Volume XXIV, Number 7 Monday, May 15, 2017

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

New Business Models for Pathology, Clinical Labs

EXPERTS OFTEN PROCLAIM THAT THE U.S. HEALTHCARE SYSTEM is slow to change and slow to adopt the management approaches, operational innovations, and new technologies that other industries use.

One example is adoption of the quality management techniques that W. Edwards Deming and the Japanese developed by the 1970s. Today, these are described as Lean, Six Sigma, and process improvement. They are incorporated in the quality management system (QMS) of ISO 9001 and ISO 15189.

It wasn't until the 1980s that Americans "discovered" Deming and his management tenets gained widespread favor. When did healthcare providers wake up to these developments? Outside of **Intermountain Healthcare** in the late 1980s, it took about two decades—roughly the second half of the 2000s—before significant numbers of hospitals, labs, and physician groups began to apply these quality management principles to their operations.

This historical perspective is useful as pathologists and clinical lab executives consider how to organize their labs to meet the changing needs of hospitals, health systems, physicians, patients, and payers. Will the U.S. healthcare system give pathology group practices and clinical labs as much as 20 years to respond to their changing needs, as was true for adoption of quality management systems?

The obvious answer is: No! Today's patients no longer tolerate the poor service, bad quality, and medical errors that their parents and grandparents accepted without question. Today's younger generations expect speedy service that meets and exceeds their expectations. Payers expect appropriate utilization of clinical procedures, such as lab tests, that produce superior patient outcomes.

Speakers at this year's *Executive War College* earlier this month in New Orleans identified these market forces and urged pathologist-business leaders and lab administrators to recognize why new business models for lab testing will be required for the laboratory medicine profession to make the transition from a volume-based payment system to value-based reimbursement.

Moving into the future, the challenge will be for pathologists and clinical laboratory scientists to acknowledge the new imperatives in healthcare, then act quickly to orient their lab organizations to meet those expectations, In this cycle of change, providers will not wait 20 years for labs to catch up. TDR

Cautious Optimism Seen At Executive War College

Growth in precision medicine balances concern about cuts to lab budgets, test prices

CEO SUMMARY: Among the major themes to emerge from the more than 60 sessions and 100 speakers at this year's Executive War College on Lab and Pathology Management were the accelerating pace of integrated care, the growth of precision medicine, and use of big data to guide physicians. Other issues centered on labs' need to prepare for Medicare fee cuts coming in 2018 and how pioneering labs and pathology groups are creating new business models to add more value.

THERE WAS CAUTIOUS OPTIMISM among the 900 clinical lab managers and pathologists gathered in New Orleans earlier this month for the 22nd annual *Executive War College on Lab and Pathology Management*.

The caution stems from recognition that the nation's clinical labs and pathology groups face challenges from several sources, the most significant being the substantial revenue erosion coming from reductions to lab budgets and test prices.

The optimism springs from the growing awareness that now—more than ever—hospitals, physicians, and payers need the clinical expertise that only lab professionals can bring to diagnosis, selection of the best therapies, and patient monitoring. Research into the human genome, proteome, microbiome, and other relevant "omes" reinforced that optimism by fostering the development of new diagnostic assays that allow labs to deliver more value. Each generation of new assays is expected to have the capability to accurately detect disease and to improve therapeutic decision-making.

For attendees at the *Executive War College*, the optimism outweighed the caution for a simple reason. They recognize that healthcare's swift transformation requires a robust clinical laboratory and pathology service for success.

"By now, it is obvious to the clinical lab industry's best strategic thinkers that this country's healthcare system is moving at unprecedented speed toward: new models of care delivery, new forms of provider payment, and rapid growth in the use of precision medicine and the use

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

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

R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

of big data analysis," stated Robert L. Michel, Editor-in-Chief of THE DARK REPORT during his speech on day one of the *Executive War College*. "Precision medicine cannot succeed without the provision of robust, high quality lab testing services.

Precision Medicine

"Physicians' acceptance of precision medicine is the opportunity that clinical pathologists, clinical chemists, and lab administrators have wished for during the past 25 years," he continued. "Year after year, at lab meeting after lab meeting, pathologists and others would take the podium and point out that lab testing is only 3¢ on the healthcare dollar, but involved in the majority of decisions to treat and monitor patients.

"Yet, since the mid 1990s, these calls to action produced little change among the nation's labs," noted Michel. "That is no longer true. Today, a small, but growing, group of innovative labs is breaking with tradition and doing radically different things. Their common goal is to get outside the four walls of the lab and engage with clinicians to improve patient care."

One example of such innovation involves the lab divisions of five nationally-prominent health systems. They have organized under the name **Project Santa Fe** and are working individually and collaboratively to implement clinical programs that help physicians improve their use of lab tests and lab test data in ways that contribute to better patient care.

Value-Based Lab Model

The Project Santa Fe members are publishing the first of these clinical improvement studies in peer-reviewed journals. They have also articulated a value-based model for labs that they call "Clinical Lab 2.0." More information about these developments is presented on pages 10-15.

Speakers explained all of these themes during the opening general session of EWC. First to speak was Shubham Singhal, Senior Partner and Global Leader of **McKinsey and Company's** Healthcare Systems and Services Practice. He provided a strategic overview of the changes happening to healthcare in the United States.

Singhal discussed two trends that are having an effect on clinical labs. He said that "atomization of networks" was a major trend. He showed data demonstrating how, each year, health insurers report narrow networks reduce costs, allowing insurers to offer lower premiums. As a result, narrow networks are here to stay. Therefore, labs—and other providers—that want to be in these networks must develop clinical services that improve patient care and lower costs.

New Business Models

Singhal also explained how healthcare needs new business models and new regulations to make these models possible and how these models could affect labs. Examples of these new business models are ambulatory surgery centers and retail clinics that are contributing to better patient care at less cost.

In response to Singhal's call for new business models in healthcare and lab testing, Khosrow Shotorbani, CEO of **Tricore Reference Laboratories** of Albuquerque, N.M., introduced the concept of "Clinical Lab 2.0" that members of Project Santa Fe are developing. *(See pages 10-15.)*

He was followed by Myra Wilkerson, MD, Chair, Division of Laboratory Medicine at **Geisinger Health** in Danville, Penna. She discussed the range of new clinical service initiatives at the health system, including the creation of a "food pharmacy" as one way to improve population health in a proactive manner.

Lab administrators and pathologists who want to hear these sessions, and the more than 60 other EWC presentations, can obtain audio recordings online at: *www.executivewarcollege.com*. TDR

Technology Update

Cyber Thieves Hit UK Hospitals During Ransomware Attack

Organizations in more than 150 countries hit, shows vulnerability of world's computer systems

AT LEAST 48 HOSPITALS, PHYSICIANS' OFFICES, and ambulance companies in Britain's **National Health Service** were among the many victims of a cyberattack Friday that affected tens of thousands of computers in as many as 150 countries, *The New York Times* reported. Hackers used malicious software developed by and stolen from the U.S. National Security Agency, the Times added.

This attack is a warning to clinical laboratories and anatomic pathology groups that they should take steps to protect their information systems from ransomware and cyberattacks.

On Friday, ransomware infections encrypted documents, files and databases of victims and demanded an immediate payment in order for victims to regain access to their files. One news report said the ransom was $300 per machine, to be paid via Bitcoin.

UK Hospitals Hit Hardest

In the United Kingdom, a number of healthcare organizations were victims of the attack. "Thousands of operations at National Health Service facilities were canceled Friday, ambulances were diverted from affected hospitals, and patients waiting for routine outpatient appointments and even chemotherapy treatment were told that their records could not be accessed and they would have to go home," *The Los Angeles Times* reported.

By Saturday, the NHS said most of its health centers were back in operation. But at least six sites had not regained access to their data and files.

Most Attacks Go Unreported

The ransomware infections were extraordinary because of the great number of computers affected in one day across the globe. Such attacks happen regularly and often go unreported.

The Guardian explained that ransomware has hit UK hospitals regularly for some time. In February, a report showed that ransomware hit 88 of the UK's 260 NHS trusts from the middle of 2015 through the end of last year. **Imperial College Healthcare** suffered 19 attacks in 12 months.

After one-third of the UK's hospital trusts were attacked in 18 months, some experts asserted that the NHS hospitals were attractive targets for this form of computer crime.

More Funding Required

The experts said the NHS has failed to provide its hospitals with the necessary funds to keep IT systems updated—and thus more protected from cyberattacks.

These facts are useful for pathologists and lab administrators seeking to keep their lab's IT systems secure. Hospitals in the UK may be more vulnerable to cyberattacks than US hospitals because American hospitals and labs invest more

money in computer security and are more diligent about updating software to repel such cyberattacks.

Hackers Go 'Phishing'

To defend against these attacks, clinical labs and pathology groups need to remind employees to be vigilant about opening email messages from unknown sources. Friday's ransomware attacks began with what are called "phishing" email messages in which recipients are fooled into clicking on phony links.

"In some cases, the malware was delivered in spam emails," *The Washington Post* explained. "Once one computer in a system was infected, the malware spread to other machines on the same network."

The ransomware attackers reportedly used a vulnerability in computers running the **Microsoft** Windows operating system. Once a user clicked a link, the attacker would deliver files that encrypt the user's data. Microsoft was reported to have patched the software.

After the system was hit, the user cannot access the data until paying a ransom, said to be $300 to start. Over time, the ransom demand rises because the hackers designed the malware to increase the amount on a set schedule and threatened to erase the data after a predetermined cutoff time. These steps raised the urgency of the attack and increased the likelihood that victims would pay, the Times reported. Computers that were not backed up were said to be the most vulnerable.

Expect More Cyberattacks

Some experts believe that the ransomware attacks that took place on Friday will generate $1 billion in payments to the cyber thieves. Since these crimes are low risk with a high return, lab executives and pathologists should expect to see ongoing attacks upon their labs' computer systems. TDR

—Joseph Burns

Medical Labs Are Targets of Cyberattacks, Ransomware

CYBERATTACKS ON MEDICAL LABORATORIES have major consequences, not the least because any lab that is attacked must typically go to manual ordering and reporting to maintain testing services.

Often, what makes a clinical lab or pathology group vulnerable to a cyberattack is that it continues to run older software on its computer systems. Some cyberattacks are reported to be directed at organizations that run the outdated Microsoft Windows XP operating system.

In January 2016, the medical laboratory at the **Royal Melbourne Hospital** in Australia, found that a computer virus had shut down its system, which ran on Windows XP. To maintain clinical services, the lab staff was forced to use paper-based methods, among other solutions.

After crippling the pathology department, the computer virus then spread throughout the Royal Melbourne Hospital by targeting computers running Windows XP. At that time, the operating system had been in use for 14 years. Microsoft no longer supports Windows XP.

Just weeks later, in March 2016, **MedStar Health** in Washington, D.C., acknowledged that a ransomware cyberattack forced it to shut down computers at 10 hospitals. At the time, *The Washington Post* reported that computer screens at MedStar were showing a message demanding payment of 45 Bitcoin, approximately $19,000, in exchange for a digital key to unlock the data.

A MedStar physician stated that the criminals gave MedStar employees the option of paying 3 Bitcoins ($1,250) for a key to access one of the locked computers, *The Baltimore Sun* reported.

IT experts regularly advise that the best defense against cyberattacks is to keep all computer systems up-to-date by installing patches and upgrades regularly.

Proposed Bill in Congress Would Regulate LDTs

New name would be '*in vitro* clinical tests,' new process for FDA approval would be instituted

CEO SUMMARY: As one response to the FDA's efforts to regulate laboratory-developed tests, some large labs and IVD manufacturers organized the Diagnostic Test Working Group. It has engaged with congressional officials to draft legislation that would establish a risk-based review of both laboratory-developed tests and in vitro diagnostic test kits, changing current regulatory protocols for manufacturers and establishing new requirements for labs within the FDA—naming these tests in vitro clinical tests (IVCTs).

ANY PROPOSAL TO REGULATE laboratory-developed tests (LDTs) has a degree of controversy within the clinical laboratory, device manufacturing, and patient communities. That controversy stems from competitive business interests between labs and manufacturers and vocal concerns among patients who want the promise of precision medicine with specific protections in place.

Such is the case with the latest idea to regulate LDTs. In March, U.S. Reps. Larry Bucshon, MD (R-Ind.) and Diana DeGette (D-Colo.) released a legislative discussion draft called the Diagnostic Accuracy and Innovation Act (DAIA) for comment. *(See TDR, April 24, 2017.)*

The approach of the proposal has the support of the nation's largest labs and would formally allow the FDA to regulate laboratory tests. "However, this bill does not use the term 'laboratory-developed test (LDTs)," stated Julie Scott Allen, Senior Vice President of the **District Policy Group** in Washington, D.C. Allen represents the **National Independent Laboratory Association (NILA)**. "Instead, this bill would create another new classification of tests, to be called *in vitro* clinical tests (IVCTs)."

In an interview with THE DARK REPORT, Allen outlined important factors for labs to consider when assessing the current language of the DAIA. The business concerns are substantial, particularly for smaller labs entering or expanding within this market.

New FDA Oversight Role

"In this proposed bill, lab directors are likely to be concerned whether their tests will be subject to new requirements, given limited grandfather protections," she noted. "Labs will also need to understand: a) how their lab will meet new FDA requirements and related inspections; b) how the FDA will respond if it finds something wrong with a test; and, c) ultimately how much labs will need to pay in user fees to support the new FDA regulatory structure.

"The foundation of this bill is the proposal that the Diagnostic Test Working Group (DTWG) outlined last year," she explained. "The DAIA incorporates that same approach. Last year, the House Subcommittee of Energy and Commerce

put out a working draft of the DTWG's proposal. This latest version in the DAIA is the second or third iteration of that working group's approach.

"Through this process, the principles of the DAIA are the same: That the FDA would be the overriding authority for regulating the clinical validity of tests, and that authority would rest in a new infrastructure within the FDA that does not yet exist," said Allen. "Also, in an effort to level the playing field for device manufacturers and laboratories, diagnostic test kits would no longer be regulated as medical devices and thus subject to the 510K approval process.

"The fact that IVCTs—whether the IVCT is a manufactured product or a lab protocol—would not be classified as medical devices is key to this bill," she continued. "That's because labs would not want to submit tests for FDA pre-market clearance under the same requirements that the agency uses to review and approve medical devices.

"That pre-market clearance review and approval process is time-consuming, costly, and thus potentially fatal to a lab developing a new diagnostic test," added Allen. "However, manufacturers, which would still be subject to such requirements when developing new assays, don't believe labs should get a pass.

IVCTs Are Not Devices

"Even if IVCTs are not regulated as medical devices, the draft legislation would authorize the FDA to regulate these tests," noted Allen. "That could be problematic for a couple of reasons.

"First, within the FDA, the same individuals involved in the oversight process for medical devices—many of whom were involved in recent FDA LDT oversight proposals issued through draft agency guidance—will oversee these tests," she explained. "These individuals are likely to have the same kind of thinking about the type of clinical evaluation these tests require.

"Second, there will be consideration about the validity of the data or studies the labs submit to support these tests," Allen added. "The DAIA proposal seeks to impose limits on how far the agency goes by limiting how much time the agency has to make decisions about whether the data supports a lab's claims to validate a test. If the FDA doesn't act in a certain amount of time, the approval goes forward anyway.

FDA Speed of the Essence

"The act is designed to minimize concerns about how much time it will take the FDA to evaluate IVCTs," she explained. "There are provisions in the bill that seek to have the tests' risk level reduced if the test meets certain metrics.

"Those are some features of the draft bill that labs are likely to support," Allen said. "But this draft bill raises lots of questions that should concern patients and should also concern laboratories.

"For instance, there is no language in the bill to outline what happens if something goes wrong with a test. Would additional review be required?" she asked. "Or should a test's original risk level be raised until it is proven safe? If so, what does that process look like?

"These issues should not be left unaddressed because, once a new complex regulatory structure is set in place, the government can go further," observed Allen. "Any discussion about the oversight of lab tests must also ensure patient protections. We do not want to have something bad happen with any IVCT and then have that one bad example cast a black eye on the industry.

"Labs will want to ensure that there are checks and balances in any bill that moves forward," she added. "Checks and balances are important because we know, for instance, that when more stringent protections are imposed under a new law, innovation can be stifled. And no one in the lab industry wants to limit innovation.

Could Proposed New Federal Bill for LDTs Create Overlap with CLIA Regulations?

ONE AREA OF CONCERN REGARDING the Diagnostic Accuracy and Innovation Act (DAIA) is whether it will create overlap among agencies that regulate labs, said Julie Scott Allen, Senior Vice President of the District Policy Group in Washington, D.C.

"Labs already have CLIA oversight, and FDA review would be a new process. Would those two be duplicative in any way?" asked Allen, who represents the National Independent Laboratory Association. The draft legislation attempts to compartmentalize the oversight, leaving all lab operations to CLIA, but for a smaller laboratory, would the defined review processes of both agencies work, given how these labs are structured?

"NILA's position has been that, with the exception of high-risk tests, CLIA oversight should continue to be the core regulatory oversight process for laboratory-developed tests/protocols," commented Allen. "NILA believes that CLIA should be modernized because it has been around since the late 1980s, and the testing market has evolved greatly since then. It could be that some simple changes could be made to address many of these issues.

"For example, we should be talking about how proficiency testing plays a critical role in test oversight, given the importance of PT in ensuring how a test performs in the field," she said.

"The current PT process would not currently work for some lab IVCTs, but could work under a modified PT program," Allen said. "NILA says systems like the one used for PT could be a practical way to ensure safety of new lab IVCT tests without breaking the bank for labs. And, a PT-like review system already comes with the infrastructure that labs understand.

"Rather than trying to boil the ocean to create an entirely new costly and complex regulatory infrastructure at a time when the Trump Administration and incoming FDA Commissioner want to reduce the federal regulatory infrastructure, it may be more palatable to simply make improvements to current operations, like CLIA oversight and modernization of proficiency testing," concluded Allen.

"At the same time, the lab industry has the goal of ensuring that tests are accurate and that there are protections for patients," she said.

"To date, a large number of labs have been leery of supporting such a new bill," noted Allen. "That lack of support is because someone needs to pay for this new process to review IVCTs. Under this bill, that new process would be incredibly expensive because the bill would authorize the establishment a new operation within the FDA. As a result, labs would have to pay new first-time user fees.

"Getting IVCTs through a new process quickly will require more staffing than currently exists at the agency," she added. "To do so, the bill calls for user fees and other undefined funds, which labs don't pay now.

"User fees can be high, and it's unclear how a lab that has very few tests would need to pay into such a new system," commented Allen. "Or, would a laboratory that very rarely introduces a new test need to pay for this new system? If it has one test, would it need to pay a substantial fee to the agency?

"In addition to these issues, there is the concern about the existing payments that are required of all laboratories," commented Allen. "At a time when Medicare and private payers are cutting the prices they pay for lab tests, it is not the most auspicious time to introduce new user fees." **TDR**

—Joseph Burns

Contact Julie Scott Allen at 202-230-5126 or Julie.Allen@dbr.com.

CEO SUMMARY: Moving away from volume-based care will not be easy for clinical labs. After all, high volume sustains labs. But labs seeking to transition away from fee-for-service to value-based care must have a seat at the table where decisions are made, said a lab CEO who is part of Project Santa Fe, which wants to foster the movement to what's called Clinical Lab 2.0. If lab directors are not involved in developing the next generation of lab medicine, then others will decide the lab's fate, the CEO said.

Five health system labs using Project Santa Fe to demonstrate value

CEO Describes Characteristics Of the Clinical Lab 2.0 Model

First in a Series

EVERY LAB IN THE UNITED STATES shares a common predicament in the next few years: how to make the transition from fee-for-service payment to value-based reimbursement without going broke.

This transformation in healthcare is good news and bad news for clinical laboratories and pathology groups. The good news is that new genetic knowledge will give labs molecular diagnostic and genetic testing tools that deliver incredible value to physicians and patients.

The bad news is that labs will no longer get fee-for-service payments for each lab test. Instead, under value-based shared savings, shared-risk, and bundled payment models, labs will need to demonstrate the value they contribute to improved patient outcomes and reduce the total cost of care to earn an adequate proportion of the global payment that all providers will share.

"This is often described as the transition from volume to value because this trend will fundamentally change how all labs are paid," said Khosrow Shotorbani, MBA, MT(ASCP), CEO of **TriCore Reference Laboratories** in Albuquerque, N.M., in his presentation at the 22nd annual *Executive War College* earlier this month in New Orleans.

"This shift from volume to value also will create new winners and losers in the clinical lab industry," he declared. "Not every lab organization will take the timely action required to introduce the value-based lab testing services that hospitals, physicians, and payers will need.

"New and different forms of value-based care, such as capitation and bundled-payment, are already replacing fee-for-service," stated Shotorbani. "Yet only a handful of labs currently have plans for surviving and thriving under these new payment models. TriCore Reference Laboratories wants to lead this transition by developing lab test services and products that deliver added value in non-traditional ways to all the healthcare stakeholders, whether they are patients, physicians, hospitals, payers, or the local community."

As part of this effort to show payers and healthcare policymakers that better use of lab tests results in better patient care and lower costs, Shotorbani was one of the organizers behind a demonstration project called Project Santa Fe last year. This project involves the lab divisions of five nationally-respected health systems. They are:

- **Geisinger Health**, Danville, Penna.
- **Henry Ford Health**, Detroit, Mich.
- **Kaiser Permanente-Northern California**, Berkeley, Calif.
- **Northwell Health**, Lake Success, N.Y.
- **TriCore Reference Laboratories**, Albuquerque, N.M.

The common interest of these five lab organizations is to validate the concept of Clinical Lab 2.0. This model for medical laboratory testing is designed to deliver undisputed value that earns an adequate share of reimbursement from bundled payment, budgeted payment, and similar value-based reimbursement models.

"The labs involved in Project Santa Fe came together because they recognized that, if lab tests continued to be considered a commodity, the consequence would be further cuts to their lab budgets," Shotorbani noted. "The goal of Project Santa Fe is to have these five nationally-respected lab divisions demonstrate the value of lab tests on total care, across the spectrum of diseases and health conditions.

"These demonstration projects will be conducted as well-designed clinical studies with careful collection of data from before, during, and after the study," he said. "Then, two things will happen.

"First, the labs will publish the results of these clinical studies in peer-reviewed journals," continued Shotorbani. "This means that health system administrators, health insurance medical directors, and healthcare policymakers will learn about the substantial improvements in patient outcomes and the potential for proper utilization of lab

tests to lower the overall cost-per-episode-of-care significantly.

Bending the Cost Curve

"Second, the five Project Santa Fe lab organizations are committed to attempting to replicate in their own health systems the success of one member lab's clinical study involving improved utilization of lab tests," continued Shotorbani. "As this happens, the participating labs will diligently gather data and work together to publish the outcomes in peer-reviewed medical journals.

"Our belief is that these clinical-study efforts—when published in scientific and health policy journals—will provide convincing evidence to policymakers and clinical leaders that clinical labs have great potential to bend the cost curve downward and improve patient outcomes," he said. "Medicine is driven by data and the results of well-designed studies and clinical trials. Our Project Santa Fe labs are already engaged with their clinicians in these efforts and the first clinical success story is being prepared for submission for review and publication.

"It's imperative that lab directors and pathologists act quickly on projects that demonstrate and deliver more value from lab tests," he added. "That's because health systems are already reorganizing specifically to deliver value-based care. During these formative months, labs must be involved in these efforts."

Engaging With Leadership

It is important for lab leaders to become engaged with their health systems' administrative leadership, Shotorbani urged. "Ask yourself: Does my lab have a seat at the table in my health system's strategic plan?" he said during his presentation. "If my lab does not have a seat at the table, then we are on the menu for cuts. Think about that. If our labs are missing from these discussions, we're not involved in health system strategic thinking. That means another provider is having that conversation and grabbing for a bigger share of the value-based payment.

"Another important question that your lab should ask is: 'Who is our champion in the C suite?" he suggested. "Does my lab have an advocate at the highest levels of our organization?"

"It's time for pathologists and lab directors to think strategically in a way they have never done before," Shotorbani advised. "I'm going to challenge the traditional wisdom. Today, clinical lab testing is a $70 billion industry that, in my opinion, is based on a simple transactional process: Accept a laboratory test order, transmit a laboratory test result. Labs insist that they cannot deliver a value unless they have an order.

Mining Data for Value

"At the same time, labs sit on a massive volume of data, yet they do nothing with those data," observed Shotorbani. "These data have inherent potential because of their predictive value.

"But the lab industry has yet to create a business model around such data because our workflow is traditional: order in; result out," he added. "Look at our operations: Our labs are not doing anything differently today than what we've done for the past two decades.

"Even in our own shop, we mostly do the same thing—although, in the past three years—we have initiated fundamental changes designed to allow us to create value from our lab test data," he noted. "Our lab has a ways to go, but our change of direction has now commenced, guided by the concept of Clinical Lab 2.0.

"At this moment, few labs are moving away from their traditional volume-based business model," warned Shotobani. "Academic medical centers have been particularly slow. Value-based care goes against the grain of academics. For years, they basically pursued high-margin, high-cost tests because the lab was an esoteric area for research. That is basically what academia does.

Academic Journal Article Describes Clinical Lab 2.0, Sante Fe Project Goals

AN ARTICLE PUBLISHED LAST MONTH in *Academic Pathology* (Sage Journals, April 18, 2017), described Project Santa Fe and the efforts of the five labs involved in the project to develop the next generation of clinical laboratories, which they call Clinical Lab 2.0. A table was included which compared the attributes of Clinical Lab 1.0 compared to Clinical Lab 2.0.

Clinical Lab 1.0: Transactional	Clinical Lab 1.0: Integrative
Sick Care	**Health Care**
• Receive test sample • Result test sample	• Population health using lab data • Total cost-of-care leveraging lab data • Time-to-diagnosis • Optimization of: diagnosis, therapy, monitoring • Care optimization • Screening optimization
Disease Screening	**Risk Management**
• Protocol-driven • Scheduled by treating physician • Lab is derivative	• Identification of risk • Real-time tracking of risk • Escalation/de-escalation of acuity
Wellness Programming	**Wellness Programming**
• Managed by treating physician • Lab is derivative	• Gaps-in-care closed using lab data • Outcomes of program using lab data **Predictive Analytics** • What will happen? When? Why?
Existing Payment Models	**New Payment Models**
• Lab is a commodity • Value is cost-per-test	• Value of lab for total cost-of-care

"Academic labs typically wanted to build their volume of molecular and genetic tests, and that volume went up sharply," he added. "But then what happened? As academic labs increased their molecular and genetic test volumes, the payer market changed. Payers began building barriers against new molecular and genetic tests while taking the first steps to introduce utilization constraints and value-based reimbursement arrangements.

"That same change is now happening in every segment of the lab industry," he said. "As payers move from volume to

value, the conversation in your lab should no longer be about the margin of the test. It needs to be about the disease burden in the population and how your lab can contribute to better outcomes.

"Your lab team should begin to ask: 'In our community, who is assessing the disease burden in the population? Can we leverage lab test data to help them with that problem?'" advised Shotorbani.

"At TriCore, our efforts to supply solutions have given us an interesting insight," continued Shotorbani. "We've learned that, by matching data from high volume, low-cost lab tests with other clinical and demographic data, we can generate considerably more value for the healthcare system! In the era of population management and precision medicine, the high-asset, high-margin tests are still useful, but they are secondary.

"This is why, in the Clinical Lab 2.0 model, the lab must become adept at producing actionable information," he explained. "Further, the lab can deliver this actionable data to more than the referring physician. It can work with regional health plans, the state Medicaid program, and with local hospitals and health systems.

Importance Of HgA1c Test

"As health systems change their perspective on which lab tests have value, the lab test for hemoglobin A1c, for example, becomes much more important," he said. "It has value because it's used to manage the care of diabetic patients under capitation or a bundled payment model.

"With bundled payment, that A1c test allows labs to deliver value in ways they could not do so before," observed Shotorbani. "A1c results have inherent, immediate clinical value. But, a lab can *go the next step and reveal the trend* in sequential A1c values to a health provider or health plan to help them put the focus on at-risk patients.

"We have used delta checks for decades inside the lab as part of quality checks. Why not move these out to our clinical colleagues?" he suggested. "Individual patient delta checks are inexpensive, high-value, precision medicine that the lab can deliver.

Assessing Disease Burden

"Today, the nation's most innovative labs are taking the first steps to solve the problem of measuring the disease burden of a population in ways that are clinically-actionable," Shotorbani added. "Take, for example, how the lab at Northwell Health is collaborating with physicians to achieve earlier and more accurate diagnosis of inpatients with acute kidney injury (AKI). There are other examples emerging from the labs participating in Project Santa Fe.

"For this presentation, I want to challenge the conventional wisdom on another point," he stated. "For decades, we have all chased the notion of the core lab concept. Under this concept, we aim to eliminate duplication of testing in multiple lab sites because in the core lab we can increase our volume, decrease excess capacity, and maximize our contribution to the profit margin of the hospital or health system.

"None of these concepts will disappear and the core lab is foundational to Clinical Lab 2.0," continued Shotorbani. "But, as health systems put greater emphasis on managing the health of populations, there will be greater value from point-of-care testing (POCT) at the right place and for the right reasons.

"As TriCore moves forward with our strategic plan, we recognize that our lab can contribute increased value by providing POCT in ways that make the test results actionable at the point of care," he noted. "Yes, POCT increases our lab's cost per unit, but it contributes to coordinated population health management because it gives clinicians a faster answer for diagnosis and makes it possible to begin the right therapy while the patient is still in the clinic.

Longitudinal Lab Data for Value-Based Care Requires Enterprise-Wide Master Patient Index

ANYONE WHO HAS MANAGED a stock portfolio knows that the best predictor of performance is not a snapshot. Instead, investors need a long-term view of performance over time, said Khosrow Shotorbani, MBA, MT(ASCP) CEO of TriCore Reference Laboratories. Healthcare is similar.

"As we move away from Clinical Lab 1.0 to Clinical Lab 2.0, we need data in a longitudinal view," he explained. "That means we need data on everything we can collect on a patient, including inpatient, outpatient, outreach, ambulatory, emergency department, and urgent care. To achieve this, we need innovative technology and the architectural support to develop an enterprise-wide master patient index. The EMPI is the longitudinal view of every patient in the system.

"The EMPI is like the foundation of your home," he explained. "That's what everything else is built on. If your laboratory doesn't have a foundational EMPI, then you are either under-counting or over-counting, neither of which will work.

"Once you have an EMPI, you can move toward using the data in your EMPI to do analytics," he said. "The EMPI will have real-time data you can use to develop a business model of the future.

"We want to augment actuarial data with lab data so that we can do predictive modeling for end-targeted interventions," he added. "Here is what may be the most important hypothesis of our strategic plan of moving from volume-based to value-based care: Clinical Lab 2.0 enables us to do risk stratification of patients so that our lab can identify any gaps in care and help manage the high-risk patients with targeted interventions before they become high-cost patients."

"In the future, we expect point-of-care testing will be a much bigger part of TriCore's cost infrastructure," continued Shotorbani. "With POCT, we can facilitate real time interventions that have the potential to keep many patients out of the hospital. That's different from the traditional approach where our goal was to get patients into the hospital, get them fixed, and then bill them or their insurers.

Serving A New Customer

"MBAs will recognize that moving to POCT will require labs to recognize that we have a new customer," he predicted. "In business school, the first question you're asked is, 'What is our business?' Next it's 'What should be our business?' Then it's, 'Who's our customer and who should be our customer?'

"Remember those core strategic questions," he advised. "Because during the transformation of the healthcare system, your lab's customers will be different.

"Under Clinical Lab 2.0, our labs will deal with organizations that carry the financial risk of delivering care," he noted. "In some cases, hospitals and health systems will bear the financial risk. In other cases, physicians will bear risk and in some places, accountable care organizations (ACOs) will be risk-bearing.

"That includes two-sided risk for many ACOS, meaning they will benefit financially if they keep costs down, but they will pay penalties if costs go above a certain level," explained Shotorbani. "For all these reasons, every lab needs to pay attention to who is the customer. Clinical Lab 2.0's diverse customer set will include healthcare professionals across the entire industry, such as payers, CMOs, CQOs, community healthcare professionals, and care managers." TDR

(To be continued.)

—Joseph Burns

Contact Khosrow Shotorbani at 505-938-8924 or khosrow.shotorbani@tricore.org.

Digital Pathology Systems Will Create Opportunities

➤Community pathologists discuss benefits of being early adopters of digital pathology

➤➤CEO SUMMARY: Advanced Pathology Associates, a 15-member private pathology group practice, had the distinction of generating data for the clinical study that Philips submitted to the Food and Drug Administration for review of its whole slide imaging system. Following the FDA's decision to clear this system for sale earlier this month, and informed by their study experience, the pathologists at APA are interested in acquiring this system. They expect it will help them expand case referrals, among other benefits.

NOW THAT THE FDA HAS CLEARED the first digital pathology system for use in the primary diagnosis of biopsied and surgically-excised tissue, every pathology group and pathology lab must answer this important question: Should we wait or adopt early?

One pathology group that made the decision to be a first-mover is **Advanced Pathology Associates** (APA) in Rockville, Md., which is interested in acquiring this digital pathology system. It manages a central pathology reference laboratory and its 15 pathologists cover seven hospitals.

➤Digital Pathology Benefits

"For pathologists considering this investment, the most obvious benefits of digital imaging systems are the promise of improved workflow, the ability to consult remotely, and fewer lost or broken glass slides," stated Nicolas Cacciabeve, MD, APA's Managing Partner. "However, whole slide imaging systems offer other advantages that are less obvious, but also significant."

In 2015, Cacciabeve's group used the **Philips** Intellisite Pathology Solution (PIPS) as a community pathology group practice study participant to generate data for the pre-market application that Philips submitted to the FDA. Last month, the agency cleared the system for sale to pathologists. *(See TDR, April 24, 2017.)*

"Because we had the opportunity to be hands-on with this digital pathology system, we saw how it changes daily workflow, improves the ergonomics of reading cases, and contributes to increased productivity," noted Cacciabeve. "Its use also opens new opportunities for our pathologists to add more value—whether it is handling more complex cases through real-time consultation or through better data management and image retrieval, or freeing up pathologists to get out of the lab to collaborate with clinicians.

"We know these benefits are possible because of what we learned during the trial," he said. "We learned, for example, that the PIPS can produce and manage a lot of images. That was important to us.

"For the trial, we had 500 cases and, for those cases, we scanned several thousand slides," he explained. "During the nine-month trial that ran from April 2015

until February 2016, we had few slides that didn't scan. "Operationally, that told us the platform was stable and ready for real-world use because we didn't have software or technological scanning breakdowns that would stop production.

Improving Workflow

"Our practice manages a reference laboratory where the slides were scanned," he said. "We wanted to get used to incorporating digital imaging into our workflow. We scanned slides overnight and found there was no slow down. The images were ready for us the next morning, which told us that we could incorporate digital imaging into our workflow without a problem.

"One change we're considering once we have our own PIPS involves looking at our current process of producing slides in large batches," Cacciabeve added. "Our lab manager began his career as a histology assistant technologist and has over 25 years in the field.

"With a digital pathology system, we plan to move to more and smaller histology batches each day so that the flow is almost continuous," he said. "If we do it that way, we will shorten the time required for histology images to get to a pathologist, which would be a big improvement over our current system of delivering slides by courier.

The Value Equation

"Clearly, there are many advantages to using digital images, and perhaps the only disadvantage is the cost of these systems," stated Cacciabeve. "That's something we'll evaluate. We'll add the cost of the equipment, but we can subtract courier costs.

"Then, we'll look at the cost-to-value ratio," he explained. "Specifically, we recognize that, even if scanning slides to create the digital images costs more money, we may get back more in value—either through new opportunities in business or through a better quality product. We will evaluate that over time."

About Advanced Pathology Associates

ADVANCED PATHOLOGY ASSOCIATES IN Rockville, Md., is a community practice of 15 board-certified pathologists serving seven hospitals in suburban Maryland and Virginia.

"We also manage an anatomic, centralized pathology reference lab and provide medical directorship for a proteomics laboratory and for a molecular laboratory," said Managing Partner Nicholas Cacciabeve, MD. "We have specialists in cytopathology, gastrointestinal pathology, head and neck pathology, hematopathology, ob-gyn pathology, and pediatric pathology."

The 17-year-old practice serves the following hospitals in Maryland:

- **Shady Grove Medical Center**, Rockville
- **Washington Adventist Hospital,** Takoma Park
- **Laurel Regional Hospital**, Laurel
- **Prince George's Medical Center**, Hyattsville
- **University of Maryland Charles Regional Health Center**, La Plata

In Virginia it serves these hospitals:

- **Reston Hospital Center**, Reston
- **Stone Spring Hospital**, Dulles.

APA's pathologists saw an opportunity to use digital pathology to change their existing practice model to increase case referrals and expand subspecialty offerings. "Networks of digitally-linked pathologists with sub-specialty expertise can provide consultations to smaller hospitals, which, in the past, had to send pathology consultations to academic centers," Cacciabeve explained.

"Based on our experience in working with digital imaging, we believe its use will ultimately make pathologists more efficient and improve accuracy in their diagnoses," he said. "Primary diagnosis using digital images is just the beginning.

"Digital imaging of tissue is the foundation of 'computational pathology' or the application of computer software algorithms to the digital image that will highlight or even recognize patterns predictive of disease," he suggested. "This information can be quite useful to a pathologist evaluating tissue.

"In addition, molecular markers producing signals identifiable in the digital tissue image can inform our clinicians of the correct therapy, such as a chemotherapeutic drug most effective in patients with the molecular marker identified in a tumor," Cacciabeve added. "Pathologists will work closely with groups of physicians to prescribe treatments and predict outcomes.

"In the healthcare system of tomorrow that pays providers for value, pathologists will need to leverage the many other things we currently do in hospitals—such as managing data and working on quality initiatives—in ways that improve patient care and contribute to lower costs," he explained.

"Digital imaging will change how pathologists access cases and make diagnoses," noted Cacciabeve. "As the cost of imaging goes down, the traditional role of a pathologist in a small office with a microscope will change rapidly because digital imaging will allow pathologists to share and consult on cases nationwide, even if the pathologist is working in a community hospital or a small town.

Easier Collaboration

"In the past, we would have shipped slides to consulting pathologists, which adds time and expense," he commented. "Alternatively, the logistics and costs of getting a group of pathology experts together to review cases in real time is prohibitive. With digital images, these are no longer limiting factors.

"Not only will the pathology profession benefit, but individual pathology groups will benefit from digital imaging as well," added Cacciabeve. "For example, at APA, we offer ourselves as a group that collectively has a lot of experience and expertise in pathology. The digitization of pathology images that a virtual network of pathologists can access, share, and consult on in real time, will help generate substantial benefit, as well as potential new sources of revenue for our group.

Lessons Learned

"In addition to the cost, there's another factor that a pathology group evaluating digital pathology must consider: it takes time for pathologists to get comfortable with the software," noted Cacciabeve. "In the beginning, our pathologists were not as efficient as they would become once they were familiar with how the system works. That's a time-limited problem that will go away with practice, particularly with younger pathologists. Older pathologists may struggle a bit more.

"Another issue involves the technology itself," he added. "Despite non-inferior performance against glass slides, in a few cases we would have preferred having more depth of focus. As the technology improves, that issue may go away.

"Having used the PIPS for nine months, we knew there would be some disadvantages, but the advantages outweighed them," he said. "Having accepted the premise that digital pathology is coming whether we want it or not, we want to participate in it.

"I tell everyone in my practice: The only thing I can promise is that things will change," he said. "If you fight change, you will not succeed. You have to be willing to adapt to change.

"It's the same with digital pathology," continued Cacciabeve. "As pathologists, if we focus on finding the best way to deliver patient care, then we'll embrace change as it comes and digital pathology systems will improve quality and make us more efficient." TDR

Contact Nicolas Cacciabeve, MD, at 240-826-6096 or ncacciab1@gmail.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

There is a new development in one of the whistleblower lawsuits filed against several lab companies that offered specialty cardiology tests. Earlier this month, the **Department of Justice** announced a settlement with **Quest Diagnostics** involving its acquisition of **Berkeley HeartLab**, which was acquired by Quest in 2011. The DOJ said that Quest agreed to pay $6 million to settle the *qui tam* case, which was originally filed in 2011 by physician Michael Mayes, MD.

MORE ON: *Berkeley HeartLab*

Quest Diagnostic's acquisition of Berkeley HeartLab came about in an indirect manner. From October 2007 through May 2011, Berkeley was a wholly-owned subsidiary of **Celera Corporation**. Then, in May 2011, Quest purchased Celera and thereby also became the owner of Berkeley HeartLab. Court documents in the whistleblower case describe how it took Quest until January 2012 to discontinue the alleged illegal inducements that were offered to physicians by Berkeley HeartLab. According to court papers, it was shortly after that date that Berkeley HeartLab became insolvent, in part because physicians directed their lab test referrals to other labs that continued to offer similar inducements.

CONSUMER USE OF GENE TESTS A THREAT TO INSURERS

23andMe recently obtained clearance from the **Food and Drug Administration** to sell certain genetic tests directly to consumers. The *New York Times* reports that consumer's access to genetic tests that assess an individual's risk of dementia (such as the ApoE4 gene) may have an interesting consequence—the end of long-term care insurance. According to Times reporter Gina Kolata, there are 5.5 million people in the United States who have Alzheimer's Disease. These individuals also represent 50% of all nursing home patients. Because a consumer-ordered genetic test does not appear in a patient's permanent health record, it is possible that only consumers with high risk of dementia or Alzheimer's Disease would purchase long-term care insurance. That would distort the risk pool and make this type of coverage unprofitable for insurers.

TRANSITIONS

• **Natera** of San Carlos, Calif., named Gail Marcus as a new member of its board of directors. Marcus has held executive positions at **Calloway Labs, Tatum LLC, Caris Diagnostics**, **UnitedHealthcare**, **Caremark**, **AdvancePCS**, and **Cigna**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 5, 2017.

UPCOMING...

- ***Why CMS Chose 'Weighted Median' as Basis for Calculations to Set Medicare Lab Test Prices.***
- ***Best Lab Test Utilization Strategies Presented at this Year's Executive War College.***
- ***Payer Audits of Lab Test Claims Create New Challenges for Labs, Pathology Groups.***

For more information, visit:

www.darkreport.com