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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 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Laboratories Lead Healthcare on Quality Systems

IS THE REST OF HEALTHCARE CATCHING UP TO THE LABORATORY INDUSTRY when it comes to the use of quality management systems like ISO-9000, Six Sigma, and Lean? In the May 2, 2005 issue of *Modern Healthcare*, there's a major story on quality management systems and how some hospitals are using same to drive major improvements in performance.

For clients and regular readers of THE DARK REPORT, this is *old news*. Since our founding in 1995, we've been first to report on the substantial benefits accruing to labs which first pioneered the use of quality management systems. It was 1998 when we were the only lab industry source to announce the ISO-9000 certification of **Quest Nichols Institute** (San Juan Capistrano, California) and provide details of specific benefits generated by this laboratory's adoption of ISO management precepts.

The laboratory industry should be proud of the fact that it is ahead of the hospital industry in accepting quality management systems. These are the management tools which will enable pathologists and laboratory managers to better meet the challenges of falling reimbursement and the need to raise the quality of health outcomes.

For those who don't know, *Modern Healthcare* can be described as a "*U.S. News & World Report*" weekly magazine for healthcare executives. It is widely-read by hospital administrators. I say this for a reason. As I read *Modern Healthcare's* story about quality management systems in hospitals, I was struck by the reporter's tone. Instead of highlighting the major improvements in operations, clinical outcomes, and productivity enjoyed by the handful of hospitals now utilizing Lean, Six Sigma, ISO-9000, and other systems, the reporter chose to characterize the champions of such quality initiatives as "enthusiasts."

The story conveyed an impression that Lean and Six Sigma practitioners in hospitals were "outside the mainstream" because of their energy and enthusiasm. I strongly disagree with this perspective. I hold firm convictions that Lean/Six Sigma-types of management philosophies are poised to trigger radical evolution in healthcare. *Modern Healthcare's* willingness to under-emphasize the powerful potential of these quality management systems might be considered a sign that it believes many hospital administrators are still unprepared to accept quality management systems as a credible tool for their institutions. TDR

Lab Innovators Point Way At *Executive War College*

Emerging trends point to more emphasis on lab service quality & physician satisfaction

CEO SUMMARY: Now in its tenth year, this Executive War College attracted a record crowd, including laboratory leaders from Europe, Africa, South America, and Asia. The unexpected finding was that, along with the growing acceptance of Lean, Six Sigma and other quality management systems by the nation's first-rank lab organizations, assertive surveying of physician and patient satisfaction is driving strategic progress.

By Robert L. Michel

SEVERAL OF THE NATION'S MOST INNOVATIVE LABORATORIES are actively raising their customer service levels as a primary strategic initiative.

This was one surprising insight from this year's *Executive War College on Lab and Pathology Management*, conducted May 3-4, 2005 in New Orleans. Specifically, these laboratories are spending money to regularly survey referring physicians, patients, and their own employees. The survey results are used to drive improvements in the operational performance of their laboratories.

In hindsight, the emphasis on boosting customer service performance is a logical consequence of how these laboratories are implementing quality management systems within their operations. After all, one of the core principles of quality management systems is that the organization regularly ask customers to define quality and evaluate the performance of the organization.

Two other central themes in strategic laboratory management emerged from the presentations made at this year's *Executive War College*. First was the growing acceptance by early adopter lab organizations of quality management systems like Lean and Six Sigma. Second was the finding that even laboratories known as "first movers" are taking a measured approach to how they establish and expand the molecular diagnostics they offer clinicians.

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

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $11.90 per week in the US, $12.50 per week in Canada, $13.65 per week elsewhere (billed semi-annually).

Another major insight gleaned from this year's event was that the laboratory industry is enjoying a period of relative financial stability. This fact was gleaned from what was *not discussed* by the 40 speakers over the course of the *Executive War College*.

Financial Stability

Absent from their presentations were comments and examples of how their laboratories were operating with negative margins. This is in direct contrast to the general tone and tenor of many laboratories during the mid- and late-1990s, when negative financial pressures were at their peak.

I considered this to be strong evidence that the nation's better-managed laboratories are taking advantage of this "financial calm" to advance their strategic initiatives. That conclusion is supported by the types of business initiatives discussed during case studies presented by **NorDx Laboratories** (Scarborough, Maine), **Sonora Quest Laboratories** (Phoenix, Arizona), and **University Hospital Health System** (Cleveland, Ohio.)

Docs Notice Improvements

Executives from these laboratory organizations described the types of management strategies they are using to push their laboratories ahead and maintain competitive market advantages they hold in their respective service markets. A common attribute from all these case study presentations was a management goal of improving daily service performance within the laboratory—by such an extent that these improvements are both noticed and valued by client-physicians using these labs.

Sonora Quest Laboratories (SQL) was a dramatic example of this trend. SQL is a laboratory joint venture between **Banner Health** and **Quest Diagnostics Incorporated**. It is considered the dominant lab competitor in the state of Arizona. COO Joyce Santis discussed how SQL regularly surveys its customers and its employees. SQL uses internationally-recognized survey firms to help it ask the right questions and respond effectively to the results.

Two examples illustrate how management at Sonora Quest Labs has used the information from these surveys. First, after the initial merger of two pre-cursor lab organizations into SQL, voluntary employee attrition was unacceptably high, running 38% in 1999. By 2001, voluntary employee attrition had dropped to 12.4% and most recently stood at 10.5% for 2004. Santis described how employee participation in the annual survey had initially been 33% in 1999. That figure had climbed to 94.8% in 2003, as employees saw how management was making positive changes, using information from these surveys.

Annual Customer Survey

The second example is how SQL uses the information developed from a survey of laboratory customers in its service area. This annual survey is conducted by an independent company. The results show that SQL's high-quality services are recognized and preferred by a significant number of physicians in Arizona.

SQL regularly meets with managed care companies to share this information and build its credibility. It is obtaining better pricing because it has evidence that its service performance is above those of other commercial lab companies serving Arizona.

When it comes to the "wow" factor, **Fleury Diagnostics** of Sao Paulo, Brazil was a clear crowd favorite. Fleury Diagnostics is probably one of the world's best examples of a high-service clinical laboratory organization. The pre-

sentation was conducted by Ewaldo Russo, M.D., Ph.D., CEO and Rogerio Rabelo, M.D., Ph.D., Product Manager, Core Lab and POCT.

As noted by Rabelo, healthcare in Brazil is basically a free market. That means both physicians and patients can choose their laboratories. Fleury decided to make itself into a high-service laboratory that would serve physicians and patients capable of paying for high quality laboratory testing.

Total Diagnostic Centers

Rabelo and Russo captured the crowd with their business strategy, photographs of their patient service centers and staff, and the financial/performance measures of their laboratory company. Fleury's patient service centers offer a full range of diagnostic services. Besides a complete menu of laboratory tests, Fleury also provides diagnostic services in nuclear medicine, imaging, cardiology, endoscopy, cytogenetics, and nine other clinical specialties.

At its busiest patient service center (PSC) in Sao Paulo, Fleury draws blood from more than two thousand patients daily. Fleury's goal is to achieve an average waiting time in all its PSCs of 2.2 minutes. It currently has an average of 3.14 minutes. Equally impressive, Fleury has the informatics capability which allows its managers to track this performance in real time.

Regular Patient Surveys

Like other case study laboratories presenting at the *Executive War College*, Fleury regularly surveys patients and physicians. It uses this information to help managers and employees "raise the service bar" on a continuous basis. When THE DARK REPORT conducted a site visit of Fleury Diagnostics in the fall of 2003, it saw a truly world-class patient service network and clinical laboratory operation.

For the *Executive War College* audience, it was a stunning vision of what laboratories can achieve. I might describe what Fleury has built as a "boutique" lab business on a large scale that is now considered the market leader by competing laboratories in Brazil.

This message resonated with the audience. Within the American healthcare system, the drive to improve patient safety, to improve healthcare outcomes, and meet patient expectations is creating new pressures on laboratory executives. Fleury's presentation was a "best of breed" look into what might possibly evolve to be a service standard in the United States in future years.

Moving to the theme of molecular diagnostics, my primary conclusion from listening to the range of speakers is that the nation's early-adopter lab organizations are moving cautiously. Speakers such as Stan Schofield, CEO of NorDx and Fredrick Kiechle, M.D., Chairman, Department of Clinical Pathology at the **Beaumont Hospital** in Royal Oak, Michigan, discussed the rigorous process used by their lab managers to introduce a new molecular assay to physician-clients.

Simple Admonition

The take-away message common to these presentations was a simple admonition: there continue to be any number of pitfalls associated with a molecular testing program, from clinical performance to inadequate reimbursement. Thus, it is absolutely essential to carefully evaluate every aspect of a new molecular test. And, erring on the side of excess caution is invariably a way to avoid unwanted problems that result if a lab launches a clinical molecular testing program "before its time." TDR

Contact Robert Michel at labletter@aol.com

Carilion Health Acquires Chi Lab Consultancy

Both buyer and seller are implementing new business strategies with this transaction

CEO SUMMARY: In selling Park City Solutions Laboratory Services Group to Carilion Health System, Park City Solutions is returning to its core competency in healthcare information technology consulting services. For Carilion Health System, this acquisition puts it firmly in the national lab consulting service arena. Carilion will operate its laboratory consultancy in total independence of its existing lab services division.

THERE'S A SURPRISING NEW HOME for the laboratory consulting arm of **Park City Solutions, Inc.** (PCS). On March 31, 2005, it was purchased by **Carilion Health System** of Roanoke, Virginia.

Carilion Health System is operating the laboratory consultancy under the name **Chi Solutions, Inc.** and it will continue to provide consulting services to laboratories throughout the United States and Canada. Kathleen Murphy, Ph.D., is the President of Chi Solutions.

Chi Solutions is the legacy business of the lab consulting company known for years as **Chi Laboratory Services, Inc.**, based in Ann Arbor, Michigan. Chi was a business always closely identified with its two principals, James Root and Jan Steiner, M.D. Both individuals recently retired (including the indefatigable Dr. Steiner, now 90 years old).

There are two stories to be told. One is why Carilion Health acquired Chi Solutions from **Park City Solutions**. The other is why Park City Solutions sold its lab consulting business.

Carilion Health's interest in Chi Solutions developed from its ongoing strategic relationship with Park City Solutions. "Carilion Health System is investing substantially in information technology throughout our system," stated Steve Harris, Vice President of **Carilion Consolidated Laboratory**. "We use a PCS product. It was through the extension of our strategic partnership with PCS that we learned that the Laboratory Services Group was for sale.

Focus On IT Services

"Our analysis showed that the Laboratory Services Group was profitable and would contribute to the system," he continued. "It also became apparent to us that the new President and CEO at PCS wanted to refocus exclusively on IT products and services.

"Chi Solutions was acquired by Carilion Health System on March 31, 2005. It is a division of our health system and is independent of our clinical laboratory operation, known as **Carilion Consolidated Laboratory**. Chi Solutions will be operated as a standalone business and will provide ser-

vices to laboratory customers throughout the United States, just as it always has," explained Harris.

When asked about Carilion's motivation to acquire a national lab management consulting firm, Harris had a simple answer. "We believe the acquisition of Chi Solutions is an excellent opportunity for Carilion to grow as a healthcare company. It fits well with Carilion's economic development strategy, bringing high-tech or knowledge companies with strong growth potential into the region.

"Acquiring Chi Solutions is Carilion's first foray into the management consulting marketplace," added Harris. "As of now, it is the health system's only venture of this type. I assume that if Chi Solutions does well in coming years, Carilion Health System may be encouraged to develop management consulting services in other sectors of healthcare."

New Business Start-up

Park City Solutions was created in 1999 by Terry Pitts and Scott Holbrook, formerly executives with **Sunquest** (now **Misys**). It was funded by **Golder, Thoma, Cressy, and Rauner** (GTCR), the same Chicago-based private equity firm that provided capital to **Dynacare** and **American Medical Laboratories**.

Going forward, PCS acquired healthcare IT companies which had expertise in specific areas, like pharmacy, radiology, etc. Its purchase of Chi Laboratory Systems, Inc. in 2000 surprised some, since CLS was a lab management consultancy and did not have a core expertise in laboratory information systems.

Sources tell THE DARK REPORT that, in recent years, Park City Solutions struggled to hit revenue and profit goals set for it by GTCR. In August 2005, Ken Rardin purchased stock in PCS and became its new Chairman and CEO. His goal was to get Park City Solutions back on an aggressive growth track.

Not surprisingly, the laboratory consulting business came up on the radar screen. Because it was not an IT consulting division, it was marked for divestiture. That decision led to the sale of Chi Systems to Carilion Health System on March 31, 2005. **TDR**

Contact Steve Harris at 540-981-7391.

Business Evolution At Chi Laboratory Systems

IT WAS AN ACQUISITION IN EARLY **2000** that made Chi Laboratory Systems, Inc. a business unit of Park City Solutions, Inc. Renamed as Park City Solutions Laboratory Services Group, the lab management consultancy has evolved into new market niches during recent years. *(See TDR, January 24, 2000.)*

In particular, the company seems to have organized around two main lines of business. One involves providing contract management to the sales and management programs for hospital labs offering lab outreach testing services.

The other is management support services for laboratories with regulatory deficiencies. Over the past two or three years, the company has been closely-involved in the turnaround of several hospital laboratories. **Maryland General Hospital**, in Baltimore, engaged a PCS lab consulting team to fix its serious operational problems. *(See TDRs, April 5, 2004 and May 17, 2004.)*

As a business unit owned by Carilion Health Systems, the newly-renamed Chi Solutions will probably continue its current emphasis on both these two areas: contract management of sales and marketing for lab outreach programs and regulatory turnaround and tune-up for needy hospital laboratories.

Phlebotomists in Calif. Undergoing Certification

Get ready for new professional acronyms; CPT 1, CPT 2, LPT to be in lab lexicon

CEO SUMMARY: State certification of phlebotomists is under way in the Golden State. By April 9, 2006, all phlebotomists in California will need to maintain state certification. This development adds complexity to laboratory management in California. However, there are no signs that other states intend to follow California's lead in requiring certification of phlebotomists.

When it comes to laboratory regulation, California is usually first to break new ground. That is certainly true of a new regulatory requirement that phlebotomists in the state must be certified.

Multiple laws affecting phlebotomy were passed in the California legislature in recent years. In 1999, AB 1557 (Migdin) amended the Business and Professions Code. The law took effect on April 9, 2003. It requires all phlebotomists working in California to obtain a state-issued certificate for either a "Limited Phlebotomy Technician" (LPT) or "Certified Phlebotomy Technician" (CPT 1 or 2) by April 9, 2006.

Several other laws that affect phlebotomy services were also passed. Among other things, Assembly Bill 371 (LaSuer) requires CPTs (certified phlebotomy technologists) to draw blood for "driving under the influence" (DUI) violations at the direction of a law enforcement officer. Assembly Bill 1087 (Frommer) authorizes insurance company phlebotomy for physical examinations and allows CPTs to draw blood for contractors under the supervision of a physician, registered nurse or clinical laboratory scientist (CLS).

Implementation of these various legislative mandates is handled by **Lab Field Services** (LFS), a division of the California **Department of Health Services** (DHS). It started the phlebotomy certification program in April 2003 to meet an April 2006 deadline that requires all phlebotomists to be certified by that date.

Chief of Lab Field Services

Recently Karen Nichols, Ph.D., Chief of Lab Field Services (LFS) addressed the meeting of the **Greater Los Angeles Chapter of the Clinical Laboratory Management Association** (CLMA). She spoke about phlebotomy certification and other regulatory issues affecting laboratories in California. "As of this date, there are 3,000 persons certified in phlebotomy," said Nichols.

"There are another 4,000 applications awaiting review by LFS staff," she continued. "Across the state, 100

phlebotomy training programs are in place and six exams have been approved. Within Lab Field Services, a shortage of staff is creating a delay of about three-months in processing phlebotomy certification applications."

Nichols can already recognize some of the changes triggered by this new legislative mandate, although the deadline for certification is still another year away. "What is interesting about the flow of applications is that most are applications from people seeking to get a certificate so they can enter the field of phlebotomy," explained Nichols. "These are very different types of applicants from experienced phlebotomists already at work.

"For example, most applicants new to phlebotomy say they have a job waiting. A large percentage of these people are also single mothers," added Nichols. "Starting in August 2005, all phlebotomists will get a notice to apply for certification in advance of the April 2006 deadline. We expect that August notice will motivate experienced, working phlebotomists to send in their applications."

Management Complexity

Laboratory managers and pathologists will recognize that state certification of phlebotomists introduces another level of complexity and cost in the management of laboratories. In California, laboratories accustomed to dealing with such regulatory initiatives, consider the new phlebotomy certification program to be another "fact of life."

As the sidebar at right points out, the requirement that phlebotomists be certified is a direct consequence of the 1999 episode where a San Francisco-area phlebotomist was discovered to be washing and reusing butterfly needles on her patients. This caught the attention of state legislators and led to the passage of AB 1557 (Migden) just months later.

What will be important to watch is the April 9, 2006 deadline, when all phlebotomists must have certificates. Because this will increase the cost of phlebotomy, it is likely to change aspects of how laboratories staff and use phlebotomists. TDR

Contact Karen B. Nichol, Ph.D. at 510-873-6360.

Calif. Needle-Reuse Case Triggered Certification Law

WHY DID CALIFORNIA'S LEGISLATURE pass a law requiring certification of phlebotomists? It was in response to the shocking discovery that a phlebotomist working in the San Francisco Bay area had been reusing needles on patients.

It was April 15, 1999 when the *San Francisco Chronicle* published the news that a phlebotomist employed by **Smith-KlineBeecham Clinical Laboratories** (SBCL) was "washing" and reusing butterfly needles on "difficult to draw" patients at her patient service center in Palo Alto, California. *(See TDR, April 26, 1999.)*

SBCL quickly offered free testing to as many as 3,700 patients seen in SBCL's Palo Alto patient service center during the 22 months she worked there. Officials from California's **Department of Health Services** (DHS) quickly decided to offer free testing to any patient ever seen in a patient service center where phlebotomist Elaine Giorgi had been working. At least 15,000 people were offered free testing to determine whether they may have become infected due to Giorgi's practice of washing and reusing butterfly needles.

California's legislature reacted swiftly to this lab industry scandal. Before 1999 ended, it passed AB 1557 (Midgen). This law mandated certification of phlebotomists working in the state by April 9, 2006.

For Molecular Tests, Evaluate All Factors

Changes in test specificity are likely to be noticed by clinicians

CEO SUMMARY: ***When this hospital lab adopted molecular screening tests for* Chlamydia trachomatis *and* Neisseria gonorrhoaea, *physicians soon noticed a change in the rate of false positives. In researching the performance of the molecular assays compared to cultures, pathologists at this laboratory gained a better appreciation of how the introduction of a new molecular assay may disturb clinicians' practice patterns.***

MANY HOSPITAL LABORATORIES, have yet to establish a molecular diagnostics testing program. The technology is still complex and the economics remain uncertain for many types of molecular assays.

Even pioneering hospital laboratories are learning new and unexpected lessons from their molecular testing programs. That's certainly the case at the laboratory of **Resurrection Medical Center** in Chicago, Illinois.

New Variables

"Each new molecular test we add to our menu introduces new variables and often creates clinical consequences we had not anticipated at the time we decided to set up and offer that molecular test," observed Michael L. Mihalov, M.D., Medical Director of the laboratory at Resurrection. "This has been consistently true during my ten years of experience in molecular pathology.

"A significant lesson learned here about molecular diagnostics is that all assays are *not* equal," he explained. "By that, I mean that the impact of a specific assay with a known sensitivity and specificity can affect clinicians in problematic ways, relative to other test methodologies.

"As an example, we are dealing with a problem of false positive results from the molecular tests we offer to clinicians for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* screening," continued Mihalov. "It was about three years ago that we set up and began offering molecular tests for these two diseases.

"Over time, certain physicians began to question some of our positive results. As we worked through these cases with the physicians, we began to appreciate how the differences in performance between culture and the molecular assay was responsible for these outcomes," Mihalov stated.

"In the past, culturing for *Chlamydia* and *Gonorrhea* was the gold standard," he noted. "Although sensitivity was not fantastic, there are essentially no false positives, so specificity approached 100%. In contrast, molecular tests for these two diseases have a much better sensitivity. But when manufacturers

unnecessarily try to push the limits of sensitivity even higher, the result is false positives and lower specificity. On the surface the sensitivity may sound great —around 97-98%.

"But that small difference in specificity between the two diagnostic test technologies was enough to affect the clinical practice of physicians ordering these tests," said Mihalov. "Our molecular assay, at 97% specificity, means that, for every 200 patients screened with these tests, on average six would get false positive results. Since our prevalence is 0.5%, the result is we got only one true positive in every 200 cases—that's a pretty poor positive predictive value."

Mihalov explained that because most physicians have had years of experience with the culture method for detection—and its near-100% sensitivity—to suddenly begin seeing a regular number of false positive results (from the molecular assays) was most unwelcome. As they contacted the laboratory and worked through each case with him, they were not sympathetic to his explanation that, in dropping the culture methodology for a molecular-based screening test, the laboratory gained speed to result but lost a recognizable degree of accuracy on the false positive side of the equation.

Physicians Respond

"One consequence of this development is that physicians become more defensive in their practice, particularly when it comes to screening tests," said Mihalov. "I am aware of one ob-gyn group practice in Chicago that stopped screening for *Chlamydia* and *Gonorrhea*. They had a very low incidence of these diseases among their patient population and one reason for stopping screening was to avoid having to deal with false positive results."

Mihalov's experience with false positives caused his laboratory team to study the problem. Their findings are instructive to laboratory directors and pathologists currently evaluating molecular diagnostic assays for their laboratory. It will not be a surprise to learn that the problem is rooted in the relationship between sensitivity and specificity. The unexpected twist is how the objectives in developing a molecular test for HIV screening affected companies that developed molecular screening assays for other infectious diseases, including *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.

"Our molecular assays, at 97% sensitivity, mean that, for every 200 patients screened with these tests, on average six would get false positive results."

"When we first established our molecular testing program for these two diseases, we were running the specimen once," recalled Mihalov. "It didn't take long for our lab to get physician calls notifying us of false positive results. At that time, we determined that in the Resurrection system, our prevalence ranged from 0.5% to 5%.

"We next called the manufacturer and obtained detailed data on their internal studies of the assay," he stated. "Their data showed that the specificity of the assay was around 97%. Actually though, to reach and maintain that level, we have to run each positive or equivocal specimen in triplicate."

"However, even at 97% specificity, we have not overcome the false negative situation with the clinicians," Mihalov said. "That's because they are accustomed to the near-100% specificity of cultures when screening for these two diseases. Certainly manufac-

turers struggle with where to set sensitivity and specificity in every diagnostic assay, but every laboratory loses credibility with physicians when it issues false positive results. As an example, our clinicians are not thrilled when they learn that the positive *Gonorrhea* tests we reported on 60 year-old women in long-term, monogamous relationships were actually false positives."

HIV Screening Objectives

Having studied the specificity problem in using molecular technologies to screen for *Chlamydia* and *Gonorrhea*, Mihalov believes IVD manufacturers designed these tests with a mindset shaped by HIV screening. "If you go back to the earliest days of HIV screening, the objective of the healthcare system then was to identify as many HIV-positive individuals as possible with the screening test," he said.

"The bell-shaped curve was intentionally shifted to detect low positives," stated Mihalov. "After all, public health authorities considered the undiagnosed HIV-positive patient to be the greatest threat. So generating a relatively high level of false positive HIV screening results was the trade-off. Clinicians using such tests understood this trade-off, so the rates of false positives were acceptable.

Counterproductive Results

"But, as you move from diseases like HIV and HCV to *Chlamydia* and *Gonorrhea*, heightened sensitivity at the cost of lower specificity in screening tests will affect clinicians and patients in ways that may be counterproductive," he observed. "Another example is pre-natal cystic fibrosis screening where false positives have serious physical and emotional implications for a patient.

"My point here is to alert others to an obvious fact that can be overlooked when making decisions to replace an existing screening test methodology with a molecular test. The molecular technology will create different outcomes—for both the laboratory and referring physicians," declared Mihalov. "Thus, the important question we now ask in our laboratory is 'What do we really want to achieve when we adopt a new molecular test over an existing methodology, like culture in the case of *Chlamydia* and *Gonorrhea*?'"

Mihalov had other observations. He believes that technologies like PCR have certain limitations. Because these assays use biological products like polymerases, they have an inherent degree of variability that can be troublesome in infectious disease testing. For these and other reasons, he predicts that demand will be strong for alternative technologies to PCR, such as signal amplification methodologies.

Molecular Versus Culture

However, there was one question Mihalov was unprepared to answer. When asked by THE DARK REPORT how his laboratory's current cost of molecular screening for *Chlamydia Trachomatis* and *Neisseria gonorrhoeae* compared to the culture method—particularly since his lab was doing triplicate molecular testing to achieve the 97% specificity—Mihalov wasn't certain.

"With our attention focused on other issues, we've not audited our costs since implementation of these molecular tests. We should evaluate the clinical-effectiveness and cost-effectiveness of molecular versus culture methods for *Chlamydia* and *Gonorrhea*," he answered candidly. "When I have that information, I'll share the findings with you!" TDR

Contact Michael Mihalov, M.D. at 773-792-5046.

LIS Market Evolving To Serve New Needs

Changes, pressures on labs are driving decisions on new lab information systems

CEO SUMMARY: Ongoing reimbursement declines, coupled with other key factors, are pushing labs to seek new capabilities for their laboratory information systems (LIS). Another influence is the growth of molecular diagnostic programs in hospital labs. Molecular testing places unique demands on an LIS, which may further motivate labs to acquire newest-generation IT solutions versus upgrading existing LIS installations.

CHANGES ARE OCCURRING to the market for laboratory information systems (LIS). Hospital laboratory customers are demanding new capabilities.

Several emerging trends illustrate these changes. Fewer laboratories are willing to undergo a disruptive upgrade or total conversion. LIS products that incorporate modern software technology are gaining favor over "legacy" LIS products designed years ago and still marketed by healthcare IT vendors.

One individual who has a unique perspective on the LIS marketplace is Gilbert Hakim, CEO of **SCC Soft Computer** (SCC), based in Palm Harbor, Florida. His company sells products for laboratory, radiology, pharmacy, and client accounts receivable/billing. THE DARK REPORT recently caught up to Hakim to conduct an exclusive interview.

Hakim points out that two specific trends are the major drivers of change in the LIS marketplace. "Neither of these two trends will surprise any pathologist or lab manager," said Hakim. "However, these are the two trends having the most impact on the LIS marketplace.

"First is reimbursement. For the last 15 years it has been going in the wrong direction," he observed. "For health systems, hospitals, and the laboratories which serve them, this creates sustained pressure to wring out every possible efficiency.

Inadequate Supply Of Labor

"Second is the dwindling supply of laboratory technical labor, even as lab test utilization increases," Hakim said. "It is widely-recognized that the average age of medical technologists in the work force continues to increase. At the same time, training programs are failing to feed an adequate supply of new medical technologists into the profession.

"Together, these two major forces have brought about a dramatic change in one dimension of hospital laboratory operations," commented Hakim. "Around 1992-93, only about 10% of the nation's hospital laboratories oper-

ated some type of laboratory testing outreach program in their community. By 2005, that number had increased to around 50%."

"This is no coincidence," he added. "I believe that hospital and health system administrators recognized the reality of their situation. Much of their inpatient volume is paid on a DRG or capitated rate. These rates, like overall reimbursement, are shrinking. At the same time there are steady increases each year in inpatient volumes and inpatient test utilization.

"Within their laboratory, administrators recognize that labor costs are increasing. But they also notice that the laboratory has unused testing capacity, particularly in the second and third shifts. At some point, the logic of a laboratory test outreach program becomes undeniable—and economically attractive," he noted.

Hakim also believes that the same factors have pushed hospital laboratories to also explore automation as a way to achieve greater efficiency. "All the factors I've described contribute to the increased numbers of both hospital lab automation projects and lab outreach programs across the United States in recent years," observed Hakim. "It is those two operational needs which now create a new checklist of LIS functionality for laboratories.

Lab Operations Issues

"Having described what I consider to be the most dominant market influences changing the way laboratories buy and use LIS products, I'd like to discuss some operational considerations," offered Hakim. "When software modules within the laboratory do not talk to each other, lab information must be manually mapped into the LIS and data repository. A number of good studies have demonstrated that costs are increased by a factor of 30% when a laboratory must manually track the same specimen across all the information modules in the laboratory.

"Let me be more specific on this point," he continued. "Typically a laboratory information system must handle anatomic pathology, clinical laboratory, blood bank, and microbiology. The emerging field of cytogenetics intensifies this problem because it must pull in data from many sources to complement the laboratory test data and provide a diagnosis. Laboratory automation and robotics introduce additional elements which need effective integration with the LIS.

External IT Demands

"The above issues are internal to the laboratory's operations," stated Hakim. "Externally, the lab outreach program creates its own set of unique problems. The laboratory must present a unified, integrated report to the physician, on a timely basis and with the flexibility to customize formats to meet the preferences of individual physicians.

"I should add another source of pressure on the performance of an LIS suite in today's marketplace. Hospital laboratory outreach programs must compete against the national laboratories. But national lab companies enjoy significant economies of scale and offer physician-clients integrated IT solutions. Effectively, they set the competitive bar which the hospital outreach program must meet and exceed if it is to succeed," commented Hakim.

"These are some of the major reasons why a laboratory currently shopping for information technology products has a different type of shopping list than in the early 1990s," he stated. "In today's environment, a critical success factor for cutting-edge laboratories is to have an information technology (IT) infrastructure which can effectively support every need within the laboratory.

Molecular Diagnostics Creates New Demands For LIS Capabilities

WHEN HOSPITAL LABORATORIES decide to launch a molecular diagnostic testing program, they generally find their existing LIS (laboratory information system) is inadequate to support molecular testing.

"There are essential differences between a cytogenetic/molecular laboratory and a traditional clinical laboratory," observed Gilbert Hakim, CEO of SCC Soft Computer (SCC). "A molecular IT (information technology) system must do more than simply collect laboratory test data when the test cycle is completed.

"Molecular testing has stringent testing protocols that must be precisely followed," he explained. "Thus, the molecular IT system must actually track the individual specimen through each step of the test protocol and guide that specimen across each instrument used in the test protocol.

"Effectively, the molecular IT system is performing a 'chain of command' function that is missing from the traditional LIS," Hakim observed. "Additionally, molecular testing has the potential to increase dramatically the volume of data which must be captured, stored, and evaluated. The IT system must accommodate this need.

"Because genetics technology is evolving so rapidly, any viable molecular IT technology must allow the software system to evolve in tandem with the testing technology it manages," Hakim said. "Our product has a feature called 'Agile Programming.' It allows the flow of code to be changed by the laboratory end user. It also allows the lab user to change test protocols in response to new IVD technology. By design, this product allows the laboratory user to adopt the system to its newest test technologies without upgrades."

SCC hopes to seize the high ground as "first to market" with a lab information system designed specifically to handle molecular diagnostics testing. SCC believes it is the only IT vendor that currently has a live installation operating in a hospital's genetics laboratory. It plans to introduce this product into the laboratory marketplace in coming months.

"Some examples are ordering rules, which today can number in the thousands. Many legacy LIS installations cannot support this function," explained Hakim. "Another is the growing interest by many laboratories to implement auto-verification.

"At **Elmhurst Memorial Hospital** in Elmhurst, Illinois, a dual initiative to implement auto-verification and pre-analytical automation reduced the number of FTEs needed in these functions by 14.5, allowing the lab to reassign these med techs to higher-value responsibilities within the lab. Total savings of $3 million per year were generated from these two projects," noted Hakim. "This illustrates how effective deployment of new information technology can generate substantial benefits for the laboratory.

Artificial Intelligence

"Information technology that incorporates artificial intelligence (AI) has the potential to increase a laboratory's capacity to handle specimens by 300%, without any increase in FTEs," he explained. "AI can flag lab test results and take direct action. AI can detect errors often not visible within a laboratory operating with manual procedures. AI can competently handle

Hakim Shares Some Advice For LIS Upgrades

SCC SOFT COMPUTER'S CEO Gilbert Hakim shared some advice for laboratories looking to upgrade their LIS.

"When looking at different LIS products, it is important to understand what level of technology is used by the system," he offered. "In the 1980s, that technology was MUMPS. In the early 1990s, the technology can be described as 'thick client server.' From about 1999-2000 forward, the technology is CORBA (Common Object Request Broker Architecture).

"CORBA is technology which allows the system to multi-task. It does this by incorporating middleware solutions to handle specific functions," commented Hakim. "That is one of the great features of a CORBA-based LIS. Think of it like a structural framework. It allows the laboratory to plug middleware modules into the IT framework as the lab needs to add functionality or upgrade the performance of a specific module.

"At SCC, our term for this is 'Dynamic Push Technology' (DPT)," he said. "It is the type of information system which can competently integrate outreach specimens with the inpatient specimen flow. It can multi-task, receiving information even while evaluating and directing work flow through the laboratory."

the mix of specimens coming from inpatient and outreach sources. These specimens have unique needs for turnaround times and other variables.

"In contrast, inpatient-only LIS installations, particularly those dating from the early 1990s, often cannot support a laboratory outreach program," continued Hakim. "Even if they do, they often offer only minimum flexibility."

Throughout this interview, Hakim has provided lab administrators and pathologists with valuable insights about how and why the marketplace for information technology in the laboratory is changing. His work with laboratory clients throughout the country has given him a unique perspective. It's allowed him to observe how laboratories are responding to trends like declining reimbursement, inadequate numbers of med techs, and the need to assertively pursue cost reductions and economies of scale.

Hakim links the growth of hospital-based laboratory outreach programs and pre-analytical automation during the past ten years to these trends. THE DARK REPORT observes that this aptly confirms that laboratories are responding to market forces. For example, despite the extensive efforts by vendors to introduce total laboratory automation (TLA) beginning in the mid-1990s, laboratories have naturally gravitated toward the use of automation in pre-analytical, the source of as much as 50% of a lab's labor costs.

Parallel Trend in IT

Viewed from this perspective, a parallel trend is unfolding in how laboratories use information technology. As explained by Hakim, laboratories are under ever-growing pressure to provide enriched laboratory information services to referring physicians, payers, and patients. This situation provides an opportunity for IT vendors with products that incorporate the latest, Internet-friendly, wireless-compatible software systems.

Lab managers and pathologists should use these insights to craft a business strategy of flexibility in their information technology. This will allow the laboratory to perform at a high level, while supporting the capability of deploying relevant new IT systems as they become available. TDR

Contact Gilbert Hakim at 727-789-0100.

Urology Revenue Loss Drives AP Lab Condos

Medicare reductions for urology services took effect on January 1 of this year

CEO SUMMARY: Urologists are motivated to operate anatomic pathology laboratory condominiums as a way to replace lost income after Medicare imposed a major reimbursement cut for a key urology procedure. Capturing revenue from ancillary services is a hot topic within the urology profession. Here are details about this exploding trend and why there is interest in anatomic pathology services.

NO WONDER UROLOGISTS are greatly interested in capturing revenues from ancillary clinical services, including anatomic pathology.

Starting last January 1, 2005, a reduction in Medicare reimbursement for an important urology procedure took effect. It reduced effective reimbursement to urologists by 69%.

On that date, the **Centers for Medicare and Medicaid Services** (CMS) implemented a new reimbursement formula for Medicare Part B administration of hormonal therapy for men with advanced prostate cancer. According to an example published in *Urology Times* in December 2004, "a [urology] practice treating 48 prostate cancer patients receiving hormonal therapy would see gross revenue decline from approximately $132,000 in 2004 to $41,000 in 2005, based on CMS's projected reimbursement rates issued July 26, 2004."

This represents a substantial reduction in the annual earnings of individual urologists. Pathologists and their practice administrators should understand how this situation is motivating urologists to proactively, if not aggressively, seek to replace this lost income by establishing ancillary services within their medical group.

Ancillary Revenue Sources

Not surprisingly, there has been plenty of discussion within the urology profession on different approaches urology groups can use to replace these lost revenues. Both clinical laboratory testing and anatomic pathology services are often mentioned.

Urology Times published such a story in its December 2004 issue, titled "New Ventures May Help Make Up For Lost Reimbursement." Both clinical laboratory and anatomic pathology were discussed as sources of ancillary revenue for urology groups. Other sources of ancillary service revenues addressed in the story were CT scans, bone densitometry studies, and clinical trials.

The *Urology Times* article was based on a presentation made earlier in 2004 by Richard Rutherford at the

American Urology Association's (AUA) Western section annual meeting. Rutherford is Director of Practice Management for the AUA.

Rutherford discussed how urology groups could profit from establishing clinical laboratory testing and anatomic pathology services in their practice. For example, Rutherford observed that office-based laboratory testing can be a profitable source of revenue for those urology offices which already order such tests.

Urology Group's PSA Lab

He offered this example. A three-urologist group orders 150 PSA tests monthly. In-office PSA testing would produce $19,656 in profit for the year. He based this on a Medicare reimbursement rate of $25.70 per test and included depreciation of the lab instrument, cost of test kits, and the cost of monthly "calibration test kits."

Rutherford also mentioned that PSA testing requires compliance with CLIA regulations, since it is classified as a moderately complex test. For that reason, some urology groups would need to obtain a different level of CLIA certification before offering PSA tests.

Rutherford also commented about the profit potential of anatomic pathology. "The biopsy is the most common specimen collected in urology after urine," he observed. "There is no reason why you can't reap some of the revenue from this in-house. You can make this profitable if you can work out a deal with a pathologist."

He observed that the urology group would have to sub-contract with pathologists to share the revenue for evaluating prostate and bladder tumor specimens. Rutherford further recommended that such ventures "require a careful feasibility study of the community to avoid turf disputes with pathologists."

Rutherford also provided basic reimbursement data. He stated that Medicare reimburses $97.03 per core for gross examination and microscopy and immunohistochemistry performed would add an additional $85.74. Rutherford further added that Medicare reimbursement was comparable for bladder biopsies.

As a point of interest for pathologists, during his presentation, Rutherford offered an example of an in-office CT scan arrangement, at three studies per day, paying for itself in a year and generating $163,000 over five years. For bone densitometry studies of prostate cancer patients taking hormonal therapy, Rutherford noted that up-front costs were about $120,000 for the equipment and software, but that Medicare only authorized a baseline scan and a follow-up scan after two years of hormonal therapy. Because of this fact, Rutherford felt in-house CT scanning by urologists would prove to be a dicey financial proposition.

Interest in Ancillary Services

For anatomic pathologists, the *Urology Times* article provides a peek into developments affecting the urology profession. For example, the fact that the Director of Practice Management for the American Urology Association is doing presentations on the profit potential of such ancillary service lines as laboratory testing and anatomic pathology means that such ventures are getting attention at the highest levels.

Anatomic pathology groups should not overlook or ignore this situation. THE DARK REPORT believes the urology profession is the spearpoint of a wider trend—that of specialist physicians developing ventures with pathologists to access both sub-specialty pathology expertise and a piece of the anatomic pathology revenue pie. TDR

INTELLIGENCE LATE & LATENT

Items too late to print, too early to report

It's been a revolving door for senior executives at **Specialty Laboratories, Inc.** during the past seven weeks. Gone by resignation is CFO Kevin Sayer (effective May 16). Gone by elimination of positions are Dan R. Angress, Sr. VP/Business Development (April 8) and Cynthia K. French, Ph.D., VP/Chief Science Officer (April 8). Gone by termination without cause is Mark R. Willig, Sr. VP/Sales & Marketing (May 3). Another resignation was Greg Mann, Director of Communications (May 13).

ADD TO: Specialty Labs

In the midst of this tidal wave of executive turnover, the interesting news is that Vicki Di Francesco was hired on May 3, 2005 to be Specialty Labs' new Senior Vice President, Sales & Marketing. Di Francesco faces a number of daunting challenges. Not the least is the fact that many sales reps at the company have been demoralized by the rapid turnover in the company's executive team.

MERCK'S HPV VACCINE SCORES WELL IN TRIALS, APPLICATION TO FDA EXPECTED IN MONTHS

In the race to be first to bring an HPV (human papilloma virus) vaccine to market, **Merck & Co.** appears to be moving faster than **GlaxoSmithKline Plc**. Merck's latest advance was a study it presented in Spain earlier this month. Its HPV vaccine, called Guardisil™, produced a higher immune system response in a group of adolescent boys and girls aged between 10 and 15 years old, compared to a group of women aged 16 to 23. This study measured immune system response by looking at the development of HPV-specific antibodies in the blood. It determined that the antibody rate in adolescents was 100% for three types of HPV virus and 99.9% for a fourth HPV type.

ADD TO: HPV Vaccine

Financial analysts responded to the news of the Merck study with predictions that the company would file an application with the FDA for approval of the vaccine by the end of this year. Glaxo's HPV vaccine is called Cervarix™. Glaxo intends to file for regulatory approval in Europe during 2006. HPV's links to cervical cancer mean that HPV vaccines will eventually impact cervical cancer screening practices. It is a new variable with the potential to alter how laboratories provide diagnostic services in support of cervical cancer screening.

HSA PREMIUMS DECLINE

Here's a provocative bit of market intelligence. Five insurance companies, including **Pacificare Health Systems**, are lowering premiums for existing HSA-eligible insurance products. HSAs (Health Savings Accounts) were created in December 2003 and involve a two-part health plan. The consumer purchases a high-deductible health insurance policy and also opens a tax-sheltered account to be used to pay for out-of-pocket health expenses. Experts say it is premature to declare that this round of HSA premium reductions is attributable to consumers directing their own healthcare.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 20, 2005.

Audio Conference: June 21, 2005

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