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CLN Clinical Laboratory News

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IMPROVING SEPSIS CARE

20%

Decrease in sepsis-related ICU mortality after PCT implemented

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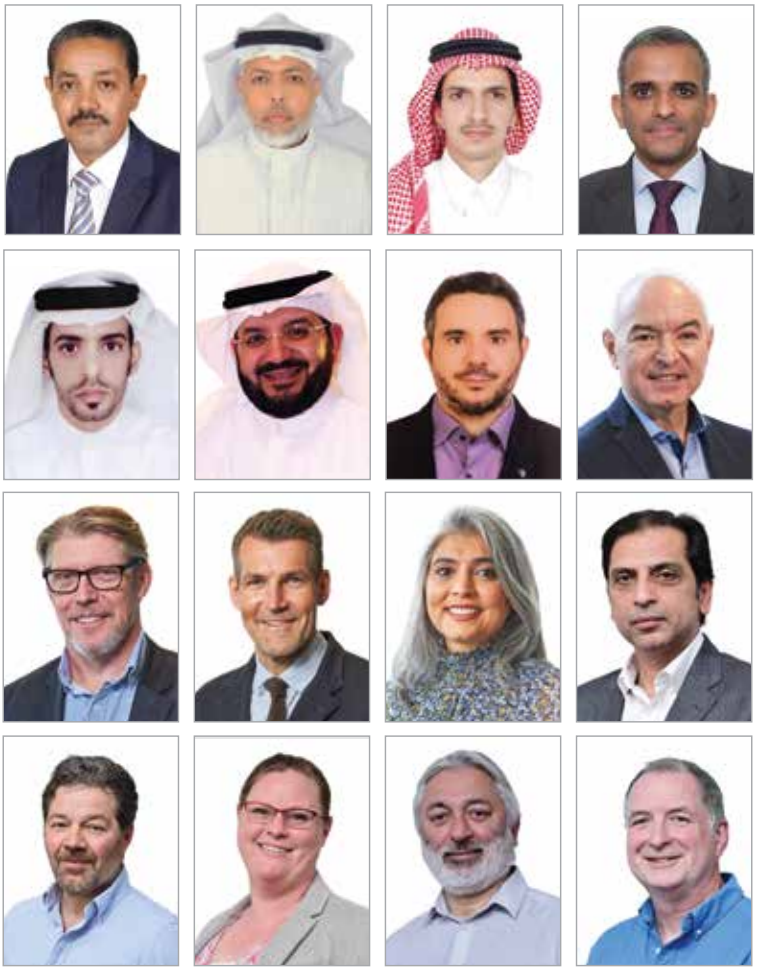
Smart Teamwork Accelerates Care Transformation



Global initiatives have demonstrated the sizeable benefits of adding high-value diagnostics implemented by integrated teams

BY KIMBERLY SCOTT

The addition of a single blood test to a patient workup can have a profound insight into a patient's diagnosis, treatment, and outcomes. As demonstrated by three global initiatives recognized for making demonstrable changes in patient lives, these projects employed innovative, interdisciplinary solutions to improve outcomes in patients care. From implementing a high-sensitivity troponin I test to initiating testing for biomarkers such as interleukin 6 and procalcitonin, the three initiatives below demonstrate how targeted interventions can save lives.

AACC, Abbott, and other leading healthcare organizations have recognized these initiatives as UNIVANTS Teams of Distinction. The UNIVANTS of Healthcare Excellence program is a prestigious global awards program designed to celebrate measurably better healthcare performance. Interdisciplinary teams, centered around labs, are judged on their development and implementation of initiatives that innovate solutions to achieve measurable, positive impact within healthcare systems.

PREVENTING CARDIOVASCULAR DISEASE WITH HIGH-SENSITIVITY TROPONIN TESTING

Cardiovascular disease is the second leading cause of death in Canada and places a significant burden on the Canadian Healthcare System. Historically, Medcan, a large, multi-disciplinary ambulatory care center in Toronto, conducted cardiovascular assessments using

stress tests, lipid analysis, and the Framingham risk score.

Because stress testing was not possible during the COVID-19 pandemic, an integrated care team implemented high-sensitivity troponin I (hs-cTnI) to replace stress testing and improve and enhance identification of future risk for cardiovascular disease.

The benefits of the innovative approach include time savings of 38 minutes per patient and over 45 minutes per day for each attending physician, according to Peter Nord, MD, chief medical officer of Medcan. Additional benefits include reduced false positivity, which translates to an annual savings of $357,500 CDN for the Canadian Healthcare System.

The impact from a population health perspective is also significant: In the first 6 months of the initiative, Medican reported 7,392 "low risk" results, 451 "moderate risk" results, and 204 "high risk" results. Many of these high-risk results triggered a medical response that was lifesaving.

The high-sensitivity cardiac troponin test is the latest generation of cardiac enzyme testing that allows for detection of extremely low levels of troponin I, which can be a forerunner of future cardiac events. If the test result suggests a lower risk, it also can provide reassurance to patients about their future risk for cardiac complications.

Utilizing hs-cTnI test helps Medcan physicians identify cardiac risk years before traditional tests, such as stress testing. Identifying cardiac risk earlier prompts more timely intervention, improves compliance, delays the development of cardiac pathology, and saves lives.

With implementation of the hs-cTnI test, the average time for completion of an annual health assessment (AHA) declined from 301 minutes to 264 minutes, a reduction of 38 minutes, largely attributed to the removal of stress testing.

Preventing Cardiovascular Disease Using A Novel Laboratory Test

38 minutes
Average reduction in time for annual health assessment

48
Number of seemingly healthy people who underwent annual health assessments who were identified as needing urgent cardiovascular follow-up

70.6%
Clinicians who agreed that hs-cTnI testing increases their ability to identify patients at future risk for cardiovascular disease relative to stress testing

$357,500 CDN
Annual cost savings by using hs-cTnI in place of stress testing

"The Ontario Health Insurance Plan delisted the annual health exam years ago, but many corporations provide them as one of their health benefits," Nord said. "Also, we're increasingly seeing people coming in with complex issues and they are hoping a full-day assessment will help to establish a health plan that they can implement. The benefits from replacing stress tests with high-sensitivity troponin testing have been significant."

The initiative has been popular not only with patients, but also with clinicians.

According to Nord, more than 73% of Medcan physicians felt hs-cTnI added value to health check assessments in patients with a high pretest probability, with a lower number believing that it adds value for those with medium and low pretest probability. Almost 38% of Medcan physicians ranked hs-cTnI with the highest rating on a 10-point scale for added value in annual health assessments.

"More than 75% of the surveyed physicians either agreed or strongly agreed that annual measurement of hs-cTnI helps to assess year-over-year cardiovascular risk and also cardiovascular treatment effectiveness," Nord said.

Alain Sotto, MD, CCFP(EM), FCBOM, a senior medical consultant for Medcan, noted that the value of high-sensitivity troponin in health assessments not only captures existing cardiac risk, similar to the former approach with stress testing, but it also identifies future cardiovascular risk.

"Stress tests have inherent patient risk for myocardial infarction or collapsing, whereas high-sensitivity troponin has zero risk in harming our patients," he said. "Both rationales underscore our measures that proactively maximize client wellness."

Beth Abramson, MD, MSC, FRCPC, FACC, a preventative cardiologist with Medcan, adds that the change from stress testing to high-sensitivity troponin in health assessments is an innovative step forward for women's health.

"Stress testing is known to have more false positives in women and high-sensitivity troponin is well known for its enhanced accuracy and precision in detecting low levels of myocardial injury," she said. "These advances enable improved risk assessments and care, especially for women."

"Stress tests have inherent risk for myocardial infarction or collapsing, whereas high-sensitivity troponin has zero risk in harming patients."
—Alain Sotto

As a result of the hs-cTnI initiative, which was recognized with a UNIVANTS award of distinction, Medcan realized an annualized savings of $284,400 CDN following headcount reduction in full-time (55.6%) and casual employees (44.4%) that were previously dedicated to stress test operations. The savings realized due to the elimination of stress testing capacity were significant at a time when resources were constrained due to the COVID-19 pandemic. In addition, the change from stress tests to hs-cTnI freed up six rooms for other services, including VO2 Max testing, an assessment of cardiovascular fitness.

A reduction in false positives for clients over 45 years of age translated to a cost savings of $357,500 CDN per year, calculated based on a reduction in stress echocardiograms (60%) and myocardial perfusion imaging (MIBI).

"Avoiding the false positive results associated with stress testing resulted in a savings to the payor that is significant," Nord said. "Fewer false positives also created a patient benefit in that there was less time, cost, and risk to the patient due to reduced downstream testing."

Medcan is the first healthcare organization in Canada to include hs-cTnI in the standard lab panel for all patients undergoing an annual health assessment, noted Nord, who expects to run 20,000 tests per year.

Results that indicate a patient is at high risk for a cardiovascular event automatically triggers a medical response, either a referral to a cardiologist or, in some cases, a referral to the emergency department. During the early days of the initiative, 48 individuals with no signs or symptoms of acute coronary syndrome were identified requiring urgent follow up with escalated investigation and treatment following biomarker-based health assessment.

"We have caught some patients just before they would have had a heart attack," said Nord. "It's clear that testing with high-sensitivity troponin saves time, saves money, and saves lives."

Medcan is expanding its services outside of Toronto and hopes to spread across other provinces, thus expanding its use of hs-cTnI testing, which Nord said adds to Medcan's value proposition.

ADDRESSING COVID-19 CLINICAL AND TRANSLATIONAL CHALLENGES

When the COVID-19 pandemic began in spring 2020, University Hospital Coventry and Warwickshire (UHCW) National Health Service (NHS) Trust and the Warwick Medical School in Coventry, United Kingdom, along with other health systems worldwide, had to pivot quickly to diagnosing the emerging novel coronavirus in a timely manner. COVID-19

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posed an unprecedented challenge to healthcare systems with limited diagnostic capacity and knowledge in managing patients with severe respiratory symptoms and high mortality. Healthcare professionals had to come together and learn quickly how to act in novel ways to meet urgent clinical care needs, to set up new infrastructure to address unmet needs, and quickly translate innovation into clinical practice.

The Coventry and Warwickshire Pathology Services (CWPS) Clinical Diagnostics Department, leading the COVID-19 response team of University Hospitals Coventry and Warwickshire (UHCW) NHS Trust, made transformative multi-faceted clinical and scientific contributions in the national effort. To meet capacity gaps, the team established a new dedicated laboratory delivering more than 3,000 nationally accredited PCR tests per day. This met the strict key performance indicator (KPI) of turnaround time – less than 24 hours for hospital admissions and care homes across Coventry and Warwickshire and South Midlands, according to Dimitris Grammatopoulos, PhD, Professor Consultant of molecular medicine and clinical diagnostics at the Warwick Medical School and UHCW NHS Trust. Rapid PCR testing on emergency department patients also enabled fast-tracking of admissions.

As a member of the COVID-19 Genomics UK Consortium, the lab contributed to national surveillance programs and investigated transmission patterns during local outbreaks. In addition, the team support the NHS Test and Tracing Technical Validation Group by evaluating new technologies and developing innovative PCR methods for screening prevalence of variants of concern (VOCs). This was used to identify VOC transmission during the second alpha/B1.1.7 VOC-driven wave.

From the initial stages of the pandemic, the team introduced a biomarker panel, based on the Royal College of Pathologists recommendations. This was used to support patient risk stratification

Improving COVID-19 Clinical and Translation Challenges

45 Minutes

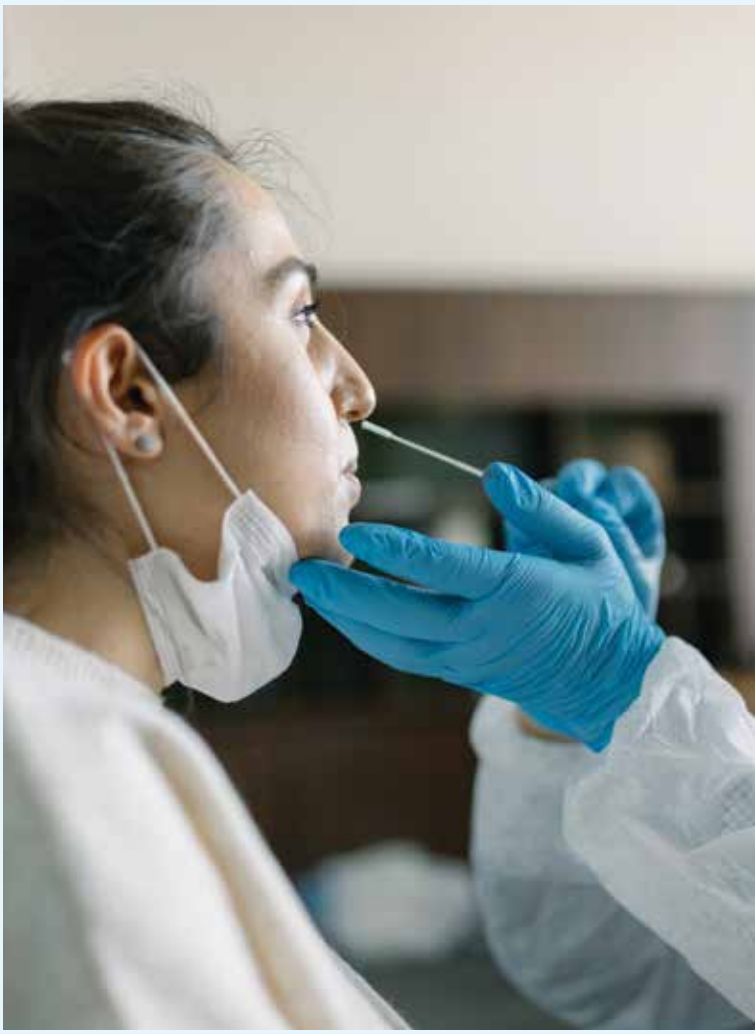
New average patient wait time post-implementation of point-of-care multiplex assay for SARS-CoV-2 testing, compared to previous 6-8 hours

<24 hours

Availability of SARS-CoV-2 PCR test results compared to more than 4 days previously. Faster availability of results led to reduced nosocomial infections.

>330

Admissions investigated for possible reinfection based on test findings from the in-house PCR variant of concern service



and treatment prioritization. The team also worked with the research and development department to establish a COVID-19 biorepository containing longitudinal routine samples from COVID-19 patients.

A National Institute for Health and Care Research clinical research network (NIHR CRN) infrastructure award enabled expansion into a West Midlands-wide resource. Extensive collaboration with academic scientists from the University of Warwick led to groundbreaking research projects around AI-based predictive tools of COVID-19 biomarkers and development of innovative solutions for disease characterization and diagnostic approaches with defined outputs.

One important and distinct facet of the team's COVID-19 diagnostic testing strategy involved early adoption of a point-of-care multiplex assay in emergency assessment units (EAUs), capable of screening for several common respiratory viruses, including SARS-CoV-2. The main driver for this initiative was the urgent need to improve the 6 to 8-hour turnaround time in the EAU. Adoption of the point-of-care-testing solutions enabled result time to be reduced to 45 minutes, which allowed earlier confirmation of patients with COVID-19 infection.

The lab also developed and introduced an end-to-end information technology solution for scheduling testing and transmitting results to patient electronic health records, making them available for clinical review without delay, Grammatopoulos said.

Since the start of the pandemic, more than half a million SARS-CoV-2 PCR assays have been processed, with the average turnaround time reduced from 4 days to less than 24 hours.

"Faster availability of results resulted in reduced nosocomial infections and improved management of patient isolation," Grammatopoulos said.

In addition, rapid translation of new knowledge and novel biomarker concepts became a critical factor for effectively treating patients during the pandemic, he said. The lab, working with multispecialist clinical teams, introduced a COVID-19 biomarker panel, which included established markers of disease such as CRP, LDH, ferritin, hematological indices such as platelets, neutrophils and lymphocytes, and the newly introduced interleukin-6, which is consistently shown in literature to correlate with COVID-19 disease severity.

Clinician requests for the panel increased during each pandemic wave, showing increased clinician confidence. The biomarker results will be used as a longitudinal tool to monitor disease progression and severity and to provide baseline values for future long COVID follow-up.

By setting up new sequencing services, CWPS Diagnostics participated in the COVID-19 consortium (COG-UK) and national strategy, with 66 journal articles already published. This has contributed significantly to the literature and improved understanding of variants, lineage, and transmission patterns.

"We used this service clinically to investigate a local example of cross-transmission across healthcare sites," Grammatopoulos said. "Sequencing 100 samples from hospitals and care homes in the Coventry and Warwickshire region specifically uncovered a common point of entry, suggesting cross infection between two sites and triggering infection control and public health responses. Knowledge of these transmission patterns as a result of staff and patients moving between hospital and care homes is a point of learning and enables continued improvement in relation to infection control in the healthcare system."

Development of a COVID-19 Biobank has so far established a repository of more than 60,000 samples from nearly 7,000 Covid patients, Grammatopoulos noted. This resource has provided samples for multiple COVID-19 research projects, both from academia and the biotech sector. CWPS has been recognized nationally as a leader in COVID-19 testing research and support, and its COVID-19 initiative has been recognized by a UNIVANTS distinction award.

The multi-faceted response that CWPS put in place to address the COVID-19 unmet clinical needs could be used as a template to guide expansion in case of other outbreaks with appropriate reallocation of resources and firm strategic guidance that encourages service and skills integration, Grammatopoulos said.

"The transformation of a local initiative – the UHCW Biobank – into a Regional Biobank through a CRN award is another example of a clinical care initiative with high scalable potential," he said. "What started as a local idea is now developing into a regional resource as an example of how this could be scalable."

> **"Faster availability of results resulted in reduced nosocomial infections and improved management of patient isolation."**
> **—Dimitris Grammatopoulos**

IMPROVING MORBIDITY AND MORTALITY IN PATIENTS WITH SEPSIS

Recognizing that patients with sepsis have higher mortality rates, King Abdulaziz Medical City in Jeddah, part of National Guard Health Affairs (NGHA) Saudi Arabia, in 2018 began

:Ergin Yalcin / iStock

using the sepsis biomarker procalcitonin (PCT) to identify patients at risk of worse outcomes due to possible septicemia. Early diagnosis in conjunction with timely and specific treatment are keys to reducing mortality from sepsis. The test is being used both in the emergency room and in the intensive care unit (ICU) to help improve turnaround time of less than one hour, enabling rapid patient management and treatment.

Patient mortality due to sepsis in the ICU decreased by 20% following the implementation of the PCT-guided protocols, according to Abobaker Yagoot, MT(ASCP), clinical biochemistry supervisor at the hospital laboratory. Using PCT has also decreased length of stay by 1.5 days, which helps reduce the risk of patients getting a hospital-acquired infection.

"PCT has helped the doctors in optimizing the patients' diagnosis and treatment monitoring," according to Yagoot. "A simple blood test added by the laboratory had a triple effect: the right diagnosis quickly, reduced length of stay, and early discontinuation of antibiotic treatment."

Asem al Saadi, MD, head of infection control for the hospital, added that using the PCT test in concordance with other biomarkers made it easier for physicians to differentiate between sepsis and non-sepsis patients and give the right treatment accordingly.

Another benefit of implementing PCT testing is that the readmission rate for sepsis patients related to hospital-acquired infections decreased by 11%, which is significant in government-run hospitals that have limited bed availability.

In a survey conducted in the ICU and Family Medicine Departments, 86% of physicians said they were satisfied with the PCT-guided protocol, including laboratory results and turnaround time of less than 1 hour in 98% of total samples.

NGHA is the first hospital in the western region of Saudi Arabia to use a PCT-guided sepsis protocol. Since implementation, three additional hospitals – both private and governmental – have replicated this best practice.

"Our laboratory is processing more than 2,800 samples per

Improving Morbidity And Mortality In Patients With Sepsis

2,800
Procalcitonin tests processed daily for hospital inpatients, outpatients, and other primary health care and dialysis centers

20%
Decrease in patient mortality in the ICU due to sepsis

1.5 days
Decrease in length of stay for patients with sepsis

11%
Decrease in readmission rates for patients with sepsis

"A simple blood test added by the lab had a triple effect: the right diagnosis, reduced length of stay, and early discontinuation of antibiotic treatment."
—Abobaker Yagoot

day, serving not only the hospital inpatients and outpatients, but also another seven primary health care centers and one dialysis center in the area covering Makkah, Taif and Jeddah cities," said Mohammed Al Mohammadi, MD, pathology chairman and medical director. "Adding the PCT test to our portfolio didn't put any extra pressure on our instruments or our staff as we have full lab automation with middleware to expedite the verification and decrease turnaround time. Adding PCT has helped us step forward in reaching our destination of full optimization."

Mitigated costs due to expedited care and treatment of sepsis patients translates to annualized savings of $250,000 per year, according to Yagoot. This includes savings of $168,000 from reduced length of stay, $35,000 from proper antibiotic utilization, and $47,000 from reduction in readmission rates.

The initiative was moderately easy to implement, said Yagoot. The hospital needed to include the test in its contract to secure the continuation of supply, and clinicians needed to be educated about the test and how to interpret results. Getting the test set up in the lab took some extra work in terms of validation, coding, and IT. The hospital is continuing education for existing and new clinicians in different departments to keep them up to date with global guidelines and changes.

"This approach is easily adaptable to similar processes in the lab or to other laboratories," said Yagoot. "The utilization of laboratory intelligence was the major component of the success of this initiative, as it contributed to consistency in the entire testing cycle and desired turnaround time."

Yagoot added that an additional benefit of the new initiative is that other hospitals have begun implementing PCT testing, which is saving lives throughout Saudi Arabia. "In addition, being pioneers in this test implementation is an added value for our reputation among other hospitals," he said.

OPTIMIZING PATIENT CARE

Whether preventing cardiovascular disease with high-sensitivity troponin testing or using procalcitonin testing to speed appropriate care for patients with sepsis, clinical laboratories around the world are making a real difference in improving patient outcomes.

These initiatives demonstrate that transformational changes don't necessarily need to be complicated. Sometimes, as is the case with the high-sensitivity troponin testing at Medcan, necessity really is the mother of invention. While the COVID-19 pandemic led Medcan to begin using hs-cTnI testing in place of traditional stress tests, the impact was so significant that the change is now permanent.

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.

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UNIVANTS 2021 Teams Recognized In This Issue

Preventing Cardiovascular Disease in a Large Client Population Through Proactive, Cost-Effective and Enhanced Identification of Cardiovascular Risk Using a Novel Laboratory Test

Medcan Health Management, Inc.

Ontario, Canada

Peter Nord
Peter Baxter
Shaun Francis
Neil Mahon
Yogini Walli

Improving COVID-19 Clinical and Translational Challenges via Multidiscipline Integrated Diagnostics Networks

UHCW NHS Trust and Warwick Medical School

Coventry, United Kingdom

Dimitris Grammatopoulos
Harpal Randeva
Lisa Berry
Asad Ali
Neil Anderson

Improving Morbidity and Mortality in Patients with Sepsis

King Abdulaziz Medical City

Jeddah, Jeddah, Saudi Arabia

Abobaker Yagoot
Mohammed Al Mohammadi
Ali Bawazeer
Bilqasem Al Barakati
Fahad Al Hameed
Asim Al Saedi
Anwar Borai

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