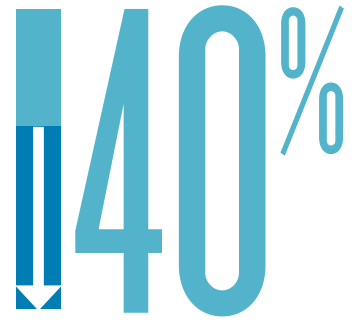


C L N

Clinical
Laboratory
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

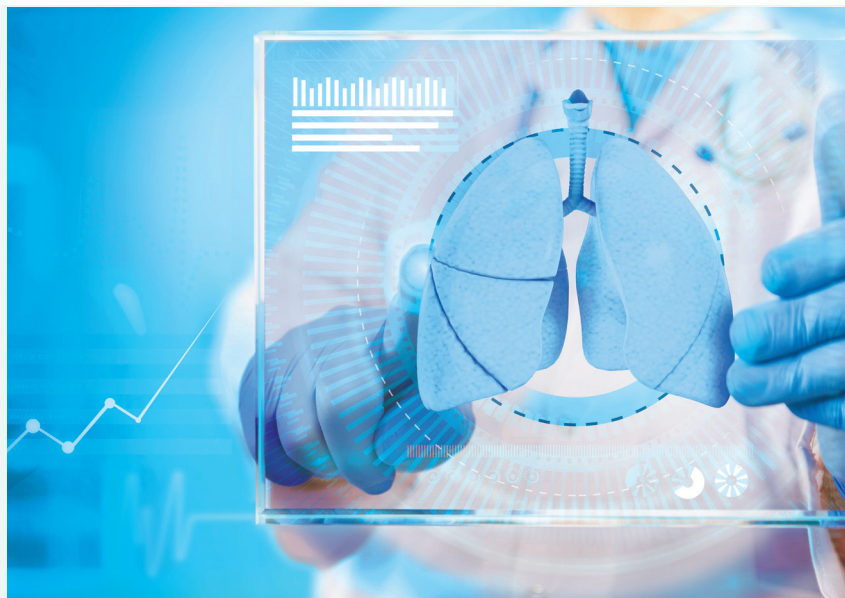
Improved Safety for Patients with Indeterminate Pulmonary Nodules Through Optimized Diagnostic Pathways for Lung Cancer

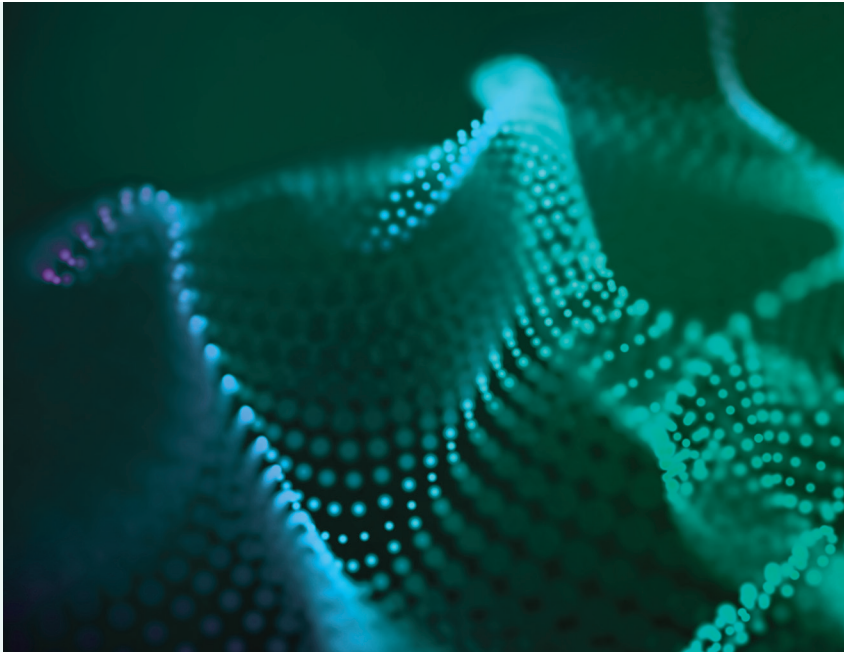
24.1%

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



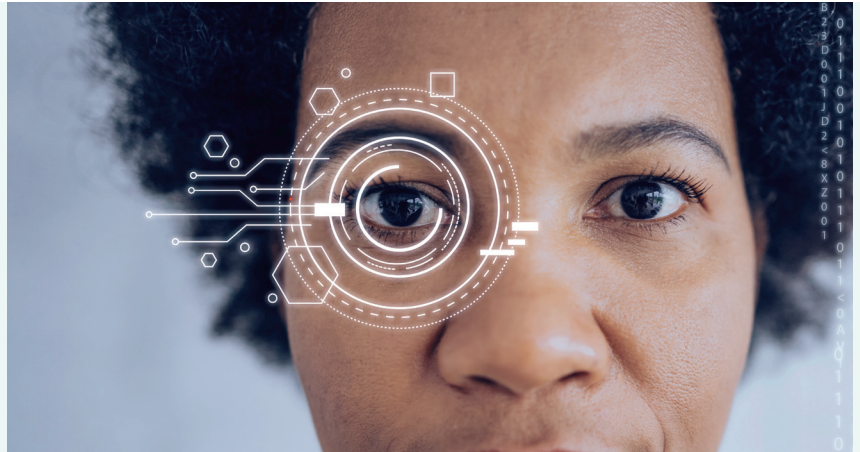
Pre-Surgical Biomarker Risk Assessments in Patients Undergoing Eye Surgery

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.

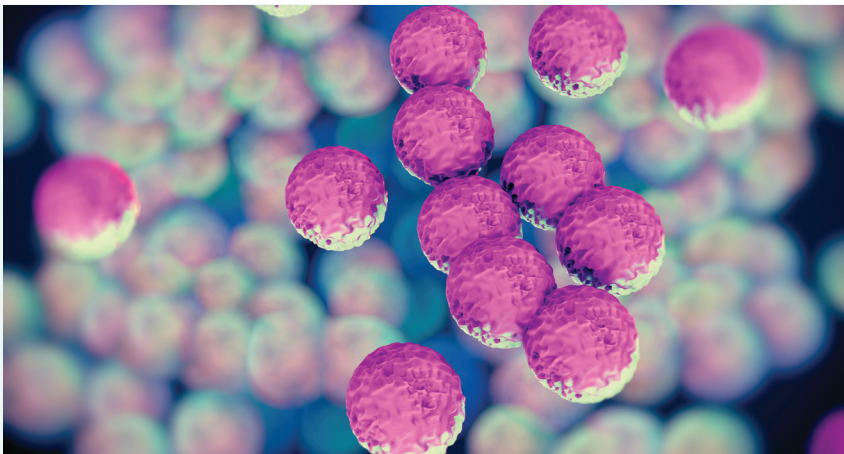
Introducing PCT in the ED of a non-specialized acute trust has helped clinicians manage a high-risk group. These patients have a 2.4-fold increase in mortality rate (7.7% v. 18.2%) and benefit from enhanced monitoring

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

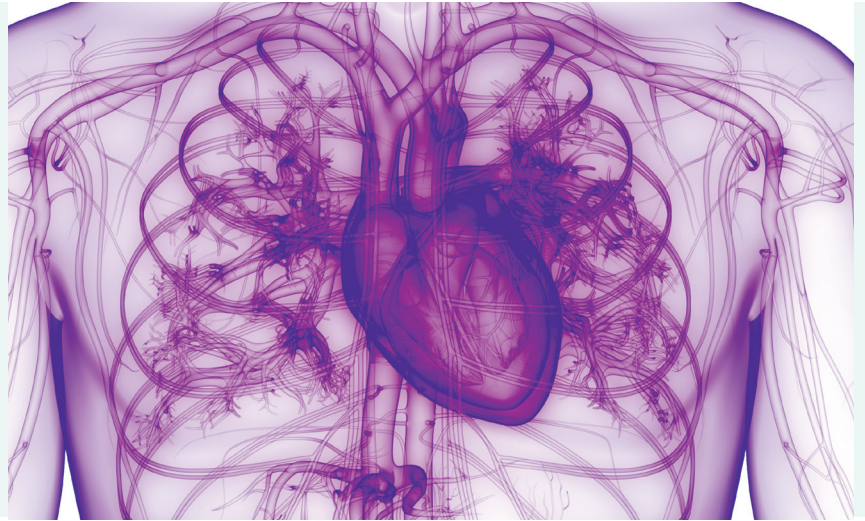
Improving Care of Patients with Suspected Cardiovascular Disease

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 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. ■

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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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