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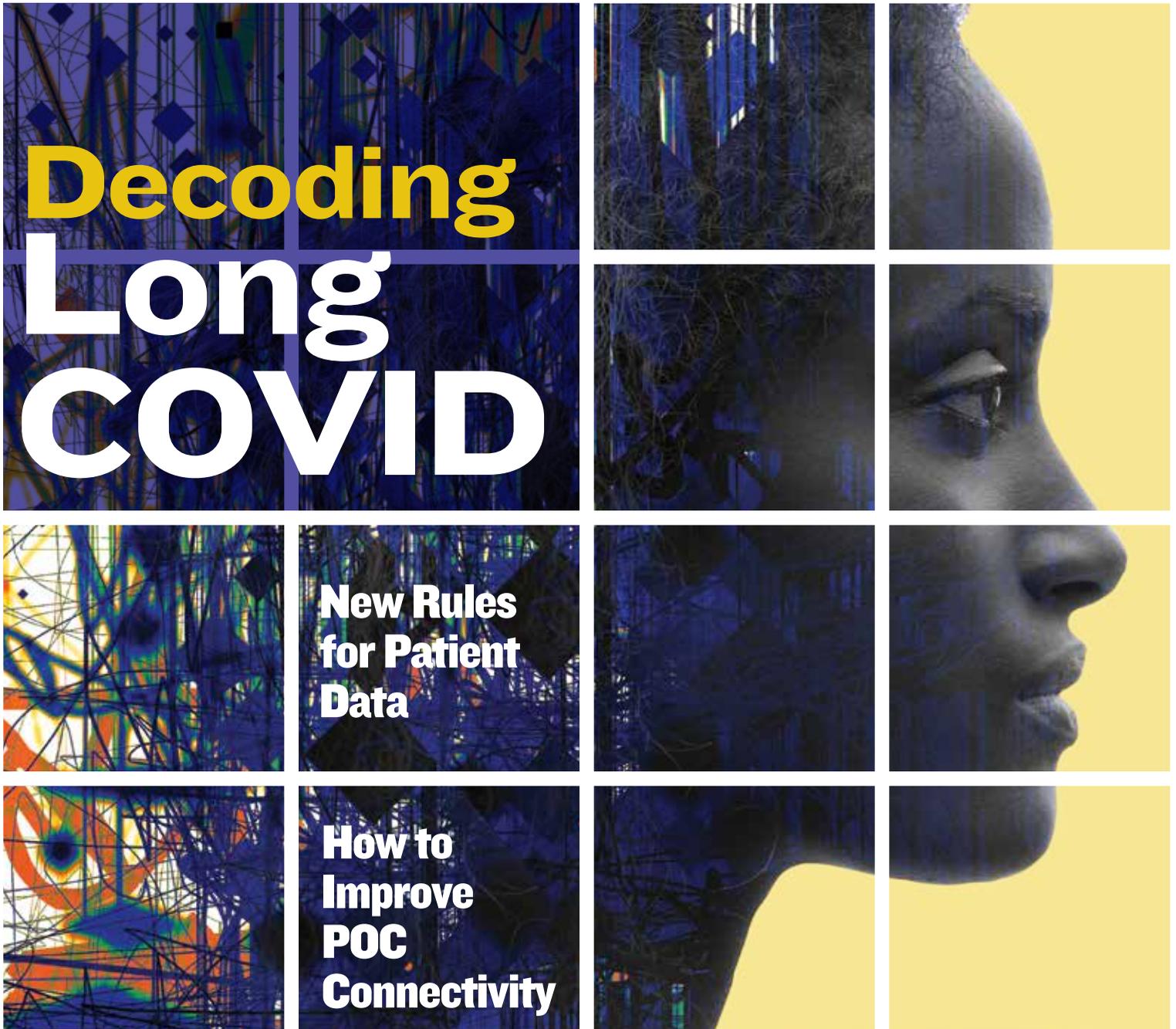
PREVENTING  
TYPE 2 DIABETES

# 25

New starting age for  
screening overweight and  
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PAGE 6

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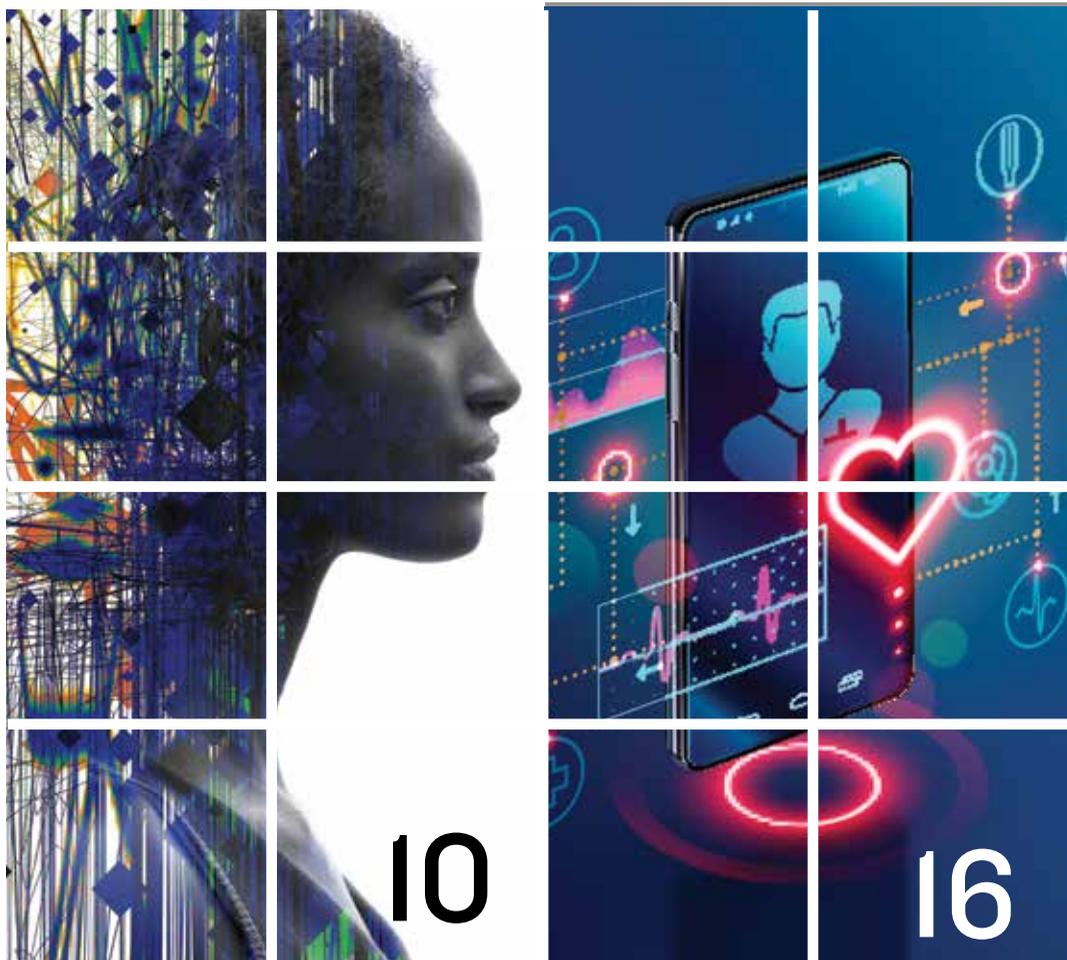
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Compassion fatigue is a phenomenon that encompasses burnout and secondary traumatic stress ... [Its] symptoms impact the physical and mental health of healthcare workers and also diminish the quality of care they deliver.

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## AACC Urges CLIAC to Take Up Modernization of CLIA Regs for LDTs

More than a dozen medical groups have joined AACC in asking that the Clinical Laboratory Improvement Advisory Committee (CLIAC) conduct a public meeting to discuss the modernization of CLIA regulations for laboratory developed tests (LDTs).

In a letter sent to Reynolds Salerno, PhD, director of the Division of Laboratory Systems at the Centers for Disease Control and Prevention and the designated federal official for CLIAC, the groups note that at the April 2021 meeting, CLIAC laid the foundation for such a discussion when it reviewed the role of LDTs within the context of the COVID-19 pandemic. They recommend that the committee build

upon that conversation by initiating a discussion on the broader use of LDTs and gathering information on how CLIA oversight can be updated to ensure that physicians, other healthcare professionals, and patients continue to have access to high-quality, accurate LDTs.

“Among the various topics that could be addressed are what constitutes an LDT, what patient risks are posed by LDTs, whether LDTs should be stratified based on risk, and whether clinical validity should be required and, if yes, how it should be demonstrated,” says the letter. “We hope that such a meeting will start to resolve the confusion and conflict surrounding this issue, lead to better patient care, and continue the process of modernizing CLIA.”



### NIH RADx INITIATIVE FUNDS DEVELOPMENT OF NEW COVID-19 RAPID TESTS

The National Institutes of Health (NIH) Acceleration of Diagnostics (RADx) initiative has awarded \$77.7 million to develop and manufacture 12 new rapid diagnostic tests for SARS-CoV-2, the virus that causes COVID-19.

The grants target the need for high-performance, low-cost home tests and point-of-care tests that can potentially detect multiple respiratory infections. These projects are part of the RADx Tech program, which involves an intensive “Shark Tank”-style assessment of concept viability conducted by a panel of technical, regulatory, and business experts. The awards support the development, validation, scale-up, and manufacturing of rapid tests.

The new awards are in addition to 33 that NIH previously disbursed through its technology development program. The RADx Tech program has resulted in 32 Food and Drug Administration emergency use authorizations

(EUAs), including the first home test EUA. Companies supported by the RADx program that received an EUA have contributed more than 840 million tests to the U.S. market since fall of 2020.

### NIMHD PROVIDES MORE THAN \$200 MILLION FOR RESEARCH ON CHRONIC DISEASES

The National Institute on Minority Health and Health Disparities (NIMHD) has awarded funds to 11 research institutions to establish and support regional comprehensive research centers on the prevention, treatment, and management of comorbid chronic diseases that disproportionately affect populations with health disparities.

These Multiple Chronic Disease (MCD) Centers received grants totaling almost \$205 million, including funds committed over a 5-year period that will facilitate research on chronic diseases, including obesity, diabetes, hypertension, coronary heart disease, congestive heart failure, chronic kidney disease, chronic liver disease, stroke, and certain cancers.

Research projects from each MCD Center are expected to address determinants of health at two or more levels of influence—individual, interpersonal/organizational, community, and societal. In addition, interventions may address one or more of the following: prevention of chronic diseases by addressing risk factors and early stages of a condition; increasing access to or quality of healthcare to detect and treat chronic diseases; enhancement of treatment quality; and self-management to manage chronic diseases and improve quality of life.

In addition, a pilot project program provides research opportunities for post-doctoral fellows, early-career faculty, or other early-stage investigators, including those from backgrounds underrepresented in the biomedical research workforce.

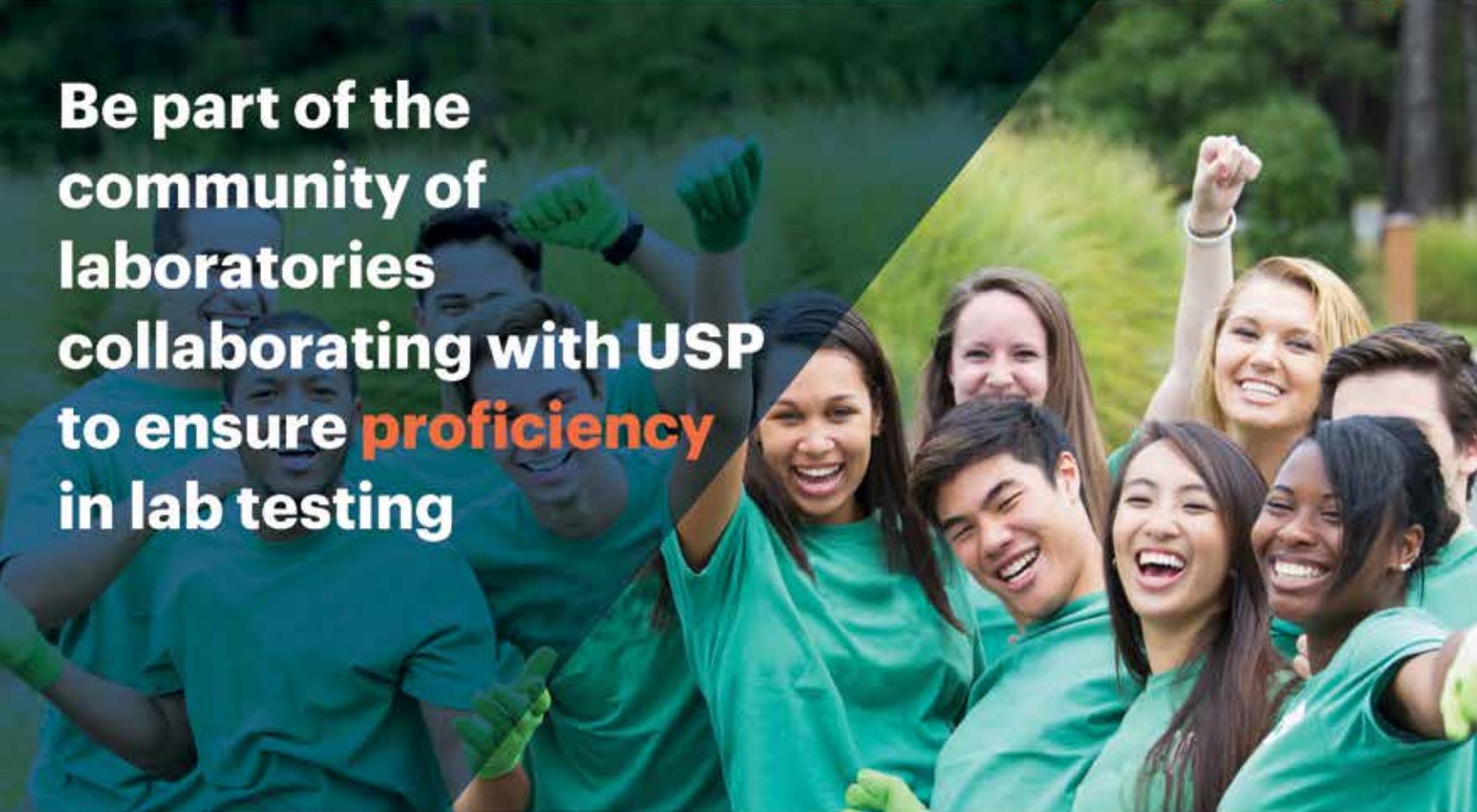
To coordinate activities across all the MCD Centers, NIMHD has also awarded \$4.5 million and committed \$18 million more over a 5-year period to establish a Research Coordinating Center.

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## Bench Matters

# Saving Your Sanity With POCT Connectivity



By Kerstin Halverson, BA, MS

**P**oint-of-care testing (POCT) is designed to place devices at or near the bedside and provide results as quickly as possible. However, the distance of these devices from the lab presents a dilemma for getting results into the patient's chart as quickly as possible. Various connectivity solutions have evolved to deal with this problem.

Some manufacturers' software enables the result to pass from the device to the lab information system (LIS) and then into the hospital information system (HIS) or electronic medical record (EMR). There are also vendor-neutral middleware solutions that can connect many POC devices, regardless of manufacturer.

When I worked in POCT, I managed more than 170 devices across seven different campuses. I could not be in two, let alone seven places at once, so such a middleware product became my lifeline. Over time, I worked with both the device manufacturers and the middleware vendor to get all devices connected through the middleware. This not only allowed for management of the results crossing into the LIS/HIS, but it also provided a repository for me to track proficiency results, calibration verification data, quality control results and lots, and finally, competency. This middleware became my one-stop shop. New test requests also warranted a look into connectivity capability for the potential device.

### A New Language

Digging into connectivity and interfacing a device can be a daunting task, though. Learning to speak IT-ese is like learning a new language. At the 2021 AACC Annual Scientific Meeting, we hosted our Point-of-Care Coordinators (POCC) Boot Camp to help POCCs learn more about key aspects of managing a POCT program. In our Boot Camp, we put together a glossary of commonly used IT terms to help a new POCC learn the language and better understand what their IT partners are speaking about while implementing a new device.

When implementing a new device and setting up an interface, it is essential to keep the project running smoothly. Oftentimes the POCC ends up being the project manager for this. A savvy POCC needs to find a project or implementation plan that works and sticks to the timeline. They will need to collaborate with both the vendor and their hospital

IT department to keep things moving along. POCCs should also work closely with the vendor to learn how the new device is programmed and how any additional pieces work to keep connectivity established. This may only happen initially upon setup, but devices break and need to be replaced eventually. Knowing how to set things up is a key sanity-saver for a POCC.

Transmitting results into the patient chart quickly and accurately is also key. Software has progressed now to the point that patient information can flow from the HIS down to the device. This is known as the Admit-Discharge-Transfer (ADT) feed. This allows for the end user to positively ID the patient being tested at the time of testing. This is a key component for a vendor to have and a much-needed feature for the POCC to prevent misidentified patient tests.

### Easy Accessibility

Having software at your fingertips that is accessible from anywhere in your hospital network is also key. Inevitably, a device isn't transmitting and the POCC needs to go up to the floor—or across town—to work on the issue. Knowing how each device connects and how the various components of the connection work are key. Devices may utilize a lantronix box or dongle to aid in transmission, and those boxes have lights. They blink with a certain frequency and often have multiple colors. As silly as it may sound, knowing the blinking patterns and what lights blink when is also key to keeping one's sanity. This can often help with troubleshooting if one isn't on the right campus that day.

### Competency Tracking

Managing competency is also a huge task for a POCC. Often, the POCC is the keeper of the records but has no management say over end users. Often, POCCs will work with education teams to assure that

competency requirements are met. Explaining lab regulations to these teams and then working with them to meet the requirements is a best practice. Tracking these competencies, however, can be a daunting task. Utilizing middleware may be a salvation for sanity.

I had approximately 2,500 operators in my system. Some operators used upwards of five devices; others used only one. I worked with my middleware vendors and our hospital eLearning system to set up what we termed an eLearning interface for competency tracking. We used the eLearning system to store annual quizzes that linked to procedures, photos, and PowerPoint slides to aid in learning retention. The system also tracked attendance at our annual competency fair, where end users would demonstrate testing and QC competency on devices. They performed troubleshooting at this fair, too. Each year we would aim to keep topics current—usually based on common errors tracked in the middleware throughout the previous year. Their quiz completion, attendance at the fair, and performance of a patient or QC test all transmitted into the middleware. The middleware automatically renewed competency if the conditions set up were met. This saved countless hours of manual renewal each year.

Connectivity can be a game changer when implemented in conjunction with a POCT program. A savvy POCC should create a network of key contacts throughout their organization that will help keep their program running smoothly and allow for troubleshooting should something go wrong.

Kerstin A Halverson, BA, MS, is a clinical applications manager, Acute Care Diagnostics Division, for Werfen North America. Prior to joining Werfen in 2017, she spent 24 years in the laboratory, 17 in POCT.

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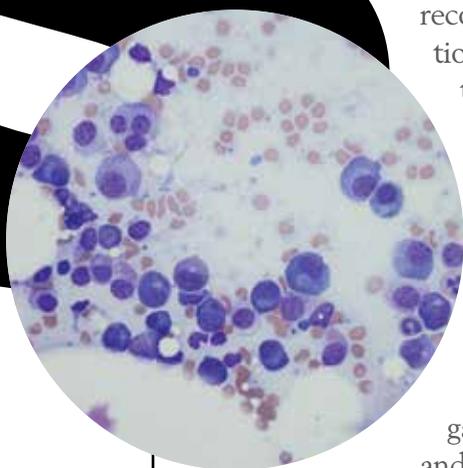
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## The Sample



## Algorithm May Aid Serum Protein Electrophoresis

A newly developed algorithm based on artificial intelligence (AI) aims to improve the reproducibility and reliability of high-throughput serum protein electrophoresis (SPE), according to a recent paper (Clin Chem 2021; doi:10.1093/clinchem/hvab133).

SPE is often used in testing for monoclonal gammopathies such as myeloma and Waldenstrom disease. Several machine-learning-based algorithms have been used to analyze SPE curves, but none has achieved a complete automation of the whole SPE analysis up to the point of medical interpretations.

The researchers described serum protein electrophoresis computer-assisted recognition (SPECTR), their AI-based tool that performs complete SPE interpretation, from raw curves associated with sex, age, and serum total concentration, into a test comments output. SPECTR analyzes raw SPE curves produced by an analytical system and produces text comments for practitioners. According to researchers, interpretation is fast and uses a standard laptop.

The researchers validated SPECTR on an external, independent cohort of 159,969 samples and had a panel of nine independent experts challenge SPECTR findings. The researchers found that SPECTR accurately identified both abnormalities with  $r$  equal or greater than 0.98 for fraction quantification and receiver operating characteristic-area under the curve (ROC-AUC) of 0.90 or greater for M-spikes, restricted heterogeneity of immunoglobins, and beta-gamma bridging. SPECTR also detected M spikes at ROC-AUC of 0.99 or more, and quantified M-spikes with  $r$  equal to 0.99. SPECTR's agreement with human experts was  $k$  or 0.632, which was higher than the rate at which human experts agreed with each other.

The researchers noted that SPECTR has not been validated by a regulatory authority and is not appropriate for clinical use. However, they envisioned enriching it by including immunotyping analysis and adding clinical data to account for potential interference.

The main limitation facing SPECTR is incomplete annotation, which the researchers said may cause SPECTR to overlook some benign conditions or artifacts in the final interpretation.

### LOWER DIABETES SCREENING AGE RECOMMENDED

The United States Preventive Services Task Force (USPSTF) has lowered the starting age for prediabetes and diabetes screening to 35 for overweight and obese patients with no symptoms of diabetes.

The USPSTF's recommendation updates a 2015 statement that had recommended beginning prediabetes screening at age 40. The current statement, issued in September 2021, recommends screening adults ages 35 to 70 with overweight or obesity and offering or referring them to effective prevention interventions (JAMA; doi:10.1001/jama.2021.12531).

The USPSTF's review found convincing evidence that preventive interventions—especially those related to lifestyle—have a moderate benefit in reducing progression to type 2 diabetes. USPSTF also found that preventive interventions reduce other cardiovascular risk factors such as blood pressure and lipid levels. Adequate evidence showed that interventions for newly diagnosed diabetes have moderate benefit in reducing all-cause mortality, diabetes-related mortality, and risk of heart attack after 10–20 years of continued use.

The recommendation suggests screening before age 35 for overweight or obese patients from populations with high diabetes prevalence, including

American Indians/Alaska Natives, Blacks, Hawaiian/Pacific Islanders, and Hispanics/Latinos, as well as patients with history of gestational diabetes, polycystic ovarian syndrome, or family history of diabetes. For Asian Americans, USPSTF recommends screening at a BMI of 23 or more, versus BMI of 25 or more for all other populations.

A fasting plasma glucose of 126 mg/dL or greater, HbA1c of 6.5% or greater, or a 2-hour post-load glucose level of 200 mg/dL or greater are consistent with type 2 diabetes diagnosis. Fasting plasma glucose level of 100 to 125 mg/dL, HbA1c level of 5.7% to 6.4%, or a 2-hour post-load glucose level of

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140-199 mg/dL are consistent with prediabetes, the USPSTF notes.

USPSTF notes limited evidence on the optimal screening interval for adults with an initial normal glucose test, although cohort and modeling studies suggest screening every 3 years may be reasonable.

### D-DIMER VALUE PREDICTS COVID-19 MORTALITY

**T**he optimal D-dimer cutoff value for predicting COVID-19 mortality is 1.5 µg/mL at admission, according to new research (PLoS One 2021; doi.org/10.1371/journal.pone.0256744).

Before the 2019 COVID-19 pandemic, D-dimer was not considered a useful biomarker for bacterial or viral pneumonia. Since then, elevated D-dimer and thrombotic complications have been widely reported in COVID-19 patients. But no optimal cutoff value for D-dimer to predict mortality had been established.

To assess the accuracy of admission D-dimer for COVID-19 hospital mortality and to establish the optimal cutoff D-dimer value, the researchers retrospectively analyzed samples from 182 patients admitted to four hospitals in Kathmandu, Nepal, during March to December 2020. This period was the relatively early phase of the pandemic in Nepal. Treatment during the study period was largely symptomatic, consisting of antipyretics, analgesics, and supplemental oxygen when required. All patients without contraindications received low molecular weight heparin.

The researchers measured D-dimer via immunofluorescence assay with results reported in fibrinogen equivalent unit (µg/mL) and used the receiver operating characteristic (ROC) curve to determine D-dimer's accuracy in predicting mortality and to calculate the optimal cutoff value.

Thirty-four patients died during their hospital stays. The mean admission D-dimer among surviving

patients was 1.067 µg/mL, whereas the mean value among patients who died was 3.208 µg/mL. ROC curve for D-dimer and mortality showed an area under the curve of 0.807 (95% CI 0.728–0.886,  $p < 0.001$ ). Optimal cutoff value for D-dimer was 1.5 µg/mL, with a sensitivity of 70.6%, and specificity of 78.4%. On Cox proportional hazards regression analysis, the unadjusted hazard ratio for high D-dimer was 6.809 (95% CI 3.249–14.268,  $p < 0.001$ ), and 5.862 (95% CI 2.751–12.489,  $p < 0.001$ ) when adjusted for age.

The authors noted that their study included neither asymptomatic patients with high oxygen saturation nor patients with incomplete laboratory tests and medical records. The four hospitals' labs used different kits to measure D-dimer in different centers, leaving the potential for measurement bias. The hospitals all used the same D-dimer reference ranges and units of reporting.

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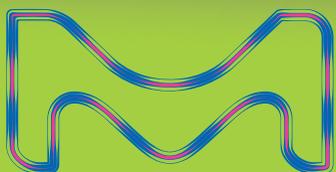
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## Evolving Approaches to Testing and Treatment for

# LONG COVID

Clinicians and laboratory professionals are striving to better understand post-COVID syndromes and develop assays to diagnose and improve care for the patients who have them.

BY SARAH MICHAUD

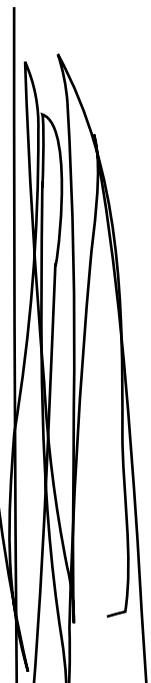
In January 2021, the World Health Organization (WHO) revised its guidelines for COVID-19 treatment to include a recommendation that all patients should have access to follow-up care in case of long COVID. However, despite ongoing studies to better evaluate this serious emerging phenomenon, long COVID is not yet fully understood.

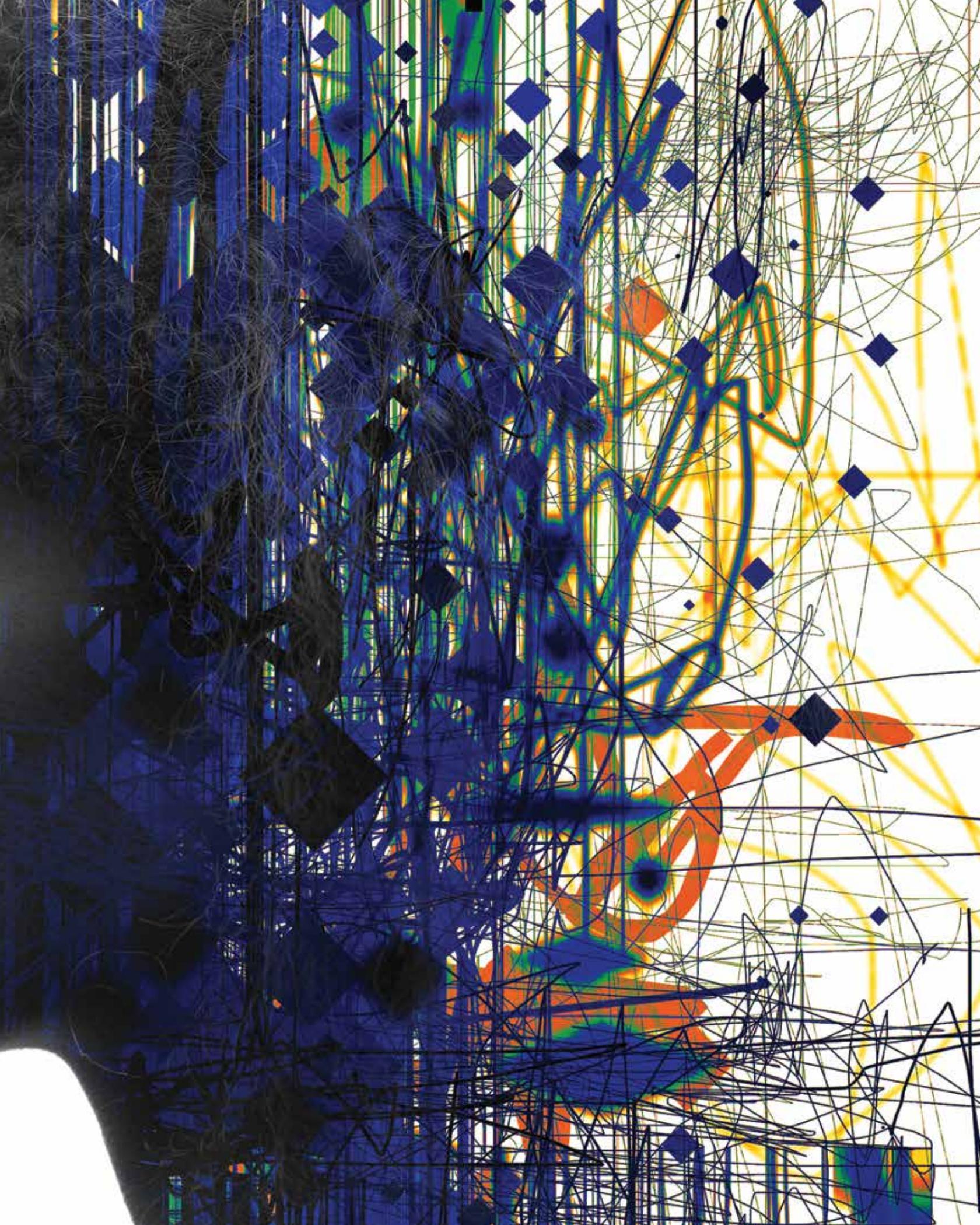
Most people recover from COVID-19 in a matter of days or weeks. Only about 1 in 10 infected with the virus will develop symptoms of long COVID, which patients experience as a cluster of symptoms such as brain fog, muscle

pain, and fatigue that persist or appear after acute infection with SARS-CoV-2. Of that 10% who experience it, vaccinated adults with breakthrough infections and young children are significantly less likely to develop long COVID syndrome.

While highly effective vaccines are indeed good news for those in countries that can access them, experts caution against jumping to conclusions about who might be vulnerable to long COVID.

“The incidence of long COVID for vaccinated adults and for children seems to be low, but these numbers are not insignificant,” said Avindra Nath, MD, clinical director of the National





Institute of Neurological Disorders and Stroke. “For example, other complications of COVID-19 can be worse in children, like multisystem inflammatory syndrome. And their immune systems are still developing, meaning they may not be capable of mounting the kind of ramped up inflammatory response we see in adults with long COVID.”

Lucette Cysique, PhD, senior research fellow at the University of New South Wales School of Psychology in Sydney, whose research focuses on how infectious diseases affect the brain and

COVID-19 with symptoms that last for at least 2 months and cannot be explained by an alternative diagnosis,” according to WHO. “Common symptoms include fatigue, shortness of breath, cognitive dysfunction, and others which generally have an impact on everyday functioning. Symptoms may be new onset, following initial recovery from an acute COVID-19 episode, or persist from the initial illness. Symptoms may also fluctuate or relapse over time. A separate definition may be applicable for children.” WHO added that data show 10%–20% of patients

in people with long COVID. However, her work is still in its early days. “I’m still analyzing data from 2 months and 6 months postinfection,” she said. “I’m just starting to look at 12 months postinfection data.”

### DIAGNOSTIC DILEMMAS

The first hurdle clinicians face in diagnosing long COVID is confirming an initial COVID-19 infection. If they can confirm an initial infection, the next move is to rule out other diseases that may present with similar symptoms, such as rheumatoid arthritis or lupus. After that, the syndrome is usually diagnosed based on a continued process of elimination. Treatment options are typically directed at individual symptoms and involve existing immunotherapeutics, including plasma exchange, steroids, antiinflammatories, as well as antiviral and interferon medications.

Now, researchers are working on several laboratory-supported approaches to diagnosing long COVID by identifying biomarkers that pop up with post-COVID-19 uncontrolled immune system activation. Potential targets include inflammatory cytokines, like IL-6 and IFN that can be detected in blood tests, and monocytes—a type of white blood cell deployed by the innate arm of the immune system—that can be measured with flow cytometry.

More novel techniques are in the works, as well. Nath and his colleagues are looking at signs of vascular damage caused by COVID-19 proteins as potential indicators of long COVID. “With more data, we hope to enable laboratory diagnoses using a battery of tests related to the immune response that will be a signature of long COVID,” he said. Nath’s team is also developing antisense molecules to prevent SARS-CoV-2 replication, which could in turn eliminate the viral proteins believed to trigger the overactivation of the immune system that causes symptoms.

Cysique is lead author on a recently published collection of culturally standardized neurocognitive and mental health tests to assess people with long COVID. “This is more than just a research exercise,” stressed Cysique. The NeuroCOVID International Neuropsychological Society Special

**“With more data, we hope to enable laboratory diagnoses using a battery of tests related to the immune response that will be a signature of long COVID.”**

**— Avindra Nath, MD**

cognition, said early reports of long COVID’s impact on the immune system and cognitive function seemed similar to the effects she saw in her work with HIV. “To me, this meant there might be chronic, possibly life-long consequences to COVID-19 infection that we need to understand,” Cysique said.

### RACING TO HELP PATIENTS WHILE DEFINITIONS EVOLVE

We now have a better understanding about who is more susceptible to long COVID, but clinicians and laboratories have until recently been working without a universally accepted definition of the syndrome, as well as no definitive methods of detecting and treating it.

When asked how he would define long COVID, Nath said, “I think it’s fair to say when you see it, you know it.” This may seem offhand, but Nath very seriously calls long COVID “a major health crisis.”

Since Nath spoke with *CLN*, WHO issued a more formal definition on October 6, referring to it as a post-COVID-19 condition. This “occurs in individuals with a history of probable or confirmed SARS-CoV-2 infection, usually 3 months from the onset of

experience lingering symptoms for weeks to months following acute SARS-CoV-2 infection.

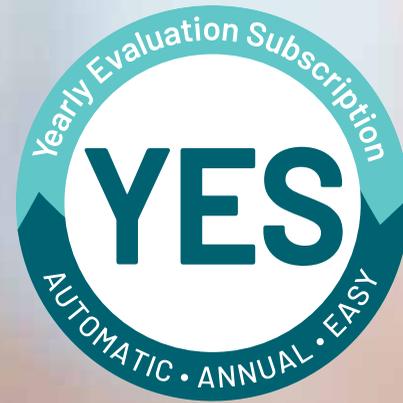
The long COVID patient population has been notoriously hard to characterize because oftentimes clinicians do not have information about the initial COVID-19 diagnosis; for example, the patient did not have access to testing when their symptoms started or received false-negative results. Nikolina Babic, PhD, associate professor of pathology and laboratory medicine at the Medical University of South Carolina, said these patients “can show up at their doctor’s office months later when they are probably in a long COVID situation, but we can’t look back at earlier tests to confirm it, so we don’t have a baseline to serve as a point of reference.”

One of the leading hypotheses for what causes long COVID is centered on hyperactivity and dysregulation of the innate immune response caused by viral persistence or proteins from the virus. An innate immune response, unlike an adaptive response, is, in a word, aggressive. It is also hard to stop once it gets going.

Cysique is one of the researchers that has linked this increased immune response to neurocognitive difficulties



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Interest Group, which Cysique chairs, hopes the data will eventually help inform treatment decisions for people with long COVID.

The group started their standardized collection of data on COVID-19 long-term neuropsychological effects early in the pandemic. Their findings culminated in neurocognitive tests for establishing a baseline for cognitive function in people with acute COVID-19 and postinfection. The tests are designed to be easy to administer bedside or virtually, and range from basic to more thorough neurocognitive assessments for different stages of the disease.

Although still in its early stages, Cysique said they are starting to see trends in the data. "It looks like people with impaired cognitive function postinfection are

undergoing an abnormal immune response and inflammation, and women are more likely to experience neurocognitive symptoms."

The group is developing a free, access-controlled repository to share their data with clinicians and researchers around the globe.

#### A CALL FOR LAB EXPERTISE AND INSIGHTS

Accessible, affordable, and early COVID-19 testing appears to be the keystone to improved detection and care for people with long COVID.

"If a COVID-19 infection is properly documented at the outset, we can better diagnose and treat the patient if they are present with continuing or new symptoms several months out," Bacic said. "I do sincerely hope that we will soon have information that will help us better

identify the patients at higher risk for long COVID but also to properly manage them quickly to minimize the degree and length of their suffering."

Nath expects that laboratory medicine researchers developing new or more refined assays related to SARS-CoV-2 will make all the difference.

"The researchers and clinicians in medical laboratories play a very important role in solving the mysteries of long COVID," Nath said. "These innovative minds are going to develop new standardized versions of the immunoassays we are currently investigating for long COVID. And if we can make these standardized tests widely available, it will have a huge impact on the health of people with long COVID." ■

**Sarah Michaud** is a freelance writer who lives in London.

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## NIH Initiative Supports Long COVID Research

The National Institutes of Health (NIH) launched the Researching COVID to Enhance Recovery (RECOVER) Initiative to investigate the long-term effects of COVID-19. The national effort includes diverse scientists, clinicians, patients, and caregivers working collaboratively to collect real-world data to answer the following questions:

- What does recovery from COVID-19 look like for different populations?
- How many people experience symptoms after the acute stage of COVID-19 infection?
- How many people experience new symptoms after acute COVID-19 infection?
- What causes long COVID?
- Why do some people develop long COVID and others do not?
- Does COVID-19 trigger changes in the body that increase the risk of other health conditions, such as chronic lung, heart, or brain disorders?

Earlier this year, NIH awarded four RECOVER infrastructure awards, listed below, to facilitate the initiative's organizational framework around which research will be conducted. These centers are tasked with building and supporting the RECOVER Initiative, its participant pool and team of investigators, and ensuring data are standardized and shared among researchers and the public.

#### **Clinical Science Core: New York University, Langone Health, New York City**

Build the RECOVER Consortium, a group of lead investigators to harmonize and coordinate data, develop methods for monitoring protocols, and guide communication and engagement with stakeholders.

#### **Data Resource Core: Massachusetts General Hospital, Biostatistics Center, Boston**

Help enable tracking and searchability across all data sources and provide expertise in statistical analysis and data standardization, access, and sharing.

#### **Biorepository Core: Mayo Clinic, Biospecimens Accessioning and Processing Core Laboratory, Rochester, New York**

Receive, manage, and make available to researchers a diverse range of biospecimens obtained from RECOVER research studies.

#### **Administrative Coordinating Center: RTI International, Research Triangle Park, North Carolina**

Provide oversight and monitoring support in addition to communication, work group, protocol development, and implementation support.

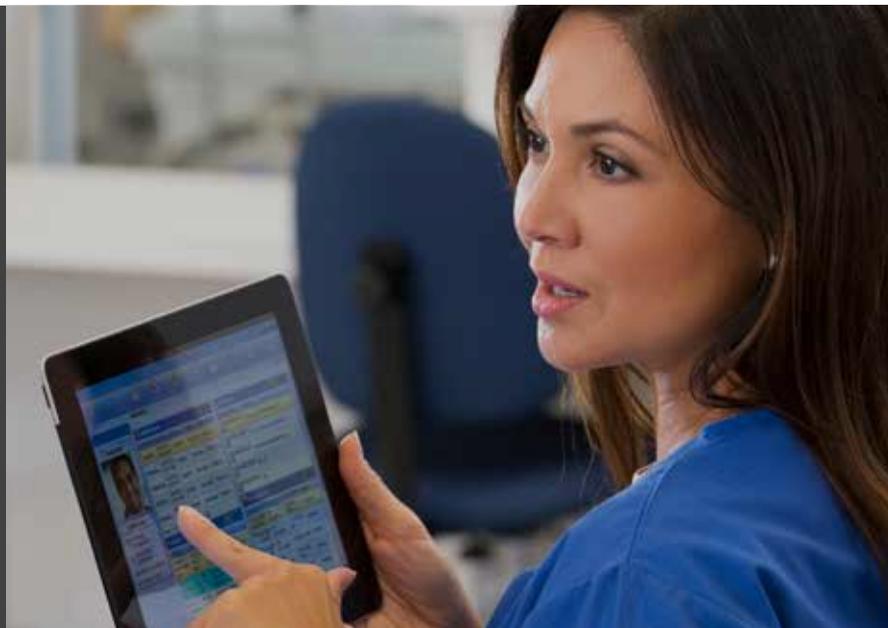
The RECOVER Initiative is asking for volunteers to participate in studies throughout the United States. Learn more at [recovercovid.org](https://recovercovid.org).

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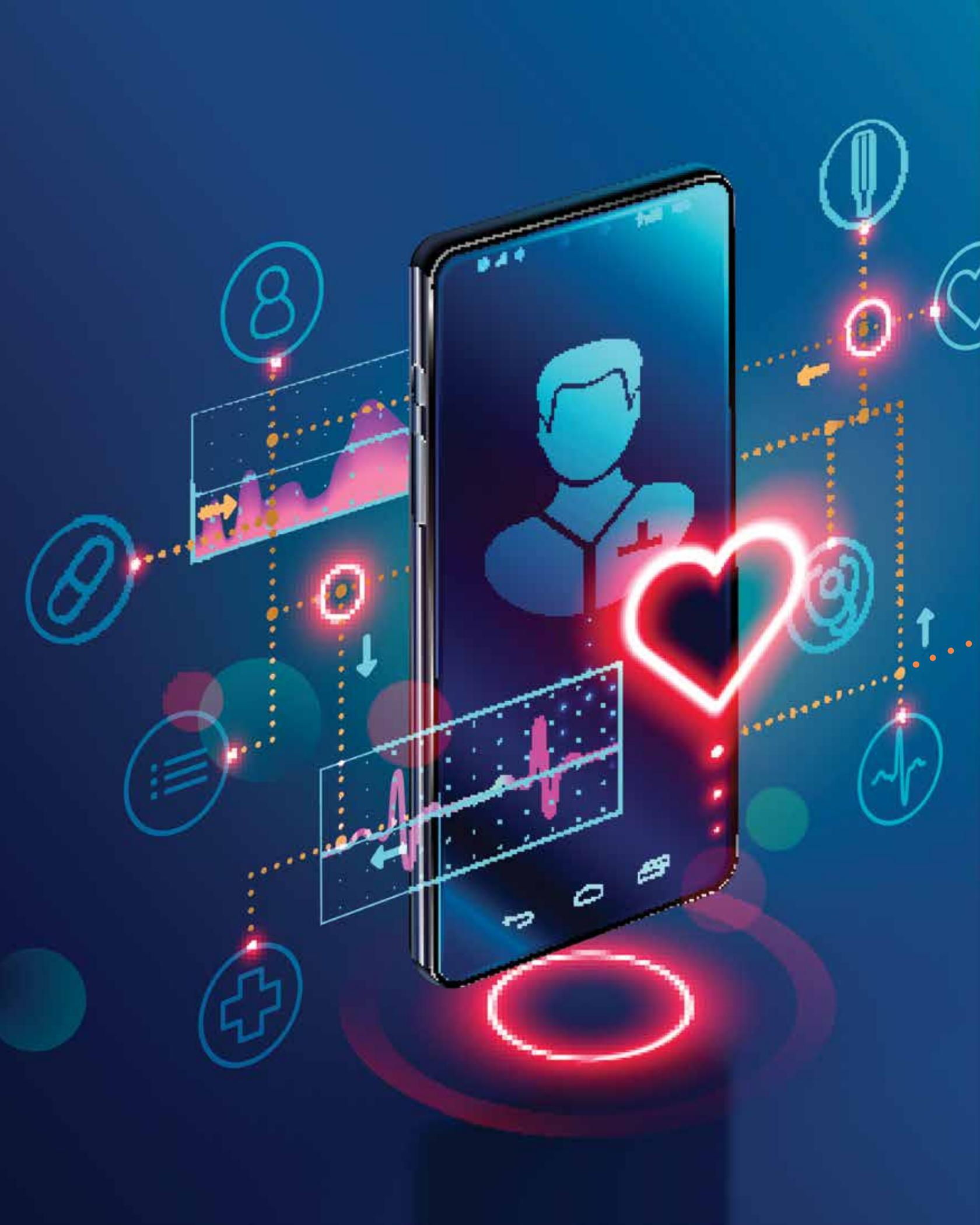
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# The Lab Is Moving From a Black Box to a Smartphone App

The 21st Century Cures Act will drive lab results directly to patients, and government penalties will catch up to those who stand in the way.

For decades, clinical laboratorians often referred to the way patients viewed the lab as a black box: Unseen by the public, clinical laboratory testing seemed like a mystery where blood tubes were whisked away and then turned into a series of sterile numbers on a patient chart. Now, Congress is accelerating the push to move healthcare into the digital age using the 21st Century Cures Act, with rules that will push lab results—and, in fact, essentially all of a patient's medical records—to be instantly accessible via apps. Information that was once mediated by a physician will increasingly be mediated only by technology.

BY KIMBERLY SCOTT

For now, laboratories and other healthcare providers have the option of using more traditional means to share records with patients as long as they respond to patients' requests. But by December of 2022, the government expects standards for apps to be finalized and for certified health IT developers and providers to catch up to the law's intent to fully digitize the experience.

Under the provision of the Cures law governing information sharing, which took effect April 5, 2021, healthcare providers may not block or delay patients' access to any eligible information, including test and study results entered and stored in their electronic health record (EHR). Providers must make a core set of clinical data available to patients in a timely fashion to encourage interoperability and portability of health data. These requirements apply to both clinical

and anatomic pathology labs.

While patients' right to their records was codified in 1996 by the Health Insurance Portability and Accountability Act (HIPAA), the 2016 21st Century Cures Act takes patient access a step further by making access easier and virtually unrestricted. To increase interoperability across EHR platforms, the Cures Act requires vendors and users to support computer and smartphone applications that give patients full and portable access to their healthcare information. As of April 5, 2021, the following eight categories of clinical notes created in an EHR must be immediately available to patients: consultation notes, discharge summary notes, history and physicals, imaging narratives, pathology report narratives, procedure notes, and progress notes.

Developers, networks, and exchanges that are found to have engaged in "data blocking" may be subject to civil monetary penalties up to \$1 million per violation. Healthcare providers

that don't release information in a timely way may also be subject to "appropriate disincentives." Specific penalties for healthcare providers have yet to be determined, although pathologists who participate in the Promoting Interoperability Program could see an impact to their Merit-Based Incentive Payment System incentives if they are found to be information blockers, said Emily Johnson, an attorney with McDonald Hopkins in Chicago.

Prohibited practices include implementing health information technology (HIT) in ways that are likely to restrict the access, exchange, or use of electronic health information—or implementing HIT in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, sharing, or using electronic health information (EHI).

The information blocking rule does not require healthcare providers to proactively make available any EHI, including lab results, to patients or others who have not requested such information; however, once a request is made, any delay in the release or availability of EHI can be viewed as prohibited information blocking. This can be especially complicated as it relates to lab results, as most healthcare providers are used to reviewing lab results before the patient receives them.

#### PREVENTING HARM EXCEPTION

As many labs have their own patient portals, once a request has been made, it is likely that patients will have access to their lab test results prior to or at the same time as the healthcare provider receiving them. If a provider believes that the receipt of test results by the patient prior to the provider having the ability to counsel the patient would cause harm, the provider can invoke the "preventing harm" exception to the rule, which may only be used on an individualized basis. Standing orders to delay delivery of laboratory results to patients would likely violate the information blocking rule.

In some cases, such as when the test results are related to cancer or to a condition that may be

## Helping Patients and Labs Connect

Clinical laboratories that don't have a patient portal and want assistance in delivering results can use a third-party vendor to serve as the conduit between the lab and the patient. LigoLab's Information Systems in Los Angeles is an example of one such vendor. LigoLab's TestDirectly Direct-to-Consumer (D2C) Portal allows consumers to order laboratory tests directly from their computer or mobile device and receive the results through the portal. TestDirectly does not need a physician referral and is only available in states that allow this type of direct-to-consumer testing.

Initially developed to eliminate bottlenecks, boost testing capacity, and improve turnaround times for COVID-19 testing, the portal now can be used for any D2C test. Patients can self-register for tests, schedule their collection appointments, upload their insurance cards and photo IDs, and receive automated notifications (text and email) when their results are ready. TestDirectly integrates with all laboratory information systems and revenue cycle management solutions.

Suren Avunjian, co-founder and CEO of LigoLab Information Systems, said the company has about 130 clinical laboratories in its network and that the portal is being used throughout the United States.

"This allows labs to meet the requirements of the Cures Act without setting up their own systems," Avunjian explained. "Once we are connected to the lab, we become their data repository. Each delay in providing patients their test results could place the lab at some risk for penalties. TestDirectly basically automates the entire process and removes the compliance risk for the lab."

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complicated, release of such results directly to patients can be problematic, said Karim Sirgi, MD, MBA, a pathologist and founder of Sirgi Consulting LLC.

“For patients who are faced with results that are complicated, it might be confusing or even devastating for them to read the results out of context,” he said. “The rule eliminates a barrier, but sometimes the barrier is in place for a reason.”

Sirgi believes the preventing harm exception does not go far enough as it has to be invoked for each instance where a laboratory believes the ordering physician should receive the results first and discuss them with the patient.

“It will be extremely cumbersome for a lab to go case by case to determine if the exception is needed,” he said. “There should be a blanket exception that can be used for certain tests.”

In the absence of a blanket exception, providers may want to add disclaimers to reports warning about potentially sensitive content, Sirgi added. During a recent roundtable discussion that Sirgi moderated, a provider shared that its health system was considering a disclaimer stating that the report might contain information that can be “emotionally difficult.” The disclaimer also would recommend that patients read the report in the presence of their clinical caregiver, who can explain and interpret the test results.

Sirgi advises that clinical laboratories and pathologists engage with referring practices and organizations about how patients should be educated about their results. Labs and pathologists could also come up with a script suggesting that the patient contact the referring clinician who requested the test in the context of their overall care.

If test results are sensitive and are of the type that could be misinterpreted by a patient, such as biopsy results or genetic testing, the process should be to send the results to the referring physician for communication to the patient, Johnson said. That way, the referring

physician, who has a patient-facing relationship, can explain the clinical significance of the results to the patient and be available to answer questions.

“If the patient calls the lab for results, the patient should be redirected to the referring provider,” she said. “This decision should be made on a case-by-case basis. This process should be clearly documented in the lab’s policies and procedures. There remains the potential that any delay could be considered information blocking. However, if there is a clinical purpose for the delay that is in the patient’s best interests and the policy is clearly documented, that may be mitigating. For routine or nonsensitive testing that leaves little room for interpretation, the lab should not delay providing those results to the patient.”

#### DELIVERING RESULTS

Test results can be delivered through a patient portal, but currently, they also can be delivered by mail, Johnson noted, who suggests informing patients that mail sent through the U.S. Postal Service tends to be

delayed, so the results may not be received immediately.

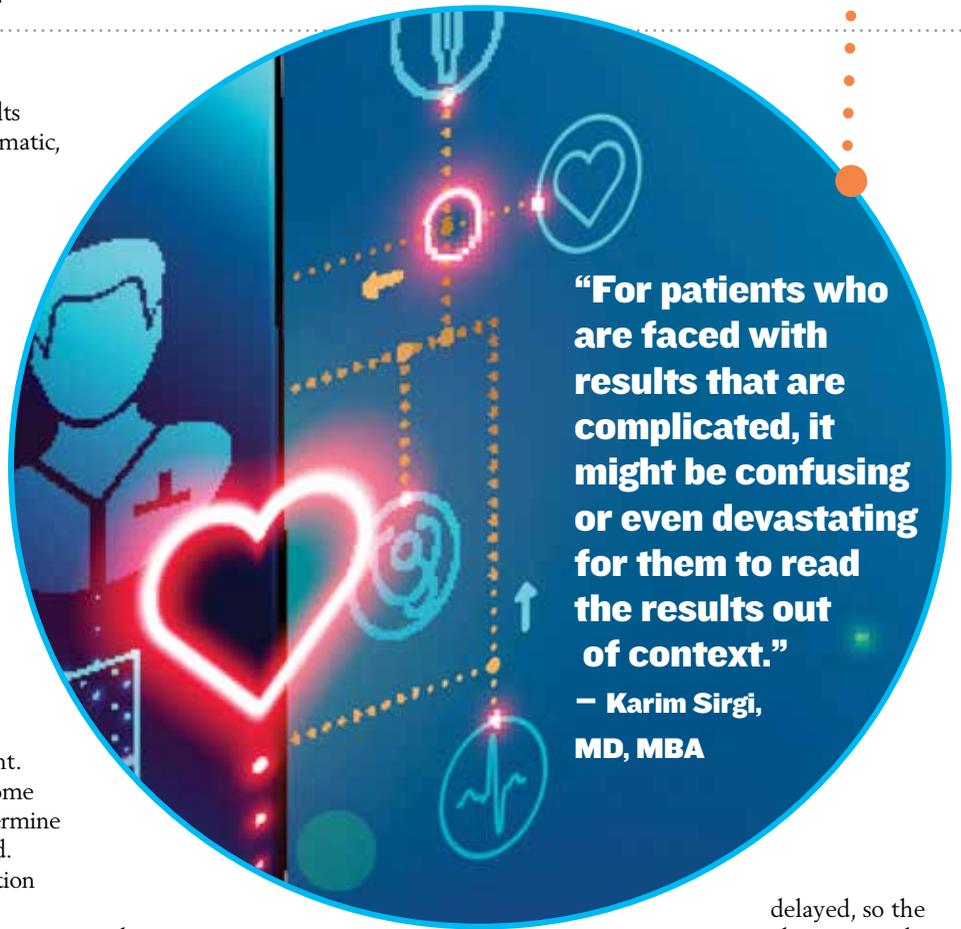
“No patient results should be sent via regular email if the patient has not consented to the use of email for the transmission of the requested records,” she advised. “Therefore, prior to sending patient information via unencrypted email, the patient should be informed of the risks of using unencrypted email and sign a form consenting to the use of unencrypted email.”

A key to ensuring compliance with the new rules is to establish clear policies and procedures stating how patient requests will be handled, Johnson stressed. Any delays in producing records in response to a patient’s request should be clearly defined.

Ultimately, having clear policies and procedures about how test results will be shared—and communicating these policies to referring physicians and patients—is key to ensuring compliance with the information blocking provisions of the 21st Century Cures Act. ■

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**“For patients who are faced with results that are complicated, it might be confusing or even devastating for them to read the results out of context.”**

**— Karim Sirgi, MD, MBA**

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**Linnea Baudhuin, PhD, FACMG**  
Professor of Laboratory Medicine  
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## Regulatory Roundup

### Blood Test Helps Predict Progression to Cirrhosis

The Food and Drug Administration has granted marketing authorization to the Siemens Healthineers Enhanced Liver Fibrosis (ELF) test. When announcing the authorization, Siemens Healthineers said that the blood test is the first prognostic tool for patients with advanced fibrosis due to nonalcoholic steatohepatitis to receive de novo marketing authorization. Used with the Advia Centaur XP Immunoassay system, the test provides a simple numeric score automatically generated by an algorithm. The score assesses likelihood of progression to cirrhosis and liver-related clinical events. High-risk patients identified by the ELF test may benefit from additional examinations, increased

monitoring, and lifestyle changes and treatment interventions.

Traditionally, identifying high-risk patients has involved liver biopsy to spot scarring of the liver. In contrast, the ELF test measures biomarkers directly involved in the active process of scarring. The test combines three serum biomarkers to assess the likelihood of progression to cirrhosis and liver-related clinical events. The biomarkers are hyaluronic acid, procollagen III amino-terminal peptide, and tissue inhibitor of matrix metalloproteinase 1.



#### AFFORDABLE COVID-19 SALIVA TEST GETS FDA EMERGENCY USE AUTHORIZATION

The Food and Drug Administration has granted emergency use authorization to a saliva-based laboratory diagnostic test for SARS-CoV-2. Developed at the Yale School of Public Health, SalivaDirect is now available to other diagnostic laboratories and has been validated with reagents and instruments from multiple vendors. This flexibility is intended to enable continued testing if some vendors encounter

supply chain issues, as occurred early in the pandemic.

According to test developers, the test is simple and uses inexpensive reagents. They added that their goal was to develop an assay useful for widespread testing to control the COVID-19 pandemic. To that end, the test does not require preservatives or specialized tubes for saliva collection. The researchers expect that labs could offer the test for about \$10 per sample.

Yale is now working to validate this method as a test for asymptomatic individuals through a testing program for players and staff in the National Basketball Association.

#### FDA APPROVES BD AUTOMATED HIGH-THROUGHPUT MOLECULAR DIAGNOSTIC PLATFORM

The BD Cor PX/GX system has received Food and Drug Administration (FDA) approval. The system integrates robotics and sample management software algorithms to automate the complete molecular laboratory workflow from sample processing to diagnostic test results. It received the CE mark in Europe in 2019.

The BD Cor system is modular and scalable, and designed to address multiple needs within laboratories

for expanding molecular testing and increasing test volumes. It has onboard capacity for reagents and samples that provide 6 to 8 hours of unimpeded system processing, thus eliminating multiple technologist interactions currently required per shift.

Now that this platform is FDA-approved, the BD Onclarity HPV assay with extended genotyping for the BD Cor system will be available to the high-throughput labs that process most cervical cancer screening specimens in the U.S.

### SEXUAL HEALTH PCR TEST USES PATIENT-COLLECTED SAMPLES

**V**isby Medical has received Food and Drug Administration 510(k) clearance to market its fast, single-use polymerase chain reaction (PCR) test for the multiplexed detection of sexually transmitted infections (STIs) caused by *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*. The test also received a CLIA waiver, enabling any healthcare site with a CLIA Certificate of Waiver to perform it during a patient's appointment.

According to Visby Medical, the test—known as the Visby Medical Sexual Health Click test—is the first for these STIs that uses PCR technology in a handheld, instrument-free format. It uses a self-collected vaginal swab and provides results within 30 minutes. By making STI check-ups more convenient for patients, Visby said it hopes that the test will help to reduce growing STI rates, especially in communities with limited access to testing during the COVID-19 pandemic.

### FDA APPROVES CO-DIAGNOSTIC FOR PREVIOUSLY TREATED IDH1-MUTATED CHOLANGIOCARCINOMA

**T**he Food and Drug Administration (FDA) has granted premarket approval to Thermo Fisher Scientific's Oncomine Dx Target test for use as a companion diagnostic (CDx). Under the approval, the test can be used to identify patients with isocitrate dehydrogenase-1 (IDH1) mutated cholangiocarcinoma (CCA) who may be candidates for Servier Pharmaceuticals' Tibsovo (ivosidenib tablets). CCA is a rare, aggressive cancer of the bile ducts within and outside of the liver. IDH1 mutations occur in up to 2% of U.S. CCA cases.

The Oncomine Dx Target test uses next-generation sequencing and first earned FDA approval in 2017. In addition to being approved for use with Tibsovo, it was previously approved for four targeted therapies for non-small cell lung cancer.

Tibsovo is an IDH1 inhibitor approved for adults with previously treated, locally advanced, or metastatic CCA with an IDH1 mutation as detected by an FDA-approved test.

### AT-HOME COLLECTION KITS GET CE MARK

**Z**ymo Research's new line of at-home sample collection kits has received CE marking for sale in the European Union. The SafeCollect Sample Collection kits are designed for consumers to self-collect both swab and saliva samples. Zymo Research scientists and engineers developed SafeCollect in response to scrutiny of the growing number of drive-through SARS-CoV-2 test sites that require consumers to collect their own samples.

The kits feature an at-home collection device that is specially engineered to enable consistent sampling, and that also includes user safety features. Tubes have a safety seal that prevents accidental spillage, contact, and/or ingestion of the sample stabilization medium. Devices are filled with Zymo Research's proprietary stabilization solution that preserves DNA and RNA at ambient temperature for at least 30 days. This solution was the first 510(k)-cleared transport medium for collection, preservation, and inactivation for SARS-CoV-2 and provides an additional layer of protection for those who come into direct contact with samples, including couriers and laboratory personnel.

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## D Industry Playbook

### Collaboration to Accelerate Genetic Diagnosis for Rare Disease Patients

Genomenon and Alexion, AstraZeneca Rare Disease have announced a collaboration intended to make critical information for the diagnosis and treatment of certain rare diseases more readily accessible.

The average path to rare disease diagnosis lasts 7 years due to the lack of information on these conditions, which can result in missed intervention opportunities. Once a diagnosis is made, the lack of information on available therapies leaves patients and their caregivers with limited options.

The collaboration's goal is to empower genetic testing labs with the data they need to diagnose rare diseases. Working with Alexion, Genomenon is using its artificial intelligence-driven genomic technology to produce a complete "genomic landscape" for an initial group of rare diseases that includes Wilson disease,

complement-mediated thrombotic microangiopathy, lysosomal acid lipase deficiency, and hypophosphatasia.

The landscape encompasses an expertly curated genetic dataset for these rare conditions, along with information on available therapies or clinical trials, to be made available to doctors, researchers, and clinicians through Genomenon's Mastermind Genomic Search Engine. More than 1,000 genetic testing laboratories and medical centers across the globe, Mastermind is connecting patient DNA to relevant scientific research to make diagnosis and treatment decisions. Mastermind information about potential treatment options and open drug trials can be easily exported into clinical reports.



#### SEBIA AND METAFORA BIOSYSTEMS STRATEGIC PARTNERSHIP AIMS TO DEVELOP ADVANCED IN VITRO DIAGNOSTICS

Sebia and Metafora Biosystems have announced a strategic partnership to develop a portfolio of in vitro diagnostic solutions based on Metafora's technology platform.

Metafora leverages a single-cell artificial intelligence-powered diagnostic platform to detect cellular anomalies, while Sebia specializes in diagnostics for myeloma and chronic diseases. The companies said that

the partnership would benefit the hematology-oncology field, which suffers from a lack of robust tests.

Metafora officials said that Sebia's investment allows their company to accelerate research and development, with an eye toward launching new products through 2023.

Sebia officials said the partnership's initial focus would be multiple myeloma. They noted that the partnership expands Sebia's electrophoresis and mass spectrometry technologies and would allow diagnosis and monitoring of other cancers and chronic diseases.

#### JUMPCODE GENOMICS AND THE TRANSLATIONAL GENOMICS RESEARCH INSTITUTE PARTNER TO FOCUS ON GENOMIC SEQUENCING OF SARS-COV-2

A new collaboration between Jumpcode Genomics and the Translational Genomics Research Institute (TGen) aims to aid investigations into the genomic epidemiology of SARS-CoV-2.

The collaboration leverages Jumpcode's CRISPRclean technology for genomic sequencing to help identify and track SARS-CoV-2 variants.

Jumpcode Genomics and TGen are validating novel solutions and clinical services that leverage metagenomic sequencing and analysis to facilitate detection of COVID-19 and other infectious diseases.

TGen officials said the partnership could help identify new SARS-CoV-2 variants and related viruses, enable better tracking of existing strains' spread, and help inform public health efforts to prevent future infectious disease outbreaks.

Jumpcode combines CRISPR-based technology with next-generation sequencing to remove unwanted sequences, thereby increasing sensitivity and enabling more efficient and cost-effective sequencing. This approach empowers scientists to obtain better data, extract more relevant information about the nature of an infection, and ultimately identify unique aspects of an infection that would have otherwise been undetected.

TGen is testing the potential of Jumpcode's CRISPRclean-mediated depletion reagents in combination with its laboratory's technologies, including protocols involving a diagnostic assay using the CRISPRclean reagents and algorithms for analyzing the resulting metagenomic sequence data. Expanded prospective clinical and epidemiological studies are planned to prove the diagnostic assay's utility in routine patient testing for infectious diseases.

#### SIEMENS HEALTHINEERS AND A1 LIFE SCIENCES AGREEMENT AIMS TO HELP TRACK SARS-COV-2 VARIANTS

Siemens Healthineers has announced a collaboration with A1 Life Sciences to support global efforts to track variants of SARS-CoV-2.

Siemens Healthineers will now offer A1 Life Sciences' Diagnostical kits, which are designed to detect and identify SARS-CoV-2 mutations and variants. A1 Life Sciences' Diagnostical portfolio, as distributed by Siemens Healthineers, will be offered for research use only around the world, but will not be offered initially in the U.S.

This portfolio of A1 Life Sciences' Diagnostical kits will complement Siemens' FTD SARS-CoV-2 assay, which is intended for the initial diagnosis of the infection. If a sample is identified as positive by the FTD SARS-CoV-2 assay, then the residual extracted nucleic acid from the original sample can be reflex tested by the appropriate A1 Life Sciences' Diagnostical kit or combination of kits to identify if the positive sample harbors a mutation or is a variant.

With single-mutation formatted assays, like those in the A1 Life Sciences' Diagnostical portfolio, laboratories can select from individual assays to create their appropriate testing scheme based on mutations prevalent in their region, Siemens Healthineers said.

#### AGREEMENT BETWEEN ROCHE AND TIB MOLBIOL EXPANDS PCR TEST PORTFOLIO

Roche has announced a definitive share purchase agreement to acquire 100% of the outstanding shares of the TIB Molbiol Group, with close of the transaction expected in the fourth quarter of 2021.

The acquisition of the TIB Molbiol Group will expand Roche's broad portfolio of molecular diagnostics solutions with a wide range of assays for infectious diseases, such as COVID-19. TIB Molbiol's comprehensive portfolio of more than 45 CE-marked in vitro diagnostic assays and more than 100 research-use assays is already available on Roche's large installed base of LightCycler PCR systems and MagNA Pure sample preparation systems.

The two companies have collaborated for more than 20 years to rapidly address critical healthcare needs including biological threats such as SARS, anthrax, avian influenza virus H5N1, MERS, the novel influenza virus H1N1 swine, Ebola virus, Zika virus, and most recently, the SARS-CoV-2 virus and its variants. At the onset of the COVID-19 pandemic, the company's collaboration provided the first research-use only SARS-CoV-2 detection test in January 2020, only days after the new coronavirus was first sequenced, Roche officials said.

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## Ask The Expert

# Compassion Fatigue in the Time of COVID-19



### EXPERT

By James H. Berry, DO

#### What is compassion fatigue?

**A:** Compassion fatigue is a phenomenon that encompasses burnout and secondary traumatic stress. Burnout is the experience of feeling perpetually emotionally exhausted, a loss of personal identity, and decreased sense of accomplishment at work.

Secondary, or vicarious, trauma is the stress a person experiences when hearing another person describe their traumatic events. Neuroimaging has demonstrated that our brain's pain networks are activated when we empathize with another's experience of pain. "I feel your pain" is more than a platitude, and it can be debilitating for healthcare workers who routinely treat traumatized patients.

#### What are the signs of compassion fatigue?

Irritability, exhaustion, problems sleeping, ruminating thoughts about the suffering of others, cynicism, avoidance, numbness, apathy, a sense of being detached, and a loss of joy in your work are all signs of compassion fatigue. These symptoms impact the physical and mental health of healthcare workers and also diminish the quality of care they deliver. At the aggregate level, compassion fatigue can lead to poor patient outcomes, absenteeism, and workers leaving the field. This is tragic, as we desperately need this talented and empathic workforce caring for the sick in our communities.

#### How has COVID-19 affected healthcare workers' compassion fatigue?

COVID-19 has placed a tremendous strain on a workforce already at risk for burnout. Even prior to COVID-19, I would have said clinician well-being should be our number one healthcare priority, as the rates of burnout, emotional exhaustion, depression, and suicide among healthcare workers were already staggering. Now, these rates are even higher. This is a crisis, as the healthcare system will fall apart without a workforce that is physically, emotionally, and spiritually healthy.

Making matters worse is the fact that the U.S. is also in the midst of a mental health crisis. Prior to the pandemic, life expectancy of Americans had declined due to so-called deaths of despair. Suicide, overdose, and liver failure contributed to the untimely deaths of hundreds of thousands over the past decade. U.S. Surgeon General Vivek Murthy, MD, identified an epidemic of loneliness as the primary driver for most debilitating health conditions in our nation.

Quarantining and other efforts to reduce the spread of COVID-19 by isolating have exacerbated loneliness, adding fuel to the mental health fire. Rates of severe psychological distress and substance abuse reached 40% nationwide in 2020, and rates of drug overdose increased by 30%. Not a week goes by where I do not hear from multiple patients of the devastating deaths of loved ones. This takes its toll and is difficult to process emotionally, particularly in the context of healthcare worker shortages and the other administrative challenges of healthcare delivery.

So, not only are healthcare workers dealing with hospitals that are overrun with COVID-19 cases and understaffed due to workers who are quarantined or have quit, but they are also facing the unintended psychological consequences of our strategies to mitigate viral transmission.

#### What can be done to help?

Both individual and system-level strategies need to be prioritized. On an individual level, recognizing the importance of self-care, balance, and boundaries is crucial. In healthcare, we tend to fall prey to the mystique of the healthcare superhero, completely altruistic and ready to serve. But we are mortal and have limits. Rest, a healthy diet, exercise, and spending time doing non-work-related activities are essential. Peer support and mentorship are also extremely valuable. A sense that we are not alone in our battles and acknowledging our distress to another can be very therapeutic.

At a system level, there need to be mechanisms in place to identify workers who are in distress and provisions in place to get them the help they need. In addition, the healthcare workplace and processes need to be creatively reimagined such that team-based practice is the norm, provider autonomy and flexibility are facilitated, and time is provided for self-care.

**James H. Berry, DO**, is chair of the department of behavioral medicine and psychiatry and director of addiction services at West Virginia University in Morgantown.

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# C L N

Clinical  
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News

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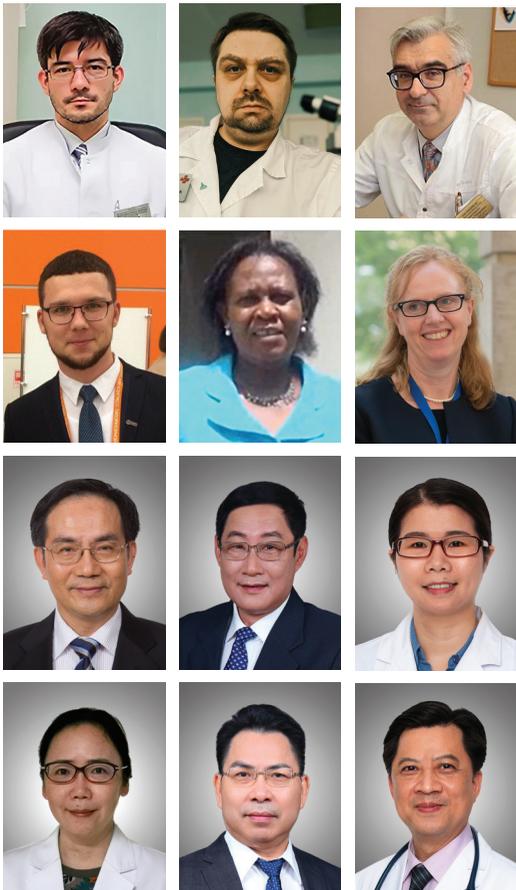
TROPONIN TRIAGE



Decrease in patients requiring referral after test implementation.

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## Building Smart, Patient-Centered Clinical Pathways



Leaders are harvesting the best ideas from healthcare transformation and amplifying the benefit to patients by imagining strategies that work best for their communities.

BY KIMBERLY SCOTT

Clinical laboratories across the globe are participating in interdisciplinary efforts to develop patient-centered clinical pathways designed to improve healthcare outcomes. From screening for lung cancer in China to implementing routine biomarker pre-surgical health checks for patients with planned eye surgery in Russia, clinical laboratories are using their ingenuity and collaborative ethos to make a real difference in peoples' lives.

AACC, Abbott, and other leading healthcare organizations have recognized a number of interdisciplinary teams through the UNIVANTS of Healthcare Excellence program for developing groundbreaking, patient-centered clinical projects. Teams are judged on initiatives that achieve measurable, innovative impact within healthcare systems. Below we highlight five initiatives recognized with distinction or achievement.

### OPTIMIZING DIAGNOSTIC PATHWAYS FOR LUNG CANCER

Early detection and intervention of lung cancer has been shown to significantly reduce mortality and overall healthcare costs. Use of low dose computed tomography (LDCT) to identify lung nodules is an effective tool for identification of potential lung cancer. The goals associated with nodule evaluation are to maximize patient outcomes by safely diagnosing and quickly treating malignant nodules while minimizing testing and invasive procedures for patients with benign nodules.

In China, the widespread implementation of lung cancer screening programs has increased identification of nodules, revealing them in 51% of screened patients. Most patients require multiple sequential CT scans and potentially invasive procedures to confirm their diagnosis. However, invasive procedures that yield a benign diagnosis may have

limited clinical use and are potentially dangerous. Moreover, multiple investigations can potentially delay care for malignant disease. With only 1% to 12% of nodules ultimately diagnosed as malignant, significant opportunities exist to ensure patient safety through routine and effective use of clinical risk models.

An integrated clinical care team at The First Affiliated Hospital of Sun Yat-sen University recognized an opening to maximize patient care, and enhance patient safety, through a novel diagnostic pathway that determines the likelihood of malignancy while reducing unnecessary invasive procedures. The implementation of a nodule risk model – lung cancer biomarker panel with LDCT – significantly increased patient safety by mitigating the need for invasive procedures in patients with benign nodules. It is also streamlining diagnosis to enable earlier treatment of patients with malignant nodules, reducing healthcare costs and improving outcomes.

The lung cancer biomarker panel (LCBP) consists of four key biomarkers: progastrin-releasing peptide, carcinoembryonic antigen, squamous cell carcinoma antigen, and cytokeratin 19 fragment. The LCBP is a fundamental component of the risk model, and therefore success of the care project relied substantially on laboratory data.

According to Lixia Huang, PhD, a specialist in the Respiratory Department at the hospital, the new

## Using a lung cancer biomarker panel that has been specifically validated in a Chinese population is a novel approach.

protocol resulted in a two-fold increase in the number of patients identified as high risk for lung cancer. In addition, 36% of patients with malignant lung nodules had expedited surgical intervention that would not have been triggered by CT alone. Use of the lung nodule risk model increased the accuracy of preoperative diagnosis by 24.1% (from 32.9% to 57%).

Moreover, for patients with malignant lung nodules, the time to inpatient treatment was reduced by 18 days. For patients with lung cancer, any delays in receiving treatment can be the difference between life and death, Huang noted. The ability to expedite care for patients with malignant disease can significantly enhance patient safety and improve outcomes.

“Patients with malignant lung tumors who are diagnosed and treated early have significantly improved outcomes with an estimated 10-year survival rate of more than 90%,” added

Canmao Xie, MD, PhD, director of the Respiratory Diseases Institute at Sun Yat-sen University.

While the new screening initiative resulted in an increase in the number of patients identified as having lung nodules, it also enabled strategic triage, reducing unnecessary procedures, and maximizing time with those who need invasive intervention. In fact, the nodule risk model enabled a reduction in the number of unnecessary invasive procedures and surgeries for patients with benign tumors, saving an average of 5,032.48 Yen (\$717) and 59,589.61 Yen (\$8,490) per patient, respectively.

“The use of biomarker panels for diagnosis is widely accepted,” Huang said. “However, using a lung cancer biomarker panel that has been specifically validated in a Chinese population is a novel approach. Our multidisciplinary approach has enabled cross-functional utility, implementation, and endorsement of the risk model across specialties for lung cancer diagnosis and intervention.”

The lung nodule initiative was recognized with distinction by UNIVANTS.

### ENHANCED DISCOVERY OF UNIDENTIFIED COMORBIDITIES

A few years ago, the clinical laboratory at Seirei Hammamatsu Hospital in the Shizuoka Prefecture in Japan implemented a logistics support function to assist physicians in recognizing

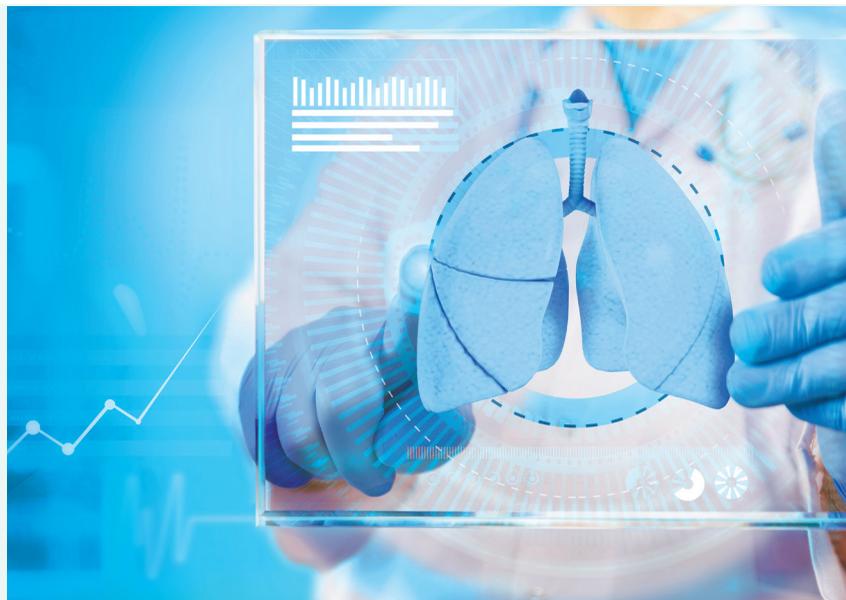
### Improved Safety for Patients with Indeterminate Pulmonary Nodules Through Optimized Diagnostic Pathways for Lung Cancer

**24.1%**

Increased accuracy of preoperative diagnosis (from 32.9% to 57.0%)

**\$8,490**

Savings per patient from avoidance of invasive thoracic surgeries in 27% of patients with benign lung nodules





## Enhanced Discovery of Unidentified Comorbidities and Diagnosis Through Laboratory Medicine Informatics

# 24.1%

**Additional diagnoses or comorbidities diagnosed during 2016-2017**

# 30.3% in 2016 to 47.0% in 2019

**Increase in reaction rate (additional test orders placed based on findings)**

unidentified comorbidities. Logistics support refers to activities that support diagnosis and treatment by analyzing test results to find the possible pathological conditions and communicating them to physicians. The laboratory physicians and technicians defined 27 diagnostic logics, special flow charts to analyze the combination of test results and patient demographic data.

The majority of the logics focus on hematology and clinical chemistry results. Clinicians tend to overlook early symptoms most often with screening tests, rather than with specialty tests that are only ordered when specific diseases are already suspected, according to Kentaro Naoda, the hospital's laboratory manager.

The logics stratify risk in three levels and result in standardized comments for physicians on possible diagnosis and recommendation on follow-up action. The laboratory uses informatics to screen all patient test results with the logics, reviews critical results, opens medical notes to determine if the clinicians are already aware of the condition, and comment on the electronic medical record. In addition, the laboratory monitors whether the clinicians order the requested tests and then provides enhanced follow-up based on the additional results.

In 2016, clinicians placed additional test orders for 240 patients in response to 791 comments from the

lab about possible diagnosis and recommendations on additional testing, a 30.3% reaction rate. This reaction rate improved over time, increasing to 44.5% in 2017, 48.6% in 2018, and 47.0% in 2019.

According to Naoda, this shows that clinicians appreciate the consultation from the laboratory since it required them to understand and agree to the possible diagnosis before they placed orders for additional testing. Multiple clinicians, especially surgeons, provided feedback that it was reassuring to have the lab as their safety net, Naoda said. The head of the medical safety center commented that this standardized approach plays a vital role in improving medical safety.

In 2016 and 2017, the logistics support function resulted in identification of 36 additional diagnosis or comorbidities. These included iron deficiency anemia (IDA), myelodysplastic syndromes, colorectal cancer, stomach cancer, lung cancer, and acute myeloid leukemia. One patient, a male in his 70s, was diagnosed with descending colon cancer after identification of microcytic anemia, followed by diagnosis of IDA with Fe/Fer/TIBC results. This led to investigation of internal bleeding with fecal occult blood testing and referral to gastroenterology.

The initiative resulted in \$80,000 in increased revenue for needed

surgeries over 3 years, as \$20,000 increase in diabetes mellitus treatment revenue over 2 years. The latter represents 39 cases of additional HbA1c test orders leading to 16 diabetes diagnoses, two hospitalizations, and 12 other treatments.

The impact of the initiative is significant, Naoda said, as there are no other hospitals that systematically analyze all patient test results for clinical indications, proactively communicate the recommendations, and follow-up with the clinicians to maximize the discovery of unidentified comorbidities.

"Promoting this initiative has strengthened the hospital brand, with the most advanced laboratory service that enhances optimal diagnosis and treatment," Naoda said. "The hospital director was commended during renewal of Joint Commission



## Pre-Surgical Biomarker Risk Assessments in Patients Undergoing Eye Surgery

# 28% to 5.2%

Reduction in percentage of patients with incomplete pre-surgical health checkups

# 1,000

patients with comorbidities detected



International accreditation about this systematic initiative to minimize overlooked or misdiagnoses.”

The initiative, which was recognized with achievement, is highly scalable as the approach is systemized in such a way that both new and experienced laboratory technicians can execute it with the assistance of an informatics tool.

### PRE-SURGICAL BIOMARKER RISK ASSESSMENTS IN PATIENTS UNDERGOING EYE SURGERY

According to the World Health Organization, 82% of people who are 50 years of age or older have ophthalmic disease, and they often need surgical treatment. City Hospital Number 2 is the largest ophthalmic center in St. Petersburg, Russia, with 250 beds for treating eye diseases. Before 2016, routine pre-surgical health checks for patients with planned eye surgery was performed in local outpatient settings, followed by a referral to the eye hospital.

The quantity and quality of biomarker testing, however, was not always reliable due to missing laboratory results, the need for retesting and/or further investigation due to decompensated, concomitant diseases. This created inefficiencies, including the need to delay surgeries—a significant negative impact on hospital resources, patient length of stay, health system reimbursement, and overall patient satisfaction. Many of the affected patients were elderly, living far from the hospital and dependent upon public transportation. Thus, every delay and need for additional visits created

new difficulties both for staff and for the patients.

In 2016, a multidisciplinary team that included ophthalmology, quality, laboratory medicine, and information technologists established a new process to develop and optimize pre-surgical biomarker checkups. The team agreed on a standardized list of biomarkers for comprehensive screening assessments in the outpatient department of the eye hospital,

## Ranking of St. Petersburg City Hospital Number 2 improved from 10th place in 2015 to fifth place in 2019 for service quality across all hospitals in the city.

ensuring standardization and high-quality testing. All biomarker results were consolidated and led through the core laboratory.

Testing included a complete blood count and eosinophil sedimentation rate (ESR); blood biochemical analysis (glucose, ALT, AST, total bilirubin, urea, creatinine, total protein, total cholesterol); coagulation check with APTT, INR, and PTI; infectious disease panel with HBsAg, antibodies to HCV, antibodies to *Treponema pallidum* and HIV combo antibody/antigen test; thyroid panel TSH, T3

free T4 free, Vitamin B12 and D, plus total PSA for men. Reimbursement of all expenses was covered by the Compulsory Medical Insurance, with no additional charge to patients.

The percentage of patients with incomplete pre-surgical health checkups was reduced from 28% to 5.2% post-implementation of the complete biomarker health assessment. Altogether, the pre-surgical health assessment enabled detection of comorbid conditions in more than 1,000 patients. Associated resource implications mitigated the need for substantial retesting and, more importantly, avoidance of surgical delays.

The team implemented the new care process, including the approved list of laboratory biomarkers and the associated reimbursement strategy, in partnership with the Territorial Fund of Compulsory Medical Insurance – a national payor. Consistently, completeness and timeliness of the health check-ups improved, enabling optimized resource utilization within the health system while mitigating unexpected surgical delays and unnecessary serial patient visits to the hospital and or clinic. The new process enabled a reduction in the overall length of stay for patients, from 3.5 to 3.3 days, while also minimizing the need for repeat laboratory testing, improving overall patient experiences, and even staff satisfaction.

Due to the improved efficiency and enhanced reputation of the hospital, the number of patients (and surgeries) increased annually, also driving increased revenue and reimbursement for the hospital, according to Timur Akhmedov, PhD, head

of the laboratory department at St. Petersburg Hospital Number 2.

Ranking of St. Petersburg City Hospital Number 2 improved from 10th place in 2015 to fifth place in 2019 for service quality across all hospitals in the city. Ranking is important for the patient when selecting the hospital and has made the hospital more attractive, especially for elderly patients. The number of ophthalmic patients was 19,554 in 2016 (78.4% elderly), 20,259 in 2017 (79.8% elderly) and 21,225 in 2018 (80.2% elderly).

The initiative, recognized with achievement, is moderately difficult to implement but highly scalable, says Akhmedov. At the hospital, it required coordination of laboratory staff, clinicians, the administration, and the payor. Payor partnerships of this nature are rare and very strategic, he notes. Activation of the pre-surgical assessment took about a year.

#### PROCALCITONIN: EARLY RECOGNITION AND MANAGEMENT OF SEPSIS IN THE EMERGENCY DEPARTMENT

Sepsis is estimated to cause 11 million deaths globally every year, with 85% of the deaths occurring in low- and middle-income countries. Even in the United Kingdom, there are 48,000 deaths from sepsis each year, with approximately 70% of cases first seen in the emergency department (ED). Early recognition of sepsis is a clinical challenge: Patients present in different ways, and other conditions mimic the signs and symptoms of sepsis. Only 25% of patients treated in the ED are

confirmed sepsis cases. ED staff need a quick, reliable test to diagnose bacterial sepsis and identify patients most at risk of deterioration and death from sepsis.

Procalcitonin (PCT) is a biochemical marker released from the thyroid gland with excellent diagnostic and prognostic value to distinguish bacterial sepsis early. PCT serum levels correlate directly with sepsis severity and can be used to monitor the body's response to antimicrobial treatment. Results guide clinical decision making but cannot replace basic management. Globally, many doctors use C-reactive protein (CRP) to diagnose possible sepsis. CRP levels do not rise early in sepsis and can take a long time to return to normal, even after full treatment, limiting its value in the ED.

The Procalcitonin Clinical Team at the Princess Alexandra Hospitals Trust introduced the PCT as an immediate routine test alongside the sepsis 6 care bundle for all patients presenting with signs of sepsis to the ED of a typical UK district general hospital. A blood culture incubator was installed in the ED to support early diagnosis of bacterial sepsis. The team used the Institute of Health Management quality improvement methodology to implement and embed the use of PCT in routine clinical practice. They also educated all junior doctors and consultants about PCT and how to apply the evidence-based criteria of PCT levels to prescribe or stop antibiotics.

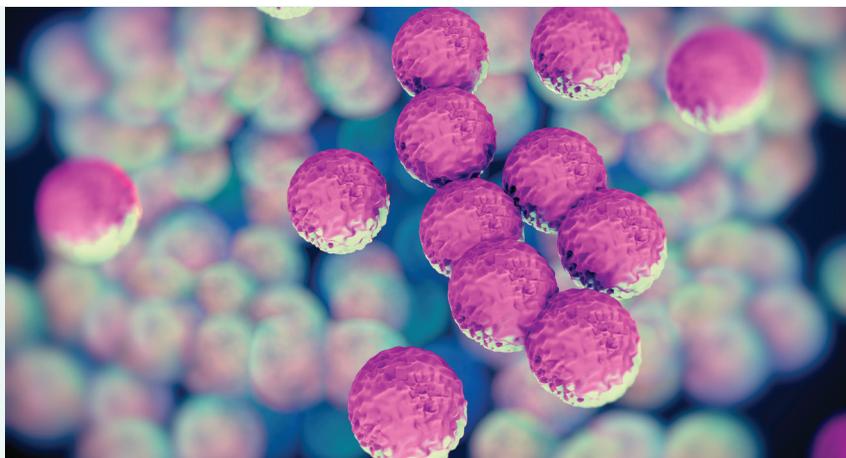
Introducing PCT in the ED of a non-specialized acute trust has helped clinicians manage a high-risk group. These patients have a 2.4-fold increase in mortality rate (7.7% v. 18.2%) and benefit from enhanced monitoring

for signs of deterioration and review by a senior doctor within the first hours of presentation. Measuring PCT in patients with signs of sepsis and administering the sepsis 6 care bundle immediately on presentation to the ED can make a major contribution to improving patient outcomes and reducing deaths from sepsis. Crucially, it also reduces the unnecessary prescription of antibiotics, said Helen Pardo, MD, chief clinical information officer in the hospital's quality improvement department.

With the goal of administering antibiotics only when appropriate and thus reducing the spread of antimicrobial resistance, the hospital, which had been one of the highest prescribers of antibiotics in the region, implemented use of PCT in the ED and subsequently reduced total antibiotics prescribed to levels comparable to, and better than, other local hospitals.

A PCT level of greater than 0.2 in the ED identifies a patient at significantly increased risk of deterioration and death. The mortality rate of patients in the ED with a PCT of greater than 0.2 ug/L was 18.2% compared with 7.7% when PCT was less than 0.2. Length of stay for patients with PCT of greater than 0.2 also is significantly greater than those under that level. Length of stay has a negative impact on patient outcomes, particularly in the elderly – 67% of all patients admitted to the hospital with sepsis are older than 65 years, and 86% of all deaths occur in people over the age of 75.

“Using a PCT level in the ED to identify those at risk of increased length of stay enables better use of



#### Procalcitonin: Early Recognition and Management of Sepsis in the Emergency Department

# 75%

Patients admitted or discharged within 4 hours of presenting to ED (target met)

# Significant

reduction in total number of antibiotics prescribed

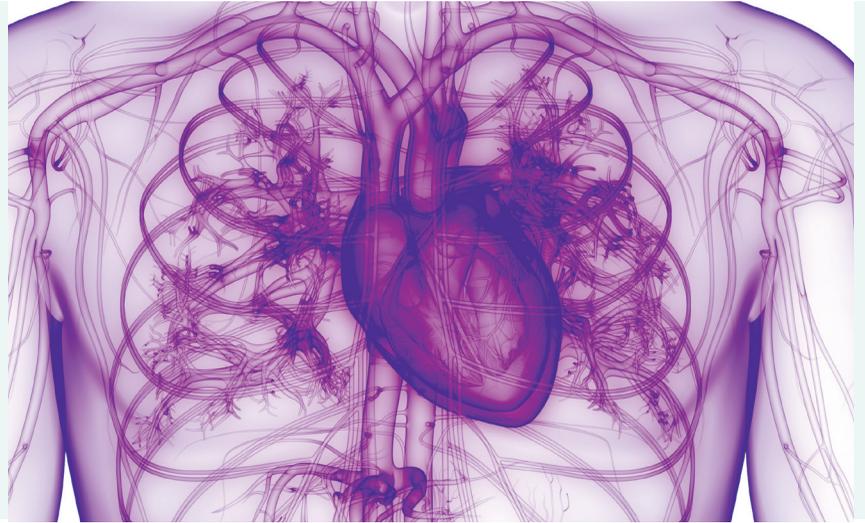
## Improving Care of Patients with Suspected Cardiovascular Disease

# One week to 4 hours

Decrease in wait times  
at referred hospital

# \$275.06 per month

Cost saving  
from use of  
troponin testing



resources,” Pardoe said. “Some of the increased length of stay is associated with prolonged use of antibiotics or their complication. Using procalcitonin-guided antibiotic therapy for all appropriate patients is known to reduce antibiotic-associated complications and in some studies has been associated with a significant reduction in hospital death rates. Improved prediction of length of stay also helps the family plan and support vulnerable family members.”

Use of PCT testing also has helped the ED improve its performance target of ensuring that at least 75% of patients are admitted or discharged within 4 hours of presenting at the ED, Pardoe noted.

The PCT clinical care initiative, which UNIVANTS recognized with achievement, is highly scalable and can be duplicated in any hospital emergency department that is supported by a clinical laboratory. Successful implementation requires planning and some financial priming for the initial expenditures on PCT tests, Pardoe noted. Clinician leadership and education is paramount to effectively train the multidisciplinary team on when to order PCT tests and how to use the test to inform clinical care and guide antimicrobial prescribing.

### IMPROVING CARE OF PATIENTS WITH SUSPECTED CARDIOVASCULAR DISEASE

In Tanzania, cardiovascular disease (CVD) is responsible for 13% of non-communicable disease deaths, with adults ages 25 to 64 being

disproportionately affected. This is due in part to a lack of available resources and high costs associated with diagnosis, treatment, and management. Faith Medical Tanzania Clinics is capable of basic triage for suspected CVD patients, such as complete blood count, urinalysis, cholesterol testing, and blood pressure measurement. However, all patients requiring additional testing and urgent treatment must be transferred to Muhimbili National Hospital. Any additional follow-up at other facilities can take a significant amount of time to complete, as hospitals tend to be very busy. Delays in testing can further delay patient care and substantially affect patient outcomes.

In an effort to streamline testing and improve treatment and outcomes for patients, the care team at Faith Medical collaborated to implement high-sensitivity troponin testing in routine clinical practice for patients with suspected CVD. In just 4 months, 37 patients referred to other hospitals had their troponin tested prior to transfer, thus reducing lengthy wait times and expediting care. In fact, wait times at Muhimbili National Hospital were reduced from one week to 4 hours, according to Joyce Muzuma, managing director of laboratory medicine at Faith Medical.

“Reducing delays in care is extremely important for improving outcomes, especially when it comes to irreversible heart damage,” she said. “Patients who arrive at Muhimbili National Hospital with troponin already measured do not require as

many additional tests and are therefore able to receive more immediate care.”

Troponin is a new test in Tanzania, and most doctors across the country are generally unaware of its value and do not appreciate its role as the gold standard for diagnosis of cardiovascular incidents, Muzuma noted, saying that the physicians at Faith Medical unanimously agree that using troponin in clinical practice has increased confidence when triaging patients and that it improves the care they provide on a daily basis. This is evident in the 40% decrease in the number of patients requiring referral to Muhimbili National Hospital for further workup.

The use of troponin testing also has helped reduce costs, Muzuma said, also pointing out that that the additional testing at Faith Medical has led to an annualized increase in revenue of TSh 640,000 (\$275.06) per month.

“Referrals, travel costs, and additional investigations can be extremely expensive [for patients],” she said. “The ability to triage and treat patients without needing to travel to another hospital for more tests can have a significant impact on the overall cost of healthcare.”

The troponin initiative, which was recognized by UNIVANTS with distinction, is highly scalable, Muzuma said. She believes all clinics in Tanzania and Africa should aim to replicate similar strategies.

### OPTIMIZING PATIENT CARE

Whether implementing a new testing protocol to quickly diagnose emergency patients with sepsis in

the United Kingdom to employing a previously unfamiliar assay to identify patients with suspected cardiovascular disease in Tanzania, clinical laboratories are working closely with other departments within their healthcare systems to develop new clinical pathways that measurably improve patient outcomes and quality of care.

In addition to the initiatives discussed above, Clinical Laboratory News in December 2020 reported on two projects focused on building smart, patient-centered clinical pathways. In New Zealand, for example, clinicians and laboratorians at Christchurch Hospital in Canterbury developed a new clinical pathway for patient care that could reduce the number of patients receiving two cardiac troponin tests while in the ED, which had been the standard of care. This reduced the amount of time spent in the ED and minimized potential exposure to SARS-CoV-2, the virus that causes COVID-19.

## Mortality related to bleeding management failure dropped from 29.3% the 3 years prior to implementation of code H to 4.3% in the 4 years post-implementation.

The team implemented a new chest pain pathway through which the majority of chest pain patients in the ED received one troponin test at the hospital and then are discharged home with orders for a follow-up troponin test done in the community the following day. The new chest pain pathway significantly reduced the amount of time patients spent in the ED as well as the number of people they were exposed to. Following implementation of the new pathway, there was a 45% increase in the total number of patients presenting with chest pain who were safely sent home within 2 hours and a

35% increase in the number of patients sent home within 3 hours. Overall, there was a 55% increase in patients being ruled out for a myocardial infarction using a single troponin result, and consequently, fewer patients requiring multiple troponin results for ruling in heart attacks.

At Hospital Israelita Albert Einstein São Paulo, Brazil, an integrated care team set out to reduce the number of catastrophic adverse events related to hemorrhagic shock by reducing barriers for risk identification. The team made strategic changes to enable comprehensive, patient-centric protocols for urgent patients, including establishing a new “code yellow,” that enables identification of patients whose vital signs indicate risk of decompensating. When code yellows are activated, a rapid response team is triggered for enhanced vital sign monitoring. If a patient continues to decompensate, a “code H” alert is called. Code H alerts are based on validated criteria for hemodynamic instability, triggering a cascade of actions across multidisciplinary health professionals through automated alerts. This includes immediate ordering of blood and blood components through a massive transfusion protocol with a 15-minute response time. Vascular intervention occurs within 30 minutes, and the intensive care unit (ICU) and operating rooms are put on standby.

After 2 years of the new protocol at Hospital Israelita Albert Einstein São Paulo, there was not only a significant improvement in indicators, but also a reduced length of stay in the ICU, reduction in use of blood components, and better cost effectiveness when compared to a control group. Most significantly, mortality related to bleeding management failure dropped from 29.3% the 3 years prior to implementation of code H to 4.3% in the 4 years post-implementation.

The initiatives highlighted above are just a few of the many projects in which laboratories are playing a critical role in transforming healthcare delivery. To learn about other UNIVANTS winners, go to [www.univantshce.com](http://www.univantshce.com). ■

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# UNIVANTS 2020 Teams Recognized In This Issue

**Enhanced Discovery of Unidentified Comorbidities and Diagnosis Through the use of Diagnostic Logics Empowered by Laboratory Medicine and Informatics** | Seirei Hamamatsu HP | Kentaro Naoda, Keiko Oba, Osamu Yonekawa, Kenta Usui, Hidenori Nakamura, Akira Yamamoto

**Improved Safety for Patients with Indeterminant Pulmonary Nodules through Optimized Diagnostic Pathways for Lung Cancer** | The First Affiliated Hospital of Sun Yat-sen University | Canmao Xie, Yanbin Zhou, Suilin Mo, Honghe Luo, Min Liu, Lixia Huang

**Improving Patient Experiences via Reliable Pre-Surgical Biomarker Risk Assessments in Patients Undergoing Eye Surgery** | St. Petersburg Hospital Number Two | Timur Akhmedov, Vadim Nikolaenko, Alexandr Pushkin, Alexey Lebedev

**Procalcitonin: A Successful Clinical Formula for the Early Recognition and Management of Sepsis in the Emergency Department** | The Princess Alexandra Hospital NHS Trust | Helen Pardoe, Andrea Annoni, Nicholas Kroll, Georgia Lucas, Angela Bartolf, Umada-Agambodi De Thabrew, Zoya Murtaza, Siddarth Kumar, Abrar Gani, Marie Parsons

**Improving Care and Overall Experience for Patients who Present to a Tanzania Clinic with Suspected Cardiovascular Diseases** | Faith Medical Tanzania Clinics | Joyce B Mung'ong'o Muzuma, Felician Kibacha, Pendo Kibona, Saum Seif



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