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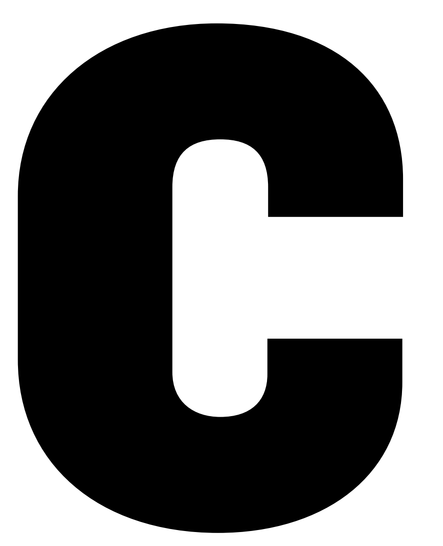

CLN Clinical Laboratory News

An ADLM Publication | Volume 51, Number 4

ASSESSING IMMUNITY

24.6%

Percentage of children whose vaccine immunity status was incorrect when determined using adult thresholds

PAGE 6

Reducing disparities in peripartum care

When NIPT detects cancer

New MLS training programs

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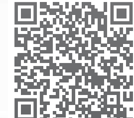

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ADLM
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Email: custserv@myadlm.org

Editorial Correspondence
Christine DeLong, Director,
Editorial and Media Relations
Phone: +1 202.835.8722 or +1 800.892.1400
Email: cdelong@myadlm.org

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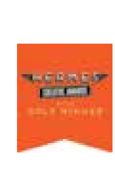

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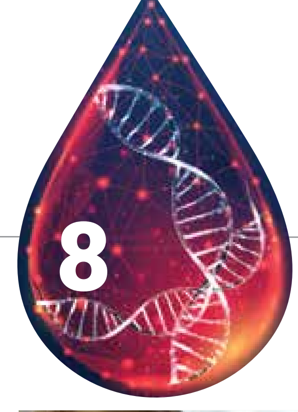

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Federal Insider

ADLM urges HHS to reinstate CLIAC advisory committee

The Association for Diagnostics & Laboratory Medicine (ADLM, formerly AACC) has requested that Robert Kennedy Jr., secretary of the Department of Health and Human Services (HHS), reinstate the Clinical Laboratory Improvement Advisory Committee (CLIAC), which advised HHS on issues involving the Clinical Laboratory Improvement Amendments (CLIA) regulations. These standards regulate more than 300,000 clinical laboratories performing 14 billion patient tests annually.

Chartered by HHS in 1992, CLIAC has identified, debated, and provided input on a broad spectrum of issues affecting the quality of testing, personnel requirements, the precision and frequency of proficiency testing, and other aspects of the patient testing process, ADLM said in a letter to Kennedy. These suggestions were incorporated in CLIA final rules published by the Centers for Medicare & Medicaid Services (CMS). Similarly, CMS has included many CLIAC recommendations in the State Operations Manual used by inspectors to ensure the standards are up-to-date and that testing is performed in a safe and effective manner.

A spokesperson with the Centers for Disease Control and Prevention confirmed CLIAC was terminated on March 31 after being deemed "unnecessary." The decision to eliminate the advisory panel came about under the aegis of a Trump administration executive order targeting the reduction of federal bureaucracy, the spokesperson said.

The CLIA program is funded by $80 million in user fees collected from the laboratory community, ADLM noted. This money is spent on educating clinical laboratories about best practices, managing quality assurance and accreditation programs, conducting inspections, and funding CLIAC. Given the vital role that CLIAC has played in improving laboratory testing and patient care, ADLM urged Secretary Kennedy to reinstate the committee.

FDA LAUNCHES AGENCY-WIDE AI TOOL TO BETTER SERVE AMERICANS

The Food and Drug Administration (FDA) this month launched Elsa, a generative artificial intelligence (AI) tool designed to help its employees — from scientific reviewers to investigators — work more efficiently. The agency is already using Elsa to accelerate clinical protocol reviews, shorten the time needed for scientific evaluations, and identify high-priority inspection targets.

Elsa is a large language model-powered AI tool designed to assist with reading, writing, and summarizing. It can summarize adverse events to support safety profile assessments, perform faster label comparisons, and generate code to help develop databases for nonclinical applications, and more.

The FDA said that Elsa was built within a high-security GovCloud environment, offering a secure platform for FDA employees to access internal documents while ensuring all information remains within the agency. The models do not train on data submitted by regulated industry, safeguarding the sensitive research and data handled by FDA staff.

The introduction of Elsa is the initial step in the FDA's overall AI journey, the agency said. As the tool matures, the agency has plans to integrate more AI in different processes, such as data processing and generative AI functions to further support the FDA's mission.

ADLM JOINS CALL FOR FUNDING FOR CDC PUBLIC HEALTH DATA MODERNIZATION

The Association for Diagnostics & Laboratory Medicine (ADLM, formerly AACC) joined numerous organizations to write to the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies chair Shelley

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Moore Capito (R-W. Va.) and ranking member Tammy Baldwin (D-Wis.) and House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies chair Robert Aderholt (R-Ala.) and ranking member Rosa DeLauro (D-Conn.) to request $340 million annually for public health data modernization at the Centers for Disease Control and Prevention (CDC).

Additionally, ADLM and the co-signed organizations asked for $55 million for the CDC's Center for Forecasting and Outbreak Analytics.

CDC's public health data modernization efforts represent a long-term commitment to building and maintaining world-class data systems and a workforce that meets the nation's ongoing need to safeguard health, ADLM said in the letter. Public health data is not only needed during an emergency response; it is also necessary for people and communities to thrive by rapidly identifying, tracking, and responding to daily public health threats of all types — acute, chronic, and emerging.

ADLM noted that data modernization plays a critical role in ensuring that public health workers and agencies receive data from the healthcare system that is essential to the disease detection and outbreak response efforts that keep communities safe and our nation secure.

Unfortunately, data modernization efforts across the country have been interrupted or completely halted by recent, abrupt CDC funding terminations, stalling progress on work that is needed to protect us from current and emerging public health threats. In light of these interruptions and the ongoing need to continue our modernization efforts, providing sustained yearly funding for public health data is key to ensuring the continuous improvement of our public health infrastructure, ADLM said.

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OWEN MUMFORD

Bench Matters

Should you use gel or capillary serum protein electrophoresis to monitor myeloma?

Eric A. Walradth, MA, MLS (ASCP)CMSHCM

Laboratory professionals play a key role in diagnosing and managing multiple myeloma, the second most common blood cancer and the most common form of plasma cell dyscrasia. According to the American Cancer Society, an estimated 36,110 people will be diagnosed with multiple myeloma in the U.S. in 2025, and 12,030 Americans will die with the disease (*1*).

The laboratory helps clinicians manage plasma cell dyscrasia by testing proteins via electrophoresis and other methodologies. Numerous medical groups, including the International Myeloma Working Group (IMWG), the College of American Pathologists (CAP), and the National Comprehensive Cancer Network (NCCN), recommend using serum protein electrophoresis (SPEP) and immunofixation electrophoresis (IFE), along with serum free light chains, for this purpose (*2-4*).

Agarose gel electrophoresis has been considered the gold standard for SPEP and IFE for some time now, with progress made over the years to increase laboratory efficiencies and lower the costs associated with these techniques.

Recent advances suggest that an electrophoretic method for interrogating serum proteins in a thin capillary tube may now be a viable alternative to the gel approach. Capillary electrophoresis technology appeared on the market in the late 1990s

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to interrogate serum proteins in plasma cell dyscrasia.

However, the capillary method still has not been widely adopted within clinical laboratories. According to one 2018 study, fewer than 32% of labs surveyed worldwide used capillary electrophoresis for diagnosing and monitoring plasma cell dyscrasia; the remainder used agarose gel electrophoresis (5).

One of the largest benefits of capillary electrophoresis over agarose gel electrophoresis is the time it saves the scientists who perform testing at the bench.

POTENTIAL IMPACT ON THE LABORATORY

Although lab leaders are generally familiar with the benefits of gel electrophoresis, they should also be aware of the potential positive impact that capillary electrophoresis could have on their laboratory. Research suggests that this method could improve efficiencies and lower costs compared to gel electrophoresis, while maintaining quality results.

One of the largest benefits of capillary electrophoresis over agarose gel electrophoresis is the time it saves the scientists who perform testing at the bench. Because agarose methods require a large degree of hands-on manipulation, they cost the laboratory more staff time (as measured in full-time equivalent hours) than capillary methods, which are far less labor-intensive.

CURRENT POINTS OF CONTENTION WITH THE CAPILLARY METHOD

Much of the data in the literature points toward capillary methods being less sensitive than gel methods, especially with regard to specific immunoglobulins or light chains. That said, little data has been published within the past 5 years that evaluates the most recent agarose gel and capillary electrophoresis technologies.

While the lack of recent data is not ideal, it should not be viewed as a deterrent. A close inspection of the literature shows that, although there are certain aspects of the capillary technique that are less sensitive than comparable components of gel preparation, capillary methodology shows similar sensitivity and specificity to agarose gel electrophoresis when evaluated as a complete method.

One of the most critical parts of the electrophoresis testing process is the interpretation of the electrophoretogram. As with any piece of laboratory testing, ensuring that lab professionals receive appropriate education and training is paramount to achieving the highest quality results. Such staff instruction is lacking in most of the published comparison studies.

Research suggests that, when proper education and training are employed, interpretations improve across the board, allowing for capillary electrophoresis to have results that are as high quality as those achieved with agarose gel electrophoresis.

Eric A. Walradth, MA, MLS(ASCP)CM SHCM, is the director of laboratory services at Hematology-Oncology Associates of CNY.

+EMAIL: ewalradth@kumc.edu

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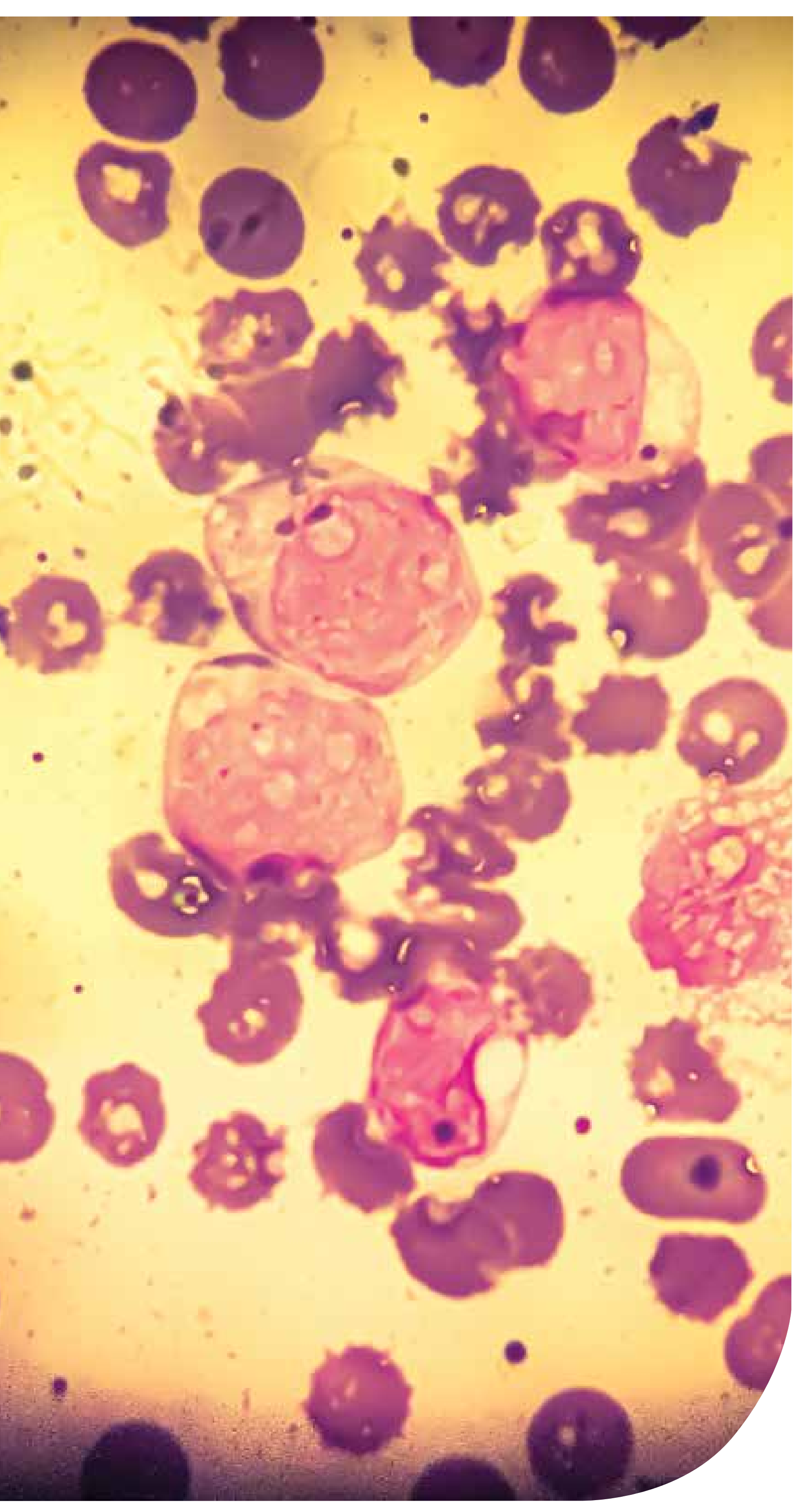

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Preimmunosuppression serologic testing questioned

A recent study suggests that the current use of hepatitis B (HepB) and varicella serology in children may be inappropriate because of rapid waning of titers (Clinical Chemistry 2025; doi: 10.1093/clinchem/hvaf020).

The researchers suggest that applying age-appropriate reference intervals to vaccine serologic tests will provide a foundation for improved treatment recommendations and standards of care.

Certain clinical situations may warrant antibody response testing in children. These include starting lifelong immunosuppression following organ transplant or treatment of autoimmune diseases, or confirming vaccination for children without related records. Meanwhile, many children with autoimmune diseases have inadequate vaccine-induced immunity at the time of presentation.

The period prior to starting immune suppression serves as the critical window for giving pediatric patients live vaccines if they do not have adequate preexisting immunity. However, age-appropriate thresholds for antibody levels have not yet been established for children. Decisions to revaccinate are based on thresholds derived from adult studies, which may overestimate durable immunity in young children because of expected titer waning as the time from vaccination increases.

In response, the researchers aimed to investigate age-specific differences in antibody levels in healthy children to guide determinations of vaccine immunity status when clinically indicated.

The researchers conducted a cross-sectional study that assessed clinical serology for measles, mumps, rubella (MMR), varicella, and HepB in an age-stratified cohort of healthy children ages 1-18 who were current on their vaccinations. Using a total of 471 remnant samples from 471 children, the study assessed clinical serology for the viruses.

Children of all ages had detectable titers to MMR, but median titers for HepB and varicella waned by ages 11-12 and 9-10 years, respectively. Children had titers above adult thresholds for MMR at all measured timepoints, retrospectively resulting in 24.6% (95% CI, 21.6%-27.8%) of children having an inappropriate MMR classification with the use of adult thresholds instead of pediatric ones.

Application of age-appropriate reference intervals for vaccine serologic tests will drive improved treatment recommendations and standards of care, the paper said. It also calls for research on age-appropriate cutoffs for other common vaccinations, including diphtheria, tetanus, pertussis, *Haemophilus influenzae*, and pneumococcus.

STUDY HIGHLIGHTS NEED FOR GENOMIC TESTING IN METASTATIC PROSTATE CANCER

Recent findings reinforce the utility of genomic testing to find metastatic prostate cancer (mPCa) patients with treatable genetic variations, with the goal of achieving more equitable outcomes among different racial and ethnic groups (JAMA Network Open 2025; doi:10.1001/jamanetworkopen.2025.9119).

National guidelines recommend next-generation sequencing of tumors in patients diagnosed with mPCa to identify potentially actionable genetic variations. Because non-Hispanic Black men are poorly represented in precision oncology cohorts, the differences in variation frequencies between non-Hispanic Black and White men remain poorly characterized.

In response, the researchers performed a cohort study to compare frequency of actionable and inactionable genetic variations between non-Hispanic Black and non-Hispanic White United States veterans with mPCa, and to better understand how the variations affect survival.

Of 5,015 veterans, 35.6% were non-Hispanic Black men at a mean age of 64.4, and 64.4% were non-Hispanic White men at a mean age of 67.4. Non-Hispanic Black veterans were younger, had higher prostate-specific antigen levels at diagnosis, were less likely to report Agent Orange exposure, and resided in more deprived neighborhoods compared with non-Hispanic White veterans.

The researchers found that 9 out of 10 of the most commonly altered genes were the same in non-Hispanic Black and non-Hispanic White veterans, but the frequencies of alterations varied by race and ethnicity. Non-Hispanic Black race and ethnicity was associated with higher odds of genomic alterations in SPOP (odds ratio [OR], 1.7; 95% CI, 1.2-2.6) and immunotherapy targets (OR, 1.7; 95% CI, 1.1-2.5), including high microsatellite instability status (OR, 3.1; 95% CI, 1.1-9.4). Non-Hispanic Black race and ethnicity was also associated with lower odds of genomic alterations in the AKT/PI3K pathway (OR, 0.6; 95% CI, 0.4-0.7), androgen receptor axis (OR, 0.7; 95% CI, 0.5-0.9), and tumor suppressor genes (OR, 0.7; 95% CI, 0.5-0.8).

Analysis that involved stratifying by race and ethnicity found that alterations in tumor suppressor genes, including TP53, were associated with shorter overall survival in both non-Hispanic Black (hazards ratio [HR], 1.54; 95% CI, 1.13-2.11) and non-Hispanic White (HR, 1.52; 95% CI, 1.25-1.85) veterans.

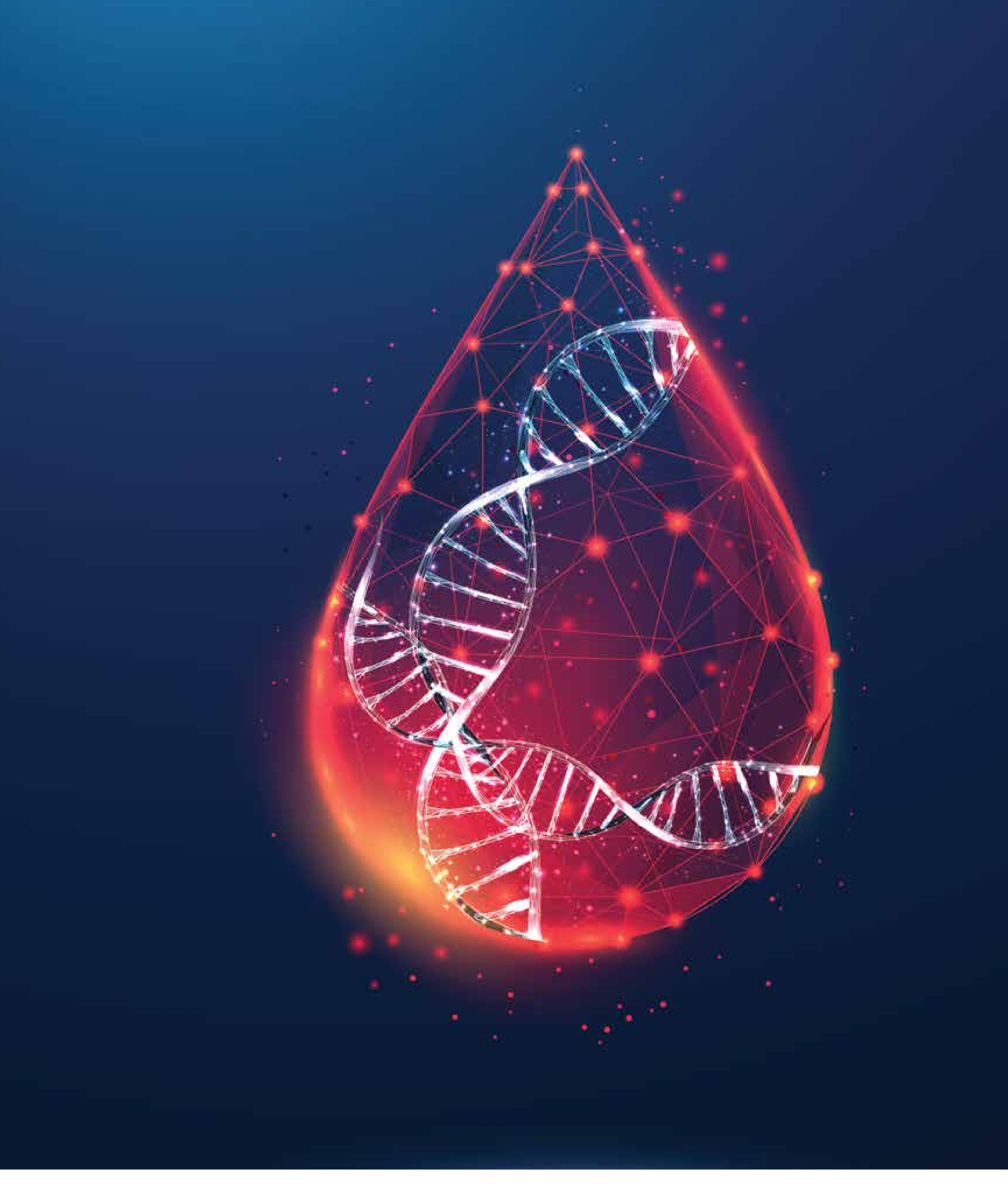
APOLIPOPROTEIN B AND LIPOPROTEIN(A) INDICATE ATHEROSCLEROTIC RISK

Measuring both apolipoprotein B particles (apoB-P) and lipoprotein a ([Lp(a)]) is best for assessing blood lipids for atherosclerotic risk, recent research shows (European Heart Journal 2025; doi.org/10.1093/eurheartj/ehaf207).

ApoB-P concentration reflects the number of atherogenic lipoproteins and is widely recognized as a key lipid risk marker. However, whether the type or size of ApoB-P adds predictive value for coronary artery disease remains unclear.

Researchers used multivariable-adjusted Cox regression models to examine the association between lipid parameters with incident coronary artery disease (CAD) in a prospective analysis of 207,368 UK Biobank participants. The participants had comprehensive lipoprotein profiling and no prior history of atherosclerotic disease, diabetes, or active lipid-lowering therapy. The researchers considered nuclear magnetic resonance-measured concentrations of apoB-P and individual lipoprotein classes, including very-low-density lipoprotein (VLDL), low-density lipoprotein (LDL), plus size subclasses, average particle diameter, and immunoassay-measured Lp(a).

Lipoprotein type or size of major apoB-P particles VLDL and LDL were generally not predictive for risk of coronary artery disease beyond total apoB-P count. Conversely, Lp(a) levels carried additional risk independent of apoB-P count. A 1 standard deviation increase in apoB-P was associated with a 33% higher CAD risk (hazards ratio [HR]: 1.33, 95% CI: 1.30-1.36). Although VLDL particles carried a higher per-particle risk (HR per 100 nmol/L: 1.22, 1.11-1.34) compared with LDL (HR per 100 nmol/L: 1.07, 1.05-1.08), this difference was counterbalanced after considering relative particle abundance (LDL 91% vs. VLDL 9% of total apoB-P). Thus, the respective hazard ratios per 1 standard deviation were 1.09 (1.05-1.14) and 1.24 (1.19-1.30). Particle diameter or size subclasses were not associated with CAD after apoB-P adjustment. Association of Lp(a) was robust even after apoB-P adjustment (HR: 1.18, 1.16-1.20) and added independent prognostic value for CAD (area under curve: 0.769 vs. 0.774, $P < .001$).



When NIPT uncovers more than a patient bargained for

Prenatal testing can indicate an unexpected condition: maternal cancer. What should clinical labs do next?

BY YAAKOV ZINBERG

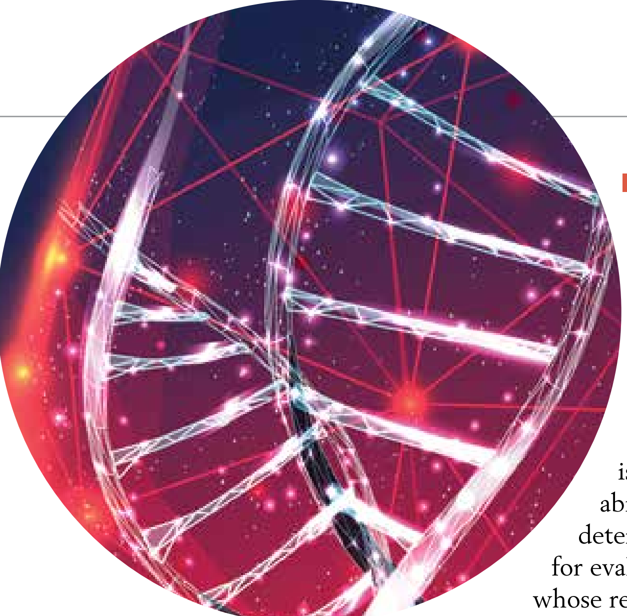
Historically, tests for chromosome-number irregularities in a fetus, such as Down syndrome (three copies, or trisomy, of chromosome 21), have involved taking samples from the amniotic fluid or placenta — invasive, painful procedures that carry a slight risk of miscarriage and other harms to the mother and fetus.

In contrast, noninvasive prenatal testing (NIPT), which became commercially available in 2011, uses a simple blood draw to more safely assess the risk of these disorders, which are collectively known as fetal aneuploidy. NIPT detects cell-free DNA (cfDNA) from the fetus that floats through the placenta into the mother's bloodstream. It's currently recommended for all pregnant people regardless of aneuploidy risk. An estimated two million patients in the United States undergo the procedure each year.

Approximately 90% of circulating cfDNA is maternal in origin; only a small fraction comes from placental DNA. Most cfDNA is released from the mother's cells into the blood during normal physiological processes, such as cell death.

But tumors also can shed DNA into the bloodstream. Indeed, not long after NIPT was introduced, reports emerged of unusual testing results in mothers subsequently found to have cancer. Although their babies were healthy, the tests indicated aneuploidy, most likely because cancer cells often have extra chromosomes.

Because NIPT tests are not designed to detect cancer, clinical laboratory professionals have generally been reluctant to report NIPT findings as "cancer-suspicious," preferring instead to label unusual results as "nonreportable" or "atypical" without offering further clarification.



UP TO HALF OF PATIENTS WHO RECEIVE ABNORMAL RESULTS THAT CAN'T BE ATTRIBUTED TO FETAL ANEUPLOIDY MAY HAVE CANCER.

But that may be changing. Recent studies have shown that maternal NIPT can accurately suggest a cancer diagnosis even in asymptomatic mothers. In fact, up to half of patients who receive abnormal results that can't be attributed to fetal aneuploidy may have cancer. These results raise questions about how these incidental findings should be handled and what the clinical laboratory's role should be in interpreting and responding to them.

IDENTIFYING MATERNAL CANCER

The initial finding that NIPT can detect maternal cancer motivated the IDENTIFY study, an effort led by the National Institutes of Health (NIH). Its purpose is to identify the cause of abnormal NIPT results and determine the best approach for evaluating pregnant patients whose results suggest cancer.

"The point of the IDENTIFY study is to generate prospective data to inform maternal medical management," said Amy Turriff, MS, a genetic counselor and co-lead investigator on IDENTIFY. "We bring patients with nonreportable NIPT results to the NIH Clinical Center and put them through a standardized cancer-screening workup to see what's the best way to evaluate women who receive these results."

In a December 2024 study published in the *New England Journal of Medicine* (*NEJM*), 107 patients without known cancer who were either pregnant or postpartum underwent a cancer-screening protocol that included whole-body magnetic resonance imaging (MRI), blood tests, and physical examinations (N Engl J Med 2024; doi: 10.1056/NEJMoa2401029). Fifty-two patients, or 48.6% of those studied, were subsequently found to have cancer, as confirmed via biopsy. The most common cancer diagnoses were lymphoma (31 patients, 59.6%), followed by colorectal cancer (9 patients, 17.3%), and breast cancer (4 patients, 7.7%). More than half of the cancer-positive participants were asymptomatic, while an additional 25% had symptoms ascribed to pregnancy and other noncancer–related causes.

Previous page and here: Alena Butusava / iStock

Of the various screens evaluated, whole-body MRI was easily the superior method for detecting cancer. It showed possible cancer in 48 out of 49 participants confirmed to have the disease. Physical examinations and blood-based laboratory tests had lower sensitivity and specificity.

Additionally — and crucially — cfDNA sequencing revealed that certain kinds of aneuploidies were far more likely to result in cancer than others. Gains and losses of partial or entire chromosomes across at least three chromosomes were found in 49 samples, 47 of which (95.9%) were from patients with cancer. Other patterns were mostly attributed to a source other than cancer, such as fibroids and placental mosaicism.

Taken together, these results suggest that pregnant people with chromosomal gains and losses should be highest priority for a follow-up MRI, the most accurate cancer-detection method in this context.

"Through the sequencing patterns, you can identify the people at highest risk for cancer, who should undergo the whole-body MRI," Turriff said.

She explained that many laboratories use genome-wide platforms that generate information for all chromosomes. However, NIPT most often assesses only for abnormalities in chromosomes 13, 18, 21, and the sex chromosomes, the most common fetal aneuploidies that result in a live birth. In the event of an unusual result, lab professionals can look at the whole genome to assess if there's a technical or sample-related issue — or if cancer is lurking.

"That unmasking of the data is when you can see what's happening across the genome and potentially identify these sequencing patterns that we described in the *NEJM* paper. The data are there," Turriff said.

SPOTLIGHT ON THE NETHERLANDS

A link between aberrations in multiple chromosomes and maternal cancer also has been identified retrospectively in studies from the Netherlands, a world leader in NIPT.

In 2014, a group of clinical laboratory geneticists and obstetricians and gynecologists formed the Dutch NIPT Consortium, which offered NIPT nationwide as part of the TRIDENT studies (TRIal by Dutch Laboratories for Evaluation of Non-invasive Testing). More than 200,000 tests were

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performed from 2017-2020, and of the 48 (0.03%) genome-wide NIPT results that were reported as suspicious for a malignancy, 16 (33.3%) of those patients had received a cancer diagnosis. When gains and losses across multiple chromosomes were found, the risk of a confirmed malignancy was nearly 70%.

Furthermore, for pregnant patients who received a diagnosis of blood cancer during pregnancy or within 2 years after delivery, genome-wide aberrations in NIPT raised, in retrospect, suspicions of cancer every time — suggesting that further diagnostic examinations could focus on specific cancer types.

"As hematologic malignancies arise from blood forming organs or lymph nodes, and maternal cfDNA originates from leukocytes, it is plausible that genomic instability occurring in neoplastic transformation of these cells can be detected relatively more often in the blood," compared with other cancers, explained Catharina J. Heesterbeek, MD, an oncologist at Maastricht University Medical Center in

the Netherlands and one of the researchers on the TRIDENT studies. Similarly, because more advanced stages of cancers were more likely to show up in the blood, cancer stage could also affect the predictive value of NIPT for cancer in certain cases.

"If you have a stage-one breast cancer … it's to be expected that there's not much cell-free DNA of the tumor in your blood, so the chance to pick it up with NIPT is really low," she added.

Thanks to the success of TRIDENT, NIPT is now offered free of charge to all pregnant people in the Netherlands. National uptake is about 70%, according to Merryn Macville, PhD, a clinical laboratory geneticist a lead researcher on the TRIDENT studies. Midwives and gynecologists provide pretest counseling to pregnant people, during which they explain that NIPT can turn up cancer in rare instances.

A MULTIDISCIPLINARY EFFORT

In the Netherlands, aberrant NIPT results are reported to a clinical geneticist, who acts as a case manager in working with oncologists and obstetrician-gynecologists. This approach allows for multiple perspectives and areas of expertise to be shared when determining a course of action for patients.

"You need a multidisciplinary team of caregivers to make sure that women are well-informed and well taken care of," Macville said.

Testing and care are not as integrated in the United States. Even the way the same results are reported can vary from lab to lab.

"Each lab is really making its own decision as to how to report results, and even within the same lab, different laboratory directors might make different decisions about these cases," Turriff said.

In thinking about how to standardize the detection of NIPT results, Turriff believes that clinical laboratory experts should take the lead.

"Clinical laboratories are best positioned to identify these cases — they're the ones with access to the sequencing information. They have the expertise to identify those cases that are most concerning for a maternal malignancy."

However, she continued, "I think where there's room for improvement is in the handoff step. Right now, it is typically very unclear from the written laboratory report alone when there is a concern for maternal malignancy." This could mean that the clinician treating a pregnant person lacks information that would shape their decision-making, like ordering cancer screening when warranted.

While it's understandable that lab professionals may feel hesitant to report cancer-suspicious results from a test intended to detect fetal aneuploidy, studies such as IDENTIFY and TRIDENT make a strong, evidence-based case for doing so. They've shown that NIPT can raise a red flag for cancer, reassuring laboratories in a position to report it. According to Turriff, a couple of laboratories now document that certain sequencing patterns they find in NIPT have previously been reported to have an association with cancer.

"Having something transparent and a common language will improve this process for women," Turriff said. "I think we're starting to move in the right direction."

Yaakov Zinberg is a writer based in the Boston area.
+EMAIL: YaakovZinberg@gmail.com

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GUIDING THE JOURNEY FROM GRAD

TO

New educational opportunities show promise for addressing alarming staff shortages.

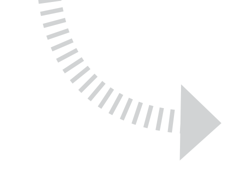
BY KAREN BLUM

Although the field of laboratory medicine continues to be affected by staff shortages, directors of two new medical laboratory scientist (MLS) training opportunities hope their efforts can help fill the gap. In January 2024, Geisinger Health System in Danville, Pennsylvania, launched an MLS program, which is now in its second class of students. And this July, the University of Utah and ARUP Laboratories in Salt Lake City will open a new facility at ARUP, allowing students in the university's MLS program, which is accredited by the National Accrediting Agency of Clinical Laboratory Sciences, to get solid hands-on experience in a

LAB

state-of-the-art training lab.

"There's always an ebb and flow when it comes to MLS programs," said Cordelia "Cordy" Kudika, MA, CHS (ACHI), director of clinical education in the MLS division at University of Texas Health San Antonio, which has operated an MLS program since 1975. "I think it's great that other hospital systems and other universities are opening MLS programs, because there is a huge need in our nation." According to U.S. Bureau of Labor Statistics projections, clinical laboratories nationwide will need to fill 24,200 openings for clinical laboratory technologists and technicians each year through 2033.



GEISINGER'S MLS PROGRAM

In Pennsylvania, hospital-based MLS programs are the biggest source of entry-level medical laboratory scientists, said Marianne Downes, PhD, MLS(ASCP)[CM], director of the Geisinger program. With a large presence in central, north-central, and northeastern Pennsylvania, Geisinger is an attractive option for people looking to extend their skills and for local universities in search of partnerships, she said. One of the only other local MLS programs takes just two trainees per year.

Geisinger's 1-year certificate program covers "the entire spectrum of what is required of a medical laboratory scientist when they enter the profession," Downes said. "We also have created a specific area for molecular diagnostics … as most new tests that are out on the market today are molecular tests." Clinical rotations are sequenced so students can advance as they go, and instructors also work the bench. "That's something unique that we did that our accreditation group thought was a benefit to the program," she said.

So far, the program is exceeding her expectations. The two students from the inaugural class have been offered positions in laboratories after successfully passing MLS certification exams and receiving their credentials. The current class has five students, and the program plans to scale up to accept as many as 12 moving forward. Prospective participants could include both post-bachelor's students and others enrolled in a 3+1, an accelerated degree program where students take 3 years of prerequisite courses at an affiliated university and then finish their training at Geisinger in the final year. Students have ranged in age from 20-45.

"There has been quite a bit of enthusiasm from the 3+1 institutions that we looked to create affiliations with," Downes said. Additionally, when she was training educators, "there were so many people who were so excited about bringing the program back — people who graduated prior to 1999 still here within the system who were so eager and ready to start teaching."

ARUP'S NEW TRAINING FACILITY

In Utah, enthusiasm also has been high for the University of Utah and ARUP's Advanced Practice Clinical Laboratory Training Center, which was built using $3 million in federal funding. In the 2,600-square-foot lab, students will complete 4-week clinical rotations (part of a required 18 weeks) working with specimens and gaining experience in blood banking and transfusion medicine, clinical microbiology, clinical chemistry, and clinical hematology, said Diana Wilkins, PhD, MS, MLS(ASCP), division chief of medical laboratory sciences and director of the graduate program in laboratory medicine and biomedical science at the University of Utah. "They will be doing quality control and maintenance procedures, and getting an immersive experience in applying quality control and quality assurance principles in the operation of complex automated instrumentation" before completing additional rotations in active clinical laboratories, she said. Equipment in the lab will include instruments for high-volume chemistry, immunology, hematology and urine testing, coagulation assays, prothrombin time and partial thromboplastin time blood tests, D-dimer tests, assays to identify microorganisms, and more.

Students are excited for the new facility, which can accommodate up to 80 of them per year. "Everybody wants to know who's going to get to go to this lab first," Wilkins said.

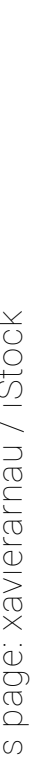
"Our hope is that we're going to generate more interest for students, create greater awareness of medical laboratory science, not only as a profession, but also as a career pathway for students within the university," she added. The goal is to encourage students to be lifelong learners in medical laboratory science.

Laboratory-university partnerships like ARUP's could serve as a model for other locations looking to address the workforce shortage, said Wilkins and Jonathan Genzen, MD, PhD, MBA, chief medical officer at ARUP.

"I truly believe this will have a local, regional, and, hopefully, national impact as well," Genzen said. "Given the need for MLS professionals throughout the country, it's a very mobile degree." In other words, MLS programs hold the potential not only to create jobs within communities, but also to open possibilities in different locations — or, as Genzen put it, "wherever one's life journey takes them."

AN URGENT NEED

Opportunities like these provide a bright light in a challenging marketplace, where lab vacancy rates continue to be an issue, according to biennial surveys from the American Society for Clinical Pathology (ASCP). The most recent survey, published in the March 2023 American Journal of Clinical Pathology, indicated that vacancy and retirement rates at U.S. medical labs were at an all-time high in 2022, said Edna Garcia, MPH, lead study author and senior director of scientific engagement and research at ASCP. This may have been because of growing fears of COVID-19 and its aftermath, particularly among supervisors close to retirement age. As a result, labs made increased use of contract staff at that time while focusing their staffing efforts on retention.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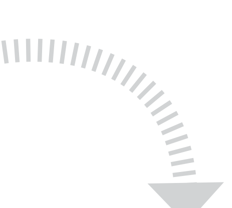
MLS PROGRAMS HOLD THE POTENTIAL TO ... CREATE JOBS WITHIN COMMUNITIES



The average overall vacancy rate increased from 8.35% in 2020 to 13.82% in 2022, said David Shiembob, MBA, manager of healthcare advisory services at ARUP, citing statistics from the report. The rise was steepest for core laboratory departments, whose vacancy rates increased nearly 75%, from 10.3% in 2020 to 18% in 2022. Another concerning trend, according to Shiembob: The MLS workforce is reaching retirement age at a 78% faster rate than the overall U.S. labor market. Half of the lab specialties surveyed said they anticipated retirement rates greater than 25% over the next 5 years.

The hiring of supervisors also took longer in 2022 compared with 2020, Garcia said: "Before, it would maybe take three to six months, and from that data it was more than 12 months. It was really hard to find staff at the time because we were already having the challenge of finding qualified personnel, and the COVID-19 pandemic just amplified the issues."

It appears that 2022 represents the peak crisis. Results of the 2024 survey, which will be published this fall in the *American Journal of Clinical Pathology*, indicate that staffing numbers are returning to prepandemic levels. "That still doesn't make it better," Garcia said. "It just means that the effects of the pandemic are going away."

TRENDS IN MLS PROGRAMS

Between 2000 and 2023, the number of MLS programs in the country decreased from 263 to 247, Shiembob said. However, the number of MLS graduates increased over that same period, from 2,333 to 4,189, suggesting that fewer programs were putting out more qualified people.

The subsequent cessation of MLS programs threatens that progress. Hospitals that recently announced closures include UnityPoint Health St. Luke's Hospital in Cedar Rapids, Iowa which ended its 73-year-old MLS program in 2024 because of declining enrollment, and the University of Maryland in Baltimore, which will terminate its program, the largest in the state, in 2027 due to budget cuts. The capacity of current programs may not be sufficient to meet industry demand, Shiembob said.

Lack of awareness of MLS careers contributes to the problem. Because MLSes don't engage in patient-facing care, their role is not well known among aspiring healthcare professionals. "I think what happens a lot of the time is, nobody really knows who does these laboratory tests," said Kudika, noting her program is now graduating up to 40 students annually to help increase numbers. "A lot of people also are not familiar with the type of education that you need in order to work in a clinical lab."

To combat this issue, ASCP, ADLM, and 26 other organizations in 2023 formed the Medical and Public Health Laboratory Workforce Coalition to build awareness of laboratory testing occupations and encourage people to consider careers in laboratory medicine. "We're all working toward visibility, recruitment and retention, and improving diversity in the laboratory," Garcia said. Experts with the program have been speaking with K-12 educators at STEM and academic counselor conferences to educate them about laboratory careers.

"Their students only know about being a doctor or wanting to be a doctor or a nurse," Garcia said. "School counselors and educators are eager and willing to learn more about laboratory careers and expose these kids to other allied health professions."

Funding is also a challenge, said Shiembob. Although some nursing programs are heavily subsidized through government funding mechanisms, he said, "that doesn't exist as much for MLS programs. They're a small number of students and expensive to run, so that's one reason why some of them are closing."

One strategy some hospitals and laboratories have employed is to hire nonlicensed staff who hold a bachelor's degree in biology or chemistry, and then train them on the job, Shiembob said. ARUP has done this for quite a while; in fact, it's how he rose through the ranks. "That's pretty new for a lot of hospital labs," he noted. "Traditionally, they'd always insist they fill the positions with licensed MLSes, and that's a level of training they're not used to having to do."

Meanwhile, the trend toward hiring temporary, travel laboratory staff seems to have receded after peaking during the pandemic, said Brittany Roemmich, MT(ASCP), a clinical research specialist at Washington University in St. Louis, who previously worked a series of travel jobs. "Labs are really trying to get more permanent workers … I think that's for the better. I don't think hospitals should be run strictly on travelers, because there are a lot of mistakes that happen when someone's here for just 4 months."

Karen Blum is a freelance medical and science writer in Owings Mills, Maryland.
+EMAIL: karen_blum@verizon.net

WORKING TOWARD

FAIR

A team at Barnes-Jewish Hospital reduced care disparities between Black and White mothers by modifying peripartum urine drug screening — without compromising sensitivity. It's a powerful example of how labs are leading the way toward health equity.

NESS

IN PERIPARTUM DRUG SCREENING AND BEYOND

BY VAHID AZIMI, MD, AND MARK A. ZAYDMAN, MD, PHD

Lab professionals bring a deep expertise in quality assurance throughout the entire testing cycle, from the preanalytic to postanalytic phases. They also have a nuanced understanding of how well-intentioned testing can sometimes cause unintended harm. By leveraging these strengths, laboratorians play a powerful role in advancing health equity.

Peripartum drug screening is a case in point. Drug use occurs in approximately 5% of pregnancies (*1*), and the American College of Obstetricians and Gynecologists (ACOG) recommends universal verbal screening throughout pregnancy. In this approach, clinicians engage in structured, nonjudgmental conversations with pregnant individuals about their substance use, using validated tools such as the 4P's Plus or the NIDA Quick Screen. The goal is to foster open dialogue, provide anticipatory guidance, and facilitate timely referrals for treatment when needed (*2*).

Despite ACOG's emphasis on verbal screening, laboratory-based urine drug screening (UDS) is frequently performed in the peripartum setting, particularly when a pregnant person presents with signs of substance use or historical risk factors (*3*). While the affect of UDS is to guide clinical management, the screening also introduces complexities that can impact equity. In this article, we describe a data-driven intervention that eliminated the UDS indications most associated with low-value and inequitable testing.

CANNABIS USE AND PREGNANCY

Because most standard drug panels include cannabis, pregnant people who have used this substance are subject to routine testing, even when the clinical significance of peripartum cannabis use is uncertain (*4*). Historically, at our institution — Washington University School of Medicine/Barnes-Jewish Hospital in St. Louis — a "history of isolated cannabis use" alone was considered sufficient justification for peripartum UDS.

Although observational studies have suggested an association between cannabis use during pregnancy and adverse fetal or neurodevelopmental outcomes, no definitive causal link has been established (*5*). ACOG discourages cannabis use during pregnancy but maintains that individuals should not face criminal or civil penalties for its use (*4*). Additionally, in the peripartum setting, a positive test for isolated cannabis use typically does not change clinical management, which raises questions about the necessity and utility of such testing (*4*).

The issue is further complicated in mandatory reporting states such as Missouri, where any positive UDS result, including one for isolated cannabis use, must be reported to Child Protective Services (CPS) (*6*). In this context, UDS can alienate patients, erode trust in healthcare providers, reduce vital rooming-in time between mothers and babies, and expose families to legal consequences (*7*).

Lauren Nacke, a former social worker at Barnes-Jewish Hospital, describes this impact firsthand:

"Collecting a UDS felt like a 'gotcha' moment on labor and delivery. While helping this first-time mom to the bathroom just hours after childbirth, the nurse informed her that her urine would be collected due to her history of marijuana use. This felt like a failure to me. Moments after birthing her first child, we inserted panic and fear with an accusation of child abuse. Without any knowledge of our urine drug screen policy or the hotline process, this young mother could assume the worst. Would her child be removed? Would the police be involved? We caused harm at a vulnerable and memorable time."

IMPACT ON EQUITY

Racial minority patient groups disproportionately bear the burden of this harm. A multidisciplinary study at at the Washington University School of Medicine that included providers from obstetrics and gynecology, pediatrics, neonatology, nursing, and social work found that Black mothers presenting to the labor and delivery unit at Barnes-Jewish Hospital were subjected to peripartum UDS at more than twice the rate of White mothers.

As a result, 1 in 4 Black mothers underwent UDS, and about 1 in 10 were reported to CPS. Most referrals were for isolated cannabis positivity — a result with low clinical utility. These findings highlight a stark inequity: Black pregnant patients are more likely to experience the harms of peripartum UDS without receiving any meaningful clinical benefit (*8*).

A DATA-DRIVEN INTERVENTION

The research team collaborated with the pathology informatics team in the department of laboratory and genomic medicine at their institution to address this disparity through a data-driven intervention (*9*). By integrating education, policy changes, and electronic clinical decision support (CDS), the multidisciplinary team eliminated the UDS indications most associated with low-value and inequitable testing — specifically, "history of cannabis use" and "limited prenatal care." Following the intervention, the pathology informatics team analyzed UDS and CPS reporting

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practices, comparing the 16 months before with the 16 months after implementation. They found that screening rates for Black mothers dropped five-fold, CPS reporting rates were cut in half, and the disparity in screening between Black and White mothers was eliminated.

Crucially, the rates of detection of illicit drug use did not change following the intervention, suggesting that it did not compromise sensitivity for clinically actionable UDS results.

UDS and CPS reporting rates for White mothers also declined following the intervention. This result challenges the notion that health equity is a zero-sum game that inherently disadvantages one group to benefit another. Instead, it illustrates that equitable policies can improve care for all patients.

WHY LABS ARE EQUITY LEADERS

These studies reveal an important insight: While laboratories are often viewed as behind-the-scenes entities, they are well positioned to advance health equity by improving fairness in laboratory testing. In other words, lab professionals help ensure that all patients can reasonably expect to realize the benefits of testing without having to shoulder a disproportionate share of the harms. As we describe below, several key characteristics make laboratories ideally suited for this role.

Labs oversee the entire testing cycle, from the preanalytic to postanalytic phases (*10*). Within the UDS project, the lab team's knowledge about testing and computerized order entry helped them identify changes to the workflow that could facilitate mindful UDS ordering and auditing.

Lab professionals have an opportunity to build on these successes. By expanding existing laboratory quality-assurance frameworks, they can identify and address unfairness in laboratory testing that could arise at any point. For example, in the preanalytics phase, they might explore ways to expand patient access to testing and improve provider ordering behaviors.

Labs have made progress with fairness metrics. A first step in this direction is operationalizing fairness metrics, such as those described in the field of algorithmic fairness (*11*), for reporting on laboratory quality. For example, demographic parity, equalized odds, and predictive parity could be applied to laboratory data to screen for unfair laboratory practices.

Implementing and scaling this approach will require new tools to complement existing laboratory quality analytics. This was the topic of FairLabs, the 2024 ADLM Data Analytics Challenge (*12*). The success of the FairLabs competition underscores that members of the laboratory medicine community are ready, willing, and able to fill this gap in our analytical toolbox.

Lab professionals also should broaden the use of their valuable laboratory and clinical data streams, which provide insights into patterns of test utilization (*13*), disparities in access to diagnostic services (*14*), and variations in results across patient populations (*15*). The data can be used to uncover systemic barriers to care and inform interventions targeted to patient demographic and socioeconomic characteristics.

In the UDS project, laboratory informatics experts were central to identifying problematic order indications, implementing CDS to circumvent the usage of those indications, and monitoring the effectiveness of the intervention.

> "COLLECTING A UDS FELT LIKE A 'GOTCHA' MOMENT ON LABOR AND DELIVERY... MOMENTS AFTER BIRTHING HER FIRST CHILD, WE INSERTED PANIC AND FEAR WITH AN ACCUSATION OF CHILD ABUSE."

Labs are well integrated across healthcare. Finally, laboratories are deeply integrated across service lines, enabling them to influence equitable care across multiple disciplines. This positioning allows them to collaborate with providers, administrators, and policymakers to ensure diagnostic testing is accessible, appropriate, and effectively utilized for all patient populations. Kim Hamlin, MD, a pediatric hospitalist at St. Louis Children's Hospital, describes the effect that laboratory stewardship had on obstetric and pediatric clinicians:

"The policy of UDS for isolated cannabis use was one that brought

> “CHANGING THE [UDS] POLICY WAS MET WITH SIGNIFICANT CLINICIAN SUPPORT AS THIS BARRIER TO RELATIONSHIP AND TRUST-BUILDING WAS REMOVED FOR A LARGE PROPORTION OF PATIENTS.”

significant dissatisfaction for clinicians. They knew the results offered little benefit for the patient or the baby, but held potential for great harm, and felt powerless that they were perpetuating an inequitable system. Changing the policy was met with significant clinician support as this barrier to relationship and trust-building was removed for a large proportion of patients and has allowed clinicians to focus their resources and support to target patients in need.”

Changing clinical practice patterns is difficult, and we attribute the success of this intervention to the multifaceted approach that leveraged interdisciplinary expertise and collaboration, education, policy change, and electronic CDS. Although we cannot disentangle these components’ contributions to the study’s outcomes, we can attest that combining policy change and CDS helped to create and reinforce accountability for guideline-concordant care. For healthcare institutions with limited resources to replicate the entire intervention, replicating the CDS component may be a practical starting point.

EQUITY MATTERS

There are many reasons for why achieving health equity should be a priority for all healthcare professionals. First, it is a moral and ethical imperative. Indeed, the core principles of medical ethics, such as nonmaleficence and justice, require medical professionals to avoid harming vulnerable patient subgroups. Second, achieving health equity can effectively improve patient outcomes by alleviating the detrimental effects of health inequity. Third, addressing health inequity reduces healthcare costs by preventing avoidable testing and complications due to poorly managed chronic diseases.

Of course, pursuing health equity can directly benefit laboratorians. By providing empathetic care that considers patients' lived experiences, clinical lab professionals can foster a stronger and more meaningful connection with those we serve. To get there, we must work together to elevate fairness to the same plane as other core quality domains in laboratory testing.

Vahid Azimi, MD, is laboratory director at Alameda Health System in Alameda County, California.
+EMAIL: vazimi@alamedahealthsystem.org

Mark A. Zaydman, MD, PhD, is an assistant professor of pathology and immunology at Washington University School of Medicine in St. Louis.
+EMAIL: zaydmanm@wustl.edu

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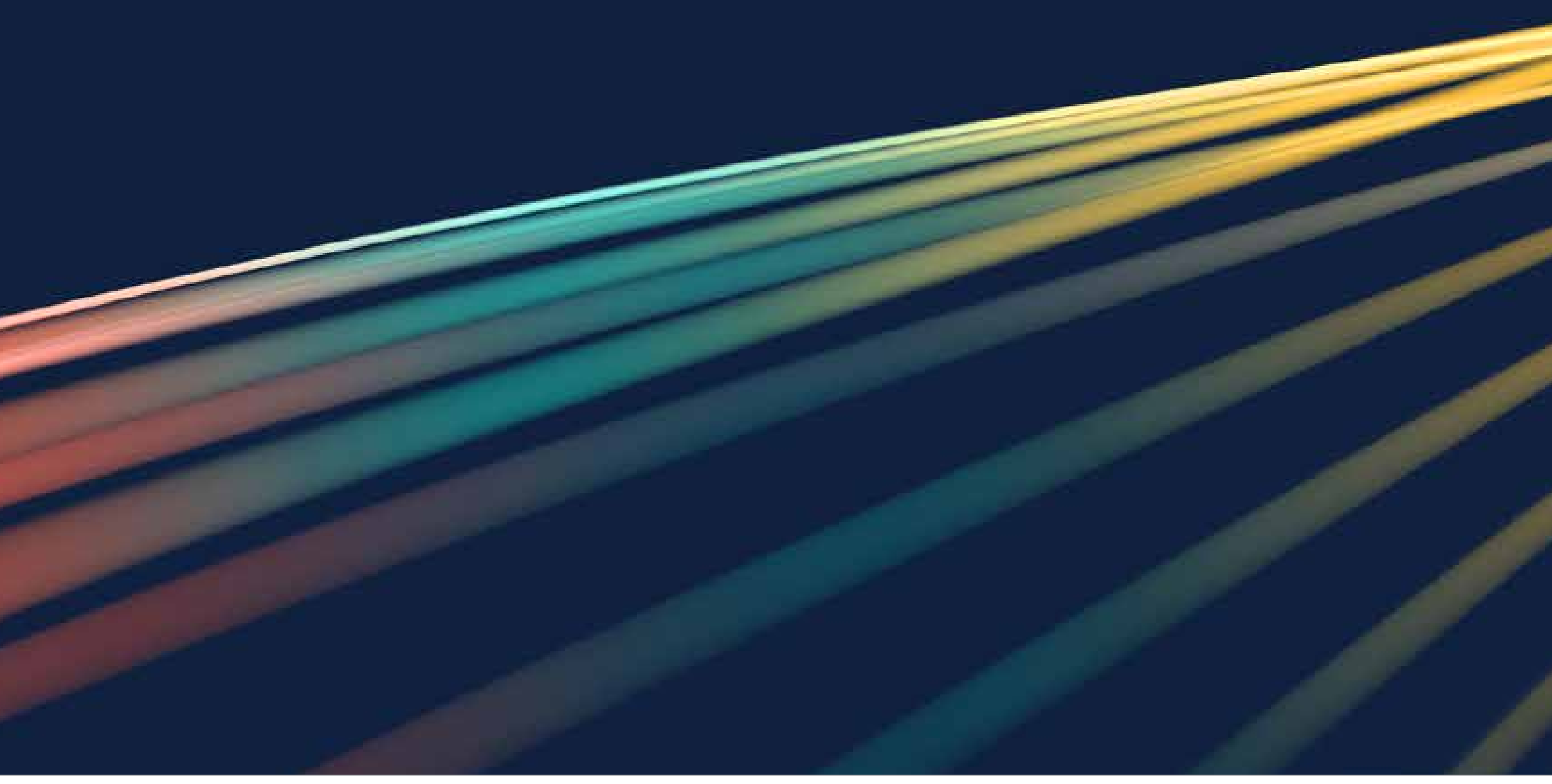
Honoring 5 years of lab-enabled healthcare excellence

As UNIVANTS marks a milestone at ADLM 2025, experts share vital insights into the program.

Now in its sixth year, the UNIVANTS of Healthcare Excellence awards spotlight transformations in which clinical laboratories play an integral role. After reviewing more than 75 best practices that received program recognition through year 5, two experts involved with UNIVANTS have gleaned important insights, which they will share at ADLM 2025 (formerly the AACC Annual Scientific Meeting & Clinical Lab Expo) in Chicago on July 29.



BY KIMBERLY SCOTT

The UNIVANTS of Healthcare Excellence program is a partnership among eight organizations: the Association for Diagnostics & Laboratory Medicine (ADLM, formerly AACC), Abbott, Modern Healthcare, the International Federation of Clinical Chemistry, the European Health Management Association, Modern Healthcare, the National Association for Healthcare Quality, and the Institute of Health Economics. With a name that combines the terms “unify” and “avant-garde,” UNIVANTS recognizes health-centered teams that collaborate across disciplines, transforming healthcare delivery and improving patients’ lives.

25% The percentage of best practices recognized by UNIVANTS that involve a new test.

Applications to the program must describe laboratory-enabled best practices that have been implemented into clinical care. They also must include at least one key performance indicator (KPI) supporting improvement for each of the following stakeholder groups: patients, clinicians, health systems and administrations, and payers. While UNIVANTS requires applicants to involve a minimum of three disciplines in their best practice, the program often gives its highest ratings to initiatives that incorporate at least five disciplines, including laboratory medicine and pathology. Each application is reviewed by at least seven judges, and all judges are selected by the partnering organizations.

This article captures insights from Christine Schmotzer, MD, pathologist-in-chief and executive vice chair at University Hospitals in Cleveland, and Tricia Ravalico, executive lead for UNIVANTS and global director of scientific leadership and education at Abbott. Schmotzer is a member of a recognized care team and has independently also served as a judge..

ENHANCED QUALITY

The quality of metrics has improved since UNIVANTS began in 2020, according to Schmotzer and Ravalico. Being able to measure the impact that a best practice has on patient care, clinicians, health systems, and payers is a key component of truly transformational best practices, they noted.

"It's not enough to have good ideas. The program requires implementation and assessment of impact," said Schmotzer. "It's often a challenge for labs to measure impact on out-of-laboratory stakeholders. One of the things we will share in our session at ADLM 2025 are examples of how people have designed and implemented collaborative work and determined measurable outcomes that they can share."

Schmotzer also noted that the number of applications — and the diversity of the teams they reflect — has increased since the awards program began. Recent best practices have addressed a variety of healthcare challenges, from improving access to testing for sexually transmitted diseases to enhancing screening for liver disease.

Initiatives that are recognized by UNIVANTS aren't necessarily complicated or "lofty," said Schmotzer, adding that there is important work to be done on what some might consider basic lab testing, such as testing for glucose or sodium.

"Often people underestimate the significance of what they do because it seems simplistic," she said. "A winning best practice doesn't have to involve creating or implementing fancy new tests. Rather, it might involve improving the way that testing is currently done."

Ravalico agrees. "You don't necessarily need 'sexy' or 'new' things to drive transformational change," she added.

In fact, only about 25% of the best practices recognized by UNIVANTS involve a new test. Process changes — which optimize the tools currently available — represent about 50% of the award-winning initiatives. Algorithms account for less than a fifth of the best practices recognized.

ENHANCED KPIs

Just as teams have improved over the last 5 years, so too have KPIs, according to Ravalico. In particular, the number of KPIs associated with patients — both quantitative and qualitative — has significantly surpassed the total number of KPIs associated with clinicians, health systems, or payers. In addition, KPIs associated with patients were notably diverse, falling into 29 unique categories.

"This highlights the fact that laboratory medicine has a true and powerful connection to patient care," said Ravalico.

While KPIs associated with patients have been robust in award-winning best practices, benefits that link lab medicine to payers appear to be the most difficult to quantify, said Ravalico.

The absence of a valid payer metric is consistently among the most prevalent reasons for program ineligibility. In year 5 alone, 72% of the submitted applications that did not receive subsequent recognition failed to fulfill the minimum criterion of a quantitative or qualitative measure of change for the payer stakeholders.

"A consistent trend across all 15 best practices with top elite honors associated with UNIVANTS shows that downstream payer benefits far exceed the cost of laboratory testing, particularly when

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The number of best practices that have received recognition from UNIVANTS over 5 years.

core laboratories are proactively involved as an integrated discipline for problem solving around an unmet need," said Ravalico.

Another challenge is measuring improvement in KPIs related to clinicians. Providers' appreciation of laboratory medicine may be caught in a chicken-and-egg conundrum: Laboratory results are not directly correlated with health outcomes despite being integral components of the clinical decision-making process that drives diagnosis and treatment, said Ravalico.

"If clinicians are the hardest stakeholder for quantifying the value of lab-enabled best practices and they are the direct recipients of insights from the lab, how do we change that paradigm?" asked Ravalico. "More can be done in this area."

EVOLVING AREAS OF FOCUS

In the first 5 years of UNIVANTS, clinical care initiatives that focused on cardiology and infectious disease, including COVID-19, represented almost half of the award winners. Also represented, although to a lesser extent, were best practices related to women's health, oncology, diabetes, kidney disease, liver disease, prenatal care, trauma, sepsis, endocrine disorders, neurology, and substance use disorder.

The absence of best practices across other disease areas is not necessarily indicative of a lack of value or excellence in laboratory-enabled best practices. It is more likely attributable to gaps in program awareness, said Ravalico.

For future applicants, opportunities abound for best practices in transfusion medicine, respiratory medicine, and anatomic pathology, added Schmotzer. Both Schmotzer and Ravalico would like to see more best practices involving algorithms and digital health solutions.

50%

Percentage of winning best practices that involve process changes.

SETTING UP FOR SUCCESS

To improve a team's chances of having a successful initiative, project leaders should be sure to choose the right stakeholder partners, advised Schmotzer. For example, initiatives trying to track financial outcomes should involve someone from the finance department in their organization.

"I have seen initiatives fail in the real world because they didn't have the right people involved," she said. "Choose your partners well and choose them early."

While laboratory medicine must be a part of the interdisciplinary team to qualify for UNIVANTS, labs do not have to initiate the projects, added Ravalico. Of course, when clinical laboratory professionals strategically collaborate with physicians and other stakeholders in proactive and crossdisciplinary ways, healthcare teams tend to have exceptional outcomes; this, in turn, makes them more likely to achieve high levels of recognition through the program, she explained.

"By contrast, clinical care initiatives derived within the laboratory, without substantial out-of-laboratory collaboration, tend to achieve lower levels of award recognition," said Ravalico. Physician-led, integrated clinical care initiatives account for a relatively small amount of the total recognized best practices, but they constitute more than 73% of the top winners.

To learn more lessons from the first 5 years of UNIVANTS, attend the July 29 session presented by Schmotzer and Ravalico. Their session, which will be held from 4:30-6 p.m. U.S. Central Daylight Time in the Grand Ballroom of McCormick Place Convention Center, is designed to maximize insights learned from the program. They hope to inspire and empower lab-enabled healthcare teams to lead best practices, measure outcomes, and, ideally, achieve global recognition for their exceptional efforts. More information about UNIVANTS can be found at www.univantshce.com.

Kimberly Scott is a freelance writer who lives in Lewes, Delaware.
+EMAIL: kmscott2@verizon.net

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Bring the wonder to the world's premier laboratory medicine conference

ADLM 2025 (formerly the AACC Annual Scientific Meeting & Clinical Lab Expo) is returning to Chicago this year from July 27-31. With more than 250 educational opportunities in the form of lectures, plenary sessions, and roundtables — and 850-plus exhibitors showing the latest technology — the conference is on track to be an awe-inspiring event that spotlights the best of science and innovation in laboratory medicine.

BY JEN A. MILLER

As the world of laboratory medicine rapidly evolves, so too does ADLM's annual meeting. Steven Cotten, PhD, the chair of this year's Annual Meeting Organizing Committee (AMOC), has made sure of that. Cotten is the director of automated chemistry and critical care testing, and associate professor of pathology and laboratory medicine, at the University of North Carolina at Chapel Hill.

He and the AMOC not only embraced the challenge of maintaining ADLM 2025's relevance to laboratory medicine today, but also expanded the meeting's offerings to appeal to a wide range of healthcare professionals.

What are you most looking forward to at this year's meeting?

I'm really excited about the plenaries this year! They highlight the spectrum of valuable and varied contributions that laboratory medicine professionals make to healthcare. From artificial intelligence to scientific misinformation, this year's plenaries cover some of the hottest topics shaping our field. Thursday's plenary addresses the threat of plastics and PFAS chemicals. As someone whose water is contaminated with PFAS, I think that one is very important.

We're also rolling out some new learning formats for 2025. For example, we'll have a "choose your own adventure" style session, during which audience members get to make their own diagnostic choices and see how they play out, and a Jeopardy!-themed scientific session.

How have recent changes in lab medicine affected the meeting?

Laboratory developed tests (LDTs) and their regulation have certainly seen a lot of change. While LDT regulations are paused for now under the current administration, their long term future remains uncertain. To that end, we're planning a session that delves into the advocacy efforts around regulation.

As ADLM grows, the content of the meeting is expanding too. We had submissions this year for sessions related to microbiology,

hematology, and coagulation, so you can see that those topics are maturing within our organization.

Why is it critical for the lab medicine community to collaborate at this type of meeting?
These days, most research projects require a crossdisciplinary team of collaborators who can learn — and apply — new information. Because your team may need to rely on people outside of your expertise to do that, it is important to identify people who bring additional knowledge and skills to help you solve problems.

Do you have a specific goal for ADLM 2025?
I want to bring new voices into the meeting. During my time leading AMOC, I made sure that we tapped into new talent with new ideas. And I'm pleased to report that we have a very diverse slate of speakers this year — not only for the plenaries

Choose your path

MICROBIOLOGY AND MOLECULAR DIAGNOSTICS

- Emerging pathogens: Science, strategy, and lab readiness
- Serologic testing in the age of molecular diagnostics
- When urine trouble and it 'snot straightforward: Clinically relevant thresholds for workup of urine and respiratory cultures
- Let's talk about STIs, baby: Considerations for STI diagnoses and pharmacologic changes during pregnancy
- Sepsis mythbusters: The what and why of sepsis
- Breaking down silos: Transfusion medicine, microbiology, and hematopathology intersections with clinical chemistry

LEADERSHIP AND LABORATORY MANAGEMENT

- You are in Jeopardy: Effective strategies for laboratory crisis management
- Beyond pamphlets and brochures: Strategic marketing skills to optimize your lab's offerings
- Enhancing engagement between laboratory medicine professionals and C-suite executives
- The fee-for-service payment system for lab tests: A challenge for labs, patients, physicians, and insurers
- Expand your reach: Unlocking hospital laboratory potential through outreach
- Speaking the same language: Essential communication skills for lab professionals

PATIENT-CENTERED POINT-OF-CARE TESTING

- Improving laboratory analysis and continuous glucose monitoring (CGM) quality to optimize diabetes therapy
- Quantitating compliance for point-of-care testing: Implementation, milestones, and metrics
- From bench to bedside: The evidence and implementation of GFAP & UCH-L1 in TBI evaluation
- Skills to solve problems and resolve challenges in point-of-care testing
- A practical guide to remote sampling: Regulatory and technical considerations for successful implementation of microsampling devices in the clinical laboratory
- Eliminating inequities in STIs using point-of-care testing: Identifying unmet needs

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but also for the scientific sessions and university courses that are new to the meeting.

Will ADLM 2025 appeal to people who aren't clinical laboratorians?

Yes, there's really something for everyone at this meeting. We've got a decent amount of content on clinical microbiology, hematology and coagulation, and much more. I come from a drug development background, and one of the sessions I'm moderating is on GLP-1 receptors; we'll explore GLP-1-mediated changes that go beyond diabetes and weight loss and what they might mean for laboratory medicine. I'm looking forward to pioneering new approaches to this meeting and its content.

Jen A. Miller is a freelance journalist who lives in Audubon, New Jersey.
+BLUESKY: @byjenamiller.bsky.social

Register, explore, and plan your conference at meeting.myadlm.org.

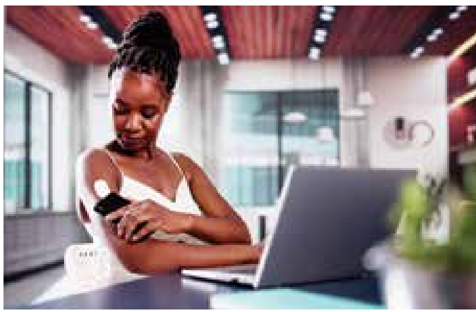
Interested in a specific area of laboratory medicine at ADLM 2025? Use these six pathways to guide your planning.

POPULATION HEALTH AND LABORATORY STEWARDSHIP

- Population screening for type 1 diabetes: Controversies and opportunities
- Laboratory test showdown! Winning with laboratory stewardship
- Supporting healthy Indigenous communities through laboratory medicine and public health
- Global working groups advancing diagnostics and laboratory medicine: Achievements, gaps, and future directions
- Do sex differences in cardiac troponin cut-offs matter?
- Contextualizing the use of race in laboratory medicine

DATA SCIENCE AND ARTIFICIAL INTELLIGENCE

- Large language models in laboratory medicine: Foundations, cutting-edge advances, and applications
- Practical considerations in evaluating and implementing artificial intelligence solutions for today's clinical laboratorian
- CCJ hot topics: Designing and implementing artificial intelligence in laboratory medicine
- Bad, better, best: Putting generative AI to the test



FRONTIERS IN ADVANCING CARE

- Metabolomics for diagnosis and monitoring treatment of inborn errors of metabolism
- The role of measuring cytokines in cancer immunotherapy
- Preeclampsia: Precision tools to improve prediction, enabling access in resource limited settings, and personalized medicine in special populations
- Proteomics in diabetes: Development and interlaboratory transfer of LC-MS/MS assays for clinical research and patient care
- Revised criteria for diagnosis and staging: An update on blood-based biomarkers in Alzheimer's disease and other dementia
- Metabolic reset in the age of GLP-1 receptor agonists: Changes in metabolism beyond diabetes and weight loss

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BY BENJAMIN MCFADDEN, BSC, MRES

Developing robust workflows for data science and analytics

In the era of big data and digital transformation, clinical laboratories increasingly use data science and analytics to enhance decision-making and improve operational efficiency. After all, laboratories generate vast amounts of data, including test results, patient information, quality-control metrics, and instrument logs.

But data analysis is only as worthwhile as the time and effort that labs put into it. Without well-structured and robust workflows, lab professionals may find the analytical process overwhelming and inefficient, and their results could be inconsistent and prone to error. Additionally, generating high-quality, reproducible data can be even more challenging when advanced technologies such as machine learning are integrated into the process.

For all of these reasons, designing workflows that streamline the end-to-end analytical process is essential. Doing so ensures that laboratories can maximize the value of their data assets, obtain meaningful insights, and maintain confidence in the results.

This article covers how to build robust analytical workflows on well-structured foundations that support the maintenance, usability, and reproducibility of laboratory data analysis. The process includes several key components, including data acquisition, cleaning, transformation, analysis, validation, and reporting. In workflows that involve machine learning techniques, labs must take additional steps, such as engaging in feature engineering, model development, and validation.

Data acquisition and extraction

The first step in any data science or analytics workflow is to acquire data. Whenever possible, collect data directly from source systems in standardized formats. Regardless of where you extract data from, it is essential to create a "data dictionary," a resource that provides detailed information about the data elements within a system, including how it was collected, where it was collected from, what its relationships are with other datasets, how it should be used, and any caveats that should be noted when applying it.

Having a data dictionary will help you avoid misusing data when you perform subsequent analytical steps. Those who develop analytical workflows should ensure that access controls and data-security measures are in place to protect the data from being accessed — and potentially corrupted — by unauthorized individuals.

Make sure to document any code or applications you use to extract the data from source systems to support maintenance, continuous improvement, and the identification of any problems that may arise.

It's also critical to use a consistent version-control method on any data extracted to ensure that it can be audited. Lastly, automate data extraction to reduce the chance of human error. However, you should also make it a high priority to test your automated models, including performing routine audits, to verify that data is being extracted correctly.

Data cleaning and preprocessing

Given that raw data extracted from source systems often is incomplete, inconsistent, noisy, or inappropriately structured for effective analysis, data cleaning and preprocessing are necessary next steps. Cleaning involves handling missing values and correcting errors as needed, while preprocessing involves standardizing the data for analysis. Poor data quality can lead to misleading insights and incorrect conclusions, making it essential for lab professionals to invest time at this stage. Be sure to do each of the following:

1) Implement checks to detect missing or inconsistent data.

2) Carefully consider how to handle missing data, including deciding whether to use imputation or replace missing values.

3) Check for duplicate records to prevent skewed analysis.

4) Employ techniques for detecting data inconsistencies before analysis.

5) Document data preprocessing steps and code, and implement version control.

Before you move on to modelling and statistical analysis, consider

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whether to take additional steps based on your plans for downstream analytical processing. For example, you might decide to encode categorical variables appropriately for statistical analysis, normalize or standardize numerical values to eliminate bias, or use domain knowledge to create new, meaningful derived variables that enhance your analysis.

Finally, it's always important to perform exploratory data analysis to investigate how the data is distributed and identify any patterns that emerge from it.

Modeling and statistical analysis

Once you've thoroughly prepared the data, you're ready to select the right analytical approach. This crucial stage may involve using descriptive analytics, statistical modeling, machine learning, or traditional rule-based algorithms, depending on the problem you're trying to solve. Choose models that align with your objectives and start with simple approaches before moving on to more complex ones — but only when required. Workflows should not be any more complex than necessary. This also seems to improve adoption in the clinical space due to familiarity of stats and the explainability of the model.

Document your methods, results, and any key decisions relating to the analysis. This includes recording "negative" results and clearly identifying which statistical methods were not effective.

If you're applying machine learning techniques, you'll need to consider and manage additional complexities, most of which are related to validation and quality control. For this process, you will:

1) Use training, validation, and test datasets to ensure models are generalizable and not overfitting.

2) When possible, benchmark models against gold-standard methods to assess performance in relation to well-established approaches or approaches not based on machine learning.

3) Conduct peer reviews and audits of analytical processes using a combination of human oversight and automated software tests.

4) Ensure that results from model training and validation can be reproduced. Without rigorous validation, results may be misleading or unreliable.

Reporting and visualization

Communicating insights effectively is essential for data-driven decision-making. Using visualizations, dashboards, and automated reports helps convey key findings and summarize your analytical results. Without clear reporting, even the most accurate analysis may go underutilized.

Some general approaches to consider when reporting and visualizing results are to:

1) Keep it simple. Complex visualizations may overwhelm stakeholders, particularly those without technical backgrounds, leading to a loss of engagement in the analytical work.

2) Automate report generation as much as possible for the purpose of maintaining a consistent, standardized approach to reporting.

3) When possible, present results as an interactive dashboard so that users can explore the outcomes of the analysis further. This also helps improve user engagement in the end-to-end analytical process.

4) Provide a transparent method for users to access the documentation relating to your analytical workflow.

Conclusion

Clinical laboratories should develop robust workflows to support data-driven decision-making, enhance efficiency, and maintain high-quality standards. By following a structured approach to data acquisition, preprocessing, analytics, validation, and reporting, lab professionals can harness the power of data science to drive operational improvements and improve patient outcomes.

Incorporating automation, documentation, version control, and best practices into workflows not only reduces errors; it also helps create an environment where reproducibility and trustworthiness are encouraged. Further, engaging in this process ensures that the products of analytics are timely, accurate, and easy to maintain.

Investing the time to develop robust workflows will pay off in the long term and allow for the effective incorporation of machine learning and other advanced analytical techniques to drive insights. Engaging in this process also fosters trust in data outputs, both within labs and across the spectrum of healthcare professionals who rely on them. As data science continues to evolve, laboratory professionals who adopt structured methodologies will be best equipped to leverage vast amounts of data and gain insights for continuous improvement and innovation.

Benjamin McFadden, BSc, MRes, is an applied data science researcher at the University of Western Australia and a senior data officer at the Western Australia Department of Health.
+EMAIL: Benjamin.mcfadden@research.uwa.edu.au

A Q & A WITH BERNARD ESQUIVEL, MD, PHD, MHA

Paving the way to physician-friendly pharmacogenetics

By Jen A. Miller

Pharmacogenomics (PGX) testing has already made a solid foothold in oncology care. PGX helps doctors and pharmacists to determine which patients are most likely to respond to specific medications.

But despite its growing potential to inform prescribing across healthcare disciplines, PGX is not yet the standard of care. Bernard Esquivel, MD, PhD, MHA, the chief executive officer of GenXys Prescribing Systems, is working to change that.

Esquivel says that integrating PGX into routine medicine will require work in multiple areas including standardizing testing and data, making PGX information easy for doctors to understand, and figuring out reimbursement. Messaging matters as well: As Esquivel stresses, PGX won't magically make all prescribing dilemmas disappear. It can, however, give clinicians a clearer sense of the overall healthcare picture for each patient.

How can laboratory and healthcare professionals work together to overcome barriers to adopting PGX?

Several elements need to be covered. First, if we want healthcare practitioners to embrace PGX, we need to do a much better job of educating doctors, nurses, physician assistants, and others across the healthcare system about what it is and how it should be used. I wasn't trained in PGX at all during my medical education. I really only learned about it after I earned my MD, worked in two specialties, and then got a PhD.

Secondly, we must understand the clinical implications of data from PGX tests. Focusing on PGX as this amazing, unique game-changer — which, don't get me wrong, it is — can fall flat with clinicians. For them, it may be more effective to describe PGX as a helpful tool. Putting on my physician hat, if you help me to understand that PGX should be considered in the same way as tests for kidney function, liver function, and comorbidities, I can begin to grasp its role in getting the right treatment to the right patient at the right time.

Another element is figuring out how to deliver the data to providers. If you've ever seen a PGX report, you know that it's a 45-page PDF of what, for most people, looks like nonsense. How can physicians be expected to review a 45-page report, find the right content, absorb the appropriate information, and then take clinical action based on it? It's not realistic, and it's not aligned with how we practice medicine.

Not only is interpreting PGX data critical, but so is finding ways to seamlessly integrate that information into physicians' workloads — as opposed to making physicians jump into our workflow. Many healthcare systems have been working on doing this and finding success, including St. Jude's and Vanderbilt.

The problem right now is that, in a lot of places, any data with "genetic" or "genomic" in its name lands in the genomic module within electronic health records. I'm a medical geneticist, but the vast number of people in medicine are not. That means they're not going to go to the genetic modules.

Rather, since PGX information is directly related to prescribing, it needs to go into the prescribing module. A physician wants to know: Should I give my patient penicillin or not? It should be as simple as that.

A third issue is standardization. For glucose levels, you're going to get the same number at any certified lab if you follow the same fasting regimen. For those kinds of well-established and routine tests, there's standardization in how labs interpret a phenotype.

We don't have that for PGX. Instead, the data you get from the lab provides information about an individual's genotype or allele, which must then be translated into phenotype. To get the actual clinical implications from that information requires a high level

It still comes back to delivering the information in the right way. As a physician, I don't need a 45-page report. Give me 2 minutes' worth of information. Tell me what I need to do now.

of analysis and expertise. The Clinical Pharmacogenomics Implementation Consortium (CPIC) has been leading the standardization process, but there is more work to be done.

What are some common myths or misconceptions about PGX testing? How can we help dispel them?

I'm going to highlight again that PGX is not a silver bullet. It should be considered as one piece of the puzzle when prescribing medication. That's the key take-away. The next most important concept is avoiding friction when delivering this information — and you do that by optimizing your messaging based on the recipient.

The third element is clearly understanding who's going to pay for it. With PGX, we're not yet there, as it's still not part of the standard of care. Here, too, we need standardization. Some payers are asking for a 6-gene panel; for others, it's up to a 10-gene panel; and for still others, it's a single-gene panel.

I see labs that don't make it past their first 2 years because they can't figure out who's going to pay for their services. At the end of the day, PGX is not a realistic out-of-pocket service for most patients, given that the tests can cost $200, $300, and even $500. It's not scalable at those price points.

But also, for clinical usage, for clinical implications, and for business growth, labs specifically need to figure out applications for PGX. With glucose, you order that test to be done every 90 days for patients with diabetes. PGX applies for life. Clinicians who start using it can figure out how to use PGX results more frequently for clinical scenarios; that's how you grow your lab business, by finding better ways to deliver value.

Beyond oncology, where do you see PGX having the biggest impact on patient care?

It has a lot of potential across specialties. The low hanging fruit could be mental health, because there is enough information in well-regarded publications that addresses how PGX could be used in that area and the possible economic benefits. Beyond mental health, we've also seen clear pathways in cardiology and anesthesia. In oncology right now, PGX is a trending topic. Whatever works to bring attention to PGX is great.

But it still comes back to delivering the information in the right way. As a physician, I don't need a 45-page report. Give me 2 minutes' worth of information. Tell me what I need to do now. And then find better ways to embed PGX into the health continuum.

We also shouldn't be leaving it up to physicians and pharmacists to explain to patients how much PGX testing costs if it's not covered by payers. It's very unusual to expect physicians and pharmacists to become sales reps. There's been some headwinds in terms of securing reimbursement for PGX from Medicare, which affects private payers, but we're not there yet. We also typically only have access to PGX at big academic healthcare systems. But in reality, that's not where most Americans go for healthcare. That's another problem in the PGX space.

Where do you think PGX will be in 10 years?

Hopefully we won't be talking about it anymore because it will be part of the standard of care! How often have you heard recently about creatinine being used to adjust dosing? You don't; it's just the accepted norm. I hope the same will happen with PGX.

Jen A. Miller is a freelance journalist who lives in Audubon, New Jersey.
+BLUESKY: @byjenamiller.bsky.social

AN INTERVIEW WITH BECKY WINSLOW, PHARMD

Translating pharmacogenomics into patient care and coverage

By Jen A. Miller

As demand for personalized medicine grows, pharmacogenomics (PGX) has become an increasingly common — and critical — part of clinical care. Specialists from all over the healthcare sector are working to make sure PGX tests are not only accurate, but also that they'll be paid for.

Becky Winslow, PharmD, is the founder and lead consultant of inGENEious RX Incorporated, a boutique in vitro diagnostic consulting firm best known for its work in advancing pharmacogenomics to become a standard-of-care laboratory test. We spoke to Winslow about her career path and how she became an expert PGX strategist, and about what clinical laboratorians need to know about the financial aspect of this vital technology.

How would you describe what you do?

Having worked as a pharmacist and laboratorian, I have a comprehensive understanding of the factors that influence PGX's successful journey from the boardroom to the bedside.

I label inGENEious RX services as fractional medical affairs services. Having witnessed firsthand throughout my career the disconnect between clinical and commercial, I built this firm to focus on the business of clinical diagnostics. We specialize in supporting molecular, genetic, and other complex testing companies with the operational and strategic expertise they need to thrive — without the cost or overhead of a full-time internal team. While traditional medical affairs groups lean heavily on publications and key opinion leader engagement, we're heavy on the "affairs": the often-neglected but mission-critical functions that tie clinical value to financial performance. Our work sits at the intersection of clinical relevance, payer expectations, utilization strategy, and reimbursement enablement. In short: We exist to make sure payers reimburse tests with proven clinical utility — and the tests stay in the market. Because clinical impact doesn't matter if the business can't sustain it.

How did you start doing this work?

Twelve years ago, a clinical laboratory recruited me to serve as a clinical science liaison between the laboratory and their physician clients. I helped physicians to clinically implement PGX testing into their workflows and apply the results to medication-therapy management. Prior to my intervention, the prescribers signed contracts with the lab, but didn't order tests because they didn't know for which patients the tests were medically necessary nor how to act on the results. My work grew from there.

What were you doing before you were recruited to serve as a clinical liaison?

I graduated as a doctor of cinical pharmacy (PharmD) in 1998. If you had told me then that I would wind up working with life-science companies and laboratories, I probably would have laughed; I had no idea a PharmD could do that.

At the start of my career, I worked as a clinical pharmacist. I provided direct patient care and directed clinical pharmacy programs in community, hospital, public health, and long-term care pharmacies. This is where I mastered convincing stakeholders to implement new-to-us products and services with proven clinical utility. I also mastered clinical implementation science because I had to drive the products' implementation into patient care once I secured approval. Commercial teams engaged me as an internal champion for their clinical products based on my advocacy and implementation success.

How has PGX progressed since you began working in this space?

The biggest change is that it's advanced outside of academia. Before, PGX was siloed mostly at academic institutions, but recently it's really flowed out into the community. Community stakeholders are championing its use — which is impressive, especially considering that there was no gold standard on how to do this. We've been paving that yellow brick road for the last 12 years to help PGX reach its potential.

What other bricks need to be laid down to move PGX in the right direction?

Payer reimbursement used to be a major issue, but that brick is

halfway established. Medicare, for example, reimburses testing, but commercial payers are not fully on board yet. For that to happen, the payers are demanding clinical-economic-utility research and evidence. That's a brick.

Professional society endorsement and inclusion in official drug-dosing or monitoring guidelines is a critical brick that has proven difficult to secure. This brick will ultimately compel prescribers to order the test. Despite the Clinical Pharmacogenetics Implementation Society authoring clinical implementation guidelines, Food and Drug Administration-mention in drug labels, and payer endorsement, professional societies such as the American Psychiatric Association have not yet endorsed PGX testing. Only recently has the National Comprehensive Cancer Network updated its guidelines to recommend considering *DPYD* genetic testing before initiating fluoropyrimidine-based chemotherapy.

And then the other brick, which I'd say we've smoothed out the dirt for, is to increase healthcare professionals' knowledge of which tests are clinically useful, which patients need testing, and how to fit PGX into workflows and apply the results to patient care. Embedded training in medical education will decrease knowledge gaps and tests' inclusion in order sets, clinical decision support systems, and electronic health record defaults will boost clinician confidence.

What role do clinical laboratorians play in advancing PGX?

Clinical laboratories must do the heavy lifting. Applying standard of care lab test strategy to PGX testing is a formula for failure. Unlike COVID and other standard of care tests such as hemoglobin A1c, PGX tests aren't selling themselves. COVID had urgency, mandates, and reimbursements baked in. Providers aren't required to order PGx, and most patients aren't asking for it. Payers want more than a CPT code — they want proof prescribers are using the test correctly. I cannot stress this enough: Labs must understand two factors that will make or break their success before they design and commercialize their test. First, what compels payers to reimburse tests and the medical necessity documentation payers require for the lab to keep the reimbursement. Second, the clinical end user support essential to generate and maintain financially sustainable test volume.

Why do you think a role like yours is important?

Initially, as a pharmacist, I did not feel confident talking about the financial case for clinically utile products and services. Pharmacy school didn't prepare me for the business side of patient care. I didn't learn to talk about costs; I learned we should just do what's right for our patients. But over time I came to realize that even the best clinical product with the best clinical outcomes can't help a single patient if nobody is willing to pay for it.

In other words, without sustainable reimbursement, PGX stakeholders don't have a test — which means patients can't benefit from it. While I'm not actually applying test results to patients' medication therapy management anymore, I now work on the other side of the coin, where I'm making the test possible. So that's how I'm contributing to overall healthcare impact — by improving patient access.

For clinical laboratorians who want to get into PGX, what do you recommend?

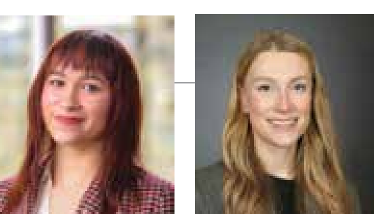
The cost for consulting is less than the costs associated with trial and error. And the best time to call a consultant is before a lab has planned a test. That way, they haven't had to contend with coverage and reimbursement yet, or with payers denying them. Or worse, a payer audit and recoupment of reimbursement.

Where do you expect PGX to be in 10 years?

All signs indicate that, in 10 years, PGX will be a standard of care test. I believe it will follow the same trajectory as lab tests clinicians currently demand to avoid toxicity, ensure efficacy, and personalize dosing when managing medication therapy. Organ function monitoring such as liver function tests and therapeutic drug monitoring such as lithium levels were not always standard of care. Non-PGX lab tests became standard of care by proving their value over time.

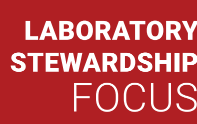
Today, we simply don't prescribe certain drugs unless we know a patient's kidney function. Likewise, in the future, we will not prescribe certain drugs unless we know the patient's pharmacogene phenotype.

Jen A. Miller is a freelance journalist who lives in Audubon, New Jersey.
+BLUESKY: @byjenamiller.bsky.social



BY PAYTON L. GABLEHOUSE, BS,
AND PAIGE HAAS, PHD, MS, CGC

Genetic testing stewardship for pediatric obesity



As clinical lab professionals know, stewardship isn't over when an approved test is ordered. In truth, the process never really ends. Our experience at Seattle Children's Hospital (SCH) serves as a case in point. After SCH's Laboratory Stewardship Committee approved the use of a sponsored genetic panel for pediatric obesity in 2020, they reassessed the test's clinical utility 4 years later. Specifically, they revisited clinical practice guidelines, gauged patients' changing needs, and gathered providers' perspectives. This work resulted in SCH's rollout of a new and improved referral algorithm in 2025.

In this article, we share how the committee partnered with other SCH healthcare and genetics professionals, with the goal of optimizing care for SCH's pediatric patients with obesity and their families.

About the genetic testing panel

In March of 2020, SCH's Laboratory Stewardship Committee approved the ordering of a sponsored test panel that sequences 87 genes associated with certain forms of obesity. A sponsored lab test is a clinical or genetic test where a pharmaceutical or biopharmaceutical company covers the cost for patients.

As a matter of policy, the committee reviews all sponsored tests to ensure they align with the standard of care, are performed in a CLIA environment, and are offered equitably to patients. This particular genetic panel is sponsored by Rhythm Pharmaceuticals, which manufactures the drug setmelanotide for the treatment of hypothalamic obesity. The sponsored pediatric obesity panel's inclusion criteria stipulate that patients must be 18 years or younger with a body mass index (BMI) greater than or equal to the 97th percentile.

After reviewing the sponsored genetic panel, the committee assessed it to be equitable and performed in a CLIA-certified lab. Although few practice guidelines on genetic testing for pediatric obesity existed at that time, the committee found that a test to assess monogenic causes of obesity fell within the standard of care.

Once the committee was satisfied with SCH's use of the sponsored test, a workflow was put into place. SCH providers who specialized in endocrinology and nutrition facilitated pre-test counseling, test ordering, and results delivery. In addition, they offered families a referral to experts in clinical genetics on an as-needed basis to discuss results.

Revisiting the testing process

In 2024, clinical genetics providers within SCH asked the Laboratory Stewardship Committee to reassess the clinical utility of the sponsored genetic panel for pediatric obesity. They shared their concern that the panel yielded a high incidence of variants of uncertain significance (VUS) that often confused families and rarely changed the medical management of patients. Additionally, they provided case examples of patients who would have qualified for testing with a broader diagnostic scope — such as exome or genome sequencing — but instead received the sponsored panel as a first-line test, potentially delaying the delivery of important diagnostic results.

In response, the committee asked SCH's laboratory genetic counseling (LabGC) team to perform a review of 93 orders of the sponsored genetic test panel from April 2022 - April 2024. The team extracted key data from the institution's utilization management database, including patient name, medical record number, ordering provider specialty, and order date. Then they conducted a manual chart review to document patients' age, BMI percentile, test results, clinical genetics referral status, and documented changes in medical management.

Limited by uncertainty

The data supported the clinical genetics providers' experiences of low diagnostic yield and a high incidence of uncertain results. Of the 93 sponsored genetic test orders, three (3%) were diagnostic. Two of these diagnostic orders identified pathogenic variants in the *MC4R* gene with autosomal dominant inheritance and no documented changes to medical management, and one order identified an incidental multigene deletion that led to a minor alteration in medical management.

Sixty-nine (74%) patients received uncertain results (i.e., at least one VUS) and 48 (52%) were referred to the clinical genetics team. Thirty-four (71%) of the referred patients were seen by clinical genetics providers, of which 18 (53%) were offered broader testing such

as exome or genome sequencing. Overall, an average appointment for patients referred to the clinical genetics team involved the discussion of two VUSs (Figure 1, online).

Leveraging collaboration

After the LabGC team presented these findings to the Laboratory Stewardship Committee, the committee recommended discontinuing the sponsored genetic panel orders at SCH and creating a plan that better served patients with pediatric obesity and their families.

From there, the committee convened a multidisciplinary working group that included representatives from LabGC, endocrinology, nutrition, and clinical genetics. The group reviewed the data and discussed alternative genetic testing workflows that could improve patient care at the hospital.

Within the working group, the experts in endocrinology and nutrition shared one of their ongoing challenges: finding time to thoroughly perform pretest counseling within the time constraints of their appointments. This matched the clinical genetics providers' experience that patients did not fully understand the purpose and possible results of the sponsored testing.

The endocrinology and nutrition providers also said it was difficult to determine when a patient would qualify for broader testing. Their fellow working-group members in clinical genetics outlined their referral process and provided contact information for individuals who could triage patient-specific questions.

When the clinical genetics providers expressed uncertainty about how genetic testing results inform medical management, those in endocrinology and nutrition shared information on when the medication setmelanotide is indicated for patients with damaging variants in *MC4R*, *POMC*, *PCSK1*, *LEPR*, or *BBS* genes.

Next stop: Literature review

The working group also reviewed current practice guidelines and published literature to inform their workflow for genetic testing for pediatric obesity. Their discussion focused on two populations: patients with non-syndromic severe obesity and/or hyperphagia (insatiable hunger), and patients with syndromic presentations (severe obesity and/or hyperphagia in the presence of intellectual disability, developmental delay, congenital anomalies, etc.).

According to the 2023 American Academy of Pediatrics clinical practice guidelines, patients with severe obesity (defined as a BMI ≥ 120% of the 95th percentile) with onset before age 5 and/or hyperphagia may be evaluated for a genetic cause.

In December 2024, the Food and Drug Administration approved setmelanotide for use in patients as young as 2 years old with melanocortin-4 receptor (MC4R) pathway deficiencies caused by variants in *MC4R*, *POMC*, *PCSK1*, *LEPR*, or *BBS* genes. For patients with intellectual disability, developmental delay, and/or congenital anomalies, the 2021 American College of Medical Genetics and Genomics clinical practice guidelines recommend exome or genome sequencing.

Taken together, the stewardship data, provider experiences, and practice guidelines informed the development of an updated genetic testing workflow for pediatric obesity (Figure 2, online). Endocrinology and nutrition providers now refer all patients with severe obesity and/or hyperphagia to their colleagues in clinical genetics to coordinate genetic testing. Clinical genetics providers then evaluate the patient for the best first-line test, provide thorough pre-test consent, and establish continuity of care for the delivery of results and subsequent discussion. Non-syndromic patients are offered a genetic panel that includes *MC4R*, *POMC*, *PCSK1*, *LEPR*, and *BBS* genes to inform their eligibility for setmelanotide. Syndromic patients are offered broader genetic testing such as exome or genome sequencing, which can inform eligibility for setmelanotide and the medical management of clinical features beyond obesity.

Impact to date and conclusion

SCH providers adopted the genetic referral algorithm for pediatric obesity in March 2025, acknowledging that the sponsored test orders that were already offered to families would proceed as planned. Since the implementation of the new workflow, order volumes for the sponsored genetic test have decreased from an average of seven orders per month to one order per month.

The immediate impact of the referral algorithm demonstrates that laboratory stewardship is iterative. Approved tests require continuous stewardship to align with updated clinical practice guidelines, the changing needs of the patient population, and ordering provider perspectives.

To view the figures and references for this article, visit myadlm.org/cln.

Payton L. Gablehouse, BS, is a laboratory genetic counseling assistant at Seattle Children's Hospital.
+EMAIL: Payton.Gablehouse@seattlechildrens.org

Paige Haas, PhD, MS, CGC, is a laboratory genetic counselor at Seattle Children's Hospital.
+EMAIL: Paige.Haas@seattlechildrens.org

BY MICHAEL L. ASTION, MD, PHD,
AND KHALDA A. IBRAHIM, MD

Five concepts to improve the ambulatory payment system

Although clinical pathologists and chemists are experts in the laboratory sciences, they often lack knowledge about the financial infrastructure required for profitable lab services. However, laboratorians who understand the inner workings of the insurance payment system are best positioned to support the lab's financial health and to protect patients from financial toxicity (*1*).

In addition, financial knowledge helps lab leaders develop and sustain power in their institution. Too often, laboratorians cede financial power to administrators and consultants who are not knowledgeable about the lab instead of partnering with these other parties as educated and formidable collaborators. At best, this throwing away of financial influence and power leads to underfunding the lab's clinical mission. At worst, the lab may be shuttered or sold due to the maneuvering that can occur without sufficient lab involvement.

This article outlines five foundational concepts that will benefit laboratorians who currently consider themselves lab economics novices. It is inspired by longer review articles that we published in the recent special edition of *The Journal of Applied Laboratory Medicine* that was dedicated to lab stewardship (*2*), as well as an article about insurance company perspectives written by Michael L. Astion, MD, PhD, and Geoffrey S. Baird, MD, PhD (*3*).

1. The revenue cycle is the system of payment for lab testing

The revenue cycle describes the steps from first patient contact through receipt of payment. But for any single test, the process may be more akin to a road race than to a cycle (Figure 1, online). The sequence of steps is: 1) patient registration including capture of demographic and insurance information; 2) test order entry; 3) test charge capture; 4) medical coding; 5) submission of a standardized electronic insurance claim that incorporates the aforementioned information; 6) claims adjudication by the payer; 7) management of denials and grievances by the payer, the patient, and the lab; and 8) payment to labs from insurers and patients.

The revenue cycle is easy to understand but seldom easy to navigate. It requires the proper raw materials, information, technology, and relationships. Failure at any point in the cycle can lead to delayed or lost revenue.

Knowledge of the revenue cycle is required to identify where stewardship interventions — such as updating the patient's insurance plan, promoting the ordering of appropriate tests, or improving coding accuracy — can reduce denials by producing clean claims. Clean claims contain all required administrative and medical data and are therefore usually processed promptly. Like burnt toast, an unclean claim needs thorough scraping to be edible, and even then, it may not be so appetizing.

2. Coding errors are a significant cause of denials

Insurance reimbursement requires accurate coding on standardized forms that have many fields. The two main forms used are CMS-1500 (electronic version = form 837P) and UB-04 (electronic version = form 837I). The primary coding systems in ambulatory medicine are CPT (Current Procedural Technology) codes and ICD-10 (International Classification of Diseases) codes.

Each CPT code describes a test or test panel (e.g., CPT 84443 = Thyroid Stimulating Hormone). ICD-10 codes, on the other hand, describe the signs, symptoms, risk factors, and/or underlying diagnoses that represent the clinical indication for testing, i.e., why the test or test panel was ordered. For example, ICD-10 code R63.4 = Abnormal Weight Loss and E05.1 = Thyrotoxicosis with Toxic Single Thyroid Nodule.

Insurance denials are frequently due to mistakes in coding. The most common coding errors are administrative, meaning that information in a particular data field is missing or inaccurate. Another frequent error is coding the claim inadequately to meet a payer's medical necessity policy (4). One common issue is the use of a nonspecific ICD-10 code (e.g., R53.8 = Other Malaise and Fatigue) when a more specific code in fact applies and would lead to payment (e.g., N18.6 = End-Stage Renal Disease). Understanding which codes

commonly lead to denials allows for targeted efforts to improve the accuracy and specificity of procedural and diagnostic coding.

3. Financial toxicity for patients is common, and labs can help reduce it

Patients can face substantial bills related to lab testing, especially when tests are ordered out-of-network and/or when claims are denied by the payer (whether for administrative reasons or for lack of medical necessity). Laboratories also face financial risk from denials: Insurance contracts may prevent or limit billing patients directly, and even when patients can be billed it can be difficult and costly to collect payment.

Ensuring patients are not exposed to surprise bills is a fundamental part of delivering laboratory services. Laboratorians play a role in minimizing patient financial toxicity by supporting stewardship practices that prevent unnecessary or non-reimbursable testing (5). For example, blocking duplicate orders for germline genetic testing that was just performed 6 months ago can save the lab and patient thousands of dollars.

Overall, foundational stewardship interventions that reduce patient financial toxicity include creating and maintaining reasonable test menus; designing decision support tools that promote ordering of appropriate and necessary tests and that reduce ordering of unnecessary tests; and managing send-out testing so that tests are referred to preferred, in-network reference labs.

4. Informatics tools enable smarter financial stewardship

Electronic health records, laboratory information systems, and other health IT systems are key pillars in laboratory financial stewardship. Clinical decision support tools embedded in order entry workflows can help ensure that medical necessity is documented, appropriate diagnostic codes are selected, and critical billing information is captured.

Beyond test utilization, informatics tools can be used to analyze payer behavior. Denial rates can be broken down any number of informative ways (e.g., by CPT code, by payer, by clinical service line). These analyses can be shared with payers to advocate for medical necessity policy changes, or with clinicians whose ordering patterns and documentation practices may be generating avoidable denials.

5. Making friends: Stewardship projects require external collaboration

Laboratorians working on financial aspects of stewardship quickly learn that the meaningful financial data — such as payer fee schedules, denial codes, or claims adjudication patterns — usually reside outside the laboratory. Collaborating with other work units, which includes teams in revenue cycle, IT, and business contracting, is necessary to access and leverage these data.

Successful projects also depend on building relationships with clinicians, genetic counselors, and administrative leaders. These partnerships enable labs to deploy interventions that are not only clinically acceptable but also scalable. Lab stewardship work is inherently multidisciplinary and often leads to new professional connections that benefit both the lab and the health system.

Conclusion

For lab leaders to provide optimal clinical services in an integrated health system, they must understand the payment landscape and use this knowledge to gain and sustain power within their system. The foundation is knowing the revenue cycle, from coding best practices to insurance claims processing. Knowledge of claims processing includes both administrative aspects as well as medical necessity determinations. The enablers for harnessing financial knowledge to improve payment are informatics tools and cross-departmental relationships. Understanding the payment system can be a path to increasing profits, reducing financial toxicity to patients, and developing balanced (and not subordinate) relationships with administrators and consultants.

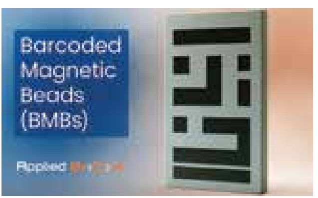
To view the figure and references for this article, visit myadlm.org/cln.

Michael L. Astion, MD, PhD, is director of regional laboratories, director of point-of-care testing, and co-director of reference laboratories in the department of laboratories, Seattle Children's Hospital and a professor of laboratory medicine and pathology at the University of Washington in Seattle.

+EMAIL: michael.astion@seattlechildrens.org

Khalda A. Ibrahim, MD, is an assistant clinical professor in the department of pathology and laboratory medicine, University of California, Los Angeles (UCLA), and a physician informaticist at UCLA Health Information Technology in Los Angeles.

+EMAIL: KAIbrahim@mednet.ucla.edu



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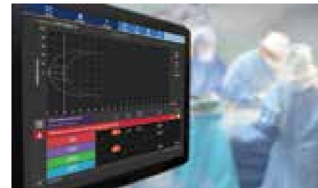

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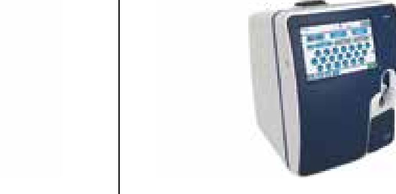

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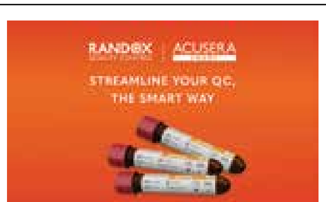

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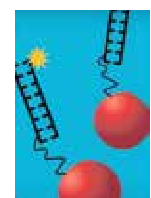

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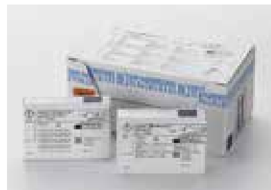

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Christina Pierre
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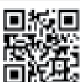

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Regulatory Roundup

FDA clears first Alzheimer's blood test

The Food and Drug Administration (FDA) recently announced marketing clearance for the Lumipulse G pTau217/ß-Amyloid 1-42 Plasma Ratio test for early detection of amyloid plaques in plasma associated with Alzheimer's disease.

As the first blood test for Alzheimer's, it is intended for adult patients ages 55 years and older who exhibit signs and symptoms of the disease.

The assay measures the proteins pTau217 and ß-Amyloid 1-42 in plasma and calculates the numerical ratio of the levels of the two proteins. The ratio is correlated with the presence or absence of amyloid plaques in the brain. The test reduces the need for positron emission tomography scans.

Clearance was based on FDA review of a multicenter clinical study of 499 individual plasma samples from adults who were cognitively impaired and tested with the Lumipulse G pTau217/ß-Amyloid 1-42 Plasma Ratio. Researchers compared results with amyloid PET scan or cerebrospinal fluid (CSF) test results. They found that 91.7% of individuals with Lumipulse G pTau217/ß-Amyloid 1-42 Plasma Ratio positive results had amyloid plaques detected by a PET scan or CSF test result, and 97.3% of individuals with negative results had a negative amyloid PET scan or CSF test result. Less than 20% of the patients tested received an indeterminate Lumipulse G pTau217/β-Amyloid 1-42 Plasma Ratio result.

This test is intended for patients presenting at specialized care settings with signs and symptoms of cognitive decline. The results must be interpreted in conjunction with other clinical information.

FDA AUTHORIZES FIRST HOME TEST FOR CHLAMYDIA, GONORRHEA, AND TRICHOMONIASIS

The Food and Drug Administration (FDA) recently announced marketing authorization for the Visby Medical Women's Sexual Health Test, the first assay for chlamydia, gonorrhea, and trichomoniasis that can be purchased without a prescription and performed entirely at home.

Intended for women with or without symptoms, the test delivers results in approximately 30 minutes.

A single use test, it includes a powered testing device, which communicates securely to the Visby Medical App. The app displays results when the test is complete.

In a study of individuals with and without symptoms, the Visby Medical Women's Sexual Health Test correctly identified 98.8% of negative and 97.2% of positive *Chlamydia trachomatis* samples, 99.1% of negative and 100% of positive *Neisseria gonorrhoeae* samples, and 98.5% of negative and 97.8% of positive *Trichomonas vaginalis* samples.

The authorization opens the 510(k) pathway to other home tests for sexually transmitted infections, FDA officials said.

Drazen Zigic / iStock

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DIASORIN TO MARKET ASSAYS FOR GRAM-NEGATIVE BLOOD CULTURE AND C. AURIS

Diasorin recently announced Food and Drug Administration 510(k) clearance for the Liaison Plex Gram-Negative Blood Culture Assay in the United States and launch of its Simplexa C. auris Direct kit in all countries accepting the CE mark.

The Liaison Plex is designed to identify 27 targets, including 19 gram-negative bacteria and 8 relevant resistance gene targets. It gives results approximately 2 hours after a Gram stain, allowing swift detection of resistance determinants and certain pathogenic bacteria.

The Simplexa C. auris Direct kit helps identify patients with possible *Candida auris* (C. *auris*) colonization, aiding infection control in healthcare settings and preventing potentially deadly infections in vulnerable patients.

The real-time PCR assay is used for the direct in vitro qualitative detection of C. *auris* DNA from a composite swab of axilla and groin and detects all six C. *auris* clades identified globally. Performed on the Liaison MDX, the test gives results in less than 2 hours.

MEDICARE TO COVER RAS MUTATION TEST

The Centers for Medicare & Medicaid Services has granted EntroGen national coverage for its CRCdx RAS Mutation Detection Kit, the company announced recently.

The kit is the first Food and Drug Administration-approved, real-time PCR-based companion diagnostic for identifying patients eligible for treatment with Vectibix (panitumumab), based on the absence of *KRAS* and *NRAS* mutations.

The coverage decision gives Medicare beneficiaries better access to precision oncology for colorectal cancer and allows labs and providers to "confidently integrate CRCdx into clinical workflows without the barrier of out-of-pocket patient costs, accelerating the adoption of personalized cancer care," EntroGen said.

LIQUID ASSAY GETS MEDICARE COVERAGE

Pillar Biosciences recently announced that the Centers for Medicare & Medicaid Services (CMS) has granted coverage for its oncoReveal pancancer solid tumor in vitro diagnostic (IVD) NGS kit.

The kit uses Pillar's proprietary stem-loop inhibition-mediated amplification technology to detect single nucleotide variants, insertions, and deletions in 22 genes using DNA isolated from formalin-fixed paraffin-embedded tumor tissue specimens.

Additionally, oncoReveal CDx has been approved as a companion diagnostic to identify patients who may benefit from epidermal growth factor receptor tyrosine kinase inhibitor therapy (class approval) in non-small cell lung cancer and Erbitux and Vectibix for KRAS in colorectal cancer.

The oncoReveal CDx has been Food and Drug Administration-cleared on the Illumina MiSeq Dx.

LIVER CANCER TEST GETS FDA BREAKTHROUGH DEVICE DESIGNATION

Mursla Bio recently announced Food and Drug Administration (FDA) Breakthrough Device Designation for EvoLiver, a biopsy-based blood test.

Enabled by a novel platform based on organ-specific extracellular vesicles circulating in blood, the test detects hepatocellular carcinoma — the most common form of primary liver cancer — in high-risk patients with cirrhosis.

The designation follows an announcement of the company's results from its MEV01 multicenter clinical study in which EvoLiver demonstrated 86% early-stage sensitivity at 88% specificity for liver cancer surveillance.

EvoLiver could "transform liver cancer surveillance by enabling earlier detection through a more accurate, accessible, and patient-friendly blood test," Mursla Bio officials said.

The company is advancing regulatory compliance for EvoLiver as a laboratory developed test in preparation for its planned product launch, while also laying the groundwork for future FDA approval through the premarket approval pathway.

INTERPACE DIAGNOSTICS TO STOP ACCEPTING SPECIMENS FOR PANCRAGEN

Interpace Diagnostics, a subsidiary of Interpace Biosciences, recently announced it will stop offering PancraGEN, a DNA-based diagnostic molecular test that assesses the risk of pancreatic cyst progression to cancer.

Interpace stopped offering the test in May after Medicare stopped reimbursing for its cost. The company explained that PancraGEN was primarily ordered for Medicare patients.

Company officials noted that, as a publicly traded company, Interpace "is obligated to help ensure profitability for our shareholders." Loss of Medicare reimbursement also necessitates the restructuring of the company, they added.

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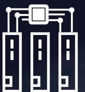

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Qiagen acquires Genoox AI-powered software

Qiagen recently announced it has agreed to acquire Genoox, which provides software powered by artificial intelligence (AI) for scaling and speeding processing of complex genetic tests.

The acquisition adds Franklin, Genoox's flagship cloud-based community platform, to the Qiagen Digital Insights (QDI) portfolio. Franklin allows labs to analyze next-generation sequencing data from targeted gene panels and genomic sequencing, and it delivers real-time, AI-driven insights to support clinical decision-making. Applications range from diagnosing genetic disorders and informing cancer treatments to supporting family planning decisions.

More than 4,000 healthcare organizations in over 50 countries use Franklin, which has powered more than 750,000 case interpretations to date, Qiagen said.

The acquisition also creates a path to integrate Qiagen's genomic content into the Franklin platform. This content includes the Human Gene Mutation Database, the Catalogue of Somatic Mutations in Cancer, and the Qiagen Knowledge Base — all of which power the company's leading QCI Interpret and QCI Precision Insights solutions, Qiagen said.

These future integrations will expand Franklin's interpretive power, which will in turn improve diagnostic yield, turnaround time, and scalability for clinical labs, Qiagen added.

COLLABORATION AIMS AT PARKINSON'S DISEASE

FYR recently announced a collaboration with Mayo Clinic intended to advance use of blood-based biomarkers in Parkinson's disease (PD) research and clinical applications.

FYI, a biotechnology company leveraging extracellular vesicles (EVs) to observe disease and treatment responses, said that under the agreement, it will collaborate with Mayo Clinic to discover EV biomarkers associated with PD. Current areas of interest for collaboration include identifying biomarkers associated with disease progression and subtypes. These biomarkers could potentially lead to the development of tools, processes, and services with clinical and commercial applications.

The collaboration will involve FYR's EV-Omics (EVO) platform, which uses valuable information from EVs. EVs from diseased cells carry cargo rich with proteins, RNA, and DNA, which provide detailed insights on disease mechanisms. FYR's technology enriches brain-derived EVs to enhance the signal and detection of disease-associated material. By analyzing EVs in blood samples from PD patients, FYR aims to improve the identification and tracking of molecular changes in the disease.

FYR officials said they are eager to combine their technology with Mayo Clinic expertise to address unmet PD needs and potentially advance precision care.

DEAL TO MAKE ORDERING GRAIL LIQUID BIOPSY EASIER

A new Grail partnership with athenahealth will integrate the ordering of Grail's Galleri multi-cancer early detection (MCED) test into athenaCoordinator Core, a service to help healthcare facilities streamline laboratory order transmission and care coordination.

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The integration will be provided through athenaOne, athenahealth's cloud-based electronic health record (EHR) solution. This integration will allow over 160,000 U.S. clinicians on the athenahealth network to more seamlessly order Galleri directly in the EHR.

The prescription-only Galleri test is recommended for adults with an elevated risk of cancer and is to be used in addition to recommended cancer screenings. After clinicians order the test, patients can take the order to blood draw appointments. Results automatically will be available in the patient chart, reducing manual entry and administrative burden for clinician practices, Grail said.

SOURCE BIOSCIENCE ACQUIRES CAMBRIDGE CLINICAL LABORATORIES

Source BioScience recently announced it has completed its acquisition of Cambridge Clinical Laboratories (CCL).

The acquisition bolsters its diagnostics portfolio by leveraging CCL expertise and state-of-the-art clinical lab facilities, enabling streamlined testing services for both preclinical and clinical research, Source BioScience said. CCL provides personalized healthcare diagnostic services spanning oncology, virology, men's health, gastroenterology, and fertility, as well as validation studies for clinical research to both the United Kingdom's National Health Service and private customers worldwide.

The acquisition expands Source BioScience's existing clinical offerings — which include molecular diagnostics, digital pathology, and clinical trial support — to provide a complete laboratory service portfolio, the company said. The deal also allows researchers to progress candidates through research and development to preclinical and clinical stages with one specialist outsourcing partner, minimizing resource requirements and data bias across the entire development process. Researchers will have the option for additional support in clinical research and diagnostics.

CCL staff and assets will be transferred to the new clinical facilities at the existing site for Source Genomics, which is a part of Source BioScience. This step will allow for expanding existing services, exploring new capabilities for future projects, increasing opportunities for collaboration between genomics and clinical services teams, and providing customers with deeper insights into their data, Source BioScience said.

VALLEY DIAGNOSTICS AND SONA NANOTECH TO ADVANCE BOVINE TB ASSAY COMMERCIALIZATION

Valley Diagnostics (ValleyDX), a Welsh diagnostics company developing next generation point-of-care lateral flow diagnostic kits, recently announced a deal to establish a licensing agreement with Sona Nanotech for the commercialization of a bovine tuberculosis (bTB) assay.

Sona developed the assay using ValleyDX biomarker intellectual property under license from Aberystwyth University in Wales. The intellectual property was derived from groundbreaking research at the university, ValleyDX said in a statement.

"[The] bTB lateral flow assay developed by Sona has the potential to be a game changer in the fight against bovine tuberculosis," ValleyDX officials said.

The agreement gives ValleyDX exclusive rights to the bTB lateral flow assay for the United Kingdom and Ireland with first refusal for additional territories. The agreement also outlines a milestone-based licensing structure with the aim of ensuring that commercial scalabilities for all parties will be aligned to market success.

bTB remains a significant challenge for the agricultural industry. Currently, a bTB diagnosis is confirmed through postmortem examination and tissue culture, a process that can take up to 12 weeks. Infected and exposed animals are typically destroyed, causing substantial losses to farmers. The disease is a pressing issue in Europe.

"This test has the potential to have a significant positive impact on how bTB is managed and help in the eradication of this disease from the U.K. and Ireland," Sona Nanotech officials said.

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Ask The Expert

Why the tests left behind at discharge matter — and what to do about them

By Andrew H. Fletcher, MD, MBA, CPE, CHCQM, FCAP

What are TPADs and how do they affect patient and financial outcomes?

a: Tests pending at discharge (TPADs) refer to any test ordered during a hospital stay that is not resulted until after the patient is discharged. All laboratorians intuitively know TPADs are problematic but rarely have insight into how often they occur. Studies have shown that up to 100% of inpatients in some institutions have TPADs and 30%-40% of these tests influence postdischarge care. In one study, two-thirds of outpatient providers reported medical errors caused by TPADs.

There are also financial burdens associated with unnecessary TPADs. If 30%-40% of TPADs influence postdischarge care, this also means 60%-70% do not contribute to patient care. These unnecessary tests can cost hundreds of thousands of dollars and erode Diagnostic Related Group payments. Additionally, poorly managed TPADs may contribute to readmissions and associated excess readmission penalties from the Centers for Medicare & Medicaid Services, which added up to more than $500 million nationwide in 2025.

What kinds of tests typically become TPADs?

No test is immune to becoming a TPAD, but some are more likely to become TPADs than others.

Microbiology cultures commonly become TPADs due to turnaround times (TATs) ranging from days to weeks. While most institutions have systems in place to capture positive culture results postdischarge, the same cannot be said for negative results. However, negative results may drive important clinical decisions in antibiotic de-escalation, promoting antibiotic stewardship, and preventing patient drug side-effects.

Common in-house tests also represent a large proportion of TPADs. Frequently, these test orders are remnants of order sets with overzealous order duration fields that healthcare providers forgot to cancel prior to discharge. These lead to unnecessary tests that often have no impact on inpatient clinical decision-making.

Reference tests are highly susceptible to becoming TPADs given their longer TATs — and the fact that clinicians may be unaware of these TATs. Many reference TPADs are critical, such as those for therapeutic drug levels, and must be carefully documented in discharge summaries. On the other hand, some represent misordered tests or tests not relevant to the hospital stay. Expensive reference tests that are ordered immediately prior to discharge out of convenience tend to fall into this latter category.

How can hospitals improve management of TPADs?

Effective TPAD communication starts with discharge summary documentation. Discharge summaries are highly focused on pharmacy reconciliation ensuring that the patient's medication list is accurate. This same process should be mirrored for laboratory TPAD reconciliation.

Initial reduction of unnecessary in-house TPADs can be achieved by reviewing standard discharge planning processes. Prior to discharge, what is the process for cancelling pending test orders? Are order sets reviewed to ensure appropriate order duration fields and reduce unnecessary daily tests?

Clinician awareness of reference test TATs often reduces reference TPADs. Some hospitals incorporate reference test TAT estimates within the order entry process. Awareness of the TAT may alter ordering since the results will not be available during the patient stay. An in-house test with faster TAT may suffice. But if the reference test is needed, awareness of the TAT may also prompt TPAD documentation in the discharge summary.

Why should labs get involved with improving TPADs?

Critical TPADs can impact patient care. By raising awareness of TPADs and recommending steps for managing them better, laboratories demonstrate that we are not just a commodity or hospital cost center, but an integral part of any healthcare system.

Andrew H. Fletcher, MD, MBA, CPE, CHCQM, FCAP, is a pathologist and founder of Eutilogic Consulting in Salt Lake City.

+EMAIL: andrew.fletcher@eutilogic.com

Product Spotlight

Sustainable, sensitive, reliable: The future of clinical sample preparation

Liquid chromatography-mass spectrometry (LC-MS) is a powerful technique utilized in clinical laboratories for its high sensitivity and specificity. LC-MS plays a crucial role in the accurate quantification of compounds from biofluids in clinical laboratories. Matrix effects from biofluids including serum, plasma, and saliva can make quantitation of target analytes challenging, especially at low concentrations. Solid phase extraction (SPE) provides cleaner samples for analysis but requires significant method development and hands-on time in a clinical analysis workflow. Clinical labs desire sample extraction methods that are fast, reliable, sustainable, and require minimal method development. Supported liquid extraction (SLE) is used widely in clinical laboratories. Minimal method development and extraction time makes SLE ideal for clinical LC-MS/MS methods to reduce hands-on time.

Strata™ SE SLE is Phenomenex's next-generation SLE product. It is engineered to deliver highly clean extracts from biological matrices, supporting sensitive and reproducible quantification in low-level analytical workflows. Optimized for the isolation of hydrophobic analytes, the media facilitates efficient partitioning into organic solvents, making it particularly suitable for modern clinical and bioanalytical applications.

Strata™ SE SLE was tested on a panel of steroids in serum where very low LC-MS/MS limits of detection are required. Chromatograms showed minimal interferences and clean backgrounds, both necessary for accurate quantitation at low concentrations. Results from samples extracted using Strata™ SE SLE for steroid analysis consistently achieved the highest level of cleanliness, with reproducible performance over multiple lots of media and finished product, which is vital where repeat extractions can consume valuable lab resources and reduce turnaround time.

Strata SE SLE provides sustainable sample preparation. Regulations are limiting the use of halogenated solvents to protect human health. Hence, more clinical laboratories are modernizing their sample preparation methods to reduce use of these halogenated solvents in their analytical workflows. Unlike legacy products that required dichloromethane for optimum performance, Strata SE SLE provides excellent recovery with minimal matrix effects using ethyl acetate for elution. Strata SE SLE is available in a standardized 96-well plate format. Every batch of Strata SE SLE is QC tested by LC-MS/MS, to meet the demands of clinical researchers and their laboratory processes.

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