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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

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Founder & Publisher

How Pathologists Earned a Place at the ACO Table

ALL ANATOMIC PATHOLOGISTS WONDERING ABOUT THEIR PLACE in a healthcare system dominated by accountable care organizations (ACOs) and similar models of integrated clinical care may find useful insights from the experience of a six-partner pathology group in Wisconsin as it established itself as a contributor in one of the state's largest integrated care networks.

As you will read on pages 3-6 of this issue, pathologists at **North Shore Pathologists** in Milwaukee, did have a place at the table from the inception of what is now called the **Integrated Health Network of Wisconsin** back in 2012. In this network are 5,700 physicians and participating providers, 550 clinics, and 45 hospitals. It is estimated that this network serves three million lives.

In learning about the steps the North Shore Pathologists took to be part of the network from its early days, a key insight for me was the advance groundwork laid by these pathologists in preceding years. As you will learn from THE DARK REPORT'S exclusive interview with Guillermo Martinez-Torres, M.D., a partner and president of the pathology group, several years earlier, North Shore Pathologists had worked with hospital administrators to add specific clauses to their contract.

For example, as early as 10 years ago, the pathology group had added language to their hospital contract to address how outreach revenue would be allotted. According to Martinez-Torres, this was done in anticipation of future moves by the hospital to expand its outreach services.

Another shrewd strategy was to study bundled pricing as part of the pathology group's strategic planning. A payment formula was developed that could be used if the pathologists were engaged in global billing with other entities outside of their parent health system.

It was Louis Pasteur who said that "Fortune favors the prepared mind." As you will read in our intelligence briefing about North Shore Pathologists and their ongoing engagement with the Integrated Health Network of Wisconsin, it was the foresight and preparation of the group in years before the formation of this integrated care network that helped them convince the organizers that there was a useful role for pathologists. Now they contribute value through better utilization of lab testing and consultative support to clinicians that helps, the ACO's providers deliver improved patient outcomes. TDR

Pathologists Contribute To Care in Wisconsin ACO

Anticipating new payment models, group supports laboratory test utilization management

CEO SUMMARY: From the launch in 2013 of a big accountable care organization in Wisconsin, the North Shore Pathologists at Columbia-St. Mary's Hospital have been involved. Among the lessons learned are the importance of structuring the pathology contract with the hospital to anticipate value-based reimbursement and having full access to the ACO's data. The pathologists are using this data to develop test utilization programs that help physicians order the right lab test for the right patient.

IN RECENT YEARS, progressive pathologists and lab directors have recognized the importance of being included in the accountable care organizations (ACOs) being organized in their communities.

Too often, pathologists have found themselves without a place at the table as hospital administrators and physicians in the region came together to organize and operate an ACO.

For pathologist Guillermo G. Martinez-Torres, M.D., President of **North Shore Pathologists** in Milwaukee, Wisconsin, it was a case of "preparation meeting opportunity" that, in 2012, enabled him to participate in the formation of a large Wisconsin integrated delivery network and its ACO.

He met with the CEO of the hospital where he worked and the CEO told him he should be involved from that day forward. It helped, of course, that Martinez-Torres is also president of the medical staff at 300-bed **Columbia-St. Mary's Hospital** in Milwaukee and Chair of Pathology and Laboratory Services there.

"At that time, I was included in the original discussions with the system leadership because I was preparing for a national pathology meeting about ACOs," stated Martinez-Torres. "As part of that process, I walked into our hospital president's office and asked, 'What are we doing with regard to ACOs?'

"On that day in 2012, he happened to have plans for a new ACO on his desk," recalled Martinez-Torres. "At the time, few people knew about this proposed integrated care network and ACO. So, for me, it was an opportunity to get involved at an early stage.

"It was serendipity that I happened to walk into his office at that time, but I knew from my work with the **College of American Pathologists** that it was vitally important to have a laboratory representative at the table when discussing the formation of an ACO," he explained. "I simply needed to take advantage of the opportunity."

Lab Had A Place In The ACO

As a result of being well prepared even for such a chance encounter, Martinez-Torres earned a place for the lab in the formation of the ACO. "The next year, 2013, Columbia-St. Mary's became a participant in this ACO, now called the **Integrated Health Network of Wisconsin**," he said. "Even though we participate in this ACO, technically we are all competitive entities and still compete against each other, while at the same time looking for ways to collaborate."

As a pathologist involved in the organization and operation of one of the nation's first large integrated care networks and ACOs, Martinez-Torres identified several lessons as most significant for other pathologists wanting to engage with ACOs in their own communities.

First, lab directors have a unique value proposition to offer to ACOs: the ability to collect and interpret lab data for population health management. Second is that when the lab is prepared to engage in value-based contracting, it will have a stronger hand in negotiations over how pathologists will be paid. And third, labs should be prepared for payment that is not based on test volume.

Data as Bargaining Chip

"Before the ACO was officially launched, I made the case that laboratory data would likely make up a major proportion of the vast amounts of data that the ACO will gather from all the hospitals and health systems in the ACO," noted Martinez-Torres. "I advised them they will need to have someone who understands that data; someone who can interpret that data; and someone who can analyze that data. Calling attention to this need and the role that pathologists could play in improving patient outcomes was one key to being allowed to participate in all the early conversations about the ACO.

"The fourth lesson from our success with the ACO is that pathologists should take steps to identify future trends and prepare for them," advised Martinez-Torres. "About 10 years ago, our pathology group put language into our contracts with the hospital that would allow the hospital to easily contract for outreach services whenever necessary.

"Our six-member pathology group is a private practice entity and we knew that putting this language into the contract might help us at some future date," he said. "At the very least, it allowed us to work into our contract the potential for global and bundled billing with the health system.

Meeting Hospital's Needs

"We incorporated this language into our contract because we anticipated the coming shift to integrated care and new payment models," he said. "At the same time, our pathology group did not want to tie the hands of the hospital in ways that would complicate its ability to pursue more outreach work because we pathologists did not have the right pricing structure.

"Ten years ago, our pathology group developed a payment formula that we could use if we were engaged in global billing with other entities outside of this health system," he added. "We determined how global billing would work, including the percentage of the fees that would go to the hospital and the percentage that would go to the pathologists. This arrangement is in place and has been used by the hospital system.

"Further, our pathology group updates this formula regularly," he stated. "Recently, when we believed we were getting closer to contracting for bundled payments, we assigned dollars to it. Now we have a fee schedule in place for any bundled billing

Key to Success for ACOs: Collecting, Storing, and Sharing Patient Data

ONE STRENGTH OF AN ACCOUNTABLE CARE ORGANIZATION is the ability to collect and manage vast amounts of data on all the patients the ACO serves.

The Integrated Health Network of Wisconsin, a statewide ACO, recognizes the value of its de-identified patient data and shares that data with all of the participating hospitals in the ACO, said Guillermo G. Martinez-Torres, M.D., Chair, Pathology and Laboratory Services at Columbia-St. Mary's Hospital. In October, Martinez-Torres made a presentation about the clinical laboratory's role in the ACO during a webinar sponsored by **McKesson Corporation**, "The Role of Pathology and Laboratory Medicine in Accountable Care Models." *(See TDR, March 9, 2015.)*

During the presentation, Martinez-Torres explained that the organization is a commercial multi-payer ACO that operates under a shared savings or shared risk model. "That means that if the cost to provide care is less than the amount of money we were paid, then we share in the revenue," he said. "But if the cost is more, then we pay more into the system.

"Data from all the participating hospitals in the system are assembled in a common database, which gives us the ability to know how much services or tests cost across the entire system," continued Martinez-Torres. "We can thus calculate the cost of care for identical diagnostics or procedure codes at each of the sites. That is a benefit. But to some providers, it can also be a risk because they are sharing internal information with other members of the network.

"Having all of this information has allowed our pathologists to create best practices, guidelines, and protocols because now we not only have the information for our individual healthcare system, but also we have the information for the entire network," he explained.

"During the first two years of operation, we developed blood and blood product utilization protocols that helped to reduce the number of red cell transfusions and the costs associated with these products and this type of care," noted Martinez-Torres. "Our pathology group has also developed protocols for managing patients with chronic and costly conditions."

arrangement that might come our way. This preparation makes it possible for the lab to transition away from fee-for-service reimbursement. Understanding this reimbursement shift was probably the biggest lesson for all the pathologists in our group.

Right Test at the Right Time

"Pathologists know that a component of our income will not come from doing more tests, but from doing the right test even if that means doing fewer tests," he observed. "Thus, one element of compensation for pathologists will be based on appropriate utilization of lab tests. That's a paradigm shift away from the current model of where the more tests a lab performs, the more it gets paid.

"In an ACO, the goal is to keep patients healthy so that they don't have to come into the hospital," said Martinez-Torres. "But then how do pathologists get paid? Does the hospital share the savings with pathology? Many pathologists are asking these questions.

"These are the reasons why we prepared for this day by adding language into our contract with the hospital that ties a portion of our reimbursement to our ability to manage test utilization," he explained. "We did that on purpose so that we would have some skin in the game.

"To deliver this value to the hospital, our pathologists needed to be involved in test utilization," noted Martinez-Torres.

"Thus, we formed a test utilization committee, which I chair.

"Our goal is to decrease the number of unnecessary tests," he added. "This is where it gets difficult because each physician has his or her favorite lab test menu.

"Additionally, most of these menus are built into the electronic health record systems, making it easy for physicians to order them," he said. "Some physicians order the same test menu over and over. Theoretically, it is possible for a patient to have six CBCs, six comprehensive metabolic panels, six hemoglobin A1Cs—all ordered and performed on the same day!

"To address these ordering patterns, we put a system in place where, if the physician orders, say, a hemoglobin A1C, he or she is allowed one per hospitalization or every 30 days," stated Martinez-Torres. "When one physician orders one hemoglobin A1C, the order will go through and the test gets done. But the next doctor who puts in an order for hemoglobin A1C to check for diabetes, for example, would get a warning screen that says: 'Hemoglobin A1C has already been performed on this date; here are the results.'

Protocol For Test Orders

"Going forward, we want to expand the menu of lab tests that require utilization management," noted Martinez-Torres. "I recently presented our utilization management program to the board of directors of the hospital system. They loved it. Also, in my capacity as medical staff president, the program was presented to the entire medical staff leadership and received unanimous support to continue.

"Our pathologists are introducing the concept of value, which means we're changing the paradigm and the culture," he noted. "That means we have to explain our rationale behind it and then ask the medical staff to go along with it, because it is the right thing to do.

"Every pathologist knows that there is a level of overutilization and a significant level of underutilization," said Martinez-Torres. "In the ACO and the integrated care environment, the opportunity for pathologists to add value comes from helping physicians order the right test for each patient every time. That is a powerful way to contribute to improved patient outcomes while controlling costs." TDR

—Joseph Burns

Contact Guillermo G. Martinez-Torres, M.D., at gtorres@columbia-stmarys.org or 414-585-1448.

Pathologist Explains the Risk of Not Participating in ACOs

CONSIDER THE RISK OF NOT PARTICIPATING in an accountable care organization, suggested Guillermo G. Martinez-Torres, M.D., Chair, Pathology and Laboratory Services at Columbia-St. Mary's Hospital. The risk is high, he added.

"The risk of not participating in the development of an ACO is that you may be seen as someone who is not a member of the care team," he advised. "The problem with being seen in this way is that other physicians will be in a position to determine what your value is as a pathologist.

"If we don't do this for ourselves, then we're basically allowing a pediatrician, a psychiatrist, a cardiologist, a surgeon, or whoever happens to be on the team to determine what the value of pathology is," stated Martinez-Torres. "No one can speak better on behalf of pathologists than pathologists themselves! But to do this, pathologists need to participate and be part of the process.

"If pathologists don't participate, they will face an additional risk because the next phase of reimbursement will involve bundled payment or reimbursement for episodes of care," he added. "If a pathology group is not participating in an ACO, it may be deemed that the pathologists have no role and thus no value in that ACO. Should that occur, no dollars will be allocated for pathology services. It's as simple as that," he concluded.

Florida Doc Says Questions Go Unanswered by UHC

Family physician in Jacksonville frustrated by lack of response from UnitedHealth, BeaconLBS

CEO SUMMARY: One common complaint about the efforts of UnitedHealthcare to introduce its unpopular laboratory benefit management program in Florida is that the insurer—and its agent, BeaconLBS, a division of Laboratory Corporation of America—don't respond to physicians when they request guidance. One family practice physician in Jacksonville said that UHC has not even acknowledged several letters he sent via certified mail, return receipt requested.

PHYSICIANS IN FLORIDA have a common complaint about the laboratory benefit management program **UnitedHealthcare** introduced last year. They say UHC and **BeaconLBS** are not providing adequate answers to questions the physicians have about what they describe as a poorly-designed system for ordering laboratory tests.

In fact, many physicians and their medical societies report that officials from UnitedHealthcare and BeaconLBS (a division of **Laboratory Corporation of America**) simply ignore requests for information about different aspects of the laboratory benefit management program.

THE DARK REPORT made requests to UnitedHealthcare and BeaconLBS to comment on this situation. As of press time, no comment had been received from either company.

Physicians consider the answers to those questions to be critically important because, during February, UHC notified Florida physicians that the "claims impact" portion of the laboratory benefit management program would begin on April 15. *(See TDR, March 9, 2015.)*

After that date, UHC will refuse to pay labs that perform tests Florida physicians order if the physicians do not obtain pre-notification or pre-authorization through the BeaconLBS system. UHC also may penalize physicians who do not use the program and exclude them as providers to UHC's insured members, UHC said.

Given UHC's firm position that it is prepared to enforce the punitive aspects of this lab test ordering program, and given the well-documented disruptions to the existing clinical and operational workflow in the offices of physicians serving UHC patients, it is easy to understand the discontent among these physicians.

No Response From Insurer

In Jacksonville, one physician said that no official from either UHC or BeaconLBS has answered any of the requests for information that he and his staff sent to the two companies.

Family physician Terry Hashey, D.O., said he and his staff have called UHC's offices and sent letters to UHC by certified mail. All have gone unanswered.

Equally troubling to him, he said, is that the UHC and BeaconLBS notices sent to his offices do not include a phone number or return email address in case physicians have questions. All this frustration has caused Hashey to refuse to participate in the program, which began October 1.

Charge: Unfair Practices

"UnitedHealthcare is not using fair business practices," Hashey said in an interview with THE DARK REPORT. "It sends us letters and email with no phone numbers or return email and so we can't even ask for clarification.

"We sent two notices [to cure] by certified mail saying the BeaconLBS program is not part of our contract and that it's not a reasonable expectation under our contract," he continued. "In our letters we said, 'You have five days to respond or we're going to ignore you. They ignored both of our letters. Since we got the receipts back, we know someone at UHC signed for those letters. But no one responded to us. So now, we have no recourse but to say no to using the BeaconLBS program.

"This insurer ignores us and so we're ignoring it," added Hashey, a former flight surgeon who served in Afghanistan. "I'm not participating. We put them on notice and they should feel free to reach out to me. But so far, I've gotten no response."

The problem for BeaconLBS and UHC is that other physicians in Florida hold the same opinion as Hashey, telling THE DARK REPORT that they are unwilling to use the lab-test decision support system. How many physicians currently refuse to use the system is unknown. Neither UHC nor BeaconLBS responded to requests for comment on this aspect of the laboratory benefit management program.

The letters from Hashey's office were sent to UHC over the last several months. "In addition to the two letters sent by certified mail, we sent four or five emails and we've called the BeaconLBS tech support line," stated Hashey. "But the Beacon tech support people say they can't help us because our problems are beyond what tech support can do. They say we have to call our representative. We've called the main number and left messages, but they never call us back. I have no idea if we even have a representative."

Hashey's comments are similar to those from other Florida physicians who have complained that the BeaconLBS system is onerous, time-consuming, unnecessary, and an intrusion into their practice of medicine. *(See sidebar at right.)*

In a recent communication, UHC advised physicians of the April 15 "claims impact" date and wrote that "If you have questions, please contact your UnitedHealthcare network manager or Provider Advocate." There is no phone number or email provided in that notice.

Hashey's practice did not get the announcement from UHC. "We got the notice from the **Florida Association of Family Physicians** (FAFP)," he said.

"My understanding is that we are supposed to have an assigned representative from UHC and BeaconLBS," added Hashey. "But I don't know if we have a name or a phone number. It seems as if both companies don't want any interaction or don't want to answer questions from physicians about their own lab test ordering program.

Help With Ordering System

"As of today, my office staff doesn't understand how to use the BeaconLBS system," he noted. "I have no idea how to do it, and no one from UHC and BeaconLBS seems willing to tell me." In his practice, **First Coast Family Medicine**, he has a physician assistant and six nonclinical support staff.

But what makes Hashey most unhappy is the intrusion into the practice of medicine that is imposed by UHC's laboratory benefit management program. "The lab tests UHC has listed are nonsensical!" declared Hashey. "These are routine lab tests that are ordered appropriately all the time. It's not like these are specific lab tests that are done only in certain circumstances.

"Previously when insurers introduced similar programs, they aimed at testing or treatments that are experimental, overused, or ordered inappropriately," he observed. "But UnitedHealthcare lists clinical lab tests which are routine, such as Pap smears and thyroid studies. The clinical significance of having to use a decision support system to order routine tests is missing and has not been provided by UHC."

Notices Of Improper Orders

What compounds this unsatisfactory situation is that, according to Hashey, the few communications he has received from BeaconLBS have been notifications when his practice did not use the prenotification system when ordering specific lab tests. In February, he said he received an email from Matt Parise, Director of Operations for BeaconLBS. The letter is not addressed to Hashey but begins, "Dear Provider, The UnitedHealthcare Laboratory Benefit Management program requires that you provide advanced notification for these Decision Support Tests for your Florida commercial fully insured patients.

"The report below identifies the test(s) that you did not provide advanced notification," continued this BeaconLBS email. "In the future, when ordering these test(s) please provide advanced notification via the PDS portal at www.BeaconLBS.com, through one of our integrated laboratory ordering systems or EMR partners."

The letter includes the date (December 12) when Hashey ordered a Thyroxine (T4) test, the procedure code (84439) and the lab in question, LabCorp. The letter closes with a phone number for Hashey to call if he needs more information "on how to provide advanced notification for these test(s)."

When Hashey called the BeaconLBS office at the number provided on the email notice, however, he was told staff at BeaconLBS could not address his problem of how to use the BeaconLBS program. Instead, he was told to call UHC, he said.

Physicians' Questions Go Unanswered by UHC

QUESTIONS PHYSICIANS HAVE about the laboratory benefit management program of UnitedHealthcare fall into three broad categories. First, why is UnitedHealthcare requiring pre-notification for about 80 common recommended clinical laboratory tests and thus infringing on the physicians' professional practice of medicine?

Physicians and their medical associations have written to UHC stating that many of the tests on the BeaconLBS pre-notification list are supported by guidelines issued by the CDC and national medical organizations.

Second, many physicians are asking why the BeaconLBS system is not integrated with more of the most common electronic health record systems? They point out that the lack of such electronic interfaces means that they and their staffs must enter the same patient data twice—and this is for lab tests that are essential to patient care and supported by widely-used care guidelines.

The third area of questions to UHC centers upon: a) the difficulties in using the complex and unwieldy BeaconLBS system; and, b) the fact that the extra time required to enter lab tests into the BeaconLBS system can add up to several hours of physician and staff time each day—for no additional compensation.

On April 15, when UHC begins making decisions about whether to pay claims or not for physicians who do not use the BeaconLBS system, Hashey believes patients will suffer.

"My understanding is that UHC will punish the patient and treat the tests that don't go through the BeaconLBS system as being non-prior approved, out of network, or something like that," Hashey explained. "A few years ago, UnitedHealthcare sent bills to doctors when patients went to the 'wrong' lab companies.

(Story continued on page 18.)

LEVEL FOUR OF LABORATORY VALUE PYRAMID

Benchmarking with the Best To Be a World Class Laboratory

Part Four of a Series

FOLLOWING PUBLICATION of each installment in this special series introducing the laboratory value pyramid, there has been increased interest among lab executives and pathologists in the concept and how it can benefit their own laboratory organizations.

Such a positive response is a sign that the profession of laboratory medicine is ready for a different approach to how laboratories are organized and operated during a time when the healthcare system in the United States is undergoing rapid transformation.

This fourth installment in THE DARK REPORT'S series about the laboratory value pyramid deals with *Level Four: Use Benchmarks to Achieve Best-in-Class*. At level four, the focus is external and the lab emphasizes the value of its lab testing services to all stakeholders outside the four walls of the lab.

When the performance of a laboratory is consistent with the attributes of level four, it will be delivering value that meets and exceeds the expectations of all its customers and stakeholders. This includes the parent hospitals and health systems, physicians, patients, payers, and even employers in the community.

The level four laboratory will have the metrics to benchmark itself against the best labs in the United States and worldwide. It will be easily recognized by outsiders as a best-in-class laboratory organization.

CEO SUMMARY : This fourth installment of this special series about the laboratory value pyramid introduces "Level Four: Use Benchmarks to Achieve Best-in-Class." This is the highest level of the four-level pyramid. When a lab organization performs at this level, it will be delivering substantial measurable value to all stakeholders and it will have the metrics to substantiate this value. At the same time, the performance of a level four lab can be validated by its use of recognized third-party benchmarks that show it is performing equal to the best labs in the United States and across the globe. It will also have customer survey data showing it meets and exceeds its customers' expectations.

A major objective shared by the team that developed the concept of the laboratory value pyramid is that lab leaders need clarity in how to guide their respective lab organizations forward during challenging times. As noted in earlier installments of this series, it is a time of unprecedented change and all types of healthcare providers are experiencing tough financial times, not the least because of falling prices.

This is as true for hospitals and office-based physicians as it is for clinical laboratories and anatomic pathology groups. Reimbursement is shifting away from fee-for-service and toward bundled reimbursement and budgeted payments.

The emphasis in clinical care is moving away from reactive care and toward preventative and proactive care. This means keeping people out of hospitals—the most expensive type of healthcare—by emphasizing early diagnosis and active management of chronic conditions. One consequence is that providers have incentives to be more careful in how they utilize lab tests.

The third trend with the greatest potential to be disruptive is the transition to precision medicine. Whereas patients have been treated according to the average, as determined in large clinical studies, precision medicine requires the physician to tailor healthcare services according to the unique circumstances of each individual patient.

Here is where clinical labs and pathology groups are poised to deliver tremendous value. The future of personalized medicine and precision care will be informed by genetic testing and molecular diagnostics—exactly the disciplines within laboratory medicine where pathologists, Ph.D.s, and all types of clinical laboratory scientists are at the forefront within the house of medicine.

Here is a review the first three levels of the laboratory value pyramid.

LEVEL ONE: Achieve Normalcy and Predictability

In starting its journey forward, the level one lab starts the process of evolving away from

the traditional management and organizational models that were appropriate for the healthcare system of recent decades. In their place, the lab begins to adopt the management models used by the world's top-performing organizations.

During level one, the lab maintains an internal focus and the goal is to put its operational house in order. This requires abandoning the system of detection/failure and adopting a system of prevention. Such a transition involves shifting to a culture of continuous improvement.

To guide lab staff, the level one lab introduces real-time, visible lab process improvement metrics and uses these in tandem with traditional QC data. All team members learn how to identify and attack sources of recurring and systemic errors. *(See TDR, September 22, 2014.)*

LEVEL TWO: Establish & Meet Standards of Value

In level two, the lab continues its internal focus. The goal is to lay the foundation for the added-value lab testing services it will develop and deliver as it reaches levels three and four.

Internal benchmarking is well-established and aids lab staff in establishing criteria for value. Level two is where the lab staff moves away from the "volume mentality" (an accurate lab test result delivered on time) and concentrates on a "value mentality" (where lab test data is converted into actionable intelligence that improves outcomes and reduces costs).

Not only are quality parameters an established part of the daily routine in all activities, but the lab staff—because of the benefits of the system of prevention adopted in level one—can now concentrate on using measurements of the satisfaction of physicians, patients, and payers to guide continuous improvement projects.

As it works to achieve level two, the lab regularly thinks and acts like a business. There is visible accountability at all levels of the organization and the lab team has the skills to develop the business case analyses needed to support major lab investments by senior administration.

The single most important capability to develop during level two involves information technology. In coming years, the importance of integrated informatics and healthcare big data makes it essential for the lab to adopt IT systems that generate real-time data in support of two activities.

The first is sophisticated informatics support of lab operations and work processes. The second is to use IT to combine lab test data with other types of clinical data in ways that help the lab deliver more value to the parent organization, physicians, patients, and health insurers. *(See TDR, November 24, 2014.)*

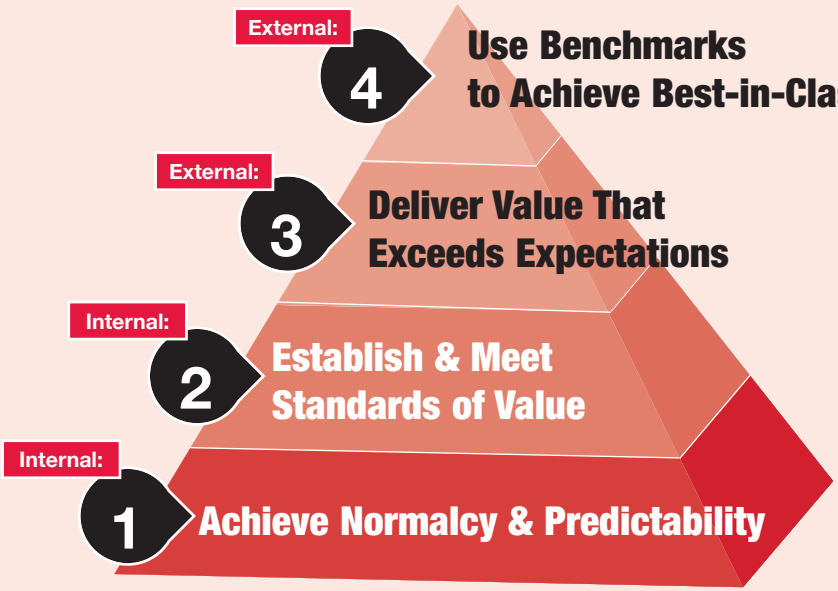
LEVEL THREE: Deliver Value That Exceeds Expectations

At level three, the lab shifts its focus from how it operates internally to how it delivers value externally. It is able to draw upon the established characteristics of system of prevention, continuous improvement, and its more advanced information technology to create value for clinicians.

The lab has now become a recognized source of value in the flow of patients at hospitals, health systems, physician offices, skilled nursing facilities, and other care settings. This is true both in contributing to improved patient outcomes as it is to patient handling, processing, and patient well-being.

Importantly, it is the sophisticated use of information technology at level three that enables the lab to leverage all its capabilities and generate more value with its lab testing services. This is consistent with healthcare's move toward big data in support of precision medicine. Also, this information technology capability provides the lab with the metrics to demonstrate its value to all stakeholders.

Laboratory Value Pyramid



Understanding Level 4:

Use Benchmarks To Achieve Best-in-Class

Four levels make up the laboratory value pyramid. Each level is a progressive step forward for any lab organization that wants to start from current state and pursue a desired future state of excellence and best-in-class performance. The laboratory value pyramid describes a simple step-by-step process to achieve that goal. Below are the attributes of level 4:

- Your lab's practices and competencies are recognized as best-in-class by your peer groups and third party reviewers.
- You are consulting with other hospitals and systems to help them replicate what you have done within your institution.
- Your lab is recognized as among "the best in the business" because of how your lab team uses all the attributes from the first three levels of the laboratory value pyramid.
- Examples of world-class labs can be found within prestigious institutions like Mayo, Geisinger, Stanford, Vanderbilt, Kaiser, Cleveland Clinic, and MGH.
- Extra credit! Your lab has created the database structure that allows it to mine the value of lab test data.

Level Four: (Lab Focus Is External)
Use Benchmarks to Achieve Best-in-Class

EVERY LAB ORGANIZATION should aspire to achieve the attributes of *Level Four: Use Benchmarks to Achieve Best-in-Class* because this is the level of performance where the lab is delivering optimal clinical value at highest quality and lowest cost.

It is also where the lab organization will realize maximum financial success, precisely because it delivers added value that differentiates it with its customers, including patients, physicians, parent hospitals, or payers.

Pathologists and lab executives studying the laboratory value pyramid are reminded that the essential foundation for the success of the level four lab is the ongoing use of a quality management system like ISO 15189, supported by effective use of Lean and Six Sigma techniques.

➤Business Skills

Another distinguishing characteristic of the level four laboratory is that all of its managers have the same business skills expected of managers in the nation's most successful companies. Managers use these skills to achieve stretch goals and create a culture of productivity and contribution across the entire lab team.

Level four managers understand how to make the financial case and demonstrate ROI for capital requests, along the information that supports the clinical care case for these capital investments. These are the resources every lab needs to deliver the advanced clinical services that contribute added value to stakeholders.

The end state for level four of the value pyramid is achieved when the lab organization can show these characteristics:

- Your lab's practices and competencies are recognized as best-in-class by your peer groups and third party reviewers from outside your parent organization.
- Your lab is managed with business best practices across all operational activities in support of delivering value to clinicians. This performance is documented by performance metrics that equal the external benchmark data of the nation's other best-in-class laboratory organizations.
- Your lab is sophisticated in its use of information technology. It is capable of assembling clinical data with lab test data and using algorithms to identify ways to help physicians use lab test data to improve patient outcomes and reduce the cost of care. It has the metrics to document these improvements.
- Your lab managers are engaged to consult with other hospitals and systems to help them replicate what you have done within your institution.
- Your lab is recognized as among "the best in the business" because of how your lab team uses all the attributes from the first three levels of the laboratory value pyramid.
- Examples of world-class labs can be found within prestigious institutions like **Mayo Clinic**, **Geisinger Health System**, **Stanford University Medical Center**, **Vanderbilt University Medical Center**, **Massachusetts General Hospital**, and **Cleveland Clinic**.
- Extra credit! Your lab has created the database structure that allows it to mine the value of lab test data and deliver that value to stakeholders, including physicians, parent hospitals, patients, payers, and employers.

Because the level four laboratory is a learning organization and organized around the continuous improvement mindset, it has no limits to the value it can deliver. More specifically, the level four lab that has mastered the skills of meeting cus-

Using Ranking and Measurement to Advance Lab's Performance to Level Four: Best-in-Class

IN THE PURSUIT OF LEVEL FOUR of the laboratory value pyramid, accurate and timely measurements play a key role.

In levels two and three, the lab began to identify and use relevant key performance metrics (KPMs) to monitor performance and guide lab staff on continuous improvement projects.

These KPMs, along with the input from outside subject matter experts (SMEs), are the important components for the development of the critical-to-quality parameters (CTQs) that become the primary measurement sets for evaluating the lab's performance.

A level four laboratory uses KPMs and CTQs for two purposes. First, these metrics support internal benchmarking and inform the lab teams as they pursue higher quality, lower costs, and increased value of lab testing services.

Second, KPMs and CTQs allow the laboratory to benchmark itself externally—against the best in the nation and the best in the world. It is these objective sets of data that enable a lab to accurately measure its performance against top-performing peers.

Of equal importance, these public measurements of a lab's performance relative to best-in-class peers is necessary for the lab to successfully obtain working capital and other resources from its parent hospital or organization that is required to further improve the quality and value of the clinical services it provides to all its customers.

Not to be overlooked is the use of CTQs to mentor the lab's new leaders who are positioned vertically and horizontally throughout the lab and its parent organization. These mentors, as responsible help managers, sustain the gains and constantly improve the value created by the lab as it moves up each level of the laboratory value pyramid.

Role Of KPMs And CTQs

KPMs and CTQs also have an important role in helping the lab tap the substantial value that can be provided by the IVD manufacturers and IT vendors. Savvy use of these metrics makes it easier for such lab vendors to help their top-performing lab customers achieve ever-higher levels of productivity, cost management, and quality.

It is also true that CTQs must continually evolve, but the quality management methods and process redesign efforts remain constant. This applies to all four levels of the pyramid.

Finally, remember the quote in the story about level two of the pyramid: "CTQ's are to Value as Westgard Rules are to QC." *(See TDR, November 24, 2014.)* This was to emphasize that best-of-class laboratories are just as diligent in pursuit of excellence in these metrics as they are in improving the lab's QC outcomes.

tomers' expectations and using quality management methods to sequentially raise the quality of lab testing services while reducing the cost of those services can be expected to enjoy sustained success.

This success can be measured by regular increases in specimen volume, adequate revenue and budgets, and recognition by physicians, patients, and payers in the community that it is the preferred provider of lab testing services.

Probably the most significant differentiator of a level four lab is its sophisticated use of information technology, particularly to analyze lab test results and clinical big data. As the transformation of healthcare proceeds, labs are uniquely positioned to analyze lab test data in conjunction with other types of clinical data and develop actionable intelligence for physicians that improves patient outcomes. TDR

Dark Index

LabCorp, Quest Diagnostics Both Say 2014 Revenue Was Up

Among other factors, the two lab firms attributed the increase in ACA-insured patients as a benefit

BOTH OF THE NATION'S LARGEST clinical laboratory companies reported increased specimen volume as a result of the Accountable Care Act (ACA), as noted in their respective fourth quarter and full-year earnings reports.

First to issue its earning statement was **Quest Diagnostics Incorporated**. On January 29, it reported fourth quarter revenue of $1.9 billion, an increase of 7.2% over Q4 revenue of $1.8 billion in 2013.

Specimen volume increased 8.8% from Q4 in 2013, the company said. Acquisitions added 9% to specimen volume, which implies a decline of 0.2% in organic volume, compared to Q4 in 2013.

Revenue per requisition for Q4-2014 was down 1.5% compared with the same quarter in 2014. Quest officials noted that acquisitions accounted for a decline in revenue per requisition of 1.5%. This implies that organic revenue was flat, compared with Q4 in 2013.

For the full year, revenue at Quest Diagnostics was $7.4 billion, an increase of 4% compared with revenue of $7.1 billion in 2013.

Explaining the effect of the ACA on volume, Quest President and CEO Steve Rusckowski said, "We continued to see signs of a modest increase in utilization. We are encouraged by the progress on exchange enrollment as the result of the Affordable Care Act. During the fourth quarter, we continued to see stability in test volumes on what we call a same-provider basis."

During 2014, Quest experienced an increase in specimen volume in states that expanded their Medicaid programs. "That was probably the most notable source of lives that we saw entering the system," Rusckowski added.

Laboratory Corporation of America issued its earnings report on February 20. The company noted that fourth quarter revenue was $1.51 billion, an increase of 5.3% over the $1.44 billion for the same quarter last year.

For the full year 2014, LabCorp's revenue was $6.01 billion, an increase of 3.5% over 2013 revenue of $5.81 billion. For the year, total volume rose 5.3%. The LabCorp press release stated that "The growth in revenue was due to organic volume of 3.5%, partially offset by a decline in revenue per requisition of 1.4% and negative impact of currency of 0.4%. In addition, acquisitions added 1.8% to sales. Total volume, including acquisitions, increased 5.3%."

Effects Of ACA Enrollment

Increased volume from ACA enrollments in the exchanges and from Medicaid expansions in 28 states was greater than company officials predicted, noted LabCorp CEO David King during a conference call with financial analysts. In addition, core testing grew faster than esoteric testing, in part because patients went from being uninsured to having insurance after enrolling on the exchanges or because of enrollment in Medicaid in some states, he

added. However, the ACA also had a negative effect on lab test prices.

Another public lab company with a significant presence in the United States is **Sonic Healthcare, Ltd.**, of Sydney, Australia. On February 17, Sonic issued its earnings report for the first six months of its fiscal year. This covered the first two quarters ending on December 31, 2014.

Sonic Is Global Lab Company

Sonic Healthcare is truly a global laboratory company. Its lab testing business in the United States represents 21% of its overall revenue. By comparison, Sonic's lab operations in Australia and Germany make up 29% and 20%, respectively.

For the first six months of its fiscal year 2015, Sonic reported revenue of $430 million from its lab operations in the United States. It stated that organic revenue growth was 1% in constant currency (5% statutory) and that it had experienced variable growth among its lab testing divisions within the United States.

Sonic also commented that it was seeing a strengthening of volume growth in the United States in recent months. One weak spot it identified was that **CBL Path**, its national pathology business, had experienced fee cuts and insourcing. This is consistent with the experience of anatomic pathology groups and national pathology labs throughout the United States during the past year.

Tough Lab Test Marketplace

Taken collectively, the full year earnings reports of LabCorp and Quest Diagnostics, along with the six-month earnings report of Sonic Healthcare, demonstrate that it was a tough market for lab testing services during 2014 for larger public lab companies. Administrators of clinical laboratories and pathology groups should incorporate the experience of these national lab companies into their strategic planning for the balance of 2015 and into 2016. TDR

Bio-Reference, NeoGenomics Have Strong Revenue Growth

TWO OTHER PUBLIC LAB COMPANIES reported stong revenue growth in their respective quarterly earnings reports.

On March 5, **BioReference Laboratories Inc.** (BRLI) of Elmwood Park, New Jersey, reported revenue of $208.8 million for its first quarter ending January 31, 2015. This is an increase of 15% over the $181.3 million it reported in Q1 2014 and gives the steadily-growing lab company an annual run rate of about $825 million.

BRLI's revenue per patient for Q1FY15 was $88.09, an increase of 8% compared with the $81.17 for the same quarter in 2014. Its patient count (specimen volume) increased by 7%, compared with Q1FY14.

Bio-Reference said its revenue per patient was $88.09. That was an increase of 8% over Q1FY15, when revenue per patient was $81.17. Days sales outstanding for the quarter was 113 days and BRLI said that esoteric testing now makes up 70% of its test mix.

In Fort Myers, Florida, **NeoGenomics, Inc.,** issued its earnings report on February 24. The company reported Q4 revenue of $25 million, a 36% increase over fourth quarter 2013 revenue, along with an increase in organic volume of 23%.

For the full year, NeoGenomic's revenue rose to $87.1 million, a 31% increase from revenue in 2013. Its acquisition of the pathology company **PathLogic** last July accounted for $4.9 million of the total revenue. For the full year of 2014, organic test volume at NeoGenomics rose by 29%.

For much of the past decade, both Bio-Reference Laboratories and NeoGenomics have demonstrated sustained growth in specimen volume and revenue, primarily through their respective introductions of unique lab test offerings, supported by in-house sales and marketing programs. Neither company has relied on lab acquisitions as a primary source of regular growth.

(Story continued from page 9.)

"After there was a big uproar about that, UHC rescinded that decision because we physicians have no control over where a patient takes a lab test requisition," he stated. "We can print LabCorp on the requisition, but if a patient takes it to **Quest Diagnostics**, that's their business."

Another aggravation for Hashey is that UHC set the start date for making claims payment decisions after open enrollment ended for Medicare and other health plans. "That means everyone is locked into place with their health insurer and their insurer's network. So physicians like me must deal with this for the next nine to 12 months before we can do anything, such as walk away from our United contract," Hashey said.

"I'm reluctant to take that step because that would be abandoning my patients. Yet here we have a situation where an insurance plan [UnitedHealthcare] that doesn't pay a lot of money to reimburse providers—yet it now requires even more work from physicians and staff without additional compensation. If our practice was to get rid of our lower-paying insurance plans, what does that do to our patients? Nothing good. So, right now, I'm unsure about what I'll do.

"I run a small practice. I'm one doc and my office has one PA. We do the best we can to deliver quality care," emphasized Hashey. "Yet, for years UHC tells me they can't adjust what they pay me because the market is tight. So I don't get any increase in revenue but now UHC wants me to do even more work by using the BeaconLBS system to order routine lab tests.

"When we spend more time with patients, we are more thorough and produce better patient outcomes. That's good medicine. But all we see from UnitedHealthcare are hostile actions. The insurer has not reached out for improved quality, or error prevention, or more wellness. It's just using bully tactics," noted Hashey. TDR

—Joseph Burns

Contact Terry Hashey, D.O., at 904-538-0950 or info@firstcoastdoctor.com.

Physicians Take Steps to Avoid Using BeaconLBS

WHEN PHYSICIANS IN FLORIDA find the BeaconLBS system to be difficult or time-consuming to use, they are adopting one of several strategies to avoid using the decision-support program when ordering lab tests.

One strategy some specialty physicians use is to send patients back to their primary care providers with test requisitions. The specialty physicians tell their patients to ask their PCPs to order the tests, physicians have told THE DARK REPORT.

This allows specialists to avoid the pre-notification or preauthorization requirements for about 80 common recommended clinical laboratory tests. But, of course, they have to hope the PCPs order the tests and send the results to them for the patient's next visit.

A second strategy some physicians use is to stop sending their tests though the BeaconLBS system. Instead, they send their test requisitions to out-of-network labs that have offered to run the tests for them. Then the out-of-network labs submit claims to UHC and hope for payment.

A third strategy may prove the most problematic for UnitedHealthcare. Some physicians have reviewed their agreements with the insurer. They are sending letters to UHC notifying the insurer that they need more information and request an answer within five days, as is common in commercial contract law [notice to cure]. If no answer is received, after five days, the physicians ignore UHC's request to participate in the BeaconLBS program.

Each strategy imposes a cost on the physician and his or her patients, without producing much benefit for UnitedHealthcare. The disruption to normal clinical workflow and clinical services provided to patients is another way that UnitedHealthcare may actually experience greater overall health costs.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Last Friday, at **Geisinger Medical Center** in Danville, Pennsylvania, members of the health systems's authority board were given tours of the new $63.4 million clinical laboratory facility. It is scheduled to open on May 4 and will feature the latest state-of-the art analyzers and lab automation systems. Located in a new building of 162,378 square feet, it will be home to more than 350 lab employees.

MOST LABS IN DUBAI FAIL PROFICIENCY TESTS

In Dubai, efforts by government officials to raise quality standards are taking much longer than anticipated. Last week, the *Kaleej Times* reported that a majority of clinical laboratories in the Gulf State are repeatedly failing proficiency testing. In 2010, the **Dubai Health Authority** made it mandatory that all clinical laboratories earn accreditation to ISO 15189. It later set a deadline of December 31, 2012, for labs to meet this requirement. According to news accounts, of 191 labs in the nation, just 66 labs have earned accreditation, with 73 more labs undergoing the accreditation process. Proficiency testing failures are one reason why many labs in Dubai have yet to become accredited to ISO 15198. "...we face this big question—for how long are we going to keep visiting them for inspections when they [labs] keep failing," observed Prabhakar Golkonda, Principal Accreditation Officer at the **Dubai Accreditation Center**. (DAC) "If a lab does not succeed in the third visit, there are serious problems in the lab which directly affect the quality of patient care and which should stop it from working." DAC is a signatory to the **International Laboratory Accreditation Cooperation** (ILAC).

TRANSITIONS

- **Sonic Healthcare USA**, based in Austin, Texas, has a new CEO. Pathologist Thomas P. Lohmann, M.D. assumed those duties in December. Lohmann held leadership positions and lab directorships at **Baylor Scott & White Health**, **med fusion**, **Quintiles Laboratories**, and **Ochsner Foundation Hospital and Clinics**.

ERRATA

- In the previous issue of THE DARK REPORT, in a story about the new clinical laboratory that **PerkinElmer** opened in Suzhou, China, the proper spelling of the 2009 acquisition is **Sym-Bio Lifescience Co., Ltd.** The price paid for the acquisition was $67.5 million.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 20, 2015.

SPECIAL SESSION!

Overview of the Draft Guidance and Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)

Alberto Gutierrez, Ph.D.

Director, Office of In Vitro Diagnostics
and Radiological Health, Food & Drug Administration

Join us for this exceptional opportunity to hear about the FDA's planned oversight of LDTs!

It's one of the biggest proposed changes in laboratory testing to come along in decades! The Food and Drug Administration's draft guidance for regulatory oversight of Laboratory-Developed Tests (LDTs) will require action by nearly every clinical laboratory and pathology group in the United States.

You have a timely opportunity to learn more about the reasons for the FDA's LDT draft guidance directly from the FDA's Director, Office of In Vitro Diagnostics. In this special two-part session. Dr. Gutierrez will present information about the draft guidance for regulatory oversight of LDTs. Following his remarks, a panel discussion will take place that includes Dr. Gutierrez, an attorney familiar with these issues, and a pathologist who is part of the Association of Molecular Pathology's working group on LDTs. Register today to guarantee your place for this important session about LDTs!

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