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New Trends, Applications, and IVD Industry Analysis

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Holiday Inn Airport (South)
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Malpractice Lawsuit Calls Out Lack of Genetic Counseling

A 36-year-old Oregon woman filed a $1.8 million medical malpractice lawsuit against her doctors and a southwest Oregon medical center for "negligent diagnosis and treatment" resulting from misinterpretation of genetic test results by a nurse practitioner, gynecologist, and a surgeon. Additionally, the lawsuit cites a failure of providers to refer to a genetic counselor.

Elisha Cooke-Moore was erroneously told her she had the MLH1 gene mutation associated with Lynch syndrome. Cooke-Moore underwent genetic testing for hereditary cancer risk (Myriad's MyRisk test) due to family history—her mother and grandmother's cancers.

While the test report stated, "no clinically significant mutation has been identified," it also flagged a variant of unknown significance (VUS) in the MLH1 gene (MLH1 c.191A>G). Based on a misinterpretation of the results by her physicians, Cooke-Moore was diagnosed with Lynch Syndrome and underwent a preventive double mastectomy and hysterectomy in 2016. It was only after her surgeries, when seeking consultation for complications, that another doctor caught the misdiagnosis.

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High-Deductible Plans Tied to Reduced Use of Health Care, Including Diagnostic Testing

People enrolled in high-deductible health plans (HDHPs) cut their use of health services, including laboratory testing, according to a study published in the October issue of *Health Affairs*. HDHPs lower health care costs as a result of a reduction in the use of health services, including appropriate services, the authors conclude.

"Our review highlights the adverse effect of HDHPs on the use of preventive services," write the authors led by led by Rajender Agarwal, director of the Center for Health Reform, in Dallas, Texas. However, the authors note that few HDHPs charge members for preventive screenings, suggesting patients don't understand they could receive these services at no cost.

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Malpractice Lawsuit Calls Out Lack of Genetic Counseling, *from page 1*

The American College of Medical Genetics and Genomics states in its 2015 guidelines for the interpretation of sequence variants that a VUS should not be used in clinical decision making. The guideline goes on to say that while efforts to reclassify the variant are underway, additional patient monitoring may be wise.

The complaint states the "plaintiff was not sufficiently informed about Lynch Syndrome or the meaning of genetic testing results." Additionally, the lawsuit specially states that the plaintiffs did not refer to a genetic counselor "before or after undergoing testing, as recommended by the National Cancer Institute."

This case highlights the importance of appropriately counseling patients about genetic risk factors particularly when non-genetic experts are ordering tests and in settings, like southern Oregon, where there are shortages of genetic counselors.

Takeaway: While this lawsuit does represent an individual case, clinical laboratories can play an important role in assisting providers regarding variant interpretation and patient counseling.

DTET

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Bilirubin as a Predictor of Neonatal Jaundice

For infants of mothers with blood group O, arterial umbilical cord bilirubin (aUCB) predicts development of neonatal jaundice due to haemolytic disease, according to a study published Sept. 20 in *BMC Pediatrics*.

"Estimation of UCB at delivery is practicable, cheap and non-invasive," write the authors led by Kelsey D. J. Jones, from Imperial College in the United Kingdom. "It could be easily integrated with the current trend towards routine umbilical cord blood biochemical evaluation practiced in many centers."

Hyperbilirubinaemia is among the most common causes of neonatal admission to hospital, but early identification of infants at highest risk enables targeted primary preventative therapy.

The U.K.-based researchers retrospectively reviewed hospital biochemistry records to identify term deliveries with recorded aUCB (February to November 2010), as well as infant medical records to identify those who developed neonatal hyperbilirubinaemia requiring treatment. It was standard procedure at the hospital to perform umbilical cord gas analysis on all obstetric-led deliveries, and that the GEM4000 blood analyzer automatically provides total bilirubin estimation.

Clinically significant jaundice developed in 2.7 percent of infants with recorded aUCB. Eight cases had a positive direct antiglobulin test (DAT), mostly due to ABO blood type incompatibility. aUCB strongly predicted the development of DAT + ve jaundice, as well as to a lesser extent all-cause jaundice. However, this effect on all-cause jaundice was "critically dependent" on maternal O blood group. Using a cutoff of 35 µmol/l for mothers with blood group O + ve/O-ve increased the pretest probability for all-cause jaundice from 4 percent to 30 percent post-test.

> *"Consideration of umbilical cord bilirubin as an index of risk for neonatal jaundice is not a new idea."*
>
> — Kelsey D. J. Jones

The authors caution about defining cutoff values, noting that the "ideal" cutoff will probably differ between the populations served by different centers.

"Consideration of umbilical cord bilirubin as an index of risk for neonatal jaundice is not a new idea," writes Jones and colleagues. " Substantial differences in reported sensitivity and specificity values may simply have reflected the use of different arbitrary cut-offs.... Our data suggest that venous and arterial values are strongly correlated, but that venous levels are consistently lower than arterial, leaving open the possibility of systematic error when comparing between study groups."

Takeaway: Estimation of aUCB should be considered as a strategy for early identification of infants at risk of neonatal haemolytic jaundice.

Innovation in Urine Collection Cuts Contamination, Retesting

Forte Medical (United Kingdom) characterizes traditional urine collection as a "start-stop-start-and-aim" endeavor that often devolves into a "hit-and-miss process." To improve the quality and "dignity" of urine sample collection, the company has developed its Peezy Midstream device.

The company's cofounder found that contaminated urine samples resulted in high rates of repeat appointments and retests for patients presenting with suspected urinary tract infections (UTIs). Accurate diagnosis of UTIs, plus other conditions like prenatal and diabetes screenings, relies on midstream collection, but samples are frequently contaminated with first-void urine.

With further investigation, Forte Medical determined contaminated urine samples are a costly problem throughout the U.K. health system. National contamination rates in the United Kingdom were estimated to be above 15 percent with each retest costing more than $13 U.S.

Enter Peezy, a simple-to-use funnel engineered to capture midstream urine in a single, mess-free process. Peezy rejects first 8mL to 10mL of potentially contaminated urine. Urine causes expansion of compressed sponge, which blocks exit, causing midstream urine to be diverted into collection tube (30mL or 10mL). When this tube is full, excess urine exits through second, separate duct eliminating the possibility of funnel overflow. In addition to eliminating collection messes, spills, or contamination, the specimen can be transferred directly onto the analyzer. This improves laboratory efficiency by removing the decanting process from the workflow, saving labor and time.

Data shows that Peezy markedly improves the quality of samples. In two U.K. trials Peezy reduced mixed growth from 23 percent to 5 percent, while a second trial conducted as part of London's Barts Health NHS Trust quality audit showed improvements in mixed growth contamination from 17 percent to 1.5 percent with Peezy-assisted collection, "representing a huge improvement in the speed and quality of diagnosis and targeted treatment, while reducing incidences of repeat specimens," says Giovanna Forte, CEO of Forte Medical. (The College of American Pathologists estimates that, similarly, approximately 20 percent of U.S. urine specimens may be unreliable.)

Peezy collection funnels are more expensive than standard collection vessels, (approximately $1.15 U.S. versus $0.12 U.S.), but Forte says use of Peezy ultimately saves money (potentially millions of dollars) when taking into account the cost of laboratory analysis for retesting.

Peezy is currently approved in both the United Kingdom and the United States. Forte Medical has its U.S. expansion planned for 2018, including opening an office within the Dell Medical Innovation Center (Austin, Texas).

Takeaway: A simple collection device markedly improves the quality of urine samples, saving laboratories time, the health system money, and patients inconvenience, all while improving timely diagnosis.

New Speed Record Set for Genome Analysis

A new world record was set for fastest analysis of 1,000 genomes on Oct. 19. The achievement was a collaboration between Children's Hospital of Philadelphia (CHOP) and Edico Genomics (San Diego, Calif.). The milestone, achieved in just under two and a half hours, brings precision medicine one step closer to mainstream clinical practice, the participants say.

The 1,000 deidentified research samples were curated to reflect the composition of CHOP's Center for Applied Genomics (CAG) biobank. The samples represent common complex disorders and rare single-gene diseases. Results from the rapid analysis will be utilized by the CAG with the hope of uncovering genetic links to common childhood diseases, including asthma, autism, diabetes, epilepsy, obesity, schizophrenia, pediatric cancer, and other rare diseases.

"The speed of this technology in processing vast amounts of raw data in a matter of minutes will allow us to deliver actionable results in hours—an important capability as we go forward in realizing the benefits of precision medicine for children and families," says Hakon Hakonarson, M.D., Ph.D., director of CAG in a statement.

The title was presented onsite by an official Guinness World Records adjudicator, and will be granted upon publication of the results in a peer-reviewed journal. Analysis began with the streaming of the 1,000 data files in standard FASTQ format from Amazon Simple Storage Service (S3) to 1,000 Amazon EC2 F1.2xlarge instances, which deployed the DRAGEN Genome Pipeline. The pipeline entailed mapping, aligning, sorting, duplicate marking, and haplotype variant calling. The process ended when a variant call format file was delivered back to a secure Amazon S3 bucket.

Edico's pipeline has been used to set another Guinness World Record: the 26-hour diagnostic genome conducted by Stephen Kingsmore and his colleagues at the Center for Pediatric Genomic Medicine at Children's Mercy in Kansas City.

Takeaway: With dramatic decreases in the time to process and interpret whole genomes, whole-genome sequencing results may be returned in time for critical clinical decision-making.

Novel Tests Emerging For Overlooked Conditions

Undeniably, much of the emerging test focus is on cancer and infectious diseases. *DTET* wants to showcase other novel tests entering the marketplace. What follows is a sampling of novel tests entering the commercial marketplace.

Optimizing Treatment Selection for Wound Infections

CogenDx (Millennium Health; San Diego, Calif.) hopes that its DxWound test will enable patients to receive faster, appropriate treatment for infected wounds. The test launched in October.

DxWound uses polymerase chain reaction technology to identify microbes responsible for wound infections. It assesses the microbes most commonly associated with skin and soft tissue infections, including aerobic and anaerobic bacteria, fungi, plus it is able to assess antibiotic resistance.

Samples are taken directly from a swab of the wound and do not require culture. A special transport buffer preserves the wound microbiome during transit. Test results are usually returned one business day following specimen receipt in the laboratory.

According to CognDx's IDWeek presentation (San Diego, Calif.; Oct. 4-8), results from the tests enable clinicians to select targeted antibiotics with greater likelihood for efficacy. This, the company says, can translate to improved health outcomes for patients and reduced costs of care, particularly when treated within 48 hours of suspected infection. CogenDx currently has a study underway to evaluate the economic impacts of inappropriate antibiotic therapy in inpatients being treated for skin and soft tissue infections.

Noninvasive Monitoring for Crohn's Disease

During the 2017 American College of Gastroenterology conference (Orlando, Fla.; Oct. 13-18) Prometheus Laboratories Inc. (Nestlé Health Science; San Diego, Calif.) launched a new serum test that measures and monitors mucosal healing status in Crohn's disease patients. The company presented clinical validation and test performance data for the Monitr test, which is the first test to provide a noninvasive tool for patient management.

"We really need an objective way to view snapshots of the mucosa without frequent scoping," said Marla Dubinsky, M.D., chief of pediatric gastroenterology and hepatology at the Icahn School of Medicine, Mount Sinai (New York). "The more noninvasive biomarkers we can assay to objectively evaluate the mucosa, the better off patients will be."

Crohn's disease is notoriously difficult to monitor because the only available diagnostic tools—colonoscopy and endoscopy—are invasive and expensive. Additionally, experts say, symptoms do not necessarily correlate to the amount of inflammation present.

Prometheus says Monitr gives the physician "flexibility" for assessing mucosal disease, as the test can be used as an adjunct to endoscopy or by itself, between endoscopies, allowing for more frequent, noninvasive monitoring. The test relies upon 13 biomarkers and delivers results through a Mucosal

Healing Index on a 100-point scale, with 0 to 40 indicating a patient is in remission or has mild endoscopic disease, whereas 50 to 100 indicates patients have endoscopically active disease. The company said the Monitr test demonstrated high accuracy and concordance rates with endoscopically visualized mucosal disease activity in adult Crohn's disease patients, regardless of the anatomical disease location or selected treatment regimens. In a trial of 412 longitudinal specimens from 118 patients with Chron's disease collected at the time of or close to endoscopy, the test accuracy was 95 percent, 90 percent, and 87 percent for ileal, ileocolonic, and colonic disease, respectively.

"This blood test may allow people with MS to begin treatment earlier, and identify the most appropriate treatment for their condition."

— Matthew Miles, CEO, MS Research Australia

New Hope for a Blood Test to Diagnose MS

Diagnosing multiple sclerosis (MS) is not easy. Current diagnostic standards require neurologists to look for disease progression in successive MRI scans in combination with other invasive tests such as lumbar punctures. There is renewed hope that a simple blood test will be able to offer more rapid diagnosis, and possibly offer insight about disease progression.

IQuity (Nashville, Tenn.) launched its IsolateMS test early this summer. The company says that it can offer a quick "rule in" or "rule out" at first sign of disease symptoms, with test results in a week. Timely diagnosis and treatment, they say, can slow disease progression.

The company's analytics process is called IQIsolate and uses machine learning to develop algorithms that analyze RNA gene expression in whole blood. Using RNA analysis, IsolateMS is able to distinguish between healthy people and patients with MS with 90 percent accuracy. The test costs approximately $1,250, which the company says is a worthy investment as it can better identify patients with MS who would benefit from costly drugs. Experts say that up to one-third of MS cases may be misdiagnosed.

Researchers from Australia recently published a study in *Nature Scientific Reports* demonstrating that nine micro-RNA molecules are capable of not only distinguishing MS patients (n=25) from healthy controls (n=11), but they can also discriminate between patients with relapsing-remitting MS and progressive MS.

"This blood test may allow people with MS to begin treatment earlier, and identify the most appropriate treatment for their condition," said Matthew Miles, CEO MS Research Australia, which funded the research, in a statement. "This, in turn may lead to fewer relapses and a slower loss of brain volume, resulting in slowing or potentially halting progression of the disease for the person living with MS."

The researchers used next generation sequencing and integrative bioinformatics to identify the micro-RNA profile found in exosomes traveling in the blood. The exosomes are released by brain cells, but cross the blood-brain barrier and can be captured through a normal blood draw.

Takeaway: While not capturing the headlines in the same way that emerging cancer tests are, these novel tests have the potential to impact clinical care decisions and health outcomes, as well as possibly being cost effective.

Laboratory Data Core to Value-Based Health Care

To thrive in the present challenging environment, laboratories need to deliberately focus on how they can create value outside of their own walls. The key to achieving this is in their data.

Speakers at G2's 35th annual Lab Institute conference (Washington D.C.; Oct. 25-27) envisioned a future health care system where laboratories play a critical role in driving system-wide efficiencies and improving patient outcomes by unlocking value in laboratory-generated data. The data already exists, but new efforts are underway at the intersection of information technology and laboratory medicine to harness new insights.

As the keepers of this data, laboratories have an exciting opportunity to redefine themselves as a "strategic asset" within the health care system, particularly to health care payers and hospital administrators eager to capitalize on the value behind the data-driven evidence.

Previous Shortsighted Focus

For too long, says **Keith Laughman**, CEO of Viewics, laboratories' emphasis has been on measuring line-item costs, like test prices, rather than measuring the total value laboratories deliver towards patient care. For instance, he told the Lab Institute audience, that test prices have been viewed in isolation rather than considering the possible negative impact cheap tests might have on clinical decision-making, like delaying care.

The opportunity exists, in part, he says, because laboratories see patients across the entire care continuum, including out in the community. This full clinical picture enables laboratories to play a central role in a data-driven clinical diagnostic improvement process. Most of the value to be realized by laboratory data is actually to be realized outside of the laboratory's walls. But, to unlock this value, laboratories need to position themselves as health care partners to "drive diagnostic optimization and diagnostic integration."

How Valuable Are Laboratory Test Results?

It is widely recognized that laboratories "touch" the majority of patients. But, when looking through a value-based lens, there is increasing scrutiny on the widely used claim that "laboratory tests are the basis of 70 percent of medical decisions."

Andy Ngo, M.D., from Virginia Commonwealth University in Richmond, published an article in the January issue of the *Journal of Applied Laboratory Medicine* that attempted to estimate the influence of laboratory tests on medical decisions. Based on data from more than 70,000 patient encounters, Ngo and colleagues came to the conclusion no single number can categorize the frequency with which laboratory tests occur in patient encounters. They found that overall 35 percent of encounters had at least one laboratory tests ordered. However, the percent varied markedly depending on the care setting. Nearly all

inpatients (98 percent) had a least one laboratory test ordered, as did 56 percent of patients seen in the emergency department. However, in the outpatient population, only 29 percent of patients had at least one laboratory test ordered.

"Although a useful surrogate, the number of encounters with laboratory testing has a number of limitations," says Timothy Amukele in an accompanying editorial. "For one, many studies have reported a striking lack of follow-up on noncritical laboratory results. ... Value must be established through careful, thoughtful studies designed to establish an impact on patient outcomes (benefit), balanced by the resources expended (costs), because in the end, this is what represents the true value of tests."

"The new challenge is a value-based world is connecting laboratories to the outcomes."

— Mike Hallworth

Laboratory Value Has Many Components

At the most basic level, a laboratory provides a valuable service if it can deliver technically valid test results—is the analyte of interest measured accurately and reliably? This criteria, though, doesn't guarantee a test result has clinical value.

A test has clinical value if it is accurate for guiding a diagnosis and has predictive value—clinical validity. Taking the value of the test one step further, is the notion of clinical utility: Does the result aid in clinical decision-making and ultimately improve health outcomes?

But, in this era of health reform and the Triple Aim, value is still defined more broadly—the overall outcome or result in terms of cost. This definition still, of course, incorporates clinical value, but also includes broader factors relating to economic considerations.

"The new challenge is a value-based world is connecting laboratories to the outcomes," said Mike Hallworth, chair of the International Federation of Clinical Chemistry and Laboratory Medicine's Task Force on the Impact of Laboratory Medicine on Clinical Management and Outcomes, speaking at the International Congress on Quality in Laboratory Medicine (Helsinki, Finland; February 2017). "In order to improve outcomes, a laboratory test must be appropriately ordered, conducted, returned with results on a timely basis, correctly interpreted and affect a decision for further diagnosis and treatment."

Linking laboratory testing to outcomes means that in the near future a laboratory's value will not be measured on how much profit it made on a test, but on how much savings that test generated for the episode of care or by enabling early detection.

Linking Laboratories to Care

Connecting laboratories to outcomes requires increasing coordination and communication between the laboratory and patients, as well as other providers across the continuum of care. Delivering timely results will no longer be enough. But forward thinkers have begun to explore strategies laboratories can take to be a partner in clinical decision-making.

INSIDE THE DIAGNOSTICS INDUSTRY

Among these forward thinkers are participants in Project Santa Fe, a coalition of major regional laboratories that have come together for the purpose of defining the future economic valuation and placement of laboratory diagnostic services in the American health care system.

"The evidence base for laboratory valuation must be established in a proximate time frame, including bringing institutional demonstration projects forward in the peer-review literature," write Project Santa Fe members, led by James Crawford, M.D., Ph.D., from Northwell Health Laboratories, Lake Success, N.Y., in the April issue of *Academic Pathology*. "In the ambulatory setting, laboratory services can constitute a driver for continuity in care, both through the longitudinal continuity of laboratory testing performed on patients with chronic diseases and through informing providers about evolving risk conditions and potential gaps in care."

In the *Academic Pathology* article, Crawford and colleagues detail the many activities that laboratories can undertake that will meaningfully connect them to clinical decision-making and value-based care decisions. G2 has categorized the activities based on their ability to influence on test utilization, create added value for laboratories, generate population-based insights, or provide added value to provider partners.

Test Utilization Management

- Establish institution-wide laboratory test formularies
- Manage utilization of expensive and esoteric testing in both inpatient and ambulatory settings
- Document and educate providers on their test utilization patterns and cost of laboratory testing through peer-to-peer benchmark comparative reports

Laboratory-Focused Applications of the Data

- Reduce of out-of-network leakage of laboratory testing for both cost-savings and to attain comprehensive laboratory data on covered populations

Population-Based Insights

- Assist providers in identifying, monitoring, and following up on patients with chronic and costly conditions
- Work with payers and accountable care organizations to identify and manage patients enrolled in disease management and care management programs
- Stratify covered populations by risk and use predictive modeling of chronic disease states in those covered populations

Added Value/Partnership With Providers

- Provide analytical services to reduce physician burden in quality measurement and reporting (e.g., HEDIS, MIPS, accountable care organization metrics)

INSIDE THE DIAGNOSTICS INDUSTRY

- Aid in test interpretation of complex test results
- Provide useful patient-specific interpretations of test results

These activities collectively have the benefits of increasing efficiencies and cost savings throughout the health care system; optimizing testing by reducing duplication, managing appropriateness of testing, and where needed, driving increased testing, particularly of patients falling through the cracks in monitoring chronic conditions.

> *"The value of laboratory medicine is extensive and greatly exceeds the laboratory's budget!"*
>
> — Keith Laughman, CEO, Viewics

Improving test interpretation (through improved reports and increasing consultative services), as well as test utilization management are the methods most actively employed today. However, merely adding alerts to an electronic ordering system is likely not enough. Thomas Joseph, president of Visiun, told Lab Institute attendees that laboratories could take further action by closely examining their menu. He suggested they stop offering obsolete tests; redesign requisitions to minimize bundling; and limit certain tests to require a consultation with a genetics counselor or pathologist. This must be reinforced with provider education and audits of provider ordering patterns.

Full integration and improved mining of laboratory data, including longitudinal data, using artificial intelligence will enable quicker diagnosis, better test ordering decisions, and better prediction of care needs.

What Will The Value-Based Laboratory Look Like?

Forward thinking laboratories are embarking on a transition period. Laboratories able to rethink their role and position themselves as a clinical decision-making partner will help to foster in a new era in health care marked by efficiency, and quality improvement

"The value of laboratory medicine is extensive and greatly exceeds the laboratory's budget!" Viewics' Laughman told Lab Institute attendees. "Take lab data and use in new ways. Very standardized, clean, combinable data can create enormous value in clinical improvement and population health. This is where dollars are saved, not pennies from lab tests."

Laughman envisions laboratories in the post-transition as known not for utilization management, but rather diagnostic optimization. Lab outreach will be replaced with diagnostic integration. And most importantly, laboratories will be viewed as a trusted partner in driving clinical decisions and stewardship of health care dollars.

Takeaway: To thrive in a challenging environment, laboratories need to deliberately focus on how they can create value outside of their own walls. To do this, laboratories must use their data to demonstrate their system-wide value to health care payers and administrators, while becoming a clinical decision-making partner to providers.

High-Deductible Plans Tied to Reduced Use of Health Care, *from page 1*

HDHPs are generally defined as a health plan with an annual deductible of at least $1,300 for individual coverage or $2,600 for family coverage. The share of adults with employer-based coverage who are enrolled in HDHPs rose from 26.3 percent in 2011 to 39.3 percent in 2016, according to the National Center for Health Statistics.

Employers and policymakers often see these plans as a potent way to curb health care costs, believing that the higher cost-sharing requirements will incent patients to make "higher-value" health care decisions. However, early evidence suggests that patients, particularly those in low-income and vulnerable populations, lower utilization of both appropriate and inappropriate services.

The researchers conducted a systematic literature review to identify quasi-experimental studies that compared an HDHP with a traditional health plan. The 28 included articles assessed health care use and spending for any health care setting, including preventive care, office visits, emergency department visits, hospitalizations, diagnostic testing, and prescription drug use.

Findings show that the plans appear to reduce health care costs by decreasing the use of both appropriate (such as cancer screening) and inappropriate (such as low-severity emergency department visits) health services. Seven of 12 studies showed that HDHPs were associated with a significant reduction in preventive care. Additionally, six of 11 studies showed a significant reduction in office visits, which led to a reduction in appropriate and inappropriate downstream care.

Only two studies specifically studied the impact of HDHPs on laboratory and diagnostic testing. These two studies showed a reduction in laboratory and diagnostic tests among HDHP enrollees, although the researchers were unable to determine whether these reductions were appropriate.

Takeaway: Early evidence suggests that diagnostic testing volumes are likely negatively impacted by patient enrollment in HDHPs, which are associated with a reduction in the use of health services, including appropriate and preventive services.

New Evidence Suggests Frequent Lipid Monitoring May be Unnecessary

Most routine testing for monitoring of lipid profiles does not result in a change in therapy, according to a research letter published in the October issue of *JAMA Internal Medicine*. This finding, combined with a recent change in lipid management guidelines calling for a risk-assessment approach rather than a target low-density lipoprotein (LDL) level may indicate low utility for frequent lipid monitoring.

Though there is insufficient data to show that monitoring lipids leads to meaningful improvements in clinical outcomes or adherence to pharmacologic treatment, 3 US guidelines recommend lipid monitoring every 3 to 12 months, whereas European guidelines advise annual lipid monitoring among patients receiving therapy.

The researchers assessed clinician rationale for ordering lipid testing and changes to lipid lowering therapy among a random sampling of 4,945 patients (aged 40 to 79 years) who had been seen by a primary care physician in the past 12 months and had been receiving statin therapy at least 3 years.

Over the 3-year study period, a mean of 3.01 lipid panels were performed per patient. For 79 percent of patients, primary prevention of cardiovascular events was the stated indication for statin therapy in the medical records. Rationale for ordering lipid tests was available for 183 patients with the most commonly reported indications including: monitoring (70 percent), follow-up of statin dosage change (8 percent), and patient request (4 percent).

"The high frequency of testing may reflect adherence to current guidelines, practice habits stemming from the historic treat-to-target approach, patient expectations, and a perception that lipid testing may allow for monitoring adherence to therapy," write the authors led by Karen Stenehjem, M.D., from University of Colorado School of Medicine in Aurora.

Despite the frequent monitoring, the researchers found that most lipid testing did not result in a change in therapy (548 of 634 lipid tests).

"Because the key clinical decision has shifted from treatment to an LDL goal to mitigating cardiovascular risk, the utility of lipid monitoring may be diminished," the authors suggest. "The appropriate frequency of lipid testing is uncertain. As attention to value-based care increases nationally, this may be a target for cost savings and warrants further study."

Takeaway: Frequent lipid monitoring does not lead to a change in treatment, which calls into question the utility of routine testing.