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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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

What Are Lab Industry's True Major Issues?

WE'VE JUST FINISHED A FASCINATING WEEK IN NEW ORLEANS, at the 23rd annual *Executive War College*. More than 820 lab leaders were present to hear 104 interesting speakers in 65 unique sessions. Collectively, this group represented as much as $20 billion in annual clinical lab and pathology revenue.

These statistics are important for a strategic planning reason. Our *Executive War College* brings together a substantial critical mass of lab leaders annually to discuss and debate the state of laboratory medicine. This is an opportunity for pathologists, lab administrators, and lab executives to get the latest business intelligence about what is working and what is not from the nation's most innovative lab organizations.

There is much positive news for our industry, along with recognition of what investors call "headwinds"—factors that make it more difficult to grow, increase market share, and build revenue. The most significant headwinds are familiar. Payers, including Medicare, are cutting lab test fees. Networks continue to narrow and hospital labs and local labs find it difficult to negotiate managed care contracts. It remains tough for new molecular and genetic tests to win favorable coverage and reimbursement decisions.

But many speakers at this year's *Executive War College* were excited about the opportunities available to those clinical labs and pathology groups willing to be innovative and that are prepared to invest the needed resources to provide hospitals, physicians, payers, and patients with specific lab testing services that deliver recognized value. The benefits can include early detection of disease, helping with decisions as to how to treat patients, or even working with select payers on population management initiatives that use lab test data—combined with other clinical data—to identify patients who would benefit from programs to help them manage their chronic diseases. Some of these primary themes are presented on the story which follows on pages 3-6. Other important developments and insights will be shared in coming issues of THE DARK REPORT and our special webinars.

The most important message that came out of last week's conference, however, is that a substantial number of those leading many of the nation's best-known laboratory organizations are optimistic about the future of lab medicine, but only if the lab industry acts collectively to create and demonstrate new ways to add value to patient care and patient satisfaction. TDR

Key Lab Trends Described At Executive War College

Speakers emphasized opportunities for labs while recognizing Medicare price cuts as a given

CEO SUMMARY: Innovative clinical labs and pathology groups are absorbing this year's Medicare Part B price cuts while continuing to pursue opportunities to add value. A common theme from many speakers at last week's Executive War College in New Orleans is that the lab must get mastery of its LIS and informatics specifically to enable it to convert raw lab test data into clinical intelligence that physicians can use to improve patient outcomes and reduce the cost of care.

ONE SURPRISING OUTCOME from last week's 23rd annual *Executive War College* in New Orleans was that innovative clinical labs and pathology groups have tremendous opportunities, but only if they proactively pursue them!

If this year's deep Medicare fee cuts are the dark cloud hovering over the lab industry, then precision medicine and new diagnostic technologies are the trends that promise sunny days ahead—at least for those lab organizations willing to act now to deliver added-value lab testing services.

For the more than 800 attendees, the *Executive War College* was an opportunity to learn about the fast-moving transformation of the U.S. healthcare system, as well as the positive opportunities labs have to serve the new modes of healthcare delivery.

"The speakers this week taught us that delivering high-quality, state-of-the-art clinical testing services to referring physicians takes plenty of focus and resources to do correctly—whether it's anatomic pathology, clinical laboratory, or genetic and molecular testing," stated Robert L. Michel, Editor-in-Chief of THE DARK REPORT, at the closing session of the *Executive War College*.

"It continues to be true that insurance companies want to pay less per test and at the same time are making coverage for new assays more difficult," he continued. "Insurers also make network access more difficult for those of you who want to offer testing to patients in your region."

For labs that specialize in clinical testing, anatomic pathology, and genetic and molecular tests, the two-day conference

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

was an opportunity to understand how the biggest trends affecting the healthcare system are buffeting labs and changing the way care is delivered.

"The drum beat we've heard at this conference for several years now is that health systems are focusing on the integration of care, specifically to be proactive and not reactive in how they deliver care to patients," noted Michel. "No longer do integrated health systems wait for patients to show up sick in the hospital, the emergency room, or an urgent care setting with some chronic and costly condition.

"Instead, the nation's most innovative health systems want their clinical labs to help physicians identify illness in patients early to ensure that these patients get the screening tests they need," he added. "If a patient's lab test numbers move in the wrong direction, then the system wants that patient to get the care needed before test numbers indicate the patient has acquired a chronic condition that is more costly to treat."

Labs as Information Firms

"In her keynote presentation, Mara Aspinall, President and CEO, **Health Catalysts**, explained why labs of all kinds are becoming information companies that collect the data the health system needs through testing, then managing and storing the data that testing produces," noted Michel. "Aspinall expects the successful lab of tomorrow will be in the information business with a wet lab on the side."

In her keynote presentation, "Are the Paths of Hospital and Health System Labs Diverging from the Paths of Independent Labs?"; **XIFIN** Executive Chairman Lâle White said that, yes, hospital and health system labs have different needs and goals than those of independent labs.

She explained that changes in reimbursement—particularly from Medicare and Medicaid—are having an effect on the entire industry that is causing a divergence among labs. Independent labs will move away from what hospital and health system labs do. In other words, the different sectors of the lab industry will serve different constituents.

Price Stability in Lab Sector

"We will continue to see stability in the molecular diagnostic pricing arena and in pharmacogenetics, and we will see investor funding coming back to the marketplace," said White. "That means we'll see more molecular proprietary testing labs resurface and specialty labs come into play."

White predicted that labs will continue to specialize, just as physicians specialize. "Independent labs will build their menus with specialty tests to balance the diversity of their menus. At the same time, they will provide education to physicians about how to order these tests."

She also predicted that the number of independent labs offering full test menus will decline because a full menu of tests means these labs will no longer be interested in offering low-margin testing. "As in other industries serving the healthcare sector, labs will consolidate with other labs and form partnerships and joint ventures," continued White. "Expect to see ongoing industry consolidation in routine testing because labs will need economies of scale to support the needed lower-cost structure and the new reimbursement structure."

JVs with Outreach Labs

She described how, for example, labs that specialize in reference testing will seek economies of scale by partnering with outreach labs. Also, independent labs will create joint ventures with hospital labs, she predicted.

One reason for these changes is how labs will be affected by the lower Medicare lab prices introduced on Jan. 1 under the Protecting Access to Medicare Act, White said, adding, "And, PAMA's impact wasn't just to Medicare. It has affected what Medicaid pays too.

Two Speakers Describe Increased Interest of Pharmaceutical Companies in Lab Testing

IN HIS CLOSING REMARKS during last week's *Executive War College*, Robert L. Michel, Editor-in-Chief of THE DARK REPORT, spoke to the comments of several speakers about the growing interest of pharmaceutical companies in clinical diagnostics, including controlling diagnostic patents and intellectual property.

Michel highlighted the presentation from Mara Aspinall, President and CEO of Health Catalysts in Tucson, Ariz. In her presentation, she said, "Diagnostics is an information business with a wet lab on the side." By itself, diagnostic testing has some value to the healthcare system. The bigger question is what value do the results of diagnostic testing have, she said. "Diagnostics is great because we have the data. But so what? What do we do with that data?" she asked. "As clinical labs, we need to be the data interpreter because data alone is not useful."

With data, labs can provide the link to appropriate therapeutics. "To do that, we need to get cozy with drug developers because diagnostics will thrive as more therapeutics thrive," she said.

"Clinical labs and pathology groups should incorporate Aspinall's recommendations into their labs' business and clinical strategies," stated Michel. "She provided powerful evidence that pharmaceutical companies want more involvement in diagnostics, particularly the companion diagnostic tests used to identify patients who will benefit from specific cancer drugs.

"This theme is one that William G. Morice II, MD, PhD, also made," continued Michel. Morice is the President of **Mayo Medical Laboratories** and Chair of the Department of Laboratory Medicine and Pathology at **Mayo Clinic** in Rochester, Minn. "In his presentation, Morice explained that pharmaceutical companies and private equity investors are increasingly willing to invest in diagnostic companies and, as they do, they have the potential to reshape the lab testing market.

"This point about the role of pharmaceutical companies is another important strategy for labs to follow," Michel explained. "Pathologists and clinical labs have long controlled diagnostics on behalf of patients.

"However, today, pathologists and the clinical lab industry have collaborators who want to control diagnostics," he continued. "Their motives are not the same motives that labs have.

"Labs are motivated by improving patient care. But pharmaceutical companies are motivated by profit and by controlling and owning the diagnostic patents and data used in lab tests," commented Michel. "Pharma companies have huge amounts of money to bring to lab testing and we need to be aware of how that money could be used to reshape laboratory testing."

"As an industry, we realize that Medicaid cannot pay higher than what Medicare pays and most Medicaid payers were paying significantly lower than the Medicare rates to begin with," observed White. "But now that Medicare has cut what it pays labs nationwide, Medicaid programs in many states also are cutting payment for lab testing. In some states in which the Medicaid program already just pays 60% of what Medicare pays, labs in those states are seeing new, deep cuts in payments from their state Medicaid programs."

During a unique session that featured executives from two health system labs and two independent lab companies, a number of interesting insights emerged from the free-wheeling panel discussion.

One such insight was the shift in how lab testing is performed at **HealthPartners** in

Bloomington, Minn. "Our health system is moving specific tests out of the core laboratory so that they can be run in physicians' offices and other near-patient settings," noted Rick L. Panning, Senior Administrative Director, Laboratory, for HealthPartners.

"The higher costs of shifting these tests is offset by a faster time to diagnosis in the physicians' offices and greater daily productivity for the physicians," he added. "Another strategy involves patients with the greatest needs, such as those who are frail and elderly. Our health system sends phlebotomists to those patients for blood draws. We do 500 at-home blood draws per day, for example, and have an increasing portfolio of point-of-care testing to go along with our phlebotomy service."

"Panning's point is important for any integrated healthcare system," Michel commented. "Making physicians as productive as possible and increasing test turnaround time so that physicians can get patients on the appropriate therapy sooner represents a new opportunity for labs."

Another useful perspective was offered by Jon R. Cohen, MD, Senior Vice President and Group Executive, Diagnostic Solutions for **Quest Diagnostics**. For labs seeking to get ahead of the curve, Cohen offered a suggestion: understand your lab's cost of testing. The reason? Many labs do not know how much they spend per test.

"In the lab management partnerships we've done with healthcare systems and hospitals around the country, virtually every single hospital health system has no idea of what their cost of testing is," stated Cohen. "This lack of knowledge about the cost of testing is a vestige of how labs and hospitals are paid. It's not the lab director's fault," he said. "The lab director gets a budget and runs the lab within that budget.

"But to actually understand the specific costs of each type of assay is a difficult and time-consuming exercise," continued Cohen. "For that reason, most labs don't do that work. However, as competition increases, labs will need to know precisely how much it costs to run each test." TDR

—Joseph Burns

Collaborations, Joint Ventures Coming to Clinical Lab Industry

USE OF COLLABORATIONS AND JOINT VENTURES BY LABS was one insight during the opening general session of the *Executive War College*. During his remarks, James M. Crawford, MD, PhD, Senior Vice President, Laboratory Services, for **Northwell Health** in Great Neck, N.Y., explained that the Northwell system was emphasizing preventive care and population health in a sophisticated strategy that uses molecular and genetic testing.

Crawford's lab needs to support clinical initiatives in preventive health, precision medicine, and population health with gene sequencing capabilities. "For our lab to participate in new precision medicine initiatives, the question we asked was this," said Crawford. "Was it better to buy gene sequencing instruments and hire the lab scientists to do sequencing within our lab, or could we collaborate with outside companies and still get high-quality, timely gene sequences? Our decision was find a partner."

"Northwell's strategy is instructive because it did not establish its own gene sequencing system," Michel said. "Instead, Northwell partnered with a division of **BioReference Laboratories** to have this sequencing division do the testing for them. The gene sequences and DNA data go to the Northwell laboratory, which does the interpretation and sends the results to the ordering physicians.

"That's a new lab business model and it involves collaboration," noted Michel. "What Northwell lab's experience tells us is that your lab doesn't have to do it all internally and you don't need to own everything. This example shows how, in the new healthcare system, it is less about vertical integration (with the health system owning all needed services) and more about horizontal integration that stresses collaborations and joint ventures with other entities that have the requisite experience and resources."

Insurers Sue To Challenge Pass-Through Bill Schemes

UnitedHealthcare and Anthem file lawsuits charging fraud against labs, other defendants

CEO SUMMARY: In two separate lawsuits filed in April, UnitedHealthcare (UHC) and Anthem each charged that drug testing companies used pass-through-billing schemes in ways the insurers say are fraudulent. UHC filed its lawsuit on April 18. One day later, on April 19, Blue Cross and Blue Shield of Georgia and other Anthem companies filed suit against lab testing and management companies. The UnitedHealth and Anthem lawsuits said defendants illegally induced requests for lab testing services.

TWO OF THE NATION'S LARGEST HEALTH INSURERS are mad as hell and they're not going to take it anymore. That seems to be the message **UnitedHealthcare** and **Anthem** are sending in court documents filed in April against lab testing companies using pass-through-billing schemes in ways the insurers charge are fraudulent.

On April 19, **Blue Cross and Blue Shield of Georgia** and 24 health insurers and other companies affiliated with Anthem and doing business as **Anthem Blue Cross and Blue Shield**, filed suit against:

- **Reliance Laboratory Testing**,
- **Medivance Billing Services**,
- Three individuals (Aaron Durall, Jorge Perez, and Neisha Carter Zaffuto),
- **Chestatee Regional Hospital**,
- **Durall Capital Holdings**, and,
- **DL Investment Holdings**.

In the lawsuit, the Anthem plans said that since 2016, the defendants engaged in a widespread scheme to bill for laboratory services that were fraudulent and violated contracts between BCBS Georgia and Chestatee Regional Hospital.

In August 2016, **Southern Health Corporation** sold the 49-bed Chestatee Regional Hospital in Dahlonega, Ga., to Durall Capital for $15 million. At the time, Chestatee Regional was an in-network provider for Anthem. Aaron Durall is the President of Reliance Labs, the CEO of Chestatee Regional Hospital, and the manager of Durall Capital, the lawsuit said.

Multiple Defendants Named

On April 18, **UnitedHealthcare Insurance Company** and **UnitedHealthcare Services** filed a lawsuit In U.S. District Court for the Western District of Texas, naming as defendants:

- Five individuals (Michael Murphy, MD, Jesse Saucedo Jr., Samantha Murphy, Lynn Murphy, Julie Pricer),
- **Alternate Health Lab**,
- **Mission Toxicology**,
- **Sun Clinical Laboratory**,
- **Sun Ancillary Management**,

- **LMK Management**, and,
- **Integrity Ancillary Management**.

UHC said the defendants illegally induced requests for lab testing services and used financially-strained rural hospitals as fronts to conceal the identity of the labs that performed the testing services.

Also, the defendants conned UHC out of at least $44 million by causing bills to be submitted for lab services, many of which were not ordered or not performed properly, the UHC lawsuit said. In addition, UHC said the defendants grossly inflated the prices of the lab testing services for their own financial gain. "The scheme steals from the insurers and its members and leaves patients with inadequate, sub-standard services and small rural hospitals in financial and operational disarray," the lawsuit said.

Anthem BCBS Lawsuit

In its lawsuit, Anthem explained the scheme. "Unbeknownst to BCBS Georgia, as soon as it took control of Chestatee Regional Hospital, Durall Capital agreed with defendant Reliance Labs, a non-participating toxicology laboratory located in Sunrise, Fla., to fraudulently bill BCBS Georgia for testing performed at and by Reliance Labs (or other non-participating laboratories engaged by defendants), as if the testing had been performed at and by Chestatee Regional Hospital. When referring providers ordered the testing, they ordered it from Reliance Labs (or other non-participating laboratories), and not from Chestatee Regional Hospital," the lawsuit said.

The non-participating labs could perform the testing ordered. "Yet, Durall Capital, Reliance Labs, and the other defendants billed the testing through Chestatee because BCBS Georgia would pay Chestatee Regional Hospital substantially more than Reliance Labs would receive if it billed BCBS Georgia directly," the lawsuit explained. Many of the claims were for urine drug testing and blood-drug testing, the lawsuit added.

"This type of arrangement—where claims are billed by an entity different than the one that performed the service—is commonly known as 'pass-through billing,'" the lawsuit said.

Under the scheme, Medivance provided billing and collections services and submitted lab testing claims to BCBS Georgia for the other defendants. Neisha Carter Zaffuto is President of Medivance.

The defendants had a nationwide network of referring providers and laboratories, who provided patients' specimens. Some of those providers submitted their patients' specimens "in exchange for a cut of the amount that Chestatee was reimbursed by BCBS Georgia," the lawsuit added.

UnitedHealthcare Lawsuit

In the first line of its lawsuit, United stated the case clearly, saying, "Defendants have executed a quintessential healthcare fraud scheme. They illegally induce requests for lab testing services. They then use financially-strained rural hospitals as 'fronts' to conceal the true identity of the lab that performed the testing services."

As in the case Anthem brought against the 14 defendants, UHC said the defendants caused bills to be submitted for lab services and many of those services were not ordered or not performed properly. In addition, the defendants grossly inflated the prices of those services.

UHC also made a point about the defendants' scheme that was similar to legal claims Anthem raised. "Defendants' fraudulent scheme not only steals from plaintiffs and its plans, it leaves patients with inadequate, sub-standard services and small rural hospitals in financial and operational disarray," the lawsuit said.

The lawsuit named San Antonio anesthesiologist Michael Murphy, MD, as the architect of the scheme and the owner and operator of a network of some of the defendants, including these companies: Sun Clinical Laboratories, Sun Ancillary

Management, Integrity Ancillary Management, Alternate Health Lab, and LMK Management.

In general, the scheme involves two steps. "First, defendants induce healthcare providers, sometimes through kickbacks, to refer United members' lab specimens to Sun Clinical Laboratories or Mission Toxicology," the UHC lawsuit said. "Second, defendants set up 'lab programs' at in-network rural hospitals, which they use to submit insurance claims to United that are intended to make it appear that laboratory test specimens were referred to, and that testing was performed by, the rural hospitals."

But, in reality, the specimens were sent to out-of-network labs that Murphy and Saucedo owned, the lawsuit said. When it submitted the resulting claims, the defendants charged as much as 50 times the actual cost of the testing and used the rural hospitals' identities, the lawsuit explained.

"United processed the claims and reimbursed the services as though they were performed by the in-network rural hospitals, even though the vast majority—if not all of the testing—was actually performed by out-of-network labs located hundreds or thousands of miles away from the rural hospitals for a fraction of the cost billed," the lawsuit said.

'Conned into Paying $44 Mil'

The result was that, "United has been conned into paying at least $44 million for improper lab claims."

After UnitedHealthcare paid the claims, the defendants instructed the employees at the rural hospitals to transfer 95% of the funds to their own entities, UHC charged.

Many pathologists and clinical lab managers will welcome the fact that two of the nation's largest health insurers decided to file lawsuits against the participants of pass-through billing schemes involving urine drug tests. TDR

—Joseph Burns

Judge Rules for Payer in Pass-Through Billing Case

IN ANOTHER LAWSUIT where pass-through billing of urine drug tests is being challenged by a large insurer, defendant labs and individuals have lost an important ruling.

In an **Aetna, Inc.**, lawsuit filed in September, a judge ruled against the defendants who had sought to get the case dismissed against five clinical lab companies, a hospital, three lab management companies, two physicians, and two other individuals. Also, Judge Berle M. Schiller in the U.S. District Court for the Eastern District of Pennsylvania transferred the case to the U.S. District Court for the Western District of Texas.

In his ruling, Schiller ruled against the defendants who asked the judge to dismiss Aetna's complaint.

In its September court filing, Aetna said the defendants bilked Aetna, its members, and its client employers out of $21 million in a healthcare billing fraud scheme. *(See TDR, Dec. 11, 2017.)*

In court papers, Aetna named 14 defendants: the **People's Choice Hospital, LLC**; **PCH Management Newman, LLC**; **PCH Lab Services, LLC**; **PCH Labs, INC.**; Mission Toxicology, LLC; **Mission Toxicology II, LLC**; **Mission Toxicology Management Company, LLC**; Sun Clinical Laboratory, LLC; Sun Ancillary Management, LLC; Integrity Ancillary Management, LLC; Seth Guterman, MD; David Wanger; Michael L. Murphy, MD; and Jesse Saucedo, Jr.

Some of these are the same individuals, lab companies, and management firms named in the UnitedHealthcare case described elsewhere in this story.

In 2016, Aetna said in its filing, the defendants gained control of Newman Memorial Hospital, a 25-bed critical access hospital in Shattuck, Okla. At the time, the Newman Hospital was struggling financially, the lawsuit explained.

In seven years, 160,000 fewer test orders!

Cleveland Clinic Lab Has Multi-year Test Utilization Success

CEO SUMMARY: Over the 24 months of a first-generation round of laboratory test utilization management projects, the Cleveland Clinic laboratories prevented more than 30,000 duplicate or inappropriate test orders, saving almost $2.7 million. Now implementing a second-generation of lab test utilization projects, the lab's seven-year effort has prevented 160,072 tests and saved more than $5 million. The primary goals of the program involved more than cost cutting and included improved quality and patient safety, and enhanced patient care and patient experience.

IMPROVING HOW PHYSICIANS use laboratory tests is becoming a widely-used operating strategy in hospital and health system laboratories today.

This strategy is popular for two reasons. First, when a lab works with physicians to eliminate unnecessary or duplicate test orders, the cost savings are immediate. Second, when physicians get better at ordering the right test at the right time, patient outcomes and patient satisfaction scores improve.

in 2011, the **Cleveland Clinic** laboratories launched an initiative to improve lab test utilization that in two years prevented more than 12,000 duplicate or inappropriate test orders, saving almost $1.2 million. *(See TDR, June 1, 2015.)*

The lab test utilization projects in 2011 and 2012 went after the low-hanging fruit, such as reducing duplicate orders and aligning standing lab test order sets to eliminate outmoded or inappropriate tests. These early projects gave the lab team experience in how to approach physicians to gain their cooperation and how to sustain improvements from these projects.

In 2011 and 2012, Gary Procop, MD, the clinic's laboratory Co-Chair of the Laboratory Stewardship Committee, oversaw the lab's utilization management and then used the lessons learned from the first two years to launch a second generation of lab utilization initiatives in 2013 that produced more impressive results. In this second phase, the clinic prevented more than 80,000 test orders and saved $5 million.

"From our first initiatives in 2011 we saw how our utilization management efforts changed our standing at the Cleveland Clinic. This fueled our second generation of utilization changes," he explained at THE DARK REPORT'S *Lab Quality Confab* in October 2017. "After starting this program, we learned that it's about much more than saving money. It's about adding value to the healthcare system.

"In our first-generation initiatives, we built trust in every lab throughout the Cleveland Clinic system," he said. "From that experience we gained the confidence to escalate the lab test utilization management program so that today we are truly changing our practice for the better.

"Every lab in the United States needs to address affordability immediately and our lab test utilization management program does that," he explained. "As pathologists and lab directors, we know that if we cut costs, we get almost an immediate positive response. But in addition to cutting costs, we also have to increase value for our healthcare system. I promise that by doing the right test, good things will follow—such as lower costs—but also by doing what's best for patients.

"Consider what happens when lab directors ask a group of healthcare providers, 'Who wants to do another cost-cutting project?'" said Procop. "You may not get a positive reply from everyone. But if you ask the same group, 'Who wants to improve the rate of indigent women getting Pap smears?' you get many positive replies.

Improving Patient Care

"When this happens, then your clinical lab has embarked on population health management and you'll have staff members—particularly the physicians and nurses—invested for the right reasons and for the long term, both of which are more sustaining than simple cost cutting," he advised.

"Our lab-test utilization management program is based on the universal principle of doing what's best for patients," noted Procop. "When our lab does this, we improve quality and patient safety while also enhancing both patient care and patient experience. At the same time, we increase our laboratory effectiveness and efficiency, cut costs, and save the clinic a lot of money.

"In addition, the projects are elevating the laboratory's position in our health system," Procop added. "Previously, no one from pathology or laboratory medicine

was on the most important clinic committees. Now it's significant that we're sitting at the table when key decisions are made.

"All of this results from asking the question: Who's going to be the leader?" advised Procop. "For lab directors and pathologists, now is the time to step up."

Five Primary Goals

After challenging lab directors and pathologists to assume more leadership roles in hospitals and health systems, Procop explained the five primary goals of the lab test utilization management program:

1. Improve quality and patient safety,
2. Enhance patient care and the patient experience,
3. Increase laboratory efficiency and effectiveness,
4. Reduce costs, and,
5. Enhance the lab's position on healthcare delivery teams.

For his presentation at *Lab Quality Confab*, Procop explained that the program cut costs while improving quality and value by using evidence-based best practices. "When our lab does this each time we take on a project, that project is automatically patient-centered," he said.

"In addition to being patient-centered, our interventions—except for our laboratory-based genetics counselor—are done through the informatics system," explained Procop. "These interventions happen at the point of order entry. That enables us to communicate with ordering physicians at the exact moment when they are placing orders, not after the blood has been drawn and it arrives in the clinical laboratory."

One of the first lab test utilization initiatives was an effort to stop same-day duplicate orders. "This happened as a result of a complaint to the former CEO about a patient being over-phlebotomized," Procop explained. "That sounds like a problem for the lab, but, actually, it created an opportunity for us.

"This complaint opened an avenue for the lab to communicate directly to the top administrators in our health system," he stated. "Now, we were talking with one of the system's hospital CEOs (or at least the next one or two administrators in the hierarchy) about how the lab would fix the problem. In other words, we had top-level support and we were addressing why this problem happened.

"By working with physicians to not over-draw patients, our lab was fundamentally improving both the patient experience and patient care," Procop said. "The added benefit was the lab was recognized for improving quality as well as cutting costs.

"That all sounds ideal," he emphasized. "But the reality is that our lab team was attempting to change a culture that's inherent in every hospital. Just a few years ago, physicians expected that if they ordered a test, the lab would run it—without question. In most cases, that paradigm continues in the prevailing culture.

"Therefore, when starting a lab test utilization management program, it's likely that ordering physicians will look at you as if you're from Mars," he cautioned. "That's what happened to me. Before that happens, labs need to answer the question: What will happen when our lab questions the need for a test a physician is ordering?

Vetted Ideas with Staff

"Keeping that question at the top of my mind made me wade into the water slowly," recalled Procop. "I did so by discussing the lab's approach thoroughly during grand rounds. I vetted our ideas with the medical staff so that we found agreement. We worked with our clinical colleagues to build evidence-based best practices to which we agreed.

"In our early projects to stop same-day duplicate orders, having those discussions first made us start slowly," he said. "It meant our lab initially established soft stops within the EHR for test ordering, instead of hard stops," Procop advised.

Success in Lab Test Utilization Projects Depends on Your Lab's Ability to Gain Physicians' Support

"FOR ANY LAB TO SUCCEED in managing lab test utilization, it must establish support from the hospital or health system leadership," stated pathologist Gary Procop, MD, Co-Chair of the Laboratory Stewardship Committee at the Cleveland Clinic.

"Our test utilization program started with a charge in the pathology department to enhance our utilization efforts throughout the health system," commented Procop. "To do so, we obtained an appointment with our chief of medical operations and asked how the clinical laboratory could be more engaged at the systems level.

"If your laboratory is not engaged at that level, find the leaders and get on the calendar," he advised. "Ask them how you can help. They want people who can make improvements. The traditional concept of pathologists and laboratorians being in a little box in the basement has to end.

"If your laboratory team is not ready, sow the seeds by talking about how you want to be more involved in enhancing patient care delivery," he said. "In our meetings with leadership we discussed the need to improve patient care. When you focus on best practices and improving patient care, you will get the support you need. The dollar savings will come naturally and people will stay engaged.

"Also, you need to have doctor-to-doctor conversations, meaning it's important to have a physician or other laboratory professional lead these discussions," noted Procop. "For all of this work, you will also need good communication skills. And you will want to have all affected departments send representatives to your meetings.

"Plus, it's absolutely critical to have strong partnerships with the staff and administrators in information technology. You will need them on your side, particularly if you plan to use clinical decision support systems to interact with the physicians at the point of order-entry.

"And, finally, I cannot stress this one enough because it will also be critical to your success with laboratory test utilization projects: You will need to monitor progress and report on the results of your interventions," concluded Procop. "One underappreciated aspect of good communication skills is having the ability to analyze what you did and show your results in a way that everyone else can understand. Doing so will build the credibility of yourself and your stewardship team, and whenever you share your successes, you will gain support."

"Doing so allowed us to gather data showing why our laboratory needed to stop some test orders," he said. "We needed to stop orders at order entry because the data showed physicians were not reading the messages shown to them during order entry.

"This point is important for any lab test utilization management program," Procop said. "By engaging physicians in discussions first, it made us address the problem providers have when reading warning messages in the EHR. It caused us to devise a means to allow physicians to override interventions should the laboratory test be medically necessary.

"If a hospital lab makes physicians at the bedside call the laboratory to address a purportedly unnecessary test, then most of the time they will not call unless they really need to order that test," he noted.

"The simple fact that physicians can override interventions by contacting the lab increases our level of safety," he added. "And now we have published the data showing that our hard-stop intervention

for same-day duplicate tests had no adverse effects on quality or patient safety.

"While devising the intervention to stop same-day, duplicate test orders, an informaticist who used to work in the laboratory suggested a great solution," stated Procop. "If a physician is looking for the result from a test we already ran, we could simply embed that test result in the duplicate test hard-stop notification, providing feedback to the ordering physician in real-time. Physicians loved this solution."

Increased Size and Stature

In January 2017, Anita Reddy, MD, a Pulmonary Medicine Intensivist, joined Procop as co-chair of the Test Utilization Committee, which was rebranded as the Laboratory Stewardship Committee. At the same time, a cadre of providers from most of the clinical institutes joined the committee. "Today, the physicians are a part of our Laboratory Stewardship team," Procop explained. "We do not tell providers what to do. Instead, we work together."

The project to stop same-day duplicate orders produced an important insight. "During this phased implementation, we learned that 35% of our orders come from non-physicians," Procop commented. "This statistic is important in our healthcare system because it shows that orders are placed by non-physicians. These individuals are following algorithms and do not have the flexibility to adjust to interventions. If that algorithm is broken, your lab will get misorders.

"When we instituted hard stops, there were institutional concerns regarding the interruption of care delivery," he said. "Therefore, we started slowly with just 12 tests. Then it went to 78 tests.

"Today, there are hard stops on more than 1,200 tests on the same-day, duplicate hard-stop menu," he continued. "To measure the effect of these hard stops, we track the number of times the intervention fires, the number of times physicians call the laboratory to override the hard stops, the absolute number of tests stopped, and our associated cost savings.

"In 2017, for example, this lab test utilization project stopped 4,563 unnecessary, duplicate tests," he said. "From the start of the program in 2011 through the end of 2017, we stopped 33,949 unnecessary, same-day duplicate tests. Our success rate varies, but generally it ranges from 80% to 95%.

"Most of these lab tests are inexpensive, but those costs add up over time," Procop advised. "You won't save a lot of money, but, as Benjamin Franklin said, 'a small leak sinks a great ship.'

"In one year (2017), we saved $54,516 with this effort, and from January 2011 through the end of 2017, we saved $522,622," he stated. "Of equal or greater significance, the lab contributed to improved value and patient care and experience by not over-phlebotomizing patients."

In addition to hard stops, Procop instituted a soft stop called Smart Alerts at regional hospitals. Physicians can override these alerts at order entry and do not require a telephone call to the laboratory. However, the hard stops were more effective. "Every time the hard stop fired, it saved $16 versus every time the smart alert or a soft stop fired, we saved $3.50," he said.

Use of Smart Alerts

"With the Smart Alerts, we stopped only about 50% of unnecessary orders in the regional hospitals, meaning it was not as effective as the hard stop," he explained. "When we presented the data to clinic administrators, they wanted to know why we weren't doing hard stops in all regional hospitals. There are a number of reasons we implemented the soft stop rather than the hard-stop intervention for the regional hospitals, but now we may move in that direction."

After 2013, the Laboratory Stewardship team launched new initiatives to control test orders, such as the expensive test notification program, extended hard stops, and a daily-orders program. The

expensive test notification initiative alerts providers of tests costing more than $500. Last year, it stopped 131 tests for a savings of $186,849. and from 2013 through 2017, the program averted 654 tests, saving $974,683, said Procop.

The extended hard-stop initiative started in November 2014 to address inappropriate test ordering for *C. difficile* PCR, excessive HbA1c ordering, and HCV genotyping, as well as two molecular hematologic studies. Last year, this program prevented 13,140 duplicate tests, saving $71,718, and from November 2014 through the end of 2017, it prevented 37,974 duplicate tests, saving $205,075.

New Efforts Introduced

Most recently, the lab launched the daily-orders initiative that Reddy championed to reduce excessive and unnecessary daily orders. The team worked in concert with hospital informatics to construct the order so that the lab could choose a default of once, every other day, or every three days. If needed, the provider could override the default. This initiative was activated for the most common daily orders, such as CBCs and chemistries. Last year, this initiative stopped an estimated 38,000 daily orders, saving $117,951.

In 2017 alone, all nine of the stewardship committee's initiatives prevented 81,517 tests and saved $841,729. And, from 2011 through 2017, these nine initiatives prevented 160,072 tests and saved $5 million, Procop reported.

In conclusion, Procop explained that "Physicians today are generally comfortable discussing new ways to utilize clinical laboratory tests. Our lab has built this trust because we progressed slowly with the utilization projects and engaged our clinical providers. Also, our data show how we influenced care delivery in a positive and patient-centered way." TDR

—Joseph Burns

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Managing Orders for Expensive Genetic Tests

THERE ARE LAB PROGRAMS TO OPTIMIZE GENETIC TESTING. "We do so by restricting ordering to certain individuals, by having a laboratory-based genetic counselor, stopping duplicate genetic tests that are needed only once in a lifetime, and by using algorithmic testing," explained Gary Procop, MD, Co-Chair of the Laboratory Stewardship Committee at the Cleveland Clinic.

"We've had a lot of experience with restrictive ordering (such as privileging), blocking duplicates, and engaging genetic counselors, and now we're working on algorithms" he continued. "To date, the absolute numbers of stopped, unnecessary genetic tests are small, but these are all expensive tests, so the savings are great.

"In 2017, the genetic counselor stopped or changed 223 orders for a cost savings of $244,828, the restricted use intervention stopped 57 orders for a savings of $67,262, and intervening on repeat constitutional genetic testing stopped 350 repeat tests for a cost savings of $45,183," he said.

"What we learned from this genetic test intervention is that we're stopping unnecessary tests and we're driving physicians into appropriate consultations with lab-based genetics counselors and medical geneticists when these tests are needed," explained Procop. "Our genetic counselor, through her interventions alone, has saved the institution $1.7 million. We know that when she picks up the phone, 58% of the time the physician will decide the test in question is unneeded, and 18% of the time either the order was correct or the physicians were persistent because they can override her counseling.

"We also know that 24% of the time, physicians were ordering the wrong test," he added. "Herein is the value added. She assists the provider in selecting the right test for the patient. This improves care because patients get the tests they need and decreases lab test costs."

Wake Forest Baptist Lab's Path Errors Teach Lessons

➤CMS inspection uncovered multiple serious deficiencies in histology and pathology departments

➤➤CEO SUMMARY: For medical directors and pathologists interested in improving their labs' compliance with CLIA regulations, a report from federal and state inspectors of an inspection of the pathology lab at the Wake Forest Baptist Medical Center offers insights into what issues caught the inspectors' attention. During their visit in February, the government lab inspectors found multiple, serious diagnostic errors in the medical center's academic pathology department.

AFTER DISCOVERING SERIOUS DEFICIENCIES in the anatomic pathology laboratory at the 885-bed **Wake Forest Baptist Medical Center** in February, the federal **Centers for Medicare and Medicaid Services** notified the medical centers that it could lose its Medicare billing privileges.

Early in February, federal lab inspectors conducted a "complaint inspection" at the hospital in Winston-Salem, N.C. On March 26, CMS sent a 54-page statement of deficiencies and plan of correction to the medical center, previously known as **North Carolina Baptist Hospital**. In the statement of deficiencies, CMS said it was considering that the hospital could be "terminated as a provider" to the Medicare program. *(See TDR, April 16, 2018.)*

Wake Forest Baptist Medical Center currently awaits the results of a review of 9,291 histopathology cases, a number that federal inspectors determined were the result of deficiencies in the Pathology Department. As of March 26, only 1,422 cases had been reviewed.

Inspectors from CMS and the CLIA staff of North Carolina's **Division of Health Service Regulation** conducted the joint investigation. The primary source of deficiencies were found in histology cases done between June 2014 and August 2017.

To provide context for the problems the medical center faces, THE DARK REPORT asked pathologist Frederick Kiechle, MD, PhD, to review the 54-page statement of deficiencies and offer some of the lessons learned for pathologists in similar settings.

➤Histopathology Issues

Kiechle, a consultant in clinical pathology in Cooper City, Fla., and the past Medical Director of **Clinical Pathology for Pathology Consultants** of South Broward, in Hollywood, Fla., suggests all pathologists should know the lessons from the Wake Forest case. The most obvious are: hire qualified and appropriately-trained staff for all supervisory positions, ensure that all staff are committed to producing high-quality clinical results every day, and never compromise patient care.

"Pathologists should be aware that CMS has a list of the top 10 standard deficiencies," he said. "When I read the CMS statement of deficiencies about what happened in the Pathology Department at Wake Forest Medical Center, it's clear that many of the deficiencies the lab inspectors uncovered are of the same type as the major deficiencies on that CMS list.

Lists of Major Deficiencies

"Other organizations, such as the **College of American Pathologists**, have similar lists, and each lab accrediting organization that keeps such a list includes all the major deficiencies the inspectors identified," noted Kiechle. "In fact, on the first page of the March 26 statement of deficiencies, CMS defines the focus the inspectors have when starting an inspection.

"This is one lesson from the pathology lab problems at Wake Forest," he added. "It is helpful for medical directors and pathologists to know the specific problems CMS will look for during a lab inspection. For this reason alone, that inspection report itself is instructive."

An expert in clinical pathology, Kiechle has served as an inspector for labs nationwide. "In my career, I have seen many of these CMS reports and this one stands out as being among the best written reports I've ever seen. It tells the story of what CMS' inspectors did, and it explains exactly why they did what they did.

"Therefore, any pathologist wanting to understand the problems identified in the Wake Forest Baptist Pathology Department and how they happened should read this report," suggested Kiechle. "Someone running a CLIA-certified pathology laboratory should know: What are the elements of lab operations that stand out as red flags for CMS and other agencies do such inspections?" he said. "What does the director of a pathology laboratory need to know to avoid getting a statement of deficiencies and having inspectors shut down the lab?

"The CMS report states that the problems at Wake Forest primarily are in histology. It noted that the lab failed, the laboratory director failed, and the supervisor failed," explained Kiechle. "The report states, for example, that the supervisor failed because he or she didn't have the educational requirements to be a supervisor. That's a serious and obvious problem and something the head of personnel should know.

"In any lab, one fundamental rule is to understand the requirements for each job and to hire the right people for the right job," he said. "That's one of the first messages in this report.

"In some of WFBMC's lab departments, the wrong people were in the wrong positions and those were important positions," Kiechle stated. "Two examples that stand out were the supervisor of histopathology and the chairman of the department.

Lack of Requisite Education

"In this case, we see that the supervisor was hired inappropriately because he or she did not have the requisite education or training," Kiechle said. "As a consequence, all of the subsequent issues arise because he or she didn't do what a supervisor is supposed to do.

"This is why lab directors always have to ask: Do we have the right person in charge of our laboratory section?" he noted. "This is a no-brainer because the rules and regulations from CLIA are clear about the education and experience required for this position.

"CMS' inspectors are interested in competency," he added. "They want to see the lab's competency records. At Wake Forest, in checking those records, the inspectors found that residents in the grossing section had not been trained appropriately.

"This brings up the question: Were residents grossing specimens properly?" asked Kiechle. "Who can know this, if they

were not trained according to the documentation? That's a serious deficiency.

"When hiring a supervisor or laboratory director, laboratories need to hire someone committed to providing excellence in laboratory services," he stated. "That someone needs to be an experienced pathologist who understands how to run a highly-efficient and clinically-excellent lab.

Trained Pathologists Depart

"Next, the CMS report said the chairman of the pathology department assigned someone to be the surgical pathologist and then both the chairman and the newly-appointed surgical pathologist left the medical center," he said.

"The CMS statement of deficiencies makes clear that they put the wrong people in charge, and as a result, the medical center compromised patient care," he added. "CMS will always be quite interested when patient care is compromised.

"This is perhaps the most important point in the CMS report: If your lab compromises patient care, CMS will be very, very concerned," noted Kiechle.

"We know the inspectors had four issues that they reported in an earlier report and then they listed 13 issues in the second report. Only four of those issues resulted in wrong diagnoses," he explained.

No Signs of Cancer

"When you read what happened to patients numbered 1, 2, and 3, those stories were really sad," he said. "One women had a bilateral mastectomy for no reason at all. She didn't have any signs of cancer.

"Also, the federal and state lab inspectors found cases that didn't match with their results, which the medical staff noticed," Kiechle explained. "It's significant that the WFBMC medical staff had to say that they had a problem with pathology service and that, after the misdiagnoses in the cases of potential breast cancer, the medical staff and the pathology department agreed to have a second pathologist review all breast biopsy diagnoses for confirmation.

"In other words, the Pathology Department didn't seem to know what they were doing because they diagnosed cancer when there wasn't cancer and some patients were treated with radiation when they shouldn't have been," he continued. "The CMS report identifies four such cases that led to bad outcomes, but that's a lot!"

"And all of those bad outcomes seem to go back to pathologist #7, who was the chairman," he said. "Problems like these really upset CMS inspectors, as they should.

"In addition to the major issues that should jump out at anyone who reads the report, there were other problems that, from a pathology laboratory operations standpoint, were not as severe, but were still important and needed to be addressed," stated Kiechle.

Failed to Validate Equipment

"For example, the lab failed to validate some new equipment and failed to validate that equipment properly," he added. "The pathology lab had different stainers and didn't use the right validation procedures or ignored the manufacturers' recommendations. The lab had no validation processes in place and it didn't have any maintenance function checks. These are all red flags that any lab director should notice."

The CMS inspection report was made public by the local newspaper, the *Winston-Salem Journal*. Pathologists and lab managers interested in reading the full CMS inspection report of the Wake Forest Baptist Medical Center pathology laboratory can access it using this URL: *https://tinyurl.com/path-errors*. TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In Sebastopol, Calif., the financially-troubled **Sonoma West Medical Center** (SWMC) dropped a controversial drugs-of-abuse testing program. The following month, without the revenue from the drug testing program, 37-bed SWMC lost $1.4 million. In 2017, the hospital entered into a pass-through billing arrangement with a Florida attorney, Aaron Durall and his lab company, **Reliance Laboratory Testing**. Earlier this year, SWMC received a letter, dated Jan. 9, from health insurer **Anthem** demanding repayment of $13.5 million that the insurer had paid the hospital for urine drug test claims. *(See TDR, March 5, 2018.)*

MORE ON: *Sonoma West*

In its letter to Sonoma West Medical Center, Anthem described the pass-through billing arrangement (sometimes called "hospital outpatient department"–HOPD) involving Durall and Reliance. It threatened legal action and demanded repayment of the $13.5 million. On March 28, in a separate lawsuit filed in Georgia involving urine drug testing, pass-through billing, and Aaron Durall, Anthem sued him and other individuals, several lab companies, and two small Georgia hospitals.

MAWD PATH BUYS CYTOCHECK LAB

On April 16, **MAWD Pathology** of Kansas City announced its acquisition of the local **Cytocheck Laboratory**. As a subsidiary of MAWD, Cytocheck provides technical pathology, cytology, and laboratory services. MAWD provides professional pathology services for both entities.

TRANSITIONS

- **PathGroup** of Nashville, Tenn., appointed Randal Sanderson as its Vice President of Business Development. Sanderson previously held business development positions at **McKesson** (now **Change Healthcare**) and **PSA, LLC**.
- **Neogenomics, Inc.**, of Ft. Myers, Fla., announced that William Bonello was its new Vice President, Treasurer, and Director of Corporate Development. Bonello's prior experience includes working at: **Craig Hallum Capital Markets**, **RBC Capital Markets**, **Laboratory Corporation of America**, **Wachovia Capital Markets**, and **Piper Jaffray**.
- Pathologist Elaine Jeter, MD, retired as Director of **MolDX** at **Palmetto DBA**. She is forming her own consultancy.

That's all the insider intelligence for this report. Look for the next briefing on Tuesday, May 29, 2018.

UPCOMING...

- ***Pap Test Program Goes Off the Rails in Ireland: Why Cytology Errors Are National News.***
- ***Building and Tracking a Performance-Based Hospital Laboratory Outreach Business.***
- ***Protect Your Lab's Financial Stability by Using Cost-per-Test Studies to Guide Cost-Cutting.***

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