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CLN Clinical Laboratory News

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HOME TESTING FOR PSA

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Correlation between capillary and venous samples in feasibility study

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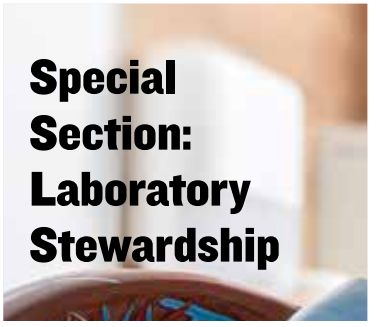
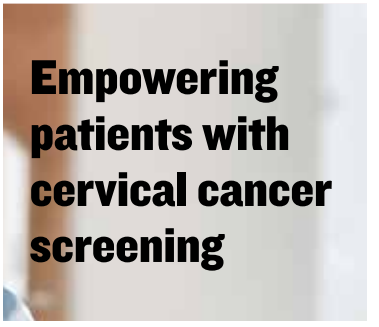
Empowering patients with cervical cancer screening





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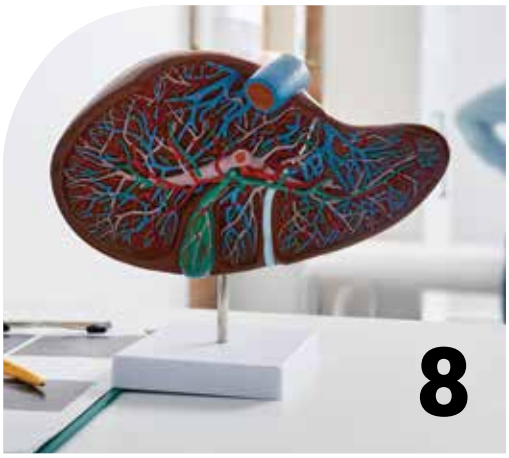

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It is important to investigate all injuries and exposures that occur in the lab, not just those that are recordable.
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On the cover: peakSTOCK / iStock

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Federal Insider

Deputy HHS secretary nominee opposed expanded FDA regulation of lab tests

U.S. deputy secretary of Health and Human Services (HHS) nominee Jim O'Neill, President Donald Trump's pick and a former HHS official during George W. Bush's administration, has previously opposed Food and Drug Administration (FDA) oversight of laboratory developed tests (LDTs) that use algorithms. O'Neill also suggested that the FDA should only consider the safety of drugs in approval decisions, and address efficacy after legalization.

As an HHS official under consideration for the position of FDA commissioner in 2017, O'Neill opposed FDA regulation of companies that perform LDTs that use complex algorithms.

"I found that really astonishing…astonishing that someone could claim the ability to shut down companies that were never touching a patient but only accurately matching algorithms," O'Neill said in a previous 2014 speech.

During President Trump's first term, he shared a similar view on LDTs and ended the FDA's bid to place these tests under duplicative FDA oversight in addition to the regulation they're already subject to from the Centers for Medicare and Medicaid Services (CMS). Under former President Joe Biden, the FDA finally published a rule asserting its authority over LDTs, but that could be reversed under the new administration.

O'Neill also said, "We should reform FDA so that it's approving drugs after their sponsors have demonstrated safety and let people start using them at their own risk. Let's prove efficacy after they've been legalized."

These remarks on drugs raised concerns during President Trump's first term. O'Neill has no medical training but has had a career as a biotech investor, which included serving as CEO of the science and technology-focused Thiel Foundation.

If his nomination for deputy HHS secretary is approved, O'Neill will oversee the daily operations of HHS' subagencies, including the FDA and CMS, and will play an integral role in public health emergency preparedness and overseeing the development of federal health regulations.

ADLM URGES DOGE CAUCUS TO REVOKE FDA LDT RULE

In a letter addressed to U.S. representatives Aaron Bean and Pete Sessions, the Association for Diagnostics & Laboratory Medicine (ADLM, formerly AACC) expressed support for their efforts as the co-chairs of the new House Delivering Outstanding Government Efficiency (DOGE) Caucus to reduce unnecessary government regulation and improve the delivery of public services. ADLM urged the representatives to revoke a rule issued by the Food and Drug Administration (FDA) that would hinder patient care, particularly for children and those living in rural areas.

The final rule (Docket No. FDA-2023-N-2177), promulgated by the FDA on May 6, would regulate laboratories that develop laboratory developed tests (LDTs) as if they were medical device manufacturers. The rule fails to recognize the difference between the two sectors: Manufacturers develop and sell their devices to anyone, whereas laboratories develop LDTs for their patients only at the request of an ordering physician. LDTs are also already regulated by the Centers for Medicare and Medicaid Services (CMS) and would continue to be regulated by CMS in addition to FDA under the new rule.

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ADLM is concerned that, if implemented, the rule will hinder the development of new LDTs, which are critical to advancing care, and significantly increase the administrative and compliance costs associated with LDT testing, thus forcing laboratories to reduce or eliminate LDTs from their test menu. ADLM urged the House DOGE Caucus to seek the revocation of this rule and preserve patient access to vital tests.

● HOSPITALS AIM TO KEEP FUNDING AS CONGRESS CONSIDERS OFFSETS TO PAY FOR TRUMP TAX CUTS

In a letter addressed to members of the U.S. House of Representatives and the U.S. Senate, Charlene MacDonald, executive vice president of public affairs of the Federation of American Hospitals (FAH), called on lawmakers to support hospitals and patients by considering the FAH's legislative priorities, including protecting access to health insurance and patient care and capitalizing on tax reform.

On average, Medicare pays only 82 cents for every dollar of hospital care provided to Medicare beneficiaries, leaving hospitals with nearly $100 billion in Medicare shortfalls in 2022 alone. Cuts to Medicare reduce access to essential healthcare services for seniors, while Medicaid covers more than 79 million individuals, including children, low-wage workers, persons with disabilities, and pregnant people. The letter called on Congress to reject any proposals that would cut the Medicaid or Medicare programs.

The tax reforms enacted in 2017 played a key role in encouraging capital investment, creating jobs, and raising wages, including in the healthcare sector, according to AHA. Allowing these tax cuts to expire would raise the costs of healthcare coverage by 90% for nearly 20 million people, lower workers' take-home pay, and lead to substantial job losses. The letter urged Congress to extend the enhanced premium tax credits for health insurance, which are set to expire at the end of 2025, and preserve access to affordable healthcare coverage for the millions of Americans who rely on it.

Is bad testing better than no testing? Evaluating nonstandard testing requests in the laboratory

Steven W. Cotten, PhD, DABCC, NRCC, FADLM

Sarah A. Hackenmueller, PhD, DABCC, FADLM

Yachana Kataria, PhD, DABCC, FADLM

Prior to implementation of clinical testing, laboratories validate and verify assays rigorously to ensure high quality, reliable results. At a minimum, this includes performance characteristics such as accuracy, linearity, reference interval, and precision. It may also include analytic sensitivity and specificity.

Despite the diligence in characterizing test performance, most labs will, at some point, receive a request to test specimens that are suboptimal or not routinely used for a specific assay. In such cases, laboratorians face a critical decision: to reject the request and cancel the test, or to proceed with testing while acknowledging potential limitations in the reliability of the reported results. When these situations arise, laboratorians must carefully evaluate several factors to guide their decision-making process.

At ADLM 2024, a scientific session explored these scenarios using real-world examples in a point-counterpoint debate. The debate was coupled withwith prerecorded videos from physicians and other treatment team members, explaining the rationale behind these unusual requests. This engaging discussion highlighted salient points and shared experiences that resonated with many laboratorians in the field.

Poor quality and atypical specimens

Generally, these types of requests will fall into two categories: Poor quality specimens, or atypical specimen types or sources (*1*, *2*). Each presents unique challenges requiring careful evaluation.

Poor quality specimens may have interferences that significantly affect test performance, such as hemolysis or lipemia. When considering testing in these situations, some questions to consider may include:

- Can the sample be recollected without significant inconvenience or harm?
- Would a recollected sample still exhibit the same presence of the interference?
- How does the interference affect test accuracy (e.g., falsely elevated or decreased results)?
- Are the clinical circumstances unique, such that a result even in the presence of an interference provides valuable clinical decision-making insights?

Requests on nonstandard specimens such as alternative fluids require a different approach. Questions may include:

- Are there peer-reviewed studies demonstrating the clinical utility of the result in the requested specimen type?
- What are the clinical risks associated with a falsely elevated or falsely decreased result?
- Does the treatment team have a clear rationale for using this specimen type?
- Does the treatment team fully understand the analytical challenges involved?
- Does the request represent an isolated situation with unique circumstances, or is it likely to lead to ongoing requests for routine testing of the specimen type?

In addition to the above points, laboratorians also should consider the feasibility of including additional experimental controls to increase confidence in the reported result.

For example, if a nonstandard dilution is requested, laboratories can perform parallel dilutions using a sample with a previously reported numeric result to validate the dilution scheme. Testing on atypical specimen types could be accompanied by a matrix-mixing study or a spiking study to demonstrate reasonable recovery of the target analyte in the sample matrix.

Good practice involves clear documentation via means of specific comments indicating an atypical testing situation. Comments should specify the context of the test, such as specimen type, dilution request, or reporting in the presence of known interferences. However, one limitation of this approach is that comments may not be as readily visible as the result, requiring clinicians to take additional steps to view the disclaimers and supporting information.

Poor quality specimens may have interferences that significantly affect test performance, such as hemolysis or lipemia.

Another critical aspect of nonstandard testing is how the results will be reported and filed in the electronic medical record. For example, if a bodily fluid result itself is charted under serum or plasma results, this could affect the trending of the results over time, potentially leading to clinical misinterpretation.

An intriguing discussion from the scientific session at ADLM 2024 centered on the justification of testing performed solely for the patient's reassurance, without clear medical necessity — a practice often referred to as "psychosocial testing." The concept is understandably controversial among laboratorians. As evidence-based medicine becomes increasingly central to the practice of laboratory medicine, the recognition of the patient's holistic needs may be lost. Striking a balance between patient-centered care and scientific best practices will remain a dynamic and evolving challenge for laboratory medicine.

In all cases, the risk of reporting an incorrect result must be carefully weighed against the consequences of providing no result at all. Engaging in a conversation with the ordering provider is essential to ensure they understand the limitations and uncertainties of the test and gain insight into how the result will be interpreted and used in clinical decision-making.

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Study shows promise for PSA testing from fingerprick samples

Capillary blood samples (CBS) and venous samples are highly correlated, with negligible bias, for total prostate-specific antigen (TPSA), according to recent research (J Appl Lab Med 2025; 10.1093/jalm/jfae144). This finding helps pave the way for remote monitoring of prostate disease.

For many patients, including patients with frailty, older patients, and people with mental health issues or learning disabilities, the typical method of collecting blood from veins is unsuitable. CBS via a finger or heel prick may offer an alternative, especially for self-testing to monitor chronic conditions such as cancer.

Globally rising life expectancies and demographic changes portend more than a doubling in cases of prostate cancer by 2040, according to researchers. Previous research has shown CBS feasibility for testing biochemical analytes, but little evidence exists relating to the measurement of TPSA in CBS using modern routine methods. The researchers aimed to determine whether CBS via fingerprick was a viable and feasible alternative to using routine venous samples for testing TPSA concentrations in men.

The researchers tested 66 adult men ages 26–63 recruited from a urology clinic. Next, they collected samples via fingerprick using validated devices and venipuncture. Validated immunoassays for both the Roche cobas 801 and Beckman DXi platforms to measure TPSA were also used.

Across a range of normal concentrations to pathological ones, results between CBS and venous samples showed strong similarities. The average bias, 1.07%, was insignificant. Overall, the researchers saw no apparent proportional or constant bias.

Data showed that TPSA may be stable in samples tested with the Roche or Beckman assays and stored at ambient temperature for up to 8 days.

Calling the study a first step toward routine home TPSA testing, the authors called for more research first using standard methodology to examine the analytical accuracy of CBS for TPSA testing and then using CBS in a clinical setting.

BREAST CANCER GENE VARIANTS OF UNCERTAIN SIGNIFICANCE ARE NEWLY CLASSIFIED

A new study of the crucial *BRCA2* DNA-binding domain hotspot for pathogenic missense variants has led to the clinical classification of 91% of variants of uncertain significance (VUS) in this part of the gene (Nature 2025; doi: 10.1038/s41586-024-08388-8).

The researchers analyzed all possible single-nucleotide variants (SNVs) from exons 15-26 that encode the DNA-binding domain hotspot for pathogenic missense variants. CRISPR-Cas9 gene-editing technology was used to analyze the functional impact of 6,959 *BRCA2* variants, definitively identifying those that increase cancer risk and those that do not. The researchers assigned variants to seven categories of pathogenicity. SNVs that encode loss-of-function missense variants were associated with increased risks of breast cancer and ovarian cancer.

For clinical classification of *BRCA2* variants, the researchers also integrated functional assay results into models from ClinGen, the American College of Medical Genetics and Genomics, and the Association for Molecular Pathology.

These findings allow molecular labs and clinicians to give more precise, personalized care to patients with VUS in *BRCA2*. Labs can notify patients and clinicians about reclassified VUS, potentially altering care. Additionally, some breast, ovarian, pancreatic, or prostate cancer patients with the newly reclassified VUSs may benefit from targeted therapies such as poly ADP-ribose polymerase (PARP) inhibitors, which block activity of an enzyme that repairs damaged DNA. The findings can be integrated with other datasets for the characterization and classification of all variants in this genetic location in individuals from all racial and ethnic backgrounds, and for all forms of cancer associated with *BRCA2*, the researchers noted.

These findings allow molecular labs and clinicians to give more precise, personalized care to patients with VUS in *BRCA2*.

OVARY REMOVAL AND APOE4 ALLELE MAY RAISE ALZHEIMER'S DISEASE RISK

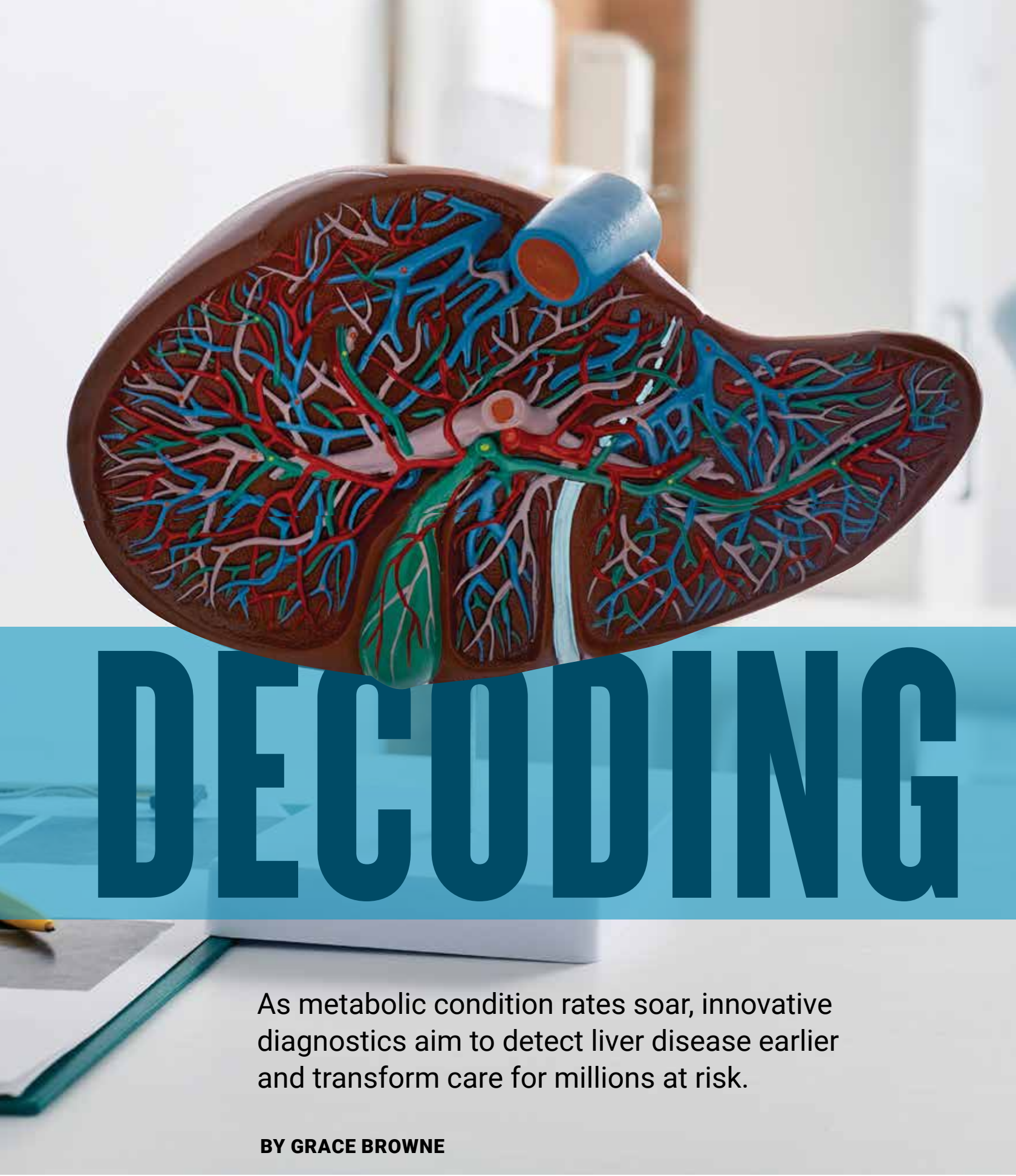
Women who have had surgery to remove both ovaries before age 50 and carry the APOE4 allele are at high risk of developing Alzheimer's disease (AD) late in life, recent research found.

Because removing the ovaries results in immediate loss of estradiol and onset of menopause, the researchers examined prevalence and predictors of AD among a U.K. biobank cohort of 33,603 women ages 60 or older without AD who had early removal of both ovaries, and those who had natural menopause. To determine AD, the researchers selected related ICD-9 and ICD-10 codes in medical records and used logistic regression to model the association between type of menopause with AD. Model predictors included age, education, age at menopause, use of hormone therapy, having the APOE4 variant, and history of cancer and smoking.

Women with early ovarian removal had four times the odds of developing AD (OR=4.12, 95% CI [2.02, 8.44]) compared with those who underwent natural menopause. Having the APOE4 variant (OR=4.29, 95% CI [2.43, 7.56]) and older age (OR=1.16, 95% CI [1.05, 1.28]) were associated with increased odds of AD in women who had ovaries removed and those who did not. More years of education were associated with reduced odds of AD for women who had ovaries removed (OR=0.91, 95% CI [0.85, 0.98]) and those with natural menopause (OR=0.95, 95% CI [0.90, 0.99]). Hormone therapy use was associated with decreased odds of AD only for women who had ovaries removed (OR=0.43, 95% CI [0.23, 0.82]).

Researchers also found a modest relationship between body mass index and AD risk, but only for the women with early ovary removal. Each additional unit of BMI was associated with a 7% decrease in risk of developing Alzheimer's disease.

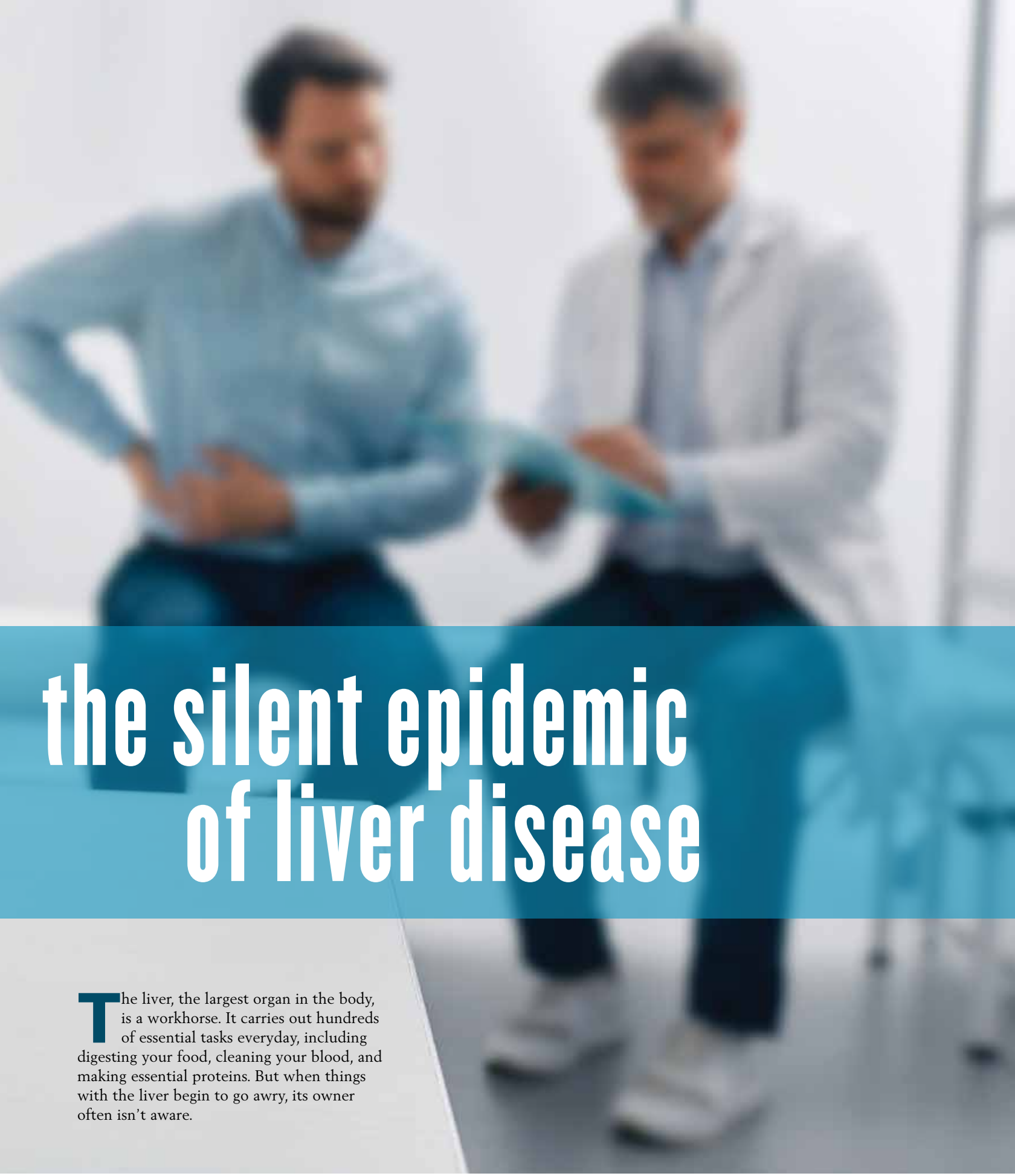
The study identifies women who had early removal of both ovaries and APOE4 as a likely at-risk group and demonstrates the importance of hormone therapy for lowering that risk. It also highlights the role of education in lowering risk of AD-associated cognitive decline in women with simultaneous menopause, the researchers wrote.



DECODING

As metabolic condition rates soar, innovative diagnostics aim to detect liver disease earlier and transform care for millions at risk.

BY GRACE BROWNE



the silent epidemic of liver disease

The liver, the largest organ in the body, is a workhorse. It carries out hundreds of essential tasks everyday, including digesting your food, cleaning your blood, and making essential proteins. But when things with the liver begin to go awry, its owner often isn't aware.

Liver disease is a major — and often underappreciated — public health issue. In general, liver conditions are associated with metabolic conditions writ large, and so are only set to increase as rates of obesity and diabetes among the general population also mushroom. An estimated 4.5 million adults in the United States have liver disease; that's 1.5% of the population, and liver disease results in around 57,000 deaths a year. Those from marginalized socioeconomic backgrounds tend to fare worse: A paper published in late 2024 found that certain groups are more affected than others. In particular, Hispanic adults showed a higher prevalence of a certain type of liver disease than other racial and ethnic groups, potentially due in part to a genetic predisposition, as well as higher rates of diabetes and obesity in this population. The authors pointed out that cases may be going undiagnosed and called for better ways of detecting the disease earlier, because catching the condition too late increases the chance of complications such as liver cancer, liver failure, and the need for a transplant.

Among those who have liver disease, another subset will develop progressive liver disease. That number is also set to rise: "End-stage liver disease is forecasted to increase over the next decade — a burden on not only the patient who suffers a poorer quality of life, but also on their loved ones, caregivers, and healthcare providers, too," said Margery Connelly, PhD, strategic director of diagnostics research and development at Labcorp. Chronic liver disease is responsible for around 2 million deaths globally every year.

Liver disease comes in a variety of forms and stems from a variety of causes, but the most widespread form of liver disease is fatty liver disease, in which too much fat builds up in the liver. Within this category exists nonalcoholic fatty liver disease, or NAFLD, more commonly referred to as metabolic dysfunction-associated steatotic liver disease (MASLD) today. Of the quarter of the global adult population who will develop MASLD, a quarter of those will develop metabolic dysfunction-associated steatohepatitis (MASH), previously referred to as nonalcoholic steatohepatitis (NASH). It's a more progressive form of the disease that has a higher risk of advancing to cirrhosis and end-stage liver disease. MASH is symptomless until it enters its later stages, when patients develop either cirrhosis, which ultimately requires a liver transplant, or liver cancer, which can be fatal. Currently, the only way to diagnose MASH is through a liver biopsy, but the invasive nature of the procedure limits widespread use. The accuracy of biopsies also depends on the pathologist's subjective interpretation.

Identifying MASH early increases the chance for patients to make the lifestyle changes needed to reverse the damage, or to receive medication. "There's a need for tests to identify this population, so they can be appropriately triaged for therapeutics," said Arun Sanyal, MD, a fatty liver disease researcher at Virginia Commonwealth University. Over the past couple of decades, there's been a catch-22 problem: The lack of past diagnostics meant there was little appetite for developing therapeutics, and the diagnostic world would question the point of developing diagnostics if no good therapeutics existed, Sanyal said.

AN INFLUX OF NONINVASIVE TESTS

This gap has spurred a new wave of noninvasive tests to fill it. There are three broad buckets of noninvasive tests emerging. The first includes simple laboratory aids based on routine tests, the most common one being the FIB-4 score, which gives an idea of how much scarring is happening in the liver and the risk of severe liver disease. It's based on blood tests that measure platelet count, the levels of aspartate aminotransferase and alanine aminotransferase — two enzymes associated with liver function — along with a patient's age. In routine practice, if a patient's FIB-4 is over a certain number, they are referred for further investigation and receive a FibroScan as a secondary test. "Increasing evidence suggests that FIB-4 scores are a convenient and cost-effective way to identify patients who do not need follow up testing and care," Connelly said.

There are other tests, such as the enhanced liver fibrosis (ELF) test. Also a blood test, it measures the burden of scar tissue in the liver and is the only test so far approved by regulatory agencies for prognostic purposes. But its use is limited by the higher cost compared with FIB-4.

New tests also identify patients with at-risk MASH, a stage in the disease when intervention significantly improves outcomes and regression of the disease. Labcorp's NASHnextTM (NIS4), a new invitro diagnostic, can identify at-risk MASH, Connelly said. The test produces a single score that identifies patients at this pivotal stage of the disease who have a higher risk of progressing to end-stage liver disease.

As a follow-up to blood tests, elastography, a type of screening,

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comes next. It is performed by either ultrasound or MRI-based approaches, though the cost of the latter makes them less than preferable. If an ultrasound is used, it's typically a FibroScan, a type of scan that measures the "stiffness" of your liver, which in turn reflects the degree of scarring in the organ.

A NIMBLE APPROACH TO NEW BIOMARKERS

Although these new biomarkers are gaining traction, "much of the biomarker literature actually really lacks scientific rigor and has methodological flaws, which is why they don't meet the regulatory bar for getting approved for specific context of use," Sanyal said.

This lack of rigor was the driving motivation behind the creation of the Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE) initiative, of which Sanyal serves as chair. The consortium was designed as a two-stage project, with the first stage aimed at analyzing existing data sets to find the leading biomarkers that could identify at-risk MASH. This stage landed on 10 noninvasive biomarkers, both blood-based and imaging-based, that showed promise for identifying people with at-risk MASH. In stage two of the project, a new prospective study will confirm the diagnostic performance of these markers for at-risk MASH.

For laboratory medicine professionals who are using these newer tests, Sanyal advised that it's crucial to first have clarity on the robustness of the assays, as well as defining the conditions under which the samples are collected and stored. "It is really important to consider the context of use," Sanyal said. What is the decision that will come out of it? What is the benefit versus risk of making a clinical decision based on that information?

USING EXISTING DATA TO CAST A WIDER NET

Even the identification of who should be tested using these biomarkers proves to be a challenging hurdle in and of itself. More often than not, the symptomless nature of liver disease means these patients go undetected until it's too late. One patient in particular sticks in the mind of Tim Jobson, BM BCh, a liver consultant based in the United Kingdom (U.K.). The patient in question was a man in his fifties, who had simply felt a bit unwell. He had some blood tests done with his primary care physician, which turned up worrying results. He was sent for an MRI, and by the time that Jobson saw him, he had advanced liver disease and liver cancer. The man had no idea that there was anything wrong with him. Yet his blood tests, which went back 15 years, could have sounded an alarm, Jobson said. "This was all avoidable."

Occurrences like this were not rare and served as Jobson's motivation to found his company Predictive Health Intelligence, which has developed a tool called hepatoSIGHT. The tool incorporates historical medical data to find patients at risk of liver disease. Out of the population of around 700,000 in Somerset, U.K., where they ran the pilot, 700 patients pinged the system and were called in for further care.

"The thought process was: Well, all of these blood tests exist already, and they're all stored electronically. We could search through those and find people with persistently abnormal tests who've yet to have the right interventions," Jobson said. It hunts for certain parameters that will pick up people who either have those conditions or who are at high-risk for them, so it could be used across the broad spectrum of chronic liver disease, Jobson said.

Jobson admits the tool won't identify everyone: It will always miss the people who haven't had a blood test done. Another big bottleneck is the way data is siloed off in the healthcare systems in the U.K., where the trial is being run. Still, there are many people they could identify as being at risk before they even go to the hospital, he said. "This translates to tens of thousands of patients benefiting. We just need to tap into this huge and valuable data resource that's sitting there, but that nobody can use, because they haven't got the tool."

The goal for the field, Sanyal said, is one day to have a validated set of tests that could be used as an initial screening to pick out patients who need follow-up testing. Ideally, these tests would be administered at the point-of-care, so that patients don't have to jump through hoops to get tested.

More than half the adult population will be living with MASLD by 2040, experts have forecasted. The need for these tests has never been more pressing. "This could impact the way healthcare is provided to over a billion people," Sanyal said.

Grace Browne is a freelance journalist who lives in London. She currently has a fellowship funded by the International Center for Journalists through the Health Innovation call.

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New draft guidelines from USPSTF elevate primary HPV screening and endorse self-collected samples, paving the way to solve disparities and improve care.

~~Writing~~ *Changing* the script on cervical cancer screening

BY DEBORAH LEVENSON

Draft cervical cancer testing guidelines from the U.S. Preventive Services Task Force (USPSTF) newly endorse women's collection of their own cervical samples for human papillomavirus (HPV) testing.

For most women ages 30 to 65, the guidelines elevate primary HPV (prHPV) testing every 5 years as the preferred cervical cancer screening method, while also continuing to recommend cytology every 3 years or a combined HPV/cytology (cotesting) every 5 years as alternatives. Cytology every 3 years continues to be the recommended screening method for individuals ages 21 to 29.

Although the guidelines do not specify self-collection location, an evidence report accompanying the draft guidelines notes that the Food and Drug Administration (FDA) has thus far approved expanded indications for self-collection of vaginal swabs in healthcare settings only. BD's Onclarity HPV Assay and the Roche cobas HPV Assay have the FDA indications.

Self-collected HPV samples would help reduce persistent health disparities, the draft says.

These disparities are driven by personal barriers such as health illiteracy, religious or social preferences, physical disability, or history of trauma, plus society-wide problems such as lack of properly trained providers in rural areas, financial insecurity, and lack of adequate insurance coverage.

The proposed recommendation is a start to fixing disparities because collection could potentially occur in any medical setting, said gynecological oncologist Jennifer Pierce, MD, MPH, division director of cancer control and prevention and professor of interdisciplinary clinical oncology at University of South Alabama. "Self-testing can potentially be offered in nontraditional healthcare settings, such as urgent care settings or FQHCs (federally qualified health centers) when there's no doctor who is trained to do a good pelvic exam."

The draft recommendations arrive as decreases in cervical cancer mortality rates have slowed. Most cases occur among inadequately screened groups.

The guidelines call out low screening rates and high incidence and mortality rates in Appalachia, the southeastern Atlantic states, and the lower Mississippi Valley. They note higher rates of disease and mortality in Hispanic women. Black women's age-adjusted cervical cancer mortality rate is about 1.5 times the rate for white women, despite similar screening rates.

The guidelines also recognize screening disparities among underinsured women and transgender men.

The self-collection recommendation brings the draft USPSTF recommendations closer to common practice in the Netherlands, Denmark, Sweden, Australia, and other developed countries.

THE RATIONALE FOR CHANGING CERVICAL CANCER SCREENING

Studies show prHPV screening with both self-collected and physician-collected samples is accurate, but the self-collection option increases screening rates, especially among groups with low screening rates, the draft guidelines say.

USPSTF reviewed 14 studies on agreement between self-collected vaginal and clinician-collected HPV samples and six studies on the absolute or relative test accuracy of self-collected vaginal HPV samples to detect CIN2+ or CIN3+ lesions.

Agreement between self-collected vaginal and clinician-collected cervical samples was high, with similar proportions screening positive. Pooled absolute sensitivity of self-collected samples to detect CIN2+ was 0.86. The pooled absolute specificity was 0.81.

Relative accuracy of self-collected vaginal samples to detect CIN2+, compared with the accuracy of clinician-collected samples, was also high. Their relative sensitivity was 0.94 to 0.99 and relative specificity was 0.98 to 1.02.

In 40 of 42 randomized controlled trials (RCT) comparing uptake of self-collected vaginal HPV testing with usual care, offering self-collected vaginal HPV tests increased cervical cancer screening rates.

CLIA requires labs running HPV assays to validate them for self-collection, the draft guidelines note.

USPSTF based elevation of prHPV testing on review of six RCTs and two nonrandomized studies of interventions, including a total of 63,241 women ages 25 to 64 years. Together, these studies showed prHPV screening detects more CIN3+ lesions in one round of screening compared with cytology.

Relative risk (RR) was 1.80. Two RCTs with a combined 67,298 subjects reported decreased detection of CIN3+ after two rounds of screening, with RR of 0.42 and 0.22. An additional trial with 13,925 participants compared self-collected to clinician-collected prHPV screening and found no differences in CIN3+ or CIN2+ detection.

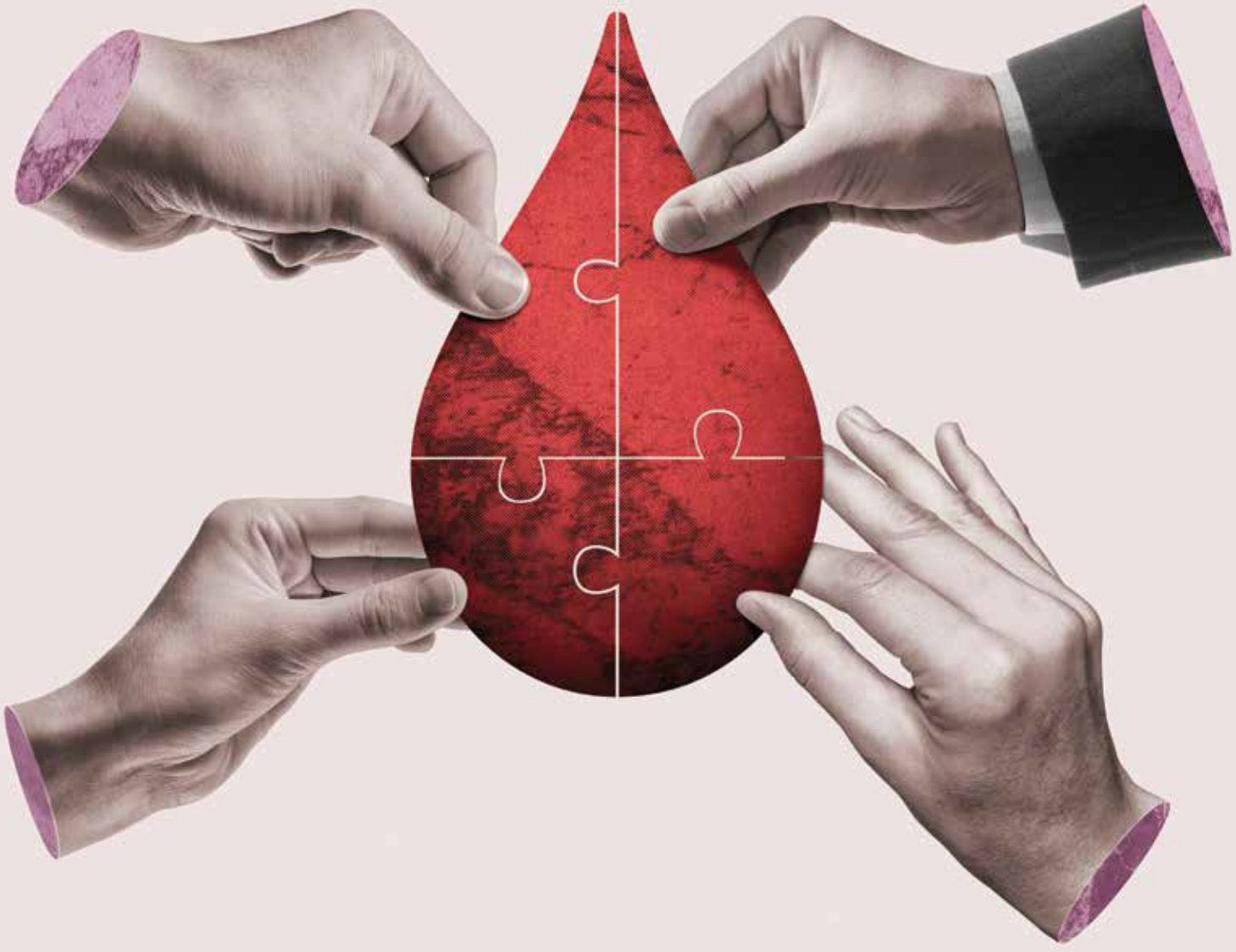
HOW EXPERTS EVOLVED ON SELF-COLLECTED SAMPLES

A statement from the American College of Obstetricians and Gynecologists, which declined to discuss the draft, said "HPV vaccination and routine cervical cancer screening are the most important tools we have for prevention and early detection of cervical cancer, and

Previous page and right: SvetaZi / iStock

No one should

withhold an opportunity for patients to have information because of paternalistic concern that people are better off in the doctor's office when some of them are never going to come in.
— Jennifer Pierce



we must ensure that these proven, evidence-based strategies are accessible to all people who need them." The statement called for improved access to care and meeting individual needs and preferences.

Pierce once preferred cotesting over primary HPV screening. But after the COVID-19 pandemic and ubiquitous home sample collection for SARS-Cov-2 and flu, she approves of prHPV with self-collection.

"HPV is also an infectious disease, and information is empowering," Pierce said. "No one should withhold an opportunity for patients to have information because of paternalistic concern that people are better off in the doctor's office when some of them are never going to come in."

The FDA is "very particular about humans collecting their own samples," said Dina Greene, PhD, clinical professor at University of Washington. "Women or people with cervices are taught to use menstrual products as adolescents, but an adult is considered incapable of swabbing their own vagina for an STI test or for their own cervical cancer screening."

Greene believes that some labs and physician practices may see a financial incentive to c ytology because it drives more billable services.

Meanwhile, prHPV provides HPV-genotype information and "a much more quantitative stratification of cervical cancer risk" than even cytology aided by artificial intelligence, said Vikrant Sahasrabuddhe, MBBS, MPH, DrPH, who co-leads the Self-collection for HPV Testing to Improve Cervical Cancer Prevention (SHIP) trial at the National Cancer Institute.

Many providers want to use prHPV because it informs disease management with a single test. But they are subject to health system directives to use cytology and co-screening, often because of system contracts. These systems could search their EHRs for patients who are under-screened and have any provider offer self-collection and prHPV, Sahasrabuddhe pointed out.

Among "individuals opting for self-collect, only those that test HPV positive (10–30%, depending on HPV positivity rate) will require a pelvic speculum exam to obtain a cervical sample for cytology-based triage testing," noted Thomas Lorey, MD, senior consultant and former director of laboratory services for Kaiser Permanente Northern California.

PrHPV screening can decrease overall costs by immediately identifying who needs to go directly to colposcopy, based on positive results for HPV 16 and 18, said Nicole Chaisson, MD, MPH, assistant professor of family medicine and community health at University of Minnesota and past chair of the American Academy of Family Physicians (AAFP) Commission on Health of the Public and Science Subcommittee on Clinical Recommendations and Policies.

Traditional cotesting may lead to more use of resources and patient time and result in cytology with atypical, yet not necessarily pre-cancerous findings, particularly if the HPV test is negative. Testing algorithms for this scenario require more frequent assessment, including repeat cotesting and colposcopy as follow-up.

For patients, this scenario involves burdens such as missing work, travel, and monetary costs,

Chaisson noted. "Cytology does not necessarily add new data in this case, but may cause confusion and lead to more testing."

HOW LABS CAN PREPARE FOR PRHPV SCREENING AS EVIDENCE ADVANCES

The National Cancer Institute's SHIP trial aims to add evidence about self-collection that could ultimately lead to women being able to collect samples at home, likely with devices obtained from health professionals, Sahasrabuddhe said. SHIP involves a master protocol as a framework for industry-specific subprotocols.

The FDA required BD and Roche's participation in SHIP as a condition of their self-collection options' approvals. The trial, which is now enrolling participants, will initially evaluate each company's self-collection devices in patients who had prior screening and need colposcopy. A total of 1,500 participants

Primary HPV screening offers "a much more quantitative stratification of cervical cancer risk" than even cytology aided by artificial intelligence.
— Vikrant Sahasrabuddhe

will use three self-collection devices (two from Roche and one from BD) and undergo clinician collection in a single visit. Future subprotocols will follow patients — including underscreened and underserved women — who need cervical cancer screening, Sahasrabuddhe said.

Labs should prepare for prHPV screening as the main default method of cervical cancer screening by making internal flow processes support it, said Diane Harper, MD, MPH, of the University of Michigan Department of Family Medicine, Obstetrics & Gynecology, and Gender Studies, where she leads her institution's participation in SHIP.

Lorey predicts "some resistance to discontinuing the time-honored Pap test." He added: "By educating clinicians and patients about the value of prHPV testing, labs can help ease this transition."

"It requires a lot of education," Pierce emphasized. "Both patients and doctors must understand that a positive HPV test means the patient needs further follow up."

Harper offered specific advice for labs on emphasizing to physicians that "prHPV screening is the appropriate default way to screen women and stop promoting cotesting."

Labs should tell clinicians they offer prHPV screening, offer related educational information, and ask clinicians to consider prHPV for patients, Harper said. Many clinicians want prHPV, but "don't know how to connect with their laboratories to make it happen," she said. "Having the laboratories proactively promote primary HPV screening … would be helpful so that we're all sending the same message."

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BY SARAH V. CLOWES CANDADAI, MS, CGC, DARCI L. STERNEN, MS, LCGC, KATIE GOLDEN-GRANT, MS, LCGC, AND KATRINA KOTZER, MS, LCGC

Standardizing demographic data in clinical genomics: A call for inclusive, evidence-based guidelines

LABORATORY STEWARDSHIP FOCUS

Clinical genetics organizations have a responsibility to assess their practices and procedures using a lens of diversity, equity and inclusion. Despite this responsibility, a lack of guidance exists about these principles from regulatory and professional organizations that laboratories typically rely on for direction. As a result, the collection of patient demographics — such as sex, gender, race, ethnicity, and ancestry — by genetic testing laboratories remains nonstandardized and lacks consensus.

Furthermore, evidence for the precise scientific value of this information on laboratory workflows and outcomes is limited. Several studies have called for the creation of consensus guidelines to help clinicians and researchers responsibly collect sex, gender, race, ethnicity, and ancestry (REA) data (*1*) aiming to reduce potential harms from confusing or inaccurate language and minimize discrimination against transgender, gender diverse and intersex populations (*2*).

To inform guideline development, we conducted a multistep study to assess the ways in which clinical genomics laboratories collect and utilize sex, gender, and REA data.

Test request form review: What data are collected?

To evaluate current practices, we first reviewed 40 molecular genetic, cytogenetic, and biochemical test request forms (TRFs) from 20 U.S.-based clinical laboratories that perform genetic testing for pediatric populations. The review included both academic medical centers and independent laboratories. Each form was reviewed for demographic field content related to patient sex, gender and REA.

A call for change in clinical genomics data collection

Recommendations for individual laboratories:

- **Conduct an internal review of test request forms (TRFs), focusing on demographic data fields.**
- **Determine the minimum set of patient demographic information required to ensure accurate testing and reporting.**
- **Use clear, specific, consistent language with a focus on diversity, equity and inclusion across all TRFs (molecular, cytogenetic, biochemical, etc.).**

Recommendations for national collaboration:

- **Undertake further studies to assess how patient demographic data are collected and used by genetics laboratories.**
- **Identify barriers to implementing updates in demographic terminology and propose solutions to facilitate change.**
- **Develop guidelines to standardize patient demographic information collection and language used on TRFs.**

The findings revealed significant variability. Some forms included structured fields with predetermined options, while others allowed free-text entries. A few forms did not include gender or ancestry fields at all. Differences in terminology were observed not only across laboratories, but also within the same organization's forms. The inconsistent and, at times, ambiguous terminology (Figures 1 and 2) underscores the need for standardized and inclusive language in TRFs to improve clarity and uniformity.

Survey and interviews: How is the data used?

To explore data usage, we developed a survey and distributed it via email to laboratory directors and genetic counselors at 30 U.S.-based laboratories offering clinical exome and genome sequencing. The survey received 11 responses (37% response rate), with respondents representing genetic counselors, directors, managers, administrators, and variant scientists at commercial, hospital-based, and academic laboratories. Follow-up phone interviews were then conducted with 10 respondents.

According to survey responses, the TRF is the most common source of patient sex, gender and REA data. All respondents reported that their laboratories collect patient sex, while only two reported collecting gender data.

Ten respondents reported that patient sex is used as a quality assurance metric in their laboratory; additional common uses include variant interpretation and customized report content.

Eight laboratories reported collecting REA data, but only three reported using these data routinely. There was significant variability in the terms used and the sources of the data. On TRFs, ethnicity was the term used most frequently to collect REA data. Among those who reported using REA data, common applications included variant interpretation, customized report content and post-testing data analyses.

Survey participants cited several factors driving their data collection practices, including clinical utility, software capabilities, regulatory mandates and historical precedent. Seven laboratories made recent changes to how they collect and use patient sex and gender data, while four reported updates in REA data collection processes.

The follow-up phone interviews were particularly informative for insight into the impact of discontinuing collection of specific demographic data. Three prominent themes emerged.

One is the reliance on sex as a quality assurance measure — no sites indicated that an alternate quality assurance method was being implemented. Multiple participants had concerns about the reliability of patient sex, gender, and REA data provided on TRFs, specifically noting risk for term conflation and the limitations of REA self-reporting. Participants also reported that the lack of published guidelines is a barrier to making changes to lab TRFs or other processes related to the collection and use of patient REA data.

Figure 1. Sex + gender field headers (n=40 forms) Variability was observed in demographic field headers related to sex and gender across labs.

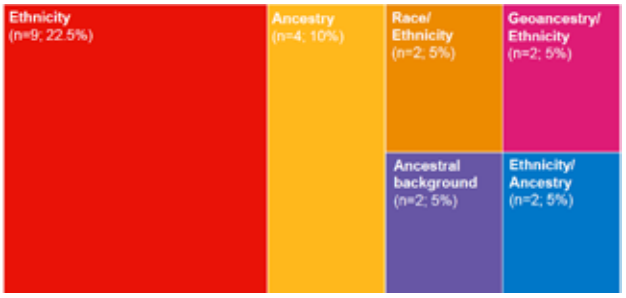

Figure 2. Ancestry field headers (n=40 forms) Variability was observed in demographic field headers related to sex, gender, and ancestry across labs.

This study highlights a ubiquitous reliance on patient sex for quality assurance and minimal use of gender data in clinical genomics laboratories. Additionally, the variability in REA data collection and the minimal utilization of such data in most laboratories underscore the need to reconsider using patient, clinical, and laboratory resources to collect it at all. These findings support the development of clear, evidence-based guidelines aimed at standardizing demographic data collection and promoting inclusive language practices by clinical genetics laboratories.

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BY JANE DICKERSON, PHD, DABCC, ALLISON CHAMBLISS, PHD, DABCC, FADLM, AND KEVIN FOLEY, PHD, DABCC, MT (ASCP)SC

Miscellaneous methods to manage the miscellaneous: Three ways to handle test requests

They go by many names — MISCREF, miscellaneous tests, MISC — but regardless of what you call them, miscellaneous tests present a unique challenge to laboratories. Providers need a mechanism to request a test that is not defined in your institution's laboratory information system (LIS).

However, these requests are wrought with challenges due to lacking or unclear information in the order. Miscellaneous orders often confuse everyone. The phlebotomy team who must navigate the appropriate sample collection in a timely manner; the laboratory send-out team who must process the request and determine the appropriate reference laboratory to perform the testing; and the ordering provider who must write a free-text entry field, which can lead to order entry errors.

Here, we describe three different ways to improve how laboratories handle MISC orders.

LABORATORY STEWARDSHIP FOCUS

Stop! Active case management at Seattle Children's Hospital

Using Epic's "follow-up worklist" feature, we created a hold process for two types of orders: miscellaneous lab request and miscellaneous genetic test request. Both require review and approval from one of four genetic counselors or one of four doctoral level consultants before coordinating.

After the order is placed in the follow-up worklist, the send-out staff create an entry in a separate web-based application. The orders then enter one of two review queues, depending on whether they are designated as a genetic or nongenetic test. The reviewer evaluates the test for order errors and medical necessity, including whether the test built, if it is a preferred lab, whether preauthorization is required, if the test received approval before. If it is a new test, we ask the provider to complete the new test request form for additional evaluation, and discuss it at the Lab Stewardship Committee meetings.

We evaluate approximately 80 cases per week, with about a third of those being nongenetic requests. About 75% of cases are approved as is, and for those that are modified or canceled, the most common modifications are updating the reference lab or recommending an alternate test.

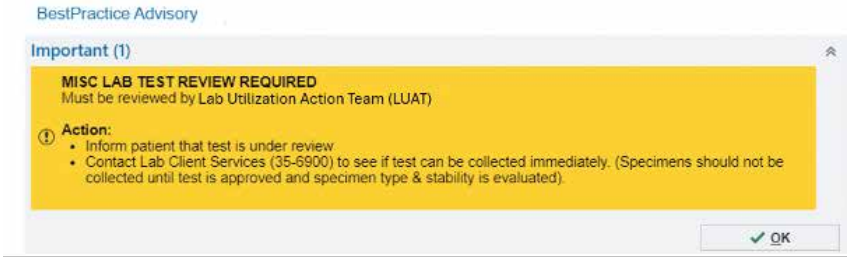
Using alerts: Kaiser Permanente Northwest BPA for MISC

The MISC test process at Kaiser Permanente Northwest has evolved over the years. It's now a much more streamlined process than it was in earlier days. Like the example above from Seattle Children's, it also relies on an Epic software feature, but with a few twists.

When a Kaiser Permanente clinician orders a MISC test, an alert immediately fires in Epic telling them that the test needs to be reviewed by our Lab Utilization Action Team (LUAT) (Fig 1).

An Epic message then drops into our lab client services shared email pool. Our client services' team evaluates the MISC order and determines whether the order is on our formulary. Our formulary is simply a shared Excel spreadsheet listing all of our approved send-out tests, and which departments are authorized to order each test.

Figure 1.Example MISC test alert in electronic health record



If client services finds that the requested MISC test is on the formulary, no further action is needed and the lab processes the test. If the test is nonformulary, clients services emails our lab genetic counselor if it's a genetic test, or one of the lab directors for nongenetic tests. These reviewers will either approve or deny the request and send the decision back to the ordering clinician using an Epic message.

We receive approximately 600 MISC tests per month. Of these, roughly 25 per month are nonformulary and require review. In 2024, we cancelled 14.8% of our nonformulary, nongenetic MISC test orders as 'not medically necessary' and redirected 9% to more appropriate labs. For the genetic tests that required review, 24% needed intervention and were modified.

Looking forward: UCLA Health's management of miscellaneous send-out test orders

Another approach to managing miscellaneous requests is to reduce their overall burden by building more tests. At UCLA Health, the lab recently began retrospective reviews of miscellaneous send-out test orders to identify new tests for inclusion as discrete orders in the electronic health record (EHR).

The process began with preparing a report of MISC orders placed in the previous calendar year. The lab then delegated the 100 most frequently ordered tests to faculty subject matter experts in the laboratory medicine division for review. This expert group included faculty from clinical chemistry and immunology, toxicology and therapeutic drug monitoring, and microbiology, among others.

That sentiment certainly holds true for the manual systems required to handle undefined tests.

These experts provided feedback about the general appropriateness of the tests and whether there are any comparable tests already available, either in-house or built in the EHR to go into preferred referral laboratories.

In 2024, the lab used this process to identify and build 37 new discrete send-out tests in the EHR. Providers who had previously ordered those tests as MISC received targeted email notifications about the newly built tests.

UCLA Health plans to continue this retrospective MISC review and new test build process every 6 to 12 months, with a goal of reducing MISC test volumes to the point that the lab can reasonably review the orders in real time. Although a separately available "miscellaneous genetics" test order has not been included in this process, those orders are already reviewed in real time by our molecular diagnostics laboratory directors and laboratory genetic counselor when they are ordered for inpatients.

Separately, we have established a process for providers to request new send-out tests to be built in the EHR. This process helps us to identify newer tests that are not yet identified by our retrospective review process of high-volume tests. The requesting provider must first fill out a digital request form with basic information about the test, as well as general medical justification and intended patient population. The UCLA Health Laboratory Stewardship Committee reviews these requests for approval decisions and EHR build prioritization (*1*).

Common threads for undefined tests

There is a twist on the old adage that says, if you've seen one way to do something, you've seen one way. That sentiment certainly holds true for the manual systems required to handle undefined tests. However, these three examples share common elements, including having medical director oversight in defining a review process and a specific process for first-time requests. Perhaps more comforting is knowing that this is a common struggle, and we can learn from each other on how to manage miscellaneous lab requests.

Most importantly, in our experience, such systemic approaches help ensure patients receive the best testing for their unique circumstances, while avoiding financial toxicity from potential miscommunication with payers.

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AN INTERVIEW WITH RYAN NELSON, PHARMD

How to make progress on precision medicine and pharmacogenomics

By Jen A. Miller

FOCUS ON MOLECULAR DIAGNOSTICS

Pharmacogenomics (PGx) testing is rapidly expanding, particularly in cancer treatment, to ensure patients receive the right drug at the correct dose at the right time. However, as the field grows, the lack of standardized guidelines and the ensuing debates about testing criteria can seem overwhelming — to laboratorians and clinicians alike.

We asked Ryan Nelson, PharmD, medical director of precision medicine at ARUP, about what he's seeing in the field. In addition to his work at ARUP, he also participated in the Standardizing Laboratory Practices in Pharmacogenomics (STRIPE) Annual Meeting and Consensus Workshop at US Pharmacopeia (USP) in October, and is part of MetaCensus, a blockchain-enabled platform that is enabling cross-discipline meta-analysis on complicated topics like this one.

How do you recommend incorporating pharmacogenomics testing into the decision-making process for selecting cancer treatments?

One of the bigger challenges we have seen is that just because you are looking to implement the test does not mean that the test is going to be ordered by the clinicians, or that they're going to be able to interpret it.

My advice is to get the appropriate department chair or clinical chair, the department of clinical pharmacology, and the case management group together, and talk about who they see as the groups of clinicians most likely to successfully implement PGx. The ones that first come to mind are usually pancreatic, colon, gastrointestinal (GI) stromal, and, if a pediatric hospital, lymphoid malignancies and myeloid leukemias.

Another crucial area is supportive care for cancer patients receiving antidepressants that are often needed to manage the inherent emotional challenges, anti-nausea medications to manage the emetogenic nature of many cancer treatments, as well as selecting the appropriate antifungal agent to ensure the patient receives therapeutic prophylaxis for bone marrow transplant patients at risk of breakthrough fungal infections.

I do not recommend an institution do a carte blanche "we're putting it everywhere" PGx approach, because they are not likely to successfully implement the program or measure the success of the program if successfully deployed. Instead, pick one or two clinical sectors with the highest chance of success, and go from there.

What specific genetic markers are clinicians looking for, or should they look for when determining a patient's response to chemotherapy or targeted therapies?

Let's start with somatic testing. If I were a clinician at any cancer center, the basic answer would be the National Comprehensive Cancer Network's (NCCN) cancer-specific guidelines and the NCCN Biomarker Compendium. Clinicians can identify the cancer type, refer to the appropriate tables, and ensure they select the correct panel.

Where things get particularly interesting is when you need both germline and somatic testing. Pancreatic, colon, ovarian, prostate, and breast cancer all have germline as well as somatic ramifications for therapeutic decision-making. NCCN provides excellent guidance on heritable cancer-related germline testing. However, they do not provide guidance on germline tests for PGx.

For PGx guidance, I strongly advocate for the use of the Clinical Pharmacogenetics Implementation Consortium (CPIC) and the Dutch Pharmacogenetics Working Group (DPWG) guidelines. Concerning which laboratory tests are most appropriate for a given clinical circumstance, I recommend the test cover the Association for Molecular Pathology (AMP) PGx Working Group's Tier 1 alleles and potentially Tier 2 alleles as well. I also recommend the lab test be certified by the College of American Pathologists (CAP).

Where do you currently see pharmacogenomics having the biggest impact on cancer?

As far as solid tumors go, lung cancer has been a leader in somatic

In many cases, selecting a test that benefits a patient now and further down the clinical road can save actual lives and money.

PGx applications in terms of therapeutically actionable targets. For germline PGx, colorectal, pancreatic, ovarian, breast, prostate, and GI stromal cancers have seen a big reduction in toxicity from chemotherapy in clinics where it has been implemented (particularly in Europe where DPYD and UGT1A1 genotype-guided chemotherapy dosing is more common). There are more, but these are the most frequently tested from my perspective.

But this landscape continues to change. Every year I go to the American Society of Clinical Oncology (ASCO) and American Association for Cancer Research (AACR) conferences, and the talk of oncology biomarkers is just more and more ubiquitous every year. I see that trajectory continuing.

Generally, is PGx testing done separately or within the same assay?

At ARUP, we offer both panel testing and individual gene testing. We try to ensure that even our panel tests offer genes with gene-drug associations tied to actionable recommendations backed by the CPIC. Of course, it really does depend on the clinical scenario.

All these choices are based on the clinicians' specific clinical applications and the individual patient decisions they are trying to make.

At the same time, we make sure we're being judicious about reducing redundancies in case there are downstream applications for that PGx testing, which is often the case.

But considering a test's potential use in the future versus immediate utility is a tricky thing for insurance companies to know how to handle. They often don't want to cover more than what is absolutely necessary at a given time point. Insurers would be wise not to let the immediate clinical decision take favor over allowing the greater clinical context to develop over time. In many cases, selecting a test that benefits a patient now and further down the clinical road can save actual lives and money.

Where do you see gaps in the PGx space overall — and how do you think those gaps can best be addressed?

One of the most significant gaps is also an opportunity. Currently, there is not enough collaboration between the CPIC, NCCN, ASCO, and the FDA. I would like to see these groups sit down at the same table and embrace their differing perspectives: Explain their rationales, and where they see gaps in the evidence.

All humans have innate biases that we think we control well for but often fail to. We must embrace our risk of blind spots in our analyses and conclusions and rely on other minds with differing views to make an informed assessment of the evidence.

One example: We held a session during the STRIPE Annual Meeting and Consensus Workshop where clinicians that author NCCN guidelines, others that treat patients guided by DPYD testing, the FDA, and ECRI participated on a panel to discuss their viewpoints around whether DPYD-genotype-guided chemotherapy should be standard of care or not. The FDA just recently reiterated a safety announcement we are encouraged by around DPYD testing.

Similarly, there is also not enough collaboration and communication among healthcare providers, namely, pharmacists, physicians, nurses, genetic counselors, and lab medicine professionals, all of whom are central to the topic of PGx and the different ways it can be applied. It's one of the reasons we created MetaCensus.

There is a growing number of centers across the U.S. — both National Cancer Institute-designated and not — that have begun to understand the importance of PGx testing. And we hope that this year we'll see a few collaborations at the University of Utah's Huntsman Cancer Institute lead to expanded PGx testing.

Supportive oncology care groups also have been expanding PGx testing for antidepressant selection, which I commend. One of their bigger challenges is a lack of support for prior authorization. It is both a logistical and policy problem.

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AN INTERVIEW WITH KELLY E. CAUDLE, PHARMD, PHD, BCPBS, FCCP

Closing the Gaps in Pharmacogenomics Testing

By Jen A. Miller

FOCUS ON MOLECULAR DIAGNOSTICS

As pharmacogenomics (PGx) propels the personalized medicine movement, the ongoing conversation centers around best practices for using the information it produces to enhance patient care.

One of the key players in these conversations is Kelly E. Caudle, PharmD, PhD, BCPS, FCCP. In addition to being an associate member of the St. Jude Children's Research Hospital faculty, she is also director of the Clinical Pharmacogenetics Implementation Consortium (CPIC), an international group that creates guidelines for pharmacogenetic tests for patient care. The group aims to deal with the difficulty in translating genetic laboratory test results into actionable prescribing decisions for affected drugs by creating, curating, and posting freely available, evidence-based guidelines.

At CPIC, Caudle coordinates writing all the clinical guidelines. Not only has she identified gaps in testing information, but she also is working to tackle barriers to implementation of this care, from how to best explain the results to patients, to standardizing information for the use of electronic health records, to tackling the persistent issue of getting health insurance companies to pay for testing.

How do you incorporate pharmacogenomics testing into your decision-making process for selecting cancer treatments?

It begins with the patient. Our patients overwhelmingly opt in to genetic testing: 96% of them say 'yes.' We have performed pharmacogenomic testing for more than 7,400 patients to date. Most of the 4% who say 'no' may not be getting major treatments here, but if they are, we treat them if we didn't know what their genetic status was. However, we always test before we prescribe a medication with high risk of toxicity like thiopurines in patients with acute lymphoblastic leukemia. Out of the 4% of patient families declining pharmacogenomic testing, the most common reason for declination is due to patients lack of interest in being genotyped.

Overall, we've implemented 16 genes impacting 75 drugs into our electronic health record (EHR) based on the CPIC guidelines. If a patient has what we call a high-risk result, that means they have some type of variation that may cause them to have increased risk of toxicity to a particular drug or it may have decreased efficacy. When a prescriber orders a medication in the EHR, and the patient has a high-risk result, the prescriber will get a post-test alert. It's an effective way to warn the provider at the point of care that this patient may have issues with that particular drug, and we also provide the recommendations from the CPIC guideline as part of that alert.

How do you explain the potential benefits and limitations of pharmacogenomics testing to your oncology patients?

To start, our nurses get consent for testing, and explain what that testing means in patient-friendly terms. We don't use big medical words and instead make it so that a layperson can understand. Generally, we tell them that some people have genetic differences that cause them to respond differently to certain drugs and talk them through that process.

After the results come in, those patients can see one of our PGX pharmacists, who can give a detailed interpretation of these results. We tell our patients up front that we will provide additional support for them if they have questions about the testing.

We also provide these results back to patients because the results do not just affect them here at St. Jude if they see another provider. It's not like a temporal glucose level. These PGx results will affect patients for the rest of their lives. There are caveats to that, though. Maybe there will be additional variants that we've discovered since the time they had that test, so they wouldn't have been tested for that particular variant.

Are there specific types of cancer where pharmacogenomics testing has proven to be particularly beneficial?

Acute lymphoblastic leukemia (ALL) is certainly a notable example. We test for multiple variants. With ALL, patients receive a lot of supportive medications for nausea, vomiting and pain, for example. Many patients also receive an antifungal at some point,

and that's also affected by genetic variation, so we test for that, too.

PGx also is beneficial in other types of cancer. For example, the DPYD gene is important for the metabolism of fluoropyrimidines, medications used to treat colorectal, breast and other cancers. DPD deficiency can significantly increase the risk of severe toxicity in patients treated with 5-fluorouracil or its prodrug, capecitabine. Consequently, testing for DPYD has become a widespread practice in colon cancer treatment.

Where do you see gaps in the PGx space overall — and how do you think those gaps can best be addressed?

We always need more research, more literature, and more evidence. We know a lot about PGx in some populations, like in Whites, African Americans, and Asians, but there are lot of populations out there that have not been studied. We want to provide the best care for everyone, and we need more information about other populations to do that, especially as the field grows.

From an implementation standpoint, the big barrier we have is lack of standardization. In the last few years, a lot of my work has focused on standardization in testing. I mentioned earlier that maybe a patient must be retested later in life because the test itself didn't have enough variants for it to be impactful. Right now, each laboratory's test is different when it comes to what variants are included and how that information is imported into electronic systems.

This lack of standardization can pose significant problems, especially when integrating this data into the electronic health record (EHR) system. It's crucial that everyone, including our computers, speaks the same "language" to ensure accurate communication and analysis.

We want to provide the best care for everyone, and we need more information about other populations to do that, especially as the field grows.

Outside of cancer, where has the use of PGX been growing?

There is a big push for PGx testing in the mental health field. At CPIC, we already have guidelines for antidepressants, and we're working on one for antipsychotics.

We also see PGx growing in cardiovascular medicine. Genes that encode enzymes implicated in the metabolism of warfarin, clopidogrel, and beta blockers are being tested. In addition, proton pump inhibitors used to treat acid reflux are also affected by variations in genes.

There are also quite a few examples in HIV treatment where PGx can be useful. It really does span almost every discipline in some way, especially since a lot of these drugs are used for supportive care.

What about pediatrics?

The data for pediatrics is quite lacking compared with that for adults. It's a huge gap. But there is some guidance, even if it's drawn from adults. For drug metabolizing enzymes, we would expect genetic variations to have the same consequence in children older than two years old, but there is a lot more variation in metabolism of drugs in children than adults, so it is important that we still study this vulnerable population.

Often, in our recommendations we don't expect it to be different in pediatrics, but we acknowledge there is a gap. The exception is ALL, since most of the studies are done in the pediatric population. Those are probably our best guidelines for pediatrics. There's great data there.

How do you think the field will continue to expand?

I think with machine learning and artificial intelligence, the field is going to keep growing in new ways. If you've had a genetic test, I think at some point, EHRs will have sophisticated algorithms that pulls all your information together to make it more informative — from renal function, liver function, smoking status, to drug interactions — anything that can affect a dose of a drug or selection of a drug.

One barrier is reimbursement of the genetic test, as some insurance companies are not covering PGx testing. Until we get through some of those issues, PGx testing will not be as widespread as it could be. In 10 years? Maybe. In 20 years? I would love to see that. Hopefully, we'll see not only broad access to PGx testing but prescribers who will have technology that can help them think through what to prescribe for that specific patient — that would be great.

Jen A. Miller is a freelance journalist who lives in Audubon, New Jersey.
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Regulatory Roundup

Roche gets CE mark for molecular systems

Roche recently announced CE certification of the newly updated cobas 6800/8800 systems 2.0.

The updated systems are designed to enhance laboratory efficiency by optimizing resources, reducing downtime, consolidating test menus and increasing throughput, all aimed at providing a more streamlined diagnostics experience for healthcare professionals and patients.

The majority of the cobas test menu is available with the release of the update, including the new temperature-activated generation of signal technology. It enables simultaneous detection of up to 15 targets in a single patient sample on the high throughput molecular diagnostic analyzers cobas 5800, 6800 and 8800.

"[The update is a] competitive leap forward in our efforts to advance PCR technology by combining unprecedented throughput together with the flexibility that laboratories require to deliver for physicians and patients," Roche officials said.

The cobas 6800/8800 systems are designed to serve mid-to-high volume molecular testing laboratories.

Following the European approval, Roche plans to apply for 510(k) clearance from the Food and Drug Administration for these systems in 2025.

QIAGEN MINI-GASTROINTESTINAL PANEL GETS FDA CLEARANCE

Qiagen has received Food and Drug Administration (FDA) clearance for the first test in a series of QIAstat-Dx Gastrointestinal Panel tests for clinical use.

The clearance involves the QIAstat-Dx Gastrointestinal Panel 2 Mini B&V, which covers five bacterial and viral causes of gastrointestinal illness, including *Campylobacter*, *Salmonella*, *Shiga-like toxin E.Coli*, and *Shigella*.

The test quickly multiplies many genetic targets using real-time PCR technology, delivering results in about 1 hour with less than 1 minute of hands-on time. Cycle threshold values and amplification curves give laboratories additional information regarding coinfections, according to Qiagen.

Soon, Qiagen plans to submit to FDA a second version of the gastrointestinal panel covering the same five gastrointestinal pathogens.

Qiagen also plans to submit for FDA clearance QIAstat-Dx Rise, a high-capacity diagnostic instrument. It provides comprehensive testing for up to 160 tests per day using eight analytical modules instead of four, the company said.

BIOFIRE TROPICAL FEVER PANEL GETS FDA SPECIAL CLEARANCE

bioMérieux has announced Food and Drug Administration special 510(k) clearance for its Biofire Filmarray Tropical Fever (TF) Panel.

Tropical fever infection presentations are often nonspecific and overlapping, complicating efforts to distinguish mild illness from more severe diseases that require prompt and targeted treatment. This new PCR testing solution offers fast and accurate pathogen identification in patients with unexplained fevers, the company said.

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The newly cleared panel has six targets, including Chikungunya, Dengue (serotypes 1, 2, 3, & 4), Leptospira, Plasmodium species, Plasmodium falciparum, and Plasmodium vivax/ovale. With a run time of about 50 minutes, the panel differentiates between Plasmodium falciparum and Plasmodium vivax/ovale and may help healthcare providers target appropriate malaria treatment faster.

The panel runs on the fully automated Biofire Filmarray 2.0 and Biofire Torch Systems with only 2 minutes of sample preparation time, according to bioMérieux.

FDA APPROVES LIQUID BIOPSY AS LUNG CANCER COMPANION DIAGNOSTIC

Foundation Medicine recently announced it has received Food and Drug Administration (FDA) approval for its FoundationOne Liquid CDx test to be used as a companion diagnostic for Tepmetko (tepotinib).

Tepmetko received accelerated FDA approval in 2021 and traditional approval in 2024 for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations (METex14). FoundationOne Liquid CDx is the first FDA-approved companion diagnostic to identify patients who may be eligible for Tepmetko.

NSCLC accounts for approximately 85% of lung cancers, 3%–4% of which are associated with METex14. METex14 skipping alterations in patients have been associated with advanced disease and a poor prognosis, Foundation Medicine said.

Foundation Medicine is the only company with an FDA-approved portfolio of tissue and blood-based comprehensive genomic profiling tests. Using a routine blood sample, FoundationOne Liquid CDx analyzes more than 300 cancer-related genes to provide genomic insights, according to the company.

Solvd Health said approval of its lab is a pivotal step in its mission to expand access to genetic testing that can help address the opioid crisis by informing decisions about pain management to potentially prevent adverse outcomes.

SOLVD HEALTH RECEIVES NEW YORK STATE APPROVAL

The New York State Department of Health has approved Solvd Health to offer the state's residents AvertD, the company's opioid use disorder (OUD) risk test.

This Food and Drug Administration-approved test assesses individual genetic susceptibility to OUD, providing valuable information to guide personalized pain management strategies.

Solvd Health said approval of its lab is a pivotal step in its mission to expand access to genetic testing that can help address the opioid crisis by informing decisions about pain management to potentially prevent adverse outcomes.

NUCLEIN RECEIVES DUAL FDA 510(K) CLEARANCE AND CLIA WAIVER FOR COVID-19/FLU TEST

Nuclein recently received Food and Drug Administration (FDA) 510(k) clearance and a CLIA waiver for its Dash SARS-CoV-2 & Flu A/B Test for use on the Dash Rapid PCR System.

The Dash SARS-CoV-2 & Flu A/B Test seamlessly integrates into existing workflows and delivers actionable results for COVID-19, influenza A and influenza B within a single patient visit, according to Nuclein.

The Dash Rapid PCR System enables point-of-care PCR results in only 15 minutes, a speed that is typically only available with antigen tests. The system is designed to offer low-cost, highly sensitive and specific results, with robust multiplexing across various sample types, Nuclein added. It also requires less than a minute of hands-on time.

The system's ease of use and fast turnaround time make it a practical tool for a wide range of healthcare settings, especially urgent cares, student health centers, physician offices, pharmacies, and emergency rooms, Nuclein said.

ALTONA DIAGNOSTICS GETS IVDR QMS CERTIFICATE

Altona Diagnostics has received the certificate for compliance with all applicable requirements of the European Union In Vitro Diagnostic Medical Devices Regulation (IVDR) for their PCR testing products, the company announced.

The certificate allows the company to launch its CE-IVD marked products under the IVDR, starting with the AltoStar Parvovirus B19 PCR Kit 1.5 in early 2025. The PCR test detects and quantifies parvovirus B19-specific DNA in human plasma. Parvovirus B19 frequently infects transplant and immunocompromised patients.

The launch of 13 AltoStar assay products, including panels for transplant and immunocompromised patients, will follow later this year.

Industry Playbook

bioMérieux to acquire SpinChip diagnostics

SpinChip Diagnostics ASA announced an agreement to be acquired by bioMérieux.

The SpinChip platform delivers diagnostic results for detecting myocardial infarction (MI). Capable of producing results comparable with central laboratory diagnostic machines within minutes near the patient, the platform is particularly suited for emergency departments and urgent care units, according to SpinChip.

SpinChip plans to launch a highly sensitive troponin MI assay during 2026. The assay has already demonstrated strong results in a retrospective clinical study, the company reported. It is now undergoing additional national and international trials, including a large multicenter European clinical study.

SpinChip added that under bioMérieux's ownership, it will develop additional immunoassays for acute care, focusing on sepsis and other cardiovascular biomarkers.

bioMérieux officials said that its acquisition will allow bioMérieux to apply its research, development, and manufacturing capabilities to immunoassays.

SpinChip officials said the transaction reflects the company's advancements and that "bioMérieux is the perfect partner to drive SpinChip's platform to commercialization and beyond."

NCI SELECTS ASSAY FOR TRIAL OF MULTICANCER DETECTION TESTS

NCI recently announced it has selected two assays to be included in the Vanguard Study on multicancer detection tests, to be conducted by the Cancer Screening Research Network (CSRN).

The assays are ClearNote Health's Avantect Multi-Cancer Detection Test and Guardant Health's Shield.

In February 2024, the National Cancer Institute launched CSRN to evaluate emerging cancer screening technologies. In 2025, CSRN plans to launch the Vanguard Study to determine feasibility of using multicancer detection tests in future, randomized trials.

Vanguard will enroll up to 24,000 people and aims to determine whether the benefits of using multicancer detection tests outweighs harms and whether they reduce deaths.

MAINZ BIOMED, QUEST AGREE TO COLORECTAL CANCER SCREENING TEST TRIAL

Mainz Biomed N.V. has announced an agreement with Quest Diagnostics to support commercialization of Mainz Biomed's next-generation screening test for colorectal cancer.

Mainz Biomed's stool-based PCR ColoAlert test is designed to detect colorectal cancer tumor DNA to aid in identifying colorectal cancer in early stages.

piranka / iStock

> I have been a member of ADLM for the last few years. It has really helped me grow a network in the point-of-care realm specifically. I have created really great, passionate collaborations with coordinators across the nation. I cannot be any more grateful to ADLM for the experiences that I've had.

Jamie Acero
BS, MHA, CPP
(MEMBER SINCE 2021)

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Preliminary data shows the test has promising sensitivity and specificity for colorectal cancer, including advanced adenomas, the company said.

Quest will provide clinical trial laboratory services for Mainz Biomeds's ReconAAsense study, which will provide data to support FDA validation of the company's next-generation test through a prospective clinical study and include approximately 15,000 subjects from 150 sites across the United States. Mainz Biomed will provide Quest the option to exercise semiexclusive rights to provide testing services based on the test kit for an eighteen-month period, assuming it is approved by the FDA.

MAYO CLINIC AND LUCENCE AIM TO ENHANCE CANCER TESTING SERVICES

Mayo Clinic Laboratories and Lucence have announced a strategic collaboration to expand international access to cutting-edge cancer testing services.

Lucence will provide access to its LiquidHALLMARK technology through Mayo Clinic Laboratories. LiquidHALLMARK is an ultra-sensitive liquid biopsy that analyzes circulating tumor DNA and circulating tumor RNA for clinically relevant biomarkers across various cancers.

Reports from the Medicare-covered test reports include graphical maps for understanding cancer genomic profiles and tracking tumor changes over time, while delivering comprehensive information on each genomic finding, the companies said. The report also includes detailed descriptions of each finding and associated clinical trials.

PHARUS DIAGNOSTICS VALIDATES EARLY PANCREATIC CANCER TEST

Pharus Diagnostics LLC recently announced the availability of its OncoSweep Pancreas Spotlight, a liquid biopsy screening test that aids in the detection of pancreatic ductal adenocarcinoma (PDAC) in people with elevated risk.

PDAC is an aggressive form of disease with a poor prognosis. The blood test can help individuals at risk for the disease to undergo regular monitoring to detect early-stage disease when they have the most options for treatment, Pharus said.

The test uses a blood sample, next-generation sequencing, and a proprietary machine learning pipeline to analyze levels of microRNA and CA19-9 biomarkers.

In January of 2024, PharusDx entered into an exclusive global licensing agreement for a proprietary panel of microRNA biomarkers with testing data demonstrating potential value for early detection of PDAC with City of Hope.

BABSON DIAGNOSTICS ANNOUNCES STRATEGIC INVESTMENT FROM BD

Babson Diagnostics recently announced a new investment in its company by BD (Becton, Dickinson and Company), strengthens their long-term strategic partnership to expand access to blood testing.

The financing supports Babson's launch of BetterWay blood testing at local pharmacies in Austin. BetterWay uses a small amount of blood — about the size of a pea — from a fingertip to diagnose and monitor a variety of chronic conditions, from hypertension to high cholesterol.

BetterWay integrates the BD MiniDraw with Babson's proprietary sample preparation and hand-warming technologies to enable retail pharmacies to collect high-quality capillary samples without phlebotomists and laboratory technicians. Samples collected at pharmacies are analyzed using Babson's proprietary microsample laboratory testing technologies at the company's lab in Austin.

In December, BD received FDA 510(k) clearances for the BD MiniDraw Capillary Blood Collection System. It makes blood testing less invasive by eliminating needlesticks in the arm and the collection of large tubes of blood. BD research has found that needlesticks are an often-overlooked challenge for patients, the company said. About half of Americans report some fear of needles, and of that group, a top reason is fear of needing multiple needle insertions, according to BD.

Index to Advertisers

Ask The Expert

Reducing your lab's overall injury and exposure rate

By Dan Scungio, MLS (ASCP), SLS, CQA (ASQ)

How can laboratories calculate their injury rate and use this to improve their safety programs?

a: Laboratories can use the following equation from the Occupational Safety and Health Administration (OSHA) to calculate their overall injury and exposure rate: (Number of injuries and illnesses X 200,000) / Employee hours worked = Incidence rate

This formula is known as the Total Case Incident Rate, and because it is a rate calculation, labs can use it over time to compare their data to national data or their own historical data no matter how lab or staffing size has changed over a time period.

If a laboratory calculates their rate for a given year of OSHA "recordable" incidents (i.e., those that require medical treatment beyond first aid, lost workdays, job restrictions, or transfers), they can then compare their data to national benchmarks. The U.S. Bureau of Labor Statistics (BLS.gov) provides annual national recordable rate data for medical and diagnostic laboratories. This allows labs to compare their own annual rates with those of other reporting labs across the nation.

Using this benchmark data can help labs to identify safety issues in certain areas while also providing labs with a realistic goal to aim for. If your lab is performing better than the national rate in a particular area, then it is acceptable to focus on other areas of your lab safety program. If not, be sure to review the root causes of the incidents and look for common causes or repeat occurrences as well. Once these are identified you can create a focused action plan which is specifically designed to reduce those incidents in your lab.

Should a laboratory track injuries and exposures that may not be "recordable" under OSHA's definition?

It is important to investigate all injuries and exposures that occur in the lab, not just those that are recordable. Slips, trips, and falls, for example, should have follow-up even if they don't result in time lost or medical treatment. The downside to tracking this non-recorded data is that there is no national benchmark to compare it with.

In order to create your own goal for non-recorded injuries and exposures, it is necessary to collect laboratory data over a period of time. It may even mean gathering incident rates for a year or two before you feel comfortable setting a reasonable non-recordable incident goal for your lab.

Once a rate goal is established, it is important to communicate it to laboratory leadership and staff so that everyone is aware of the current lab standing and the hoped-for target goal. If the lab then reaches the goal, reduce the target rate over time with the intent of consistently reducing the number of laboratory accidents and injuries.

What are some specific steps that labs can take to reduce their injury rates?

There are several different types of injuries and exposures that can occur in the lab setting, including splash exposures, sharps injuries, ergonomic disorders, and falls. While collecting the incident rate data for your lab, you should also look at each individual event. Talk to the staff involved, find out exactly how the accident occurred, look at the location, and check for system failures such as faulty procedures or inadequate engineering controls or personal protective equipment. Ask for input from the staff involved about how to prevent the incident from happening again. Closing the loop on all safety events and working to actively reduce your departmental injury and exposure rates will play a vital role in improving your overall lab safety program.

Dan Scungio, MLS (ASCP), SLS, CQA (ASQ), is a laboratory safety officer for Sentara Health, a hospital system in Virginia and North Carolina. He also works as Dan the Lab Safety Man — a trainer, speaker, and lab safety consultant.

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ADLM (formerly AACC) collected 60 mL of blood from volunteer donors attending the AACC Annual Meeting in Atlanta, GA in order to establish the 99th percentile for cardiac troponin in a healthy population in 2015. In 2021, ADLM collected 60 mL of blood from volunteer donors to investigate the durability of SARS-CoV-2 vaccines and T cell immunity and establish a repository of samples for academic and commercial purposes. In both studies, after collection, the blood was processed on site and transported to the CDC for storage at -80°C. Samples were de-identified and no SARS-CoV-2 test results will be provided. Sets of donor samples are being offered to IVD manufacturers and researchers for clinical assay development, standardization, reference range studies, and any other applications for which the samples might be useful. ADLM has undertaken this activity as part of its mission to further scientific research. THE DONOR SAMPLES ARE PROVIDED "AS IS." ADLM DISCLAIMS ALL WARRANTIES INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.