Volume XX, Number 14 Monday, October 21, 2013

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

Coming Soon to Your City: More Hospital Mergers

UPON THE COMPLETION OF THEIR MERGER AT THE END OF SEPTEMBER, **Baylor Health Care System** and **Scott & White Healthcare** became the largest not-for-profit health system in Texas, boasting $8 billion in assets and annual revenue of about $6 billion.

Now known as **Baylor Scott & White Health**, the system operates 43 hospitals and 500 patient care sites. Affiliated physicians total 6,000 and there are 34,000 employees. The reason I am calling your attention to this mega-merger between two big health systems is that it is not unique!

Also on the last day of September, the merger was finalized between **New York Mount Sinai Medical Center** and **Continuum Health Partners**. This created one of the largest not-for-profit health systems in New York. It has 3,500 beds on seven campuses throughout the New York City metro area. It employs 36,600 people and has 6,600 affiliated physicians.

The creation of huge health systems via merger is a sign of the future. Health system administrators recognize that **Kaiser Permanente** and **Geisinger Health**—among the integrated health system models studied by experts tasked with creating the accountable care organization (ACO) model—are very large integrated care systems that cover a big geographical area. This is one reason behind the belief that larger ACOs will be more successful at controlling the cost of care and thereby earning adequate reimbursement from one year to the next.

If true, then it is easy for me to predict that we shall continue to see ongoing consolidation of hospitals and health systems, particularly in the nation's largest cities. It is possible that cities like Chicago, Houston, and San Francisco will eventually see just three or four super-sized integrated health systems that dominate healthcare across the entire urban area.

For anatomic pathologists, this points to the need for smaller pathology groups within an urban metro area to consolidate into larger pathology practices. The mega-sized health systems that emerge in these cities will want to do business with pathologists who practice in a setting that offers local sub-speciality expertise and the latest molecular and genetic technologies.

For hospital laboratories, this same ongoing hospital and health system consolidation is likely to mean a further concentration of inpatient and outpatient testing into the larger core lab facilities owned by these mega-health systems. TDR

Nation's Lab Innovators Attack Systemic Errors

All labs have sources of recurring bad quality and this is a rich target for cost-saving efforts

CEO SUMMARY: One keynote speaker at this year's Lab Quality Confab meeting tackled the sensitive subject of recurring bad quality within the lab and the costs associated with it. Lucia M. Berte, MA, MT(ASCP), showed a rapt audience how many sources of recurring bad quality exist and why lab staff must have adequate budgets to support the activities of prevention and appraisal. She then provided a road map of how labs can identify recurring sources of bad quality and fix them.

ONE-BY-ONE, LAB ORGANIZATIONS across the United States are learning that the cost of poor quality in their laboratories is unsustainable. But that's just part of the story.

Progressive pathologists, lab directors, and lab managers are recognizing that declining reimbursement and shrinking lab budgets put their lab organizations at increased risk, in multiple ways.

First, when budgets shrink in an arbitrary manner, labs have less money to spend on maintaining the quality and the integrity of the lab test results they produce. This compromises patient care and diagnostic accuracy while exposing the laboratory to increased malpractice risk and regulatory enforcement.

Second, inadequate lab budgets can trigger a reduction in the laboratory's use of controls and similar quality steps that are part of the normal daily workflow and often exceed the regulatory minimums specified by federal and state laws. This also has the potential to undermine the quality and reproducibility of the test results produced by the laboratory and that could lead to unwelcome consequences.

Third, poor quality in a laboratory can directly contribute to client dissatisfaction with the lab's services. In turn, this can increase the number of lost clients, thereby further reducing the lab's income.

Fourth, in absolute terms, ongoing decreases in lab test reimbursement and reduced lab budgets can undermine the financial sustainability of the laboratory organization if management does not respond with effective cost-cutting and revenue enhancement strategies.

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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All of these issues were front and center at the Seventh Annual *Lab Quality Confab* which took place earlier this month in New Orleans, Louisiana. Because of the financial pressures confronting clinical labs and pathology groups throughout the United States, a record crowd was keenly interested to learn effective ways to cut costs while sustaining and improving quality.

Recurring Bad Quality

For this reason, keynote speaker Lucia M. Berte, MA, MT(ASCP), captured the full attention of the attendees when she spoke about the true cost of recurring bad quality that exists in every laboratory. Berte is President of **Laboratories Made Better! PC**, based in Broomfield, Colorado.

"The lab services market has reached the point where no lab organization can ignore the costs and consequences of recurring bad quality," noted Berte. "Recurring bad quality affects patient safety even as it undermines the financial integrity of clinical labs.

"Unfortunately, most laboratory directors and managers don't know how to attack recurring bad quality using the latest methods," she continued. "Their training and experience are rooted in traditional models of laboratory operations. But much has changed in this field over the past decade, including new methods for identifying and eliminating the sources of recurring bad quality.

Three Areas Of Expertise

"Any lab that wants to deal effectively with recurring bad quality needs to have expertise in three distinct management skills," she said. "One skill is in finding sources of recurring bad quality. The second skill is in fixing the causes of recurring bad quality. The third skill is to sustain the fixes that eliminate sources of recurring bad quality."

Berte introduced the audience to the concept that the resources a laboratory spends on prevention and appraisal activities—some of which are required by federal and state regulators—are the foundation for identifying and eliminating the costs associated with recurring bad quality. They also backstop the integrity of the lab's analytical processes.

"Here is where both lab management and hospital administrators are shortsighted," observed Berte. "Too often, hospital administrators view the resources a lab devotes to appraising the integrity of internal operations and work processes as a place where the budget can be cut.

"This is not only false economy, it exposes the hospital to greater risk should the lab fail to detect such common occurrences as misidentified specimens or inaccurate test results," she added. "We have examples of such failures. Recall the lab test failures affecting thousands of patients at Baltimore's **Maryland General Hospital** that became national news in 2004."

Hospitals Closed In New York

Another validation of Berte's observation comes from the fact that, in 2012, the **New York State Department of Health** closed two hospitals—one permanently—due to problems with quality in their respective laboratories. In both cases, news accounts mentioned that deteriorating finances of the parent hospitals meant that their labs lacked adequate staffing and the necessary reagents and controls to sustain quality at an acceptable level, as revealed by state inspections of the laboratories.

"When it comes to costs, the lab spends money in four different ways," explained Berte. "Two ways are easily visible and two ways are buried in the budget as overruns and unexpected expenses.

"The first two ways are activities that involve prevention of errors and appraisal of testing activities," she noted. "The second two ways involve failures that are internal and external to the lab.

"Everyone is familiar with the costs associated with failure," observed Berte.

Every Lab's Costs of Recurring Bad Quality Are Substantial and a Major Cost-Saving Target

IN HER REMARKS AT *LAB QUALITY CONFAB* in New Orleans earlier this month, Lucia M. Berte, MA, MT(ASCP), President of **Laboratories Made Better! PC** identified the cost of recurring bad quality that can be found in every clinical laboratory and pathology group. Each of the items below is the source of recurring costs attributable to bad quality.

Berte explained that, in order to save money, labs will frequently cut the budget for activities associated with prevention and appraisal of the lab's testing activities. Included are such activities as competence assessment, equipment calibration, quality control, proficiency testing, and method comparison testing. "These are false economies," observed Berte, "because these are the activities within the laboratory that allow lab staff to identify recurring sources of bad quality and the often-substantial amount of wasted costs associated with them."

Laboratory Path of Workflow: Failure Costs

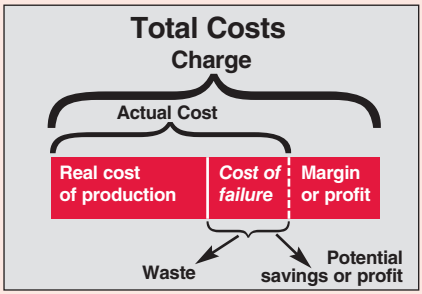
Preanalytic
- Wrong orders
- Wrong order entry
- Unacceptable samples
- Recollected samples
- Accessioning and processing errors

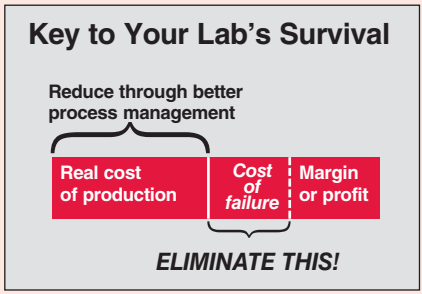
Analytic
- Repeated tests
- Incomplete test runs (instrument issue)
- Invalid test runs (calibrator or control failures)

Postanalytic
- Result recalls
- Reprinted reports
- Redelivered reports
- Remedial action on occurrences
- Complaint resolution
- Lawsuits

Laboratory Management Infrastructure: Failure Costs

- Foregone revenue from lost clients
- Lab safety accidents
- Staff turnover and replacement
- Expired reagents and supplies
- Overstock
- Equipment downtime
- LIS downtime
- TAT outliers
- Resolving document problems
- Confidentiality violations
- Resolving system interface issues
- Recurring NCE "corrective actions"





The two charts presented above were used by Berte to show how the "cost of failure"—or recurring bad quality—makes up a significant portion of every lab's cost structure. Her recommendation was to use quality management methods to identify and eliminate all costs associated with failure and with recurring sources of bad quality.

"All the 're's' are examples of failure, including rework, reinspection, retesting, and repair.

"Other sources of recurring bad quality and failure are workflow errors, expired reagents, downgrading, and nonconforming material review," Berte said. "All of these events are internal and occur before delivery of the test results to the referring clinician.

"External failure costs happen after the laboratory has delivered test results," she noted. "This list of failures is made up of customer complaints, misdiagnoses, report recalls, and malpractice claims and lawsuits.

"Of course, all of these incidents of bad quality can incur costs to the lab that far outweigh the money spent on prevention and appraisal within the laboratory," explained Berte. "Just one malpractice lawsuit can cost the laboratory and its parent organization millions of dollars, for example."

Yet, as Berte acknowledged, across the nation, laboratories are experiencing reduced reimbursement and shrinking budgets. One common response to these developments is for hospital administrators to cut the lab's budget for quality control and activities associated with prevention. Yet that is a false economy and a policy that can quickly turn out bad for both the laboratory and the patients it serves.

Prevention And Quality

"Lab managers at all levels must educate hospital administration about why the money spent on prevention and quality is essential if labs are to meet the expectations of their physician clients and patients for accuracy, reliability, and integrity," noted Berte. "It is a failure of lab management at every level when hospital administrators are allowed to cut the lab's spending on prevention, quality control materials, and quality assurance activities."

On this point, Berte recommended that lab managers learn how to make a return-on-investment case to administration in defense of adequate funding for the activities of prevention and appraisal within the laboratory—exactly the activities that can identify recurring bad quality and eliminate it.

"Every lab manager in your organization should know the four types of quality costs," she said. "They are prevention, appraisal, internal failures, and external failures.

"It is smart to identify all costs on your laboratory's budget associated with prevention and appraisal," continued Berte. "Where possible, you should create line items in the budget to make these costs clearly visible.

Cost Of Internal Failures

"Once this is done, the lab team should calculate costs associated with known internal failures and external failures in a report format to show administration," she stated. "These reports become the basis for justifying adequate funding for the laboratory's prevention and appraisal activities.

"Then, going forward, your lab's prevention and appraisal efforts should reduce internal and external failures, thereby saving the costs associated with these sources of recurring bad quality," commented Berte. "Detailed reports of these savings should be provided to administration.

"Remember, the language of every C-Suite is money," concluded Berte. "When your laboratory team can document how increased spending on prevention and appraisal produces measurable savings from the elimination of sources of recurring bad quality, hospital and health system administrators understand why it is important to maintain adequate funding for these activities." TDR

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Portland Lab Leverages Informatics for Growth

Legacy Laboratory Services sees opportunity in delivering enriched informatics capabilities

CEO SUMMARY: In Portland, Oregon, Legacy Laboratory Services, a division of Legacy Health, continues to post strong volume growth. One driver supporting this growth is the lab's ability to implement connections between its laboratory information system (LIS) and the electronic health record (EHR) systems of its office-based physician clients. Further, the lab's strategy is to leverage its enriched informatics capabilities to serve accountable care organizations and medical homes.

IT'S BEEN A DISCOURAGING FINANCIAL ENVIRONMENT for hospital laboratory outreach programs in recent years. Yet some outreach lab companies are finding a path to success.

That is the case for **Legacy Laboratory Services**, a division of **Legacy Health** in Portland, Oregon. The 22-year-old laboratory company serves Legacy's six hospitals and also provides outreach lab testing services to office-based physicians and other clients.

One way that Legacy Laboratory Services is fueling growth from the outreach market these days is by leveraging its ability to deliver data connectivity to office-based physicians, other laboratories, and employers in the region.

Data Connectivity

"For us, data connectivity is one of the competitive elements we have when we compete with other labs," stated Don Toussaint, Vice President of Laboratory Services at Legacy. "We derive competitive advantage when we can quickly complete an interface with an office-based physician and then offer that new client the capabilities of our laboratory.

"However, it was not easy to reach this point," he said. "Like other labs, in the early days of the federal meaningful use program, it was a struggle to fully connect our lab with new clients. We changed this situation for the better because of how we engaged our information technology vendors.

"As most lab administrators know, office-based physicians have two expectations of the laboratory provider when it comes to informatics," explained Toussaint. "First, they want a fast implementation of the interface and connection to their electronic health record (EHR) system. Second, they want our LIS to work smoothly with their EHR.

"To gain competitive advantage, we decided to engage our informatics vendors and some third-parties," he said. "That was a smart decision. Our vendors have helped us make it easier and quicker for us to connect.

"More specifically, we've tapped our vendors' expertise to handle a wide variety of file formats," continued Toussaint. "Their experience is in health information exchange. Therefore, they can apply what

they know from that field to get us connected quickly. That shortens the time to implementation.

"We see two major benefits from our strategy of fast and robust connections between our LIS and the EHRs of office-based physicians," he said. "One is an immediate benefit. The other is a long term benefit and is associated with healthcare's transition to integrated clinical care.

Competitive Advantage

"In the short term, we get competitive advantage because physicians see a smooth implementation of our LIS-to-EHR interface," Toussaint explained. "It all happens in the background, even as they gain new capabilities to access lab testing services and utilize lab test data in patient care.

"In the long term, we think our informatics strategy will be essential to serving the needs of physicians practicing in an integrated care delivery organization—whether it is an inpatient, outpatient, or outreach setting," he stated. "As we all know, accountable care organizations (ACOs) and patient centered medical homes (PCMHs) are being formed.

"But that is not the whole story," explained Toussaint. "Along with these new care delivery models will come new payment models for these ACOs and PCHMs.

"Here in Portland, labs have not yet been asked to participate in these models on a large scale," he added. "But these new payment systems are on the drawing board and we know their time is approaching.

Connecting Labs To ACOs

"Like most, we don't know precisely how ACOs and PCMHs will affect labs," emphasized Toussaint. "But we do know that our laboratory will be required to connect to them just as we now connect with physicians' offices.

"Whereas 10 or 15 years ago, few wanted this connectivity, today everyone wants to be connected electronically," noted Toussaint. "As well, we know that ACOs and PCMHs will want to have lab data to support population-wide outcomes management and to control costs.

"These are the reasons why Legacy Laboratory Services needs to have the right information technology vendors working with us," he continued. "Our lab must be prepared to connect to providers operating in any of the new models of healthcare delivery. We think working with vendors familiar with health information exchange (HIX) technology could be a significant success factor for us in the next few years."

Here is where Legacy Laboratory Services is investing dollars today to position itself as a competitive lab test provider for the future. It is working with **Certify Data Systems** (CDS), a health information technology company in San Jose, California.

Few lab administrators or pathologists are familiar with this company. Certify Data Systems specializes in developing health information exchange systems for hospitals, health systems, labs, accountable care organizations, and other providers. Last year, CDS was acquired by **Humana Inc.**, the managed care company in Louisville, Kentucky.

Connecting Labs To Docs

"Certify Data Systems does make it simpler and faster for our laboratory to hook up each physician," stated Toussaint. "When adding a new outreach customer, our biggest challenge is to get the electrons flowing through the wires. This requires us to resolve issues with the phone company, the servers, the network people, and security. To make it all work, there are a lot of moving parts that have to be aligned and we want our informatics vendors to do that for us.

"Of course, the need for physicians to demonstrate meaningful use to qualify for federal EHR incentives is a big factor in

today's marketplace," he commented. "Meaningful use requirements drove physicians to purchase and implement a wide variety of EHR products, which created a problem for us.

"Today, there are so many EHR systems in the market that every lab must be flexible enough to adapt its LIS to whatever EHR system is in use by the doctor's office," Toussaint added. "This is another place where we call on our vendors to help us normalize the levels of quality we find with so many different EHRs.

"Further, because the labs were the first ones to work with physicians installing their EHRs, it falls to us to educate and communicate with the doctor's office staff," he continued. "It's remarkable how unprepared they are to handle an EMR interface. They think it's like a TV, where they buy it, plug it in, and watch the show.

"But an EMR is not like a TV at all. For us, we have do daily monitoring and sometimes babysitting, depending on the capability of the staff and the EMR," concluded Toussaint. "It requires constant communication with our customers to fix problems as they arise." TDR

—Joseph Burns

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Market May Encourage Different Strategies For ACOs to Achieve Uniform Lab Test Data

LEGACY LABORATORY SERVICES is a lab outreach program that is structured as a business and run as a business.

"We operate as an independent business under the umbrella of Legacy Health," stated Don Toussaint, Vice President of Laboratory Services. "Thus, we are not operated by the health system's hospitals."

The lab has a staff of 600 employees working in lab facilities spread across Oregon and into Southwest Washington. It also works with 18 pathologists from **Cascade Pathology Services Corporation**, an independent pathology group in Portland.

This summer, the lab broke ground for a two-story 63,000 square foot lab in Portland that will serve as its new home when it opens next year. "The new facility will accommodate the current level of lab testing volume, which is about 4.3 million billable tests annually," stated Toussaint. "It has the capacity to support our expected future growth.

"Our lab has two main components," continued Toussaint. "One is serving the inpatient needs of the hospitals and clinics in the Legacy Health system," he added. "But most of our business comes from outside of Legacy Health.

"For this reason, we see ourselves as a regional reference laboratory," said Toussaint. "By contrast, a hospital outreach program is often one or two hospitals selling excess testing capacity off the back loading dock of the hospital. The outreach testing goes to the hospital where it is simply an extension of the hospital's overall outpatient business.

"We operate as a regional reference lab and compete against other regional reference labs such as **PeaceHealth Laboratory** and **PAML**," noted Toussaint. "We also compete against **Providence Health**, **Quest Diagnostics Incorporated**, and **Laboratory Corporation of America**.

"Our growth in specimen volume and revenue comes from several primary sources," he said. "We add tests that have value to our current customers. We regularly expand our geographic footprint into new communities. And, as noted earlier, we offer enriched laboratory informatics services to office-based physicians and others."

Specimen volume growing by 14% per year

Ottawa Pathology Lab Cuts Turnaround Time By More Than 50%

CEO Summary: Pathologists at Ottawa Hospital not only must handle a large volume of specimens regularly, but are experiencing a 14% per year growth in the number of specimens. Last year, when the average turnaround time for a case was nine days, the pathology department embarked on a series of Lean and process improvement projects. In a matter of months, changes in both histology and in scheduling of the anatomic pathologists contributed to a 50% reduction in average turnaround time. In turn, the faster TAT has improved patient care.

Faced with a growing backlog of specimens and a nine-day average turnaround time (TAT), anatomic pathologists at one of Canada's largest hospitals turned to Lean and process improvement methods to achieve a reduction in TAT of more than 50%.

The anatomic pathology (AP) department at **Ottawa Hospital** in Ontario, is holding average turnaround time to four days, compared with an average TAT of nine days that it ran at the end of 2012.

This is an important accomplishment, because it shortens the time to diagnosis for patients with cancer and other diseases, thus contributing to better patient safety and improved patient outcomes. Moreover, the lab team at Ottawa Hospital was able to accomplish these goals in a matter of months.

The Ottawa Hospital, a 1,149-bed academic health sciences center, serves 1.2 million residents of Eastern Ontario. It operates three facilities and handles almost 48,000 annual admissions. Staff numbers 11,813, including 1,300 physicians. The anatomic pathology lab has 27 pathologists and a staff of 100.

This story starts in November 2012. That is when Dr. Diponkar Banerjee, MBChB, FRCPC, Ph.D., assumed the position as head of the Division of Anatomical Pathology in the **Eastern Ontario Regional Laboratory Association** at the **Ottawa Hospital**. He is also a Professor of Pathology and Laboratory Medicine at the **University of Ottawa**.

"At that time, I concluded that our pathology laboratory had adequate resources for our specimen volume," stated Banerjee. "Recent recruitment and the creation of new positions meant that we had close to the right mix of subspecialist pathologists. The lab facility had been renovated in recent years and an LIS upgrade had also been done. A barcode system was in place and some training in Lean had been completed.

"Still, the lab was under stress because of the continual increase in pathology specimens," he noted. "Our volume growth is averaging 14% per year, primarily due to the cancer incidence in an aging population."

Upon his arrival, Banerjee and William Parks, the newly appointed Operations Director, quickly identified one major cause of long turnaround times. "Like most pathology labs, we were organized around large batch processing," he said. "But with an unbalanced specimen flow in the laboratory, the staff was struggling to prioritize work."

That workload is substantial. Last year, the AP lab handled 71,000 cases involving 109,000 specimens and 419,000 slides for interpretation, including cytopathology. "That's roughly 400 anatomic pathology specimens or 2,500 slides per day," observed Banerjee. "For Canada, that's a fairly high volume. We are one of the highest-volume AP laboratories in Canada. Also, being an academic health sciences center, we are engaged in teaching and research."

Unbalanced Workflow

In addition to high volume, the pathology lab had suboptimal workflow. "Workflow was unbalanced because we were trying to second guess the urgency that was required for each specimen," recalled Banerjee. "Staff tried to anticipate which specimens needed to be processed first.

"That was a problem," he said. "For example, if a specimen that was not processed early turned out to be cancerous, then the wait time for that patient's report might have been nine days or more.

"To resolve this logjam, we decided to apply the Lean principles we had used in other process improvement projects in the lab," stated Banerjee. "Our goal was to do workflow balancing throughout the whole process—receipt of specimens through delivery of the pathology reports.

"We wanted to balance the flow of incoming specimens with the flow of outgoing reports—as close to first-in/first-out as possible," he explained. "However, applying the first-in/first-out rule to all specimens is a challenge because of the complexity in the range of the cases we see.

"Our process improvement project started with a review of existing rules,"

Banerjee said. "These rules addressed the need to handle some specimens with urgency, but were complex, imprecise, and subject to individual variation.

"Some cases considered to be nonurgent would sit around for too long untouched," he said. "Once pathologists got to these nonurgent cases, they might find something of clinical significance that would require urgent action by the oncologists.

"Of course, each time that a malignant specimen was at the end of the queue because of these workflow rules, that was a problem for patients and the clinical staff," noted Banerjee. "After all, for cancer or other serious illnesses, time to diagnosis is a critical factor in whether a treatment will be successful or not.

"Another problem with the existing processing rules is that they created a big pile of unprocessed specimens in the histology laboratory at the end of each day," he added. "That situation needed fixing.

Improving Workflow

"We did a value stream map and our analysis showed us that, if the specimens that came in first were processed first, we could move away from large batch processing," noted Banerjee. "And that's what we did. Starting early this year, we began running smaller batches multiple times throughout the day.

"For example, our histology lab moved to first-in/first-out specimen processing," he added. "The exception involved certain small and large specimens because of the time involved for grossing and fixation.

"It was quickly recognized that smaller biopsies couldn't be held up just because staff was working on a large resection," said Banerjee. "For that reason, we did fine-tuning of histology workflow to correct and improve this situation.

"Another change we made in the histology laboratory that improved workflow was to run small batches of specimens in the processors throughout the day," recalled Banerjee. "Another improvement was to organize tissue blocks into small batches of the same specimen types.

Color-Coding Different Cases

"These small batches remain organized right up to when cases are routed to the pathologists," he noted. "We also instituted color-coding of specimen cassettes for the same types of cases to improve organization of work.

"These visual cues help staff recognize the different types of specimens at all stages in the workflow," said Banerjee. "Also, the color organization ensures workload balance in histology so that all pathologists receive a flow of work throughout the day.

"Grossing saw its own share of improvements," explained Banerjee. "Smaller and moderate-sized specimens are grossed during the first 1.5 hours of the shift, thus ensuring these tissues can be processed the same day.

"We did this to take advantage of the fact that staff are far more efficient at the beginning of their shift," he noted. "Thus, the output of small specimens is much higher than it is at the end of a shift. We also used predefined text and templates to reduce the time staff spends on specimens."

These changes in grossing and tissue processing, by themselves, did not produce a sufficient reduction in average turnaround time. Therefore, the lab decided to change how and when specimens arrived in the participating labs.

"We turned to the clinics within the hospital and worked with them to have surgical pathology specimens delivered throughout the day," Banerjee stated. "This was consistent with our goal of moving to small batches and continuous flow. It stopped the practice of these clinics sending all the day's specimens to us at 3 p.m. each day.

"In histology, the day shift is now organized around shorter processing schedules throughout the day, both for biopsies and for smaller or moderate-sized tissue samples," he added. "Next, the

afternoon-evening shift in histology can prepare larger and remaining specimens so they are ready for the pathologists to review in the morning of the next day.

"All these workflow improvements required changes in the staffing schedule," explained Banerjee. "For example, an evening shift was implemented in the histology laboratory to make better use of the microtomes. This change specifically supported the flow of work first thing every morning to the pathologists.

"A weekend shift on Saturdays was instituted in the gross room to deal with the work received on Fridays," he stated. "That contributes to improved turnaround times for Friday biopsies.

"One Lean principle we used was standard work," continued Banerjee. "This made it easier to have staff rotate through embedding and microtomy to keep the batch size smaller and allow for more variation in their ergonomics to reduce repetitive strain injuries."

Pathologist Scheduling

The other opportunity to improve workflow and move away from batch processing involved how surgical pathologists were scheduled to read cases. This change made an equally important contribution to the reduction in average TAT.

"Like other subspecialty pathology practices, we have complex areas that may have low case volume." said Banerjee. "Existing pathologist scheduling arrangements often resulted in under-utilized time and underused pathologists. At the same time, we had pathologists who were overloaded.

"The existing policy scheduled pathologists in a manner that was more like a specialized practice," he continued. "A pathologist would cover renal pathology one day. The next day, he or she would work in a different specialty area. For example, someone might cover gynecological pathology on Monday, then urology on Tuesday, and breast pathology on Wednesday.

"The flaw in this arrangement was that it was impossible to anticipate how much work each pathologist in each subspecialty would get each day," stated Banerjee. "This arrangement was the source of regular backlogs. Cases not completed on Monday formed the backlog on Tuesday.

"Moreover, if they didn't complete that work, they had a backlog on Wednesday,"

AP Lab Staff Gains Time From Improved Workflow

FOR THE PATHOLOGISTS and staff in the anatomic pathology laboratory at the Ottawa Hospital, the biggest surprise from process improvement was fewer hours.

"The staff anticipated that they would need to work more hours and work faster once we made all these improvements," said Dr. Diponkar Banerjee, the head of Anatomic Pathology for the Eastern Ontario Regional Laboratory Association and the Ottawa Hospital, one of the largest in Canada. "But in fact it has been the opposite. They get their work done at the end of the day. That leads to the question of whether our volume has gone down.

"Not at all. In fact, it's the opposite. The volume has gone up," he added. "We are a large academic medical center and it's a high volume lab. The slightest glitch in specimen flow can lead to an immediate backlog. Our challenge is to keep the flow going without any hiccup.

"Now that we have a balanced workload throughout the week, the staff no longer needs to catch up on evenings or weekends. They feel less stressed out and can go home at the end of the day.

"We have even freed up enough time for individual pathologists to do research for which they have grants but previously couldn't find time to do that work," Banerjee explained. "Now, they get their abstracts submitted on time and their research is running ahead of time."

he said. "Pathologists did have Thursdays and Fridays to reduce the backlog because on those days they did not receive new cases. Plus, they would try to catch up in the evenings or on weekends. But the backlog was continual. Every day compounded the problem.

Subspecialty Work

"In March, this workflow was changed to specifically balance out each subspecialty workload," explained Banerjee. "A schedule was established so the subspecialists work on just one specialty for the full week.

"The workload calculation is based on a simple slide count," he noted. "We established the maximum number of slides each pathologist could safely report each day and adjusted that number for complexity.

"After implementing this method of scheduling the pathologists, the slide count was adjusted to a daily maximum," recalled Banerjee. "This is when we realized that our original scheduling rules had underestimated the time required for pathologists to do their work each day for certain high-volume subspecialties.

"It was the right solution to have subspecialists operate on a weekly schedule," recalled Banerjee. "If the workload fluctuations overwhelmed a pathologist on Monday, the backlog could get caught up by the end of the week—if the right number of pathologists were covering that subspecialty practice.

"In addition to scheduling the proper number of subspecialists for each area, it was necessary to account for vacation days, continuing medical education, and other reasons why a pathologist would be gone from the lab," he noted. "Because there were a minimum number of subspecialists required each day, the need for scheduling vacation and CME time could create problems.

"Our solution was to have each subspecialty group of pathologists manage their own schedules for vacations, CME, and other time off," explained Banerjee. "That was the final step in our process redesign.

"By having the staff do its own fine tuning, we allowed the solution to a problem to come from those who do the work," said Banerjee. "When Lean is done properly, the solutions to problems usually come from the grassroots level.

"To support our first-in/first-out approach, it was not necessary to buy additional equipment or hire more staff in the histology lab," he added. "This was because of the foresight of the previous laboratory leadership.

"For the past five years, the pathologists and laboratory managers had researched and purchased the newest technologies available," Banerjee stated. "In recent years, the following technologies were purchased: multi-chambered processors that allow for short processing times, automated immunohistochemistry instruments, a barcode-driven laboratory information system, a dual linear stainer for H&E, and an automated single-slide stainer that is used exclusively for special stains.

Improving Productivity

"Productivity was also improved by introducing a voice recognition system that is used in the grossing of specimens and when pathologists produce their final pathology reports," he said. "With this system, no transcriptionists are needed.

"At the moment, we don't have digital pathology technology for use in diagnostic work," added Banerjee. "But that technology is occasionally used for teaching rounds. Plans are to take a fresh look at digital pathology strategies next year.

"Looking back on all the improvement projects we completed, Lean methods played an essential role," he observed. "At the same time, we always looked at the big picture and used common sense.

"Why not design the system so that every patient gets the same turnaround time?" asked Banerjee. "Not until the slide is reviewed will the disease state be known. A specimen could be cancerous and show significant lesions that the surgeons did not anticipate.

Can Pathology Labs Use Hospital Info Systems To Help Plan for the Volumes of Incoming Cases?

IS IT POSSIBLE TO LINK a laboratory information system (LIS) to a hospital information system so that the LIS could know weeks or months in advance what kind of pathology specimens the lab could expect?

To answer this question, Dr. Diponkar Banerjee, head of the Division of Anatomical Pathology in the Eastern Ontario Regional Laboratory Association and at the Ottawa Hospital, has begun to take action.

"We want to work with the hospital's IT team," he said. "If we can interact with operating room schedules and with the schedules for first patient visits and follow-up visits, this information would allow us to anticipate what the pathology workload will be. Perhaps we can look ahead three months to know how many and what kind of specimens to anticipate.

"When you think about how patient visits are scheduled in a hospital, this should be possible," Banerjee continued. "Most patients are scheduled weeks or months ahead.

"If we could connect that information into our information system automatically, it would give us a heads up about how busy we might be next week or next month," he added. "It might tell us what months would be busiest.

"At most hospitals, the senior surgeons get their first priority for vacations," noted Banerjee. "In their absence, the junior surgeons get more time in the operating room. When they get into the OR, surgical pathology gets different cases than when the senior surgeons are here.

"This knowledge has practical value," he added. "If more than the usual number of prostate cases is coming through, we wouldn't want the majority of our urology pathologists to be away. Similarly, if the hospital expects a large number of breast cancer patients, we would want an adequate number of breast cancer pathologists to be here on duty.

"Our pathology department wants to be more intelligent about planning and scheduling," observed Banerjee. "We have a large volume of work that is increasing. This requires constant juggling. With the right information, we can better align our pathologist work, vacation, and CME schedules with the expected number and mix of specimens."

"After all this review and revision to workflow in our pathology laboratory, we cut the turnaround time for everything—including biopsies and resections—from nine days last November to just 4.5 days last summer," he stated. ""Since that time, additional improvements to workflow have helped us to drive down turnaround time for biopsies to two days and our standard deviation is plus or minus two days. Most biopsies get turned around in a day or two days. Larger resections get done in about four days on average.

"Further, our test volume is going up by almost 14% per year because of the aging population and the incidence of cancer," he added. "The workload is not decreasing. We have to make the system as efficient as possible without sacrificing quality or patient safety. That's the challenge.

"In a pure fee-for-service system, there is less pressure for labs to become efficient," concluded Banerjee. "But here in Canada, our system requires us to spend every dollar judiciously. We do not have volume-driven funding. That's a significant point about how we work and may become important in the U.S. healthcare system in the coming years." TDR

—Joseph Burns

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Market Update

Calif. Pharmacists to Order Tests, But Will Laboratories Get Paid?

'Advanced Practice Pharmacists' will be able to order and interpret laboratory tests effective January 1

A NEW LAW IN CALIFORNIA allows pharmacists to order laboratory tests for monitoring patients' medications. But it is unclear if labs will be paid for such tests under the law.

California Governor Jerry Brown signed the bill, SB 493, into law on October 1. It raises the status of pharmacists as healthcare providers and widens their scope of practice, according to an article in *Modern Healthcare*.

The Pharmacy Law authorizes the California State Board of Pharmacy to recognize an "advanced practice pharmacist" who can "order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies…" The law also allows advanced-practice pharmacists to perform patient assessments.

"Regarding payment, the bill does not address payment for the ordering or interpreting of lab tests, nor for the coverage of lab tests ordered by pharmacists," Brian Warren wrote in an email. Warren is the Vice President, Center for Advocacy, for the **California Pharmacists Association**.

"It will be up to individual payers to determine whether or not to pay for tests ordered by pharmacists, and until they are covered, you probably won't see many pharmacists ordering tests," stated Warren. "This is all designed to complement the medication adherence and other clinical services that pharmacists are increasingly providing to patients. As payers contract with pharmacies to manage patients, we envision that these tests will be necessary and will be covered.

"Pharmacists in California have been able to order lab tests for several years, though it was generally restricted to pharmacists working in hospitals and integrated systems such as **Kaiser Permanente**," continued Warren. "In a number of states, including North Carolina and New Mexico, pharmacists can order lab tests. Additionally, pharmacists order lab tests throughout the country through the care they provide in the I**ndian Health Service**, **Veterans Administration**, and other federal health programs."

Reimbursement Is Uncertain

Blue Shield of California (BSC) supports the law, according to spokesman Sean Barry, but BSC was unable to confirm if it would pay for lab tests ordered by pharmacists. The state **Department of Health Care Services**, which runs the Medi-Cal program, said labs would not be paid under the law.

The willingness of the California state legislature to widen the scope of practice for pharmacists and allow them to order and interpret lab tests is one more marketplace indicator of the changes unfolding across the American healthcare system.

For pathologists and clinical lab managers, this change in California raises an interesting question. Will the new pharmacy law create a new type of customer for clinical laboratories? TDR

Contact Brian Warren at 916-779-4517 or bwarren@cpha.com.

Dark Index

Two Blood Brothers Report Declines in Revenue-Per-Req

Expect the next bitter market share battle to involve BRCA testing as national labs push their BRCA tests

REIMBURSEMENT FOR CLINICAL laboratory testing has declined, particularly for molecular tests. As a consequence, the nation's two largest laboratory testing companies are feeling the negative effect of lower lab test prices.

Both **Quest Diagnostics Incorporated** and L**aboratory Corporation of America** issued their third quarter earnings reports last week. Their respective performances provide insights into several unfolding trends in the laboratory testing marketplace.

Quest Diagnostics was first to report its financials. Last Thursday, it stated that revenue for third quarter was $1.78 billion. This was a decline of 1.9% from Q3-12, when revenue was $1.82 billion.

For Q3-13, specimen volume was up by 2% and revenue per requisition decreased by 4.3%. Quest executives said that 1% of the revenue decrease was attributable to its acquisition of **Concentra**, a toxicology testing company. The remaining 3.3% of the decrease was due to declines in lab test reimbursement.

LabCorp's Financial Report

At LabCorp, the financial news it made public on Friday, the following day, was a bit brighter. Its Q3-13 revenue was $1.46 billion and that was an increase of 3% over the $1.41 billion revenue number for Q3-12. Also for third quarter, LabCorp's specimen volume increased by 5.1% even though its revenue-per-requisition declined by 1.9%.

LabCorp attributed the decline in revenue-per-requisition "due largely to previously-discussed government payment reductions, payment issues related to molecular pathology codes and strong growth in the company's toxicology business."

For the first nine months of 2013, Quest Diagnostics posted revenue of $5.4 billion. This was 3.9% below the revenue of $5.0 billion for the first nine months of 2012. For LabCorp, its nine-month revenue was $4.37 billion versus $4.26 billion for the first nine months of 2012, an increase of 2.5%.

Reimbursement Challenges

Both national laboratory companies have struggled to meet the expectations of Wall Street investors going all the way back to the start of the last recession in early 2009. These third quarter earnings reports show that it is a much tougher market environment for each company.

This fact was acknowledged in the statement made by Steve Rusckowski, President and CEO of Quest Diagnostics. "We are disappointed with our third quarter performance, particularly after generating revenues early in the period that were in line with our expectations. Healthcare utilization and reimbursement continue to be a headwind for our industry, and our results reflect that," he said.

For his part, David P. King, Chairman and CEO of LabCorp acknowledged the same factors. "Government payment

reductions and continued reimbursement challenges for molecular testing negatively affected our reported results in terms of revenue growth, price and margins," he said in the company's press release.

Reimbursement Challenges

One trend which got little attention during the conference calls each company conducted with financial analysts is the impact of higher patient deductibles and out-of-pocket requirements. A growing number of Americans now have health plans which require them to pay 100% of the first $1,500 to $6,000 of their annual individual or family healthcare costs.

LabCorp's King hinted at this development when he noted that, relative to the company's days sales outstanding number of 50, that number remained elevated "due to our experience with the molecular pathology codes... increased utilization by uninsured patients and increased patient billing due to plan design changes. During the quarter, our bad debt remained 4.3%."

It was a similar perspective at Quest Diagnostics. Its DSO for the third quarter was 48 days—unchanged from the same quarter last year. However, Mark J. Guinan, CFO at Quest Diagnostics, told analysts during the conference call that "bad debt expense as a percentage of revenues was 3.6% or 30 basis points higher than the prior year. The increase can be partially attributed to benefit plan design as patients shoulder an increasing portion of healthcare costs."

Collecting From Patients

These comments about larger patient deductibles are useful warnings to pathologists and lab managers at independent labs and hospital outreach lab programs. It is both timely and smart for their lab organizations to begin collecting from patients at the time of service. This will be essential if patient bad debt is to be kept at manageable levels. TDR

—Joseph Burns

Will National Labs Find Riches in BRCA Testing?

BOTH OF THE NATIONAL LAB COMPANIES are targeting BRCA testing as a way to increase specimen volume and revenue. This will put them in direct competition with **Myriad Genetics, Inc.**, of Salt Lake City, Utah.

Days before its third quarter earnings release, Quest Diagnostics announced the launch of its BRCA testing service, which it calls "BRCAvantage." It intends to charge about $2,500, which is less than the $3,400 that the Medicare program reimburses Myriad Genetics for its BRCA test.

During its third quarter conference call, executives at LabCorp disclosed their plans to enter the market with their own BRCA test. They expect to launch this testing program during fourth quarter of this year.

Because of its patents and intellectual property, Myriad Genetics has had a lock on BRCA testing in the United States for almost 20 years. This year's Supreme Court decision on the patenting of genes has opened the door for competing labs to bring their own BRCA tests to market.

Quest Diagnostics and LabCorp are each targeting a ripe plum. BRCA testing at Myriad was worth more than $450 million during Myriad's last fiscal year that ended on June 30, 2013. Moreover, Myriad has seen specimen volume and revenue growth exceed 15% annually for several years.

Thus, it is smart for the two national lab companies to shoehorn their way into the BRCA testing marketplace. Not only should there be ample profit margins on their respective BRCA tests, but every 10% of Myriad's existing market share they can wrest away gives them $45 million per year in increased revenue.

Of course, these new entrants may well trigger a price war. Analysts believe that competition among the labs intending to offer this test may cause the price of BRCA tests to decline steadily in the coming years.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

There is progress on the integration of digital pathology systems and proprietary algorithms designed to help pathologists make diagnoses. This month, **Visiopharm** and **Omnyx LLC**, announced a joint venture. On its own, in Europe last year, Visiopharm earned a CE mark for its "in-vitro diagnostic (IVD) software module for the breast cancer marker HER2." Visiopharm says it is close to releasing several other CE-marked software modules for the diagnosis and classification of breast cancer. The two companies intend to integrate Visiopharm's products with Omnyx's digital pathology system.

MORE ON: *Digital Pathology Integration*

As most pathologists know, many IVD manufacturers usually go to Europe first to get market clearance for their newest analyzers and assays. That seems to the be the strategy of Visiopharm and Omnyx. The two companies said that they intend to "improve the quality of care by offering clinically validated image analysis algorithms that are reagent agnostic. Omnyx will be distributing these approved algorithms upon Visiopharm's completion of the integration and validation."

MD ANDERSON USES IBM'S "WATSON"

For readers who are tracking the progress of **IBM's** "Watson" computer, the latest development involves the **The University of Texas MD Anderson Cancer Center**. IBM and MD Anderson announced the fruits of their collaboration: "a prototype of MD Anderson's Oncology Expert Advisor powered by IBM Watson." The partners hope to use Watson to expand clinicians' precision in treating different types of cancer.

TRANSITIONS

• **Sunquest Information Systems** announced the appointment of Keith Laughman as the Executive Vice President Community Care Solutions. Laughman was most recently President and CEO of **med fusion**. He has also held executive positions at **Speciality Laboratories, AmeriPath,** and **Mayo Medical Laboratories**.

• **Laboratory Corporation of America** announced the retirement of CFO Brad Hayes. He is expected to step down in 2014. No replacement has been hired. Hayes started at LabCorp in 1996 and has held several positions at the company. A CPA, he was formerly with **KPMG**.

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DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...how the U.S. military is training more than 500 laboratory technicians annually and, upon completion of their service commitments, these individuals are available for employment by clinical labs in their communities.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

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

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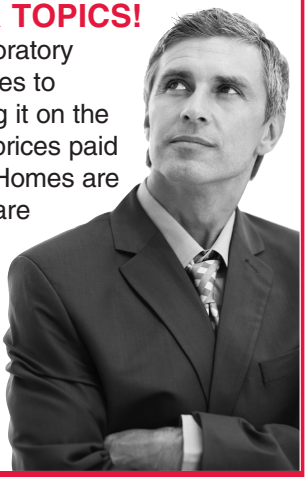

Big changes are unfolding in both clinical laboratory and anatomic pathology testing! When it comes to fee-for-service reimbursement, labs are taking it on the chin as Medicare and private payers reduce prices paid for lab tests. Meanwhile, ACOs and Medical Homes are reshaping the healthcare landscape. Obamacare creates even more changes.

You're invited to send us your suggestions for session topics. We're now selecting speakers for the upcoming 19th Annual *Executive War College on Lab and Pathology Management*.

Contact us at: rmichel@darkreport.com

For updates and program details, visit www.executivewarcollege.com

UPCOMING...

- **Lessons Learned from Labs Being Paid as Part of an ACO Global Payment.**
- **Preparing for ICD-10 Implementation: What Every Lab Needs to Do Before October 1, 2014.**
- **Predicting the Future of Hospital Lab Outreach: Why Some Labs Succeed and Some Labs Fail.**

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