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CLN Clinical Laboratory News

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DETECTING MATERNAL CYTOMEGALOVIRUS

23%

Reduction in congenital CMV transmission

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2022 UNIVANTS "Teams of Distinction"

Lead Change Through Collaboration

BY KIMBERLY SCOTT

When it comes to improving healthcare and patient outcomes, clinical laboratories around the world are showing that success is a team effort. The three initiatives highlighted below have been recognized by the UNIVANTS of Healthcare Excellence Awards as the 2022 "Teams of Distinction."

These prestigious awards were created by Abbott in partnership with ADLM (formerly AACC) and other leading healthcare organizations to recognize teams that collaborate across disciplines to transform healthcare delivery. In addition to demonstrating the critical role of clinical laboratories, the winning teams are a testament to the power of partnering with others to achieve a common goal—in this case, improving care and saving lives on a global scale.

Better Drug Testing for Monitoring Controlled Substances

45.5%
Increase in drug-screen orders in ambulatory setting with appropriate confirmatory testing.

35%
Increase in UH Healthcare System physicians who are compliant with the urine drug-test recommendations.

25%
Reduction in opiate/benzodiazepine confirmatory drug-test costs associated with moving testing in-house.

This supplement explores the outstanding accomplishments of the Teams of Distinction, which include enhancing drug testing for controlled substances, speeding screening of organ donations, and reducing the transmission of cytomegalovirus from mothers to babies. In each instance, clinical lab leaders worked with their own staffs, other healthcare teams, patients, and communities to effect meaningful change.

BETTER DRUG TESTING FOR MONITORING CONTROLLED SUBSTANCES

With the number of deaths from drug overdoses on the rise, healthcare systems are developing local responses to help save lives. More than 100,000 Americans died from overdoses in 2021, a 10% increase over 2020. Opioids continue to account for the largest proportion of deaths.

In 2018, University Hospitals (UH) of Cleveland convened an interdisciplinary team to address the goal of effectively using urine drug-testing as a component of safe controlled-substance prescribing in this evolving environment, according to Jaime Noguez, PhD, director of clinical chemistry and toxicology in the department of pathology at UH Cleveland Medical Center. The collaboration included clinical, laboratory, and risk-management leaders who sought to increase the ease, accuracy, and confidence with which physicians ordered and interpreted lab testing for controlled-substance monitoring.

"What started out as a few inquiries to the lab about testing capabilities and how to interpret complex test results turned into this very large initiative with a significant impact on patient care," she explains. "The lab recognized the need to assemble a larger group

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to discuss and plan drug-testing strategies and capabilities for several different patient populations throughout our health system. We pushed for the creation of a systemwide Drug Testing Committee with representatives from various specialties, including pain-management, primary care, addiction and recovery, emergency medicine, and obstetrics and gynecology. From that meeting, we realized there was so much that could be improved upon in the controlled-substance monitoring space that would benefit all of the clinical specialties."

The team's first step was to modify the drug-test panels to include more of the drugs that were being prescribed and abused in the region, to make the test names more intuitive and easier to find when physicians placed drug test orders, and to create automated reflex testing for presumptive positive urine drug-screen results, explains Noguez.

"We also created several educational resources in various formats to empower our physicians in regard to controlled-substance prescribing and monitoring using lab testing. These resources were rolled out along with a complementary laboratory toxicology consultation service to help physicians interpret complicated drug-test results and guide test selection," says Noguez. "It's truly been a collaborative and iterative process that started in 2018 and continues to be improved upon."

In 2019, the lab brought the confirmatory testing in-house to decrease the turnaround time for test results. It also developed a more comprehensive custom drug-test panel to monitor prescription compliance in patients who were prescribed opiates, opioids, and benzodiazepines. In the years since, the team has continued to improve the way in which drug-test results are displayed in test reports and provide more interpretive information so that physicians can more easily make clinical decisions about whether to refill prescriptions.

> "What started as a few inquiries to the lab about how to interpret complex test results turned into this very large initiative with a significant impact on patient care."
> —Jaime Noguez

The team has also automated some of its methods for collecting and analyzing data to assess provider compliance with the prescribing guidelines for urine drug-test orders. Dashboards were created to assess controlled-substance monitoring compliance at the system- and provider-level, providing actionable information for the team to follow up on with providers.

The involvement of the clinical laboratory in the initiative has been extremely significant, says Noguez, noting that lab-test data are critical for comprehensively assessing urine drug-test results and ordering patterns to gain actionable insights into how to best guide care providers.

Since the drug-screening option with an automated reflex was implemented, the number of drug-screen orders in the ambulatory setting with a reflex to confirmation has increased by 45.5% (53% to 98.5%), says Noguez. Also, the built-in reflex to confirmation has prevented 25% of patients from having to return to the lab to submit an additional sample for follow-up testing. The confirmatory testing also helped identify false positives, with 10% of presumptive positive urine drug-screens identified as false positives and 4% of specimens identified as diluted, a result that could lead to false negatives.

In addition, the number of providers ordering, and unique patients receiving, comprehensive controlled-substance testing more than doubled through this program. Clinician compliance with testing guidelines increased by 35%, with physicians reporting increased confidence in their ability to use drug testing as part of their care for patients who have been prescribed controlled substances.

The benefits of the initiative are many, says Noguez. "We saw a threefold increase in the number of patients receiving comprehensive and appropriate controlled-substance testing and prescription monitoring," she says. "We can identify the potential for unsafe drug interactions that can lead to overdose. We can quickly recognize drug diversion or misuse to facilitate substance-abuse treatment services. Our collaboration also allows us to rapidly identify changes in prescribing trends or new drugs of abuse in our community that may require modification to the current panels."

Noguez says the process that the team used to implement the drug-screening initiative can be scaled

Real-Time Organ-Donor Screening

94.7%
Improvement in turnaround time of tissue-procurement testing (from 18 hours and 22 minutes to 57 minutes).

2.5%
Increase in eligible donors following implementation of new test system.

8.9%
Patients authorized for tissue donation who were ultimately deemed ineligible prior to commencement of organ procurement.

for other clinical goals. For example, many healthcare outcomes could be improved by creating an interdisciplinary team with full institutional support that is dynamic, persistent, and responsive, enabling laboratory testing to be incorporated more deeply into clinical practice guidelines.

"Establishing lab testing as a key component to the success of a larger initiative and integrating lab-focused education within a broader context is not limited to the topic of controlled substance monitoring or our institution," she says.

REAL-TIME ORGAN AND TISSUE-DONOR SCREENING

Organ-procurement organizations (OPOs) are required to screen potential organ, tissue, and/or eye donors for relevant communicable infections, including human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV), using screening tests approved by the Food and Drug Administration (FDA).

Previously, at Mid-America Transplant in St. Louis, Missouri, tissue-donor screening for infectious diseases was performed in batches with an average turnaround time of 18 hours and 22 minutes. Because tissue procurement must take place within 24 hours of a donor's death, timing is critical. However, results from infectious-disease testing were not available until after tissue procurement, leading to excess waste and resource expenditure when procured tissues could not be used due to a test result indicating infection.

"We identified that serology testing was a bottleneck in our workflow due to the manual, hands-on nature of the testing and the necessity of batch testing," explains Amber Carriker, laboratory director. "We hypothesized that the use of a rapid, real-time method for serology

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testing could improve workflow and result in process efficiencies."

In early 2021, Mid-America Transplant's Performance Excellence Team was charged with identifying the challenges and gaps with their current process and facilitating an improvement. It took approximately four weeks for them to identify gaps and solutions, test a new process, and implement their solution—a fully automated donor-serology testing platform, which was rolled out in April 2021.

The FDA-approved test system (Abbott Alinity s) enables real-time screening for the qualitative detection of HBV surface antigen (HBsAg), HBV core antigen (anti-HBc), HCV (anti-HCV), HIV p24 antigen and antibody to HIV-1/HIV-2 (HIV Ag/Ab Combo), and antibody to Human T-Lymphotropic Virus Type I and II (anti-HTLV), on both pre- and post-mortem specimens.

"The new process begins with a 'yes' from a donor hero's family," explains Carriker. "Upon the donor's arrival to our facility, the donor-services team notifies the tissue procurement coordinator that the donor has arrived, and a blood sample is collected and taken to the laboratory. The tissue-procurement team utilizes the infectious-disease screening results to determine acceptability and either begin the tissue-donation process or determine that tissue donation will not proceed."

After the new system was implemented, workflow improved by 94.7%, with an average turnaround time of 57 minutes from specimen receipt to results.

"Given this remarkably shortened workflow, serology results are available prior to tissue procurement, significantly transforming the tissue-donation and recovery process," explains Carriker. "This includes the capability to defer potential donors with positive serology—in other words, with results identifying infectious diseases that disqualify them as donors—before tissue recovery."

"Given this remarkably shortened workflow, serology results are available prior to tissue procurement, significantly transforming the tissue-donation and recovery process." —Amber Carriker

The improved resource utilization has resulted in a savings of more than $105,000 across 18 months in supplies and consumables, in addition to indirect cost savings related to workforce and operating rooms. In addition, the initiative has improved safety of the workforce and clinicians through an 89.9% decrease in exposure to screened infectious diseases, according to Carriker.

This new process is transformative for the organ and tissue-donation landscape because it opens up opportunities for previously "unapproachable" donors who may be hemodynamically unstable, or whose family impose significant time constraints, says Carriker. The new process also facilitates expedited organ placement.

"Overall, the initiative leads to higher satisfaction from stakeholders, including the donor families, funeral homes, tissue/eye processors and OPO staff," she explains. "The new workflow also helps to optimize resource allocations for tissue and eye donation, as well as laboratory operations."

According to Carriker, Mid-America Transplant was the first OPO in the nation to use the testing platform in this manner and the first to perform tissue-donor screening in real-time prior to the procurement. The project was moderately challenging to implement, but is highly scalable, she says.

"In our work, time is of the essence, so the dramatic improvement brought about by a more rapid testing process literally translates to saving and healing more lives," says Carriker. "We're proud to be the first organ-procurement organization to utilize this particular equipment to automate donor screenings and make more transplants possible."

EARLY DIAGNOSIS OF MATERNAL CYTOMEGALOVIRUS

Congenital cytomegalovirus (cCMV) is the leading non-genetic cause of hearing loss and neurodevelopmental disabilities in children. However, despite contributing to a significant disease burden, cCMV is underrecognized by many health authorities and remains relatively unknown to the general public.

For example, less than 9% of women know how to reduce the risk of acquiring CMV during pregnancy. As a result, approximately one out

Early Diagnosis of Maternal Cytomegalovirus

2.6 times
more pregnant women identified as having a CMV infection (from 10 to 26 women over 2.5 years).

23%
Reduction in congenital CMV transmission from mothers to babies.

766,444 Euros
Estimated cost avoidance per child through prevention of long-term health problems related to congenital CMV.

of three women will pass CMV to their unborn baby in cases of primary infection during pregnancy, according to Sébastien Hantz, Pr, MD, PhD, a physician with the National Reference Center for Herpesvirus, University Hospital Center (CHU), in Limoges, France. A mother with a past CMV infection can also transmit the virus to their fetus in cases of reactivation or reinfection (secondary infections).

Congenital cytomegalovirus is challenging to identify in newborns, since 90% of babies born with it will present as asymptomatic. Some babies with cCMV will not have any health impairments or visible developmental delays, while others may experience hearing loss, mild vision loss, microcephaly, or enlarged spleens and livers. In rare cases, the condition is fatal.

Currently, no standard exists for universal CMV screening during pregnancy, and in many countries, such screening is not recommended. Due to the lack of newborn screening for cCMV, the virus's prevalence and impact are likely much higher than current estimates reflect, says Hantz.

An integrated care team at CHU Limoges sought to change the paradigm and adopted a universal CMV screening program for pregnant mothers to improve early diagnosis of CMV infections and identify those with non-primary infections. Since the inception of the Universal CMS Screening Program in 2020 at CHU Limoges, the number of pregnant women identified with a CMV infection increased by 2.6 times—from 10 to 26 over a 2.5 year period—according to Hantz.

"Broad adoption of the program demonstrated a significant impact in the care of pregnant mothers with a CMV infection and helped in early neonatal management by initiating antiviral treatment in 68%

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"Knowing we're doing everything we can to prevent potentially avoidable transmissions to CMV from pregnant mothers to their babies can be emotionally rewarding." —Hugues Caly

of pregnant mothers during the first trimester of pregnancy," he says.

In addition, the screening initiative and subsequent treatment resulted in a 23% reduction in CMV transmission from pregnant mothers to their babies (from 50% to 27%). This reduced cCMV progression is estimated to lead to a cost avoidance of 766,444 euros per affected child by preventing hearing loss, vision loss, and intellectual disabilities.

"Knowing we're doing everything we can to prevent potentially avoidable transmissions to CMV from pregnant mothers to their babies can be emotionally rewarding, especially when symptomatic mothers are concerned for their unborn child," says Hugues Caly, MD, an obstetrician at Limoges Hospital. "Early antiviral therapy offers hope."

Integrating CMV education and prevention pamphlets in all obstetrics and gynecology departments has increased patient awareness, notes Hantz, who says the efficacy of these actions on the rate of CMV infection during pregnancy will be evaluated during the next follow-up period. The program has already been adopted by seven hospitals in France and is planned to be implemented in other French hospitals.

CLINICAL LABORATORIES MAKING A DIFFERENCE

Each of these initiatives demonstrates the critical role that clinical laboratories play in transforming healthcare. Beyond simply providing test results, these labs are actively preventing the spread of disease, enhancing resource utilization, and increasing the accuracy of prescription-compliance monitoring.

In addition, they are harnessing the power of collaboration to develop integrated care practices that are improving current standards for various diseases. For details on these winners and others, visit univantshce.com.

UNIVANTS 2022 Teams Recognized In This Issue

Getting to Zero Harm in Controlled Substance Prescribing: Increasing The Accuracy of Prescription Compliance Monitoring Through Enhanced Drug Testing Support

University Hospitals Cleveland

Jamie Noguez, Christine Schmotzer, Sean Hoynes, Heidi DelVecchio, Jeanne Lackamp

Enhanced Resource Utilization, Reduced Waste, and Expedited Transplantation Through Real-Time Donor Screening for Infectious Disease

Mid America Transplant, St. Louis, Missouri

Amber Carriker, Linda Martin, Erica Hinterser, Lindsey Speir, Kevin Lee

Early Diagnosis of Maternal Cytomegalovirus for Improved Management and Reduced Risk of Fetal Transmission and Complications

National Reference Center for Herpesvirus, University Hospital Center

Sébastien Hantz, Perrine Coste-Mazeau, Sophie Alain, Elodie Ribot, Melissa Mayeras

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"If we as organizations want to call ourselves healthcare organizations, we have to be involved in more than just the delivery of medical care after someone gets sick."

MICHAEL DOWLING
President and CEO,
Northwell Health, USA

"Sometimes things are not in the budget but sometimes we have to figure out how to do it, particularly if it is going to make a huge difference for patients."

QUINT STUDER
Co-Founder, Healthcare Plus Solutions Group, USA

"We have opportunities to develop appropriate clinical algorithms that can help ensure that patients get the care that they need"

OCTAVIA PECK-PALMER
Division Director, Clinical Chemistry,
Associate Professor of Pathology,
University of Pittsburgh
School of Medicine, USA

"Many of us have the ideas, the plans and the scientific knowledge, but we need to be able to ensure that it aligns with what people are able to do."

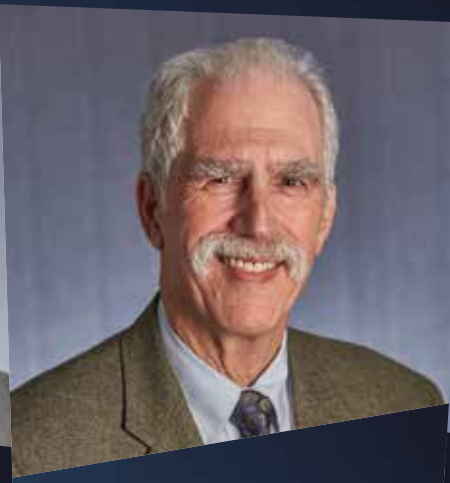
YIN LING WOO
Professor of Obstetrics and Gynaecology, Consultant Gynaecological Oncologist,
University of Malaya,
University Malaya
Medical Centre, Malaysia

"Every voice matters as we collaborate to improve the health of individuals and populations around the world."

CHRISTINA CARABALLO
Vice President, Informatics,
HIMSS, USA

"We have to completely reimagine what is the role of the clinical lab, not at a test level, but in the longitudinal way of data that gives us a meaningful way to predict risk."

KHOSROW SHOTORBANI
President, Executive Director,
Project Santa Fe Foundation, USA
Founder and CEO,
Lab 2.0 Strategic Services, USA



"Together, we can address diagnostic error which the NASEM reports to not only be possible, but a moral, professional, and public health imperative."

PAUL EPNER
Vice-Chair,
Sepsis Alliance, USA

"Through the use of a new biomarker, multiple health systems were able to save and mitigate downstream costs while improving health for the entire ecosystem."

TRICIA RAVALICO
Director, Scientific Leadership and Education, Core Diagnostics,
Abbott, USA

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