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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Ending 'Lab Tests as a Commodity'

WITH HEALTHCARE POISED TO MAKE FUNDAMENTAL CHANGES in both the delivery of care (think integration, ACOs, medical homes) and how providers are paid (less fee-for-service, more budgeted payment methods), it is time for the entire profession of laboratory medicine to tackle the elephant in the room: lab tests bought and sold as commodities.

The commoditization of lab tests since the mid-1980s has done consistent financial harm to independent labs, anatomic pathology groups, and hospitals with lab outreach programs. In classic economics, a commodity product is, by definition, identical. Think salt, aluminum billets, soy beans, and pork bellies.

Pathologists often argue that there are clinical labs of high quality and labs of low quality. But when payers ask the lab profession: "Why should we pay more for lab A's chemistry test than for lab B's chemistry test?" The lab profession cannot provide evidence to support the assertion that one lab's chemistry test result is better than another lab's.

Consequently, since the 1980s, payers have regularly chosen the lab that offers them the lowest price per test. Because the national public lab companies have the lowest average cost per test, they can bid managed care contracts at prices lower than independent labs, anatomic pathology groups, and hospital laboratory outreach programs.

That game changes, however, in healthcare's next era. Integrated health systems, ACOs, and patient-centered medical homes must demonstrate to payers and employers that they can meet two goals. First, they must keep patients healthy. Second, they must cut the cost of care because their patients are staying healthy.

Local labs, hospital labs, and pathology groups have the opportunity to do more than simply offer an accurate test at a low price. They can add value by taking the commodity-priced chemistry test or CBC and wrapping it inside a lab test service offering that helps physicians order the right test at the right time, then assists him or her with interpreting results and selecting the best therapies for patients.

Adding value is the essential attribute of clinical lab 2.0. At the *Executive War College* in New Orleans on May 2-3, first-mover labs learning to add value in these ways will be sharing their successes and lessons learned. TDR

Lab Innovators Advocate Need for Clinical Lab 2.0

Lab 1.0 is the low-paid commodity lab, while lab 2.0 gets paid more for the value it contributes

CEO SUMMARY: It is generally recognized that the clinical lab industry faces a financial squeeze of unprecedented dimensions. Lab test prices are falling steadily and more major cuts are coming to Medicare Part B fees in just 11 months. At the same time, obtaining favorable coverage and reimbursement decisions from payers is becoming tougher. This is why a group of forward-thinking lab leaders is advocating that labs embrace the clinical and financial concept of clinical lab 2.0.

By Robert L. Michel

In the United States, the clinical laboratory industry is about to face an unprecedented financial crisis. This crisis will result from the successive fee cuts to be enacted by Medicare and private payers in 2018 and beyond.

The coming financial crisis will create new winners and new losers among the nation's labs. This will be true for both clinical labs and anatomic pathology groups.

The losers will be lab organizations that continue to operate under the traditional lab 1.0 clinical and financial model. The winners will be labs that move swiftly to transform themselves into the clinical lab 2.0 model.

Stated differently, the test results produced by labs operating under the lab 1.0 business model are considered to be commodities by payers. It is why payers award their business to the lab with the lowest prices. After all, argue the payers, why should they pay more for one lab's chemistry test results than another lab's—if the quality is equal and the test results are accurate?

That is not the case for the lab testing services provided by labs moving to adopt the lab 2.0 business model. These labs are developing lab testing services that go beyond simply reporting an accurate test result in the accepted turnaround time.

Instead, these labs offer physicians, patients, and payers lab testing services that directly contribute to improvements in patient care and the overall cost per episode of care that can be demonstrated by appropriate metrics. For this added

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value, payers will reimburse more for these enriched lab testing services.

Stated a third way, clinical lab 1.0 is the commodity lab, generally paid on the basis of lowest price. By contrast, clinical lab 2.0 is the value-added lab that is paid for the recognized benefits that result from the enriched lab testing services it delivers.

The term "clinical laboratory 2.0" was coined by the handful of clinical lab innovators who are participating in Project Santa Fe. *(See CAP Today, "Lab 2.0: Changing the conversation," July, 2016.)* It describes the lab that adds value with how it helps clinicians use its tests and clinical services to improve patient outcomes and contribute to reductions in the overall cost of care, as defined above.

The operational differences and clinical focus of these two lab models are radically different. The clinical lab 1.0 is fixated on producing an accurate test result that is reported within the allotted turnaround time. Its staff spends relatively little time outside the four walls of the lab collaborating with stakeholders to help improve the utilization of lab tests.

Improving Patient Outcomes

By contrast, clinical lab 2.0 is the emerging model in which the entire staff understands that the primary goal of the organization is to identify opportunities to use tests in ways that improve patient care, then collaborate with physicians, patients, payers, employers, and others to help them utilize lab tests and test results in ways that are transformational to both patient care and the cost of the overall episode of care.

One attribute of clinical lab 2.0 is that the organization is an intense user of information technology. That's because value is created when lab test data is combined with clinical, demographic, and other types of data.

Another attribute of clinical lab 2.0 is that its primary focus is external, in the clinical care environment. Its lab team spends much time outside the four walls of the lab interacting with physicians, nurses, and other caregivers.

At the upcoming *Executive War College*, scheduled for May 2-3, in New Orleans, "Clinical Lab 2.0" will be one major theme, along with sessions about PAMA Medicare fee cuts expected in 2018, analysis of how the new Congress and administration are handling healthcare issues, and new developments in lab management, operations, and finances.

Two Labs In The Forefront

Two lab organizations now taking steps to evolve their labs from the lab 1.0 model to the lab 2.0 model are **Geisinger Health**, of Danville, Pa., and **TriCore Reference Laboratories**, of Albuquerque, N.M. In the opening general session of the *Executive War College*, TriCore CEO Khosrow Shotorbani will discuss clinical lab 2.0 and offer examples of how his lab is combining lab test results with other clinical data to provide enriched information to physicians and payers in New Mexico. He will share both the clinical and the financial metrics from programs delivering value-added lab testing services to physicians and their patients.

The next presentation will be by Myra L. Wilkerson, MD, Chair, Division of Laboratory Medicine at Geisinger Health. Geisinger is one of the nation's leaders at providing integrated care and has been at the forefront of building a biobank and a repository for genetic data on its patients.

Wilkerson will provide an inside perspective on what Geisinger is learning as it strives to implement precision medicine and addresses the need to be more proactive about managing patients with chronic conditions. She will also demonstrate how her laboratory organization is tailoring its services to deliver more value and to support the new clinical approaches being used at Geisinger Health. TDR

Why Project Santa Fe and Clinical Lab 2.0 Are Important to the Clinical Laboratory Industry

FOR 30 YEARS, the clinical laboratory industry has seen lab test prices spiral downward because the public lab companies with the lowest test costs used their market power to underbid competing labs, whether the competitors were independent labs or hospital/health system labs.

Now the healthcare system wants to end fee-for-service reimbursement and pay providers—including labs—using different methodologies. This is the source of the much-used phrase, "from volume to value."

Leaders of five major health system lab organizations recognized that they will not win higher reimbursement from payers unless their respective labs can deliver test services worth more to the healthcare system than an accurate test result delivered on time. They understood the need to shift the basis of the discussion on lab test prices and lab budgets away from price. Instead, they must demonstrate to payers how their labs can deliver lab test services that improve patient outcomes while also helping to lower the overall cost per episode of care.

This strategic thinking underpins the creation of Project Santa Fe. In March, 2016, teams from five health system labs met in Santa Fe, N.M., with the goal of collaborating to create "clinical lab 2.0," a clinical and business model for lab testing that is organized to deliver high value-added lab testing services to all healthcare stakeholders, and for which stakeholders will reimburse appropriate to the value provided by their labs.

The Project Santa Fe participants are the laboratory divisions of:

- **Geisinger Health**, Danville, Pa.
- **Henry Ford Health**, Detroit, Mich.
- **Kaiser Permanente-Northern California**, Berkeley, Calif.
- **Northwell Health**, Great Neck, N.Y.
- **TriCore Reference Laboratories**, Albuquerque, N.M.

Participants in Project Santa Fe have written that they "want to provide thought leadership and develop the evidence base for the valuation of clinical laboratory services in the next era of American healthcare."

The idea is for Project Santa Fe to serve as a think tank for innovation. Using clinical pilot programs, its participants will introduce value-based lab testing services to their organizations and document the outcomes, both in how patient care improved and reductions in healthcare costs.

Several of these labs have already completed pilot programs. The results have been shared and other Project Santa Fe labs are in the process of implementing the same programs to demonstrate that they can be replicated by other hospitals and health systems.

It is the goal of Project Santa Fe to publish the results of their programs to add value with lab testing services in peer-reviewed journals so that health system CEOs and healthcare policymakers will have the evidence of how lab testing can contribute significant value—and thus should be funded amply to support improvements in patient care.

Workshop On Lab Value

At the upcoming *Executive War College* on May 2-3, in New Orleans, leaders from the Project Santa Fe laboratories will deliver sessions on clinical lab 2.0, how to develop value, and how to collaborate with clinicians to help them improve patient outcomes.

There will also be a full-day workshop on May 4, titled: "Moving to Clinical Lab 2.0: Deliver More Value! Get Paid More $$$!" Project Santa Fe labs will discuss, in detail, how they are refocusing their labs to deliver more value. Executives will share successes from pilot programs to improve diagnosis and treatment of acute kidney injury, how to leverage lab informatics, and how to create collaborations with physicians and nurses.

Lab Market Update

Mount Sinai Health System Sells Outreach Lab to LabCorp

Unlike most hospitals that sold outreach labs, Mt. Sinai has been profitable in recent years

ANOTHER ACADEMIC MEDICAL CENTER decided to cash in on the value of its outreach lab. On Jan. 10, **Laboratory Corporation of America** announced it would acquire the lab outreach business of **Mount Sinai Health System** of New York City

Terms of the transaction and purchase price were not disclosed. The deal is expected to close by the end of the first quarter.

In a press release about the sales agreement, LabCorp explained that Mount Sinai will continue to provide "laboratory testing for patients registered at its hospitals and ambulatory facilities as inpatients or outpatients, as well as laboratory testing services for physicians in their professional practices in the areas of anatomic pathology, molecular pathology, and genetics."

For its part, LabCorp, "will offer clinical pathology testing, including cytology and cytology-related molecular testing" to the Mount Sinai's lab outreach clients. LabCorp will also take over operation of six patient service centers now operated by Mt. Sinai.

One interesting aspect of this sale is that Mount Sinai Health System is financially stable. The company has reported positive operating margins in recent years. It has been working to integrate the four **Continuum** hospitals it acquired in 2013, including **St. Luke's-Roosevelt Hospital Center** and **Beth Israel Hospital**, both of which were losing money when acquired.

Modern Healthcare reported that Mount Sinai explained its interest in selling its lab outreach business with this statement: "This particular [lab outreach] business, while successful, is no longer a core business of Mount Sinai. This transaction will allow Mount Sinai to continue to invest in our core strategic programs, such as cancer and cardiac services, and to advance our mission across the system."

Were Lab Costs A Factor?

The Mount Sinai statement further added an interesting element that may have been one motivation in the decision to sell the lab outreach business. "Under LabCorp, the cost of outreach lab services would be lower," wrote *Modern Healthcare*.

This could be an indication that the outreach lab business was experiencing pricing pressure, either from payers that wanted lower prices or from patients with high-deductible health plans—or both.

If these factors were in play, it could be that financial planners at Mount Sinai predicted that the profitability of its lab outreach business would decline in coming years. Thus, they decided to sell at this time to obtain the maximum price, based on existing specimen volume.

In recent years, LabCorp has continued to acquire smaller labs and pathology groups. However, it does not announce smaller purchases. This makes it more difficult to understand the pace of lab consolidation in the United States. TDR

Another PGx Lab Hit With Audit, Repayment Demand

Pharmacogenomic lab faces hardship as CMS seeks recoupment of multiple millions of dollars

CEO SUMMARY: In 2014, during a ZPIC audit of an unnamed pharmacogenomic testing lab, a federal auditor reviewed a small number of claims that had been filed over a period of several years. Despite supporting letters from physicians, the auditor rejected those claims, then extrapolated the findings to declare payments for thousands of tests over that same period to be illegal. The lab now owes the federal government multiple millions of dollars, payable immediately. The unnamed lab is fighting the case.

ARE FEDERAL AUDITORS TARGETING pharmacogenomics laboratories with deep-dive audits and demands for steep overpayments?

Sources tell THE DARK REPORT that as many as six pharmacogenomic labs have been audited in recent years. In each case, a small number of claims has been identified as improperly paid, and then the auditors extrapolate that small number of rejections to all claims filed over a period of years. The result has been demands for each targeted lab to pay multiple millions of dollars.

After THE DARK REPORT published a story about the Medicare audit and subsequent bankruptcy filing of **Pharmacogenetics Diagnostic Laboratory LLC** (PGXL), of Louisville, Ky., an unnamed company official from a second clinical laboratory reported that his lab was hit with an audit from a Zone Program Integrity Contractor (ZPIC) and the circumstances were similar to those of PGXL. *(See TDR, January 9, 2017.)*

The company official did not want to disclose his name or that of his laboratory, saying the case was under appeal and any attention on the case involving his specific laboratory could result in retribution that might complicate and prolong the matter. In agreeing to discuss the circumstances of the audit, the company official requested that all identifying details of the case be left out of this article.

Minimal Review of Claims

The circumstances for this unnamed lab were eerily similar to the case of PGxL. As in the PGxL case, **AdvanceMed**, the ZPIC auditor, began an audit of the laboratory's claims and requested documents on tests ordered over a multi-year period.

In the audit of the unnamed lab, AdvanceMed reviewed a small number of claims and declared that Medicare should not have paid any of those claims. In making this charge, AdvanceMed said the tests were not medically necessary, the official said. There was never any allegation of fraud or any other impropriety, he added. The auditor did not agree that the tests ordered by the treating medical provider were medically necessary, he added.

Then, the auditor extrapolated from the small number of claims to all claims

filed over many years, the official explained. The result: a demand for overpayment of multiple millions of dollars.

Maximum Penalty Assessed

"We were under a similar audit as PGXL," the company official said. "The auditors focused on a minimum number of records. From those claims, the auditor determined that 100% of claims submitted during the extended universe of time were not medically necessary. The result is a demand for repayment of 100% of the claims reimbursement for the entire universe of the time under audit.

"During the appeals process of our case, it became increasingly clear that the auditor did not follow the Medicare Program Integrity Manual," the lab official added. "Indeed, AdvanceMed's audit was so haphazard, it contained no less than four serious errors, each of which would invalidate the audit on its own merit. Together it shows a complete disregard for the audit rules.

"In many of the cases, the laboratory obtained letters from the ordering physicians," the official said. "Those physicians explained that they ordered the tests for specific patients, how the test results were used to amend the patients' treatment regimen, and how the patients responded to the changes in treatment.

"Despite the errors in procedures and the letters from physicians, AdvanceMed denied all the claims for the same reason: a lack of medical necessity," he added. "This seems to be a catchall when they fail to find anything else the laboratory may have done wrong."

A Hindrance to Appeals

After the audit, the unnamed pharmacogenomic testing lab began the appeal process and found it was challenging. "There are several levels of appeal a laboratory can go through, all of which are within the responsibility of various CMS contractors," the official said. "The first level of appeal is back to AdvanceMed itself. The next level of appeal is to the area Medicare Administrative Contractor (MAC). Typically the ZPIC works under the direction of the MAC.

"The next level of appeal is to a Qualified Independent Contractor (QIC)," he said. "This is another contractor, typically in a different area of the country. The next level of appeal is to an administrative law judge (ALJ).

"When a case goes before an ALJ, this step is the first independent review of the audit by a party who is not a CMS contractor," the official explained. "In April 2013, CMS began delaying the assignment of cases to the ALJ for 24 months. This delay has created a tremendous backlog of cases. The current wait time for a case to be assigned to an ALJ is over two years.

Growing Backlog of Cases

"The problem is that recoupment of the alleged overpayment is allowed to resume while the provider waits for an ALJ assignment," he added. "This means many, many small providers may be forced out of business entirely or into bankruptcy protection, as was the case with PGXL."

In a letter to the federal **Department of Health and Human Services** last year, the **American Hospital Association** cited statistics that show the average appeal after an audit is about 30 months and growing. Ashley Thompson, the AHA's Senior Vice President, Public Policy Analysis and Development, explained that figures from DHHS' Office of Medicare Hearings and Appeals (OMHA) show appeals taking longer and longer.

"The most recent statistics released by OMHA show that the average appeals processing time was 935.4 days in the third quarter of fiscal year 2016—an increase of 75 days from the prior quarter and 140 days since the beginning of the fiscal year," Thompson wrote. "This is movement in the wrong direction, and it is clear that

merely tweaking the appeals system will not adequately address the problem."

Thompson's letter was addressed to Nancy J. Griswold, the OMHA's Chief Administrative Law Judge and specifically detailed problems with the Recovery Audit Contractor (RAC) program. The letter did not address ZPIC audits. But OMHA uses ALJs when providers appeal decisions by RACs and ZPICs, according to Rich Marotti, an attorney with the firm **Murphy Austin Adams Schoenfeld LLP**, in Sacramento.

Providers Win Most Appeals

In an article on his law firm's web site, Marotti also reported that the AHA has published success rates for those who file ALJ appeals. In 2014, AHA reported that healthcare providers were successful in 67% of cases before an ALJ, he wrote.

"The result of the current years-long wait to be assigned an ALJ makes the playing field heavily slanted in favor of the large corporations and against small lab companies," said the lab official. "The largest lab companies have the resources to fight these audits because they believe in most cases they will win at the ALJ level of appeal. Plus, if a provider wins, the provider gets the recoupment returned plus earns interest on those funds at a rate of 9.5%.

"Those providers may view the whole process as an acceptable risk, in part because, if the smaller provider organizations cannot survive, then the larger providers have fewer competitors," concluded Marotti.

Fearful Of Publicity

There is little public information about this situation. Pharmacogenomic lab companies that have undergone ZPIC audits and been hit with demands for recoupment totaling millions of dollars, or tens of millions of dollars are reluctant to discuss the details of these cases. They are fearful that making this information public may bias the appeals process against them.

ZPIC Audits of PGx Labs Raise Serious Questions

DETAILS IN THE CASE OF PHARMACOGENETICS Diagnostic Laboratory LLC (PGXL), are similar to those of the unnamed lab hit with an audit and demand for repayment.

In October, **CGS Administrators, LLC**—the Medicare contractor for region J15 that serves Louisville—sent a letter to PGXL, demanding payment of $26,333,173. In the letter, CGS said this amount was an overpayment based on an audit conducted by **AdvanceMed**, an auditor for Medicare's Zone Program Integrity Contractor initiative. *(See TDR, January 9, 2017.)*

A molecular diagnostic testing lab for physicians, clinics, and hospitals, PGXL has 21 employees and expected gross revenue of $8.8 million in 2016. On Nov. 8, PGXL filed for bankruptcy protection in U.S. Bankruptcy Court for the Western District of Kentucky.

According to court documents, when reviewing PGXL's claims, AdvanceMed did a post-payment audit of 30 patients' records that were filed between January 1, 2012, and September 23, 2015. After reviewing these 30 claims, AdvanceMed decided that CGS should not have paid any of those claims. Then, AdvanceMed took that 100% denial rate for the 30 claims and applied it to all claims PGXL had submitted in those 45 months. As a result, AdvanceMed decided that all payments to PGXL in that time should not have been paid. By extrapolating in this manner, CGS concluded that it had overpaid PGXL by $26.3 million.

But what is significant is that there are at least two pharmacogenomics labs that now face a recoupment demand of $26 million (for PGXL) and multiple millions for the unnamed lab that provided information for this story. Other labs undergoing ZPIC audits are invited to contact THE DARK REPORT in confidence to share information about their audits' outcomes. **TDR**

—Joseph Burns

CEO SUMMARY: One essential element of precision medicine will be the regular use of pharmacogenomic testing to provide additional guidance to physicians when selecting the most appropriate therapeutics and optimal dose for each individual patient. Despite the reluctance of private payers and Medicare to reimburse for pharmacogenomic tests, Avera Institute for Human Genetics (AIHG) in Sioux Falls, S.D., has used pharmacogenomic testing over the past six years to support clinical care and improve patient outcomes.

Pharmacogenomic tests for surgical inpatients

Health System Lab Is Genotyping to Identify Best Drugs for Patients

PHARMACOGENOMIC TESTING is one of laboratory medicine's new frontiers. Physicians and pathologists know that patients metabolize medications at different rates. Pharmacogenomic testing is also expected to play an integral part in personalized and precision medicine.

Yet today, few health systems gather this information on every patient, due partly to the cost of genotyping and partly because research into the clinical value of this information is ongoing.

As most clinical laboratory scientists know, currently few health insurers pay for such testing. In 2015, the federal **Centers for Medicare and Medicaid Services** stopped paying, saying such assays were screening tests *(See TDR, June 22, 2015)*. Despite these concerns, **Avera Health**, a health system in Sioux Falls, S.D., has put itself at the forefront of personalized medicine.

The health system's largest hospital, 545-bed **Avera McKennan Hospital and University Health Center** in Sioux Falls, performs pharmacogenomic testing on all surgery inpatients. The tests determine how well these patients metabolize pain medications.

In addition to inpatient surgical pain patient testing, AIHG also performs pharmacogenomic testing for psychotropic, anti-platelet, statins, and other medications. AIHG staff work with Avera McKennan providers and the pharmacy department to gather information that proves to be useful for about half of the patients tested, especially when evaluating the drug-drug-gene interactions.

"Avera Health seeks to determine the economic value of pharmacogenomic testing to a health system," stated Krista Bohlen, PharmD, the Director of Personalized Pharmaceutical Medicine at the **Avera Institute for Human Genetics**. A research pharmacist on the genetics research team, Bohlen said Avera is collecting data on the cost effectiveness of the program and is planning to publish those results in a peer-reviewed journal this year.

Avera's interest in pharmacogenomics testing began in 2006. "Since then, we have regularly pursued genetics research opportunities by genotyping human subjects involved in registries and other projects," explained Bohlen. "Then, in 2009 and 2010, we added a study for pharmacogenomic testing for psychotropic medications for behavioral health patients.

CLIA Certification

"We started a research protocol for testing CYP2C19 for the antiplatelet agent clopidogrel in 2011," she said. "Next, in 2013, the AHIG lab earned its CLIA certification and we started performing clinical pharmacogenomic testing for pain patients.

"Our administration recognized the potential of pharmacogenomic testing to improve patient care and to reduce costs through quicker treatment success and fewer adverse effects," Bohlen added.

Early work on pharmacogenomic testing was funded by Avera Health, through a desire to promote research and recognition that someday, such testing would be reimbursed. "We pursued research to show the value to treating physicians, along with patients and researchers," Bohlen said.

Seeing the Potential

By 2013, Avera reached the important milestone of placing pharmacogenomic testing results into Avera Health's electronic medical record system [**Meditech**]. "Now, treating physicians had that data at the point of care," said Bohlen. "This meant our lab test results could have clinical impact in real time versus the retrospective research we'd done up to that point."

Three studies are underway involving patients with depression who were tested with Avera's psychotropic genotyping panel. These studies include information about clinical outcomes from the EMR as well as data from validated patient questionnaires.

"We hope to show how appropriate use of pharmacogenomic testing improves patient outcomes," emphasized Bohlen.

"Along with improved patient outcomes, we hope to demonstrate that such tests also reduced the overall cost of care for these patients.

Multiple Co-morbidities

"With depression patients, there are often multiple co-morbidities," she observed. "Thus, for our studies, we started with depression patients who fit certain criteria—meaning those who would not have many confounding effects from other medications."

"To do all this, a team was assembled that includes clinicians from pharmacy, the clinical laboratory, a nurse practitioner from clinical implementation, a nurse-project leader and a variety of other staff," noted Bohlen. "These are the people who implemented our program of pharmacogenomic testing for individual patients in the specific clinics. We have a significant opportunity to improve care in the 300 Avera hospitals, clinics, and other facilities in our five-states.

"Researchers have looked at the impact on patients when they undergo a panel of tests for depression," she added. "Our studies intend to add to that research by answering these questions: Do these patients get better; meaning is there an improvement in their depressive symptoms? And, how often do patients get put on the right medication?

Selecting Right Medication

"Pharmacogenomics is a tool that helps clinicians to narrow their choices for medications from as many as 20 or more down to maybe eight to 12 medications," Bohlen said. "Such testing allows physicians to target the right medication for each patient while doing their best to avoid adverse effects.

"Once our laboratory reports the test results, then physicians follow the dosing guidelines published by the **Clinical Pharmacogenetics Implementation Consortium** (CPIC) and **Pharmacogenetics Working Group of the Royal Dutch Association for the Advancement of Pharmacy**," she said. "In addition to these guidelines, we also evaluate primary literature."

Avera's journey to bring pharmacogenomics testing from research to bedside was not without challenges. Laboratory Operations Manager Trisha Lauterbach, MLS (ASCP) CM, CHT (ABHI), said one early challenge was implementing a smooth transition from paper orders to electronic test orders. Other challenges overcome included: entering structured lab results into the EMR, managing a clinically useful turnaround time, and developing clinical decision support that used flags triggered by new lab test results and the medications being ordered.

Overcoming Hurdles

A key hurdle was logistics. "Any pharmacogenomic testing program like this needs a rapid turnaround of results from the lab," Lauterbach explained. "For example, if the specimen is collected by 8 a.m., our lab would want to deliver the results by that afternoon or—in some cases—within 24 hours so the results are available to the physician at the point of care.

"To do this, our lab does the genotyping and then enters the result into the EMR so that the physician knows the recommendation for which medications may be best metabolized," she explained. "Having this information in the EMR means physicians can take this action without having to go outside of their normal workflow."

Bohlen continued, "This allows the doctor to get the patient on the right medication that same day. We want the patient to be stabilized and make sure the medication is effective for pain before the patient is discharged, especially in our efforts to prevent readmission," she said.

"In addition, we had an EMR system that wasn't initially designed to handle pharmacogenomic results," noted Bohlen.

Avera McKennan Health's Molecular Lab Team Gets Positive Feedback Directly from Patients

RESEARCHERS AT THE AVERA INSTITUTE FOR HUMAN GENETICS are collecting data to use in peer-reviewed studies that demonstrate the value of the institute's pharmacogenomic testing program. Later this year, they plan to publish the data.

In the meantime, the staff has been collecting testimonials about the value of pharmacogenomic testing from patients themselves, stated Krista Bohlen, PharmD, the institute's Director of Personalized Pharmaceutical Medicine.

"We see patients who need a knee replacement and maybe they've already had one knee replaced," added Bohlen. "These patients may be worried about having another replacement surgery because the pain was so bad the first time. They tell us that the pain medications they've had in the past have not worked well.

"This is where the pain genotyping panel is useful to identify the best medication for these patients," she stated. "Following the surgery, they tell us how surprised they were that the medication we prescribed was more effective for them. They will say things such as, 'So this is what actual pain relief is like!'

"It's a similar experience for patients who have depression," continued Bohlen. "Physicians outside of Avera Health might have tried up to eight different medications and still had poor results. But then when we run our psychotropic test panel, we can help choose the most effective medication and avoid adverse effects. This testing helps us to get to treatment success sooner for these patients."

"To resolve that, our EMR analysts implemented results reporting and clinical decision support alerts into the workflow for providers.

"Today, we have alerts built into the EMR so that it operates as a clinical decision support system," commented Bohlen. "For example, if a provider tries to prescribe a medication that is inappropriate based on the pharmacogenomic test result, the system will issue an alert with alternate recommendations."

A Reimbursement Challenge

Fair reimbursement was another hurdle to overcome. "The theory behind this program is that there are benefits to doing preemptive pharmacogenomic testing, but a big barrier to such testing is getting health insurance companies to pay for these tests," observed Bohlen. "For that to happen, we need more data on patient outcomes and further data to confirm that testing helps prevent adverse drug events.

"Second, we need to demonstrate to payers that clinicians used these tests to put patients on the recommended medications," she added. "With such data, health plans may be more willing to pay for these tests.

"Right now, health insurers don't pay for pharmacogenomic screening tests," Bohlen said. "So we also have to work through prior-authorizations if the drug we identify as being the most appropriate for that particular patient is not on their list of approved medications

"If the patient's insurance company doesn't recognize the alternate medication as a tier-one drug, then it might not pay for the prescription or charge a higher co-pay or co-insurance," noted Bohlen. "We use our specialty pharmacy patient advocates to help identify the anticipated co-pay and coverage to help the clinical team decide which medication to prescribe given the financial barriers."

A significant part of Avera's journey was improving efficiency and reducing cost. To accomplish that, the lab changed its testing protocol. "We started using polymerase chain reaction (PCR) testing

Timeline for Avera's PGx Test Initiative

FOR MORE THAN 10 YEARS, MOLECULAR GENETIC testing has been performed at Avera Institute for Human Genetics. Here is a timeline for this innovative program.

2006 AIHG is founded. Funding is from a federal grant. Institute works with Netherlands researchers to learn how environment and genetics affect the development of certain traits and diseases among twins.

2009 Initiates pharmacogenomic testing research study involving psychotropic medications for behavioral health patients.

2011 Initiates research study with pharmacogenomic testing on patients who were prescribed clopidogrel, the anti-platelet medication.

2013 Initiates research study with pharmacogenomic testing for pain patients. CLIA certification.

2014 Clinical pharmacogenomics launched with scanned lab results and personalized pharmacogenomic reports in the EMR.

2015 Initiates electronic ordering, structured lab results, and clinical decision support alerts in the Avera EMR. Initiates pharmacogenomic testing for pain medications for all surgical inpatients at Avera McKennan.

2016 Obtains CAP accreditation. Providers regularly order clinical pharmacogenomics testing for pain, psychotropic, and anti-platelet medications.

2016 Avera Institute for Human Genetics partners with The Netherlands Twin Register (NTR) to expand scientific collaboration between Avera and VU to learn how environment and genetics affect the development of certain traits and diseases among twins. Avera Twin Register, South Dakota's only genetics registry of twins, is launched.

instead of microarray technology," Lauterbach explained. "Microarray provides significantly more data, but the turnaround time can be up to five days and is costlier.

"With PCR, the turnaround time is 24 hours and the cost is significantly less than microarray," she noted. "That's a big difference because PCR enables us to do the testing almost in real time at a fraction of the cost."

Bohlen agreed, explaining that the cost of testing was one of the biggest challenges the team faced initially. "Now that the costs are going down and this testing is more comparable to the costs of other lab tests, reimbursement is not such a significant barrier, especially if patients are willing and able to afford out-of-pocket costs if insurance denies the claim," she added. "We are continuing to monitor the advantages that can accrue to the patient and to the health system as well."

A Need for Collaboration

"To get the whole process to work efficiently, AIHG needed to develop a multidisciplinary approach to delivering care," said Lauterbach. "As an example, for inpatient surgeries at Avera McKennan, pain genotyping blood samples are drawn in the morning on the day of the surgery and resulted by that afternoon. We enter the structured laboratory results into the EMR and our team then interacts with physicians and pharmacists on the pain team.

"In that way, there's a lot of interaction—or a lot of passing the baton, if you will—from the laboratory staff to the pharmacy staff; then to the patient's physician and clinical pain team," she said. "The clinical implementation strategy is the key factor to making this work."

"Our multidisciplinary team allows us to improve patient outcomes during the patient's hospital stay by implementing the results, monitoring the alternate therapy, educating the patient, and ensuring

the patient can afford the alternate medication in the outpatient pharmacy setting," added Bohlen.

Benefits of Integrated Care

"Our lab can affect care quickly because we bundle the pharmacogenomic test panel with other testing the patient needs immediately before surgery," noted Bohlen. "It's a big benefit for Avera to be a completely-integrated health system.

"Our laboratory is available to do everything from the most basic molecular genetic tests to whole genome sequencing. And it's right in the same hospital and health system, so we can deliver the results into the EMR in real time. Our tests are not being sent out so we don't have all that additional overhead or intermediate cost."

As with any multidisciplinary program, communication and education are critical components.

"Educating all providers in the value of pharmacogenomics and how to utilize results is needed to ensure that these tests are ordered and used in patient care," Bohlen said. At Avera, education for providers started with discerning which patients would benefit the most and how they would benefit, how to find the lab results and discussing recommendations with patients, what strategies to use for patients with significant polypharmacy, and then evaluating the insurance and reimbursement strategies.

Elements For Success

"Ultimately, we can have tremendous science behind it," concluded Lauterbach, "but this program will not work if the turnaround time is too long, if providers don't know how to use or find the results, or if they have to pass along a cost of over $1,000 to the patient."

The decade of experience in research and the clinical use of pharmacogenomic testing is why the teams at Avera Institute for Human Genetics and Avera Health are demonstrating that this testing does contribute to improved patient care. TDR

—Joseph Burns

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Avera's Genetic Institute Joins Twins Research Program

WHEN THE AVERA INSTITUTE FOR HUMAN GENETICS (AIHG) was established in 2006, it began developing key collaborations, the first of which was the Netherlands Twin Register (NTR).

In the late 1980s, researchers at the **Vrije University** in Amsterdam started one of the first biobank efforts. The Netherlands Twin Register (NTR) was established in 1987 and designed to provide insight into how genetics and the environment influence individual differences. The NTR examines the contribution of hereditary predisposition to such characteristics as personality, development, disease, and risk factors for disease.

Since the NTR began, over 7,000 sets of twins between ages 15 and 70 and 28,000 sets of twins between birth and age 15 have registered. "In fact, the Avera Institute for Human Genetics started with a federal grant and worked with Dr. Dorret Boomsma and researchers from the Netherlands Twin Register," Bohlen told THE DARK REPORT. Through this partnership, AIHG has analyzed thousands of DNA samples from the NTR.

Last year, the institute announced a new partnership with the NTR to expand the scientific collaboration between Avera and VU to learn how environment and genetics affect the development of certain traits and diseases among twins. As part of this new partnership, the institute also started the **Avera Twin Register**, South Dakota's only genetics registry of twins.

In Texas, BeaconLBS Start Will Be Delayed

UnitedHealthcare has yet to announce new date for when laboratory claims impact will commence

CEO SUMMARY: UnitedHealthcare will not implement the claims impact part of its laboratory benefit management program in Texas on March 1, 2017, as it had previously announced. Opposition to the program and the requirement that physicians use the BeaconLBS system when ordering about 79 lab tests is building among physicians in Texas. Officials from the Texas Society of Pathologists and the Texas Medical Association are voicing concerns about this scheme.

THERE'S A NEW TWIST in the plans by **UnitedHealthcare** to launch its controversial laboratory benefit management program in Texas. Having run the test phase of the program since Jan. 1, UHC decided to delay implementation of the claims implementation portion of the program. This part of the program was due to start March 1.

The delay comes as the **Texas Society of Pathologists** raises questions about the potential conflict of interest that exists in UnitedHealthcare's contract with **Laboratory Corporation of America** to implement LabCorp's **BeaconLBS** system as a way to manage lab test utilization and determine whether labs will or will not be paid for performing tests. BeaconLBS is a subsidiary of LabCorp.

In an email to TSP members on Jan. 20, TSP President Kevin D. Homer, MD, outlined risks to clinical labs that participate in the BeaconLBS program. "At our most recent conference, TSP learned that claims for 'decision support tests' submitted by 'labs of choice' will be paid by BeaconLBS from capitated funds the program receives from UHC," Homer wrote. "This means that BeaconLBS, a wholly-owned subsidiary of LabCorp, will have access to claims data from 'laboratories of choice' in Texas, including information about fees, clients, volumes, and ordering patterns.

"UnitedHealthcare claims there is a firewall preventing data flow from BeaconLBS to its parent company and asks Texas pathologists to trust that LabCorp will not receive or use any such information," Homer added. "Obviously, this situation is unacceptable to the TSP."

Texas Labs Have Concerns

TSP is considering bringing the issue to the attention of the Texas Legislature, he added. Also, he wrote, during the delay, BeaconLBS will discontinue outreach to network providers. In addition, UHC said it will continue to work with TSP about its concerns about the programs, he noted.

In its correspondence with UnitedHealthcare, "TSP has detailed specific concerns about the implementation, utilization, and quality impact of this program," Homer continued. "Our society will continue to consider all options to

ensure that Texans continue to have access to high quality pathology services, including potential legislative changes to protect patients during the current legislative session, which runs through the end of May 2017." The Texas Society of Pathologists held its annual meeting in Bastrop on Jan. 20-22.

UHC Promises 90-Day Notice

Although UHC did not announce a new start date for what it calls the 'claims impact' part of the BeaconLBS program, the health plan said it would notify providers in Texas 90 days before the program would affect lab test claims payment. The nation's largest health insurer, UnitedHealthcare is implementing the decision-support system in Texas for the 500,000 members in its commercially insured health plans.

In a statement to THE DARK REPORT, UHC said the delay is due to concerns about BeaconLBS' advance-notification process that physicians are required to use when ordering any of 79 tests listed on the UHC website. One interesting aspect in the statement UHC issued is a reference to the Beacon program in Florida and concerns about the advance-notification process. *(See sidebar on this page.)*

In addition to the issue TSP raised about the risks from data sharing, Texas pathologists expressed other concerns about the program in articles published in successive issues of THE DARK REPORT. *(See TDRs, Dec. 19 and Jan. 9.)* Since those articles were published, other pathologists have reported being worried about the effect the program will have on their ability to be paid for testing and the additional time required to use the BeaconLBS system.

One of those pathologists is Susan M. Strate, MD, a pathologist in the **North Texas Medical Laboratory** in Wichita Falls, Texas. The speaker of the House of Delegates of the **Texas Medical Association**, Strate said she is concerned about many aspects of the BeaconLBS program, especially portions of the program that could affect patient care.

UHC Issues Statement on BeaconLBS Delay in Texas

IN RESPONSE TO A REQUEST from THE DARK REPORT, UnitedHealthcare issued a brief statement on its plan to delay implementation of the claims-payment portion of the BeaconLBS program.

Here is the statement in its entirety:

The Lab Benefit Management Program gives physicians real time, evidence-based guidelines, and helpful patient information right as lab tests are ordered. We've been closely monitoring progress of the Florida pilot and are evaluating additional refinements based on data, experience and feedback from care providers, including concerns associated with the advanced notification process.

UnitedHealthcare will continue to engage professional societies who have concerns about the program.

Network physicians continue to have access to the physician decision support tool and are encouraged to use it when ordering decision support tests. We will notify providers 90 days in advance of the new claims impact effective date.

Impact On Rural Areas

In addition, she expressed concern that the program might make it difficult for physicians to use the system to order lab tests, particularly physicians in small practices serving patients in rural areas.

"I have several concerns," stated Strate. "For example, I have not personally seen data that shows the quality benefit of the system. Also, a physician cannot order certain tests if those tests are outside the balance of some of the algorithms in UHC's laboratory benefit management program.

"There are algorithms programmed into the BeaconLBS system so that it does not allow the physician to order certain lab tests if they are outside the system's parameters," added Strate. "There also could be problems if the physician can't get into the system with his or her EMR interface.

Issue Of Clinical Significance

"Another issue is of clinical significance," she observed. "There is no place to enter comorbidities that justify the test a physician is ordering. Doctors know that treating patients is both an art and a science. Practicing medicine is not just following simple cookbook rules. Every patient is different and every patient has certain comorbidities that we need to consider.

"This BeaconLBS program is a significant concern because it puts a complete roadblock in some places where physicians will want to order the appropriate lab test for the patient," Strate explained. "There is no good option within the program to appeal decisions in order to get a certain test performed. Even if a physician can get into the decision support system, he or she can't appeal a decision.

"Therefore, each time a test a physician believes is appropriate is simply denied by the BeaconLBS system, that may compromise patient care," she said. "And we do not accept programs that are detrimental to patient care.

What Is Cost-Benefit Ratio?

"In addition to these valid concerns, it is also important to consider the cost-benefit ratio of any new regulatory burden that we're adding," Strate commented. "Patients today struggle to pay for care while deductibles and the cost of insurance both are skyrocketing. We need to reject any additional administrative burden that costs money."

Like the TSP, the Texas Medical Association is considering bringing the issue to the Texas Legislature, she said. "That's one of several issues that the TMA has under review," she said.

"We've heard clear and compelling evidence on how the BeaconLBS program was implemented in Florida," she said. "And what we've heard about the administrative burden makes it a concern here in Texas because we have many small and rural practices.

"The majority of the practices in Texas are classified as small practices—especially those delivering primary care," added Strate. "A new administrative process [for ordering these lab tests] could be particularly difficult for any small practices in rural areas. Physicians already have difficulty getting the lab testing done that they need, along with getting the consultants they need. This type of system could make all of those processes more difficult. So in that way, this program could be especially devastating for them."

Need For Additional Staff

In Florida, some medical practices needed to hire additional staff to complete the process of ordering tests through the BeaconLBS system. The need to take on the added costs of additional staff to comply with the UHC program is a concern among physicians in Texas.

"I have a number of sites where I practice that are distinctly rural and those physicians need systems that help them get their work done," concluded Strate. "If they must use a decision-based support system that does not have an interface to the electronic health record systems they use, that could have a detrimental effect on the ability of those physicians to order tests and do what they need for patients."

Texas has a bi-annual legislature that is now in session and scheduled to adjourn on May 29. Could UnitedHealthcare be delaying implementation of claims impact until the legislature concludes, so as to avoid having angry providers complain to their lawmakers? TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In New Jersey, a U.S. attorney has put laboratory sales reps on notice that they can be prosecuted for violating federal anti-kickback laws and sent to prison. On January 18, Paul Fishman, U.S. Attorney for New Jersey, announced the sentencing of Michael J. Zarrelli, of Berkeley Heights, N.J., formerly a sales representative with the now-defunct **Biodiagnostic Laboratory Services, LLC** (BLS), of Parsippany, N.J. Zarrelli, 50 years old, had earlier pled guilty to two counts of conspiring to bribe a doctor and money laundering. He was sentenced to 20 months in federal prison. He must also forfeit $247,264, the amount of money he received from BLS.

MORE ON: *Lab Rep Sentenced*

In statements about the case, federal officials said the doctors bribed by Zarrelli generated more than $400,000 in lab test referrals to Biodiagnostic Laboratory Services. Zarrelli's guilty plea and sentencing brings to 41 the number of individuals convicted in the BLS case. This includes 27 physicians. Sales reps working for lab companies that chose to loosely interpret federal anti-kickback laws are now on notice that they face the possibility of a criminal conviction for their part in implementing schemes that involve illegal inducements to physicians in exchange for referrals of Medicare patients.

MONTEFIORE, QUEST TO COLLABORATE

On Jan. 27, **Montefiore Health System** of New York City and **Quest Diagnostics Incorporated** announced a lab testing agreement. In the press release, the two parties stated, "Quest will perform a portion of low complexity diagnostic tests at its Teterboro, N.J., lab facility. The remainder of the laboratory testing will continue to be done at Montefiore hospitals under the direction of the Montefiore and Einstein Department of Pathology." This describes an arrangement where Montefiore is outsourcing some of its routine, non-time-sensitive testing to Quest Diagnostics while continuing to manage its own inpatient laboratories. Montefiore operates 10 hospitals and 200 outpatient sites.

TRANSITIONS

• Krista Tinsley is leaving her position as Executive Director at **ProPath**, the regional pathology group based in Dallas, Texas, as of Feb. 6. Tinsley served at ProPath for almost 23 years. She formerly worked at **AmeriTrust Texas**.

That's all the insider intelligence for this report. Look for the next briefing on Tuesday, February 21, 2017.

SPECIAL SESSION!

What every lab must know about coming Medicare fee cuts!

Lâle White

Executive Chair and CEO, XIFIN, Inc.

Preparing for PAMA's Part B Price Cuts: What XIFIN's Impact Analysis Predicts for Labs Like Yours in 2018

Deep cuts to Medicare Part B lab test fees are coming in just 11 months! The Dark Report and many experts predict this will be the single most financially-disruptive event to hit the clinical lab industry in two decades.

To ensure that you and your lab are prepared for deep fee cuts and the financial consequences of the PAMA market price reporting rule, Lâle White will present a comprehensive analysis of the data Medicare officials are using to set new prices for Medicare Part B lab fees. You will learn why the lab industry is concerned about the biases in the final rule and how they will reduce your lab's revenue.

Of greatest importance, XIFIN handles the billing for more than 200 labs in the United States. You will see what actual price data from hundreds of millions of claims reveals about the reduced revenue that your lab will see in 2018. Act today to guarantee your place!

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- *Useful Strategies for Labs Negotiating Contracts with Accountable Care Organizations, Medical Homes.*

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