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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

Delivering Added Value = More Lab Reimbursement

WILL HISTORY LOOK BACK ON 2013 AND DECLARE IT to have been a watershed year for the clinical laboratory testing industry? I ask that question because many of you are telling us here at THE DARK REPORT that you expect rapid and unprecedented changes in the lab testing marketplace in your community or region.

In my 18 years as Publisher Emeritus of THE DARK REPORT, I have never heard so many veteran pathology business leaders and lab administrators paint such a gloomy picture of their lab organization's short-term prospects. Why just last week, a pathologist who owns a major independent pathology company called to ask for advice.

At his lab, CPT 88305 makes up 40% of his volume and the deep cuts in Medicare reimbursement for CPT 88305-TC that took effect on January 1, 2013, will immediately bury his lab in red ink. This pathologist—a very savvy businessman—was at a loss as to how his lab company can respond in the short term and stay in business

That's just one example. For the sizeable number of small, independent clinical laboratory companies that do lots of nursing home business, the 4% cuts in Medicare Part B Clinical Laboratory Test Fees (2% per Accountable Care Act and 2% from last February's SGR temporary fix) that took effect at the first of the year will immediately tip these enterprising businesses into red ink. That's because many of these small lab firms currently have profit margins of 4% or less.

So what's a pathologist business leader or lab administrator to do? Federal and state governments don't have enough money to fund the current demand for health services, so additional fee cuts should be expected. On the other hand, 320 million Americans continue to need laboratory tests.

To me, this is opportunity that all clinical labs and pathology groups must put on their radar screen. In the face of shrinking budgets, the healthcare system will pay for lab testing services that add value: meaning, lab testing services that improve patient outcomes and at the same time reduce the overall cost per healthcare encounter. That is the sweet spot that labs must serve to survive financially. On pages 3-8, you will read about a Midwest health system that is engaging its laboratory to deliver added value in ways that measurably contributes to improved outcomes and a lower cost of care. Going forward, I consider this to be one essential strategy that will help nimble labs sustain themselves financially. TDR

Boosting the Lab's Role In Collaborative Care

Sharing lessons in how this health system lab contributes to improvement in patient outcomes

CEO SUMMARY: Collaborative care is an essential element of accountable care organizations (ACO) and other emerging models of integrated clinical care. At MedCentral Health System, one clinical chemist has held a key place on the physician team that develops order sets and clinical alerts. He is using this opportunity to leverage the clinical laboratory into an added value asset that includes more consultations and regular interaction with MedCentral's physicians and other caregivers.

MANY HOSPITALS AND HEALTH SYSTEMS are promoting collaborative care in which clinicians in various specialties are encouraged to work together. The goal is to improve patient outcomes and reduce readmission rates.

This is exactly the type of clinical interaction which plays to the strengths of pathologists and Ph.D.s. In fact, it was six years ago when one health system in Ohio took this path. It has a clinical chemist working closely with referring physicians to offer advice on how to use laboratory test results most effectively.

The early adopter of this strategy is **MedCentral Health System**, a cancer and heart hospital in Mansfield, Ohio. In 2006, MedCentral saw the opportunity to develop a proactive consultative service for physicians. Health system administrators encouraged clinical chemist Eugenio H. Zabaleta, Ph.D., to consult with ordering physicians in an effort to improve patient outcomes and cut costs.

Since then, Zabaleta has worked with referring physicians, nurses, and other clinicians at MedCentral to develop a computerized physician order entry (CPOE) system and an electronic alert system. The goal is to identify patients who are at high risk of developing complications, the types of conditions that raise the cost of care.

When the alerts work as expected, clinicians can act to minimize complications, thus keeping costs down. One clinical decision support alert is for physicians treating patients with congestive heart failure (CHF). Another alert is for physicians treating patients who show signs of having a heart attack.

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

Improvement in how MedCentral's physicians treat CHF patients has helped MedCentral cut the length of stay for Medicare patients with CHF. MedCentral's heart attack alert project saved Medicare an estimated $300,000 annually by alerting providers to clinically significant changes in cardiac troponin levels in real time. Similar savings have accrued to private health plans as well, but those savings are more difficult to calculate.

Developing 'Smart Systems'

Zabaleta is one of a handful of laboratory scientists and pathologists in the nation who are at the forefront of developing "smart systems" that help physicians improve patient outcomes in two ways.

First, patient outcomes improve when physicians get better at ordering the right test at the right moment. Second, patient outcomes also improve when physicians become more proficient at interpreting lab test results and developing the most appropriate therapeutic approach for patients.

"There are several important healthcare trends which play to the strengths of pathologists and clinical chemists," noted Zabaleta. "One trend is Medicare's program that penalizes hospitals for high rates of readmissions. Another trend is the development of accountable care organizations (ACOs)."

These are reasons why Zabaleta's work at MedCentral is instructive. It demonstrates how pathologists, Ph.D.s, and other lab scientists in ACOs can play an essential role in improving patient care that is cost-effective.

Collaborating With The Lab

Further, physicians are open to working in closer collaboration with their laboratory medicine specialists. This is particularly true as physicians practicing in ACOs feel the pressure to show continuous improvement in how they achieve ever-higher patient outcomes. These dynamics are playing out at MedCentral Health.

"Doctors want to order the right tests at the right time, and, in ACOs, the value of all lab tests is becoming more important," declared Zabaleta. "Here in MedCentral's clinical lab, we see what doctors need for their patients and believe we can help them improve care. That is why we are striving to go beyond reporting clinical data in the form of lab test results. We want to create added value by delivering actionable information that improves patient care.

"The concept of having teams provide care to a patient is evolving," he noted. "Our lab team now does formal consultations with ordering physicians. Via actual clinical practice, we are demonstrating how the laboratory can help doctors improve patient care by consulting with them and by developing alerts for them.

"This effort is focused on two priorities," Zabaleta explained. "The first priority is to expand the ordering of laboratory tests through the computerized physician order entry (CPOE) system.

Creating Order Sets

"By writing and implementing evidence-based order sets, we standardized what physicians could request when ordering each laboratory test," he commented. "An order set is one form of clinical decision support and is the foundation of MedCentral's CPOE.

"When evidence-based medicine is used to develop an order set for laboratory orders, the right test will be performed on the right patient at the right time," added Zabaleta. "This improves quality while reducing errors and clinical variability. In turn, this improves patient and physician satisfaction.

"The second step is to help improve the interpretation of laboratory results," he said. "Our strategy here starts with the delivery of accurate test results in a timely manner. We consider it imperative that there be effective and efficient integration between information systems and laboratory diagnostic technology.

"This integrated informatics capability is the foundation for our consultative

Lessons Learned in Developing Order Sets That Help Physicians Improve Outcomes

AT MEDCENTRAL HEALTH SYSTEM, administrators recognize the importance of leveraging clinical laboratory test results to achieve improved patient outcomes. It is why a clinical chemist was included on the team that develops clinical guidelines.

"This initiative began in 2006, when Michael Patterson, D.O., MedCentral's VP and Chief Medical Officer, wanted a laboratorian to be on the physician-advisory committee drafting the CPOE order sets," Zabaleta said. "He asked me to do it.

"It took much effort and some detective work on my part," he continued. "Before I could write the order sets for each laboratory test, I had to shadow ordering physicians to see how they worked. I saw that some tests were underused, some were overused, and sometimes physicians ordered the wrong test or off-label use of tests.

"One important finding was that it would be relatively easy to create order sets for routine lab tests and procedures," he said. "But it was more challenging when it came time to create order sets for esoteric tests. For one thing, it was clear that we couldn't prohibit physicians from ordering tests. Therefore, it was necessary to develop a way to advise physicians without stepping over that line that could be considered telling them how to do their jobs.

"Our approach was to be educational," continued Zabaleta. "By showing physicians what we are able to do in our clinical laboratory, we got their attention. Doctors want to do the right thing for patients.

"Another lesson we learned is that, as physicians better understand the different ways that our laboratory experts can help them, they are eager to work collaboratively," concluded Zabaleta. "That's what led to the alerts we developed for troponin levels in patients with chest pain and for acute myocardial infarction. These alerts have already helped improve patient outcomes."

service," stated Zabaleta. "It is how alerts are sent to the clinicians, for example."

Zabaleta is a part of the team of physicians who write the order sets for MedCentral's CPOE system. The alerts are electronic communications generated by middleware from **Pacific Knowledge Systems** in Sydney, Australia.

The payback from the alerts and order sets happened quickly. "After creating the order sets, the cardiologists noticed that the emergency room did not always identify every patient who was having a heart attack," explained Zabaleta. "This problem occurred with patients who have comorbidities and who present with chest pain, which can have many causes.

"One way to diagnose a heart attack is to do serial troponin level measurements," he said. "Troponin is a protein released into the bloodstream when heart muscle is damaged, such as during a heart attack.

"However, simply reporting a patient's troponin level is not enough," he continued. "That is just data. We produce lots of data in the lab, and sometimes we just spit it out to the ordering physicians. The physicians will benefit from having someone point out in real time what is clinically relevant and what is not. Having that information makes them more efficient and effective.

Alert Is Processed Data

"This is an important distinction," Zabaleta added. "We emphasize to clinicians that the alert is more than data. The alert is itself a product of processing data and turning it into useful, actionable information.

"The problem in most clinical labs is that they are too detached from physi-

cians and patients," he noted. "That's why MedCentral created my position as a bridge between the lab and the ordering physicians. In this position, I can accommodate physicians who are providing patient care. I spend equal amounts of time both inside and outside the lab.

"To be an effective consultant, I closely watch how our physicians use lab results," Zabaleta added. "Lab scientists usually know more about lab tests than most clinicians. But we often don't know what physicians do with our lab tests or why they order tests in a certain way versus the correct way to order tests. That has to change and we can help!

"One approach that we use is to profile doctors on their lab test utilization," he stated. "As we understand what types of lab tests they are ordering, we then provide them information about which tests may be best to order for their patients and how they can use the resulting lab test data to improve patient outcomes.

"These utilization profiles are an effective tool to help physicians learn which are the most appropriate tests for their individual patients," continued Zabaleta. "This educational and consultative process also is designed to provide them with a better understanding about how to interpret the test results.

A Work in Progress

"We have made a lot of progress since the CPOE system became fully functional just last month (December 2012)," Zabaleta said. "But we are not finished. Even though we are still learning, there are several lessons that we can pass along.

"First, pathologists should get involved in developing order sets for CPOE systems," he recommended. "At first, physicians may balk at the idea, but in the end, they will appreciate the improvements in clinical performance that results.

"Second, the lab team needs to go outside the laboratory more frequently and engage personally with the clinicians," he added. "It is surprising how quickly most physicians warm up to the availability of this specialized knowledge in laboratory medicine and diagnostics. Physicians recognize that no one in the hospital knows more about the analytical characteristics of the tests, and the limitations and clinical uses of each diagnostic assay."

There is another insight Zabaleta wanted to offer. "It is quite enlightening to follow physicians around and see how and why they select the lab tests for their different patients," he observed. "At the same time, this closer interaction opens the door for pathologists to gain an understanding of how to create solutions that make communication between the lab and provider more efficient and more clinically meaningful."

In other words, there is a significant opportunity for pathologists to become more involved with clinicians by breaking down the silos that exist in almost every hospital. MedCentral's initiative demonstrates the value of having lab professionals collaborate with clinicians to improve patient outcomes. TDR

—Joseph Burns

Contact Eugenio Zabaleta at 419-526-8836 or EZabaleta@medcentral.org.

About MedCentral

MEDCENTRAL HEALTH SYSTEM in Mansfield, Ohio, has 351 beds in two facilities, one of which is a critical access hospital. It also has seven outpatient centers.

The two hospitals specialize in open heart surgery and cancer treatment. Its competitors include the **Riverside Methodist Hospital** and the **Ohio State University Medical Center**, both in Columbus, and the **Cleveland Clinic**.

The MedCentral lab does 1.5 million tests annually, 40% of which are for inpatients. The balance is for outpatient testing and a laboratory outreach program that serves physicians' offices and 54 nursing homes in the Mansfield area. MedCentral's laboratory has 113 full-time equivalent employees.

Lab Lowers CHF Readmits, Cuts LOS for AMI Patients

Electronic notifications sent to clinicians help improve outcomes and reduce costs

CEO SUMMARY: Labs today are finding ways to send actionable information to referring physicians. The laboratory at MedCentral Health System in Ohio uses electronic alerts to inform clinicians about test results that may be significant. One alert helped the lab cut length of stay for patients by 1.5 days and saved $300,000. Another test identifies congestive heart failure patients who are most at risk of readmission and thus helps the hospitals avoid penalties by keeping its CHF readmission rate low.

ONE STEP ON THE PATH toward more consultative laboratory medicine at a Midwest health system involves the use of electronic alerts to inform physicians about laboratory test results that may be clinically significant

"Our lab's goal is to develop effective ways to send actionable information to referring physicians in real time," stated Eugenio H. Zabaleta, Ph.D. "The time is fast-approaching when it will no longer be adequate simply to send a lab test report back to the referring physician."

Clinically-Significant Results

Zabaleta is a clinical chemist in the laboratory at **MedCentral Health System**, a cancer and heart hospital in Mansfield, Ohio. MedCentral is using electronic alerts to inform physicians about test results that may be clinically significant.

"One alert is associated with lab testing done to identify patients with CHF," he noted. "In this case, the lab runs tests to assess patients' relative risk so the hospital can manage closely any patients likely to be readmitted.

"Another alert helps physicians make a more accurate and faster diagnosis of patients having a heart attack after they present in the emergency department (ED). When patients show up in the ED with chest pain, treating physicians need to rule out the possibility of acute myocardial infarction (AMI)," he continued. "The electronic alert for patients who may be having an AMI is based on the patient's troponin levels in serial measurements.

"Troponin indicates a possible heart attack because it is released when heart muscle is damaged," Zabaleta said. "This electronic alert was developed after ED physicians found we were not immediately identifying all patients who suffered a heart attack. In the lab, our goal was to provide them with an alert that would give them actionable information in real time.

"For certain patients in the ED, heart attack can be difficult to diagnose because they may have comorbidities or be on pain medications and not realize they are having an AMI," he said. "Plus, they may have the symptoms of a heart attack (such as chest pain), but not actually be having an AMI.

"The problem was that we were missing some of these diagnoses initially," Zabaleta said. "Each patient missed in this fashion required extra days in the hospital and thus increased costs. Our goal was to identify each AMI patient as soon as possible. Delayed diagnoses meant we were spending an extra $300,000 on Medicare patients each year.

"To identify these patients immediately, we record their troponin levels upon admission and again after 6 and 12 hours," he noted. "By tracking the levels over time, we can see a sharp spike that would indicate a heart attack.

"Due to patient severity and comorbidities, some patients are admitted as inpatients," he said. "But the ED test orders are continued, making the AMI diagnosis possible in the inpatient setting. The continuity of patient care should be smooth and not disruptive, which is one goal of accountable care.

Middleware Supports Alerts

"But it's not enough simply to give the ED physicians the lab test results," he continued. "We wanted to show the trend over time and develop an alert that would prompt the lab to call the provider when a patient's troponin level spiked. To prompt the phone call, we added middleware to the laboratory information system (LIS).

"After installing this middleware from **Pacific Knowledge Systems** in Australia, we conducted a study," said Zabaleta. "Patients in the control group had a length of stay (LOS) of 7.89 days. By contrast, patients in the study group had an LOS of 6.17 days, more than 1.5 days shorter than that of the control group.

"The only difference was the use of the troponin alert system for the study group, which meant we identified those patients in the study group who had an AMI earlier and they were treated quickly, reducing LOS," Zabaleta explained.

"By cutting LOS for these patients, we saved Medicare about $300,000," he said. "The bottom line is this project is improving timely communication between the lab and the provider, which leads to more effective and efficient care." TDR

—By Joseph Burns

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Reducing Readmissions of Patients with CHF

RISK STRATIFICATION FOR PATIENTS with congestive heart failure helps MedCentral Health manage CHF patients aggressively.

Like the electronic alert for acute myocardial infarction (AMI), the alert for CHF patients uses middleware from **Pacific Knowledge Systems**. For this initiative, the hospital administrators wanted to reduce the readmission rate for CHF patients.

"Called Heart Success, this initiative is based on assessing the relative risk according to each patient's troponin levels over time and on the patient's BNP levels," stated Clinical Chemist Eugenio H. Zabaleta, Ph.D. "The B-type natriuretic peptide (BNP) is measured in the blood. BNP rises when heart failure symptoms worsen and falls when heart failure symptoms become more stable.

"After performing these two lab tests, we can calculate a risk score for each patient," he continued. "The higher the risk, the greater the chance the patient will be readmitted.

"We stratify patients according to their BNP and troponin results and base the electronic alert on this lab test data," explained Zabaleta. "The alert automatically sends this information by email to nurses and clinicians in the Heart Success program. This helps clinical staff know which patients will require the most attention upon discharge.

"This alert program is quite successful, as shown by the numbers," he said. "In 2011, CMS reported the national rate for readmission within 30 days of disharge for patients with heart failure is 24.8% and can be as high as 40%. At MedCentral, that rate for patients who are not enrolled in Heart Success is 26.7%. But for our enrolled patients, it is only 4%!"

HIPAA Update

Four Labs and Billing Company Pay $140,000 Fine in HIPAA Case

In 2010, billing company dumped pathology records of 67,000 patients in a municipal garbage facility

WHEN A BILLING SERVICE company disposes of patients' lab test records, it should do so in compliance with federal and state privacy rules. That means all protected health information (PHI) should be shredded or incinerated.

Four pathology groups in Massachusetts learned this lesson the hard way when they and their billing company agreed to pay collectively $140,000. This settled charges of illegal dumping of patients' records in the town dump in Georgetown. Massachusetts State Attorney General Martha Coakley announced the settlement on January 7.

In a court complaint, Coakley alleged that Joseph and Louise Gagnon, doing business as **Goldthwait Associates**, a pathology billing company in Marblehead, violated state data security laws when they mishandled and improperly disposed of medical records at the Georgetown dump.

The records contained PHI from four Massachusetts pathology groups, Coakley said. The medical records contained unredacted names, Social Security numbers, and medical diagnoses from more than 67,000 patients, Coakley said in a statement.

In July 2010, a photographer for *The Boston Globe* noticed the papers in a pile at the dump and alerted the newspaper. The photographer saw a "huge pile of paper 20 foot wide by 20 foot long," the newspaper reported. *(See TDR, August 23, 2010.)*

Jane Pine Wood, an attorney with **McDonald Hopkins**, observed to lab directors and pathologists that Coakley filed this complaint under state rules regarding PHI. Wood advised that labs nationwide could be liable for similar security violations under the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Responsible for Others' Acts

"This case shows that any healthcare provider is responsible for what its business associates do with patient records," Wood commented. "When this case first became news, we alerted our clients that they need to be careful when working with billing companies. It is important to get assurances from these companies that all patients' records are disposed or destroyed in appropriate ways."

The defendants involved in the settlement were Joseph and Louise Gagnon, former owners of Goldthwait Associates; Kevin B. Dole M.D., former President of **Chestnut Pathology Services, PC**; **Milford Pathology Associates, PC**; **Milton Pathology Associates, PC**; and **Pioneer Valley Pathology Associates, PC**.

Clinical laboratories and pathology groups may want to conduct a proactive review as to how patient records are handled to avoid violations of HIPAA and state laws. Since HIPAA took effect, a regular number of PHI breaches have made local and national news. TDR

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➤➤ ***CEO SUMMARY: When pathology labs discover instances of a misidentified or contaminated tissue specimen, there is a new service that allows them to retrospectively use DNA to properly match that specimen to the correct patient. In part two of our series, we look at how some pathology labs are using the Know Error service to catch these errors before the lab report is issued to physicians and patients.***

New system can accurately match misidentified specimen with right patient

Pathology Labs Want Method To Correct Specimen ID Errors

SECOND OF TWO PARTS

MAYBE THE WORST THING that can happen to any anatomic pathology laboratory is to report the wrong patient results because a tissue specimen was either misidentified or contaminated—and the resulting error negatively affected the medical care delivered to the patient.

Indeed, it is a daily fact of life in anatomic pathology laboratories that errors do happen in the labeling and identification of tissue specimens. It is also recognized that contamination during processing is another way the integrity of a patient's tissue specimen can be compromised.

Not only can there be harm to the patient who got the wrong diagnosis, but the pathology lab can face the considerable expense of malpractice claims. If news of the mistake is picked up by the media, there can be local and national news coverage of the event.

Recall the case of the unnecessary double mastectomy that happened in 2003 at **United Hospital** in Minneapolis, Minnesota. A pathologist at **Hospital Pathology Associates** misplaced slides and paperwork for different patients that were in the same folder. In this case, two patients each received the wrong test report. National news headlines resulted from the case. *(See TDR, February 10, 2003.)*

In New York state, in 2007, a patient got inaccurate pathology test results due to a specimen labeling error in **CBLPath's** histology lab. She chose to undergo a double mastectomy that proved to be unnecessary. National news accounts of this incident put CBLPath in a most unwelcome spotlight.

Now evolving technology and the new Know Error service offered by **Strand Diagnostics** of Indianapolis, Indiana, gives pathology laboratories a "retrospective" solution to resolve tissue identification errors or instances of specimen contamination. The technology can be a lifesaver if the error is detected within the lab *before* the patient report is issued. That helps the lab accurately report the right results for the right patient.

Use of the Know Errror system following the lab's detection of a specimen identification or contamination error can also eliminate the need to recollect another tissue specimen from the patient. That alone can be a major benefit to both the pathology lab and the patient.

But in cases where an error goes undetected until after the patient report was issued, the Know Error system can also play a role. It can help the pathology lab accurately associate the misidentified specimens or contaminated specimens to the correct patients.

In a pathology laboratory, individual work processes in tissue processing may have a statistical rate of failure that is at the level of 3.5 sigma to 4.0 sigma (4.0 sigma is 6,210 defects per million events). Because patient safety can be compromised, these are unacceptably high rates of error.

Today's patient has an expectation of "zero errors." That puts every anatomic pathology laboratory under pressure to move the performance of its lab's operation toward a 6 sigma level, which is just 3.4 defects per million events.

At the same time, following any significant medical error, pathology labs are equally under pressure to properly conduct a root cause analysis of each error, and then take the right corrective action to prevent such an error from occurring again. This is true whether the lab discovers the tissue identification error before the results are reported to the patient or whether it was after the report was issued that the error was discovered.

It is for these reasons that pathology laboratories are contacting Strand Diagnostics for the express purpose of using its "positive patient identification" technology and approach to resolve instances where patient specimens were misidentified. Before attempting to recollect tissue from those patients affected by such labeling errors,

these pathology groups want to use the Know Error technology and service to establish a positive patient identification for the misidentified tissues.

"We originally designed Know Error to be a *prospective* diagnostic system that prevents, to the practicable degree possible, a patient's tissue specimen from becoming misidentified," stated C. Michael Harmon, Vice President, Marketing & Communications for Strand Diagnostics. "To date, we have marketed this service directly to specialty medical groups where tissue specimens are regularly collected. *(See Part One, TDR, December 10, 2012.)*

"When Know Error is used prospectively as intended, both the physician's office that collected the tissue specimen and the pathology lab handling it can have a high degree of confidence that misidentification of specimens will not occur," noted Harmon. "However, over the past 18 months, we have been surprised at how often pathology groups have contacted us to ask for help in resolving errors involving some tissue specimens.

"We see a steadily-growing demand by pathology groups to use Know Error in this *retrospective* way," continued Harmon. "Thus, when the lab suspects that the tissue specimen is probably misidentified, our Know Error service provides a way to make a positive identification of that specimen. This avoids a potential medical error and means that the specimen originally collected can be used with confidence for diagnosis.

Specimen ID Errors

"Misidentification of pathology specimens is a problem," observed Harmon. "We have a solution. Moreover, our solution covers the range of locations where the possibility of a specimen misidentification can occur. This includes all the stages—preanalytical, analytical, and postanalytical phases as well.

"Specimen misidentification errors can occur in physicians' offices when specimens are being collected," he said. "Other errors may occur in transport. But a large number of errors occur within the pathology lab and these include misidentification errors or contamination of specimens.

"When a lab finds an error that involves misidentification or contamination of a specimen, they can call us," Harmon stated. "At that point, a lab director or pathologist suspects an error has occurred involving that specimen, but is unable to identify the patient accurately.

"The pathology lab knows it has a certain number of samples that it cannot identify properly and wants our help," he continued. "At that point, it's our job to identify the patients involved and match those patients to the specimens in question. And, of course, we want to solve the problem without inconveniencing the patients beyond collecting a cheek swab.

Cheek Swabs for Reference

"In most cases, for each patient involved, we collect a cheek swab to use as a reference sample," noted Harmon. "The vast majority of the time, we can resolve a case without requiring a rebiopsy. By either using the slides used for diagnosis or having the lab retrieve the sample block and submit some tissue—along with a reference sample known to be from the patient—we can provide the critical information needed.

"From the buccal swabs, we next do a DNA analysis in order to match that DNA to the specimen the lab has on hand," he said. "The DNA allows us to identify all specimens accurately.

"An error in identification of a specimen presents pathology labs with an interesting dilemma," observed Harman. "Even if the error occurred outside the laboratory, the lab is nearly always responsible.

"If a switch was made in the physician's office, the pathology lab would have no way to know that—but would still be responsible," he said. "Your lab could be doing a great job, but that does not mean you're getting properly-identified samples coming in your door.

Pathology Groups Use DNA Testing to Link Misidentified Specimens with Right Patient

WHEN A PATHOLOGY LABORATORY discovers that a specimen has been misidentified or contaminated, it needs a reliable method to properly associate that specimen with the correct patient. In recent years, pathology groups have begun to turn to Strand Diagnostics and use its Know Error system to achieve positive patient identification.

"This is a *retrospective* use of Know Error," stated C. Michael Harmon, Vice President of Marketing and Communications at Strand Diagnostics. "Simple steps are needed for us to assist the laboratory in matching a misidentified tissue specimen with the correct patient.

"The first step is to collect a cheek swab from the patient or patients who may be the source of the misidentified specimen," he explained. "The buccal swab is sent to us. The lab also sends us a sample from the misidentified specimen.

"We run the DNA Specimen Provenance Assignment (DSPA) test on the tissue sample they send us and on the cheek swab," noted Harmon. "That's how we can confirm the identity of the patient's sample.

"It goes without saying that this service can be a lifesaver for any pathology laboratory that discovers a misidentified or contaminated specimen," he added. "The accurate and positive identification of the patient with his/her specimen means that the pathology lab has confidence that its diagnostic report is the right one for that patient.

"However, there are instances where, because of a specimen misidentification or contamination error, the pathology laboratory has transmitted an erroneous report," observed Harmon. "Only after treatment is the mistake discovered. This is when we may get a call from the pathology lab or even a patient with a request to help in the investigation and to provide a positive patient identification of the misidentified specimen. This is another retrospective use of Know Error."

"That is another interesting part of the challenge of preventing errors: A lab often does not know an error occurred until a physician calls after getting the lab report and treating the patient," continued Harmon. "At that point, when a lab calls us for help, all we can do is start a retrospective analysis of the problem."

The frequency of misidentified specimens in pathology laboratories is confirmed by the number of pathologists who contact Strand Diagnostics directly. In fact, a growing number of patients are also contacting Strand Diagnostics directly to find out about the Know Error service!

"Each month, we get calls from as many as 20 different pathology labs that are dealing with misidentified or contaminated specimens," stated Harmon. "But of even greater interest is the fact that we get a similar number of inquiries from patients who question their pathology test results and want a verification. These patients find us on the Internet. Although most of our patient customers live here in the United States, we have had customers contact us from Japan, Dubai, and other countries.

Focus on Error Prevention

"Up to this point, we have talked about the retrospective use of the Know Error system, as it is used by either pathology labs tracking down errors or patients seeking a confirmation," Harmon explained. "Those customers want a retrospective method to look back at their results.

"However, there is another element to the story of Know Error that is equally important," he said. "There is interest among risk managers from large self-insured healthcare provider organizations for our work in this field.

"Risk managers understand the implications of the work we do on reducing lia-

Two Studies Show the Value of DNA Testing to Reduce Diagnostic Errors in Pathology

TWO RECENT PEER-REVIEWED STUDIES show that the use of DNA testing to match biopsy samples can help to reduce common diagnostic errors.

John Pfeifer, M.D., Vice Chairman for Clinical Affairs, Pathology and Immunology at **Washington University** in St. Louis, Missouri, was the co-author on both studies. "The potential for misidentification of a patient's biopsy results is a real concern in anatomic and clinical pathology with potentially devastating consequences," he wrote. "While many physicians have long suspected that specimen provenance complications (SPCs) occur, these results provide the first estimate of their frequency."

One study was published in the January issue of *American Journal of Clinical Pathology*. In this study, researchers showed that as many as 3.5% of patients initially diagnosed with cancer were subject to undetected specimen switches or contamination that could have compromised diagnosis accuracy.

In this study, researchers examined the rate of specimen provenance complications among 13,000 prostate biopsies processed in more than 50 pathology labs. For these biopsies, DNA Specimen Provenance Assignment (DSPA) testing was performed as part of routine clinical care.

The second study was published in *Value in Health*. In this study, researchers concluded that performing a simple DNA test to confirm the provenance of malignant tissue samples is a cost-effective way to improve patient safety and the accuracy of diagnostic testing.

bility risk for all providers involved in handling patient specimens, not just the pathologists," Harmon added. "This is an interesting dimension to the market acceptance of our system.

"Last year, we were approached by a healthcare system with a case involving a misidentified tissue specimen," he stated. "The patient had received the wrong diagnosis because of the error in specimen identification.

"The health system wanted us to help it accurately match the right specimen to the right patient as part of its root cause analysis and as part of the steps it needed to take in its resolution of the problem with the patient," noted Harmon. "One consequence of this interaction is that this health system now uses the Know Error system in a prospective manner with every positive result to ensure that the right patient gets the correct lab test report.

"From a risk management standpoint—and to meet their internal goals for patient safety and improve patient outcomes—they consider the prospective use of DNA testing through Know Error to be appropriate," he noted.

"These developments have been noticed by liability insurers," added Harmon. "Based on the growing number of labs and physicians with positive experiences with the Know Error system and its role in helping prevent errors, we know there is interest among liability insurers to write policies that will provide a discount to physicians and labs that use this and other similar error-reduction protocols. If they do, the introduction of liability policies that carry lower premiums for use of these methods would be significant for both referring physicians and pathology labs."

These developments are a sign to lab administrators and pathologists that more attention to error reduction and error detection will be necessary for labs to meet the higher bar for patient safety. TDR

—By Joseph Burns

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Anticipating 2013 Trends In Clin Lab and Pathology

Upcoming *Executive War College* to provide insights and best strategies for success in 2013

CEO SUMMARY: Biggest news for 2013 will the impact of significant price cuts for both clinical lab and anatomic pathology testing services. But the bad news doesn't stop there. Employers and private payers will be more aggressive in taking steps to reduce what they spend on lab testing. This means every clinical lab and pathology group should be developing strategies to exploit the best business development opportunities. There will still be ways to profitably build specimen volume and revenue.

By Robert L. Michel

IF 2012 WAS A TROUBLING YEAR for the clinical lab testing industry, then 2013 holds the potential for more of the same. There is not likely to be much good news in coming months.

Both clinical laboratories and anatomic pathology group practices will see substantial reductions in overall reimbursement for testing services going forward. That is because of actions taken by Congress and federal health administrators during 2012, complemented also by the actions of private health insurers to reduce what they pay for lab testing services.

Of course, there are other trends actively reshaping healthcare and the laboratory testing industry that will influence events during 2013. These range from hospitals and insurers acquiring physician practices and the fast-growing number of accountable care organizations (ACO) to the increased physician use of electronic health records (EHR) and consolidation within the anatomic pathology profession.

Certainly there has been plenty of news about the reductions to the Medicare Part A Clinical Laboratory Test Fee Schedule that became effective during 2013. Equally significant are the deep cuts to Medicare reimbursement for 88305-TC that took effect on January 1, 2013. Pathologists are still pondering the consequences of that development.

What Comes Next In 2013?

However, what is off the radar screen of most pathologists and lab industry executives is the fact that all medical specialties and ancillary clinical services are seeing comparable reductions in what they are paid by government and private payers. This is an important point and is essential for lab executives and pathologists to keep in mind when they ask the question: "what comes next?"

My reading of the tea leaves causes me to answer by saying "more of the same." In other words, there will be no short-term financial relief for clinical laboratories and anatomic pathology group practices during 2013. In fact, the odds are in favor of more cuts to the prices government and private payers are willing to pay for laboratory testing services.

Simply said, there is no more money. The federal government's fiscal woes are getting daily headlines. From a strategic business perspective, it is rational to anticipate that Congress will need to take more money away from healthcare providers as it desperately attempts to fix the immediate budget gaps.

Employers Cutting Prices

At the same time, the nation's employers are becoming more aggressive in taking steps to reduce what they spend on health benefits for their employees. On this point, managed care companies are willing accomplices to cut provider prices.

Despite these trends, there are still opportunities for nimble clinical labs and pathology groups to increase market share and bolster their financial stability. That is because each of the trends described earlier are disrupting the status quo and those laboratory organizations which don't respond effectively will experience erosion in their market share and revenue.

All of these trends and opportunities will be the subject of numerous presentations at the upcoming 18th Annual *Executive War College on Lab and Pathology Management*, which takes place on April 30-May 1, 2013 at the Sheraton Hotel in New Orleans.

Speedier Pace Of Change

It is also important to keep in mind that the pace of change in the American healthcare system is accelerating. By itself, this is a significant trend and should be fully recognized and acknowledged by your lab's strategic planning team.

Because the pace of change is accelerating, that leaves clinical labs and pathology groups less time to react to the most important trends and changes in the marketplace. This will have major consequences, since traditionally, most lab organizations in the United States have been quite slow to change and respond proactively to new threats and opportunities.

Special Sessions Scheduled for *Executive War College*

TO PROVIDE CONCENTRATED LEARNING and useful business knowledge, several unique workshops and extended seminars will take place at this year's *Executive War College*, scheduled for April 30-May 1, 2013, in New Orleans, Louisiana.

Offering specialized and proprietary tests is one opportunity labs have to build specimen volume and revenue. That will be the theme of a full, one-day workshop titled: **LDT Boot Camp–Achieving Success with Molecular and Genetic Tests**. It will feature experts for the areas of managed care contracting/reimbursement, validation/clinical documentation, legal/compliance, and market development/sales.

Adding profitable new clients is essential for success. In a lab industry first, we are offering: **Powerful Sales Closing Secrets of Top-Performing Lab Sales Reps**. This is also a one-day workshop and is designed to teach effective sales and closing techniques to beginning and intermediate lab sales reps. It is also useful for lab managers responsible for outreach marketing, sales, and business development.

Of course, we are again offering the always-popular, full-day workshop: **Lean for Lab Leaders: The A-to-Z of Achieving Top Performance in Your Laboratory**.

Full details about these special workshops, along with the entire *Executive War College* program, can be viewed at: *www.executivewarcollege.com*.

I feel safe in predicting that we are likely to see an unexpectedly large amount of consolidation among private pathology groups during the next 12 to 24 months. This will happen because many smaller pathology groups are already financially weakened and lack needed capital. Merging or selling will thus be attractive to them. TDR

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Dark Index

Quest Sells OralDNA, HemoCue To Clear Its Decks for 2013

Company wanted to divest both business units because they were small and growing slowly

THIS WEEK, **Quest Diagnostics Incorporated** will issue its fourth quarter and full year 2012 financial report. In anticipation of this, the nation's largest lab company has been cleaning out its closets, so to speak.

With its new CEO finishing out his first eight months of service, Quest Diagnostics is taking the opportunity to dispose of some of the more disappointing business lines within the company. This is within the window of the time when financial analysts expect the new CEO to take bold steps to restructure the company and prepare it for more aggressive growth. Thus, the analysts won't punish the company's share price for divesting poor performing businesses and writing down any costs associated with these divestitures.

First to go on the chopping block was **OralDNA Labs**. On December 31, 2012, Quest Diagnostics announced the sale of this business to **Access Genetics** of Minneapolis, Minnesota. The purchase price was not disclosed. Access Genetics had provided services to OralDNA Labs since 2008. OralDNA Labs was acquired by Quest Diagnostics in 2009.

HemoCue To Also Be Sold

Next to go was **HemoCue**, a company that manufactures and sells point-of-care tests. On January 16, Quest Diagnostics stated that it intended to sell HemoCue and it would report both HemoCue and OralDNA Labs as discontinued operations when it files its fourth quarter 2012 earnings report.

Long-time readers of THE DARK REPORT may recall that Quest Diagnostics purchased HemoCue back in February, 2007. This was in the weeks after the January 1, 2007 date that **Laboratory Corporation of America's** exclusive 10-year national contract with **UnitedHealth** had become effective.

At that time, Quest was telling investors that it would write off as much as $400 million in revenue associated with the loss of the UnitedHealth contract. Thus, executives at Quest were looking for ways to give investors a brighter picture of the company's future. *(See TDR, February 19, 2007.)*

Quest Diagnostics paid approximately $420 million for HemoCue, a company that had annualized revenues of about $90 million at that time. Numbers recently released by Quest Diagnostics indicate that the HemoCue acquisition did not work to Quest Diagnostic's financial benefit.

In announcing the sale of HemoCue, Quest Diagnostics stated that, in the fourth quarter financial report, the combined sales of OralDNA and HemoCue were to be reported as $117 million in 2012 and $119 million in 2011. The company also stated that, for fourth quarter 2012, it would "take related after-tax charges in discontinued operations for the estimated asset impairment associated with HemoCue and the loss on sale associated with OralDNA, totaling $89.5 million..."

What still remains at Quest Diagnostics that is believed to be an underperforming business unit is **AmeriPath**. For the past

six years, insiders have told stories about the struggles Quest executives have had in increasing the revenue and net margins of this business division.

However, for many reasons, it would be difficult for Quest to find a buyer willing to pay an adequate price for these assets at this time. That is even more true, given the recent cuts in Medicare fees for CPT code 88305-TC and uncertainty over how molecular diagnostic tests will be reimbursed by both government and private payers.

New Lab In Marlborough

The other significant development at Quest Diagnostics that will be closely watched is its acquisition of the laboratory outreach business from **UMass Memorial Medical Center** of Worcester, Massachusetts. This transaction was closed before the end of 2012.

The surprise twist to this acquisition is that, in a separate agreement, Quest was also able to buy the anatomic pathology outreach laboratory business of UMass Medical Center. That deal was closed before the end of 2012.

Now Quest Diagnostics plans to build a large laboratory facility in Marlborough, Massachusetts. This "super lab" will consolidate testing from Quest's existing Cambridge lab facility, from its **Athena Diagnostics** division, and from the newly-acquired UMass lab outreach business. The new lab is expected to be fully operational within 18 to 24 months.

UMass' Option To Invest

One of the terms of the deal with UMass is that the health system has an "option to invest in a minority financial stake in Quest Diagnostics' business in Massachusetts." That may mean that both parties are hopeful that, once the Marlborough lab facility is in full operation, UMass may want to refer some portion of its inpatient testing to the facility in order to benefit from the lower costs that would result from economies of scale at that location. TDR

Speculation and Rumors About AmeriPath

FROM ITS INCEPTION IN **1996** as an employee-model pathology practice management company, AmeriPath, Inc., has had its share of ups and downs.

Yet there was always a buyer willing to pay a strong price for the company. By 2002, the company was reporting revenue of $478 million, but its share price was not meeting many investor's expectations. That is when **Welsh, Carson, Anderson & Stowe** stepped in and paid $627 million and assumed AmeriPath's debt to acquire the company and take it private. *(See TDRs, November 4, 1996 and March 3, 2003.)*

In 2005, AmeriPath paid $344 million to acquire **Specialty Laboratories, Inc.** At that time, Specialty Labs had annual revenue of about $150 million, but was losing money every quarter. For that reason, some financial analysts questioned the high price that AmeriPath paid for Specialty Labs. *(See TDR, October 4, 2005.)*

Then two years later, in April, 2007—and while still feeling the sting of the loss of its national contract with UnitedHealth—Quest Diagnostics paid $2 billion to acquire AmeriPath. At that time, AmeriPath had annual revenue of about $800 million. Financial analysts estimated that Quest Diagnostics paid one of the highest prices ever for a lab company—about 17 times EBITDA (earnings before interest, taxes, depreciation, and amortization). *(See TDR, April 23, 2007.)*

This is the backstory to the struggles Quest Diagnostics has had with its integration of AmeriPath. Some former AmeriPath employees have said that premium price paid for AmeriPath has made it challenging for Quest Diagnostics to generate an acceptable return on investment from this big acquisition. As to the truth of these statements, Quest executives have not publicly provided details that deny or confirm these rumors.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Not-for-profit **Boston Children's Hospital** will have majority interest in a new lab testing company. **Claritas Genomics** will be based in Waltham, Massachusetts, and will develop genetic and molecular diagnostic testing solutions. **Life Technologies Corporation** is a partner in the new company. Boston Children's Hospital is incorporating into Claritas the "expertise, assets and personnel of the hospital's Genetic Diagnostic Lab, a CLIA-certified center that already offers more than 100 genetic tests, including many specialized diagnostics developed at Boston Children's." This venture is expected to be a model that not-for-profit hospitals will follow as a way to access new sources of capital for growth and expansion.

FDA CLEARS NEW LUMINEX ASSAY

Luminex Corporation of Austin, Texas, announced FDA clearance of its xTag Gastrointestinal Pathogen Panel (GPP). This multiplex assay "simultaneously tests for 11 of the most common gastroenteritis-causing viruses, bacteria, and parasites." The assay can deliver results in as little as five hours. This test has already been cleared for clinical use in Europe. GPP is another example of how molecular technologies are shortening the time-to-answer when testing for infectious diseases.

TRANSITIONS

- Earl Buck recently announced his semi-retirement. He will continue to provide consulting services for **Chi Solutions, Inc.**, on a part-time basis. He has also formed **EC Buck & Associates, LLC**, for certain consulting projects. Buck held executive positions at **MDS Laboratories** and **Sonora Laboratory Sciences**. He also participated in the founding of the **Clinical Laboratory Management Association** (CLMA) at its inception in 1975.

- **Sonic Healthcare USA** has appointed Ken Botta as its new Vice President, Western Operations. Past positions held by Botta were at **Cleveland Heart Lab**, **SED Laboratories, AmeriPath**, **Dynacare**, **Laboratory Corporation of America**, and **National Health Laboratories**.

- Todd G. Johnson was appointed as Vice President of Sales and Marketing for **Pathway Genomics Corporation** of San Diego, California. Johnson has previously served with **Abbott Laboratories**, **Ventana Medical Systems**, **Biocept Laboratories**, **Insight Health**, and **Laboratory Corporation of America**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 11, 2013.

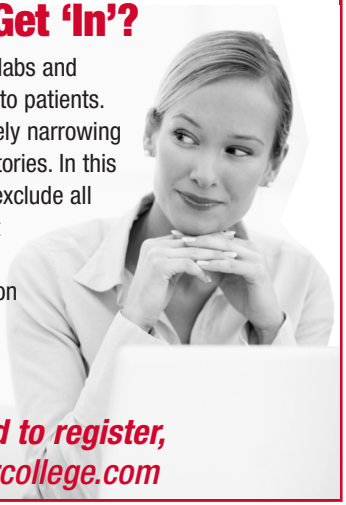
Registration NOW OPEN!

EXECUTIVE WAR COLLEGE

April 30-May 1, 2013 • Sheraton Hotel • New Orleans

Preview–Michael Snyder on...

Payer Access: Why Your Lab is 'Out'! Can Your Lab Get 'In'?



One critical success factor in 2013 for both clinical labs and pathology groups is keeping and expanding access to patients. However, private health insurers are now aggressively narrowing their networks expressly to push out smaller laboratories. In this important session, you'll learn why payers want to exclude all but the largest laboratories. You'll get insights about effective ways to deliver value to payers that larger lab organizations often can't match. This presentation offers you methods and strategies that you can use to position your lab as an essential resource for the important payers in your community.

For program details and to register, visit www.executivewarcollege.com

UPCOMING...

- ***How One Health System Is Boosting the Value of Lab Testing in Shared Accountability Organizations.***
- ***Upcoming Consolidation in Anatomic Pathology: Best Strategies for Smaller Pathology Groups.***
- ***Getting Paid All That's Legally Due Your Lab: What Innovative Labs Do to Raise Total Collections.***

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