies and promote alignment and comparability of data.

IBN
International Biomonitoring Network

International Biomonitoring Network

The International Biomonitoring Network (IBN) was established in 2018 bringing together national-level human biomonitoring programs. Ten international jurisdictions currently participate in the network, including Canada, United States, Germany, Japan, Belgium, Spain, France, South Korea, Taiwan and Israel. The goal of IBN is to provide a forum for exchanging information relevant to these programs, and to identify and facilitate opportunities for internal and external partnerships and collaborations. Broad themes of interest for IBN include operations and program delivery, interpretation and communication, and analytical methods. An online platform is used for ongoing information exchange and annual in-person meetings provide an opportunity for more in-depth discussions. When areas of focus require further examination, specific working groups may be proposed.



Second in-person meeting of IBN in Kaunas, Lithuania, at the ISES conference on August 20, 2019. From left to right: Shoji Nakayama (Japan), Yukiko Nishihama (Japan), André Conrad (Germany) , Antonia Calafat (US), Annie St-Amand (Canada), Victor De Jesus (US), Argelia Castaño (Spain), Greet Schoeters (Belgium), Jurgen Buekers (Belgium), Benjamin Blount (US), Marike Kolossa-Gehring (Germany), Alain Leblanc (Canada), Romuald Tagne-Fotso (France), Julie Yome (Canada), Ching-Chung Lin (Taiwan), Pau-Chung Chen (Taiwan), Julia Hurraß (Germany), Jiyoung Yoo (Korea), Meng-Shan Tsai (Taiwan), Jueun Lee (Korea), Jovile Raudoniute (Lithuania), Po-Chin Huang (Taiwan). Photo: Patrick Bélanger (Canada)

International Human Biomonitoring Guidance Values Working Group
i-HBM

New i-HBM Working Group

In 2020, the IBN initiated the development of the International Human Biomonitoring Guidance Values (i-HBM) Working Group under the International Society of Exposure Science (ISES) to further investigate the potential for harmonization of approaches for the development and use of human biomonitoring guidance values. The interpretation of biomonitoring data is a key challenge to translating results for priority setting, risk assessment and risk management. Establishing a common understanding of the interpretation tools available and consensus on the uses and limitations of these tools is an essential starting point.

Workshop, Symposium and a New Tool

To launch the i-HBM Working Group, two events were held at the 2020 ISES Annual Meeting— a symposium on interpreting and communicating human biomonitoring data using per- and poly-fluoroalkyl substances as a case study, and a pre-conference course on the development of derivation and application of human biomonitoring guidance values. The content of this workshop and symposium are available until the end of August to ISES members.

In addition, the i-HBM Guidance Value Database and Comparison Tool was created as a repository for currently available human biomonitoring guidance values and to facilitate understanding of how they may be used as screening tools in interpretating human biomonitoring data.

Ultimate Goal

The aim of these international collaborations is to maximize the use and incorporation of human biomonitoring data in public health decision making. Networks and collaborations allow us to maximize efficiencies and resources and anticipate emerging issues. Leveraging the collective power of expertise from colleagues around the world is extremely valuable to keep pace in a field that is rapidly evolving. ■

Strengthening links between programs and increasing global harmonization of approaches will allow programs to better leverage expertise, maximize efficiencies, and promote alignment and comparability of data.

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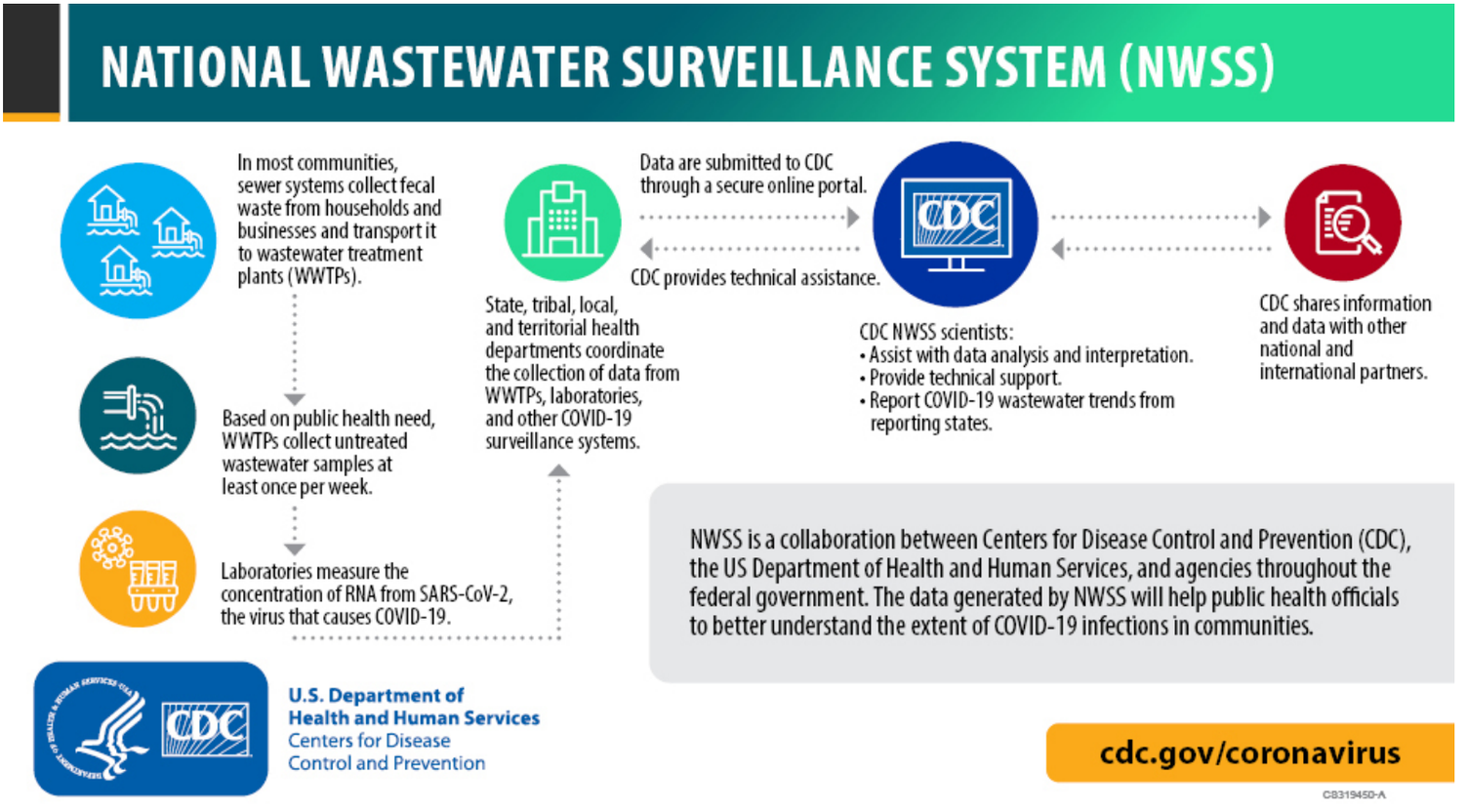
SARS-CoV-2 Wastewater Monitoring:
A Tool to Support COVID-19 Public Health Decision Making

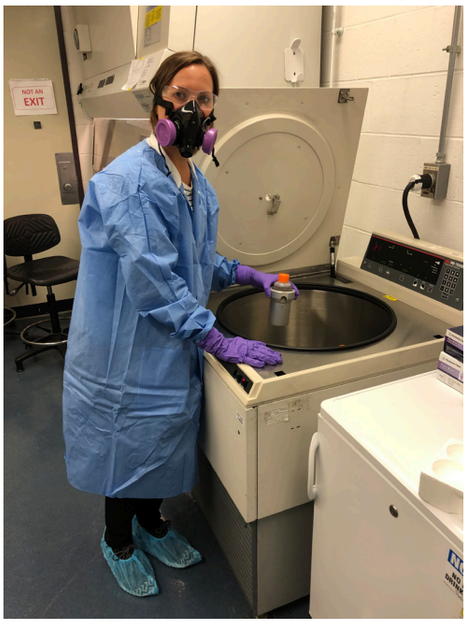
By **Mia Catharine Mattioli**, PhD, MS, science and engineering lead, National Wastewater Surveillance System, Division of Foodborne, Waterborne, and Environmental Diseases, Centers for Disease Control and Prevention and **Michaela Burns**, science communications contractor, Oak Ridge Associated Universities, Office of Research and Development, US Environmental Protection Agency

Wastewater surveillance—identifying the presence of pathogens in wastewater to complement traditional public health monitoring of disease—has been used for decades to detect viral infections such as poliovirus. But until now, it has not been used in the United States on a national scale for a viral outbreak response. Research from across the country and the world has demonstrated that SARS-CoV-2 can be detected in wastewater by looking for its genetic markers.[1,2] Quantifying these markers in wastewater has been demonstrated to reflect COVID-19 community infection trends (from symptomatic and asymptomatic individuals) sometimes days to weeks before cases are reported. In the US, this is often at the sub-county level.[3-6] The US Centers for Disease Control and Prevention (CDC) and the US Environmental Protection Agency (US EPA) are working to develop resources and tools to support states and communities in generating and incorporating wastewater surveillance into their public health response.

The National Wastewater Surveillance System (NWSS)

The CDC National Wastewater Surveillance System (NWSS) is a new public health tool for monitoring SARS-CoV-2 infection levels in communities. CDC is supporting health departments across the US using SARS-CoV-2 wastewater data to inform public health decisions. Through NWSS, participating health departments coordinate with utility partners to collect wastewater samples at least twice per week from areas of public health concern. Specialized environmental molecular laboratories then quantify SARS-CoV-2 in these samples. Health departments submit testing data and associated utility metadata into the NWSS data submission portal. CDC analyzes the data and reports wastewater SARS-CoV-2 RNA trends and normalized concentration back to NWSS partners through an internal dashboard. Data appear alongside case data from the





Researcher Nichole Brinkman prepares samples to partition SARS-CoV-2 in solid material. Photo: US EPA

area served by the utility, and account for differences in fecal contribution and laboratory methods.

Academic researchers and wastewater utilities began COVID-19 wastewater surveillance as a grassroots effort, demonstrating the power of this public health tool. As wastewater surveillance to support the COVID-19 response grows into a sustainable, nationwide system, wastewater testing will need to transition out of specialized, environmental university laboratories, and into industry and public health laboratories with the necessary capacity and public health reporting abilities. Public health laboratories are particularly well suited for wastewater surveillance testing because they can rapidly coordinate with public health partners.

NWSS is a flexible surveillance platform that can incorporate new targets (e.g., antibiotic resistance genes, as well as waterborne, foodborne and hospital-associated pathogens). APHL has formally partnered with CDC to support public health laboratories' participation in wastewater surveillance for the COVID-19 response and beyond. Alongside CDC, APHL is working to build this innovative capacity for wastewater testing in public health and environmental laboratories.

APHL has formally partnered with CDC to support public health laboratories to participate in wastewater surveillance for the COVID-19 response and beyond. Alongside CDC, APHL is working to build this innovative capacity for wastewater testing in public health and environmental laboratories.

Monitoring SARS-CoV-2 Virus Levels in Wastewater to Assess Trends in Community Infection Levels

This past spring, US EPA's Office of Research and Development began working with Ohio's EPA, Department of Health, universities and wastewater utilities to initiate a SARS-CoV-2 wastewater monitoring network for the state. Since a standard, validated method is not available for quantifying coronaviruses in water, the research initially focused on rapidly assessing methods to detect SARS-CoV-2 within wastewater. Once a suitable approach was identified, researchers began using it to measure the number of viral RNA molecules in wastewater samples received from utilities across the southwest corner of Ohio.

This effort is an example of the fast-paced, solutions-oriented research being conducted by US EPA to meet a national need. An interlaboratory comparison of methods to quantify SARS-CoV-2 in wastewater funded by the Water Research Foundation showed internal precision but varied in absolute quantification of viral RNA among protocols.[7] This indicates the need for standardization of protocols for wastewater surveillance. In the next few months, US EPA hopes to have validated, robust genetic- and culture-based methods that can be shared broadly.

In October 2020, Ohio began posting wastewater monitoring results on its public Coronavirus Dashboard, allowing data to be used by state and local officials to prioritize public health advisory efforts. Through this collaboration, the organizations are working together to share analytical and modeling approaches, conduct interlaboratory comparisons, and standardize utility and laboratory data reporting approaches. In December 2020, Ohio began submitting their statewide data into NWSS. ■

DIGITAL EXTRA: **Contact APHL and NWSS for information on setting up wastewater testing in your public health laboratory.**

References:

1. Ahmed W, Angel N, Edson J, Bibby K, Bivins A, O;Brien JW et al. First confirmed detection of SARS-CoV-2 in untreated wastewater in Australia: A proof of concept for the wastewater surveillance of COVID-19 in the community. Science of the Total Environment 2020, 728, 138764.
2. Medema G, Heijnen L, Elsinga G, Italiaander R, Brouwer A. Presence of SARS-Coronavirus-2 RNA in Sewage and Correlation with Reported COVID-19 Prevalence in the Early Stage of the Epidemic in The Netherlands. Environmental Science & Technology Letters 2020, 7, (7), 511-516.
3. Gerrity D, Papp K, Stoker M, Sims A, Frehner W. Early-pandemic wastewater surveillance of SARS-CoV-2 in Southern Nevada: Methodology, occurrence, and incidence/prevalence considerations. Water Research X 2021, 10, 100086.
4. Graham KE, Loeb SK, Wolfe MK, Catoe D, Sinnott-Armstrong N, Kim S et al. SARS-CoV-2 RNA in Wastewater Settled Solids Is Associated with COVID-19 Cases in a Large Urban Sewershed. Environmental Science & Technology 2020.
5. Gonzalez R, Curtis K, Bivins A, Bibby K, Weir MH, Yetka K et al. COVID-19 surveillance in Southeastern Virginia using wastewater-based epidemiology. Water Research 2020, 186, 116296.
6. Peccia J, Zulli A, Brackney DE, Grubaugh ND, Kaplan EH, Casanovas-Massana A et al. Measurement of SARS-CoV-2 RNA in wastewater tracks community infection dynamics. Nature Biotechnology 2020, 38, (10), 1164-1167.
7. Pecson BM, Darby E, Haas CN, Amha Y, Bartolo M, Danielson R et al. Reproducibility and sensitivity of 36 methods to quantify the SARS-CoV-2 genetic signal in wastewater: findings from an interlaboratory methods evaluation in the US. Environmental Science: Water Research and Technology 2021. Available from https://doi.org/10.1039/D0EW00946F

Virginia Responds to Severe Hypoglycemic Reactions Induced by Ingestion of Herbal Supplements

By **Shane Wyatt**, lead scientist, Division of Consolidated Laboratory Services, Department of General Services, Commonwealth of Virginia

The Division of Consolidated Laboratory Services (DCLS), under the Department of General Services, is the public health laboratory for the Commonwealth of Virginia. DCLS provides analytical testing services to other state agencies in suspected poisoning cases. In August 2019, several individuals were admitted to emergency rooms in Richmond and Lynchburg, VA, for severe hypoglycemia. In total, 17 patients were hospitalized for recurring episodes of extremely low blood sugar (Figure 1).

All individuals were male and self-reported use of an herbal supplement as an aid to sexual performance. The products were marketed under the name "V8" and sold three at a time in clear plastic bottles. The cases were first reported out by Virginia Poison Control to local health departments in affected areas. The Virginia Department of Agriculture and Consumer Services was enlisted as the regulatory agency with oversight of the sales of the supplement and to assist in removing stock from shelves. A task force of the involved agencies was created to investigate the cases and determine the cause of the severe hypoglycemia.

# Patients	Age Range	Blood Glucose Range	# Days Hospitalized	# Days of Supplement Use Prior to Episode
17	33 - 73	11 - 66	1 - 6	1 - > 1 month

Figure 1: Summary of demographic and clinical data of individuals suffering from extreme hypoglycemia

Laboratory Response

DCLS received several supplements from the affected individuals, as well as pills that were pulled from retail stores as part of the confiscation, for analysis. DCLS is a Laboratory Response Network Level 1 Chemical Emergency Response Laboratory (LRN-C), as well as a Food Emergency Response Network Cooperative Agreement (cFERN) laboratory. As part of these programs, DCLS has trained staff that respond to suspected chemical exposures by analyzing clinical, food and environmental samples for unknown chemical compounds and have responded in this capacity for 20 years. For this investigation, a literature search found similar cases reported in 2009 with severe hypoglycemia after ingestion of a supplement contaminated with a sulfonylurea drug.

DCLS screened the supplements using high-resolution liquid chromatography mass spectrometry (HRLC-MS) for sulfonylurea drugs, or other active pharmaceutical ingredients. HRLC-MS is a very useful technique since it provides the exact molecular mass of the analytes detected, making identification of unknown compounds simpler. Analysis of the supplements found that all of the pills contained the active ingredient sildenafil and several of the supplements contained the sulfonylurea drug glyburide. All of the supplements collected from individuals suffering from severe hypoglycemia had glyburide (Figure 2). It should be noted that the concentration range of sildenafil in the suspected tablets was the same as the recommended low and high dosage in commercial products. The concentration range of glyburide, however, was 5-10 times higher than the therapeutic dose for the treatment of diabetes. Glyburide was only found in pills that had the low concentration of 55 mg/pill of sildenafil.

Active Ingredient	Concentration Range Detected
Sildenafil	55 – 156 mg/pill
Glyburide	90 – 100 mg/pill

Figure 2: Concentration ranges of active ingredients found in V8 herbal supplements





Left: Back of herbal supplements suspected to contain sulfonylurea drugs. DCLS received samples in the original packaging, similar in shape and color to commercial erectile dysfunction medications. Photo: DCLS

Right: Front of herbal supplements suspected to contain sulfonylurea drugs. DCLS received samples in the original packaging, similar in shape and color to commercial erectile dysfunction medications. Photo: DCLS

Glyburide is an oral diabetes medicine that helps control blood sugar levels. Glyburide is used together with diet and exercise to improve blood sugar control in adults with type 2 diabetes mellitus. Maximum recommended dose: 20 mg/day.

Discussion

Herbal supplements are sold over the counter and with little to no regulation of ingredients by state and local agencies. In this instance, the supplements were imported and sold without labeling of ingredients of any kind. The intentional addition of sildenafil to promote sexual performance in males is an illegal activity in the US and places these supplements in the category of counterfeit drugs. No reason for the use of glyburide in the supplements has been found, however its addition created a public health concern that could have resulted in serious injury or death. The ability of public health laboratories to screen for and identify unknown compounds is of distinct benefit to the communities they serve. This investigation also highlights the importance of rapid response capability of analytical testing and the necessity of active collaborations with other stakeholders in a public health crisis. ■

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DIGITAL EXTRA: Read more in the June 19, 2020 MMWR.

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APHL

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"The future isn't what it used to be":
Managing Data Privacy in Kenya in Wake of COVID-19 Pandemic Response

by **Rufus Nyaga**, informatics technical manager, APHL Kenya and **Reshma Kakkar**, informatics manager, Global Health

The COVID-19 pandemic has created a unique quandary for data privacy proponents. On one hand, sharing of detailed data is critical to ensure appropriate actions such as contact tracing. On the other hand, it is also important to assure that data remain protected.

In Kenya, APHL, through critical partnerships with the Ministry of Health (MoH)/National Public Health Laboratories (NPHL), has not only established a centralized national laboratory data repository for consolidating COVID-19 laboratory data, but also achieved consensus from private and public laboratories throughout the country to share COVID-19 laboratory data with the repository. This is no mean feat, especially when many developed countries are challenged with convincing all testing laboratories to share their data in a timely manner for accurate reporting to the World Health Organization (WHO) and other key institutions to guide national and global response efforts.

Laying Foundations Early

A primary reason for this accomplishment was early engagement about the importance of laboratory data sharing and reporting with all laboratories that were testing or planned to add COVID-19 testing capability. With Kenya's decentralized approach to testing, county (equivalent to states) and private laboratories independently conduct COVID-19 testing after receiving certification from MoH. To address the range of data privacy concerns resulting from the need to share testing data, NPHL developed agreements with both public and private laboratories sharing data with the repository, as well as external entities that utilize data from the repository to govern privacy and confidentiality.



APHL and the MoH Information and Communication Technology (ICT) team configured the repository as an extension of the established Laboratory Information Management System (LIMS) at NPHL, enabling security features that ensured only authorized users had access to these sensitive data. Any result submitted to or accessed from the repository by any user is fully audited. Therefore, at any point in time, the repository can generate a detailed report (audit trail) on who accessed the data, what was accessed and when. All authorized repository users also sign non-disclosure agreements. All application programming interface (API) integrations with external systems are through previously declared internet protocol (IP) addresses that are whitelisted on NPHL's server, thus adding further security to the data submission and retrieval process.

Key highlights of the data management efforts to support Kenya's COVID-19 response include:

- 100% of laboratories conducting COVID-19 testing are now sharing data with the National COVID-19 data repository. This was possible due to NPHL and APHL establishing data privacy requirements. Of these laboratories, 40% are private and the remaining are public facilities.
- Data integration with external systems was also feasible due to measures instituted for data privacy and confidentiality. This secure integration was instrumental in enriching the data available to surveillance and other existing systems to support their core mandate.
- Dashboards providing daily/monthly summary on COVID-19 testing status have been valuable to the MoH and NPHL and no personally identifiable information is available through these tools. ■

Innovation In A Time of Crisis:
Mozambique's Laboratory Information Systems

By **Sofia Viegas**, PhD, director, National Public Health Laboratories, Instituto Nacional de Saúde; **Solon Kidane**, senior laboratory manager, APHL Mozambique; **Reshma Kakkar**, MA, informatics manager, Global Health and **Palmira Mangae**, specialist, Global Health

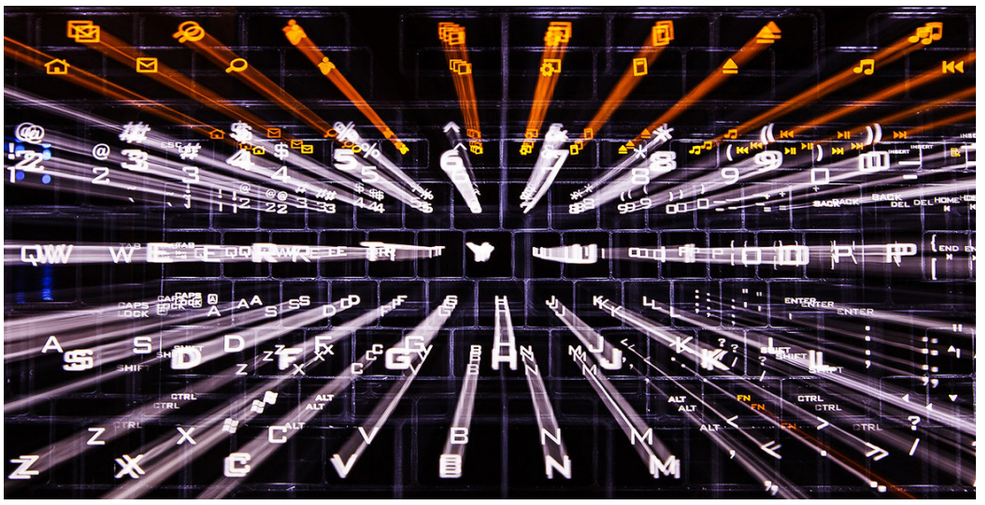
The COVID-19 pandemic has pushed public health professionals around the world to innovate and implement new ways of delivering care. Faced with managing large volumes of testing and limited resources, APHL, in collaboration with the Mozambique Ministry of Health (MISAU) and Instituto Nacional de Saúde (INS), got creative and repurposed the previously implemented laboratory information systems (LIS) to support COVID-19 testing.

While the LIS was originally deployed to support the needs of HIV care and treatment, modifications enabled them to be used to manage laboratory data needs of the COVID-19 pandemic, from data and sample tracking from points of collection to testing laboratories. In addition, the systems provided management of COVID-19 laboratory data at the national level, daily caseload reporting to MISAU, and results authentication by the Mozambique government for purposes of travel. The collaboration between APHL, MISAU and INS, while strategizing a rapid and innovative response, also supported the need for data privacy and confidentiality—areas of particular concern with COVID-19 data.

Some specific and successful activities carried out through this collaboration include:

- Enhancing the national laboratory data repository, a trusted resource for MISAU and INS thanks to a successful track record demonstrating secure storage and reporting of laboratory data
- Use of one data source (i.e., the laboratory data repository) for all reporting including the critical COVID-19 daily standardized summary report that required synthesis of data from disparate data sets
- Submission of this daily report in electronic format to local and regional authorities
- Minimal human intervention for report generation from the laboratory data repository, resulting in not only a sustainable process requiring fewer resources, but also reducing number of staff requesting access to data thus improving data security
- Reports that can be used by local and regional authorities for public health surveillance, contact tracing and to make informed COVID-19 response decisions
- Initiation and rollout of a secure short message service (SMS) alert system for communicating negative COVID-19 test results to patients across the country while maintaining data privacy
- Development and deployment of an application to collect COVID-19 test data from private laboratories and merge these data into the national laboratory data repository
- Designing a solution to authenticate COVID-19 test results to determine an individual's ability to cross Mozambique's borders into any of the six neighboring countries. Using a secure mobile app from the LIS provider, APHL built capability to authenticate the results of a COVID-19 test based on scanning a barcode printed on a traveler's printed test result. No personal identifiable data is displayed on the app and no data are stored locally.

With these tools in place, public health officials with authorized access are able to securely monitor the nation's testing capacity, inform public health policy and practice and ensure validity of test results. Both the LIS and the national laboratory data repository that are maintained and managed by APHL for MISAU are seen as a key reason for the successful utilization of data in guiding the COVID-19 response. These powerful tools have demonstrated they can be used to serve Mozambique for routine testing and sample management, as well as act as a gateway to stand up a national response for emergency and unprecedented public health threats. ■



The Role of High-Throughput Open Channel Platforms in a Pandemic Response and Beyond

by **Ashley Nenninger**, PhD, Scientific Affairs, Hologic

In the face of a rapidly emerging public health threat, an equally rapid diagnostic response is critical. As SARS-CoV-2 accelerated into a pandemic, public health laboratories were called to manage the significant diagnostic challenges presented by this global crisis and act quickly to implement new assays while dealing with an overwhelming testing volume never before experienced.

Open channel automated platforms are well-suited to meet these specific challenges, allowing swift implementation of laboratory developed tests (LDTs) to address new, urgent diagnostic needs while still providing high-volume testing capacity. Compared to the manual workflows traditionally used to run LDTs, automation significantly alleviates hands-on labor requirements, giving staff more walkaway time for other tasks.

Open channel automated systems give individual labs the opportunity to quickly make high-throughput LDTs available during outbreak responses, potentially ahead of availability of manufacturer-developed tests. As shown by Cordes and Heim, previously published SARS-CoV-2 real time PCR assays targeting the E and RdRp genes were readily adapted for use on a fully automated open channel platform—the Panther Fusion® system—prior to commercial test availability.[1] Details of the primer/probe sets and cycling protocol were included in the publication, allowing other Panther Fusion instrument users to quickly adopt these LDTs in their labs.

While the open channel feature of the Panther Fusion® system (Open Access™) gave individual labs the agility to rapidly develop SARS-CoV-2 LDTs,[1] it also allowed for expedited Emergency Use Authorization (EUA) test development by Hologic. The Panther Fusion SARS-CoV-2 assay made use of an established Hologic product, the Open Access Enzyme Cartridge, which contains dNTPs, enzymes and buffer necessary for RT-PCR reactions, and only required design and validation of SARS-CoV-2-specific primers and probes. This expedited test development led to an EUA test early in the pandemic response on March 16, 2020.

Beyond their utility in outbreak response efforts, open channel platforms enable laboratories to build upon an in vitro diagnostic (IVD) test menu with LDTs. Test menus can be customized based on local infectious disease or public health challenges, changing clinical needs facing specific communities, patient testing needs for which a commercially available test does not exist, or platform consolidation where even low-volume, esoteric tests can be kept in-house rather than sent out. The Panther Fusion® system can run IVDs alongside LDTs, using the same eluate from a single sample extraction. This was recently demonstrated by Stellrecht et al., where a Flu A/B/RSV IVD assay was complemented with influenza A typing LDTs.[2] The influenza A typing LDTs run on the Panther Fusion® system had clinical sensitivities superior to other commercially available Flu A assays; meanwhile, the automation and platform consolidation improved laboratory efficiency and reduced labor needs significantly.

When the coronavirus pandemic subsides, automated platforms with an open channel feature will continue to provide flexibility to adapt test menus as routine testing needs evolve, while maintaining high-throughput, rapid response capabilities when future public health threats emerge. ■



A scientist loads Open Access cartridges onto the Panther Fusion system. Photo: Hologic

[1] Cordes AK, Heim A. Rapid random access detection of the novel SARS-coronavirus-2 (SARS-CoV-2, previously 2019-nCoV) using an open access protocol for the Panther Fusion. *J Clin Virol.* 2020;125:104305.

[2] Stellrecht KA, Cimino JL, Maceira VP. The Panther Fusion system with Open Access functionality for laboratory-developed tests for influenza A virus subtyping. *J Clin Microbiol.* 2020;58:e00188-20.

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The Panther Fusion® SARS-CoV-2 assay:
- *has not been FDA cleared or approved;*
- *has been authorized by FDA under EUA for use by authorized laboratories;*
- *has been authorized only for detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens;*
- *is only authorized for the duration of the declaration that circumstances exist justifying authorization of emergency use of IVD tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless authorization is terminated or revoked sooner.*

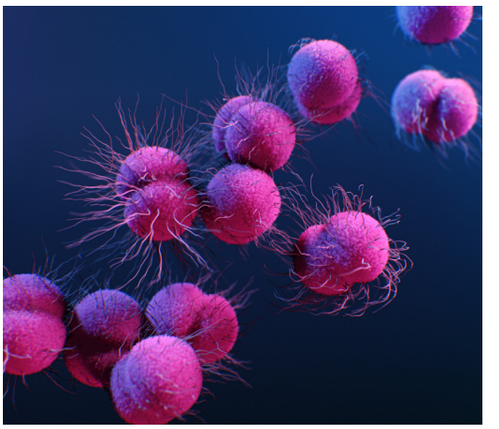
AR Lab Network Launches New Pilot Programs

by **Nikki Marchan**, senior specialist, Antimicrobial Resistance

The Antibiotic Resistance Laboratory Network (AR Lab Network) was established in 2016 to support nationwide laboratory capacity to rapidly detect antimicrobial resistance (AR), identify emerging threats and inform public health response efforts to prevent the spread of new infections. Since its establishment, testing has increased within the network in response to AR trends seen in the United States and globally. The increased laboratory capacity addresses growing concerns of infections within the community, which puts more people at risk and is more difficult to contain, as well as concerns of the emergence of new forms of resistance that can be spread in the environment. Two pilot programs were introduced in 2020 to tackle such threats.



Aspergillus



Neisseria gonorrhoeae

The AR Lab Network has strengthened the domestic infrastructure to detect, track and contain AR threats. This has put the US in a better position to respond to this public health threat and improve health outcomes. Additionally, by continuing to adopt new testing strategies, the AR Lab Network will generate the data to allow public health experts to stay ahead of new threats across healthcare, agriculture and the community.

Drug-Resistant Gonorrhea

Over the last 40 years, recommended treatment regiments for gonorrhea have changed due to emerging resistance. Penicillin, tetracycline, ciprofloxacin and fluoroquinolones, while once prescribed, are no longer recommended, leaving a single regimen as the recommended treatment for gonorrhea in the US. Unfortunately, there has been recent emergence of *Neisseria gonorrhoeae* isolates displaying resistant phenotypes to this treatment option in Europe and Australia, necessitating the need to enhance detection of drug-resistant gonorrhea in the US.

In recent years, there has been a shift from culture-based testing to nucleic acid amplification tests in many clinical laboratories. In the absence of an approved US Food and Drug Administration (FDA) assay for molecular detection of drug resistance, there is a need to have access to antibiotic susceptibility testing (AST) results as quickly as possible for certain circumstances, including assessing for treatment failure. Gradient strip AST methods are relatively simple to perform and have a short turnaround time following growth of an isolate. In the new pilot program, the Maryland Public Health Laboratory will conduct gradient strip AST on cultured isolates in compliance with Clinical Laboratory Improvement Amendments (CLIA) regulations to provide gonococcal AST results to healthcare providers for suspected treatment failure patients. This new addition to testing performed by the AR Lab Network was added in anticipation of the increased need for testing for clinical management.

Azole-Resistant *Aspergillus*

Aspergillus is a common mold that most people come into contact with on a daily basis. However it has the potential to cause different types of infections, with *Aspergillus fumigatus* causing the most human infections. A growing concern is azole-resistant *A. fumigatus,* an emerging pathogen in the US that originates from the environment. As there are only three types of antifungal drugs, with azoles being the most commonly used class of antifungals, resistance can severely limit treatment options and is especially concerning for patients with invasive fungal infections.

While further research to determine disease prevalence and resistance mechanisms is needed, most laboratories do not have the capability to perform antifungal susceptibility testing for *A. fumigatus*. This is where the AR Lab Network steps in. In this new pilot program, the Tennessee and Maryland public health laboratories will collect, confirm and characterize *A. fumigatus* isolates from hospitals, commercial, clinical and public health laboratories within the Mid-Atlantic and Southeast regions of the US. This addition to the AR Lab Network testing directory is an expansion of testing that the US Centers for Disease Control and Prevention has been conducting in its own laboratories for over a decade and will enhance understanding of azole resistance in this pathogen. ■

Advances in Testing Mark 2020 World AIDS Day

by **Anne Gaynor**, PhD, manager, HIV, Hepatitis, STD and TB Programs

Every year on December 1, the United States and countries around the world recognize World AIDS Day to bring attention to the HIV epidemic, increase HIV knowledge and awareness and speak out against HIV stigma. In 2020, the theme for World AIDS Day, "Ending the HIV/AIDS Epidemic: Resilience and Impact," mirrored the five-year US plan for Ending the HIV Epidemic (EHE).



New Diagnostic Tools

One of the four pillars of EHE is "Diagnose" with the goal of diagnosing all people with HIV as early as possible. As we reflect back on 2020 and continue to move forward in 2021 there are several notable advances to help meet the goals of EHE, including the FDA-approval of eight new HIV assays, with seven approved as an aid in HIV diagnosis:

- First HIV-2 NAT (cobas® HIV-1/HIV-2 Qualitative, Roche Molecular Systems, Inc.)
- First diagnostic test to detect HIV and Syphilis simultaneously (DPP® HIV-Syphilis System, Chembio Diagnostic Systems, Inc.)
- First HIV-1 NAT with a "dual-claim" that can be used for qualitative diagnosis and viral load monitoring (Aptima® HIV-1 Quant Dx, Hologic, Inc.)
- A second supplemental antibody differentiation assay (VioOne™ HIV Profile™ Supplemental Assay, Avioq, Inc.)
- Three additional HIV antigen/antibody screening assays (Elecsys® HIV Duo, Roche; Alinity I HIV Ag/Ab Combo, Abbott Laboratories; LIAISON® XL MUREX HIV Ab/Ag HT, DiaSorin, Inc.)
- One additional quantitative NAT for viral load monitoring on a new platform (Alinity m HIV-1, Abbott Molecular, Inc.)

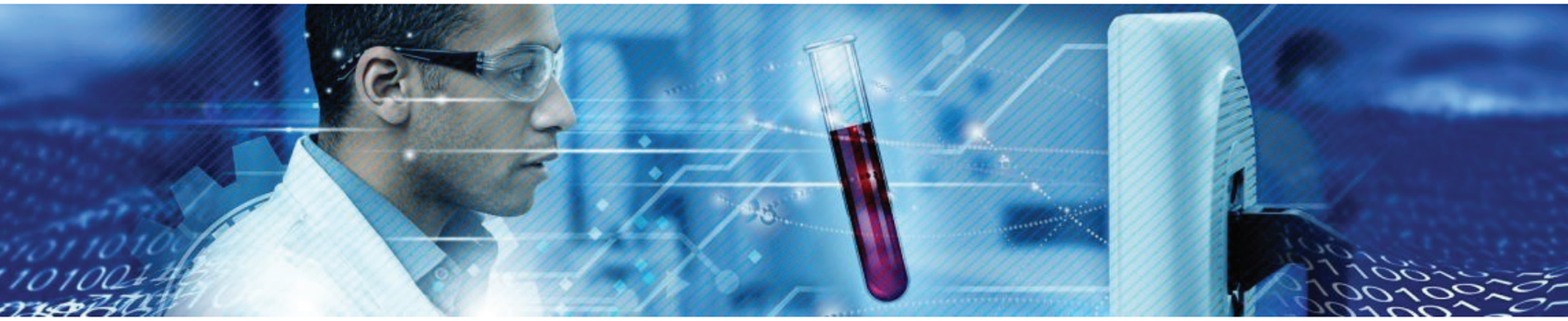
In addition to all of the newly approved assays, the US Food and Drug Administration (FDA) has also proposed re-classification of HIV assays for diagnosis and monitoring from class III to class II with special controls. If this proposed re-classification takes place, which we anticipate, we are hopeful that more innovative assays are able to be more readily developed, evaluated and approved for use in the US.

Making Testing More Accessible

Another aspect of the EHE initiative is to expand testing to meet people where they live. This includes improving availability of testing, addressing concerns about privacy and considerations for less invasive specimen collection methods. The US Centers for Disease Control and Prevention (CDC) and several national agencies are pushing for increased rapid testing. However, there are no FDA-approved point-of-care confirmatory tests for HIV testing at this time, so any person with a preliminary positive HIV result should still have blood drawn and sent to a laboratory. There is increasing interest in using alternative specimen types such as dried blood spots (DBS) that can be collected by fingerstick and are straightforward to package and mail to a laboratory for testing. However, the specimen type and approach (collection in a non-clinical setting) is not without its challenges as it is not an approved specimen type on any laboratory-based FDA-approved HIV diagnostic test and the performance may differ from the FDA-approved test (i.e., decreased sensitivity, inability to detect HIV-1 p24 antigen, etc.).

Public health laboratories exploring this option with their health department may be able to offer testing (screening or confirmatory) to previously unreachable populations with alternative specimen types and collection methods that would improve acceptability and uptake of testing. We look forward to seeing more growth in this area over time such as FDA-approved methods that include this specimen type. ■

Introduction to Laboratory Informatics: Free Online Courses



These free courses sponsored by CDC and APHL provide the learner with an introductory overview of laboratory informatics, told through the journey of a single tuberculosis specimen making its way through the laboratory. Through these modules, the learner runs through processes in the lab that showcase the relevance of what they do, key components of laboratory informatics, and reveals how data and information drive all aspects of laboratory business. Participants can earn P.A.C.E.® credits upon completion.

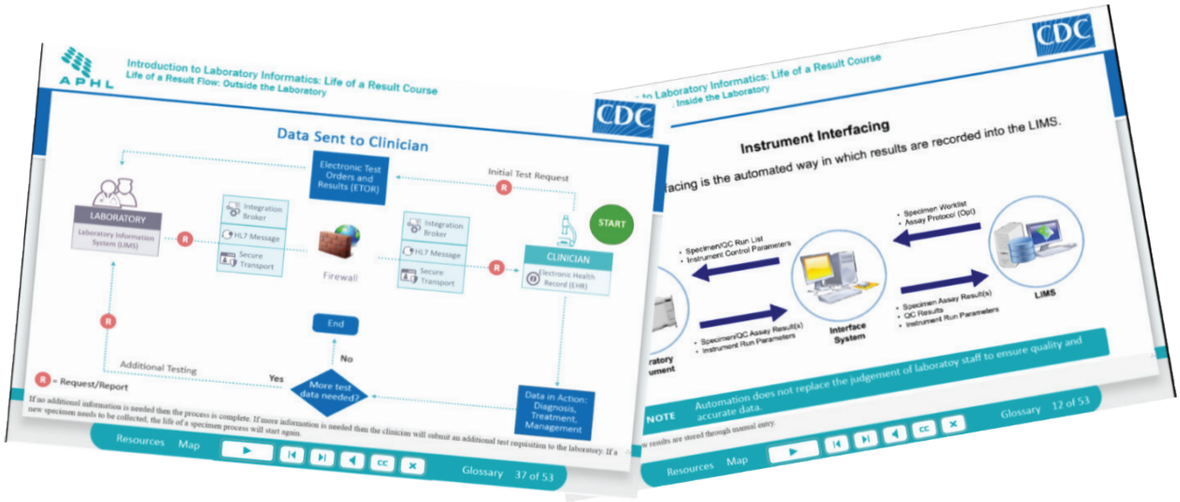
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The Life of a Specimen

In this first introductory course, learn the roles of various personnel in the laboratory informatics enterprise, data relationships, data quality and standards, and the generation and flow of information as a specimen progresses through the pre-analytic, analytic, and post-analytic phases.

The Life of a Result

The second course will help the student understand how data and information move through the laboratory and then outside the laboratory to impact clinical care and public health. Learn characterization of the recipients of laboratory data, data and results storage, and the communication of data and results (especially electronically) to various stakeholders.



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Emerging Cloud-based Solutions for Newborn Screening Workflows

By **Bryce Asay**, PhD, newborn screening bioinformatics and data analytics fellow, Utah Public Health Laboratories; **Nicole Ruiz-Schultz**, PhD, bioinformatician, Utah Public Health Laboratories and **Andreas Rohrwasser**, PhD, MBA, director, Newborn Screening, Utah Public Health Laboratories

Newborn screening (NBS) is an essential public health service that has successfully detected, diagnosed, and prevented serious and life-threatening outcomes in babies with genetic and metabolic diseases. On average, nearly 4 million babies born in the United States benefit from screening for up to 60 disorders every year. Screening is performed primarily using biochemical assays, with second-tier and confirmatory testing increasingly utilizing next-generation (NGS) or Sanger sequencing and genomic variant analysis (GVA). In biochemical assays, the concentration of a biochemical marker is measured and the value generated is compared relative to populations with and without the disease. With GVA, whole genomes or whole exomes are sequenced and variants of interest are identified using various databases containing variants that have been correlated with the disorder of interest. These approaches are computationally extensive, expensive and often require experts trained for a particular technology.

A New Future

When current technologies were originally adopted, NBS laboratories relied on on-site computing infrastructure, laboratory information management systems (LIMS) and network-attached storage devices that were maintained and run by information technology specialists, health informaticists and bioinformaticians. The system was optimized to handle peak load times to prevent bottlenecking. As a result, knowledge and resources became compartmentalized to specific individuals and departments. Today, much of the initial program-specific infrastructure is aging and the NBS workforce has failed to retain and/or recruit individuals with current training and knowledge of technologies and algorithms. Consequently, current systems are inadequate to handle the current and future requirements needed to address bioinformatics needs.

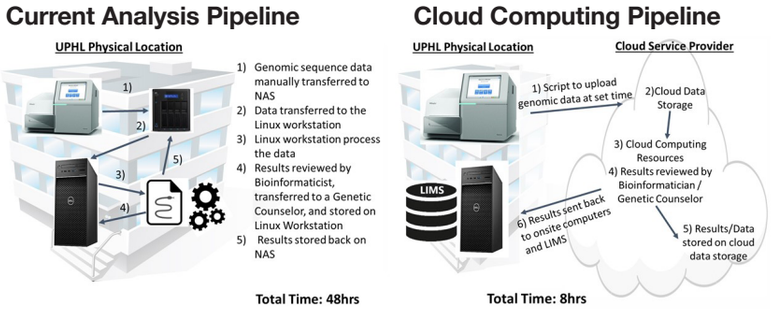


Figure 1. Illustrative comparison of current and proposed cloud computing analysis pipeline. The big advantage of the proposed pipeline is that the analysis could be done in about eight hours regardless of the number of samples while the current analysis pipeline takes about 48 hours for a limited number of samples (2-8).

Since 2006, cloud computing service providers (CCSPs) have become publicly available and can greatly enhance NBS analysis pipelines. However, broad utilization is not a common practice. Commonly perceived barriers to adoption include data security concerns as well as a lack of expertise regarding rapidly advancing infrastructure and tools. In reality, CCSPs are one of the most secure and HIPAA-compliant technologies available, suggesting that when implemented properly they may be more secure than on-site environments. CCSPs also lower the burden on system experts as the providers maintain the infrastructure and security protection.

A Flexible Work Flow

The main advantage of CCSPs is the availability of on-demand resources to handle computational surges. This elasticity and scalability guarantee that the turn-around time advantages are independent of throughput demands. Secondly, with cloud computing infrastructure all data and resources can be centrally located and accessed remotely. This has become especially important in the context of the current COVID-19 pandemic when the workforce had to quickly adopt distributed solutions. Lastly, CCSPs provide flexibility for laboratories to move entirely to the cloud or adopt hybrid solutions integrating with current on-site networks. With no need to entirely replace current systems, laboratories can "ease in" by optimizing processes that are computationally intensive and/or require remote access. In view of these benefits, the NBS community at large might benefit from integrating cloud computing into workflows.

Referencing an actual implementation strategy, Utah Public Health Laboratories will begin by automating the upload processes of raw genomic data to a cloud computing storage service every night (Figure 1). Next, the data will be processed by analysis pipelines which will create a summary report. This data will be stored both on-site and redundantly on the cloud where it will be reviewed by a bioinformatician followed by a genetic counselor. The final results or reports will be generated in the cloud environment but will be accessible through the LIMS.

The big advantage of the proposed pipeline is that the analysis could be done in about eight hours regardless of the number of samples while the current analysis pipeline takes about 48 hours for a limited number of samples (2-8). But this implementation will also centralize tools, allow remote access, and significantly reduce analysis times. In the long-term, this transition not only improves analysis speed but will also reduce costs, and improve the patient experience. ■

Connecting NBS Laboratorians and Epidemiologists to Understand Data Capabilities

by **Tory Whitten**, MPH, senior epidemiologist, Minnesota Department of Health, Newborn Screening, Minnesota Department of Health; **Hiral Desai**, MS, specialist, Newborn Screening Bioinformatics; **Careema Yusuf**, MPH, manager, NewSTEPs and **Guisou Zarbalian**, MS, MPH, manager, Newborn Screening

There are long-standing, symbiotic relationships between infectious disease laboratorians and epidemiologists in public health laboratories. But there are also partnerships between newborn screening (NBS) laboratorians and epidemiologists within NBS programs. As a former infectious diseases epidemiologist starting a new role in Minnesota's NBS program, Tory Whitten wondered whether a network of NBS epidemiologists existed across the country, as exists in infectious disease. It turns out many NBS programs are utilizing epidemiology, and their epidemiologists answered the call to help create a platform for consistent communication and collaboration. With the interest and support of these epidemiologists, the Minnesota Department of Health, in partnership with APHL, created the NBS Epidemiology User Group to connect and give a platform to NBS epidemiologists.



Members of the Newborn Screening Epidemiologist User Group

The activities and priorities of this group may serve to strengthen newborn screening data-driven outcome assessments, a seminal goal of APHL's Newborn Screening Technical assistance and Evaluation Program (NewSTEPs). We look forward to advancing epidemiology, data analytics, and data quality through the upcoming user group meetings and are thankful to the many epidemiologists and active participants of this user group.

Building a Knowledge Base

There is growing involvement of NBS epidemiologists in early hearing detection and intervention (EDHI), critical congenital heart disease (CCHD) and dried blood spot screening (DBS) programs, which illustrates the utility and expansion of data processes that are critical for screening methodologies across NBS programs. However, until now, little was known about the epidemiologic methods and other data analytics procedures that programs have implemented to tackle challenges such as missed screening for new infants, determining demographic risk factors of infants lost to follow-up and improving screening algorithms. Understanding these processes guide the mission and goals of the newly formed user group. As of the writing of this article, there are over 40 participants.

While the ultimate goal is to use epidemiology to improve NBS systems, the group's aims include:

- Learning from NBS epidemiologists across the country how data are being used in specific programs
- Expanding on data analytics capabilities
- Collaborating on new projects
- Learning about program-specific goals
- Sharing tools and resources.

These aims are fundamental to providing support to each other and co-existing as a community for continuous quality improvement.

Connecting and Sharing

The NBS Epidemiology User Group has met virtually three times so far. The initial call kicked off on September 23, 2020 to get to know epidemiologists from all specialties across the nation. During the second call, participants learned about the Tennessee NBS data experience from Yinmei Li, PhD, MD, state chronic disease epidemiologist. Li explained the procedure for linking vital records or birth data with newborn screening specimen data to identify newborns without a screen, and the uses of newborn screening data to monitor the completeness and timeliness of DBS screening. This information was useful to programs to learn about new methods of identifying newborns without a screen and create summary reports of hospital quality indicator data at the state and local level. During the third call, Ankit Sutaria, MBBS, MS, child health epidemiologist from the Georgia Department of Public Health spoke about the NBS epidemiology initiatives regarding DBS and CCHD. ■

Strengthening Electronic Laboratory Reporting for Response

By **Sam Abrams**, MPH, senior specialist, Public Health Preparedness and Response

Responding to a potential biological or chemical threat requires coordinated efforts among public health stakeholders. As members of the Laboratory Response Network (LRN), public health laboratories utilize electronic information systems to collect testing data and provide results to sample submitters and other external partners. These data are used to determine appropriate treatment options for individuals and, on a population basis, may be used as part of a surveillance program. COVID-19 and past outbreaks illustrated the importance of timely laboratory results. Today, an urgent need still exists for modernized electronic data systems, including Electronic Laboratory Reporting (ELR).

Strengthening ELR

APHL and the US Centers for Disease Control and Prevention (CDC) have partnered to strengthen the public health system by assisting laboratories with the implementation of ELR to ensure that important testing information is sent quickly and securely to partner agencies. Via funding from CDC, APHL is supporting up to 12 public health laboratories with enhancing electronic data exchange of biological and chemical threat agents and metabolites, which include anthrax and nerve agents, among others. The implementation of ELR represent significant advancements for electronic data exchange over current generation technology used for LRN data messaging. These include improving the speed and accuracy of data transmission to CDC while ensuring consistent report formatting despite originating from different sources. This approach enables both CDC and state and local public health agencies to mount a more effective response, providing appropriate preventive treatments and limiting exposure to other individuals.



Maintaining Standards

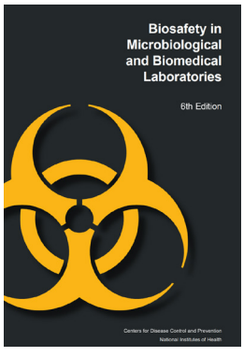
Successful implementation of ELR hinges on the utilization of Health Level 7 (HL7), which provides standards and guidelines to ensure that individual laboratories across the country can communicate to CDC uniformly. Although LRN laboratories employ a range of electronic information systems, maintaining HL7 standards guarantees that critical information will be accurately received by CDC. Public health laboratory staff are working closely with informatics vendors and the CDC Informatics and Data Science Branch LRN Data Integration Team to complete updates to their systems by June 2021.

ELR integration into laboratory information systems provides a significant step in advancing public health laboratory data reporting capabilities. In supporting public health laboratories, both APHL and CDC are strengthening the nation's laboratories' ability to mount effective response measures for a range of biological and chemical threats. ■

DIGITAL EXTRA: **For more information about how your LRN laboratory can participate in the ELR Data Integration Project, contact Sam Abrams.**

Sixth Edition of *Biosafety in Microbiological and Biomedical Laboratories* Now Available

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



The *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) guide was published by both the National Institutes of Health (NIH) and the US Centers for Disease Control and Prevention (CDC) and provides guidance and best practices for safe handling of biological hazards in laboratory settings. Since its creation in 1984, the BMBL has become the foundation for biosafety practices across the United States. In 2016, a stakeholders workshop was held for revisions towards the BMBL 5th edition by NIH and CDC. APHL staff and members were in attendance and, through the Biosafety and Biosecurity Committee, provided multiple recommendations including:

- Inclusion of clinical and public health representatives on the BMBL steering committee and editorial board
- Inclusion of the need for rigorous risk assessments prior to assignment of biosafety levels (BSL)
- Recommendations for working with unknown clinical samples
- Guidelines towards pathogen inactivation
- Inclusion of a new appendix for specific diagnostic and public health laboratories' biosafety and biosecurity needs and to indicate the differences, in terms of risk assessment, between public health, clinical and research laboratories.

In November 2020, CDC announced the release of the *Biosafety in Microbiological and Biomedical Laboratories 6th Edition*. The new chapters, agent summary statements and appendices address several biosafety-related topics that have evolved since the previous edition.

Figure 1: Relevant Changes in the BMBL 6th Edition

Contents	Relevant Changes
Section II—Biological Risk Assessment	• Included the need for institutional leadership to support a culture of safety by improving risk assessment and communication among staff • Introduced a six-step cycle to assessing risks
Section IV—Laboratory Biosafety Level (BSL) Criteria	• Removed most of the "should" and "must" language from recommendations • Included a detailed description of requirements needed for a written Biosafety Manual for BSL1 and BSL2 labs.
Section VI—Principles of Laboratory Biosecurity	Emphasized a systematic biorisk management approach, highlighting the International Standard Organization (ISO) 35001, Biorisk Management for Laboratories and Other Related Organizations
Section VII—Occupational Health Support for Biomedical Laboratories	Stressed the need for a risk-based approach for providing occupational health support to laboratories
Section VIII—Agent Summary Statements	Included additional resources including the Public Health Agency of Canada's Pathogen Safety Data Sheets and American Biological Safety Associations International's Risk Group Database for agent information
Appendix A—Primary Containment for Biohazards	Recommendations provided for institutions who choose to use ultraviolet light as a disinfection method in biological safety cabinets (BSCs)
Appendix B—Decontamination & Disinfection of Laboratory Surfaces and Items	Revised the list of chemical disinfectants to distinguish the relationship between concentration and activity levels
Appendix K (New)—Inactivation and Verification	Written in consultation with the CDC's Division of Select Agents and Toxins, the new appendix provides risk-based guidance on validation and inactivation procedures for select agents
Appendix N (New)—Clinical Laboratories	• New appendix that emphasized the use of risk assessments and hierarchy of controls to minimize the risk from clinical samples that may contain unknown pathogens. • Identified "trigger points" in the clinical laboratory setting where high-risk activities or potential pathogens can be identified that prompt staff to continue to conduct work in a BSC.

Overall the 6th edition incorporates a more robust risk assessment-based approach compared to previous editions. Figure 1 identifies some of the other major changes.

APHL will continue to review the BMBL 6th Edition through the Biosafety and Biosecurity Committee, and plans to conduct a webinar describing major updates in the near future. ■

Keep in mind the BMBL is a set of best practices that may or not fit the needs and/or activities of your institution. It is *your role* to determine what best practices are appropriate for your institution. And please email biosafety@aphl.org with any biosafety or biosecurity questions.

Building Capacity While Fighting COVID-19 in New Mexico

by **Jody DeVoll**, MAT, writer

In October 2019, Michael Edwards, PhD, HCLD(ABB), the new director of the Scientific Laboratory Division (SLD) of the Public Health Department of New Mexico, walked through the laboratory's doors, ready to begin work. Three months later, the first cases of a deadly emerging disease, COVID-19, appeared in the US. By March 2020, with COVID-19 decimating communities nationwide, SLD, like many other public health laboratories, plunged into surge mode. It continues to operate at that level a year later.

Though Edwards could never have foreseen that his new job would welcome him with the worst pandemic in a century, he is sanguine about the experience: "Chaos and crisis are a great way to develop relationships. COVID-19 has been a bonding experience. I've been able to get to know my staff and partners quicker than I would have otherwise."

Since SLD is one of only two laboratories in the state that conduct COVID-19 testing, the laboratory has assumed a lead role in shaping state response to the pandemic. Edwards is a regular on statewide planning calls for COVID-19 response. He and the SLD team also have helped underserved groups, including the large indigenous populations, with laboratory testing and consultations.

Facility

Located adjacent to the University of New Mexico in Albuquerque, the 10-year-old facility houses SLD as well as laboratories for the state medical examiner and state veterinarian. In the fall of 2019, the SLD fit within its allotted space albeit with no room to spare. However, "The COVID-19 pandemic pushed the boundaries of our facility. We had to get creative." Staff repurposed every available space to manage the thousands of samples arriving each day. For example, the all-hazards receiving facility became overflow space for sample receiving.

SLD's laboratory information management system (LIMS) has provided reliable reporting throughout the surge. "Initially we had to massage our system to handle the increased volumes, but we solved that problem, and we've been able to keep up with frequent changes to COVID reporting requirements thanks to our resourceful staff. We also brought on several LIMS enhancements to increase our efficiency."



Chemist Janice Y. loads the LC-MS/MS instrument in the Chemical Terrorism Analytical Response laboratory.
Photo: New Mexico SLD

Staff

In 2019 SLD staff numbered 130. When the surge hit in March 2020, staff labored in shifts 24/7, logging countless overtime and weekend hours. By mid-April, they were exhausted. Reinforcements were needed ASAP, but "There's not a lot of microbiologists hanging out in New Mexico." So SLD pulled recruits from all available sources—bringing in members of the National Guard, tapping recent graduates of the University of New Mexico, soliciting talent from temp agencies and hiring microbiologists with funding provided through the federal CARES Act of 2020. As of January 2021, the SLD has 200 staff members, all working full out.

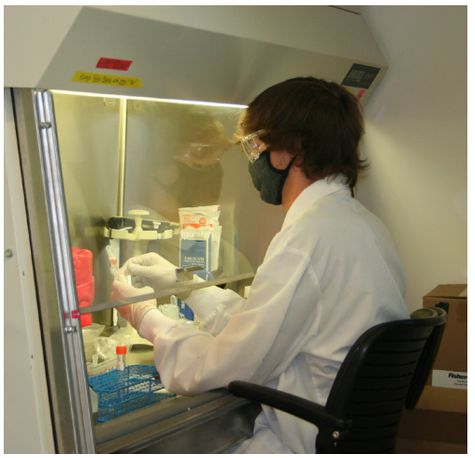
Director

A microbiologist by training, Edwards is a California native who has worked in public health laboratories since 2006. Prior to coming to New Mexico, he was the director of the San Joaquin County Public Health Laboratory. "I got lots of experience, because you have to be a jack-of-all-trades at a local lab." He finds public health laboratory work rewarding because "You're constantly changing and upgrading and learning new things plus you know that what you're doing is helping people." He also has found New Mexico to his liking.

"They're great people here at the lab and across the state. I can see myself staying in New Mexico for many more years."

Revenue

The laboratory's $15.9 million annual budget is funded through a combination of state general funds, federal grants and some fee-for-service work. The state court system pays the Forensic Toxicology Laboratory to support DWI enforcement.



Virology analyst Tahoe A. prepares a COVID-19 specimen for analysis. Photo: New Mexico SLD

Testing

SLD delivers testing services through its three scientific bureaus:

- The Infectious Diseases Laboratory tests for common infectious diseases (pertussis, measles, mumps, TB, seasonal influenza, etc.), foodborne diseases and diseases endemic to the region including tularemia, hantavirus and plague. Currently it is the hub for COVID-19 testing at SLD.
- The Environmental Chemistry Laboratory analyzes hazardous materials and pollutants for potential health threats. It tests both drinking and surface water and supports New Mexico's new medical cannabis program with testing, technical assistance and inspections at select laboratories. It recently completed validation of its array of cannabis testing methods and is in the early stages of bringing on PFAS testing, since PFAS was discovered in groundwater near two air force bases in 2018.
- The Forensic Toxicology Laboratory is responsible for alcohol and drug testing for DWI cases and for testing in sexual assault cases. Toxicology staff also appear frequently in court, which makes it difficult for them to complete their work at the laboratory. SLD is tackling the problem by developing time-saving testing efficiencies.

Successes

- Increasing COVID-19 testing capacity tenfold in 10 months (300-400 samples per day in March 2020 to over 3,000 per day in January 2021). In addition to expanding staff, SLD was able to purchase instrumentation that increased test throughput substantially.
- Reliably performing all laboratory functions throughout the course of the pandemic.
- Obtaining funding to purchase new instrumentation for testing of designer drugs and to integrate toxicology testing into the LIMS system.

Challenges

- "COVID-19 required us to change how we did everything. Of course, there's always challenges. Going into a pandemic without having relationships established with public health decision makers in the state was challenging for me, but it was also an opportunity."
- SLD anticipates challenges in obtaining funding to adequately pay staff, move technology to the next level and maintain readiness for the next event. Historically, PHL funding increases during major events and falls off precipitously once they pass. Said Edwards, "Some of the equipment we've used for COVID-19 testing was purchased during the last major public health event, the 2009 H1N1 pandemic. This is an example of how public health funding works–or doesn't work."



Environmental Microbiology analysts Kodi L. and Jessica E. prepare retail meat samples for surveillance testing. Photo: New Mexico SLD



Specimen Receiving staff members Susan T., Pam R. and Anna P. check in specimens for testing. Photo: New Mexico SLD

Goals

- Prepare for the next event. "We must maintain preparedness for all hazards. We may be in the middle of the worst pandemic in a century but who is to say what will happen in the next few years? Pathogens don't respect pandemic fatigue."
- Take care of the staff's mental health. "This is my first priority once we get through the surge phase of the pandemic. We've been running around the clock seven days a week. Staff burnout is real. We have so many good people. They love what they do. I ultimately want what's best for them, but I want them here, not at another laboratory. If we don't take care of our staff, we risk losing them [to institutions outside the public health laboratory system] and weakening the system overall."
- Continue to build next generation sequencing and bioinformatics capabilities.
- Expand cannabis testing, guidance and inspection; continue to identify testing efficiencies to support staff who appear in court and continue to develop methods to detect designer drugs. ■

APHL Fellowship Programs Continue Critical Work into 2021

by **Heather Roney**, MA, manager, Fellowships

APHL completed recruitment for its 2021 Fellowship Programs and applications are currently under review. Incoming fellows will begin their assignments in APHL and CDC public health laboratories in the fall.

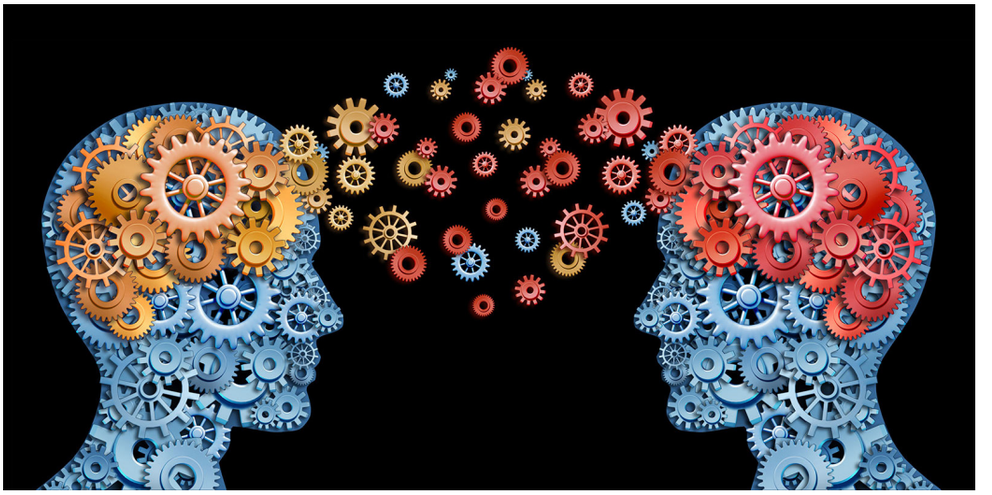
In response to the COVID-19 pandemic, APHL launched the COVID-19 Laboratory Associate Program to rapidly deploy scientists to meet the immediate, short-term workforce needs of APHL member laboratories. Over 25 associates are currently working in local and state public health laboratories.

COVID-19 Response Fellows continue to provide support to public health laboratories across the country, including:

- Verification of laboratory tests
- Development of validation protocols
- Development of training materials for point of care testing
- Evaluation of SARS-CoV-2 rapid antigen test
- Participation in the workflow of SARS-CoV-2 sequencing
- Analysis of quality control metrics.

Fellow Valeria Patritti accepted a new position as project manager at Memorial Sloan Kettering's Integrated Genomics Operations Unit.

Bioinformatics Fellows continue in their fellowships, with projects spanning involvement in COVID-19 response to assisting with an ongoing project related to next generation sequencing (NGS) quality management. Several fellows learned about nationwide sequencing work by attending AMD Virtual and the American Society of Microbiology's (ASM's) NGS conferences. Current fellow Tara Gallagher and former fellow Sarah Schmedes were part of the winning team for AMD Virtual's first-ever AMD Bioinformatics scavenger hunt contest.



Newborn Screening Fellows continue to progress in their projects and participate in weekly journal clubs to learn about sequencing, variant discovery, variant annotation and genomic databases. Samantha Marcellus presented at the 2020 NBS Symposium on integrating Cloud capabilities for infectious diseases and newborn screening for Texas Department of State Health Services. Bryce Asay created web scraping tutorials as a resource to extract data from the web. He also helped create a NBS curriculum for fellows, develop a tool to convert custom .vcf files into readable hash table format, and an in silico database tool for benchmarking bioinformatics pipelines at the Utah Public Health Laboratory. Jessica Respress trained with the core sequencing facility at the Wadsworth Center and new MySEQ machine, and is part of the initiative to start using a custom 55 gene panel for severe combined immunodeficiency (SCID). Lauren Nufer evaluated Cystic Fibrosis, Lysosomal Storage Disorders (LSDs), Hemoglobinopathies, and Galactosemia workflows to implement changes to the NBS program at Virginia's Division of Consolidated Laboratory Services. Scott Riley is optimizing the biotinidase assay for detecting biotinidase deficiency in newborns as well as SCID and spinal muscular atrophy (SMA) assay at the Maryland Department of Health.

Antimicrobial Resistance Fellows continue assisting host laboratories with programmatic priorities, test implementation and surveillance activities. Several participated in the national AR Lab Network All-Region Meeting through facilitation of discussions and presenting to laboratory and epidemiology partners across the nation. Former fellow Mimi Rey assisted in the response to the *Candida auris* outbreak in California and gave a presentation on antifungal resistant *C. auris* during ASM's Southern California Branch meeting, highlighting the growing public health threat. ■

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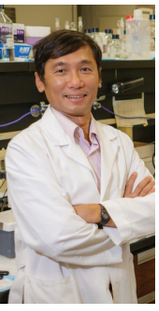


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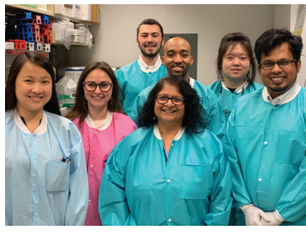
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If you have any questions, please contact APHL Membership at membership@aphl.org.









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