Volume XX, Number 6 Monday, May 6, 2013

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Unpaid for Molecular Tests, Some Labs Are Closing

THERE IS GREAT FRUSTRATION ACROSS THE LABORATORY MEDICINE PROFESSION on the subject of getting paid for claims covered by the new Tier I and Tier II molecular test CPT codes. We are now in the fifth month of the year and pathologists are still waiting for an acceptable resolution to this situation.

Last week in New Orleans, at the *Executive War College on Lab and Pathology Management*, speakers gave plenty of attention to this topic. Simply put, the Medicare program was scheduled to implement pricing for these new CPT codes at the beginning of 2012. Program officials delayed that until January 1, 2013, in order to have the time they needed to develop appropriate pricing.

As most of you know, when January 1, 2013, arrived, Medicare contractors across the nation were unprepared. That was equally true of most private health insurance plans, since they often follow Medicare's lead when establishing their own coverage and reimbursement guidelines. As a result, the vast majority of laboratories performing molecular tests covered by these CPT codes have gone unpaid for a full four months!

The financial chaos caused by this situation is without precedent. THE DARK REPORT is learning about laboratory testing companies that have closed their doors already as a result, in some significant part, of having gone unpaid for the molecular tests they have performed on behalf of patients, but for which Medicare contractors have yet to issue payment. We hope to report on the specifics of these cases in upcoming issues.

In the meantime, every clinical laboratory and pathology group directly affected by the four-month non-payment of these molecular test claims should be actively communicating with their elected officials. At the *Executive War College* last week, leaders from the **American Clinical Laboratory Association**, the **California Clinical Laboratory Association**, and the **National Independent Laboratory Association** were asking lab executives and pathologists to contact their respective offices and provide information about the non-payment of the molecular test claims they have submitted.

These laboratory trade associations are preparing lists of labs affected by this situation and will use them in lobbying and education efforts. An impressive number of labs at the *Executive War College* provided details of their situation, so it is a lengthy list that will grow even larger as labs like yours respond. TDR

Exec War College Sessions Center upon Three Trends

Declining lab reimbursement dominates discussions as labs cope with revenue hits

CEO SUMMARY: There was an interesting blend of anxiety and optimism as a record crowd gathered in New Orleans last week for the 18th annual* Executive War College on Laboratory and Pathology Management. *The anxiety was rooted in the shrinking prices paid by payers for lab testing services. The optimism was based on recognition that individual clinical laboratories and pathology groups have the opportunity to deliver substantial value by helping improve patient outcomes while reducing the cost of care.

THREE MAJOR THEMES dominated the sessions at last week's 18th annual *Executive War College*. One theme was lack of money across the entire healthcare system and its negative impact on the finances of medical laboratories.

The second theme was the need for clinical labs and pathology groups to convert lab test data into information that adds value to physicians and patients. It was a call for labs to move away from simply reporting lab tests results and to develop enriched consultative services that directly help clinicans achieve better patient outcomes.

The third theme involved the rate of change in healthcare and the fact that this rate of change was accelerating. All three of these themes have profound implications for clinical laboratory executives and pathologists.

On the issue of money and adequate reimbursement for laboratory tests, there was universal recognition that, over the past 24 months, both government and private payers have implemented reimbursement policies that are significantly reducing the money paid for clinical laboratory testing.

"If there is one single thing to take away from the presentations of the past three days, it's that there is not enough money for healthcare—whether it comes from the federal, state, county, or city governments," said Robert L. Michel, publisher of THE DARK REPORT, which

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

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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).

sponsored the three-day conference in New Orleans, Louisiana. "Every lab organization should build that knowledge into its core strategic assumptions.

"Remember that the crisis in public funding is not limited to healthcare," continued Michel. "At every level of government, there is intense competition to spend more on education, on social services, on defense, and on infrastructure, such as highways and bridges. Healthcare is just one voice among many.

"At the same time, policy makers in Washington are trying to shift a 70-year pattern of taxation and spending to accommodate the demographics of an aging population and rising levels of chronic illness, both of which are outrunning the ability of the system to pay for the services these people need," he emphasized. "At some point, reality intrudes on all of this and that was one strong message delivered by our speakers here this week."

The payment morass associated with the 114 new Tier I and Tier II molecular test CPT codes was given plenty of attention. Many speakers discussed how Medicare contractors have not paid invoices that clinical labs have submitted since January 1, 2013, for these molecular CPT codes. *(See TDR, April 15, 2013.)*

During a general session on Tuesday, when Michel asked for a show of hands of labs that had not received any payments since the beginning of the year, about 50 lab representatives responded. By contrast, only about 10 lab representatives raised their hands in response to a question about whether they had received any payments for molecular test claims submitted in this same time.

Seeing the Big Picture

Moving past the immediate consequences of declining reimbursement and payers scrambling for ways to pay labs less in the short term, the second theme at this year's *Executive War College* was equally important. That is the shift within the American healthcare system away from fee-for-service reimbursement and toward value-based reimbursement.

Speakers were emphatic that this was the single biggest issue requiring a response by all lab organizations. Clinical laboratories and anatomic pathology groups need to demonstrate that lab testing has value beyond simply providing lab test results. Labs can do this by demonstrating that they can deliver this extra value in the form of lab test information that is actionable by clinicians and directly improves patient outcomes while lowering the overall cost per healthcare encounter.

During his presentation, David A. Dexter, President and CEO for **Sonora Quest Laboratories, LLC**, in Phoenix, Arizona, framed this need to demonstrate value quite succinctly. "The facts are that lab results are essential to preventive care, wellness, and chronic disease management," he said.

Laboratory Is Enabler

"Lab results impact more than 70% of all diagnostics decisions and are 50% of the data elements in an electronic health record," continued Dexter. "Lab data are essential for an effective health information exchange (HIE) and for coordinated patient care. The laboratory is an enabler for the entire health care system.

"Why is this so important?" he asked. "It's important because we face transformational change in healthcare. All healthcare stakeholders, including labs, have to reassess and refresh their value proposition in this new era of healthcare reform.

"Labs need to reassess their value proposition because the walls of traditional healthcare delivery are blurring," he added. "At this moment, no one knows what the new healthcare delivery system will look like. Therefore, many health systems and provider organizations are hedging their bets. Yesterday's competitor is often tomorrow's collaborative partner. Believe it!"

Dexter provided examples of such hedging that included hospitals and health systems buying health plans and health insurers developing or acquiring office-based physicians. "Different health insurers recently acquired **LifePrint Clinics** and **Concentra Clinics** in Arizona to manage patients with chronic disease. Another reason health systems and other providers are hedging is because accountable care organizations (ACOs) may not succeed," he said.

"If you are a hospital system, you might venture onto the episodic side of care and might be left holding the bag if ACOs significantly reduce your hospital's inpatient census," observed Dexter.

Adaptation Required

Such significant shifts in the healthcare marketplace mean it is important for labs to adapt as well, he said. "If you are a lab, you must realize and act on a fundamental industry paradigm shift. Under the old paradigm the lab was in the business of diagnostic testing," stated Dexter. "In the new paradigm, the lab is in the business of diagnostic testing and information services.

"This is Sonora Quest's vision: To be the trusted leader in diagnostic testing and information services," he added. "It isn't enough just to have IT capability and technology. You must leverage it."

Richard Atkin, President of **Sunquest Information Systems**, delivered a similar message. "The foundation of an efficient and effective healthcare system is an efficient and effective laboratory operation," he said. "The best patient outcomes and the lowest cost of treatment are enabled by fast, accurate, error-free lab results. But to deliver these results requires IT solutions that operate and interoperate seamlessly across the entire continuum of care.

"In fact, physicians and caregivers today require intuitive and accessible informatics solutions to allow greater time for patient care," Atkin said. "Recognizing these facts, chief informa-

Different Issues for Labs In 2013 and Beyond

IT WAS BOB DYLAN WHO SANG "The Times They Are a-Changin" and made it a big hit back in 1964. However, even today, his words are useful to clinical labs and pathology groups.

The pace of change unfolding in both healthcare and the lab testing industry was on full view at last week's *Executive War College*. A record crowd was surprisingly optimistic about the opportunities that lie ahead. At the same time, attendees were realistic about the setbacks and challenges that must be addressed by every laboratory if it is to successfully make the transition from today's fee-for-service healthcare system to one where value-based reimbursement and bundled reimbursement are the norms.

In particular, there was plenty of discussion about the Affordable Care Act of 2010 (ACA) and how its mandates are expected to play out in coming years. All healthcare providers recognize that the goal of the legislation is to bring health insurance coverage to 30 million Americans.

On one hand, this seems to be a positive thing for all providers, including clinical labs. On the other hand, there is already a recognition that the myriad elements of the ACA and the scarcity of funds to implement these elements may portend financial woes for hospitals, physicians, and laboratories.

These facts were recognized during the presentations and mostly accepted by the audience. There was a strong sense of skepticism that the ACA will play out as planned. It was for that reason that speakers recommended that labs take a position of "watchful waiting" as they develop and refine their strategies for dealing with the coming changes triggered by the ACA.

tion officers in hospitals and other care settings have three main priorities.

"They are: 1) strengthening the 'information value chain'; 2) building IT business skills; and, 3) getting closer to business," he explained. "The reason CIOs want to get closer to business is because they want to replace retrospective analysis with real-time analysis of patient care as it is being delivered. That is one reason why healthcare organizations are looking for real-time data on patient care within one hour of the activity."

Real Time Data Required

Among the organizations that will be looking for real-time data analytics are accountable care organizations (ACOs). Dexter defined ACOs as partnerships between health insurers, hospitals, and primary care physicians to manage all healthcare for members of the organization. "The ultimate goal of ACOs is to improve quality and patient care outcomes through focused coordinated care in a manner that reduces the total healthcare cost," stated Dexter.

"For labs, the development of ACOs is important because more than 400 ACOs have been certified to operate in the United States and 200 others are being developed," he said. "An estimated 25 million to 30 million patients are in ACOs today and that number is expected to grow exponentially. Yet, despite this rapid growth, labs are generally last at the ACO contract table."

Atkin agreed, saying ACOs will emphasize quality care through provider networks even as they seek to decrease reimbursement rates. "That means hospitals have to find new ways to manage costs," he said.

"We expect that ACOs will want their labs to contribute to operational cost savings through fewer errors, improved specimen routing, and the ability to make proactive and preventive care decisions in collaboration with referring physicians.

"One way ACOs will seek to drive down costs is through bundled payments, and programs in which all providers share any financial savings and the financial risks of any losses," Atkin said. "In ACOs, we may see reimbursement for an individual lab test cease to exist. In addition, ACO patients will pay an increasingly greater share of their medical expenses."

Atkin also recommended that laboratories address the integrity and quality of their internal work processes. In speaking to the efforts of his company, Sunquest, to work with the **Food & Drug Administration** to clear his company's software products under the medical device regulations, he stated that "every lab should be striving to achieve best practices in internal operations and work processes."

"As this is done, the laboratory should use a third party to endorse these best practice achievements," continued Atkin. "This recognition is something that will be meaningful to patients, payers, and employers, as well as other providers. It reflects the growing recognition by purchasers of healthcare services that the bar on quality is being raised."

Pace Of Change

The third theme of the 2013 *Executive War College* was that of an accelerating pace of change across the length and breadth of healthcare. "Not in the past five decades have such swift and deep changes been seen in the healthcare system of the United States," stated Michel in his opening address.

"What underpins this change is the transition we are making from primarily fee-for-service reimbursement to new forms of payment to providers that incorporate outcomes and overall cost of care," continued Michel. "By changing the way money flows from payers to providers, healthcare policymakers are guaranteeing that hospitals, physicians, labs, and other providers will be responsive to supporting the new goals.

"Therefore, we should all expect continued and swift evolution of healthcare," concluded Michel. "Labs are well advised to be nimble and open to change."

—Joseph Burns

Dartmouth Builds New Lab To Serve Growth in Testing

Expansion puts clinical molecular diagnostics next to translational and investigative research

CEO SUMMARY: Demand for specialized reference and esoteric testing is so robust at Dartmouth Hitchcock Medical Center in New Hampshire that the academic center is building an expanded laboratory facility to accommodate the increased volume of tests it handles each year. A favorable trend supporting these developments is the steady decline in the cost of performing molecular testing. This is particularly true for assays that utilize next-generation gene sequencing technologies.

ACADEMIC MEDICAL CENTERS are well situated to be important regional sources of reference and esoteric testing. One example of this trend is **Dartmouth Hitchcock Medical Center** (Lebanon, New Hampshire) and the **Geisel School of Medicine** at Dartmouth in Hanover, New Hampshire.

In fact, the robust demand for advanced lab testing is one reason why DHMC is about to spend $116.5 million on a new six-story building that will house laboratories for molecular pathology, microbiology, and translational research.

The expansion of laboratory testing at DHMC is an excellent example of how a pathology department at an academic medical center can generate specimen referrals for reference and esoteric tests across the immediate region it serves. In this case, the lab at DHMC serves physicians in New Hampshire and parts of Vermont.

"As a regional medical center located between Boston and Montreal, we treat a large number of patients who are very sick," stated Gregory J. Tsongalis, Ph.D., HCLD, CC, Director of Molecular Pathology and Co-Director of the Translational Research Program in the Department of Pathology at the 396-bed DMHC. "These patients are referred to us from smaller hospitals, often after clinicians were unable to identify the clinical problems for cases that are often very complex."

Demand for specialized testing at DHMC is such that hospital administrators estimate that the medical center will recoup its $20 million investment in the new clinical laboratory in eight years. "That is a realistic goal," commented Tsongalis.

Increased Specimen Volume

"Our current lab facility was built in 1993," he noted. "Since 2004 the volume of tests has more than doubled and the number of specimens is increasing at a steady pace.

"For these reasons, we are becoming more of a regional reference lab, particularly in the automated areas such as hematology, clinical chemistry, and microbiology," Tsongalis said. "Other hospitals send us tests they can't do or because we can offer them better pricing through our expansive outreach program that we maintain with all the hospitals in the area.

"Expansion of our laboratory facility is also needed so we can set up new tests that we currently send out," he continued. "The current budget for send-out testing is $8 million annually. That is a big number and we expect to bring it down by keeping those tests in house when we expand."

In the current lab facility, the 300-member Pathology Department has about 25,000 to 30,000 square feet. In the new facility, space devoted just for molecular pathology and microbiology will total 15,000 to 18,000 square feet, Tsongalis said.

"Molecular and genetic testing is our biggest area of growth," he noted. "These new molecular diagnostic tests also happen to make up the majority of our send-out test costs. Of that $8 million send-out bill, a significant amount goes to about 15 to 20 small esoteric labs that do just a few gene tests.

➤ Evaluating Send Out Costs

"Our cost may be from $2,000 to $10,000 per test for these send-outs," explained Tsongalis. "Thus, there is immediate financial benefit when we can perform these assays in our lab.

"Of course, specimen volume plays a role in determining which send out tests we can shift into our lab," he stated. "There are the tests for unusual conditions that we typically see only once or twice a year. Those we would continue to refer to outside laboratories. But for everything else, we expect to do those tests in house."

Tsongalis said the ongoing improvements in diagnostic testing technologies are benefiting their laboratory. "A big game changer in molecular and genetic testing is the technology for next-generation gene sequencing," he said. "That technology is allowing us to quickly sequence a lot of genes at a very low cost.

"The cost of this technology has come down dramatically in recent years," noted Tsongalis. "You see that in the declining prices for the next generation sequencing instruments manufactured by **Illumina** and **Life Technologies**, among others.

"This is a benefit to our molecular lab in two ways," continued Tsongalis. "First, gene sequencing equipment is relatively inexpensive today compared with the cost of other analyzers that we have in the diagnostics laboratory. Second, our experience is that the cost of next-generation sequencing and other molecular testing is declining steadily.

"That's why we review our send-out testing each month," he said. "We track those numbers over time. If a particular test is high volume, then we'll consider bringing that test in. If it's a lower volume test—but the cost of sending it out is so high that it will be prohibitive—then we will consider bringing that test in as well.

"Within molecular diagnostics, our fastest growing area is in oncology," noted Tsongalis. "In fact, at an April retreat for the staff at the cancer center, we presented our newest data on the tests we can run using next-generation sequencing applications. This retreat gave our oncologists their first look at new ways of detecting the disease and new information for tailoring therapeutic management strategies for our patients."

In the new building, molecular pathology and microbiology will occupy the fourth floor. "The other five floors will house translational and investigative research," observed Tsongalis. "Our institution recognizes that pathology must be involved to have a successful translational research program. It is impossible to transition basic science discovery into clinical practice without the involvement of pathology. Our department bridges that gap."

Construction of a new lab facility to support the sustained growth in molecular and genetic testing at Dartmouth Hitchcock Medical Center shows that academic medical center labs can successfully develop a robust lab outreach business within the region that they serve. **TDR**

—Joseph Burns

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Mass Spec, Collaboration Produce Dramatic Results

Methodist Hospital lab and pharmacy team up to speed targeted treatment of blood infections

CEO SUMMARY: When the Department of Pathology and Genomic Medicine at the Methodist Hospital in Houston, Texas, worked with the Pharmacy Services Department, the outcome was a dramatic reduction in the time needed to more accurately identify and treat the pathogens causing gram-negative bloodstream infections. This successful program reduced the average length of stay by 2.6 days. The hospital estimates that annual savings from this intervention can total $18 million.

THERE ARE FEW DISEASES more critical to diagnose and treat rapidly than bloodstream infections (BSIs). For hospitals, this is a condition associated with high morbidity and mortality, along with high costs.

That makes bloodstream infections a perfect target for the hospital laboratory that wants to step up and add value. One outstanding example can be found at 1,000-bed **Methodist Hospital** in Houston, Texas.

LOS Reduced by 2.6 Days

The lab, in a innovative collaboration with the pharmacy department, has achieved and sustained a 2.6 day reduction in the average length-of-stay (LOS) for patients diagnosed with BSI. The value of these developments is worth an estimated annual savings of $18 million to Methodist Hospital.

The laboratory did three things that improved diagnostic accuracy and shortened time-to-answer for patients suspected of having a blood system infection. First, the lab implemented work flow redesign that improved individual work processes, starting with the collection of specimens and including start of patient treatment.

Second, the laboratory began using new mass spectrometry technology to shorten the time needed to provide physicians with an accurate answer. Third, the laboratory and the pharmacy worked together to speed up the process of identifying the pathogen and the appropriate antibiotic for each patient with a BSI.

"We accomplished these things under our collaborative antimicrobial stewardship program (ASP)," stated James M. Musser, M.D., Ph.D., who had a lead role in this effort. Musser is Chair of the Department of Pathology and Genomic Medicine at **Methodist Hospital** and a Professor of Pathology and Laboratory Medicine at the **Weill Cornell Medical College of Cornell University**. He is also the Director of the Center for Molecular and Translational Human Infectious Diseases Research at the **Methodist Hospital Research Institute**.

"The goal of this project was to improve the process of diagnosing and treating patients with gram-negative BSIs," noted Musser. "We first recognized that the process—from drawing the blood to treating the patient—could be improved and accelerated.

"We identified three bottlenecks," he explained. "First, we wanted to do rapid species-level identification of a pathogen using a mass spectrometer.

"Second, we wanted to run rapid (meaning as rapid as possible) antimicrobial susceptibility testing for these pathogens," he continued. "This second step led to a question of whether we could more precisely target the antimicrobial therapy for the patient. And that question led to our third bottleneck: how best to inform the treating physicians."

Musser and the lab staff addressed the first two bottlenecks by using relatively new technology: matrix-assisted laser desorption ionization-time of flight (MALDI-TOF) mass spectrometry. Clinical laboratories worldwide are finding that MALDI-TOF mass spec effectively circumvents many of the drawbacks of traditional testing methods and offers a rapid and relatively inexpensive way to identify bacterial and fungal organisms. Methodist Hospital uses the MALDI Biotyper from **Bruker Daltonics Inc.**, based in Billerica, Massachusetts.

Increased Precision

"Use of mass spec dramatically cut the time needed to identify the pathogen," stated Musser. "The mass spec was faster than many traditional testing methods, with increased analytical precision over many existing diagnostic methodologies. We also re-engineered our antimicrobial susceptibility testing strategy. To do that, we used material obtained directly from early-positive blood cultures."

Musser and his team quickly recognized that the third bottleneck—informing physicians about the test results—would be a challenge. "You can think of our effort as a three-headed approach to improving care," he said. "The crucial issue was to maximally use new technology, re-engineer work flow, and partner with the Department of Pharmacy and their infectious diseases pharmacists.

"Using the mass spectrometer allowed us to do rapid identification of the pathogens, but rapid identification is only part of the solution," he emphasized. "If we simply report that information in a passive fashion—as most hospital labs do and as we do most of the time when sending reports back to treating physicians on the floor—that wasn't going to achieve maximal time and cost savings."

At this point, Musser sought advice from Katherine K. Perez, PharmD, BCPS, a Clinical Specialist in Infectious Diseases in the hospital's Pharmacy Services Department. "We asked Dr. Perez to get involved and she deserves an immense amount of credit for spearheading this project," Musser said.

"It was clear that the wisest course of action was for us to push the information out to the treating physicians rather than to passively report the information," he explained. "But making that part of the improved diagnostic process workflow was critical to success. It requires one-to-one interaction between a pharmacist and the treating physicians.

"Recognizing the problem, she made herself available 24 hours a day, 7 days a week," recalled Musser. "In that time, she was the person on call to whom we pushed the lab information. Where necessary to alter or otherwise adjust antimicrobial agent therapy, Dr. Perez then directly interacted with either the medical record or the treating physicians."

When the laboratory identified the pathogen, the laboratory staff would call Perez. She would then review the patient's electronic medical record and call the treating physician to identify the most effective antimicrobial therapy.

"Initially, the MALDI-TOF MS analysis was done three times daily," stated Musser. "Later, we added a fourth run. Currently, the lab runs it five times daily.

"We want to further shorten turnaround times by offering these diagnostic tests more frequently," he noted. "For that

2.3 Day Reduction in Length-of-Stay Generates Annual Savings Estimated at $18 Million

EFFORTS to speed up the process of identifying the best antimicrobial agent for patients with gram-negative bloodstream infections paid big dividends at Methodist Hospital in Houston, Texas. Medical personnel there cut average length-of-stay (LOS) by 2.6 days for these patients.

"Personally, I know of no other single process or approach in recent years that has identified on average a 2.6-day decrease in LOS," declared James M. Musser, M.D., Ph.D., Chair of the Department of Pathology and Genomics Medicine at The Methodist Hospital.

"From an economic standpoint and from an individual patient standpoint, cutting LOS is important," he said. "This LOS reduction was for the first 100 patients in our study. We believe that for larger numbers of patients, we will show a statistically significant increase in patient survival as well."

Musser and his colleagues published the results of their research project on December 6, 2012, in the online edition of *Archives of Pathology & Laboratory Medicine*.

"Many strategies have been proposed and tried to further improve the consequences of these detrimental infections," the researchers wrote about gram-negative BSIs. "However, our study is the first to demonstrate that integrating rapid molecular analysis by novel application of mass spectrometry with antimicrobial stewardship in near real time significantly enhanced clinical care and financial outcomes."

The researchers reported a decrease in average LOS from 11.3 days for these patients to 8.7 days. The annual savings are projected to total $18 million.

Cutting LOS helps to control expenses and the researchers showed that costs for each patient treated in the program were $26,162 versus $45,709 for those in a control group. This produced savings of 42%, or $19,547 per patient. Researchers estimated that if the program had been used for all patients with gram-negative bloodstream infections at Methodist Hospital, the savings would total $18 million in a year.

reason, we've purchased a second MALDI-TOF MS. That machine is being brought on line now. When we have two machines, we will be able to run these tests more frequently, perhaps every other hour.

"Typically in a microbiology laboratory a bloodstream infection requires us to withdraw material from the patients' blood specimen and culture it overnight, which requires at least eight hours and sometimes more than 24 hours," he noted. "The beauty of mass spec is that you can withdraw the blood from the blood culture bottle and identify the organism at the species level within a half hour. That's a significant improvement in the time needed to get to species-level identification.

"We then perform antimicrobial agent susceptibility testing directly from the early-positive blood culture, thereby decreasing the time required to institute targeted therapy," noted Musser. "In addition to adding a second instrument, the lab uses this same approach of rapid testing with antimicrobial stewardship for patients with gram-positive and other types of microbial infections."

Methodist Hospital laboratory's contribution to reduced patient length of stay and to lower costs for treating gram-negative BSIs is a useful roadmap that other hospital and health system laboratories can follow to deliver similar value. **TDR**

—Joseph Burns

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Standard Bar Code Labels Can Reduce Lab Errors

Opportunity to reduce specimen ID errors while improving patient care and cutting costs

CEO SUMMARY: Standardization of bar code labels is a concept whose time has come. After implementing CLSI standard AUTO12-A, first-mover clinical labs report fewer specimen identification errors, a reduction of costs associated with specimen handling errors, and a boost in lab productivity. Moreover, accrediting bodies such as The Joint Commission and the College of American Pathologists are moving to require labs to comply with the bar code label standard in coming years.

ACROSS THE NATION, all clinical labs and pathology groups now have the opportunity to institute a simple change in lab operations that can unlock major improvements in tracking specimens, reducing specimen ID errors, and boosting the productivity of the laboratory.

That simple change is to adopt the universal standard for bar code labels that was developed by advisors from the clinical lab industry and is published by the **Clinical and Laboratory Standards Institute** (CLSI) in Wayne, Pennsylvania. The standard is "AUTO12-A, Specimen Labels: Content and Location, Fonts, and Label Orientation."

Implementing The Standard

There are examples of first-mover and early-adopter labs that have implemented this bar code label standard. These clinical lab organizations acknowledge that adoption of the standardized bar code label has unlocked new and continuing opportunities to improve the performance of their labs.

Benefits include a reduction in the number of errors associated with specimen ID and improvements in specimen handling, tracking, and storage. In turn, laboratory costs have been reduced, and the accuracy and quality of lab test services delivered to referring physicians and their patients has improved.

There is a message to the wider clinical lab and anatomic pathology profession from these first-mover labs. The adoption and use of the standardized bar code label requires a small up-front investment, but then becomes the "gift that goes on giving."

Further, at a time when lab budgets are shrinking even as the pressure increases on labs to continuously reduce errors, the minor cost to adopt the standardized bar code label enables labs to more easily achieve cost savings and a reduction of errors.

It may surprise most clients and readers of THE DARK REPORT to learn that the CLSI effort to standardize bar code labels has been around for a very long time. As early as 2005, CLSI had proposed such a standard.

"The latest approved version of the standard was issued by CLSI in 2011," stated Charles D. Hawker, Ph.D., MBA, FACB, the Scientific Director, Automation and Special Projects, for **ARUP**

Is It Time to Rethink the Lowly Bar Code Label? Opportunity for Labs to Spend a Little, Get a Lot

ATTENTION ALL LEAN AND SIX SIGMA PRACTITIONERS in clinical labs and anatomic pathology groups! It is now time to reconsider the lowly bar code label and its contribution to unnecessary and expensive errors as a way to reduce errors and improve the productivity of laboratory automation systems.

It is a common perception within labs that, by using bar codes, a high level of accuracy results when identifying specimens and tracking them through the laboratory. This is certainly true when compared to manual handling of specimen tubes. But bar code labels have their own failings.

First, there is the quality of the bar code label. The label itself may not take the printing in a way that allows readers to accurately scan that label. The label printer may be using ink that does not transfer well to the label.

Of course, the label printer may be malfunctioning. Deferred maintenance of the label printer can cause it to produce bar code labels that may appear acceptable to the human eye, but that fail or are misread when scanned by mechanical label readers.

The next common source of errors is literally the "Tower of Babel" caused by bar code labels flowing into the lab from multiple sources with different formats.

This fact was described by the committee for the Clinical and Laboratory Standards Institute (CLSI) that designed a standard for bar code labs. "A collection of labels from different laboratories provided by one committee participant showed a variety of formats and fonts," said Charles D. Hawker, Ph.D., Scientific Director, Automation and Special Projects, for ARUP Laboratories in Salt Lake City, Utah. Hawker chaired the committee for CLSI.

"Some specimen labels had the patient name on the first line, some on the second line, and some on the third or fourth," he said. "Sometimes, the patient name was left-justified and sometimes it was in the center. Sometimes it was above the bar code and sometimes it was below.

"There were even some specimen labels on which the name was turned 90 degrees to the length of the tube, sometimes toward the top of the tube, and sometimes toward the bottom of the tube," explained Hawker. "Such variety was not useful and contributes to errors within the laboratory."

Given this information, it would be timely for all process improvement leaders in labs across the country to consider adoption of the CLSI standard AUTO12-A for bar code labels. The cost to implement the software and formatting changes that support the bar code label standard is minimal.

In return, use of the standard bar code label format eliminates one more source of variability in lab automation and work processes. It positions the lab to pursue the goal of Six Sigma quality across each individual work process within the laboratory.

Laboratories in Salt Lake City, Utah. "CLSI has said all labs should comply with the standard by April 29, 2014. If labs don't act now, they may need to engage in considerable last-minute activity.

"This standard was needed because misidentified or mislabeled specimens happen in laboratories with a greater frequency than what would represent good patient care," explained Hawker. He

chaired the CLSI committee that prepared the standard. "A variety of labels also impedes the ability of labs to standardize and process specimens quickly."

Considered an expert on total laboratory automation, Hawker has published several peer-reviewed studies demonstrating that use of non-standardized bar code labels on patient specimens contributes to a surprisingly high rate of errors. One study was published by *Clinical Chemistry* in 2010, titled "Bar Codes May Have Poorer Error Rates Than Commonly Believed." *(CC 56:10—1513–1514, 2010.)*

Eliminating Standard Options

"Published references cited in the CLSI standard show mislabeling error rates in the United States range from 0.1% to 5%," he commented. "Among the published references that were cited, one report revealed an error rate of nearly 1 per 1,000 in 147 participating clinical laboratories. Another report in the cited sources indicated a mislabeled error rate of 1.12% on blood bank specimens. This latter value is astoundingly high!"

In one report published in 2005, the average cost of a misidentified specimen was $712. "This did not include immeasurable costs, such as patient anxiety and discomfort and the delays in diagnosis and treatment," observed Hawker. "This amount also does not include the consequential costs, such as those for any possible ensuing litigation for actual incurred patient harm.

"A conservative estimate for the total cost of mislabeled specimens was $280,000 per million specimens tested," he continued. "This amount does not include litigation or settlement expenses. This estimate comes from multiplying the average cost of $712 per mislabel incident times a low published incidence of mislabeled specimens of 0.039%, according to a one report.

"When laboratory employees constantly have to readjust their focus to find patient names in different locations on the labels—or if those names appear in inconsistent fonts and formats—the likelihood of errors rises," he added. "Therefore, it stands to reason that institutions that implement the bar code label standard will benefit from lower rates of errors resulting from mislabeled specimens.

"If these benefits, ranging from saving costs and reduced errors to improved patient care, are not enough to justify adoption of the standard for bar code labeling, there is another reason for labs to comply with the standard," declared Hawker. "It will become a requirement for lab licensure and/or accreditation.

"For example, in December 2012, **The Joint Commission**, which inspects all hospitals in the United States, reported that it intended to list the bar code label standard as a reference in its Prepublication Requirements document," he noted. "The bar code label standard also will be studied by the **College of American Pathologists** (CAP) next year (2014) or in 2015 with a goal of including it in the checklist.

Bar Code Label Standard

"The purpose of the standard is to serve as a precise typographical map for specimen labels," explained Hawker. "The standard specifies the horizontal and vertical rule locations, font types, and font sizes on all specimen labels for certain essential, human-readable elements. These elements include the patient's name, a unique secondary identifier, the patient's date of birth, the specimen collection date and time, and the specimen collector's identification.

"One feature of the standard is a suggested format for doctor's offices and other providers who handwrite labels for specimens to be submitted to a laboratory," concluded Hawker. "With this established standard in place, labs now have the opportunity to use it to further reduce errors and improve patient safety." TDR

—Joseph Burns

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Labs Should Prepare for Larger Patient Deductibles

Employers, insurers shifting costs to patients by expanding enrollment in consumer-directed plans

CEO SUMMARY: Employers are taking active steps to control the year-over-year increases in the cost of health benefits. One strategy gaining favor is to move employees away from traditional health plans and enroll them in high-deductible health plans (HDHPs). This is a trend with huge financial implications for clinical labs and pathology groups. It means all labs would be smart to put procedures in place to collect directly from patients who may have an annual family deductible of as much as $5,000.

EMPLOYERS IN THE UNITED STATES are making significant changes in their health benefit plans that will affect most clinical labs and pathology groups in the coming year.

Several different market dynamics are motivating employers to restructure the health benefit programs they offer to employees. What many of these changes have in common is that employers will require beneficiaries to pay more money out of pocket for laboratory tests, particularly if they use out-of-network laboratories.

These are unwelcome developments for lab administrators and pathologists. First, local labs may find themselves out of network for a growing proportion of the patients in their community. Second, labs will need to collect larger amounts of money from patients for lab testing services, due to new requirements for patients to pay higher annual deductibles.

One factor shaping employer's thinking is last summer's U.S. Supreme Court decision that upheld the Affordable Care Act (ACA). With this cloud over the law removed, employers began aggressively moving to comply with the law, according to a recently-published report. It is the 18th annual **Towers Watson** and **National Business Group on Health** (TW/NBGH) Employer Survey on Purchasing Value in Health Care.

The survey contains aggregate responses from 583 organizations with a collective $103 billion in total 2012 health care expenditures. Authors of the study stated that employers are moving rapidly to manage rising costs of health benefits. Employers also want to avoid triggering ACA's excise tax on high-cost plans that starts in 2018.

Shifting Costs To Workers

The primary strategy employers are using to contain the rising cost of health benefits is to shift those costs to workers, explained the report. They are using a form of high-deductible health plan that goes by the new acronym of ABHP, for account-based health plan. ABHPs are simply a consumer-directed health plan (CDHP) that is linked to a health savings account (HSA) or a health reimbursement account (HRA).

This trend of employers shifting more healthcare costs to employees and family members directly affects all clinical labs and pathology groups. It will mean that labs must be more vigilant about collecting copayments and deductibles from patients at the point of care—or see a big increase in their lab's bad debt.

Moreover, this trend is another reason that every lab organization should be implementing procedures to allow all patients to pay at the time the specimen is collected, typically in a patient service center. Other providers are moving to do the same, thus conditioning patients of the need to pay their deductibles and co-pays at the time of service.

For the TW/NBGH study authors, ABHPs will be one cornerstone in employer's efforts to manage the cost of their health benefit programs. "ABHPs can be an important strategy for reining in costs in advance of the 2018 excise tax and facilitating the shift toward greater accountability from employees and more consumer-like behavior in their purchase of health care," the report said. "Today, 66% of companies have an ABHP in place, and 13% expect to add one by 2014."

Eliminating Standard Options

Lab executives and pathologists should understand that ABHPs are going to crowd out more traditional forms of health insurance. Many employers are using ABHPs to eliminate standard health insurance plans.

This is happening at a fast pace. Just during this year alone, about 15% of responding employers used an ABHP to replace their standard insurance plans. That number is double the rate from 2010.

During this same period, enrollment in ABHPs rose from 15% in 2010 to nearly 30% in 2013. What's more, about 25% of all respondents may offer *only* an ABHP next year, the survey showed.

Among the largest employers (meaning those with more than 1,000 workers) responding to the survey, 66% offered at least one ABHP this year and 80% will do so next year. This trend is moving as swiftly as the abandonment of closed-panel, fully-capitated HMOs did in the second half of the 1990s.

In March, Kaiser Health News reported on this trend, commenting, "Historically, one of the perks of working at a big company has been generous health benefits with modest out-of-pocket costs. But increasingly, large companies are offering their employees only one option: a plan with a relatively high deductible linked to a savings account for medical expenses."

Early Insights About Trend

This swift growth in ABHPs was described at the *Executive War College* last year by Paul Mango, a Director with **McKinsey & Company**, in Pittsburgh, Pennsylvania. He told the audience that the introduction of ABHPs is a little-known trend among employers and insurers that permits them to significantly reduce that they spend on healthcare. By introducing high-deductible health plans, insurers and employers are shifting medical risk to consumers, he said. *(See TDR, June 12, 2012.)*

"This shift is the biggest stealth issue of the last four or five years because it has resulted in a dramatic increase in HDHP enrollment," declared Mango. He went on to say that, in recent years, the market for HDHPs has tripled. There are now almost 30 million people enrolled in these products, or about 20% of the insured population.

HDHPs typically require consumers to pay for everything out of pocket until they reach an annual deductible of $5,000 or more, observed Mango. That high level of spending makes consumers very conscious of price. It means they place great importance on value. Labs must respond to this trend by raising the value proposition they provide to patients.

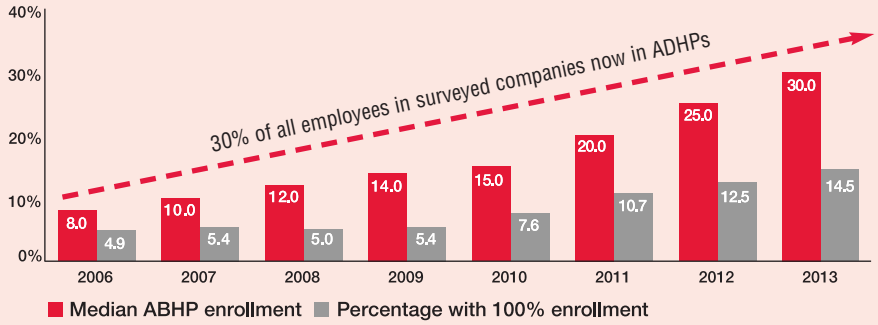
Mango also explained that: "Health insurers have other ways they can use to

Trend Among Employers Is to Offer Employees Account-based Health Plans (ABHPs)

ONE FAST-MOVING TREND is for employers to introduce account-based health plans (ABHPs) to their employees as a way to manage the rising cost of health benefits. This trend has major implications for all clinical laboratories and pathology groups because it means that a growing proportion of patients must meet significantly higher annual deductibles and out-of-pocket spending requirements as defined by the ABHPs.

These findings were reported by Towers Watson and the National Business Group on Health (TW/NBGH) following its 18th annual "Employer Survey on Purchasing Value in Health Care." The survey authors wrote that there has been "...a substantial increase in employee enrollment in these plans, which has risen significantly over the past three years, from 15% to 30% [see below]. We've seen a steady increase in enrollment in both account types, with HSA enrollment rising from 13% in 2011 to 20% today, and HRA enrollment rising from 28% to nearly 40% in 2013." The growing adoption of ABHPs means that laboratories should prepare to collect money from patients at the time of service.

ABHP Enrollment Rates Rising at a Rapid Pace



Note: Data by Towers Watson and the National Business Group on Health. Estimates are based on companies that offer an ABHP in various years: 2006 is based on the 12th annual National Business Group on Health/Towers Watson survey; 2007 is based on the 13th annual survey; 2008 is based on the 14th annual survey; 2009 is based on the 15th annual survey; 2010 is based on the 16th annual survey; 2011 is based on the 17th annual survey, and 2012 and 2013 are based on the 18th annual survey (current).

exit the traditional health insurance business. Health insurance companies can serve self-insured employers in arrangements known as administrative services-only (ASOs).

To Mango's point, last fall, **Aon Hewitt**, a consulting firm in Lincolnshire, Illinois, issued the findings of a survey it conducted last fall. It said that CDHPs surpassed health maintenance organizations (HMOs) as the second most common plan design U.S. employers offered.

Aon Hewitt's survey of nearly 2,000 U.S. employers showed that 79% of respondents offered a preferred provider organization (PPO) in 2011. Next, 58% of respondents offered CDHPs and 38% offered HMOs.

The message in these trends for clinical laboratories and pathology groups is

that more consumers will be paying more out of pocket. With annual family deductibles of $5,000 or more, it means labs should be prepared to collect 100% of a bill directly from patients. This will be true for a growing proportion of every clinical lab's and pathology group's test claims.

It hasn't gone unnoticed that this trend toward increased patient responsibility for the cost of care makes it more difficult for all providers to collect the money patients owe. **ZirMed, Inc.**, a company in Louisville, Kentucky, that offers revenue cycle management systems to providers, recently published its own report on this situation.

"Thanks to higher-deductible plans, the greater number of uninsured patients, and the larger co-pays, more of the money owed to providers is coming directly from patients' pockets," ZirMed said in a report titled, "Collect More from Patients Without Hurting Satisfaction." Collecting from patients is one of the biggest challenges hospitals and practices face, ZirMed said.

New Collection Challenges

"And as those funds start making up a larger percentage of providers' incomes, collecting them is becoming more and more critical," wrote the report's authors.

As might be expected, when patients pay a greater share of a lab's income, the level of bad debt rises. Statistics reported by the **Association of Financial Professionals** (AFP) illustrate this point. AFP noted that a healthcare survey revealed that, in 2010, while only 10% of providers' overall annual revenue came directly from self-pay patients, more than 58% of bad debt came from self-pay patients.

Since 2010, the proportion of total revenue that comes from individual patients has risen and is now estimated at about 30%, according to ZirMed. "As hospitals and physician practices work to improve cash flow, collecting more of what they are owed from patients will be one of the areas that has the biggest impact on the bottom line," reported ZirMed.

Labs face a challenge in this regard. Like most providers, labs are well prepared to bill insurance companies and rebill if needed. But they are not well prepared to collect revenue from patients, ZirMed said. It also noted that many provider organizations often make no changes to their collection procedures out of fear of offending patients and thus damaging patient satisfaction scores or losing them as customers.

Steps Labs Should Take

Among the steps labs and all providers can take to increase collections at the point of care is to implement new processes that allow providers to estimate or calculate exactly what patients owe. Many health insurers are introducing tools that allow patients to know what they owe in real time for most health care services. These tools even calculate the amount that remains of a patient's deductible throughout the year.

ZirMed offers a patient estimation tool that uses data from a national database of healthcare payment information to make predictions about what patients owe. But knowing what patients owe solves only part of the problem. The bigger issue is collecting what's owed.

For this, labs need to collect when patients arrive for service because the longer a debt exists, the less likely the organization will collect. Some 52% of patients are willing to pay at least some of what they owe at the point of care using a credit or debit card, ZirMed said.

Taking Payments Over Time

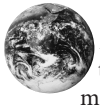
It should be possible for labs to collect at least a portion of the amount owed when a patient schedules an appointment, ZirMed added. Then, they could pay the balance at the point of care or over time. Just knowing what the patient owes will allow the lab to make arrangements to pay. TDR

—Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report



Much is happening in the anatomic pathology market in the Pacific Northwest. **PAML, LLC** (Spokane, Washington), and **CellNetix** (Seattle, Washington) finally executed the agreement whereby PAML made an equity investment in CellNetix. Now, the two lab companies will collaborate on developing a reference and esoteric anatomic pathology testing service with national ambitions. Within days of this press release, **Incyte Pathology** of Spokane announced that it would change its name to **Incyte Diagnostics**. It said "The [name] change follows the merger last year between InCyte Pathology and **Eastside Pathology** [of Bellevue, Washington]."

CYTOLOGY LAB OPENS IN IRELAND

Pap smear testing is returning to Ireland. **MedLab Pathology** (MLP), a division of **Sonic Healthcare Ltd.**, is opening a state-of-the-art cytology laboratory in Dublin. MedLab holds a contract to perform 50% of the 338,000 Pap smears performed annually on Irish women. MLP has 91 employees that include 34 medical scientists and two consultant pathologists. In 2008, the **Irish Health Service** had outsourced 100% of cervical cancer screening tests to **Quest Diagnostics Incorporated**, which performed these tests in the United States. *(See TDR, August 31, 2009.)*

ADD TO: *Irish Paps*

Pathologists and other physicians in Ireland were unhappy with the decision of the Irish Health Service to outsource all the nation's Pap smear testing. Among other things, it was pointed out that it would be impossible to train young pathologists in cytology if all such testing were performed outside the country. Currently, MLP is reporting about 160,000 Pap tests annually. A cervical cytology training unit has also been established within its lab facility.

TRANSITIONS

• **PathXL** of Belfast, Ireland, a company that provides "web-based solutions for digital pathology," said it had appointed John Durborow as Director of Sales and Business Development for North America. He has held executive positions with **Aperio Technologies**, **Hologic**, and **Cytyc Corporation**.

That's all the insider intelligence for this report. Look for the next briefing on Tuesday, May 28, 2013.