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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

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Founder & Publisher

A Tale of Two Laboratories

ON OPPOSITE COASTS OF THE UNITED STATES, two of the nation's larger laboratory companies are charting very different courses. Yet, in this tale of two laboratories, each lab company has important lessons to teach hospital CEOs about the many benefits that accrue from a well-run hospital laboratory outreach program.

On the East Coast, **Solstas Laboratory Partners** (formerly **Spectrum Laboratory Network** and **Carilion Laboratories**) continues to grow steadily and build upon its founding roots as a laboratory outreach business launched by three major health systems in the Greensboro metropolitan area of North Carolina.

It was in the mid-1990s when the three health systems came together and built an off-site core lab and began to ramp up sales activity. They were: **Moses Cone Health System**, **High Point Regional Health System**, and **Novant Health System**. After floundering for a few years, Spectrum gained direction under a new CEO. By January 2006, a majority stake in this laboratory company was sold to a private equity company for a price that THE DARK REPORT estimates was between $160 million and $185 million.

For the three health system partners in the original lab company, this was a princely return on their outreach laboratory business. The proceeds from the sale could now be invested in furthering their mission of patient care.

Meanwhile, at about the same time in the 1990s, **Pathology Associates Medical Laboratories, LLC** (PAML), then owned by **Providence Health & Services** (PH&S), developed a unique approach to partnering with community hospital laboratories to jointly develop outreach laboratory programs.

It helped form **PacLab Network Laboratories**, which started with eight hospital laboratories in the Seattle metro. Today, PAML's use of hospital laboratory outreach and joint ventures *(see pages 7-9)* has helped it grow into one of the nation's largest privately-owned independent laboratory companies. More importantly, all the hospitals associated with PAML and its lab outreach joint ventures are enjoying the benefits of declining average cost of inpatient testing, stronger clinical bonds with office-based physicians, and increased income from a thriving laboratory outreach program.

Given the demonstrated multi-year successes at PAML and Solstas/Spectrum, it is a mystery as to why so many hospital and health system CEOs still fail to recognize the clinical value and revenue potential from a well-run hospital laboratory outreach program. TDR

Time to Think About ACOs And Medical Homes

Is Medicare's value-based reimbursement a threat or an opportunity for clinical laboratories?

CEO SUMMARY: In less than nine months—on January 1, 2012, the new health reform legislation mandates that Medicare commence value-based purchasing. Medicare must also begin contracting with accountable care organizations (ACO). Experts say these two developments will initiate a cycle of broad change to the nation's healthcare system. At this year's* Executive War College*, a special series of speakers will provide lab leaders with insight and advice on the best ways to respond to these healthcare models.

IT'S A COUNTDOWN THAT SHOULDN'T BE IGNORED by clinical laboratories and pathology groups. On January 1, 2012, the ObamaCare legislation mandates that the Medicare program establish a value-based purchasing model for all hospitals.

That date is just nine months away! It leaves providers with a steadily diminishing window of opportunity to understand this new Medicare payment arrangement and develop an appropriate strategy.

Along with value-based purchasing of hospital services, January 1, 2012, is the first date that accountable care organizations (ACOs), as defined—very loosely—in the Obamacare health bill of 2010, can begin to contract with the Medicare program.

The third reform with the potential to be disruptive is the ObamaCare bill directive that the Medicare program establish a national pilot program for bundled payments by January 1, 2013. The goal of this new reimbursement model is to reduce hospital re-admission rates for Medicare patients.

Plans are for the bundled payment pilot program to pay a single bundled reimbursement for an episode of care that begins three days before admission to the hospital and ends 30 days after the Medicare patient is discharged. The hospital and physicians involved in the patient's care will share in the bundled reimbursement.

For clinical laboratory administrators and pathologists, these innovative experiments in reforming the delivery of healthcare are fraught with risk and uncertainty. By encouraging hospitals and physicians to come together and deliver integrated

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patient care from a single business unit and share a single Medicare payment for service, government health regulators are opening up a Pandora's Box—and the lab testing industry may turn out to be an unwilling guinea pig.

For example, as ACOs develop their clinical services, will they want to leverage their clout with laboratories in the community by seeking deeply-discounted pricing for laboratory tests in exchange for access to the ACO's patients?

This is not an idle question. Remember the impact that DRGs (diagnostic related groups) had on reimbursement for Medicare Part A clinical pathology professional services? Even today, pathologists continue to deal with the ongoing changes triggered by Medicare's one basic change to one lab testing reimbursement policy that was implemented back in 1983.

➤Paying For Lab Test Services

Another source of financial risk for the laboratory testing industry could result if ACOs and medical homes found it financially remunerative to directly contract for lab testing services using a global payment scheme or a capitated arrangement.

This practice remains common in California, where independent physician associations (IPAs) continue to benefit from the deeply-discounted lab test contracts offered to them by the national laboratories. Should the ACO care delivery model develop in viable ways—and should ACOs end up negotiating very low prices for lab testing in a global contracting arrangement—this would be a financial setback for independent labs and hospital lab outreach programs.

But, the ACO and medical home sword could cut the other way and end up benefiting local laboratories. Some lab industry experts speculate that, since hospitals and health systems are aggressively buying physician groups as they assemble the pieces of their proposed ACOs, it would be expected that hospital/health system-owned ACOs would mandate that all physicians in their ACO must use the hospital laboratory for all lab tests.

Experts point out that there are sound clinical and operational reasons to mandate that office-based physicians in the ACO use the hospital laboratory. It means that all testing done on behalf of the patient, whether in inpatient, outpatient, and outreach settings, would be tested by the same laboratory. It also means that all laboratory test results would be run by the same methodology and would have the same reference ranges.

➤Single Data Repository

Further, since the providers in the ACO would be working from a single patient data repository, all cumulative lab test data—from inpatient, outpatient, and outreach testing—for a patient would be instantly available in the patient's full electronic health record (EHR).

Finally, it means that the pathologists and laboratory scientists working within the ACO would be positioned to provide a richer level of professional support and consultations to the referring physicians. The importance of this should not be underestimated, since hospital-based pathologists in the community generally develop a very detailed understanding about many patients in their community.

➤Continuity In Patient Care

This is because the hospital-based pathologists will discuss inpatient cases with physicians, and then recognize the same patients as tests are later performed in support of office-based care. This is continuity in patient care and the ACO model has the potential for pathologists and PhDs to establish a value proposition that is instantly recognized by referring physicians in that ACO.

Look at this same issue from another perspective. The national lab companies would argue that differences in test methodology and reference ranges between

Bringing Together Top-Flight Experts to Discuss ACOs, Medical Homes, & Value Reimbursement

DURING THE NEXT FIVE YEARS, predictions are that the American healthcare system's holy trinity of reform will be Accountable Care Organizations (ACOs), Medical Homes, and Value-Based Reimbursement.

It is essential that clinical laboratory administrators and pathologists understand the strategic implications and marketplace ramifications of these new healthcare delivery models. At the upcoming *Executive War College on Lab and Pathology Management*, which takes place on May 3-4 in New Orleans, a special extended session will tackle these important topics.

Addressing the subject of Accountable Care Organizations will be Tom Williams, Director of California's **Integrated Healthcare Association** (IHA). IHA just released a White Paper that evaluated California's 30 years of experience with ACOs. Williams also actively participates in administering a major physician pay-for-performance program that pays out more than $100 million in incentives each year to physicians in the Golden State.

Medical Homes And More

On the topic of Medical Homes, one of pathology's brightest thinkers has been tapped to speak on this subject at the *Executive War College*. James M. Crawford, M.D., Ph.D., is the Chair of Pathology and Laboratory Medicine at **North Shore Long Island Jewish Health System** in Great Neck, New York. Crawford chairs the working committee which is developing North Shore LIJ's medical home program. He will share his insider perspective on how doctors practicing in medical homes will be different users of laboratory tests and lab test data.

Value Reimbursement

Speaking about the ways that value-based reimbursement will create opportunities for clinical labs and pathology groups to add value to clinicians will be George Lundberg, M.D., Ph.D., the noted pathologist and longtime editor of several major medical journals. Lundberg is an active commentator on healthcare trends and the reform movement.

This is an unprecedented opportunity for lab managers and pathologists to see, hear, and network with knowledgable experts on these three important health reform topics. After their presentations, there will be an open panel discussion so the *Executive War College* audience can ask focused questions and gain insights on their areas of keenest interest.

The full agenda can be viewed by visiting *www.executivewarcollege.com*. Lab leaders interested in attending this year's *Executive War College* are encouraged to register early so as to guarantee their place at this information-filled conference.

their test menus and those of the hospital lab that serves a particular ACO should not be a significant factor. They are also likely to assert that their deeply-discounted prices offer ACOs an important economic benefit.

Reference And Esoteric Tests

National labs of all sorts will also assert to the ACOs that their particular expertise in reference and esoteric testing will be a significant source of value to the ACO. Not only do these labs happen to offer a very large number of different types of assays, but they will point out that they test significant volumes of specimens.

It will be argued that ACOs benefit because the national laboratory company develops professional expertise from working with a large number of specimens for each type of esoteric assay. As well, the large pool of patient data for the assay represents clinical experience that can aid in more accurate interpretation of results for individual patients.

THE DARK REPORT offers these pro and con arguments to make a point. Assuming that ACOs and medical homes set down roots and become a permanent part of the nation's healthcare system in the next one to five years, then the laboratory industry is going to have a major new type of customer for the first time since the emergence of closed-panel, gatekeeper-model HMOs in the first half of the 1990s.

Just as the new contracting and pricing strategies of HMOs—including capitation and full risk—disrupted the finances of the nation's clinical labs and pathology groups during the 1990s, now, in the 2010s, ACOs, medical homes, and value-based reimbursement are likely to unleash an equally disruptive cycle of competition.

In city after city, this new cycle of competition will pit hospitals and health systems against each other in new ways, because of their participation in ACOs and their need to demonstrate how they produce better patient outcomes than other ACOs in their communities.

Similarly, this new class of users and buyers of laboratory tests will create a different type of competition among clinical laboratories and anatomic pathology groups. At this time, few pathologists and senior laboratory administrators have considered the strategic consequences of these changing competitive factors.

New Cycle of Competition

There is another powerful reason why this competition will be intense, disruptive, and widespread. ACOs, medical homes, and value-based reimbursement will be a totally new game in healthcare. It will be the first time that, on a wide scale across the United States, hospitals, physicians, and other providers have willingly put themselves into a single organization focused on clinical care.

Another radical element in this new healthcare game are the two new payment models for reimbursing hospitals, physicians, and laboratories. One is value-based purchasing by Medicare and private payers. The second is a payment program that bundles reimbursement for inpatient and post-discharge patient care. Both of these payment arrangements will be linked to how the ACO achieves a target level of patient outcomes for specific procedures or diseases.

Stay Ahead Of Developments

Simply stated, for hospitals and office-based physicians, these significant changes mean a radical shift in thinking and in the operational delivery of healthcare. Pathologists and laboratory administrators will want to be ahead of these developments.

For clinical laboratories and anatomic pathology groups, the good news is that all lab testing providers start from a relatively level playing field as these different reforms are implemented by Medicare and emulated by private payers. However, once the new game commences, only those clinical labs and pathology groups with an effective strategy and a willingness to try different service delivery approaches will compete effectively against the national lab companies.

To help laboratory executives and pathologists prepare effective strategies for these coming developments, the 16th Annual *Executive War College on Lab and Pathology Management* has invited the leading thinkers and experts in ACOs, Medical Homes, and Value-Based Reimbursement to speak. During the May 3-4 conference, these experts will conduct a special extended session on the coming healthcare reforms.

Details about these speakers and their topics are provided in the sidebar on page 5. Information about the full agenda and how to register can be found at *www.executivewarcollege.com*. These presentations on ACOs, Medical Homes, and Value-Based Reimbursement will be the first time that all three topics have been addressed from a strategic perspective to a single gathering of laboratory leaders. TDR

PAML to Enter Kentucky With New Laboratory JV

Three Saint Joseph Health System hospitals want to expand their laboratory outreach program

CEO SUMMARY: This latest laboratory joint venture, in partnership with Saint Joseph Health System, gives Pathology Associates Medical Laboratories, LLC (PAML), a solid presence in Kentucky's laboratory testing marketplace. Over the past 10 years, PAML, which is based in the Pacific Northwest, has proved adept at developing laboratory joint ventures with hospitals and major health systems as a way to enter new regional markets. This is the third significant lab JV for PAML in the past six months.

On March 7, it was announced that **Saint Joseph Health System** of (SJHS) Lexington, Kentucky, and **Pathology Associates Medical Laboratories, LLC** (PAML), entered into a laboratory joint venture (JV).

Kentucky Laboratory Services (KLS) will be the name of the new enterprise. It will be based in Lexington and will serve office-based physicians throughout the state of Kentucky.

"Our plan is to grow the outreach business at three of SJHS' eight hospitals," stated Noel Maring, PAML's Senior Vice President and Chief Marketing Officer. "This will enable the laboratory joint venture to keep 85% to 90% of the testing in Kentucky.

"Within the joint venture, Saint Joseph Health System will provide several resources," said Maring. "For example, its hospital laboratories will provide the lion's share of the laboratory testing. The joint venture will also use patient service centers (PSC) owned and operated by the SJHS hospitals. These PSCs are typically located in prime locations at the hospital and in nearby medical office buildings."

For its part, PAML will provide an integrated informatics solution that manages the laboratory test data and connects the JV labs with the office-based physicians served by the joint venture. PAML will act as the managing partner of the joint venture and will handle sales, marketing, courier, billing/collections, customer service and other operational support for the joint venture. PAML will also provide reference and esoteric testing for Kentucky Lab Services.

Three Hospital Laboratories

Three SJHS hospitals will participate in the laboratory joint venture. They are:

- **Saint Joseph Hospital** (468 beds)
- **Saint Joseph Hospital-East** (174 beds)
- **Saint Joseph-Jessimine** (ambulatory care center)

One unique trait of the Kentucky market for laboratory testing may help Kentucky Laboratory Services build market share rapidly. "No national lab company operates a sizeable lab facility in the state," noted Maring.

"This favorably positions our joint venture laboratory company to be the

state's largest local provider of lab tests," he added. "By contrast the other major lab companies operating in the Bluegrass State primarily have just courier services and limited stat testing services in some areas of the state."

Kentucky's Market Is Unique

"This makes Kentucky different from some of the markets where PAML has laboratory joint ventures with local hospitals," explained Maring. "In these other markets, we often compete directly with lab competitors who operate major lab facilities in the community, along with significant infrastructure to support their regional activities.

"What makes the Kentucky market different from other regional markets is that the biggest lab competitors must transport specimens out of state for testing," he said. "By contrast, since Kentucky Laboratory Services will be the local laboratory, we think this fact will give us significant competitive advantage.

"It also means we will keep testing and keep the healthcare dollars in Kentucky," declared Maring. "There are physicians and patients who will be very loyal in supporting their local laboratory because it keeps jobs in these communities while boosting the local economy."

This new laboratory testing joint venture in Lexington, Kentucky, is a direct result of PAML's business relationship with **Catholic Health Initiatives** (CHI) of Denver, Colorado. CHI is one of the nation's largest health systems It has annual revenue in excess of $6.8 billion.

CHI Invests In PAML

In 2009, CHI invested substantial capital and became a 25% equity owner in PAML. *(See TDR, November 2, 2009.)* At the time, both CHI and PAML announced that they would collaborate to make PAML the preferred reference lab for CHI's 78 hospitals, located in 20 states. CHI and PAML would also work to develop lab joint ventures with CHI hospitals in each of these regions.

First fruits from this business relationship was a laboratory joint venture that was made public in August, 2010. **Providence Health & Services of California** and PAML formed a new clinical laboratory company that is called **California Laboratory Associates, LLC** (CLA). This lab venture utilizes the laboratories of three of five hospitals owned by Providence in Southern California.

PAML's second lab joint venture with a CHI-owned health system was **Colorado Laboratory Services, LLC** (CLS). This deal was announced in September, 2010. Its partner in this venture is **Centura Health System**. Centura has 12 hospitals spread across the Denver metro and all these hospitals participate in Colorado Laboratory Services.

Growth Prospects

For its part, PAML is excited about the prospects of expanding laboratory outreach in Lexington. "The Saint Joseph Health System is a forward-thinking organization that holds a dominant position in this market," observed Maring. "Further, Lexington is a great location.

"For example, this city is just 90 miles from Cincinnati and 90 miles from Louisville," he stated. "These are both attractive markets for laboratory testing and would be logical cities for expansion."

THE DARK REPORT notes that PAML has a business model that is unique in the United States. It is a commercial laboratory company that is owned by two multi-billion dollar Catholic Health Systems. Its primary growth strategy is to create laboratory joint ventures with local hospitals.

For these reasons, C-Suite administrators at innovative hospitals and health systems would find it instructive to study both this business model developed by PAML and the financial success it brings to the local hospitals that are partnering with PAML. TDR

Contact Noel Maring at (509) 755-8918 or nmaring@PAML.com.

New Laboratory Joint Venture Hopes to Use Faster Test Turnaround Times to Win Share

IMPROVED LAB TEST TURNAROUND TIME may differentiate Kentucky Laboratory Services (KLS) from the national laboratories that serve office-based physicians in Lexington, Kentucky, and the surrounding regions.

"We expect this new laboratory joint venture will offer turnaround times that meet and exceed the current turnaround times that competing laboratories offer to office-based physicians in Lexington, Kentucky, and surrounding communities," observed Noel Maring, Senior Vice President and Chief Marketing Officer for PAML, which is the managing partner in the KLS laboratory joint venture.

Same Day Lab Test TAT

"First, as much as 90% of all testing will be done by the three SJHS hospital laboratory partners that are located in and around Lexington, Kentucky," he continued. "Because these labs are in full operation and busy with inpatient testing throughout the day, it gives us the capability to report many test results the same day, as well as in the early evening.

"Our market research team determined, that in this region, both **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** send the specimens they collect in Kentucky to laboratories they operate in other states," added Maring. "Both lab companies typically transmit the electronic lab test reports back to their physician clients in Kentucky in the middle of the night.

"This positions us to raise the bar on the laboratory testing services that KLS provides to office-based physicians in this region," he noted. "It should be equally true that turnaround times for our laboratory joint venture's reference and esoteric testing will be equal to, or better than, what competing laboratory companies provide.

"We are confident that we can meet and beat existing turnaround times for lab test reporting because we have an established reference and esoteric testing program in place with all eight hospitals in the Saint Joseph Health System," continued Maring. "Transporting specimens in a timely manner from the hinterlands of Kentucky to the PAML main lab in Spokane, which is located in eastern Washington, turns out to be surprisingly easy.

"Working in tandem with **Federal Express**, our reference and esoteric specimens from Eastern Kentucky are picked up by couriers and end up at the FedEx sorting hub in Memphis, Tennessee," he said. "Here, these specimens are combined with all our specimens from other parts of the country, including the East Coast.

"At the FedEx Memphis hub, we keep a specially-designed transport container," continued Maring. "One section of this container is refrigerated. The other section maintains room temperature. FedEx delivers this container to our Spokane laboratory by 6:00 a.m. every morning.

"To further improve lab test turnaround time, in Spokane, we ramped up testing capabilities to coincide with the arrival of those specimens," stated Maring. "At a minimum, this arrangement allows us to equal existing service levels in regional markets like Kentucky, But in many cases, we've successfully improved turnaround time for reference and esoteric testing that we provide to hospital laboratories."

Lab JV's Business Prospects

The existing business relationships that PAML currently maintains with the eight hospitals owned by Saint Joseph Health System in and around Lexington, Kentucky, are one reason why both partners in the KLS laboratory joint venture are optimistic about the future of this new enterprise. Many of the transportation logistics and informatics links are already in place and market-tested.

CEO SUMMARY : After several decades of steadfastly maintaining their independence from other pathology groups in their community, progressive hospital-based pathology groups are beginning to create regional laboratory testing networks. These collaborations generally start small and often involve just a few simple testing services. In North Carolina, one pathology group has created two separate test exchange networks. One is with a pathology group and the other is with a physician group.

Regional laboratory networks are bac

Pathology Grou Lab Test Excha

COLLABORATIVE LAB TEST NETWORKS ARE BACK! But unlike the mostly-failed efforts at creating regional laboratory networks during the mid-1990s, current test exchange arrangements are often simple and anchored by a common laboratory informatics platform.

THE DARK REPORT was first to identify and describe this nascent market trend. In a very quiet fashion, clinical labs and pathology groups have begun to ask their LIS vendors to add functions that enable and support various type of collaborative activities among laboratories participating in a collaborative testing arrangement. *(See TDR, February 28, 2011.)*

In Milford, Massachusetts, **Psyche Systems Corporation**, a laboratory information systems (LIS) software company, has fielded regular requests from different lab clients to support collaborative testing arrangements they are creating. Recognizing that this trend was likely to grow, Psyche coined a name—Test Exchange Network, or TEN—to describe the new lab informatics business model, and then trademarked it.

During the 1990s, in many communities around the country, it was primarily hospital and health system laboratories that engaged in regular meetings to establish a regional laboratory network. The goals were usually to

save money by achieving economies of scale and to negotiate region-wide managed care contracts as a single entity.

The majority of these hospital lab-based regional networks never developed into viable organizations. However, the best of these regional laboratory networks have enjoyed great success for as long as two decades. Among them are **Joint Venture Hospital Laboratory Network** (JVHL) in Detroit (founded in 1992) and **PACLAB** in Seattle (founded in 1996.) *(See TDR, May 12, 1997.)*

In contrast to lab networks of the 1990s, the emerging lab test networks of the 2010s involve smaller labs and often include anatomic pathology groups. Another distinguishing trait is that the collaborative arrangement is often something simple. The goal of the test exchange network is not to tightly integrate the operations of participating laboratories, but rather to allow one lab to tap the resources of another lab in a way that is fast, efficient, and useful to both parties.

Two motivations drive these networks. One is the constant pressure of declining reimbursement. The other is competition from national laboratory companies that causes smaller laboratories in the community to come together and develop collaborative services.

In Winston-Salem, North Carolina, **Pathologists Diagnostic Laboratory** (PDL) is involved in multiple lab testing collaborations. PDL handles over 100,000 accessions annually. It has nine pathologists.

"In our case, we've used the test exchange network as an incubator to help another pathology group start up their own independent laboratory in their service area," noted Michael G. Hitchcock, MBChB, Medical Director at PDL. "Our laboratory supports this start-up lab with facilities it might otherwise not be able to afford."

In fact, PDL collaborates in two distinct networks. "One TEN involves the start-up lab I just mentioned," explained Hitchcock. "The second TEN is with a group of physicians in the region."

"This way of operating brings a new competitive dynamic into the marketplace and that's the fascinating aspect of it," he added. "Whether it is an unrelated pathology practice that is just getting started or a client physician practice ramping up their in-house pathology services, there are substantial hurdles and lots of overhead.

"By collaborating on resources and, in particular, by piggy-backing on a single LIS that is already up and running, they can introduce and support lab testing services more safely and at lower cost than if they had to start from nothing," Hitchcock said. "This also speeds up the entry to market for these new labs."

k, but with a new form and structure

up Establishes nge Networks

In both networks, it is PDL's automated testing capabilities and its LIS in Winston-Salem that are used by the other parties. Each of these collaborating laboratories operate in other cities in North Carolina.

LIS Anchors The Network

"Our information system is the Pysche WindoPath LIS," stated Hitchcock. "This LIS has the capability to partition the database. That means our test network collaborators can independently use our LIS. Because of the internal firewalls that are programmed into this LIS, only the laboratory in the network which is working on the case can view that lab's patient data. Lab partners cannot view PDL's patient data.

"For any laboratory interested in developing a collaborative laboratory test network, this is an essential feature," commented Hitchcock. "Federal privacy rules under the Health Insurance Portability and Accountability Act (HIPAA) mandate this level of data protection and patient privacy."

In one test exchange Network, PDL collaborates with another pathology practice located in a different North Carolina city. This TEN is designed to support their newly-formed independent pathology lab company.

Collaborative Test Network

"With this start-up lab, we have the reverse situation of our other collaborative test network," stated Julie Williams, PDLPath's Director of IT. "Pathologists working in a community hospital recently established their own independent laboratory company.

"In this collaborative laboratory testing network, we receive the specimens from their referring clients," she said. "Our laboratory does all the technical component services. This includes grossing, processing, staining, and preparation of the slides. Our laboratory directly bills the payers for the technical component (TC).

"We then send the slides to this pathology group," Williams stated. "They do the analysis, sign out the case, and bill for the professional component (PC).

"In this collaboration, we do all the technical work in our laboratory," she stated. "Because we have cytotechnologists and their group doesn't, we perform all the normal Pap tests and HPV tests. Abnormal Pap tests and histology cases go directly to these referring pathologists for them to read.

"Their pathologists sign out these cases using our LIS and their database partition within our LIS," noted Williams. "We also handle distribution of the reports for this pathology group. Each of their client physicians is set up in our LIS and these physicians can access the reports via an electronic interface.

Flexibility Of The Network

"One aspect which illustrates the flexibility of these types of collaborative laboratory testing networks is accessioning," she said. "This pathology group collects its specimens, then can accession them at their site.

"Their laboratory staff enters the information into their database partition on our LIS," Williams explained. "This is possible because they have WindoPath site licenses that allow them to access their own database that exists within our laboratory information system.

"Once their pathology group assigns the case numbers and enters the data into the LIS, these specimens come to our laboratory to be processed," she said.

"This collaborative lab testing arrangement minimized the front-end capital needed by these pathologists to establish their independent laboratory company," explained Williams. "It also reduced their business risk. That's because they took advantage of our excess capacity and available resources as their sales team went into the market and brought on new physician clients.

Cornerstone of Lab Test Exchange Network Is Partitioned Patient Data on Single LIS

BY DEVELOPING COLLABORATIVE LAB TESTING NETWORKS, Physicians Diagnostic Laboratory (PDL) boosted its lab test volume by about 10%.

"From a business perspective, these are important relationships," explained Michael G. Hitchcock, MBChB, Laboratory Director at PDL, in Winston-Salem, North Carolina. "In one collaborative lab test network, we have a contract with a physician group. In the other collaborative lab test network, we have a contract with a start-up laboratory launched by pathologist who serves a large multi-hospital health system in another city.

"Separate from the profitability issue, we found it be a good exercise in relationship building for us to work with pathologists at that health system," he noted. "We don't serve the same geography, so in that way it was a professional pleasure to help them launch their new lab in a way that avoided the types of missteps they might have otherwise experienced."

In building the two different laboratory test exchange networks (TEN), Hitchcock said that the common use of a single laboratory information system (LIS) is a key factor in the success of these collaborations.

"Every pathologist and lab administrator knows how expensive and time-consuming it is to purchase an LIS, then make it function in support of the laboratory," noted Hitchcock. "When we began discussions with our partners in these two collaborative lab testing networks, we all quickly realized that working from a single LIS would be both better and cheaper for all parties.

"In this regard, we found our LIS vendor, Psyche Systems in Milford, Massachusetts, to be surprisingly flexible in pricing the software at a low enough price so that smaller labs could use it on larger systems," Hitchcock commented.

Partition The Database

"Equally important, they were ready to facilitate writing the code to support every conceivable business model that we could throw at them," he said. "They made it possible to partition the database so that multiple laboratories could work from our single LIS, yet still fully comply with federal and state patient privacy laws.

"Our experience with the use of a common laboratory information system that has partitioned databases to serve each participating laboratory in the test exchange network has been positive," noted Hitchcock. "This also demonstrates how integrated informatics solutions can support laboratories seeking to collaborate."

"As the volume of specimens increases, these pathologists can then build out their own technical laboratory," she commented. "It also allows them to hire cytotechs and other staff based with confidence that they have enough specimens to support these positions.

"In fact, in the next month or so, their laboratory will begin operation," continued Williams, "but our test exchange network won't end. Rather, we will continue to collaborate by performing certain tests, such as gonorrhea, chlamydia, and HPV testing. These are tests which their lab is not yet equipped to perform."

TC/PC Test Network

PDL's other test exchange network was actually the first one it established. It used the concept of a collaborative lab testing network to enable high grade LIS functionality in a new category of anatomic pathology case referrals. "We started this first collaborative testing arrangement

about 18 months ago with a physician group in another North Carolina city," commented Hitchcock.

"This group of physicians had established an in-house histology laboratory," he continued. "They do the technical component of the work and bill for the technical component (TC). Then they pay for access to our IT system and, as owners and operators of our own separate pathology laboratory, we perform the professional services and bill for the professional component (PC).

"Prior to developing this business model, we evaluated several other payment models to ensure compliance with federal and state laws," added Hitchcock. "This collaborative test network meets those requirements and our legal team says that our laboratory test network utilizing this TC/PC arrangement puts us on the safest possible end of the compliance spectrum.

TC/PC Compliance

"As most pathologists know, when a physician group wants to globally bill for the TC and the PC, one of the compliance requirements to bill Medicare is that the pathologist contracted to read the physician group's slides must perform that professional service in the offices of the physician group," he noted.

"In the case of our client, this would require them to hire a pathologist to work as part of their group practice," said Hitchcock. "Alternatively this physicians group would need to contract with a pathologist to come to their office to read the slides and sign out the cases.

"Our test exchange network offers several benefits to both parties," declared Hitchcock. "First, the foundation of the arrangement is an arm's length contact between the participating labs which meets all compliance considerations.

"Second, because our LIS database was partitioned, the physician group only pays for their specific use of the LIS," he noted.

"Third, because we both use the same LIS, the pathology informatics is integrated between all participating sites and all parties involved in this collaborative testing arrangement," Hitchcock added. "This improves productivity, reduces errors, and contributes to better patient care.

Reference Laboratory

"Fourth, our pathology laboratory is set up to offer an extensive menu of tests," Hitchcock said. "The physician group can refer those cases to us for special stains or other expertise when necessary. That saves a big capital expense for them, while allowing them to access our economies of scale.

"This collaborative arrangement benefits the referring physicians in another way," observed Hitchcock. "It gives them immediate access to the expertise of our subspecialist pathologists—and that wouldn't typically be true if they were to hire their own pathologist, for example. We are also of sufficient size to have 24/7 coverage."

The emergence of these new forms of regional laboratory networks should not be a surprise. Pathologists and laboratory administrators have long recognized that collaboration with certain laboratory services can generate substantial cost savings while allowing the different participants to then deliver enhanced lab testing services to their client base.

Ceding Control To Network

In past years, what prevented the business model of a regional laboratory network—or a collaborative laboratory testing arrangement—to become more common was typically the unwillingness of individual laboratories to cede control of some aspect of their business to the network.

This has been particularly true of anatomic pathology group practices. THE DARK REPORT has regularly observed that, despite the multi-decade sustained sales and marketing success of the clinical lab-

Could the Spread of EHRs Foster Growth of Collaborative Test Exchange Networks?

PHYSICIANS ARE ADOPTING electronic health record (EHR) systems in growing numbers. This trend is likely to foster the spread of another trend, that of test exchange networks, says Jane Pine Wood, an attorney with the national law firm of **McDonald Hopkins**.

"As more physicians adopt electronic health record (EHR) systems, they have the ability to use these systems in a variety of ways," noted Wood. "For example, EHRs can send requests to lab information systems (LIS). This is one way that expanded use of EMRs can make it easier for labs to establish collaborative test networks."

Using The Same LIS

Among her clients, Wood has seen many examples of situations in which one lab allows another lab to use its laboratory information system for a discreet project or for certain tests, just as Physicians Diagnostic Laboratory (PDL) of Winston-Salem, North Carolina, is doing.

"I have clients who have similar lab testing collaborations and who have done so using home-grown LISs," she commented. "Over the years, we've had clients operate test exchange networks. What is different today, compared to earlier years, is the widespread use of EHRs by physicians.

"When putting these deals together, the key is that all collaborating laboratories in the network need to have a lawyer review the agreements," Wood advised. "There are contractual issues to consider in the agreement itself, as is true with any basic vendor agreement. But there are also federal privacy issues and inducement issues that must be appropriately addressed as well.

"The collaborative test network would need to have all the firewalls in place, for example," continued Wood. "A firewall is needed to limit access to patient data. As well, the LIS needs to be configured to restrict access to patient data only to those providers authorized to provide care to the patient.

"The LIS should also track who accessed a patient's records and which files they accessed," she said. "Each participating laboratory in the network should be restricted to viewing only its own patients' information. This is a basic privacy issue under the federal Health Insurance Portability and Accountability Act (HIPAA).

"In addition, laboratoraties participating in a collaborative network must take care that there is no inducement, meaning the lab with the LIS cannot offer anything of value to induce the other party to send more work to the lab running the LIS," observed Wood. "This is a basic compliance issue under the Stark law and the Medicare anti-kickback laws.

"A laboratory cannot pay physicians or another lab to send it work and vice versa," she added. "Labs dealing with physicians need to ensure compliance with the Stark law and any lab working with another lab would be concerned about the Medicare and Medicaid antikickback law.

Legal Review Advised

"To be safe, any clinical laboratory or anatomic pathology group that has an arrangement that involves both a referral source and the use of an interface—such as the common use of an LIS by a laboratory test exchange network—should have an attorney review the arrangement, plus all the related agreements to ensure that the lab is in compliance with appropriate state and federal and state compliance requirements," she concluded.

oratory testing services provided by JVHL in Detroit and PacLab in Seattle, the anatomic pathology (AP) groups serving the member hospital labs in each network have never come together on their own to collaborate in a similar and comprehensive fashion.

Networks In Seattle & Detroit

Yet, as an AP testing network, in both the Detroit and Seattle metro areas, these pathology groups have had an ideal opportunity to piggy-back on the sales programs of each regional laboratory network. The benefit would be an increased volume of AP case referrals, probably at a lower sales cost because of the economies of using the existing sales teams at JVHL and PacLab.

Thus, it should be considered an important development in the laboratory testing marketplace that, in various cities and for different reasons, local clinical labs and anatomic pathology groups are now coming together to develop different models of collaborative lab testing services. This is a new phenomenon and is clearly a response to shrinking reimbursement and intensified competition from national laboratory companies.

New Models Of Healthcare

Further, with accountable care organizations and medical homes expected to play a greater role in healthcare in coming years, it may turn out that collaborative lab test networks may be helpful as local laboratories restructure to serve these new healthcare business models.

THE DARK REPORT invites pathologists and lab administrators currently involved in similar collaborative lab test networks to contact us with details about their lab testing network's activities. TDR

Contact Michael G. Hitchcock, MBChB, at 336-760-1388 ext 21 or mikeh@pdlpath; Julie Williams at 336-718-2912 or jwilliams@pdlpath.com; and Jane Pine Wood at 508-385-5227 or jwood@mcdonaldhopkins.com.

—Joe Burns

Lab Start-Up Saves Money on IT Solution

ONE CLEVER ASPECT to the collaborative laboratory testing networks created by Physicians Diagnostic Laboratory (PDL) is how use of a common LIS by the participating network laboratories can save money and accelerate entry into the marketplace.

"Running the program on a site license, minimizes the start-up lab's investment and allows it to get started quickly," stated Julie Williams, PDL's Director of IT. "It also allows them to learn the database, which is the most important part of the LIS.

"Learning the database means that, at such time they may want to purchase the full LIS program, they are knowledgeable about how it works," she noted. "Further, that full LIS will run the same database that they've been using as part of the laboratory test exchange network.

"This avoids the substantial up-front expense of acquiring a full LIS and implementing it at the start of their business plan, when cash flow is at a minimum," continued Williams. "As part of the lab test network, they pay a fair market rate for the use of our LIS, along with qualifying for the volume discount that comes as a result of our combined specimen volume.

"Another source of savings for the start-up laboratory is that they don't need to hire their own IT staff or quality assurance staff," Williams added. "That is because we already have these skilled individuals fully-trained and already in place.

"By using our LIS and support resources in this manner, the start-up lab gains the privilege of using a mature large laboratory information system without the steep initial investment cost that would come with buying such an LIS," concluded Williams. "The start-up lab also gains valuable experience in how the LIS supports the entire range of daily testing activities."

Controlling Test Utilization By Physician Use of CPOE

CPOE Use at Illinois hospital lab reduces use of blood units by 33%, saving $200,000 annually

CEO SUMMARY: Systems for computerized physician order entry (CPOE) and clinical decision support can contribute to better utilization of laboratory tests while achieving improvements in patient outcomes. At Decatur Memorial Hospital, use of CPOE helped physicians slash the volume of blood products used by one-third, even as the risk of adverse patient events declined by a similar amount. Growing numbers of hospitals and health systems are implementing CPOE and clinical decision support systems.

OPTIMAL UTILIZATION OF LABORATORY TESTS BY PHYSICIANS is an ideal that is seldom realized. However, some hospitals are achieving noteworthy improvements in lab test utilization, lower costs, and improved patient outcomes through the use of both computerized physician order entry (CPOE) and evidence-based medicine rules.

At **Decatur Memorial Hospital** in Decatur, Illinois, a special program to improve physician utilization of blood products is showing impressive results. The laboratory worked with physicians to develop the ordering guidelines for blood products. The hospital uses the CPOE and clinical decision support system known as **McKesson** Horizon Expert Orders, along with the HorizonLab LIS.

Since this program was initiated in 2007, the 365-bed hospital has reduced usage of blood from a monthly average of 290 units to about 200 units per month. "This use of CPOE saves our hospital more than $200,000 per year," stated John Little, Administrative Director of the laboratory. "It has measurably improved patient care and also decreased the risk of adverse events. Both our laboratory and the physicians consider this use of CPOE to be a win-win outcome."

Little explained that use of the CPOE assists physicians in determining the appropriate amount of blood to transfuse, based upon the laboratory values and other criteria. In turn, this has reduced the number of incidents where a patient was over-transfused.

Changing the Philosophy

"Historically the rule of thumb used by physicians at our hospital was that, when ordering a transfusion, good practice was to order two units," said Little. "The thinking was that, if a patient needed one unit, it was likely the patient would need more than one unit. On the other hand, if there were indications that a patient needed only one unit, there was the possibility that perhaps the patient did not need to be transfused at all.

"We wanted to add clinical precision to the process of evaluating the patient and ordering blood products," he continued. "CPOE was a positive way to improve uti-

lization of blood products. The physician is more involved in evaluating the patient.

"In each case where the CPOE and evidence-based rules help the physician either transfuse less blood, or avoid the need for a transfusion, there is a direct reduction in the patient risk of infectious disease," added Little. "This is supported by many studies that conclude that transfusing blood—even if it's the patient's own blood—is risky. Therefore, each time the volume of blood transfused is reduced, risk to the patient is reduced as well.

"As a solution to inappropriate utilization of blood products or laboratory tests, use of CPOE is appealing because it requires the physicians to assess the patient against the appropriate evidence-based medicine guidelines at the time they are considering the transfusion," he noted.

Patient Evaluations

"For example, the CPOE system might help the physician realize that he or she was looking at yesterday's hemoglobin levels," said Little. "In this situation, the CPOE will prompt the physician to review or to order hemoglobin levels for today."

Little offered another example of how the CPOE can guide the physician. "Every time a patient's hemoglobin is low and the need for a transfusion is indicated, the CPOE and evidence-based rules have the physician re-evaluate that patient's oxygen-carrying capacity and the patient's vital signs before the system allows a first, second, or third unit of blood," he added.

"This was a primary goal of implementing the CPOE," stated Little. "Having the physician re-evaluate the patient at this point during treatment was expected to avoid some of the second- and third-unit transfusions that were actually clinically unneeded. In turn, the physician could achieve the desired patient outcome even as fewer blood products were used."

"We know from the clinical literature that a patient does better and length of stay can shorten if the patient can avoid being transfused," observed Little. "Overall, it is a positive thing for the patient, for the hospital, and for the physicians when blood products are transfused only in the appropriate amount and in the appropriate situations."

Decatur Memorial Hospital is using CPOE and clinical care algorithms that include laboratory values to better manage physicians' utilization of blood products. It is important to note that these care pathways were developed in collaboration with the laboratory and the physicians. That means the CPOE system presents physicians with patient care algorithms that were developed by their colleagues in the hospital and reflect the current published evidence.

If Horizon Expert Orders has a familiar ring to long-time readers of THE DARK REPORT, that should be no surprise. This is the expert system developed by the **University of Vanderbilt Medical Center** in Nashville, Tennessee, early last decade. Called "WizOrder" by Vanderbilt, the software system was licensed by McKesson. Laboratory Administrators at Vanderbilt told THE DARK REPORT that, in each department where WizOrder was implemented, utilization of laboratory tests declined by an average of 35% to 40%.

Contributing Factors

Vanderbilt's lab leaders attributed this decline in lab test utilization to a variety of factors. Since the CPOE showed pending lab test orders, physicians didn't order duplicate tests, for example. Also, the care algorithms in the clinical decision support function helped physicians avoid ordering tests that were clinically unnecessary.

The experience of the laboratory at Decatur Memorial Hospital at improving utilization of blood products demonstrates that today's generation of CPOE systems and clinical decision support tools are effective ways to improve patient care while controlling the cost of care. **TDR**

Contact John Little at jlittle@dmhhs.org or Joseph Stabile at 404-338-4363 or joseph.stabile@mckesson.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Regulation of genetic tests by the **Food and Drug Administration** (FDA) continues to move forward. Earlier this month, an FDA advisory panel conducted hearings on this subject. The Molecular and Clinical Genetics Panel of FDA's Medical Devices Advisory Committee discussed several aspects of direct-to-consumer (DTC) genetic testing. Experts on the panel advocated that consumers should only access "clinical genetic tests" through their physicians.

ADD TO: *Genetic Tests*

More relevant for pathologists and clinical lab administrators were public statements made by FDA officials during this meeting that address the agency's intent to regulate at least some genetic testing. "It's not under question that [DTC genomics firms] will be regulated," declared Alberto Gutierrez, Director of the Office of In Vitro Diagnostics in FDA's Center for Devices and Radiological Health, during the meeting. "They will be."

BRLI SUSTAINS DOUBLE-DIGIT RATE OF GROWTH

If there is one public laboratory company that has maintained a sustained rate of double-digit growth throughout the recession and the slow economic recovery, it is **Bio-Reference Laboratories, Inc.** (BRLI), of Elmwood Park, New Jersey. On March 3, the company reported its first quarter 2011 earnings. The company increased its net revenues by 23%, from $99.3 million in Q1-10 to $121.7 million in Q1-11. Its patient count grew 20% during the same period, from 1.2 million to 1.5 million.

GLOBALIZATION OF LAB MEDICINE ADVANCES IN AFRICA

Earlier this month, at a meeting conducted in Addis Ababa, Ethiopia, the **African Society for Laboratory Medicine** (ASLM) was launched. Eight African countries sent officials from their respective ministries of health to the meeting. In a press release about the event distributed by the **American Society of Clinical Pathology** (ASCP), it was noted that "ASLM will serve as a professional body to guide laboratory network development and strengthen efforts in Africa; guide the process of certification of laboratory medicine training; and work... to develop and implement laboratory policies and guidelines in the African region."

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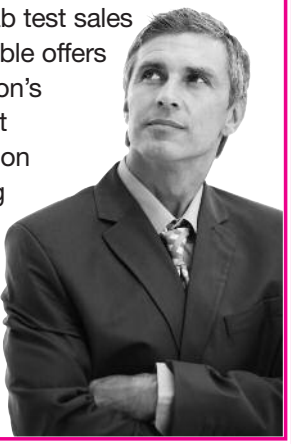

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