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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

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Founder & Publisher

Does Private Practice Pathology Have a Future?

IN RECENT DECADES, A PROPORTION OF PATHOLOGISTS has been proud of the fact that the pathology profession—to a large extent—had managed to protect the vast majority of private pathology group practices from any number of powerful trends and market forces.

In the 1990s, HMO contracting practices triggered a major wave of consolidation of hospitals, primary care physician groups, and specialist physicians. Most private pathology groups were able to preserve their independence. It was a similar story in the 2000s, when larger urology and gastroenterology groups (having consolidated during the 1990s into regional supergroups), decided they had enough specimen volume to establish in-house histology labs and anatomic pathology services. Again, most private pathology practices, despite losing access to these specimens, maintained their independence.

Now, in 2016, the anatomic pathology profession faces a fundamental question: Can the business model of the private pathology group practice survive healthcare's current transition toward integrated clinical care organizations (such as ACOs and medical homes) and a provider payment system that no longer uses fee-for-service, but pays physicians—including pathologists—based on value or with a bundled fee?

THE DARK REPORT is exploring how innovative pathology groups are responding to these trends. In coming months, you will see our incisive analysis of how current healthcare market forces are seriously eroding both the clinical foundation and financial solvency of smaller pathology groups.

To this point, our editorial team is organizing a major event designed to give pathologist-business leaders and their practice administrators a comprehensive view of the transformational forces in healthcare and how innovative pathologists are responding. This will take place at the upcoming *Executive War College on Laboratory and Pathology Management*, which happens on April 26-27.

Along with the sessions on the business of pathology during those two days, on April 28, a special one-day workshop will bring together the nation's leading experts. Titled, *Private Practice Pathology's Present and Future: What's Working… What's Not… with Strategies to Protect and Enhance Pathologist Income*, this will be a must-attend event for every pathologist and pathology practice administrator who wants to stay ahead of key trends. TDR

Palmetto Issues Guidance On Billing NGS Test Panels

Medicare contractor attempts to accommodate growth in clinical use of NGS through billing codes

CEO SUMMARY: Across the lab industry, next generation sequencing is taking hold as an effective and efficient testing platform. In response, payers are developing coding and payment policies that may affect the finances of clinical labs. Last month, Palmetto GBA, a Medicare contractor, issued NGS test guidelines that some experts see as an attempt to recognize the value of NGS testing as a technology that could lower the cost of care while giving physicians new tools to diagnose disease more accurately.

In January, **Palmetto GBA** revised its billing guidance for next-generation gene sequencing. By taking this action, Palmetto is acknowledging that NGS is a fast-growing technology that is gaining widespread acceptance by physicians and clinical laboratories nationwide.

But Palmetto also signaled that it is taking an approach to coding for certain tests that is unlike that of other payers and Medicare Administrative Contractors, according to experts who observe how payers and MACs view coding and price setting for molecular and genetic tests. In the guidance ["Next Generation Sequencing (NGS) and Tier 1 and Tier 2 Coding and Billing Guidelines M00130, V2"] issued in late January and updated February 16, Palmetto recognized the growth of NGS testing and seeks to accommodate that growth through billing codes.

Kuo Bianchini Tong, MS, CEO of **Quorum Consulting Inc.,** observed that, with these new NGS testing guidelines, Palmetto is taking a nuanced and sophisticated approach to coding for molecular and genetic tests compared with that of other payers. In contrast to Palmetto's approach, many other Medicare contractors and private health insurers are simply setting low prices on most molecular and genetic tests, Tong pointed out.

"In general, payers are taking one of two approaches to setting prices for molecular and genetic tests," stated Tong. "One approach is like that of Palmetto, which is nuanced and sophisticated. The other approach is cruder and focused on keeping prices low. Many other payers are

still on the sidelines, so it remains to be seen how this all plays out.

"Keep in mind that each of these two approaches represents a different way to make a business decision about price setting," he explained. *(Tong offers additional comments on pages 5-7.)*

Palmetto's NGS Guidelines

When Palmetto announced its NGS coding and billing guidelines for Tier 1 and Tier 2 MolDx tests, it said:

When the AMA developed and published the descriptions for the Tier 1 (T1) and Tier 2 (T2) codes in the Molecular Pathology Procedure Section, the technology for NGS was not fully developed. At that time labs typically used polymerase chain reaction (PCR) and non-NGS sequence analysis to interrogate a single gene or gene component. Therefore, the T1 and T2 codes describe services for a single or occasionally two-genes test and subdivide the descriptions by full gene sequence, common variants, duplication/deletion variants, and known familial variants.

NGS platforms have the ability to target and detect multiple specific genes of interest, including common variants, duplication/deletion variants, and known familial variants in one run to create a single report. Therefore, MolDx considers an NGS panel a single test with multiple potential indications. The AMA describes NGS gene panels in the 'Genomic Sequencing Procedure and Other Molecular Multianalyte Assay (GSP) Section.'

In a commentary on Palmetto's announcement, Bruce Quinn, MD, PhD, an expert on Medicare policy and a consultant with **FaegreBD Consulting**, said Palmetto's MolDx policy aims to distinguish between 'hotspot' tumor panels (meaning those targeting 5 to 50 genes and 51 or more genes) versus 'sequencing' tumor panels, and the policy states that labs cannot submit hotspot or sequencing tumor panels using the same AMA CPT codes.

"The MolDx program uses a distinctive approach to coding, billing, and pricing which cannot always be predicted by the use of the AMA CPT code book and price tables from the Clinical Laboratory Fee Schedule," he said. "The AMA has what it calls 'genomic sequencing procedure' codes 81445 (for 5 to 50 genes for a solid tumor), 81450 (for 5 to 50 genes for a hematologic tumor), and 81455 (for any tumor with more than 50 genes).

"But now—under the new MolDx policy—NGS "comprehensive genomic profiling" (Palmetto's term) is to be coded differently," noted Quinn. "For MolDx, the AMA CPT codes are eligible for use with hotspot or traditional sequence method panels. This may be a relief to some labs because CMS gave two of these codes (81445 and 81450) very low list prices of about $700 through the 2015 gapfill method, and those low list prices became effective January 1, 2016."

Benefits of an Unlisted Code

For pathologists in states where Medicare follows the MolDx guidance, labs that perform NGS testing that fit MolDx's definition of comprehensive genomic profiling are now instructed to bill with an unlisted code, 81479. "After using this code, MolDx will assign a price it determines to be appropriate," Quinn said.

Tong agrees. "What Bruce is saying is that Palmetto is pricing hotspot panels and if your lab is not submitting a hotspot panel to Palmetto, your lab must still obtain a separate and unique test code, which is good," he said. "It is important for labs to understand the Palmetto NGS guidelines because these guidelines represent one of several approaches to pricing molecular and genetic tests that are being used by other Medicare contractors and private payers." TDR

—Joseph Burns

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Payer Update

Payers Using Two Approaches To Price Molecular, Genetic Tests

One is nuanced, sophisticated, the other is more about lower prices for genetic tests

PRIVATE PAYERS AND MEDICARE contractors are taking divergent approaches to establishing coverage policies and setting prices for molecular and genetic tests. That's what Kuo Bianchini Tong, MS, CEO of **Quorum Consulting Inc.**, sees happening.

"One approach seeks to recognize the clinical utility and value of these tests with nuanced, more discreet coding and pricing," he observed. "Other payers are less inclined to differentiate based on content, and are simply applying a one-size-fits-all price to these tests.

"Neither approach can be considered wrong or fundamentally better than the other," noted Tong. "Rather, each approach is an effort to solve the challenges that the explosion in the number of molecular and genetic tests has presented to private payers and Medicare Administrative Contractors (MACs).

"If you look at what individual private payers and MACs do when coding and setting prices for all these tests, there are definite differences," explained Tong. "For example, **Palmetto GBA**, recently set new rules for hotspot tests versus more comprehensive panels. By doing this, Palmetto carved out hotspot tests using this new set of rules. By contrast, other MACs and private payers prefer not to make such distinctions for hotspot tests.

"What we may be seeing, then, is the first evidence that payers are aligning into different camps based on which approach they prefer when deciding how to cover and price molecular and genetic tests," said Tong. "When it comes to coding and pricing, Medicare contractors and other payers know exactly what they're doing. The net result is we can see these different philosophies in the marketplace.

"My view is that Palmetto is trying to take a subtle and nuanced approach by making interpretations based on the evolution of lab-developed tests and other assays," he added. "Palmetto knows that FDA-approved panels will be coming into the clinical marketplace. Thus, its newest coding and pricing may be built to reflect that reality.

Cruder Methodology

"By contrast, there are other MACs, such as **National Government Services** (NGS), and some commercial health insurers that use what might be called a cruder methodology—one that is designed to force these tests to a lower price point," explained Tong.

"It's not that one method is right and one is wrong or that one approach is ignorant and one is enlightened," he said. "I've watched payers struggle with these coding and pricing issues. Each payer has to develop an approach to coding and pricing that works for them. It's whether a payer wants to apply a fine surgical knife or a blunt machete to the field.

"Unfortunately, labs can find themselves caught in the middle of these different approaches to coverage and reimbursement," added Tong. "That's

because price can vary based on the payer or geography. Thus, the price a lab gets for its molecular or genetic test can depend on the payer to which it submits its request and which approach that payer takes.

Comprehensive Panels

"Look at how different health insurers and MACs view comprehensive panels, for example," he noted. "Reading into what the payers and some of the contractors say, it appears that they don't like comprehensive panels. They appear to be saying that there is much content in these panels that lacks clinical significance. Also, it appears that they don't like the price point that the labs request for these panels.

"Every payer has a choice," continued Tong. "Each payer can either fight the labs on every one of these panels or it can just slap a low price point on each panel and be done with it. In reality, that is a very pragmatic business decision.

"Labs could argue that the payers should not set prices that way," observed Tong. "But once the CPT codes were written and the gapfill prices came out for 2016, the MACs had a tool that allowed them to address the 900-pound gorilla in the room.

"Look at it from point of view of payers and MACs," he said. "Labs were complaining that they wanted the MACs to set prices for these tests. Some of the lab companies are publicly traded, which is why stock analysts also were complaining about the need for pricing decisions. *(See TDRs, April 15 and May 28, 2013.)*

Potential Legal Liability

"In addition, health insurers and MACs faced a potential legal liability as a result of the backlog of tests they needed to review and approve," continued Tong. "So, what could they do?

"By setting a price—even if it was low—they could solve their problem in one fell swoop," he stated. "Given the position all the payers were in, that's a very sophisticated decision, whether you agree with it or not. And, I'm not making a judgment about whether they were right or wrong. That's just what they did.

"At the end of the day, it doesn't matter much because the pace of the evolution of molecular and genetic tests is staggering," declared Tong. "Today, a lab could have a hotspot panel with eight markers and tomorrow that lab could introduce one that has nine markers. When it does that, it has created a new test that needs to be evaluated for payment. How can the payers keep up that this rapid pace of new test creation?

Codes Based on Old Tech

"Here's how I explain the situation to labs, payers, and venture capitalists: The train has left the station," he said. "There was a rush to create codes because many people in the lab industry mistakenly believed that setting codes was the answer. In fact, the rush to create what may be imperfect CPT codes is what has gotten us to this point.

"These new codes were not forward-looking enough," continued Tong. "By that I mean, the new CPT codes were overly broad. They didn't really address the question of whether we want future innovations and iterations to be captured all in single, broadly defined codes.

"When it came time to write codes for MolDx tests, payers wanted transparency in knowing what they were paying for compared with the old code-stacking approach," he continued. "The AMA, specialty societies, payers, and other stakeholders worked with the labs to write codes that were transparent.

"But the labs should have been more aware that coding begets rate setting, and if you can't control the rate-setting process, then codes may not serve your primary objective, which is obtaining a payment rate that you desire," observed Tong.

Consultant Warns That Setting Up New CPT Codes Inevitably Leads to Setting Prices for Lab Tests

WHEN CLINICAL LABORATORIES work with any entity to create new codes for clinical laboratory tests—whether it's the AMA CPT committee, or individual payers and Medicare contractors—doing so inevitably leads to price-setting. Therefore, it might be best for labs not to rush into writing new codes, suggested Kuo Bianchini Tong, MS, CEO of Quorum Consulting Inc.

"When it comes to setting CPT codes, the problem is that people don't read the tea leaves the right way," he said. "The general rule about coding is that if you are a lab that supports the creation of new codes, you should do so only if you have input on the price point. If you lose control of the price point, why would you want a code? It's like walking off a cliff."

In Tong's opinion, when labs got involved in establishing new CPT codes for multigene panels, there was not enough consideration given to how payers would establish payment amounts or what would happen if prices were too low.

"We created generic placeholder codes for multigene panels, then the payers set prices that were too low for these panels," explained Tong. "The panels got lumped in with all other codes, and we ended up with broad buckets of codes. Such broad buckets do not allow for appropriate price setting.

"Now that the codes are written and the prices are mostly set, labs and lab consultants have talked with the AMA about withdrawing panel codes. But there is not much appetite for that," Tong added. "So, unfortunately, this is one test-pricing factor that is already behind us.

"Labs may get a reprieve on prices when the federal **Centers for Medicare & Medicaid Services** issues rules under the Protecting Patient Access to Medicare Act," added Tong. "Under PAMA, advanced diagnostic tests, multi-analyte tests with algorithms, and FDA-approved tests could be set at more appropriate rates.

"The end result is that, again, we have a two-class system," he said. "There is one class for tests that don't go through FDA approval or don't have an algorithm. For oncology panels of fewer than 50 genes, those tests are starting to get priced around $600. And remember that price will only go down from here. It's not going up.

"The other class is for MAAAs with algorithms and FDA-approved tests," he observed. "These may offer some safe harbors under PAMA. But there will be no middle ground anymore. That's what we are telling investors and the lab community.

"What this means is that the vast majority of hospital labs and labs offering LDTs are really in a bind because most of those tests are priced at $600," he concluded. "For these reasons, labs must now hope that any new FDA-approved lab tests will qualify for the new PAMA codes. Ideally, in these cases, labs billed under those CPT codes will get a reset on price."

"Thus, it could be argued that the lab industry hurt itself by thinking it was on the right path to work with the payers without negotiating the process in which the price would be set for these molecular and genetic tests," he added.

"The classic example is one company that did not want a Tier 1 code because, by using an unlisted CPT code, it was getting paid $3,000 or more for its tests," noted Tong. "But then as soon as payers set up a code that would cover that test, they started chipping away at the price. Now, that lab company gets paid a fraction for that same test!" **TDR**

—Joseph Burns

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How Mentors Can Best Train Young Lab Leaders

Upcoming generation of lab managers needs additional skills, savvy, to help their labs succeed

CEO SUMMARY: Mentoring will be the theme of a special learning track at this year's Executive War College. Two nationally-respected experts on mentoring and leadership development will work with participating lab mentors and mentorees to help them advance their mentoring relationship. All of this is designed to help your laboratory prepare its younger managers to step up and contribute to the ongoing clinical excellence and financial sustainability of your lab.

SUCCESSION PLANNING at the nation's clinical labs and anatomic pathology groups is getting little notice. Few labs have a formal program designed to prepare up-and-coming managers for top leadership positions.

One proven way to identify and cultivate the most promising leadership candidates on your lab's management team is to have a mentor/mentoree program in place. One big benefit of such mentor and mentoree relationships is that they are low-budget and high impact. That is essential at a time of reduced lab budgets and a shrinking number of middle management positions.

Mentoring Younger Managers

But of greatest importance, by taking the time now to mentor your lab's up-and-coming young managers, you can ensure the clinical success and financial sustainability of your clinical lab or pathology group.

It is for these reasons that you have the opportunity to participate in the clinical lab industry's first-ever mentor/mentoree development program! It will take place on April 26-27, 2016, at the 21st annual *Executive War College on Lab and Pathology Management*. Two of the nation's most respected experts in mentoring and leadership development will guide you and your mentoree in a rich learning experience during the conference.

Your mentoring guides and teachers will be Colonel Jeffrey McCausland, USA, Retired, CEO of **Diamond Six Leadership** and W. Brad Johnson, PhD, Professor of Psychology in the Department of Leadership, Ethics and Law at the **United States Naval Academy**.

Johnson is a nationally-recognized expert on the subject of mentoring and is the author of several books on mentoring, including *The Elements of Mentoring* and *On Being a Mentor*. McCausland conducted the popular one-day workshop on leadership that took place at last year's *Executive War College*. This mentoring program is designed to build upon that leadership workshop.

McCausland and Johnson have prepared a learning experience customized to

the unique needs of clinical laboratory and pathology managers and administrators. The mentor/mentoree learning experience starts with a pre-conference webinar on March 31. McCausland and Johnson will lay the groundwork and give the mentors and mentorees guidance on how to use the regular learning sessions at the *Executive War College* to advance the mentoree's knowledge and skills.

Next, on Monday afternoon, April 25, before the *Executive War College* commences, McCausland and Johnson will conduct a workshop to present the proven methods of mentoring. Each pair of mentors and mentorees will meet and interact with the mentors and mentorees from other labs.

To sustain the learning and networking, McCausland and Davis will provide guidance and counseling each day at a private lunch session open only to the mentors and mentorees. Then, after lunch on Wednesday, April 27, there will be a two-hour session to wrap-up the learning experience for all mentors and mentorees.

Post-Conference Follow-Up

To reinforce this rich learning experience, McCausland and Johnson will conduct a webinar about 30 days after the *Executive War College* for the mentors and mentorees. This session allows participants to review progress and learn how to take the mentoring relationship in the directions that have greatest value to the mentorees.

Every senior lab executive and administrator has a legacy that remains after their departure. Developing the best management talent as part of succession planning contributes to that legacy. This mentor/mentoree program is an opportunity to advance that legacy. TDR

MENTORING YOUR LAB'S YOUNG LEADERS

Mentors are invited to bring their mentorees at a special discounted registration price. Program details are available at: *www.executivewarcollege.com*

Special Opportunities At Executive War College

IN RESPONSE TO THE MAJOR CHANGES now happening in the clinical lab market and the U.S. healthcare system, important learning opportunities will be available at this year's *Executive War College*, which takes place on April 26-27, 2016, in New Orleans.

To help pathologists who are CEOs and their practice administrators, there will be a full-day workshop on Thursday, April 28, titled, *Private Practice Pathology's Present and Future: What's Working… What's Not… with Strategies to Protect and Enhance Pathologist Income*.

For lab sales and marketing managers and lab managers responsible for their lab's outreach sales program who are seeking ways to increase revenue and specimen volume, also on Thursday, April 28, will be a full-day workshop titled, *Sales Performance Coaching for Clinical Labs, Pathology Groups, and Specialty Labs: Achieving Sales Success in Tough Markets*.

Separate two-hour roundtables will take place for lab CFOs; lab CIOs and informatics managers; lab sales and marketing VPs; and lab compliance officers. Each roundtable enables personal networking opportunities and problem-solving in a rich learning environment.

For owners, executives, and investors in labs offering proprietary and patent-protected molecular and genetic tests, there will be a four-hour session titled, *New Business Opportunities in Molecular Diagnostics and Genetic Testing for Lab Owners and Investors*.

Overall, this year's *Executive War College* will feature more than 60 sessions and 100 presenters. It is now the nation's largest lab program devoted to the management and operation of labs and pathology groups. Full details about speakers and sessions and registration information can be viewed at: *www.executivewarcollege.com*.

Metrics Show Improved Quality and Greater Revenue

Henry Ford Health System Lab Combines Lean with ISO 15189

CEO SUMMARY: As healthcare transitions away from fee-for-service payment and adopts new models of reimbursement, every clinical lab will need to deliver more value with its lab testing services. At Henry Ford Health System in Detroit, the laboratory division has blazed a path of improving lab performance specifically to enable it to add value to the health system, physicians, patients, and providers it services. Part one of this multi-year journey was to introduce Lean throughout the laboratory. Part two was to adopt the QMS of ISO 15189. Now comes part three, where these accomplishments position the lab to add value to improve patient care.

LABS ACROSS THE COUNTRY MUST DEAL with the twin squeeze of shrinking budgets and the need to test more specimens with those reduced resources. This is why some innovative lab organizations are adopting the quality management system of ISO 15189.

The benefits of a quality management system (QMS) are substantial. Labs that have incorporated ISO 15189 into their daily operations report significantly lower costs because of the ability of lab teams to identify systemic sources of errors and reduce or eliminate them. Revenue at these labs typically increases because the lab does a better job meeting and exceeding the service expectations of physicians and its other clients.

Of equal importance, labs using ISO 15189 today report that this QMS is now the essential foundation that supports the lab team's effort to deliver more value to the stakeholders it serves, including hospitals, physicians, patients, and payers.

Lower costs, improved quality, and increased revenue are among the major benefits that resulted from what is believed to be the nation's largest deployment of ISO 15189 in a major laboratory organization. At **Henry Ford Health System**, in Detroit, its five largest hospitals are now accredited to CAP 15189.

It is important to understand that the implementation of ISO 15189 across all of these HFHS laboratory sites is no one-off management strategy. "Rather, this step was taken after a full 10-year journey to introduce Lean, Six Sigma, and process improvement techniques into the daily operations of our labs," explained John Waugh, the System Vice President of Pathology and Laboratory Medicine at HFHS.

"Currently, we have outside ISO inspections at the laboratories of our five largest hospitals," he said. "We operate to ISO standards at a total of 34 laboratory sites in our health system."

According to Waugh, use of this QMS has measurably improved the productivity and performance of the clinical laboratory division at HFHS. "Our lab outreach program increased net revenue by $2 million," he said. "Meanwhile, rates of errors—a metric to which we rigorously manage each day—decreased by 73%. For example, complaints associated with phlebotomy dropped by 64%."

What makes these performance metrics impressive is the size of the laboratory division at Henry Ford Health System. Staffed by more than 700 people, the labs perform millions of tests annually for the system's acute-care hospitals, nine emergency rooms, and 30 clinics in and around Detroit.

"In 2005, we began our Lean journey with a vision to create a world-class laboratory organization," he stated. "One year later, in 2006, we developed the Henry Ford Production System.

"We started with three goals," he continued. "One, to become a world-class laboratory organization. Two, to adopt a culture of relentless improvement; and three, to establish a culture in which the staff are taught Lean and empowered to use Lean."

Implementing Lean Culture

Waugh described the first steps taken in 2005 to introduce, train, and sustain a Lean culture in the HFHS laboratories. "Our strategy was to establish visual environments throughout each area of the labs," he noted. "We used simple visual controls and standardized work processes to accomplish this.

"At all times, we supported the goal of having laboratories that were safe, while also teaching the staff to understand the philosophies of Lean thinking, which means the language and the lexicon," continued Waugh. "This was done by teaching them about 5S workspace and visual controls, and related techniques.

"Staff and managers were taught about the need to capture defects, make quick fixes, and use the plan-do-check-act (PDCA) cycle," he said. "We also have standardized work, value stream mapping, single piece and unidirectional flow, kanbans, and we are trained to recognize and eliminate waste.

"All our lab's Lean and process improvement team leaders go through two-day lean training courses that are taught by our staff and Richard J. Zarbo, MD," added Waugh. "Zarbo is the Chair of Pathology at HFHS and Senior Vice President for Pathology and Laboratory Medicine.

"Additionally, our entire staff is trained in Lean," he emphasized. "That means every pathologist, every technical and support staff, every secretary, every courier driver! Even our informatics people go through a minimum of eight hours of Lean training and we regularly conduct 15-minute Lean refresher modules.

"From 2005, when we started to introduce and train the staff in Lean," said Waugh, "it took us until 2012 to achieve a culture of Lean and continuous improvement. That was the foundation for our next phase in this journey, which took three years.

"Going forward from 2012, having trained all the staff in Lean, our goal was for everyone on the lab staff to become owners. By that, we mean, 'find your place. You've got a role here.'

Lessons From Manufacturing

"To do that, we borrowed a lot of examples from the automotive world," recalled Waugh. "For example, on many occasions, we went on the **Ford** factory tour at the Ford F150 pickup truck assembly plant. We found excellent lessons from outside of healthcare and we've imported those in our laboratory environment and also into our health system.

"We are continually fascinated at the similarities between a manufacturing environment and what we do in clinical labs," he said. "In manufacturing, they put things together. In clinical labs, it's the reverse. We take apart tissue and blood and look at cells, proteins, biomarkers, and DNA.

"In many respects, it is a perfect fit if you run the factory model backwards in your laboratory workflow," noted Waugh. "By doing that, it is both easy and effective to adopt and apply those concepts within the laboratory to make process improvements that improve quality and contribute to better patient care.

"As is true in manufacturing, our lab formed a quality systems division," he said. "Just as your lab needs experts in blood banking, chemistry, and microbiology, your lab also need experts in quality. This is an important lesson that's easy to overlook.

Training Lab Staff In Lean

"Every lab needs people trained in Lean to do prep work, to gather data, to observe work processes, to plan meetings, and to teach new people how to work in this environment," Waugh said. "The effort to improve quality is important work and, in a lab, it's just as important as microbiology or chemistry.

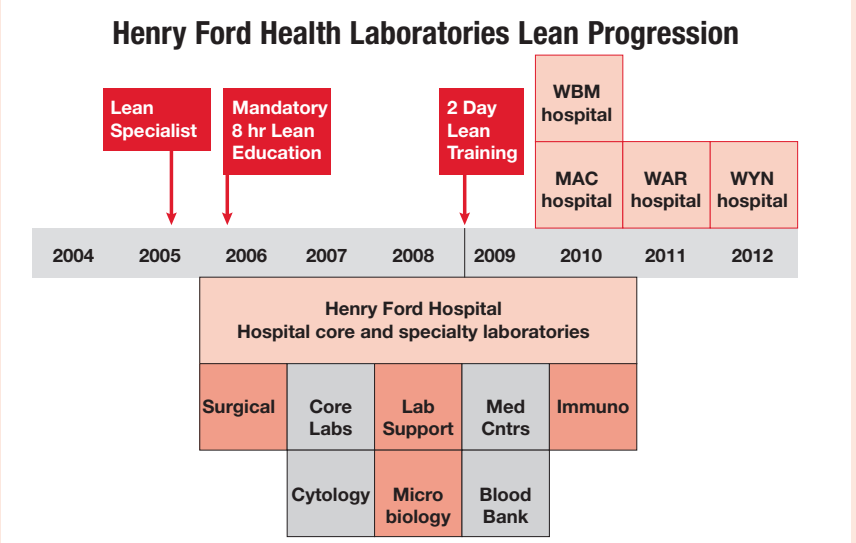
"Our lab conducts monthly quality meetings that run 90 minutes long," he continued. "Attendance is either in person or by dial-in. Typically 45 or 50 people participate each month.

"This is highly important because, if your lab does not spend enough time to have quality meetings once a month, it is not spending enough time on quality," advised Waugh. "You have to put your money where your mouth is and make this investment in time for the Lean culture to take root in your lab and become a core value for the entire staff.

"As you can see, we did all this work in order to get Lean in place, but it was clear to all of us that we had to take it to the next level and create value," he explained. "For our lab division, that next level was ISO 15189.

"Thus, in 2012, our next step in our quality journey was to get our labs accredited to ISO 15189 under the **College of American Pathology**," stated Waugh. "Having already established a quality culture built around Lean, much of the preparatory work for an ISO accreditation

Multi-Year Journey to Develop Lean Culture At Henry Ford Health System Laboratories



Accreditation to ISO 15189 happened at the Henry Ford Health System laboratories only after the lab staff had been trained in the principles of Lean and Lean methods were in use in every department of every laboratory. The Lean effort began in 2005 and, by 2012, the lab leadership considered the timing right to introduce ISO 15189.

was already in place. Thus, we invited a team from **CAP** to come in and conduct an ISO gap inspection.

"The gap analysis team was impressed with what we had done but they also found a number of gaps that we needed to close," he recalled. "At that meeting to report those gaps, they looked at us and said, 'You're ready. We'll see you in six months.'

Accreditation Assessment

"That meant they were coming back for the real ISO 15189 inspection in six months and our lab still had a lot of gaps to fill," explained Waugh. "Having reached this point, we were determined to succeed in our effort to earn the ISO accreditation," Waugh explained.

This was an opportunity for yet another lesson learned. "The lab staff and the lab leaders were already engaged in the daily application of Lean methods," he said. "Now, the ISO accreditation initiative would require them to address and fill all the gaps during the next six months.

"Thus, staff began to pepper us with such questions as, 'Is ISO 15189 important? Do we really need to do this?'" continued Waugh. "Our management team always had a consistent answer, 'Yes, we really do have to do this. ISO 15189 is the train we're on. It has left the station. We're going. If you can't do it Tuesday, do it on Wednesday. If you don't think you can do it, we have people to help and if that doesn't work, we'll help you. I'll help you get there because earning ISO 15189 accreditation is important.'

"In fact, how we engaged the entire lab staff during this time was an important take-home lesson for all of us," emphasized Waugh. "The lesson is that we had great quality leaders and we paired them with people that lead operations.

"By doing this, we created partnerships within all sections of the lab, which is important because this work is hard for any one group to do alone," he explained. "Partnership is one ingredient in a successful Lean journey for a clinical laboratory. In fact, I consider partnership to be the 'secret sauce' in achieving these ambitious goals."

Use of Huddle Boards

Waugh then described another strategy borrowed from industry that played a important role in the HFHS lab's ISO implementation. "We created what we call huddle boards. That was another tactic that we took from manufacturing," he said. "Huddle boards started with the idea that we need to focus on five elements: quality, timeliness, inventory, productivity, and safety. Or 'QTIPS' as everyone in our lab calls these elements.

"These five terms are used every day, particularly during team huddles," Waugh continued. "Huddle boards are built around these terms. However, staff build their own huddle boards according to what they think are the most important factors for their area of work.

"Each team builds their own version," he said. "We gave them the tools and said they didn't even have to use the term QTIPS. And, some used QTIPS and some didn't. Either way, it was for them to use in their work area. Remember, people who are closest to the work know how to fix things, but only if management gets out of their way!

"To support this independent problem-solving and process improvement, huddle boards are always posted closest to where the staff participates in that daily huddle work," he stated.

Unique Milestone

Because of this focused effort, the example the lab administration set, and the engagement of the entire laboratory staff, the laboratory division at Henry Ford Health System achieved a milestone unique among laboratories in the United States. "In September 2013, we earned accreditation to CAP 15189," noted Waugh. "This accreditation covered the laboratories at the five largest hospitals operated by HFHS. This is the first multi-hospital lab 15189 accreditation in the United States."

As noted earlier, in parallel with the effort to implement the QMS of ISO 15189 in the eight hospitals, this same QMS was implemented in the other 34 laboratory sites within the HFHS laboratory division. "There were a number of reasons why we opted for this approach, including cost and the added time required to accommodate accreditation activities," stated Waugh. "What was important for us was that every laboratory site in our system now operates from a single QMS. Our staff understands these requirements and this adds flexibility when staff members work at other laboratory sites."

Adding Value For Clinicians

Having achieved the goal of accreditation to ISO 1519, lab administration was ready to look for ways to add value to its lab testing services. "It took a lot of work to implement Lean and get accredited to CAP's version of ISO 15189," recalled Waugh. "Yet, these remarkable accomplishments were just the first major steps. It was time to leverage the talents and expertise of our lab team to achieve a higher level of quality in how our lab contributes to patient care.

"One starting point was to assess how we could improve our lab's targets," noted Waugh. "For example, did we have any targets that were at 90%? If your car started 90% of the time, you'd walk home, once every two weeks!

"Quality management teaches that the best way to set your targets is to base them on the needs of your customers," he said. "This is not what happens in most of healthcare. In healthcare, we hear a lot about being at the median and stretching

Lab Uses New Diagnostic Technology to Cut Turnaround Times and Hospital Length of Stay

WHEN MAKING PROCESS IMPROVEMENTS in any clinical lab, pathologists and lab directors are likely to introduce new analyzers. That's just what happened at the Henry Ford Health System.

"Right now, we have the coolest new tools in the laboratory of anybody in healthcare," said John Waugh, HFHS' System Vice President of Pathology and Laboratory Medicine. "That includes equipment for next-generation sequencing and mass spectrometry with matrix-assisted laser desorption ionization time-of-flight. We use MALDI-TOF MS as an analytical method for microbial identification and characterization based on the fast and precise assessment of the mass of molecules in pathogens.

"Under the leadership of pathologist Gurav Sharma, MD, we use the results from these new tools to reduce length of stay from bloodstream infections and reduce medication costs," he noted. "Sharma is a Senior Staff Pathologist and Associate Medical Director of the Core Laboratory, Quality Systems and Regulatory Affairs at HFHS.

"With MALDI-TOF we have improved workflow by about 50%," Waugh explained. "We did so by cutting the time required to identify a bacterial-infection pathogen from 2.2 days to one day and by slashing the time required to identify yeast infections from four days to 1.4 days.

"Since 2014, these improvements in our microorganism identification time enabled us to go from reporting 50% of outpatient tests by midnight of the same day to 90% by midnight of the same day," stated Waugh. "Further, we report 98% of these pathogens by 6 am the next day.

"Cutting the time to identify infections allows us to decrease length of stay for sepsis patients by 33%," he said. "This is significant given how much it costs for a patient to spend one day in a hospital.

"Candida is a good example," added Waugh. "For patients with candida, we found that use of MALDI-TOF MS allowed us to reduce the length of stay by 30%, saving $4,500 per day for these patients!"

to get to the 75th percentile. It is time for the clinical lab industry to stop focusing on yesterday's level of quality. That was great for yesterday, but it won't get our labs to the level needed to support the reforms now happening in healthcare.

"Here's an example. In our critical values area, each day we make 150 calls from the laboratory to the ordering physicians," observed Waugh. "The people in that area of the laboratory know that these calls are about patients.

Addressing Critical Values

"We make these calls to ensure patient safety and it's important that 100% of critical values are called," he explained. "We have a visible system to ensure we call 100% of critical values. If this team misses one call out of 150, they got a red dot for the day.

"This is not a computer-generated thing," Waugh noted. "A felt-tip marker is used to color in the chart used in the daily huddles. This is so the staff in that department can own the process right where they work. Behind every red dot is a patient. That's what makes this work critically important.

"Patient safety is an area of critical concern to clinicians," emphasized Waugh. "We know that. And we know that an area of critical concern to healthcare executives is reimbursement, which is healthcare's 900-pound gorilla.

"We can track increased revenue to our lab because of our Lean culture and how we use Lean tools throughout the system," he noted. "We can measure how these capabilities, along with our lab's accreditation to ISO 15189, all contribute to better lab reimbursement."

Waugh said that one essential requirement when looking for opportunities to add value is to understand the lab's current performance level with its individual work processes. "Take the pre-analytical and analytical stages in lab testing," he commented. "We are diligent about measuring the performance of the processes within these stages. This allows our lab team to internally benchmark themselves and understand how to drive performance to higher levels.

"Since 2005, we've devoted considerable attention and resources to improve our lab's performance in the pre-analytic, analytic, and post-analytic stages," continued Waugh. "Now our focus is on increasing the value of our lab testing services to our clinicians and our parent health system.

"One area in which we recognized the opportunity to add value involved our post-analytic processes to deliver outpatient results," he stated. "Improvements to our work processes for lab test reporting meant that we began to have physicians tell us their patients got their lab results before the physicians did!

Physicians told us that their patients were calling on the phone to ask for an explanation of their test results," noted Waugh. "The patients wanted to know, 'What is this bun [lab test result]?'

Reporting Results Faster

"This happened because our process improvement efforts enabled us to report those tests which were not cultures or send-out tests on the same day we received the specimen," said Waugh. "Outpatient tests reported by midnight went from 50% to 90%! Even better, we improved to the point where we were pushing 98% of our results out by 6 am the next morning. We've been doing that for five years. Those are very good turnaround times.

"Here's another example, also from our lab outreach program," observed Waugh. "Because of the increased efficiency and productivity of our lab, we were able to grow our net revenue by about $2 million in just over 24 months. That is tangible value creation for our health system.

"We also cut turnaround times for emergency department and for inpatient lab testing," he noted. "Our lab went from delivering 90% of our emergency room stat tests within 60 minutes to delivering 90% those tests within 30 to 35 minutes. Troponin TAT was cut to just 35 minutes with 95% performance. For inpatient lab testing, the time it took us to deliver 90% of inpatient stat tests fell from 90 minutes to just 45 minutes.

Phlebotomy Dashboard

"By introducing a phlebotomy dashboard we cut phlebotomy wait times sharply and now we're introducing online appointment scheduling for patients who need to have blood drawn. Now they can schedule that in advance," explained Waugh.

"In summary, along the way, we had our share of missteps in introducing Lean and achieving ISO 15189 accreditation," recalled Waugh. "But most of what we did, we did well for several reasons.

"First, we gathered accurate data and used it to inform improvement efforts," he said. "Second, the partnerships we developed between lab management and lab staff were an important and lasting achievement.

"Third, and probably the most important element in our success, is something many clinical labs and pathology groups fail to recognize: There are great tactics and strategies outside of healthcare that we can adapt to healthcare and to clinical laboratory testing.

"That is why I advise labs to steal shamelessly from anybody they can," advised Waugh. "Here at HFHS labs, we will give your company full credit as long as we can adapt your ideas to solve problems in our lab that contribute to improved patient care and lower healthcare costs!" TDR

—Joseph Burns

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Dark Index

LabCorp Now Larger than Quest, Two Labs Report 2015 Earnings

CEOs at both lab companies also discussed PAMA lab test price reporting, FDA LDT regs

IN RECENT WEEKS, the nation's two largest lab companies reported fourth quarter and full-year earnings for 2015. The earnings reports reveal how the paths of the two companies are diverging.

The companies are diverging because of a major acquisition made in February 2015, by **Laboratory Corporation of America**. LabCorp bought **Covance Inc.**, in a deal valued at a minimum of $5.6 billion. Covance is a major player in the clinical trials business and offered synergies that LabCorp considered to be attractive.

Covance had revenue of $2.5 billion in 2014. When the Covance revenue was added to LabCorp's 2014 revenue of $6.0 billion, the combined company represented $8.1 billion in revenue. That is larger than the 2014 revenue of **Quest Diagnostics Incorporated**, which was $7.4 billion.

Thus, LabCorp has taken a major step to begin diversifying from its core clinical laboratory business. Currently, about 70% of LabCorp's revenue comes from clinical lab testing and the other 30% comes from the clinical trials business of Covance.

In reporting fourth quarter 2015 financial performance, LabCorp stated that its LabCorp Diagnostics (clinical lab) business had revenue of $1.55 billion, compared with $1.49 billion in Q4-2014. This was growth of 4.4%. Requisitions for the quarter increased by 1.8% (of which 0.2% came from tuck-in lab acquisitions). Revenue per requisition increased 2.2% for Q4-2015, benefiting from increased prices and tuck-in acquisitions.

For the full year 2015, LabCorp's diagnostics business generated revenue of $6.2 billion, compared with $5.9 billion in 2014. This was an increase of 4.9%. LabCorp did not disclose the full year 2015 increase in requisitions.

Quest Diagnostics Incorporated reported its earnings on January 28. Revenue was $1.85 billion for the quarter, an increase of 0.6% when compared with Q4-2014. The number of requisitions grew by 0.3% over the same quarter in the prior year and revenue-per-requisition increased by 0.1% during that same period.

For the full year, Quest had revenue of $7.5 billion, an increase of 2% over revenue of $7.4 billion in 2014.

PAMA And FDA Issues

During their respective conference calls to discuss the earnings reports, analysts asked the executives at both lab companies about two subjects of keen interest to most pathologists and clinical lab executives. One subject involves lab test price reporting to CMS, as required under the PAMA law. The other subject was about the FDA's proposed LDT guidelines.

LabCorp's CEO, David P. King, fielded the question about PAMA during his company's conference call. "...there were some very positive developments from our perspective in terms of strong letters going from the House, from the Senate and from the Chair and Ranking Member of the Finance Committee encouraging both the inclusion of at least

a selection of key hospital labs as well as a delay in the implementation of PAMA.

"We continue to believe that the inclusion of key hospital labs is absolutely vital to accomplish the Congressional purpose, which was a market-based price for Medicare," continued King. "Realistically, we're at the end of February and the rule has not been finalized. It's hard for me to imagine how this could be implemented in January of 2017 in a way that would be fair to our industry. So that's the [LabCorp] view on PAMA."

Lab Test Price Reporting

Stephen H. Rusckowski, CEO at Quest Diagnostics, responded to a similar question during his company's conference call. "As you have heard me say before, PAMA needs to be built on a representative view of the market. The current proposal limits the definition of an applicable lab to exclude a large portion of the market," he commented. "We also believe that a 2017 effective date will be a significant challenge for all parties.

"We believe they [CMS] did not get it right as far as the applicable labs; it needs to include hospitals," continued Rusckowski. "We've got a lot of support now from the **American Medical Association**, **American Hospital Association**, and Congress to help us with that."

FDA's LDT Regulation

In response to questions about the FDA guidelines for regulation of laboratory-developed tests, Rusckowski stated, "As far as the FDA, as I just mentioned, we continue to work with Congress on a legislative action. We believe that's the best approach for this issue. We believe it is a good start.

"And again, as a trade association, we believe... the FDA does not have the statutory authority to regulate laboratories," he emphasized. "...We're hopeful that we can come up with something with Congress, and we'll see where that leads us. But this is going to be done step-by-step... and we'll see where this evolves over the next several months."

LabCorp CEO King doubled down on these same points. Regarding the FDA LDT guidance, "We continue to work closely with Congress and [are] attempting to work with the FDA, as well, on a solution that would be a legislative solution, that would bring clarity to whatever regulation there is going to be of laboratory-developed tests," he stated. "And it would not depend on sub-regulatory guidance as a proposed long-term solution. We feel, again, we've been very clear about this; we feel very strongly that guidance is the wrong way to go about this and that we will continue to oppose that path."

Lab Acquisitions

Both lab companies told analysts and investors that they continue to be optimistic about lab acquisition activities as a way to grow clinical lab testing revenue.

To this point, Quest's Rusckowski noted that, "We've shared our view that hospitals will look to partner with us to develop and execute their lab strategy. In November, we announced the acquisition of **Hartford HealthCare's** outreach business. In December, we announced a professional lab services relationship with **Barnabas Health**, New Jersey's number one health system. Under this relationship, we will manage inpatient laboratory test services for seven of their locations throughout New Jersey."

During the LabCorp conference call, King declared, "...we feel great about the M&A pipeline and we certainly have plans to... acquire about 1% of revenue; that we're going to do tuck-in acquisitions that will account for about 1% revenue growth... and I think there is ample opportunity to execute on that."

Another common element during the conference calls of both lab companies was an emphasis on improving operations and cutting costs. This is a response to the ongoing decline in lab test prices by payers. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Sandy, Utah-based **Sure Genomics** is the latest genetic testing company to get a letter from the **Food and Drug Administration** asking why the company is marketing its SureDNA genetic testing kit to consumers without first obtaining clearance from the federal agency. The FDA sent the letter to Sure Genomics earlier this month and noted that the SureDNA test "...is intended to collect saliva samples for DNA sequencing and reporting of patient information such as disease risks and likelihood of drug reactions." Since 2010, the FDA has been sending similar warning letters to lab companies offering direct-to-consumer genetic tests. In 2013, a similar FDA letter to **23andMe** made national news.

ADD TO: *Sure Genomics*

Sure Genomics launched earlier this month. It offers to sequence a whole human genome for $2,500. It says, "the price includes full DNA sequencing by a CLIA-certified lab, HIPAA-compliant data storage, ongoing reports, DNA re-analysis every six months, and one-hour consultation with a trained genetics professional. After the first year, a $150 annual subscription fee covers data storage and semi-annual DNA analysis against new and clinically validated markers."

TRANSITIONS

• Kenneth J. Bloom, MD, is now Head of Oncology and Immunotherapy at **Human Longevity Inc.**, based in San Diego. He previously served at **Clarient, Inc.**, and **US Labs** and held clinical leadership positions at the **USC School of Medicine,** as well as **Rush Presbyterian-St.Luke's Medical Center**.

• **CellNetix Pathology & Laboratories, LLC,** of Seattle, named Kathleen Fondren as its new CEO. Fondren had served as COO of CellNetix since August 2014. Prior to that, she held administrative positions for 27 years at **Highline Medical Center** in Burien, Washington.

• **Asuragen, Inc.**, of Austin, Texas, appointed Colin Hill as its new Senior Vice President of Commercial Operations. Hill formerly was with **Ortho Clinical Diagnostics**, **Siemens Healthcare**, and **Bayer Healthcare Diagnostics**.

• **Stanford University School of Medicine** in Palo Alto, California, announced the appointment of Thomas Montine, MD, PhD, as the new Chair of the Department of Pathology, effective May 1. Montine is currently Chair of Pathology at the **University of Washington**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 21, 2016.

By Demand!

Genome Sequencing & Genetic Medicine: How It's Changing Healthcare and What Providers Can Expect Going Forward

Brad Perkins, PhD

Chief Medical Officer, Human Longevity, Inc.

With 24,000 whole human genomes sequenced, learn about new insights that inform clinical care

Here is a rare opportunity to understand how whole genome sequencing is poised to transform how we think about human health, and how that information will be used in medicine and healthcare.

Human Longevity, Inc., based in San Diego, has already sequenced 24,000 whole human genomes. In this exclusive session, you'll hear from Brad Perkins, PhD, about how this innovative company is analyzing this genetic data and working with various partners in different scientific and medical disciplines.

This session will put you front and center in the technology race to understand the human genome and put that knowledge to work to improve patient outcomes and enrich the quality of life. A co-founder of Human Longevity, Inc., is C. Craig Venter, PhD, who was one of the first to sequence a whole human genome back in 2000. It is another reason why Dr. Perkins will have unique viewpoints to help you get the insider's perspective on this vital topic. Register today and guarantee your place!

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