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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Healthcare Reform and Laboratory Testing

WE ARE ONLY 120 DAYS FROM IMPLEMENTING another round of programs mandated by the Patient Protection and Affordable Care Act (PPACA) of 2010 and associated legislation. Certain programs become effective on January 1, 2012.

On that date, the transition to HIPAA form 5010 takes effect. All clinical laboratories and pathology groups should be prepared for this step. Use of this form by providers and payers is a necessary step if the scheduled implementation of ICD-10 codes in 2013 is to prove successful.

Effective on January 1, 2012, the **Centers for Medicare and Medicaid Services** (CMS) can begin contracting with accountable care organizations (ACO). CMS issued a draft of the rules for this program earlier this year. National associations for hospitals and physicians responded with plenty of criticism about the proposed language of these rules. Nonetheless, CMS will be taking forward steps to begin contracting with ACOs after the New Year.

Another significant program that launches during 2012 is Medicare's value-based purchasing (VBP) program for hospitals. It becomes effective on October 1, 2012. This is an important reform because it represents a major effort to begin evolving the existing fee-for-service system towards a reimbursement model that rewards providers for improving outcomes across an identified population of patients that meet or exceed pre-established targets.

Of course, I don't need to tell you that, at the same time that major efforts to reform healthcare like those described above are happening, the marketplace for clinical laboratory and pathology testing continues to evolve at its own rapid pace. New buyers are flooding into the market looking for lab companies they can buy, for example. Of course, specialist physicians continue to open their own in-clinic pathology laboratories, thus reducing the access to specimens for many community hospital-based pathology groups. *(See pages 3-8.)*

Taken collectively, these events cannot be ignored by pathologists and lab administrators tasked with developing the strategies their lab organizations need to deliver state-of-the-art lab testing services in a financially-sustainable manner. The lab testing profession is about to enter a new cycle of accelerated health reform initiatives. That makes it imperative that every lab organization remain nimble and open to smart changes in response to these developments. TDR

How In-Clinic Path Lab Benefits GI Practice

Specialist physicians value shorter test TAT, more access to pathologists, and added revenue

CEO SUMMARY: In Manassas, Virginia, a five-physician gastroenterology group is using its in-clinic anatomic pathology laboratory to advance patient care, while boosting revenue associated with this ancillary service. In this exclusive interview, the group's physician business leader shares the different ways that this in-house pathology service benefits both patients and physicians. Patients like the faster turnaround times for reports and doctors like the close clinical consultations with their pathologists.

MANY PATHOLOGISTS KNOW THAT urology groups and gastroenterology groups are busily establishing their own in-clinic anatomic pathology laboratories. This trend is actively reshaping the form and structure of the anatomic pathology profession.

Yet, despite the importance of this trend on the clinical and financial future of private pathology group practices, little information has been made public about the impact that in-clinic anatomic pathology laboratories have on the urology groups and gastroenterology groups that operate them.

To fill that knowledge vacuum, THE DARK REPORT went searching for a representative case study and found one in Manassas, Virginia. This is where **Associates in Gastroenterology, P.C.**, is now in its second full year of operating its own anatomic pathology laboratory.

As a direct result of adding this clinical service, the five physicians at Associates in Gastroenterology found they have: 1) improved patient care; 2) increased practice revenue; and, 3) added to the value of their medical group practice.

"Once our in-house pathology laboratory opened, we saw a major improvement in the average turnaround time for pathology test results," stated Kenneth N. Josovitz, M.D., who is President of the group. "Both patients and physicians consider this a major benefit.

"We spent between $300,000 and $350,000 to open our in-office pathology service," noted Josovitz. "At that time, we hired two part-time pathologists with experience reading gastrointestinal cases."

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Since then, the practice has added a second gastroenterology practice of 10 physicians who send tissue specimens to the new in-office pathology lab. "To accommodate this increased case volume, we hired a third part-time pathologist," he commented. "This in-house clinical service helped Associates in Gastroenterology increase annual revenue by an estimated 5% to 10%."

Two Other Groups Join

A third gastroenterology practice is about to start sending specimens and a fourth is considering the option, said Bernie Ness, a consultant with **In-Office Pathology** of **Lakewood Consulting** in Lake Forest, Illinois. Josovitz worked with In Office Pathology to open the new pathology service in his practice. In August, the laboratory passed its CLIA inspection.

"Previously, we sent out all our tissue specimens," said Josovitz who founded the gastroenterology practice in 1998. "We saw the importance of having the ability to run pathology tests on site and get the test results the next day. Before we started our in-office anatomic pathology service, we often had to wait several days for the pathology results. Now we get the results right away.

"Also, by keeping the specimens in-house, attending pathologists have much more control over the samples and over the quality of the process," he continued. "Because specimens stay right here, we have more confidence in the process.

"Let me explain that," said Josovitz. "When a group like ours refers tissue specimens to an outside laboratory, the referring physicians do not know where the specimens are being processed.

"Similarly, we won't necessarily know the quality of the physicians who read and interpret the test results," he added. "We don't know if a breast pathologist or a dermatopathologist is reading our gastroenterology specimens.

"It's not necessarily bad to send out specimens," he commented, "but it is much more comfortable for us as gastroenterologists to have a pathologist experienced with GI reading our GI samples.

"Further, we get an extra level of comfort about the quality of the professional service because we hired our own pathologists, meaning we selected pathologists we already knew from previous experience," observed Josovitz.

Before opening the in-office pathology service in April 2010, the practice hired one pathologist and later added two more. Each has years of experience in GI pathology and is paid on a fee-for-service basis.

"Initially, at the launch of operations, we had one part-time pathologist," stated Josovitz. " A second part-time pathologist was added so we had back-up and coverage in case of a vacation or illness.

"In June of this year, we added the tissue specimens from a 10-member GI group also located in Northern Virginia," he said. "That's when we hired our third part-time pathologist. In each case, we hired senior-level pathologists we had known previously."

Josovitz's group has three offices in Northern Virginia. It operates two endoscopy suites, and has a 30-member staff. This includes three histotechnologists and one medical technologist.

Number Of Tissue Specimens

"Even before we added the pathology specimens from the second group, we had five physicians collecting patient samples from our two endoscopy centers," explained Josovitz. "Now, we have samples coming from two groups and that means we may run 20 to 200 samples per day, or roughly 1,000 jars per month.

"As a physician, it is comforting and reassuring for me to tell the patient that when we remove a specimen, we will look at it right here," he commented. "We can also communicate directly to tell the pathologists that, although a particular specimen may not be a medical emergency, that patient may be worried about the test results. Having that close interac-

Gastroenterology Group Went to Consultants For Help to Establish Its In-Clinic Pathology Lab

LIKE MANY SPECIALIST GROUPS INTERESTED in operating an in-clinic pathology laboratory, Associates in Gastroenterology, P.C., decided to utilize an outside consulting company. This would help the group design an efficient laboratory and meet all compliance requirements with a minimum of delays.

"The group, based in Manassas, Virginia, needed about 300 square feet of space and an investment of approximately $300,000 to $350,000 in equipment," stated Bernie Ness, a laboratory consultant with **In-Office Pathology** in Lake Forest, Illinois. Ness is also the founder of **BJ Ness Consulting, LLC**, in Toledo, Ohio.

"To start offering its own in-office pathology services, the group needed a pathologist, of course," Ness explained. "The group also needed a tissue processor, a multistainer, embedding stations, along with slide and cassette writers. The most expensive of all this equipment is the immunohistochemical stainer.

"The value of the in-house pathology laboratory is that the specimens never leave the practice," he said. "For a gastroenterology practice, this eliminates the need and expense of logistics and shipping.

"When tissue specimens must be shipped overnight, the overnight delivery companies can make mistakes and can easily lose or damage specimens in transit," noted Ness. "Moreover, when the tissues are shipped out of town, the reimbursement for these cases does not stay in the local economy.

"In some communities, sending out $2 million to $3 million per year of pathology testing would be a significant hit to the local economy," Ness explained. "The in-clinic pathology laboratory allows those specimens to remain in the community. Plus, by hiring local people and local pathologists, that also helps the local economy. In a small town, that might be noticeable.

"Under current regulations, practices may share a pathology laboratory," he added. "Since the GI groups sharing this laboratory do not serve Medicare patients, they do not need to be in the same building. The practices share the lab expenses monthly and each has its own laboratory information system (LIS) to prevent co-mingling of patient specimens and test reports. This arrangement is technically known as a 'block-shared lease agreement'."

tion and comfort with our pathologists really makes the process tick.

"Another advantage of the in-office pathology service is that our multiple pathologists allow us to get a second opinion within our own group," he added. "For most patients, a second opinion may not be needed. But for the difficult case, having two or more GI pathologists who can look at that sample is quite reassuring for the physician and for the patient.

An Increase in Revenue

"In addition to improving patient care, the service also has increased our revenue," Josovitz said. "Even though it's a small percentage of our total revenue, in a time of decreasing compensation, this service plays a big role for us and possibly for other physicians as well. It is somewhere in the range of 5% to 10% of total revenue."

On the subject of accountable care organizations (ACO), Josovitz said that he did not know if the in-office pathology service will be helpful were his group to want to participate in an ACO. "At this time, we are not considering participating in either an ACO or a medical home," said Josovitz. "However, we do consider having an in-clinic pathology laboratory as a valuable tool when we are ready to recruit new physicians, both because of its clinical value and how it adds financial value to the practice." TDR

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AP Labs in Doc's Clinics Now an Established Fact

➤Urology and gastroenterology groups value having an in-clinic anatomic pathology service

➤➤CEO SUMMARY: It started about eight years ago and shows no signs of slowing down. Specialist physicians, particularly urologists and gastroenterologists, have learned about the benefits of operating their own in-clinic anatomic pathology laboratories. One-by-one, these specialty practices are investing in this ancillary service. As they do, local pathology groups lose access to these tissue referrals. This major shift in the pathology marketplace gives many indications that is a trend that won't be reversed.

OVER THE PAST DECADE, there has been a steady shift in how specialist physicians refer their anatomic pathology specimens. With increasing frequency, these specialists choose to build their own in-clinic pathology laboratory and take responsibility for the anatomic pathology testing performed on behalf of their patients.

This trend is disruptive to community hospital-based pathology groups, for a simple reason. In most cities, the largest source of specimen referrals to local pathology groups has been urology and gastroenterology groups located in the same community.

➤Lost Access To Specimens

Thus, when these local specialists establish their own in-clinic anatomic pathology laboratory, there is a significant fall-off in specimens flowing to the local anatomic pathology group. If the decline in case referrals from long-time client physicians is significant, it can trigger serious operational and financial issues for the pathology group which lost access to these cases.

Pathologists are justified in their concern about the long-term consequences of this trend—both on the future of their pathology group practices and on their profession. However, many pathologists fail to understand the larger transformation going on in the anatomic pathology testing marketplace, of which specialist in-clinic pathology labs represents just one element.

The same attractive economics that made the profession of anatomic pathology such a good place to make a comfortable living across many decades has caught the full attention of the investment community. These economic fundamentals are bringing an entirely new business mindset to the production, delivery, and marketing of anatomic pathology testing.

At the same time—and independent of the desirable financial opportunities in anatomic pathology—basic healthcare reform trends are about to exert powerful dynamics on how the U.S. healthcare system orders laboratory tests and reimburses for them.

It is necessary to bring both of these sources of change together to understand, for example, why specialist physicians have found it relatively easy to establish and operate their own in-practice anatomic pathol-

ogy laboratories. Further, these same market fundamentals argue that the rather slow and sleepy competitive market for anatomic pathology testing that was standard in the 1990s will not survive the 2010s.

Canary in the Coal Mine

In fact, the trend of specialist physicians bringing anatomic pathology testing in-house might be considered a powerful "canary in the coal mine" warning for the majority of the nation's smaller community hospital-based pathology groups. As go the highest-referring sources of tissue, is likely to go the other sources of tissue referrals.

That implies that other traditional sources of tissue referrals from the outreach community that flow to community hospital-based pathology groups could be similarly diverted. This would happen as investors and more progressive pathologists act decisively to organize a delivery model designed to outperform the turnaround times, the quality, the informatics features, and the customer service typically offered by a smaller pathology group practice.

Caught By Surprise

Because of their daily workload, few pathologists have time to consider how their profession is evolving. That is why they are frequently surprised when physician-clients in their community suddenly decide to switch to another pathology lab company. The warning signs of competitive sales activity were likely visible, but went unseen by the local pathologists because of the loyal referral relationship they had long enjoyed with those office-based physicians in the community.

Similarly, even as many pathologists focused on their daily practice of pathology, new delivery models of anatomic pathology services were enjoying impressive successes. The numbers tell the tale. **Dianon Systems, Inc.**, of Stratford, Connecticut, shifted its business emphasis to anatomic pathology in 1995, a year when its revenues were about $50 million. By 2002, the year it was

Who to Blame for Changes? Urocor? Dianon? Impath?

EACH YEAR, THE COMPETITION FOR ANATOMIC PATHOLOGY SPECIMENS grows more intense. New competitors regularly enter the market and new delivery models for pathology testing constantly spring up.

All of this is the direct opposite of the quiet—and very collegial—anatomic pathology market of the 1980s and later. During this era, the nation's 3,300 independent pathology group practices generally had a defined service area and served office-based physicians within this regional market with little or no competition.

So what changed? And who was responsible? Much of the blame can be attributed to **UroCor, Inc.**, when it was a public lab company in Oklahoma City, Oklahoma. Back around 1992, following a Chapter 11 bankruptcy, UroCor re-organized with a strategy of offering both lab testing and pharmaceutical services to urologists across the nation.

Immediately, UroCor began growing at double digit rates. It did not take long before Dianon Systems, Inc., of Stratford, Connecticut, noticed this growth. By 1995, Dianon was building its own national sales force to call on urologists and gastroenterologists to solicit pathology specimen referrals.

Contemporary with these developments, **Impath, Inc.**, of New York, New York, had entered the market with sophisticated breast cancer assays. It also grew at double-digit rates as hospital-based pathologists referred cases for the secondary diagnosis.

The culminating event to these developments probably came in 2002. In just seven years, Dianon had grown from about $50 million in annual revenue to more than $190 million yearly. It was acquired that year by Laboratory Corporation of America for a whopping price of $598 million!

This acquisition caught Wall Street's attention. Since 2002, hundreds of millions of dollars have been invested to buy and operate anatomic pathology companies.

acquired by **Laboratory Corporation of America**, it had grown to more than $190 million in annual revenue.

Eight Years To $100 Million

Bostwick Laboratories, Inc., of Glen Allen, Virginia, offers a similar example. Founded by David G. Bostwick, M.D., in 1999, it grew to almost $100 million in annual sales by the end of 2007. For investors, these are remarkable rates of growth. They've watched similar successes at other national pathology companies, including **Ameripath**, **Caris**, **CBL Path**, and **Poplar Healthcare** (the renamed **GI Pathology Partners**), to name a few.

For all the decades since World War II, the private group practice was the dominant business model for anatomic pathology. Not until the second half of the 1990s did another business model emerge that proved capable of capturing the tissue referrals of office-based physicians. *(See sidebar on page 7.)* That business model proved to be the national pathology company which sends sales reps to crisscross the country to wrest pathology case referrals away from local pathology group practices.

AP Condo (Pod) Labs

Next, during the decade of the 2000s, specialist physicians began to learn about the financial benefits of operating an anatomic pathology laboratory. The first anatomic pathology laboratory condominium (pod labs) emerged in 2002. *(See TDRs, July 19, 2004, and August 9, 2004.)*

Opposition to this business model by the pathology profession and rather swift regulatory action curtailed this business model within several years of its appearance. However, by that time, the genie was out of the bottle. Urologists and GIs had quickly learned that there were financial benefits and clinical advantages to having an in-clinic anatomic pathology laboratory. Over the past five years, a steadily-growing number of these specialist groups invested to create their own pathology laboratories.

Pathologists who comment publicly about this trend often attribute financial motives to the decision by specialist physicians to create their own anatomic pathology laboratories. After all, who better understands the favorable economics associated with processing and diagnosing tissue than pathologists?

But this trend has other important drivers. Specialist physicians face greater pressure to deliver improved health outcomes for their patients. Medicare and private payers are designing reimbursement incentives which reward physicians when they improve patient care.

Patient Satisfaction Surveys

At the same time, payers are measuring patient satisfaction with their physicians. Office-based physicians know that they must also continually do better at meeting the expectations of their patients—as measured by patient satisfaction surveys.

All of these factors are reasons why a specialist physician can defend the operation of a pathology lab within his or her group. Sure, there is money to be made, but, as the physician business leader who was interviewed on pages 3-5 pointed out, the gastroenterologists in his group enjoy a 24-hour turnaround time for their pathology testing, have more control over the quality of the tissue that is collected and processed by their in-house pathology lab, and enjoy much closer contact and ongoing consultations with their pathologists.

It will benefit pathologists who are reading all these tea leaves to understand that, whether the competitor to the community hospital-based pathology group is a national pathology lab or in-sourcing by local specialist physicians, the referring physicians have a choice about where to send their tissue specimens. The local pathology group can compete successfully—but it must first step up its own service level and sales program. TDR

The Dark Index

Sonic Healthcare Ltd., Reports Full Year Earnings For FY 2011

Australian-based laboratory company now holds third largest share of doc's office referral tests in U.S.

On August 23, **Sonic Healthcare Ltd.,** of Sydney, Australia, released its financial results for its fiscal year ending June 30, 2011. This provided an opportunity to assess Sonic's impact in the United States, where it has regularly expanded its testing activities.

Sonic reported statutory revenue in FY 2011 of A$3.1 billion, compared to A$3.0 billion of statutory revenue in FY 2010. The company said that this growth was 3.4%. During the same period, earnings before EBIDTA grew from A$544 million to A$570 million. This was an increase of 11.3%

In U.S. dollars, Sonic's FY 2011 revenues were $3.3 billion. This compares to the FY 2010 revenues of **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** of $7.4 billion and $5 billion, respectively.

Buying Labs In the U.S.

Since 2005, Sonic Healthcare has been a regular acquirer of clinical laboratory companies and pathology companies in this country. It is now the third largest U.S. laboratory company serving the physicians' office market segment.

For FY 2011, Sonic reported annual revenues from its U.S. operations of A$721 million (US$768 million). This represents 23% of Sonic's total revenue. By contrast, Sonic generates A$923 million of revenue from Australian lab operations and A$541 million from European lab operations.

To achieve its current market share in the United States and Europe, Sonic has invested substantial capital. In its FY 2011 earnings report, it disclosed that, since 2005, it spent US$1.36 billion purchasing laboratory companies in this country. It also stated that it has invested €430 million (US$610 million) in Germany alone since 2007.

Major Global Lab Presence

The importance of the United States to Sonic's long term growth strategy can be seen in the company's FY 2011 financial report. In Australia, it is the nation's largest provider of pathology and clinical lab testing services. Opportunities to further grow market share in Australia are limited.

By contrast, in less than six years, it has been able to build a lab testing business in the United States that has gone from zero to US$768 million. This U.S. book of business now represents 23% of Sonic's total yearly revenue. Moreover, the company still has the potential to significantly increase its share of lab testing in the United States.

In its hunt for new lab acquisitions in the United States, Sonic has earned a reputation as a disciplined and careful buyer. It has been outbid for several of the larger lab companies that have come to market. But independent lab owners often favor selling to Sonic, since its federated business model means it typically keeps the name, the lab facilities, the management team, and the staff of the lab companies it does acquire. TDR

NEWSMAKER INTERVIEW

How Digital Pathology Helps Pathologists Deliver Added Value

"Pathologists have the opportunity to take on a new clinical role as the integrator of all that digital pathology information, in combination with the patient's other clinical data collected from a wide variety of sources."

—Dirk G. Soenksen, M.S., M.B.A., *Founder and CEO, Aperio*

CEO Summary: During the 1990s, the pathology profession was exploring ways to use telepathology services. But it was only in the last decade when digital pathology technology became robust enough to support a variety of clinical uses in anatomic pathology. One of the first companies to offer such digital pathology systems was Aperio Technologies, Inc., of Vista, California. Dirk G. Soenksen, M.S., M.B.A., is the Founder and CEO of Aperio. In this exclusive interview with The Dark Report, he discusses major trends in healthcare that are actively reshaping the anatomic pathology profession. In part one of this two-part interview, Soenksen provides insights that will help pathologists and pathology group practice administrators develop effective clinical and financial strategies for their laboratories.

Part One of Two Parts

EDITOR: On a macro level, let's begin by identifying the major trends in healthcare that you believe will most affect lab testing services and anatomic pathology.

SOENKSEN: What immediately comes to mind is personalized medicine and integrated clinical care. Over the next decade, both trends will open new doors of opportunity for pathologists and clinical laboratory professionals.

EDITOR: In the realm of personalized medicine, would you comment about how knowledge of the human genome is likely to play a role? After all, pathologists already perform diagnostic tests that involve the analysis of DNA, RNA, and proteins.

SOENKSEN: Consider what happens when it is possible to sequence the whole human genome in 20 minutes for less than $200. First, this makes it economical to do a whole human genome sequence for every patient. Second, this genetic information will be essential as the physician develops personalized care plans for each of his or her patients.

EDITOR: How might this change the role of the pathologist?

SOENKSEN: Certainly pathologists and other laboratory scientists will advise physicians about how to interpret genetic information, then how to develop a proactive wellness and care plan for the patient. But don't forget that the health system will still need a pathologist to identify abnormal tissue—particularly where there is cancerous tissue.

EDITOR: Pathologists play that role in today's health system. So what do you think will be different?

SOENKSEN: Pathologists will continue to do all the things they currently do now in diagnosing disease. Certainly the pathologist will need to identify the tissue that goes into the sequencer or the mass spectrometer and interpret the results. But where the pathologist takes on a new role is that he or she can become the integrator of all that information in combination with other clinical data collected from a wide variety of sources.

EDITOR: This ties into your view that there will be more and tighter integration of the clinical care provided to individual patients. As this happens, is the pathology profession positioned to step into the role of the "information integrator"? Will pathologists become a primary source of consultative expertise to physicians?

SOENKSEN: Yes. Recognize that many types of disparate data will flow into the patient record, including from the gross specimen, the H&E, the IHC, flow cytometry, and genetic testing. Those are data that originate in the anatomic pathology laboratory. At the same time, this data must be integrated with the full patient history, radiology, pharmacy, and other relevant information. Pathologists have the knowledge, the training, and the experience to pull all this information together and to deliver an integrated answer to the physician. This integrated answer can first be the diagnosis. But the

patient's physician will next want guidance on selecting appropriate therapies and monitoring the patient's progress.

EDITOR: Do you believe the pathology profession will want to step into that role as integrator and consultant?

SOENKSEN: If healthcare is to deliver personalized medicine and do it within an integrated care delivery model, then there is a clear need for a physician who can pull together all the data associated with an individual patient. It will require a specialist to assess this information in a way that helps the patient's physician understand all the relevant parameters. I predict that this role will be filled by the pathologist.

EDITOR: Historically, the pathology profession has not been proactive about stepping into new roles. Can it transition into this clinical opportunity?

SOENKSEN: That is the right question. Can pathology become the preferred integrator of that information? It presents pathologists with both an opportunity and a challenge.

EDITOR: I want to explore another area of pathology now. With the explosion in molecular diagnostics and steady advances in genetic technologies for diagnostic and therapeutic purposes, how do you see pathologists responding to these trends in today's marketplace?

SOENKSEN: Molecular pathology is on its way to becoming a much more important subspecialty in pathology. As that happens, pathologists must find ways to become more efficient.

EDITOR: Are you saying that the productivity of individual pathologists will need to increase in order for them to handle greater volumes of work?

SOENKSEN: Yes, because pathologists will require additional time on a single patient case. Not only to diagnose the tissue, but also to integrate disparate types of information so they can help the referring physician understand all this data and make the right decisions about the patient.

EDITOR: I'll bet that's a point most pathologists have not considered. As they continue to do the primary and secondary diagnosis of the tissue, they have the opportunity to pull together all the relevant data in the full patient health record, then use that information to consult with the referring physician.

SOENKSEN: That is well said. It is why the pathology profession must find ways to automate the routine and more mundane work they are doing now.

EDITOR: Do digital scanning and digital pathology systems offer a way to automate what you call the "mundane" work that currently makes up part of every anatomic pathologist's working routine?

SOENKSEN: Digital pathology is a catalyst for automating that mundane work. We envision that the pathologist will work in what we describe as the pathologist's "cockpit." This is a work station with multiple screens and software that gives the pathologist access to all the pathology data and the patient's other relevant clinical data.

EDITOR: You describe a working environment where the pathologist takes on a new role, not just in diagnosing the tissue, but also in integrating all relevant diagnostic data for the patient.

SOENKSEN: Certainly this process does start with digital access to the microscopic information for the gross specimen. The design of this cockpit is to allow the pathologist to integrate that information with other disparate sources of information into a single unified viewing environment.

EDITOR: It makes sense. Having an integrated care continuum creates the demand for a specialist—such as a pathologist—to pull together all the diagnostic and prognostic information.

SOENKSEN: That's true. Having all this information in one place will be incredibly valuable to the pathologist and ultimately to the oncologist treating the patient. This future state of the pathologist's cockpit should be exciting for pathologists. Yet to make this concept a reality will require strategic thinking by the pathologist community. Pathologists must understand how to process that information and move into that consultative role with physicians.

EDITOR: This concept of the pathologist as an information integrator is something that you and your Chief Medical Officer, Jared N. Schwartz, M.D., Ph.D., have advocated for several years now. How do others accept this prediction?

Dirk Soenksen

➤"Molecular pathology is on its way to becoming a much more important subspecialty in pathology. As that happens, pathologists must find ways to become more efficient."

SOENKSEN: When we talk with customers, we share our vision for where pathology will go. The vast majority of pathologists and healthcare professionals we speak with agree with this vision: there will be the need for a specialist to collect and interpret all the patient's information.

EDITOR: Are there other physician specialities that might take on this role?

SOENKSEN: Some people do ask "if the pathologist doesn't do it, then who will?" It's not easy to identify another medical specialty or physician type who is well suited to perform this service.

EDITOR: That's true, since pathologists are trained to understand the diseases and health conditions for which laboratory tests are used in diagnosis, prognosis, and patient monitoring.

SOENKSEN: It goes beyond that. Pathologists are ideally suited for this expanded role. They are trained in systems biology. It is already in their nature to integrate disparate sources of information. These attributes make them ideally suited to sit in the cockpit and provide information that is actionable for oncologists.

EDITOR: We've discussed your vision for pathology that is anchored around personalized medicine, molecular testing, and molecular pathology specifically. This will take a few years to become reality. Can we shift gears now and talk about what is happening today in the anatomic pathology marketplace? How do you see the traditional practice patterns of the community-hospital-based pathology group changing?

SOENKSEN: Demographics are about to hit private practice pathology with a powerful series of blows. This is already changing the supply of pathologists even as the demand for anatomic pathology testing grows at double-digit rates.

EDITOR: It is generally known that the average age of a pathologist today is 55 years old and the oldest baby boomers turn 65 during 2011. So the retirement of significant numbers of baby boomer pathologists is now a reality. What other supply-demand factors do you see?

SOENKSEN: The total number of pathologists in the United States is decreasing. That's because the number of young physicians who select pathology already falls short of replacing the number of pathologists who retire each year.

EDITOR: Isn't the skill mix also changing?

SOENKSEN: Yes, because in recent years, pathology residents are acquiring subspecialty expertise. Meanwhile the pathologists who retire mainly have general pathology experience.

EDITOR: Why is this shift to subspecialty pathology expertise significant?

SOENKSEN: It creates a logistics challenges. For example, how do you deliver the right slide to the right pathologist quickly enough to support acceptable turnaround times?

EDITOR: That makes sense, since the subspecialist pathologist may not be located close to where the patient's specimen was collected and processed. What other trends are important at the moment?

SOENKSEN: Another factor is that the population is aging and this increases the number of biopsies from one year to the next. Similarly, there are more surgical procedures which may require the surgeon to collect a needle biopsy. That also is increasing the number of pathology tests that need to be performed. The third trend is the steady growth in the number of new diagnostic tests that utilize new biomarkers. These trends create pressure on community hospital-based pathology groups.

Dirk Soenksen

➤A digital pathology system makes it easy to support consultations and second opinions. It is generally an efficient way to have the right pathologist look at the right slide."

EDITOR: Dirk, you've provided a great capsule perspective on the primary trends in the anatomic pathology marketplace. Now let me ask about the use of digital pathology in today's marketplace. What factors are driving adoption of digital pathology today?

SOENKSEN: Several primary benefits can be seen by observing how pathology groups that acquire digital pathology systems use them. For example, many groups view digital pathology as a way to have the right pathologist analyze the right slide at the right time with the right tool.

EDITOR: Please explain this.

SOENKSEN: Here in the United States, we do not have a shortage of pathologists. Rather, we have an inefficient deployment of pathologists based on subspecialty expertise. That is why many groups use digital pathology systems to deliver the images of a case to the right subspecialist.

EDITOR: That would be one reason why academic center pathology labs have been among the first to acquire and use digital pathology systems.

SOENKSEN: Yes. In addition to such uses as teaching and tumor board meetings, a digital pathology system makes it easy to support consultations and second opinions. It is generally an efficient way to have the right pathologist look at the right slide.

EDITOR: That makes sense.

SOENKSEN: It does. You want a pathologist with breast tissue expertise to look at breast tissue slides. The digital pathology image doesn't have to be shipped to him/her, nor does he/she have to drive somewhere to look at the glass slides. Because those slides are digitized, the images are available on a network or over the Internet.

EDITOR: Dirk, this is a good place to end part one of our interview. During part two of this interview, we can discuss how the pathology market is using digital pathology technology to add value. We can also learn more about the economics of acquiring and using a digital pathology system.

SOENKSEN: Thank you. Our discussion is about to get very interesting because of how digital pathology, in combination with new diagnostic technologies, will help pathologists offer new clinical services and meet the financial challenges from declining reimbursement. TDR

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Part two of this Newsmaker Interview will focus on pathologist acceptance of digital pathology and how first-mover pathology laboratories are using digital pathology technology to add value to physicians and payers. It will be presented in an upcoming issue of *THE DARK REPORT*.

Market Strategies

Rhode Island Lab Educates Consumers about Lab Prices

TWIN TRENDS NOW CREATE an opportunity for clinical labs and pathology groups to build market share. But tapping these new buyers of laboratory tests will require labs to communicate more effectively with consumers.

One trend is the growth in enrollment in health plans that require higher deductibles. Consumers with this type of health coverage are highly motivated to shop around. They want to find the clinical laboratory that offers them the best combination of lab test quality at the lowest price.

The second trend is the increased number of unemployed or underemployed individuals in this country. The recession of 2008-2010 added millions of people to the unemployment rolls. As "cash customers," many of these consumers must get their lab tests done at an affordable price. Otherwise, they don't have the lab tests performed at all because they simply don't have money to pay the lab test charges.

Consumers Want Low Prices

Across the nation, local clinical laboratories are recognizing that these two groups of consumers represent a good business opportunity, particularly since they can pay cash for their laboratory tests at the time the specimen is collected. However, most clinical labs have never targeted consumers with sales and marketing campaigns. Thus, they are not experienced at reaching these consumers.

One lab company in Rhode Island has begun taking steps to help consumers cut healthcare costs associated with laboratory testing. **East Side Clinical Laboratory** of East Providence, Rhode Island (a business unit of **Sonic Healthcare, Ltd.**), now operates a standalone website designed to educate consumers about laboratory testing and the steps they can take to cut the cost of lab testing.

An Example to Other Labs

East Side has built a consumer-oriented website at *www.labchoice.org*. Under a headline that says "Relief!", it prominently offers four discussion points, along with information designed to educate consumers that they do have a choice when it comes to ordering and paying for clinical laboratory tests. The questions are:

- Why Use an Independent Lab?
- Common Questions on Choosing a Lab
- About East Side Clinical Lab
- Find a Lab

In addition to this website that provides information to consumers about how they can lower the cost of their laboratory testing, East Side Clinical Laboratories has gone one step further. It has a patient list price schedule that its customer service department uses to quote prices to consumers who call the lab seeking to save money on their laboratory tests. The company believes this price transparency gives it competitive advantage with consumers who need to access lab testing at the lowest possible price.

Today, cash-paying consumers represent a small, but fast-growing segment of the market. For that reason, clinical labs and pathology groups may want to consider how they can better serve these price-motivated buyers of lab tests. TDR

Georgia HIE Helps All Labs Feed Test Data to Docs

➤Lab hub will interface to physicians' EHRs to support lab orders and lab results reporting

➤➤CEO SUMMARY: In Macon, Georgia, an innovative effort by a regional extension center and a health information exchange (HIE) will level the playing field for hospital labs and independent labs in the state. Their goal is to build a secure and flexible clinical integration platform known as a "lab hub." This common interface will allow all physicians in the network to use their electronic health record (EHR) systems to order lab tests and receive structured lab test results directly into a patient's health record.

TODAY, OFFICE-BASED PHYSICIANS send and receive electronic data in a wider variety of formats than ever before. But getting lab test results into their electronic health record (EHR) systems in a useful way continues to be a challenge for many physicians.

To further complicate this situation, health information exchanges (HIEs) are becoming operational in many regions across the country. They represent another "layer" through which lab test orders from physicians and lab test results from laboratories may need to pass.

To solve this problem, in Macon, Georgia, the **Central Georgia Health Network** (CGHN) and the **Georgia Health IT Regional Extension Center** (GA-HITREC) have teamed up with **Halfpenny Technologies, Inc.**, of Blue Bell, Pennsylvania. To help physicians get lab test data transmitted seamlessly into their EHRs, CGHN has deployed a "lab hub" portal solution developed by Halfpenny.

In Georgia, all laboratories can participate in this lab hub, which is designed to enable the seamless and secure exchange of clinical data for the 700 CGHN physicians participating in the region's HIE initiative. Halfpenny installed the system as part of a six-month demonstration project that started this summer.

CGHN has more than 700 physicians in 128 medical practices in and around Macon. The lab hub from Halfpenny will send all of the lab orders from these physician members to various commercial and hospital labs throughout Georgia. These same labs will transmit lab test results back through the lab hub and into the EHRs of the referring physicians.

➤Seamless Lab Data Access

Before sending the orders, the system assigns Logical Observation Identifiers Names and Codes (LOINC), a universal code system for sending and receiving laboratory and clinical data. LOINC is managed by the **Regenstrief Institute, Inc.**, in Indianapolis, Indiana. Using LOINC to send orders and receive results allows both the physicians' EHRs and the labs' information systems to communicate easily.

Georgia Physicians Insisted on Getting Lab Test Results at the Point of Care

WHEN SURVEYED ABOUT WHAT THEY WANT from a health information exchange (HIE), physicians in the Macon, Georgia, area were quick to identify the importance of reliable access to laboratory test result data.

One primary objective of this HIE, which is called the Central Georgia Health Network (CGHN), is to allow participating physicians to send and receive data from their electronic health record (EHR) systems. According to Stephen Barry, COO of CGHN, physicians indicated that, at the point of care, they want speedy and accurate access to view lab test results and then to act upon that information.

To develop a lab hub that can deliver this access, CGHN partnered with the Georgia Health Information Regional Extension Center (GA-HITREC) and Halfpenny Technologies, Inc., of Blue Bell, Pennsylvania. The lab hub will be the interface engine that connects all Georgia labs with CGHN's 700 physicians who run 18 different EHR systems.

"The biggest hurdle is getting different vendors to work with each other," declared Barry. "During our four years of effort to become clinically integrated, if there has been a wrinkle, it has come from a disagreement between vendors.

"The 700 providers in 128 different practices use different EHRs and each practice is an independent entity," he noted. "The lab component for the Georgia Health Information Technology Regional Extension Center (GA-HITREC) is one of the most important enhancements. We want a physician in the emergency room to be able to pull up a patient's chart and see what happened with that patient in real time, perhaps even something that happened the day before, such as a lab test result.

"This system is important to us because it will also allow us to use the data for quality measures," Barry added. "For example, take a patient who is 45 years old, is on a statin drug, and needs an enzyme check every six months.

"We want physicians or other caregivers to look at the data and be able to see whether that enzyme check was actually done," he concluded. "If this test wasn't performed, the physician knows he or she should order that test. Having that information readily available at the point of care allows us to deliver quality care."

This development is significant for lab directors and pathologists because it allows smaller laboratories to compete with large regional and national labs for physicians' lab test orders without being at a technological disadvantage. Often, larger lab companies try to lock up physicians with proprietary information systems that smaller labs cannot provide.

"If the Georgia demonstration project is successful, it could be expanded statewide," said Dominic Mack, M.D., MBA, Director of GA-HITREC and Deputy Director of the National Center for Primary Care at **Morehouse School of Medicine**.

"Most HIE platforms have generic pass-through systems that do not go the last mile to allow physicians to get structured lab data into their EHRs," explained Jerry Baker, President and CEO of Halfpenny. "Recognizing the complexity of lab data, we built the lab hub to handle both the outbound order-entry side from a physician EHR system to a hospital or a reference lab and the inbound transmission of structured lab test results from labs back to the EHRs.

Two Big Advantages

"Our system has two significant advantages," he added. "First, it is built around the workflow of the physicians and we ensure that everything we do is transparent to them. Physicians will generally use a new system only when it complements their existing workflow.

"Second, and perhaps more important, is the LOINC mapping we do," Baker

said. "The multiple hospitals and reference laboratories participating in the demonstration project have different test-naming nomenclatures and they use different methodologies to perform the tests.

"That means the values of the lab test results can mean different things to different physicians," he noted. "Obviously, that approach won't work in a lab hub serving all healthcare providers on the same system."

The key to making it work is to provide structured lab test results to the EHRs, which is accomplished by Halfpenny's team of medical technologists and programmers. "Our dedicated staff of credentialed medical technologists map all of the participating labs to the LOINC standard," Baker explained. "When the data gets to the HIE, it has already been normalized.

"Normalizing the lab data is the crucial part of the process," he added. "You don't want different lab results to mean different things at the HIE level. You need apples to apples."

Helping Local Labs

Baker observed that local labs will directly benefit from participating in the HIE. "In this way, we have leveled the playing field for interconnectivity," he said. "It means that smaller labs can compete more successfully with larger national labs.

"Connectivity is one strategy that larger labs use to gain competitive advantage and try to own the transmission of these lab data," Baker noted. "This is a very inefficient approach because each physician's office must be connected and interfaced one at a time. The end result is hundreds and thousands of point-to-point interfaces, which the national labs must manage and maintain.

"The benefit of a lab hub, by contrast, is that all the participants need only one pipe to connect to the hub," continued Baker. "This is far more efficient. It is also cost effective and easier to support."

"Aggregating health data at the hub level is important for another reason," stated Baker. "It allows health plans and the Medicaid program to manage the care of a population for disease management and pay-for-performance programs."

Solving A Major Problem

Mack stated that, for physician members of CGHN, the inability of their EHRs to get test results from commercial and hospital labs was one of their biggest problems. "Whenever we implemented an EHR system, we needed to integrate the lab data with that EHR," he said.

"We also wanted a connectivity vendor that would be neutral in two ways," noted Mack. "First, it would be neutral as to the lab providing testing services and second, it would be neutral to the EHR product the physicians use.

"GA-HITREC was established to help physicians with the selection and implementation of certified EHR systems," noted Mack. "This will include assisting physicians in achieving meaningful use so that they can qualify for federal reimbursement.

"Another major goal is to improve clinical outcomes and care delivery, particularly in under-served communities," he said. "GA-HITREC is funded with a $19.5 million grant from the U.S. **Department of Health and Human Services** (HHS) that is administered by **National Center for Primary Care**."

THE DARK REPORT observes that this Georgia HIE provides an early example of how new information technologies will make it easier for local labs and hospital laboratory outreach programs to serve office-based physicians. It will also help these physicians meet meaningful use criteria and qualify for federal incentives associated with EHR adoption. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Cleveland Heart Lab closed on a Series B financing round that totals $18.4 million. The money was provided by **Excel Venture Management**, **Healthcare Ventures**, and existing investors. Executives at Cleveland Heart Lab said the new funds will be used to further promote its proprietary diagnostic tests that assess risk of cardiovascular disease. The company also intends to triple the size of its facilities, located in Cleveland, Ohio, as well as to bring new proprietary biomarkers to market. It plans to introduce a new lab test for assessing HDL cholesterol in early 2012.

TRICORE LABS ANNOUNCES 15189 ACCREDITATION

In Albuquerque, New Mexico, **TriCore Reference Laboratories** announced on August 24 that it had earned accreditation to the CAP 15189 quality management system (QMS). One distinction TriCore claims is that it is first in the United States to earn 15189 accreditation as a multi-site laboratory.

MORE ON: *TriCore*

On its website, the **College of American Pathologists** (CAP) lists 16 laboratory organizations which have current CAP 15189 accreditation. It introduced the program in 2008. The CAP 15189 accreditation is based on quality standards of "ISO 15189 Medical Laboratory," as published by the **International Organization for Standardization** (ISO).

TRANSITIONS

• Effective September 1, 2011, James C. New retired as CEO of **Aurora Diagnostics Holdings, LLC**, of Palm Beach Gardens, Florida. He will continue to serve as Chairman of the Board. Prior to joining Aurora Diagnostics, New had served as Chairman and CEO of **Ameripath, Inc.**, between 1996 and 2004.

• Stepping into the role of CEO for Aurora Diagnostics on September 1, will be Jon L. Hart. During his career, Hart has worked at **Genzyme Genetics**, **Quest Diagnostics Incorporated**, **SmithKline Beecham Clinical Laboratories**, and as a CPA with **Arthur Young & Company**.

• **Cardinal Health, Inc.**, of Dublin, Ohio, has named David King as a director, effective September 1. King is Chairman, President, and CEO of **Laboratory Corporation of America**. He is also currently **Chairman of the American Clinical Laboratory Association** (ACLA).

That's all the insider intelligence for this report. Look for the next briefing on Tuesday, September 26, 2011.