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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

Another Milestone in Physician Pay-for-Performance

EFFORTS TO EXPAND AND IMPROVE physician pay-for-performance programs are ongoing. The latest big news is the announcement by a consortium of California's largest health insurers, employers, and physician groups that its existing pay-for-performance program will expand to pay quality-based bonuses equal to 10% of physicians' income within five years.

This goal was contained in a report released on February 6 by the **Integrated Healthcare Association** (IHA) of Sacramento, California. The report was a five-year strategic plan that included the outcomes from the first five years of its pay-for-performance (P4P) plan. Currently IHA's plan includes 225 participating physician groups which employ about half of the state's 70,000 physicians. These physicians provide care to 6.2 million commercially-insured patients.

IHA's P4P program rewards physician groups for improvements in three areas: patient satisfaction (30% weighting), utilization of information technology (20%), and improvements in specific clinical measures (50%), ranging from providing immunizations to screening for cancer. Currently it pays a bonus that equals about 1.5% of a physician group's annual income. IHA's strategic plan calls for the bonus amount to grow to 10% of a physician group's income within five years.

The first year for performance measurements was 2003. IHA paid bonuses totaling $37.7 million to 80 physician groups for 2003. Bonus payments for 2004 were $54 million, paid to 179 participating physician groups. Bonus awards for 2005 have not yet been announced.

During the first 24 months of the program, there was substantial documented improvement in all three areas. In the clinical area, 87% of participating physician groups showed improvement. Patient satisfaction scores were increased in 66% of the groups. IT capability showed substantial improvement. In year one, only 34% of the groups were using IT solutions. This had increased to 54% by the end of year two.

For lab administrators and pathologists, the success of this broad-based P4P program in the nation's most populous—and progressive—state is a noteworthy development. It points to further expansion of this trend, not just within California, but across the United States. TDR

Lab "Day of Disaster" Provides Useful Lessons

Valuable insights about how to improve contingency and disaster response plans

CEO SUMMARY: On Friday, May 5, laboratory administrators and pathologists who guided their labs through some of the nation's biggest natural disasters and emergencies will gather in Miami to share their experiences in contingency planning and disaster response. It is no understatement to say this knowledge can help your lab save lives and protect the well-being of lab staff during future emergencies and disasters.

WETHER THEY KNOW IT OR NOT, laboratory directors and pathologists will be held to a higher standard of performance next time an emergency or natural disaster affects their laboratory.

Hurricane Katrina provided the most powerful example to date of the importance of effective disaster preparation and emergency response. This 400 mile-wide hurricane cut a wide swath of destruction, making landfall on the Gulf Coast and pushing deep into the United States with destructive winds and rain.

A large number of hospitals and laboratories were extensively damaged—and discovered there were often no functioning hospitals nearby to depend on for extra help (as planned) because they had been destroyed or severely damaged themselves. Some of these hospitals and laboratories based their disaster plans on the assumption that they could draw upon the resources of neighboring hospitals. With these neighboring hospitals destroyed or damaged, the ability to respond with maximum effectiveness was compromised. Media coverage of the most spectacular failures was swift, creating a public relations problem and longer-term business issues for some well-known hospitals in the afflicted regions.

To help all laboratories and pathology groups better prepare for these types of events, a special one-day program will take place in Miami on Friday, May 5. Titled "Readiness for

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

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Laboratories...with a Capital 'R'!", it is an optional program immediately following the May 3-4 dates for the *Executive War College on Lab and Pathology Management*.

This is an historic first for the laboratory industry. Coming together on the same day will be pathologists and lab administrators who have personally guided their laboratories through some of the biggest natural disasters of the past decade. They will tell their stories and share the lessons learned.

Get The Inside Story

These individuals have first-hand experience at guiding their laboratory through major disasters. For the first time, lab managers and pathologists responsible for contingency planning and disaster response at their laboratory will have direct access to this valuable experience and knowledge.

The list of laboratory and hospital "disaster case studies" is extensive: hurricanes, earthquakes, massive failure of the power grid, and SARS, to name a few. It is an unprecedented opportunity—one not likely to be repeated.

A rundown of the presentations reveals the scope and depth of what we refer to as the laboratory "day of disaster." Opening the day will be Thomas Williams, M.D., who is Medical Director, Pathology at **Methodist Hospital** in Omaha, Nebraska.

Within the pathology profession, Williams has been at the forefront of contingency planning and disaster response preparation, both nationally and in his home town. He will discuss the specific requirements for disaster planning and how the laboratory's plans must integrate into those of hospitals and the community at large.

In recent years, Williams has represented his hospital in planning and emergency exercises conducted by disaster response officials in Omaha. He understands how local, state, and federal efforts are designed to work collaboratively during disasters.

Concerns about bird flu, epidemics, and bioterror make the next presentation timely for all laboratories. It is a case study of the SARS outbreak in Toronto in the winter of 2003. Susan Poutanen, M.D., Microbiologist & Infectious Disease Consultant at **Toronto Medical Laboratories** (TML) and **Mount Sinai Hospital** in Toronto, Ontario, Canada, was directly involved, from start to finish, in the effort to diagnose what was then an unknown disease, treat affected patients, and control the spread of the disease.

Be prepared for some shocking lessons in laboratory management. TML is a consolidated laboratory organization, serving multiple hospitals and other sites. The emergence of SARS, transmitted by airborne infection, forced the laboratory to reconsider such basic issues as open space labs, the daily or weekly rotation of med techs between different hospitals and lab sites, and how the hospital infection control team should interact with the microbiology department during outbreaks of diseases spread by airborne transmission.

When The Power Failed

Remember the great power grid failure of August 2003? From Toledo, Ohio in the West to most of New York State in the East, electrical power failed and stayed off for more than 48 hours in many cities.

The laboratory department of **Detroit Medical Center** (DMC) in Detroit, Michigan, serves 10 hospitals and 1,900 beds. The extended blackout revealed many deficiencies in contingency planning. In Detroit, the power failure caused a shutdown in the

municipal water system. This meant DMC's labs could not produce de-ionized water. Another unanticipated consequence: with no running water in the hospital, toilets couldn't be flushed. Other issues involved the ability to air condition the lab instruments, as well as the computer hardware running the laboratory information system (LIS). William Neeley, M.D., Medical Director of Labs at DMC, will discuss the lessons learned.

This same power grid failure is the backdrop on the session which deals with IT contingency planning and disaster recovery for hospitals and laboratories. Across town, at **Hospital Consolidated Laboratories** (HCL) in Southfield, Michigan, Gary Assarian, D.O., is Director of Laboratories. Something of a computer guru, Dr. Assarian created his own LIS that supports testing at HCL.

The 48 hour-long electrical blackout brought unanticipated problems to a well-prepared IT team. These ranged from adequate fuel for generators to complete failure of the telephone and cellular phone systems across Michigan. Assarian will share the "command center" approach to IT disaster response and how it performed superbly in dealing with problems unforeseen in years of emergency planning sessions and exercises.

Dealing With Katrina

Next up on this "Day of Disaster" is Hurricane Katrina. This unprecedented natural disaster is examined from three perspectives. First is the experience of the laboratory at the 580-bed **Oschner Foundation Hospital** in New Orleans, Louisiana. Oschner was the only hospital in the area which maintained services before, during, and after Hurricane Katrina and the flooding which followed.

One pathologist who was at Oschner during the entire crisis was

How Labs Responded To Natural Disasters

Here's the complete line-up for this special, one-day program on "Readiness for Laboratories... with a Capital 'R'!" For full details, go to ***www.darkreport.com.***

8:00 AM–9:00 PM **Laboratory Contingency Planning and Omaha's Disaster Preparedness Efforts**–*Thomas Williams, M.D., Medical Director, Pathology, Methodist Hospital, Omaha, NE*

9:00 AM–9:50 AM **Epidemics & Bioterror Preparedness: Lessons Learned from Toronto's SARS Outbreak**–*Susan Poutanen, M.D., Microbiologist & Infectious Disease Consultant, Toronto Medical Laboratories & Mount Sinai Hospital, Toronto, Ontario*

10:10 AM–10:55 AM **How the Laboratory at Detroit Medical Center Responded to 48 Hours without Municipal Power and Water**–*William Neeley, M.D., Medical Director of Laboratories, Detroit Medical Center, Detroit, MI*

10:55 AM–11:45 AM **Hurricane Katrina and its Aftermath: Contingency Plans at Oschner Foundation Hospital Keep the Laboratory in Operation**–*Francis R. Rodwig, Jr., Chair, Department of Pathology & Laboratory Medicine, New Orleans, LA*

12:45 PM–1:35 PM **Establishing the Emergency Laboratory During Disaster: Ben Taub General Hospital's Laboratory "Moves" into the Astrodome**–*Sylvia Waller, Administrative Director of Pathology, Ben Taub General Hospital, Houston, TX*

1:35 PM–2:20 PM **Earthquakes: Lessons in Preparation, "Riding It Out," and Staying Operational**–*Donald P. Sharar, Director of Laboratory Services, Northridge Hospital Medical Center, Northridge, CA*

2:35 PM–3:20 PM **How Laboratory Vendors Can Help During Disasters and Emergencies**–John Kane, Director, Customer Service Operations, Abbott Laboratories, Inc., Abbott Park, IL

3:20 PM–4:05 PM **IT Contingency Planning & Disaster Recovery for Hospitals and Laboratories**–*Gary Assarian, D.O., Director, Hospital Consolidated Laboratories, Southfield, MI*

4:05 PM–4:15 PM **Essential Lessons in Laboratory Readiness and Disaster Response**–*Thomas Williams, M.D.*

Francis R. Rodwig, Jr., Chair, Department of Pathology and Laboratory Medicine. Emergency preparations at Oschner were extensive and the hospital is unique in having its own water wells.

But even detailed emergency plans could not prepare the laboratory staff for the natural disaster which unfolded hour after hour. With insufficient air conditioning in the lab to keep instruments cool, lab staff took hand-held point-of-care instruments into the hallways to run needed tests. Lab industry vendors played essential roles in enabling the Oschner laboratory to maintain services during and after Hurricane Katrina.

The second perspective on Hurricane Katrina comes from Houston, Texas, which saw 200,000 evacuees enter the city before, during, and after the storm. The three hospitals of the **Harris County Hospital District** sent laboratory staff and resources to the Reliance Center to create, on the fly, a full working laboratory to support lab testing needs of the 27,000 evacuees housed there and in the nearby Houston Astrodome.

Creating A Lab Overnight

Sylvia Waller, the Administrative Director of Pathology at **Ben Taub General Hospital**, was a key figure in organizing this ad-hoc laboratory. She will share the lessons learned. The lab team used roving phlebotomists to collect specimens, instituted a patient identification system, and provided a broad lab testing menu. Throughout the operation of this temporary laboratory, quality control standards were maintained at the same level as fully-accredited laboratories.

The third perspective on Hurricane Katrina comes from a major IVD manufacturer. John Kane, Director, Customer Service Operations at **Abbott Laboratories, Inc.**, in Abbott Park, Illinois, will provide the remarkable stories of how lab industry vendors responded to the needs of laboratories operating in the areas destroyed or damaged by Hurricane Katrina. In the case of Abbott Laboratories, it moved its Architour trucks into the disaster zone. One operated as a mobile laboratory at Houston's Reliance Center, in support of Sylvia Waller's laboratory operation there. Another Architour truck was sent to Oschner Foundation Hospital in New Orleans to support laboratory testing needs at that location.

Lab Vendors Can Help

One positive development from Hurricane Katrina is that lab industry vendors are now revamping their own contingency plans and disaster response capabilities. THE DARK REPORT predicts that, as a consequence of Hurricane Katrina, the resources and capabilities of lab industry vendors will be included in the contingency planning of their laboratory clients.

Earthquakes are next on this unusual "Day of Disaster." Along the West Coast and into the Rocky Mountains, the American earthquake zone affects several thousand hospitals. At 4:30 a.m. on the morning of January 17, 1994, a magnitude 6.7 quake shook the San Fernando Valley in Southern California. At ground zero of what is now called the Northridge Earthquake was the laboratory of **Northridge Hospital Medical Center** (NHMC).

The Northridge Earthquake

Donald P. Sharar, Director of Laboratory Services, made it into his lab that morning. He will be in Miami to tell his laboratory's story and make recommendations on how to better prepare for earthquakes.

This destructive quake killed nine people and injured 9,000. It left 22,000 people homeless. Nine hospitals, representing 2,500 beds, were closed. Yet the

American Board of Disaster Medicine Announced on February 1, 2006

HERE'S MORE EVIDENCE that contingency and disaster response planning is gaining in importance and emphasis.

Earlier this month, the **American Board of Physician Specialties** (ABPS) announced the creation of the **American Board of Disaster Medicine**. The announcement was made on February 1. Goal of the new board specialty is "to address the ever-increasing need for physicians trained in disaster planning."

Physicians of all specialties can apply. The board will begin accepting applications from interested physicians on May 1, 2006. It will administer the first examination before year's end.

THE DARK REPORT believes the new board specialty of disaster medicine is consistent with the trend of improving healthcare's ability to respond to natural disasters, emergencies, terrorist events, and epidemics. The ability of hospitals, laboratories, and physicians to deliver needed care during a time of crisis is getting more attention.

That is why it is important to bring together those pathologists and laboratory administrators who have guided their laboratories through some of the biggest natural disasters and emergencies seen during the last decade. The knowledge and experience they will share can help other laboratories save lives during similar emergencies.

It also provides the knowledge necessary to better protect laboratory staff—and their families—during these emergencies. Every laboratory and pathology group should have someone attend "Readiness for Laboratories...with a Capital 'R'!" in Miami on May 5. It's knowledge that can mean lives saved in the next disaster.

laboratory at Northridge Hospital Medical Center was back in full operation in 30 minutes after the quake hit. Here's an opportunity to learn the practical lessons of how laboratories can best respond to an earthquake and its aftermath.

Post-Disaster Planning

In discussions with each of these speakers, THE DARK REPORT learned about a dimension of contingency planning that is often overlooked. That is the post-disaster period. Once the actual hurricane or earthquake is over, a region may be so damaged that normal life is impossible for weeks or months.

During this recovery period, extraordinary measures are often required for a hospital laboratory to restore and maintain operations. For example, in August 2004, Hurricane Charley hit Punta Gorda and Port Charlotte in Florida with winds of 145 miles per hour and a storm surge of 15 feet.

Lab staff living in areas which still had full power did laundry for lab employees living in communities without power. They would also bring in bottled water, and help with clean-up efforts at other lab employee's damaged homes.

There will be plenty of insights like this on May 5. It will be the first time that these individuals—who personally led their laboratories through major disasters—are gathered in one place to share their experiences and compare the lessons learned. It's a unique opportunity to acquire lifesaving knowledge. TDR

Spectrum's IT Strategy Now Includes EMRs

First laboratory in nation to offer an EMR system to client-physicians

CEO SUMMARY: By offering client-physicians an electronic medical records (EMR) system, Spectrum Lab Network expects to gain competitive advantage. The EMR solution supports Spectrum's strategy of providing enhanced and integrated informatics services to all users, including physicians, payers, and patients. Until now, no lab has ever offered to be a source of EMR sales and service to office-based physicians.

COMPETITION IS HEATING UP among laboratories using enhanced information technology (IT) services to compete for the business of office-based physicians.

In Greensboro, North Carolina, **Spectrum Laboratory Network** is now selling an electronic medical record (EMR) system to its physician-clients. THE DARK REPORT believes Spectrum is the first laboratory company in the United States to offer an EMR system for sale.

Called "Spectrum Plus," it is an ASP (application service provider), thin-client software system. Developed by **eCast Corporation** of Raleigh, North Carolina, Spectrum Plus includes a fully integrated and bi-directional lab ordering and resulting module.

Spectrum's strategy is based on a belief that it can differentiate itself from competing laboratories by offering enhanced information technology services to referring physicians. It is a sign of ongoing changes in the competitive marketplace for lab services.

In recent years, larger national competitors, like **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**, have regularly added functions to their basic IT products. Along with Web browser-based lab test ordering and results reporting, lab companies have added direct interfaces to the physicians' practice management and EMR systems, improved integration with electronic pharmacy ordering systems, and similar types of features.

Benefits To Physicians

"To avoid any compliance issues, our clients sign an agreement that Spectrum Plus will be used solely to support our laboratory services," stated Nate Headley, CEO of Spectrum. "Benefits to client-physicians include the elimination of all manual charting and labor cost savings. Physician groups can achieve savings of 1.5 to 2 FTEs after implementing Spectrum Plus.

"In the Spectrum IT model, we do all the connectivity programming, host the system, and provide the laboratory

test results," stated Headley. "Our Atlas Labworks® connectivity solution is embedded in Spectrum Plus."

"There's another significant benefit for physicians," continued Headley. "By converting from paper records to our Spectrum Plus EMR, the physician is now positioned to participate in various pay-for-performance programs. EMR systems can provide a data repository to allow clinicians to more easily demonstrate high quality practice standards to their third party payers in order to negotiate higher reimbursement."

Advanced IT Strategy

In recent years, aggressive use of information technology has been a fundamental business strategy at Spectrum Laboratory Network. Internally, the company uses advanced IT solutions to capture data and integrate the flow of that data throughout the organization.

Externally, Spectrum Laboratory Network has been equally aggressive with its use of IT. It has worked diligently to convert existing and new client-physicians to its Atlas electronic system for lab test ordering and results reporting. As technology and economics improve, the eventual goal is to eliminate the paper test requisition and have 100% of test orders and lab results transmitted electronically.

"In many respects, Spectrum sees itself as an information services company, increasingly organized around the Internet," explained Headley. "We use a network approach—Internet and automation in the field—for ordering and results. Each day, we serve an average of 11,500 patients and 81% of test orders and results are transmitted over our network."

Spectrum's high volume of electronic requisitions has slashed many costs within the laboratory. It has also improved work processes in ways that contribute to higher customer satisfaction. "By reducing the volume of paper requisitions, we've dramatically cut the need for manual data entry in our lab, along with the costs associated with that function," noted Headley.

"In fact, the core lab has seen an 86% reduction in data entry FTEs," Headley observed. "Errors associated with this work have been reduced to an average of three per month! These savings are compounded when you consider the reduction in calls to clients triggered when an error occurs, plus the potential for additional errors that can occur during communication."

Spectrum finds that physicians are receptive to IT solutions that can benefit their practice. "Clinicians are becoming very alert to efficiencies, such as e-charting, offered by electronic systems," said Headley. "They have become conscious of time and motion. To sustain revenues, they need to see more patients. That is why anything that increases practice efficiency is of interest. We've created an electronic interface with our laboratory that is simple and intuitive. We can fully train new users on our Atlas order entry system in as little as 30 to 60 minutes."

Converting Clients

Ease of use is not the real secret of Spectrum Lab Network's success in converting so many clients to electronic lab ordering and test resulting. A major factor has been the performance of Spectrum's sales force and field service staff. "Rapid deployment is a key factor in gaining clients. If the physician's office has broadband in place, we could install the Spectrum system the same day. If the necessary broadband is not in place, our implementation time is 10 to 12 days," stated Headley.

"The thin client architecture allows us to make changes at the controller level and all accounts are automatical-

ly updated," stated Dave Moore, Spectrum's CIO. "With a thick client system, different software versions are scattered throughout the network causing inconsistencies in test compendium, specimen requirements, etc.

"We believe our thin client system gives us a distinct competitive advantage," added Moore. "We can do all our upgrades—software, test catalogue, nomenclature—on our server at the core lab. All back-ups occur automatically from the server. We maintain client accounts and monitor client usage from a single, central location."

Given Spectrum's fast rates of growth in patients and revenues during recent years, Moore probably understates the impact that Spectrum is having in North Carolina, South Carolina, Virginia, Tennessee, and Georgia. As the 1990s ended, Spectrum was doing about $22 million per year in outreach revenue. For 2005, it generated an estimated $125 million in net revenue.

Headley attributes this substantial and sustained growth to the Spectrum's business objectives. "Our marketing strategy is two-pronged," he stated. "First, we market based on superior service levels that factor in both IT and business capabilities. Up front, we identified customer expectations and then defined service levels we believed would give us competitive advantage.

Client Expectations

"We go through a fairly exhaustive process to find out how people perceive the services we provide to them," continued Headley. "We align our organization and IT services with end-user service level expectations, then exceed them. We believe Spectrum is defining competitive service levels in our markets. That puts competitive pressure on existing benchmarks for service.

"The second prong of our marketing strategy is to use sophisticated IT capabilities to give client-physicians enhanced services," he said. "Our goal is to use IT tools to create integrated flows of information, to replace manual processes with automation wherever possible—including client offices, and electronically connect all users within the Spectrum family. This is a major undertaking. We have 740 Atlas sites and 22 service reps in the field to do installs and training of our Atlas system.

Two Business Challenges

"We now have two business challenges," observed Headley. "The first is to keep upgrading our information technology capabilities to retain that competitive edge. The second is to maintain our growth rate. We get 40 new accounts every month and two-thirds become users of our Atlas-based system.

"To sum up," stated Headley, "our goal is to lead the field in our region in IT integration. We'll continue to expand our test menu, particularly with regard to personalized medicine. We'll continue to seek out value-added opportunities in service levels. In the end, that's really where the competitive advantage is. Technology is great, but it all goes for naught if you lack quality service."

THE DARK REPORT observes that, in making the decision to offer EMR products to its clients, Spectrum Laboratory Network is introducing a new variable into the laboratory services marketplace. Lab directors and pathologists will want to watch the competitive response to Spectrum's innovation. TDR

Contact Nate Headley and David Moore at 336-664-6100.

—By Pamela Scherer McLeod

Learn More about Spectrum's IT Strategy

David Moore will speak at the upcoming Executive War College in Miami on May 3-4, 2006. Details at www.darkreport.com.

Step-by-Step, Spectrum Lab Network Built its Information Technology Platform

WHEN SPECTRUM LABORATORY NETWORK began taking active steps to build the information technology (IT) infrastructure necessary to support enhanced services to office-based client-physicians, it was playing catch-up to the national laboratory competitor who dominated the North Carolina market.

"In order to compete, we started in 2000 with a product called Quextron, which is a DOS-based interface program," recalled Nate Headley, CEO of Spectrum. "This technology came with a major benefit. It allowed us to introduce a series of bar-coded requisitions. These reduced manual data entry in our laboratory."

As next-generation technology evolved, Spectrum Laboratory Network selected Atlas Labworks, developed by **Atlas Development Corporation**. This was a product designed around central server architecture. The new technology allowed Spectrum to create integrated IT networks which link laboratory production facilities with client offices. "We evaluated four or five products before selecting Atlas Labworks," stated David Moore, CIO of Spectrum. "It met our specifications for functionality, scalability and configurability.

Six-Month Collaboration

"We actually collaborated on research and development with Atlas for about six months in 2002," noted Moore. "We wanted to expand the functionality of the program to give us additional competitive benefit in the marketplace. On our side, the development team included a cross-section of drivers, specimen handlers, field reps, billing clerks, IT people, and MTs from our lab. Our goal was to develop a system that allows us to gain maximum efficiency."

"A major feature developed from this collaboration was touch screen capability," stated Headley. "The touch screen capability was a key unifying element allowing all applications to function and to look exactly the same for our clients."

Following that round of product development, Spectrum began to deploy its IT solution. "In the summer of 2002 we did alpha installs in client offices," explained Moore. "In November and December 2002, we began introducing the system to our clients. By January 2003, we hit our stride. Installations accelerated from this point forward.

Continuous Improvement

"Using feedback from users of the system, throughout 2003 and 2004 we issued several new releases of the system, constantly adding functions," he said. "During this time, we also merged our thick-client and thin-client systems to assure consistency in appearance and use. We're now working on a version that will be able to transmit AP (anatomic pathology) images. Soon we will introduce the ability to interact Atlas Labworks with PDAs used by client-physicians.

"Currently we are in our sixth version of Atlas Labworks," stated Moore. "Within the last couple of weeks we've embedded Atlas with an **eCast** product, significantly expanding the functionality of our system. We're super-excited about this innovation."

"We believe that Spectrum Laboratory Network has a three-year lead on any laboratory trying to enter this industry now," observed Headley. "That's how long it has taken us to both develop and roll out our system. A competitor would have to set up an automated laboratory and be prepared to provide the electronic service capabilities equivalent to what LabCorp, Quest, and Spectrum now provide–just to meet the competitive threshold in our markets."

Letters to the Editor

Technical/Professional Billing Split Is A Threat to Pathology

EACH SECOND YEAR, when we publish our bi-annual trends in anatomic pathology, we get feedback from our clients and regular readers.

This year, a particularly insightful letter was received. The writer wants to add another trend to our list of 11. He puts forth his arguments in the letter we reproduce below:

Letter To The Editor

Dear Editor,

Your recent issue about current trends in anatomic pathology was read with great interest. Once again, you've done another fine job! My disappointment is that most pathologists are not likely to act upon anything you point out to them.

I'd like to nominate another important trend in anatomic pathology that should be added to your list. In those states that outlaw discounted client billing, and in cases where a medical practice of physician specialists is not large enough to build their own pathology laboratory, the TC/PC billing (technical component/professional component) phenomenon is taking place–big time!

I was just on the East Coast. In New York and New Jersey, states which both outlaw client billing arrangements, every specialist group that I visited was doing TC/PC to capture revenues from pathology procedures performed on their patients.

The business model of PC/TC began decades ago in the dermatology specialty. That's when dermatologists began sending their specimens out for processing, then had the slides returned for diagnosis by physicians within their group. Now the urologists and gastroenterologists are doing it. Urology and GI groups send their biopsies and cytology specimens to a laboratory for processing. I believe ***US LABS*** *may have been first to present this business option to specialty physicians in Maryland in recent years. It seems to have then been introduced in other regions.*

In this arrangement, the laboratory bills for the technical component. The slides are sent back and the specialty group hires a local pathologist to read the cases, bills for the professional component and keeps the difference as its profit. These groups have legal opinions that view such arrangements as falling within the in-office laboratory exception of the Stark Laws.

A three-physician urology group can net $100,000 per year doing this. The capital investment is small ($7,000 for a microscope) and that's about all they require to support this business.

I understand that ***DIANON Systems*** *is also doing this maneuver. Could this be due to cross-fertilization of sales tactics at both US LABS and DIANON Systems, now that they are owned by the same company?*

For the pathology profession, the TC/PC split billing trend has devastating implications. This is moving west across the United States at a rapid clip. I know of urology and GI groups being offered PC/TC arrangements in the Midwest. It appears to be perfectly legal and won't go away.

I'm hearing that certain pathology laboratories already feel the financial pain. Pathology labs specializing in serving urologists, like ***Bostwick Laboratories*** *and* ***Oppenheimer Urologic Reference Laboratory****, either can't do TC/PC or won't do it. They are losing urology clients and specimen volumes are flat or declining.*

In addition to this TC/PC trend, pathologists are probably unaware of what's unfolding in the ***Quest/LabCorp*** *world. One of these lab companies hired 125 pathologists in 2005 and is on pace to hire another 125 during 2006. It is now building a sales force to feed specimens into these pathologists.*

For my money, this is going to be a head-on confrontation with local pathology groups. This could really mess up the waters for them. Local pathologists are likely to lose the outsourced pathology cases they currently get in their area and they will now have to compete head-to-head with the 800-pound gorilla.

These are my arguments why the trend of TC/PC billing arrangements belongs on your list. I invite you to print this letter, because I think pathologists need to understand what a serious threat TC/PC split billing is to the entire profession. If you do print my letter, please withhold my name, for professional reasons.

I'm curious as to your thoughts on this subject. Are you hearing about this from many pathologists? Has TC/PC billing popped up in southern or in western states yet?

Yours truly,

Name withheld, per request.

Editor's Response

You raise several important and well-articulated points in your letter. **THE DARK REPORT** did not include TC/PC split billing as a trend because of the difficulty in ascertaining how widespread the practice has become.

Further, we have been watching to see if any compliance risk emerges from this practice; more specifically, how will federal healthcare regulators view this business arrangement as it becomes more common? After all, if the compliance risk is minimal and the economic return worthwhile, specialty physicians will have a powerful economic incentive to establish and maintain TC/PC arrangements for their case referrals.

To help us better evaluate how widespread TC/PC split billing arrangements have become in today's marketplace, we invite local pathology groups to contact us and explain how this business arrangment has gained momentum in their community. A short email to *labletter@aol.com* is a good way to communicate this information.

It would also help us if local pathology groups sent along samples of sales materials and documentation handed to specialty physicians by labs offering TC/PC billing arrangements. There are several varients of this business arrangement and some do, very clearly, violate compliance guidelines.

THE DARK REPORT concurs that the TC/PC split billing arrangement is a threat to community hospital-based pathology groups. It is another reminder that local pathology group practices should be developing strategies to protect and expand their access to referring physicians in their service areas. TDR

First Lab Reports on Its Unannounced Inspection

It was January 3, 2006, when CAP inspectors arrived at Kern Medical Center to inspect the lab

CEO SUMMARY: Here is the lab industry's first report from a laboratory which has undergone an unannounced inspection under the College of American Pathologist's new accreditation program. Lab management at Kern Medical Center say the process went smoothly–but that effective preparation and a detailed contingency plan are "musts." Once the inspection starts, conventional procedures are followed.

THIS IS THE YEAR that unannounced inspections commence for laboratories accredited by the **College of American Pathologists** (CAP) and the **Joint Commission on Accreditation of Healthcare Organizations** (JCAHO).

CAP is wrapping up its pilot program for unannounced inspections. In mid-April, it expects to begin unannounced routine inspections for laboratories reapplying for CAP accreditation.

Kern Medical Center (KMC) in Bakersfield, California, participated in the pilot program. Its unannounced inspection was conducted on January 3, 2006, making it among the first laboratories to undergo CAP's new inspection process. KMC is a county-owned, 244-bed teaching hospital with level II trauma center. The laboratory performs about 650,000 billable tests annually.

"In October 2005, CAP called our Chairman of Pathology at KMC to ask if we would like to participate in the pilot program," stated James Pusavat, MT(ASCP)SM, Supervisor of the Microbiology Section at Kern Medical Center. "CAP needed to do some trial runs before the beginning of the unannounced inspections.

"We immediately formed a team to develop a contingency plan," recalled Pusavat, who was a member of this team. "In this group were the chairman and key members of the leadership team. Representation included both day and night shifts and every section of the lab, such as hematology, urinanalysis, point of care testing, chemistry, microbiology, coagulation, blood bank, etc. We met almost every week until early December to put together a contingency plan.

Preparing For Inspectors

"We organized our contingency plan around three major areas: personnel, paper, and place," he explained. "Under personnel, we needed to develop a list of staff members who would be available and willing to work on short notice in the event of an inspection. This was challenging for our lab, because we operate our laboratory with a very lean staff on all shifts.

"As it turned out, most everybody asked was cooperative," continued

Pusavat. "In the event of an unannounced inspection, they all agreed to come in on their days off. By asking them in advance, it helped us to sustain good morale levels in the laboratory. We also identified the executive staff who would need to be notified immediately in the event of an inspection."

Communication Tools

The second area involved the laboratory's written communications tools, including checklists and task lists. "I've kept annotated checklists in my microbiology section for nearly 10 years," noted Pusavat. "These checklists cover four things that are critical during an inspection: 1) what it is; 2) where it is; 3) what it looks like; and, 4) how to retrieve it. We keep the checklists and all relevant documents in binders marked with a green fluorescent dot, so they can be located quickly and easily.

"Prior to the unannounced inspection pilot program, no one in Microbiology was required to read the CAP checklists," he added. "As part of our preparation, I made copies of the checklists for each staff member in my section. Everyone was required to read the checklists and be able to locate every document named in the checklists.

Organized in Binders

"I know these binders are a point of differentiation compared to some laboratories," stated Pusavat. "Some labs are poorly organized with these documents. As a result, it may take a long time to locate a specific document. This can slow down an inspection process. It also wastes valuable personnel time.

"Our binder organization did not go unnoticed by the CAP inspector. It took less than one minute to locate any document when asked by the inspector," he recalled. "All materials in the binders are clearly labeled and are listed in a master table of contents. We store the microbiology binders on 20 feet of overhead shelves along the wall of the microbiology section. Only the instrument print-outs are not in binders. We store these print-outs in boxes.

"Another key area of our preparation for an unannounced inspection concerned the checklists in the binder" added Pusavat. "Like most laboratories, we make and revise annotations to our checklists annually. Upon review, we realized that some of these annotations may have been a little cryptic, and thus unclear to someone responding to an inspector's inquiry.

"We updated the notations to be sure they were written clearly and legibly," he noted. Our goal was to have checklists that met my "Rule of 4," allowing

Using CAP's Resources To Prepare the Laboratory

HAVING DONE WELL with its unannounced inspection last month, the laboratory at Kern Medical Center (KMC) in Bakersfield, California has several lessons to share.

"My main advice is to establish a good contingency planning team and give it the time and resources to do a good job," said James Pusavat, MT (ASCP)SM, Supervisor of the Microbiology Section at KMC. "The contingency plan is what guides your laboratory staff when inspectors do show up–at the most unexpected moment.

"Second, you'll find lots of useful and detailed information on the Web site of the College of American Pathologists (CAP), located at *www.cap.org*," noted Pusavat. "This information provides a good roadmap to prepare for the unannounced inspection.

"Third, remember that continuous improvement follow-up is now part of the inspection program," Pusavat explained. "The contingency plan your lab develops will form the basis for ongoing improvements that fulfill this part of the CAP accreditation process"

anyone looking at them to determine: 1) what it is; 2) where it is; 3) what it looks like; and, 4) how to retrieve it.

Giving Inspectors A Place

"Our third area of preparation involved a place where the inspectors could do their work," said Pusavat. "Our lab has a conference room. Part of our contingency plan is for the secretary to call and cancel all appointments scheduled for the conference room the day of the inspection. During our pilot program inspection, some inspectors preferred to sit within the department, rather than in the conference room."

Contingency planning by the laboratory team at Kern Medical Center was done by the middle of December, 2005. As it turned out, the timing of KMC's unannounced inspection came on the heels of the holiday season.

"On January 3, 2006, we were surprised at around 7:45 a.m. by a CAP inspection team," recalled Pusavat. "It was a total surprise. Many people were just returning from the holidays. The chairman of the pathology department and one of the supervisors were out with the flu! But everyone in the lab knew exactly what to do. We simply followed our checklist and our contingency plans."

Good Preparation Pays Off

Once the unannounced inspection commenced, it proceeded along in a conventional manner. "Essentially, this inspection process was the same as it used to be during announced inspections," observed Pusavat. "The key is to have a detailed contingency plan that everyone in the lab understands—whom to contact, where to locate and how to retrieve documents and records. Good preparation paid dividends for us."

Pusavat has several recommendations about how other laboratories can better prepare for an unannounced inspection. "The first place to start is the CAP Web site, which is *www.cap.org*. It has all the information anyone needs to prepare for an unannounced inspection," he said.

"Another useful resource is the information the CAP presented during its audioconference on the unannounced inspection process in November 2005," stated Pusavat. "This information is available on the CAP web site. There is also a useful page on frequently asked questions (FAQs) and a tips page, which was probably compiled based on feedback from the unannounced inspections pilot program."

Getting Good Information

"In addition to the customized checklists sent to the lab on a CD-ROM, CAP has also posted checklists with different formats on-line," he added. "In our microbiology section, I have a copy of our annotated checklists in Adobe PDF format at each workstation in Microbiology. This is useful for the techs on a routine basis, in addition to being convenient for inspectors.

"Using the 'find' feature in searching the PDFs of checklists, it becomes easy and quick to access specific information by checklist number or keywords," said Pusavat. "This saves time for busy techs. If Adobe software is not available to create PDF files, it is also possible to use security-protected MSWord files. The password protects against unauthorized editing.

"In summary, good advance contingency planning, a well-organized storage system, and following the CAP tips are the most effective ways to assure a successful unannounced laboratory inspection experience," advised Pusavat. TDR

Contact James Pusavat at jpusavat@yahoo.com.

—By Pamela Scherer McLeod

MDS Intends to Divest All Lab Testing Assets

One of Canada's major lab companies is actively selling its laboratory business

CEO SUMMARY: As part of a major corporate restructuring, MDS Inc. is selling three business units, including MDS Diagnostic Services. Within the Canadian healthcare system, this is a major event. MDS operates some of the nation's largest laboratory facilities in its most populous provinces. However, finding buyers may be difficult. Since announcing divestiture plans five months ago, MDS has yet to sell a lab.

JUST AS IT EXITED the laboratory testing business in the United States, **MDS Inc.** of Toronto, Ontario is moving to sell all of its laboratory testing assets in Canada.

This is a noteworthy development for the Canadian healthcare system. MDS has been one of the major independent providers of laboratory testing services in Canada. Its laboratory testing division, called **MDS Diagnostic Services**, generates revenues of about US$350 million per year.

Intent To Divest

On September 1, 2005, MDS Inc. announced a major corporate restructuring. It intends to divest three of its six business divisions. This will allow it to focus on its existing business in the "fast growing life sciences markets."

Along with the diagnostics business, MDS disclosed its intent to also sell **Source Medical** (Canada's largest distributor of medical, surgical and laboratory supplies) with annual revenues of US$350 million and **MDS Capital** (source of venture capital to emerging life sciences companies) with assets of about US$870 million.

On December 6, 2005, MDS Inc. disclosed that it was in negotiations to sell its 25% interest in **Calgary Laboratory Services** (CLS), a joint venture, regional laboratory organization based in Calgary, Alberta. The MDS interest is likely to be purchased by the **Calgary Health Region**, which already holds a 50% interest in CLS. The remaining 25% interest in CLS is owned by **Dynacare Kasper Medical Laboratories**, based in Edmonton, Alberta. This is a laboratory business unit of **Laboratory Corporation of America**.

CLS makes up about 17.5% of MDS' lab testing revenues. During 2005, MDS says it booked revenues of US$61 million and net income of US$1.3 million from its 25% share of Calgary Laboratory Services.

CLS is one of three major laboratory operations owned by MDS. **Toronto Medical Laboratories** (TML) is a joint venture partnership

between MDS and **University Health Network** (**Toronto General Hospital**, **Toronto Western Hospital**, and **Princess Margaret Hospital**). TML also includes two community hospitals and four specialty hospitals.

Another MDS laboratory in Ontario is **Integrated Health Laboratory Services**, which is a partnership between MDS and hospitals in the Windsor area. The company also partners with hospitals in the Niagara region, as well as several other organizations in Ontario.

In British Columbia, **MDS Metro Laboratory Services** is one of the province's two largest independent laboratories. Its main lab facility is in Burnaby and a smaller lab is located in Victoria.

Major Changes Ahead

The decision by MDS to exit the laboratory testing business in Canada is a significant development. In the private sector, MDS and Dynacare have been dominant providers of lab testing services. One factor behind MDS' decision is likely to be the difficult politics of trying to sustain a profitable business that serves a single-payer, government-directed health system.

In fact, knowledgeable observers of the laboratory marketplace in Canada say there are no obvious private buyers for the MDS laboratory assets, notwithstanding the usual rumors of interest by Dynacare/LabCorp and **Quest Diagnostics Incorporated**.

If no private buyers step to the table to acquire MDS' laboratory assets, they are likely to be picked up by the regional health authorities, similar to the negotiations now involving Calgary Laboratory Services. However, that is likely to be a time-consuming process and would probably not result in strong sales prices for MDS' share of the laboratory assets.

For lab executives and pathologists in the United States, events in Canada may be relevant in at least one respect. Canada's universal health system, funded and directed by the government, tends to have certain biases against private health providers, including laboratory companies.

Chronic Underfunding

Combine chronic underfunding for laboratory testing services over time with an institutional bias by government health program administrators against for-profit laboratory companies, and it should be no surprise that one of Canada's major laboratory testing providers is looking for the door.

How will the vacuum left by MDS' departure be filled? That is the key element to watch in this unfolding story. Just as Medicare and Medicaid reimbursement for lab testing has declined precipitously in the United States during the past 22 years, so also has the Canadian health system squeezed significant amounts of money out of laboratory testing budgets.

Private vs. Public Labs

The laboratory industry may soon learn whether the sustained reductions in laboratory reimbursement over the past 15 years now make most Canadian provinces unattractive for private laboratory operators. That is certainly one conclusion that could be argued if no private companies step forward to acquire the MDS laboratory operations and they are absorbed back into the various regional health authorities.

That may prove to be the case. After all, it's now been five months since MDS Inc. publicly declared that it would sell its laboratory interests. As of press time, no buyer for any MDS lab property has been announced. **TDR**

—By Pamela Scherer-McLeod

INTELLIGENCE LATE & LATENT

Items too late to print, too early to report

There's lots of management turmoil under way at **Pathology Partners, Inc.**, based in Dallas, Texas. On or about February 3, President and CEO Stephen L. Spotts and several other senior executives exited the company. Since then the management page on Pathology Partners' Web site has noted that it is "under construction" and lists no names. It is not known if the near-simultaneous departure of multiple members of the corporate suite is related to the arrival of new owners in June, 2005. Whatever the reason, this is a significant event for this fast-growing lab services company.

MORE ON: Path Partners

It was in June 2005 that **Caris Ltd.** paid $120 million to purchase a majority interest in Pathology Partners from the founding investors. David D. Halbert, is founder and Chairman of Caris. He also serves as Chairman at Pathology Partners, Inc.

BRITISH NECKTIES MUST GO IN FIGHT AGAINST MSRA INFECTIONS

Over the years, in many hospitals, laboratorians have tested neckties worn by physicians and other staff to see what types of bugs might be present. Now the **British Medical Association** (BMA), which represents 75% of the physicians in the United Kingdom, has issued a call for physicians to stop wearing ties and other "funtionless" clothing. The recommendation was contained in a report released on February 19 that called for heightened measures to control infections. The increase in MRSA (methicillin-resistant *Staphylococcus aureus*) infections is one reason that neckties and other types of clothing were singled out.

ADD TO: Doc's Neckties

Although the BMA's report detailed a number of significant steps to better control infections, the British press jumped on the specific recommendation, made by Vivienne Nathanson, Head of Ethics and Science at BMA, that "ties, in our view, are an unnecessary piece of clothing. We recognize that people touch their ties and wear them for a long time. People have to recognize the potential danger." In one recent study, all the ties worn by physicians in an orthopedic unit in Sussex were determined to carry bugs frequently found in the infected wounds of patients. The BMA's recommendation involving ties and other "functionless" clothing is a sign of how campaigns to reduce infections will increasingly seek to reduce or eliminate even relatively minor potential sources of infection.

An exposé published by *The Oregonian* newspaper in Portland, Oregon on February 12, 2006 revealed that, for a seven-year period, placentas from women with difficult births were harvested (without specific patient permission or notice) at hospitals in three states. The placentas were then sent to a lab in Portland funded, in part, by a malpractice insurance company. A pathologist at the lab studied the placentas and prepared reports that were later used by hospitals to defend against malpractice claims. Public knowledge of this scheme surfaced as a result of malpractice lawsuits.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 20, 2006.

PREVIEW #3

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All That's New in Lab Automation: Our A-to-Z "Consumer Reports" Review of Products

Over the past five years, the lab industry has seen a steady flow of new automation products and new vendors enter the marketplace. This gives laboratory directors and pathologists a wide variety of choices, whether the goal is total laboratory automation (TLA) or a simpler project to automate a single work process. To help lab leaders sort out this fast-growing segment of the lab marketplace, Rodney S. Markin, M.D., Ph.D., Professor & Vice Chair, Pathology & Microbiology at the University of Nebraska Medical Center, will review the spectrum of laboratory automation solutions now available.

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