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INSIDE THIS ISSUE

Federal Effort to Control HIV Depends on Increasing Testing, Treatment Adherence

To control the spread of HIV in the United States, HIV infection must be diagnosed early and persons with HIV infection must be quickly linked to sustained care and treatment. These are the core tenets of the Trump Administration's proposed 10-year initiative, Ending the HIV Epidemic—A Plan for America. However, knowing one's status, linking newly diagnosed patients to care, and maintaining treatment adherence pose barriers to curtailing the HIV epidemic.

"Providers should screen patients for HIV infection at least once and test some patients more frequently; rapidly link, engage, or re-engage patients into comprehensive HIV care; and encourage patients to

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Microbiology Testing Rates Low For Hospital-Acquired Infections

The European Centre for Disease Control and Prevention (ECDC) estimates that there are 9 million cases of health care-associated infections (HAIs) across Europe each year, according to a study presented at the European Congress of Clinical Microbiology & Infectious Diseases (Netherlands; April 13–16). The survey also reveals low microbiological testing rates that vary widely between countries.

"Our analysis shows that health care-associated infections still pose a major public health threat in European countries and health care institutions", says **Pete Kinross** from the ECDC. "Culture-directed antibiotic treatment is an important aspect of the treatment and control of these kinds of infections. The variability of microbiological testing suggests poor availability of information for effective treatment, as well as alertness to potential outbreaks."

The ECDC conducted point prevalence surveys of HAIs and antimicrobial use in both acute care hospitals and long-term care facilities in European Union and European Economic Area countries

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Federal Effort to Control HIV Depends on Increasing Testing, Treatment Adherence, *from page 1*

sustain viral suppression for their own health and because of the tremendous prevention benefits," write the authors of a recently released *Vital Signs, HIV Transmission Along the Continuum of Care*, published in the March 18 *Morbidity and Mortality Weekly Report*.

DTET

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Fax: 855-649-1623
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According to the U.S. Centers for Disease Control and Prevention (CDC), everyone aged 13 to 64 years should be tested at least once. However, people at higher risk for HIV should be tested at least annually. Sexually active gay and bisexual men need even more frequent testing—every 3 to 6 months. It is known that real-world testing rates fall far below these guidelines and not knowing one's HIV status contributes to ongoing transmission.

In the Vital Signs, CDC released findings of its update to the Progression and Transmission of HIV (PATH 2.0) model to estimate 2016 U.S. transmission rates by step along the HIV care continuum. The CDC researchers found that in 2016, approximately 80 percent of new infections occurred due to persons with HIV infection who did not know they were infected and persons with diagnosed HIV infection who were not in care. More than one-third of transmissions (38 percent) occurred among the 15 percent of people living with HIV who were unaware of their status. In all, CDC estimates that approximately 165,000 Americans live with HIV, but do not know they have it.

Stopping Transmission Among Those in Care

The CDC findings show that 20 percent of new infections occur from the 11 percent of persons with HIV infection who are in care but not virally suppressed. In addition to maintaining viral suppression to prevent sexual transmission to partners, pre-exposure prophylaxis (PrEP), a daily regimen of two oral antiretroviral drugs in a single pill, has proven to be highly effective in preventing HIV infection for individuals at high risk. While known to be effective, many patients are not compliant with the PrEP regimen.

At the Conference on Retroviruses and Opportunistic Infections (Seattle, Wash.; March 4–7) researchers presented early data on a novel point-of-care (POC) antibody-based assay that can assess patients adherence to treatment. Real-time, POC detection of non-adherence can permit immediate intervention by providers to optimize PrEP outcomes.

Matthew Spinelli, M.D., from University of California, San Francisco, and colleagues measured urine tenofovir (TFV) levels using this novel antibody-based assay and compared TFV levels to detection levels using the gold standard liquid chromatography tandem mass spectrometry (LC-MS/MS) of hair and dried blood spot (DBS) samples among 125 men and transwomen participating in a PrEP demonstration trial.

They found that urine TFV levels were significantly correlated with other pharmacologic measures with high specificity in detecting sub-optimal dosing (low adherence). The median urinary TFV level by the immunoassay was 15,000 ng/ml (in those who remained HIV-negative), 5,500 in 11 individuals

who eventually seroconverted, and undetectable (less than 1,000 ng/ml) in all nine individuals at the time of seroconversion.

"What we found is low versus high levels of TFV with this amino acid test were associated with 14-fold higher risk of developing HIV in the future. The idea is that if we have this adherence information at the bedside through the means of a POC test we can intervene and help support our patients and prevent HIV infections Spinelli told *MedPage Today* at the conference. "Because PrEP is a prevention intervention, it's not like a lot of other diseases ... where I have sort of a surrogate marker of how people are doing, like A1C in diabetes or the viral load in HIV."

Spinelli says the goal of this POC test would be to have more information about patients' adherence to have that conversation with them at the visit and support them and motivate them to have good adherence on PrEP to stay HIV negative.

Takeaway: Testing will play an important role in a federal push to curtail the spread of HIV in the United States by increasing HIV screening and through possible future adoption of POC tests able to detect PrEP adherence.

EmergingTests: Improved Accuracy of Point-of-Care HbA1c Tests May Expand Access to Testing

The U.S. Food and Drug Administration-cleared POC Afinion HbA1c Dx test (Alere Technologies a subsidiary of Abbott Laboratories) is accurate and precise for diagnosing diabetes using both fingerstick and venous whole blood samples, according to a study published in the *Journal of Diabetes Science and Technology*.

While the American Diabetes Association recommends HbA1c for use in diagnosing diabetes, the variable performance of previous POC testing devices, in combination with a lack of mandatory proficiency testing in some POC settings, has prevented the ADA from endorsing of POC HbA1c methods, the authors say. Yet, it is recognized that POC testing holds speed and convenience advantages, particularly for patients in underserved areas.

The National Academy of Clinical Biochemistry (NACB) recommends that clinical HbA1c assays should achieve an imprecision of less than 3% coefficient of variation (CV) and should be NGSP- (formerly called the National Glycohemoglobin Standardization Program) certified. Currently the NGSP requires 92.5% of results to be within ±6% of a reference method traceable to the Diabetes Control and Complications Trial, which will be tightened this year to 90% of test results within ±5% of the reference method result

The current trial was conducted at three diabetes and endocrinology

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Improved Accuracy of Point-of-Care HbA1c Tests May Expand Access to Testing, *from page 3*

research centers using the same three lots of test cartridges and Afinion AS100 Analyzers. HbA1c values across the assay range were evaluated to assess clinically relevant HbA1c intervals.

The precision and accuracy of the POC test using fingerstick and venous whole blood samples was compared to values obtained by an NGSP secondary reference laboratory (SRL). Two fingersticks were collected per each of the 120 participants and tested on two cartridge lots. Each of the three sites assessed one participant at each of the four pre-specified %HbA1c levels (low, threshold, medium, and high) using whole blood for a total of 12 participants (three per level) enrolled July to August 2015. Four replicates were tested on each of the three test cartridge lots, two times per

Comprehensive, School-based Cardiovascular Screening Is Feasible, Effective

Comprehensive screening for cardiovascular risk, including testing for cholesterol and diabetes, is feasible in middle schools, according to a small study published in the *Journal of Pediatrics*. Furthermore, screening in some school settings has a high yield of abnormal test results.

While The American Academy of Pediatrics, the American Heart Association, and the American Diabetes Association recommend screening older, school-age children for weight status, hypertension, lipid abnormalities, and diabetes, it is known that the majority of children are not being screened in primary care offices.

Researchers from Cincinnati Children's conducted a pilot to assess the feasibility of universal screening for diabetes, lipid abnormalities, and hypertension in the middle-school setting. Diabetes screening (hemoglobin A1c [HbA1c] testing) was offered to all participating students, since medical histories were not available. Only one mailing requesting consent was mailed to families.

Of the 290 seventh and eighth grade students, 16 percent of parents consented at Northwood Middle School, located in a city of 20,000 people without a pediatric practice in its city limit. Screening was conducted during two 4-hour morning sessions. A letter was sent home with the screening results and suggestions for follow-up, if needed, with a primary care provider or an appropriate pediatric subspecialist, if indicated. Guardians of children with critical screening values were called and appropriate follow-up was arranged.

Of 45 children screened, more than one-third of children (34.8 percent) had lipid or hbA1c abnormalities. Two students had HbA1c values in the diabetes range, while two students had a cholesterol level above 200 mg/dL with a calculated low-density lipoprotein greater than 140 mg/dL. Three additional students had a total cholesterol between 169 and 200 mg/dL with normal calculated low-density lipoprotein values. Of the two students with HbA1c above 5.6, both were asymptomatic and referred to a pediatric endocrinologist for evaluation where one was diagnosed with maturity onset diabetes of youth type 1 and the other girl was diagnosed as with type 2 diabetes.

"We were shocked with the diabetes screening results," said lead author **Robert Siegel, M.D.**, in a statement. "Most studies show that around 20 percent of kids will have abnormalities, so we weren't too surprised by the results of the lipid screening. Our message is to get screened."

day for 10 consecutive days resulting in 240 measurements per site (720 measurements for each HbA1c level).

Across the assay range, POC test results from fingerstick and venous whole blood samples were highly correlated with results from the NGSP SRL (Pearson correlation = 0.99). The mean bias was –0.021% HbA1c using fingerstick samples and –0.005% HbA1c for venous samples. For fingerstick, imprecision ranged from 0.62% to 1.93% CV and 1.11% to 1.69% CV for venous samples.

"These results demonstrate that both the precision and accuracy of the POC test evaluated here meet the performance standards of the NGSP and NACB and that the test is therefore suitable for use in the diagnosis of diabetes and in the identification of people at risk of developing diabetes," write the authors led by **William D. Arnold**, Ph.D., from Abbott Rapid Diagnostics (San Diego, Calif.). "This has important implications for clinical care, as POC HbA1c testing has the potential to expand patient access to diabetes diagnostic testing and expedite medical decisions and interventions aimed at the prevention of diabetes and its complications, particularly for those who face challenges in accessing traditional health care settings or attending multiple laboratory and physician follow-up appointments."

Takeaway: New POC HbA1c testing tools show improving accuracy and precision, which should enhance their use in underserved areas and nontraditional health settings, thereby improving access to testing and expediting diabetes diagnoses.

EmergingTests: New Point-of Care Paper Test May Improve Diagnose of Preeclampsia

The Congo Red Dot (CRD) Paper Test is a simple, rapid, non-invasive tool that that may improve triage and the accuracy of preeclampsia (PE) diagnosis at the point of care, according to a pilot study published in *E-Clinical Medicine*. Further, the CRD Paper Test outperforms previously proposed serum and urine markers for PE. The authors say adoption of the CRD Paper Test as a triage tool could not only improve diagnosis, but could avoid unnecessary pre-term deliveries.

"It is not only inexpensive, easy to use, highly accepted by the nursing staff, but identifies women with PE within 3 minutes," write the authors led by **Kara Rood**, from Ohio State University in Columbus. "If the CRD Paper Test results were available to obstetrical providers, a negative CRD Paper Test could improve wait times in obstetrical triage areas, avoid unnecessary admissions and lower the associated health care expenses."

PE is typically diagnosed by hypertension and protein in the urine.

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New Point-of Care Paper Test May Improve Diagnose of Preeclampsia, *from page 5*

However, its diagnosis is complicated by presentation of other nonspecific symptoms, including headache. Yet, PE is responsible for a significant proportion of prenatal and pregnancy-related maternal mortality and morbidity worldwide. Delays in diagnosis exacerbate these serious complications. Previous research showed that proteins in the urine of PE patients bind to Congo Red dye (urine congophilia).

In the present study, researchers designed, developed, and validated a simple point-of-care, paper-based urine test kit. Test performance was evaluated for rapid triage and diagnosis of PE among 346 consecutive pregnant women evaluated for PE in the labor and delivery triage unit of a tertiary medical center (July 2014 to July 2015).

CRD Paper Test results were compared to an expert adjudicated diagnosis in each case, as well as to urine and serum analytes (placental growth factor and soluble fms-like tyrosine kinase-1), previously proposed as diagnostic aids for PE.

The researchers found that during the first triage visit just under one-third of all women received a clinical diagnosis of PE; yet, 63 percent of all women were admitted for an in-patient diagnostic work-up or delivery. The CRD Paper Test was positive in one-fourth of all participants (n = 86). Expert-confirmed diagnosis was made in PE in 96 cases. Urine congophilia was detected in 14 patients (12 percent) admitted with an uncertain diagnosis and in only 59 patients (58 percent) admitted with a diagnosis of PE. Among patients discharged home without a PE diagnosis, there were nine positive congophilia tests (8 percent), while the CRD Paper Test was positive in four patients discharged with a diagnosis of PE (36 percent).

The CRD Paper Test outperformed serum and urine markers with performance of 80.2 percent sensitivity, 89.2 percent specificity, 92.1 percent negative predictive value, and 86.7 percent accuracy. The CRD Paper Test had a positive post-test probability of 74 percent and a negative post-test probability of 8 percent, meaning one in 1.44 patients with a positive test has PE, while one in 1.1 patients with a negative test does not have PE.

"The operational simplicity of the CRD Paper Test fulfills the current needs for a diagnostic tool to aid in the rapid assessment and triage of women with uncertain PE diagnosis," writes Rood and colleagues, two of whom have financial ties to GestVision Inc., which holds the license for the CRD test developed by the authors. "The CRD Paper Test adds clarity to help differentiate PE from PE imitators, which should result in fewer iatrogenic preterm deliveries."

Takeaway: The CRD Paper Test is a simple, rapid, non-invasive tool that that holds potential to the accuracy of PE diagnosis at the point of care.

Testing Trends: Progress Seen With EGFR Testing, But Adoption Still Lagging

Incomplete implementation of EGFR testing guidelines remains a problem in the realm of non-small cell lung cancer (NSCLC), according to a study published in the *Journal of Global Oncology*. The authors say that non-testing means a large proportion of patients cannot receive life-extending targeted therapies.

While international guidelines recommend testing for EGFR mutation at diagnosis of advanced NSCLC to guide treatment, the extent of adoption of testing has not been fully understood. Thus, an international group of researchers conducted two surveys, 18 months apart, to identify changes in EGFR mutation testing and treatment practices.

The first online survey questioned 562 physicians (oncologists, pulmonologists, and thoracic/respiratory surgeons) from Canada, France, Germany, Italy, Japan, South Korea, Spain, Taiwan, the United Kingdom, and the United States (December 2014 to January 2015). The second round surveyed 707 physicians in the same countries, plus China, between July and August 2016. All respondents verified they had a role in treatment decisions for patients with NSCLC (an average of 70 patients per physician).

The researchers found that globally, physicians requested EGFR mutation testing for 80 percent of patients before first-line therapy, with slightly lower rates in North America (77 percent). In 2016, 18 percent of requested results were not received before initiating treatment, a significant drop since 2015 when results were not received in time for 23 percent of requests. In the 2016 survey, respondents were asked how quickly results were available and for the majority of EGFR tests, results were available within 10 business days. However, nearly one-quarter of test results were received later.

Excluding tumor histology, in 2016, the main reasons for not testing included insufficient tissue (63 percent), poor performance status (40 percent), not believing results would impact therapy decisions (21 percent), and long turnaround time (21 percent). Notably the excuse of turnaround time significantly dropped from 30 percent in 2015.

"Although the two surveys do show a year-on-year improvement, some patients with advanced lung cancer carrying activating EGFR mutations appear to receive care that is not in line with current evidence and guidelines," conclude the authors led by **Matthew Peters, M.D.**, from Macquarie University in Australia. The study was funded by the pharmaceutical company Boehringer Ingelheim.

Takeaway: While progress has been made in EGFR testing to drive targeted treatment for NSCLC, adoption of testing guidelines remains far from universal.

TestingTrends: Serial CRP Results Predict Continued Risk Following Heart Attack

Serial Measurements of Inflammatory Marker After Heart Attack IDs Residual Risk

Serial measurement of high-sensitivity C-reactive protein (hsCRP) levels following acute coronary syndrome may help better identify patients at greater risk for recurrent cardiovascular events or death despite optimal medical therapy, according to a study published March 6 in *JAMA Cardiology*. These high-risk patients may benefit from more intensive treatment.

Data for this study came from secondary analysis of the Vascular Inflammation Suppression to Treat Acute Coronary Syndromes clinical trial that included 5,145 patients (treated at 362 academic and community hospitals in Europe, Australia, New Zealand, India, and North America). The 4,257 included patients (73.8 percent male; mean age 60.3 years) were optimally medically treated with antiplatelet and cholesterol-lowering medications and had available baseline and longitudinal hsCRP levels measured at weeks 1, 2, 4, 8, and 16 after randomization.

"Serial measurements of hsCRP during clinical follow-up after ACS may help to identify patients at higher risk for mortality and morbidity. Further studies will be required to determine whether initial and serial hsCRP measurements can help guide the use of targeted antiinflammatory therapies after ACS to help further reduce residual cardiovascular risk in this vulnerable population."

– Preethi Mani, M.D, Cleveland Clinic Ohio

The researchers found that both baseline and longitudinal hsCRP levels were independently associated with increased risk of a major adverse cardiac event (MACE), cardiovascular death, and all-cause death over 16 weeks of follow-up. Findings remained even after adjusting for drug treatment and baseline hsCRP. Each standard deviation increase in longitudinal hsCRP concentration was associated with a 15 percent increased risk of MACE, 25 percent increased risk of all-cause death, and 26 percent increased risk of cardiovascular death.

"Serial measurements of hsCRP during clinical follow-up after ACS may help to identify patients at higher risk for mortality and morbidity," write the authors led by **Preethi Mani, M.D.**, from the Cleveland Clinic in Ohio. "Further studies will be required to determine whether initial and serial hsCRP measurements can help guide the use of targeted antiinflammatory therapies after ACS to help further reduce residual cardiovascular risk in this vulnerable population."

Takeaway: Patients with increasing inflammation markers following acute coronary syndrome have residual risk for cardiac events and death. Serial measurement of hsCRP may help to customize higher intensity treatment for these high-risk patients.

TestingTrends: Universal HCV Screening of Pregnant Women Is Cost-Effective, Should Be Adopted Nationally, Study Urges

Universal hepatitis C virus (HCV) screening among pregnant women in the United States is cost effective and improves detection of HCV among women and children, according to a study published in *Clinical Infectious Diseases*. The authors call on national professional societies to endorse universal testing.

HCV infection rates among pregnant women have doubled nationally between 2009 and 2014 to about 0.7 percent (or roughly 42,000 pregnancies annually), but infection rates reach as high as 8 percent in rural Tennessee. These increases are largely associated with increases in opioid injection.

Risk-based screening of pregnant women is recommended by the Society of Maternal-Fetal Medicine (SMFM), the American College of Obstetrics and Gynecology (ACOG), and the U.S. Centers for Disease Control and Prevention (CDC), while the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America has joint guidelines recommending universal screening. As of now, Kentucky is the only state to pass HCV testing regulations requiring all pregnant women to be tested during their first prenatal visit with a health provider.

The researchers developed a model to evaluate from a payer perspective the cost-effectiveness of universal HCV screening of pregnant women followed by treatment after pregnancy versus risk-based screening. Baseline assumptions, based on national data, included: 0.73 percent HCV chronic prevalence among pregnant women, no Medicaid reimbursement restrictions for treatment by fibrosis stage at baseline, new HCV drug costs of $25,000/treatment, and a willingness to pay threshold of $50,000 per quality-adjusted life year (QALY) gained.

The model showed that universal HCV screening for pregnant woman was associated with incremental costs of $53.20. Universal screening was cost-effective in all treatment eligibility scenarios, with mean incremental cost-effectiveness ratios of less than $3,000 per QALY gained). Screening remained cost-effective at 0.07 percent prevalence, the lowest estimated prevalence of any U.S. state (Hawaii). Screening the estimated 5.04 million pregnant women in 2018 could result in detection and treatment of 33,000 women based on current fibrosis restrictions.

“Our results support calls for a change of SMFM/ACOG and CDC guidelines to recommend universal HCV screening of pregnant women,” write the authors led by **Antoine Chaillon**, from University of California San Diego. “Our results also provide additional economic evidence in support of the updated AASLD/IDSA guidelines and Kentucky legislation recommending screening pregnant women.”

Takeaway: Given the rise of HCV infection as a result of the opioid epidemic, there is growing momentum to increase HCV screening among U.S. pregnant women.

Compliance Alert: Inova Genomics Warning Letter May Signal Step-Up in FDA LDT Enforcement

By Danielle Sloane and Elaine Naughton, Bass, Berry & Sims PLC

Although it's a continual topic of discussion, FDA enforcement in the realm of laboratory developed tests (LDTs) has been relatively quiet in recent years. But that might have all changed on April 4, 2019 when the FDA issued a warning letter to Inova Genomics Laboratory (Inova) for "illegally marketing certain genetic tests that have not been reviewed by the FDA for safety and effectiveness." Here's a look at the warning letter and what it may portend for labs and the lab industry.

The FDA Warning Letter

The warning letter is aimed at Inova's MediMap tests, which are genetic tests marketed for predicting medication response, reducing negative side effects from certain medications, discovering the right drug and the right dose for a patient and avoiding trial-and-error prescribing by testing patient receptivity to drugs. Specifically, the warning letter highlights a pair of tests:

MediMap Plus, which is designed to provide insights into how a patient might respond to a variety of drugs including those used for anesthesia, cancers, infections, attention-deficit/hyperactivity disorder, depression, anxiety, and diabetes; and MediMap Baby, which analyzes a newborn's genes that influence response to 24 medications.

According to the FDA, Inova's website claimed that the tests provide "actionable and informational guidance" and that "[h]ealthcare providers can use these results confidently in making treatment decisions." Many of the drugs for which the tests produce results include antidepressants or opioids, which can pose serious health risks if the improper dose is given or if the patient stops taking the medication altogether.

The FDA Press Release

In its press release announcing the warning letter, the FDA commented that it "is unaware of any data establishing that Inova's test can help patients or health care providers make appropriate treatment decisions for the listed drug." The FDA stated that this warning letter "reflects the agency's commitment to monitor the pharmacogenetics test landscape and take action when appropriate to address a significant public health risk."

The Director of the FDA's Center for Devices and Radiological Health explained that the FDA is "particularly concerned about pharmacogenetic tests that claim to predict patients' responses to specific medications where such claims have not been established and are not described in the drug labeling and continue to warn patients and health care professionals that they should not rely on these tests for treatment decisions."

What It Means

The warning letter highlights that, according to Inova's website, the "MediMap tests may be ordered by a lab physician in which case test results are provided directly to patients," which "could lead to patients inappropriately increasing, decreasing, or stopping their medication without their physician's involvement. . . ."

We have explored the FDA's skepticism of laboratory relationships and affiliations with the ordering practitioner before. (See "Marketing Laboratory Tests to Consumers: Is a Practitioner Order Enough to Avoid FDA Enforcement?" *Lab Compliance Advisor (LCA)*, March 21, 2016. And what we've seen is that it's not only a physician order, but the independence of the physician behind the order, that may make the difference between LDT enforcement discretion and direct-to-consumer (DTC) enforcement action.

The letter gave Inova 15 days to respond to the FDA with the steps it has taken to correct the noted violations. In an email, Inova stated that it has promptly responded, it takes the FDA's concerns seriously and it's assessing the appropriate path forward to address them.

Takeaway: This warning letter should serve as a reminder to the lab industry on two important points: The FDA can and will take action against LDTs, particularly ones being marketed directly to consumers; and If the physician who orders the test is affiliated with the lab, the physician order may not be sufficient to extricate an LDT from being considered DTC in the eyes of the FDA.

About the Authors:

Danielle Sloane, of Bass, Berry & Sims, helps national life science and healthcare clients navigate the complex maze of federal and state healthcare laws and regulations. With an analytical eye, Danielle helps her clients mitigate legal risk and achieve regulatory compliance consistent with their business goals. Danielle's practice involves fraud and abuse, compliance, regulatory and operational matters, transaction structuring and diligence and government investigations. Danielle advises clients on how they can best innovate, evolve and improve patient care within the confines of current healthcare regulatory laws. Danielle was recognized by Law360 as a Rising Star in healthcare in 2017.

Elaine Naughton provides healthcare regulatory counsel as it relates to compliance, operational and transactional matters. Prior to joining Bass, Berry & Sims, Elaine served as a law clerk to the Honorable David J. Hale of the U.S. District Court for the Western District of Kentucky.

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between 2016 and 2017. The voluntarily participating acute care hospitals and long-term care facilities reported on every patient or resident who was present on the day of the survey. Analysis included 310,755 patients from 1,209 acute care hospital in 28 countries and 117,138 residents from 1,798 long-term care facilities in 24 countries.

One in 15 patients in European acute care hospitals and one in 24 residents in European long-term care facilities have at least one infection on any given day. A microorganism was reported for just over half (53 percent) of the HAIs in acute care hospitals. Antimicrobial susceptibility testing results were not available on the day of the survey for 11 percent of the microorganisms reported. In long-term care facilities, only 19 percent of HAIs had a microbiological test result available to guide treatment and control.

There was great intra-country variability in testing rates, with rates lower in Hungary, Lithuania, and Romania and higher in Belgium, Finland, and the United Kingdom. Countries with lower testing rates detected fewer HAIs. The most common HAIs were respiratory tract infections (particularly pneumonia), accounting for one-fourth of all HAIs in hospitals and one-third in long-term care facilities, followed by urinary tract infections which accounted for one-fifth of hospital HAIs and one-third of long-term care HAIs.

Takeaway: More needs to be done to apply testing guidelines and recommendations in European hospitals and long-term care facilities to boost microbiology testing rates for detection of HAIs and potential outbreaks.