



Making a Difference in the Health of Populations Worldwide

Clinical laboratories demonstrate how combining collaboration and innovation breaks down barriers to better health. **BY KIMBERLY SCOTT**

As clinical laboratories continue to focus on adding value beyond individual test results, their role in improving the health of populations has become critically important. Whether detecting gestational diabetes early enough to prevent complications or using less invasive means of detecting colorectal cancer, laboratory testing is essential to population health.

Below, we highlight four initiatives involving clinical laboratories that have made a difference in the health of specific populations in various parts of the world. These initiatives have been recognized by AACC, in conjunction with Abbott and other leading healthcare organizations, through the UNIVANTS of Healthcare Excellence Awards. The awards recognize interdisciplinary teams around the globe that have achieved measurable, innovative impacts within healthcare systems.

Over the past two years, *Clinical Laboratory News* has been profiling initiatives recognized through the UNIVANTS program, including three population health initiatives highlighted in the December 2020 special supplement: Kidney Check: The Next Generation of Surveillance for Hypertension, Diabetes



and Chronic Kidney Disease; Early Diagnosis and Improved Management of Patients with Diabetes Through Strategic and Automated Test Algorithms via Primary Care; and Novel Collaborative Approach Among Public and Private Sectors for Streamlined SARS-CoV-2 Testing Toward Optimized Patient Outcomes During the COVID-19 Pandemic.

EARLY DETECTION AND MANAGEMENT OF GESTATIONAL DIABETES MELLITUS

Prevalence of gestational diabetes mellitus (GDM) is increasing worldwide, mainly driven by increases in obesity, older age of pregnant women, and higher prevalence of sedentary lifestyles. GDM has direct associations to adverse outcomes in mothers, their babies, and pregnancy-related complications. Short-term complications of GDM include pregnancy-induced hypertensive disorders, premature labor, shoulder dystocia, caesarean section, and low or high birthweight. Long-term complications include risk of developing glucose disorders, cardiovascular disease, and increased likelihood of cancer.

In 2006, the Hospital Clinic San Carlos in Madrid, Spain, defined a new pathway for diagnosis of GDM in pregnant women. The central laboratory helped coordinate obstetrician consultation and blood draws, as well as all related testing and follow-up. Women were screened between weeks 24 and 28 of pregnancy with a two-step process. First, they were screened using the O'Sullivan test, and if the glycemia



value was higher than 140 mg/dL, the patient underwent a 100g oral glucose overload, using the Carpenter-Coustan criteria for the diagnosis of GDM.

"The clinical laboratory coordinating the diagnostic process was fundamental for improvement both at the care level and in terms of patient satisfaction," said Maria Jose Torrejon, MD, head of the Hormones and Metabolism Laboratory at San Carlos. "The number of medical appointments was reduced, and the time for the final diagnosis of GDM was reduced from 24 to 4 days. Further, 96% of pregnant patients served by the hospital had GDM screening carried out before week 28."

The expedited testing procedures meant that fewer patients were lost to follow-up, and more at-risk patients were identified that were previously missed. The hospital implemented the one-step International Association of Diabetes and Pregnancy Study Groups (IADPSG) recommendations for GDM screening and used the approach to detect and treat more pregnant women with GDM, including those with low hyperglycemia.

As a result of the screening initiative, diagnosis of GDM increased from 10.6% to 35.5%, resulting in targeted treatment and reduction in GDM-related complications for mothers and their newborns. Overall direct cost savings of 15,000 euros per 100

women were achieved, corresponding to an annual savings of 250,000 euros. Although the team expected—and observed—an increase in pregnant women diagnosed with GDM, overall healthcare costs were reduced due to fewer complications: gestational hypertension problems (-14.6%); premature births (-10.9%); Caesarian sections (-6.5%) and admissions to the NICU (-24.4%).

"Without global consensus or standardized guidelines for diagnosis and treatment of GDM, there are differences of opinions with respect to how and whom to treat," said Nuria Garcia de la Torre, MD, a consultant endocrinologist. "With the expansive research performed at our site, however, driving positive outcomes for our patients, we know our process works, enabling us to give high quality care."

This highly scalable GDM screening initiative was recognized by the UNIVANTS of Healthcare Excellence program with distinction.

ENHANCED IDENTIFICATION FOR HCV AND HIV IN THE ED

Hepatitis C virus (HCV) and human immunodeficiency virus (HIV) are underdiagnosed and untreated chronic diseases with growing health concerns. Globally, an estimated 71 million people have HCV and 38 million have HIV2, representing major

10.6% to 35.5%
Increase in the percentage of pregnant women diagnosed with GDM

24 days to 4 days
Reduction in time from first visit for GDM screening to final diagnosis

Hospital Clinic San Carlos, Madrid

public health burdens. The World Health Organization estimates that 21% of HIV-positive individuals are unaware of their status. Thus, identifying individuals with unknown disease while successfully enabling treatment is essential for disease containment and prevention. Linkage to care is especially complicated in high risk and underserved populations who utilize emergency care services as their primary healthcare option.

An integrated clinical care team at the University of Alabama-Birmingham (UAB) Hospital sought to change this paradigm by enhancing identification and care for patients with undetected HCV and HIV. In partnership with the emergency department (ED), infectious disease physicians, linkage coordinators, information technology, and the clinical laboratory, the team developed and implemented an opt-out screening program within the ED coupled with disease-specific linkage-to-care services. The HIV screening program was implemented in 2011, and the HCV screening program was implemented in 2013.

Active education and physician-level endorsement led to an increased uptake in population screening, resulting in a 61% increase in the number of patients with newly identified HCV infections linked to HCV treatment and care, and 100% of acutely infected HIV and 84% of chronically infected individuals linked to care. Dedicated care coordinators enhanced patient engagement and ensured sustained linkage to care with routine consultation and subsequent confirmation, as appropriate. In addition, 99 known HCV positive individuals previously identified by HCV antibody testing were re-engaged to care. This care coordination and improved access to HCV providers led to a 91% reduction in the average days between testing and initial medical appointments, enabling rapid treatment and reduced overall healthcare costs.

"Early diagnosis is critical for linking someone with care shortly after their diagnosis, while it's still fresh in their mind," said Joel Rodgers, clinical research administration manager in emergency medicine at the UAB. "If someone tests positive for HIV at the screening level in the ED, we perform a rapid confirmatory test. If that comes

back positive, the ED physician gives the patient a packet of information and has a conversation with the person. A linkage coordinator follows up to schedule an appointment. We do the same for HCV, although there is no rapid test to confirm."

Given that ED visits are costly and can lead to other high-cost services, the screening initiative resulted in a 76% reduction in healthcare costs when primary care appointments were used in lieu of emergency department visits (\$1,067 versus \$13,898 per visit).

Since implementing the initiative in Birmingham, the university has expanded it to two other hospitals within the system, Rodgers noted. The HCV/HIV screening initiative was recognized by the UNIVANTS of Healthcare Excellence program with distinction.

USE OF FIT TO SCREEN FOR SIGNIFICANT BOWEL DISEASE

Recognizing that patients presenting to general practitioners (GPs) with new bowel symptoms can be difficult to assess, as symptoms are poor predictors of pathology, the National Health Service (NHS) in Tayside, Scotland, in 2015 implemented a new screening initiative for significant bowel disease.

In Scotland, colonoscopies are not standard screening exams but are used to diagnose patients who present with new bowel symptoms. During the pilot for the screening initiative, at least 35% of patients were referred for colonoscopies after presenting with bowel symptoms, but colorectal cancer was identified in only 2 of 4,000 patients screened, and inflammatory bowel disease was identified in 5%.

Clinicians believed there had to be a better way to investigate these patients than simply referring them for colonoscopies and thus introduced fecal immunochemical tests (FIT) to quantify fecal hemoglobin (fHb), which then determines whether patients should be referred for a colonoscopy. Tayside now uses FIT to screen for significant bowel disease, along with clinical history and other blood tests. The FIT test is sent home with patients, who collect their own samples and returns them to the lab. Results are typically returned in less than 24 hours, allowing GPs to quickly refer patients who have a high fHb.

In practice, this translates to

2,349/195

Newly diagnosed HCV/HIV infections in patients seen in the emergency department

91%



Reduction in average days between testing and initial medical appointments

University of Alabama-Birmingham Hospital

approximately one-third of patients who present to their GP with new bowel symptoms who in the past would have been referred for a colonoscopy now being screened with FIT. In Tayside, that means almost 1,400 patients each year do not have to be referred for invasive testing. Patients with a very high fHb have a greater than 50% risk of SBD and are referred for urgent colonoscopy. Since the initiative began, referrals for colonoscopies have dropped by 15%.

"For an individual patient, the impact is extremely significant," said Judith Strachan, BSc, FRCPath, a consultant clinical scientist with NHS Tayside. "First, a negative FIT test in the absence of other worrying signs and symptoms means that they are highly unlikely to have significant bowel disease. This means that they do not need an invasive and unpleasant colonoscopy and can be reassured that they do not have significant disease, thus reducing anxiety and a wait for further tests. For patients with ongoing symptoms, advice and safety netting is available with repeat FIT testing if necessary. For patients with elevated FIT results, they may well be 'fast tracked' to more investigations, thus leading to a quicker diagnosis of significant bowel disease."

In the first year since introducing FIT as a standard test available to GPs, referrals in NHS Tayside from primary care via the Colorectal Pathway fell 9%, and referrals to gastroenterology fell 24%. Overall reduction in referrals was 15%.

70,000

Number of people in Mexico who have become more aware of the complications and risks of HCV

221

Number of people confirmed to have active HCV infections

Biomédica de Referencia and Mexican Foundation for Liver Health

The FIT work led by NHS Tayside has made a significant contribution to patient care, Strachan said. Due to Tayside's pioneering work, FIT testing in primary care is now universally available in NHS Scotland. The service was in place before the COVID-19 pandemic, but its value to diagnostic services has been greatly emphasized during the recovery phase, Strachan said. The FIT initiative was recognized by the UNIVANTS of Healthcare Excellence program with distinction.

SCREENING FOR UNDETECTED HEPATITIS C

Left untreated, patients with chronic hepatitis C (HCV) can develop cirrhosis or liver cancer. To improve the identification and treatment of patients

with HCV, Biomédica de Referencia, a clinical laboratory and imaging company in Mexico City, in 2007 partnered with the Mexican Foundation for Liver Health (FundHepa) to develop a screening program for HCV. An integrated care team formed to overcome key barriers for HCV identification and treatment, such as lack of public awareness, cost of testing, access to education, follow-up, and treatment.

The team led comprehensive media campaigns to raise disease awareness, collaborated with partners to make HCV screening available free of charge, and developed treatment strategies that linked all HCV-positive patients to relevant education and care.

The program has had significant, and enduring, success. Between 2007 and 2019, there was an eight-fold increase in the number of patients screened for HCV—1,170 people in 2007 to 9,372 people in 2019. To date, more than 70,000 individuals in Mexico have become more aware of the complications and risks of HCV. Further, 367 people with detectable anti-HCV antibodies (0.5%) have been identified by the program. Among those, 221 were confirmed to have active HCV infection. Identification of these individuals enables rapid treatment, prevents disease progression, and reduces health-care costs. Success of the program has led to 29 additional companies and six clinical laboratories across Mexico joining the initiative with a collective goal of improving public health in Mexico.

While the initiative started as a social responsibility project coordinated by a committee of 10% of Biomédica de Referencia's employees, the campaign now involves almost half of the organization's workers, something of which the chief executive officer and clinical director of Biomédica de Referencia is proud.

"Too often medicine is reactive," says CEO Clara Corona de Lau. "Our care initiative has proactively identified hundreds of patients who need care, who have benefited from treatment, and who ultimately helped reduce the spread of this deadly disease. Our entire staff takes great pride in supporting HCV elimination and favorably impacting public health."

Given that the average cost of treatment for late-stage complications of HCV infection is more than three times higher than the cost of treatment in the early stages of the disease, the screening initiative also has significant cost savings implications.

"Discovering HCV-positive patients in the early stages of the disease truly increases the chance of better outcomes and reduces downstream treatment costs substantially," said David Kershenovich, MD, PhD, hepatologist and Director of the National Institute of Health Science and Nutrition Salvador Zubiran.

EARLY INTERVENTION IS KEY

Detecting diseases and chronic conditions early enough to have a significant effect on patient outcomes is essential to improving the health of populations. Early detection is a core element in all four of the initiatives highlighted. These interdisciplinary initiatives have made measurable positive impacts on targeted populations while at the same time contributing to cost savings, as treatment in the early stages of a disease almost always costs less than treatment in more advanced stages.

These are just a few of the projects in which clinical laboratories are playing a critical role in transforming healthcare delivery. To learn about other initiatives recognized through the UNIVANTS of Healthcare Excellence program, go to www.univantshce.com. ■

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UNIVANTS 2020 Teams Recognized In This Issue

Identification and Care for Patients with Undetected HCV and/or HIV via Opt-Out ED Screening with Active Education and Linkage to Care | University of Alabama Birmingham Hospital | Lauren Walter, Sonya Heath, Joel Rodgers, Adrienne Moore, Kelly Ross Davis

Use of Fecal Immunochemical Tests Unlocks the Door to Efficient and Effective Investigation of Patients with New Bowel Symptoms | NHS Tayside | Judith Strachan, Ian Kennedy, Andrew Cowie, Craig Mowat, Lynne Taylor

Improving Population Health through Screening for Hepatitis C to Enable Treatment for Undetected Viral Infections | Biomédica de Referencia | Clara Corona de Lau, Dana Lau Corona, Evelin Nájera López, Emma Alicia Arana Grimaldo, María Concepción Gutiérrez Ruiz

Early Detection and Management of Gestational Diabetes Mellitus for Improved Outcomes of Mothers and their Babies | Hospital Clínico San Carlos | María José Torrejón, M. Cruz Cárdenas, Miguel Ángel Herráiz Martínez, Alfonso L. Calle-Pascual, Nuria García de la Torre Lobo