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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Tougher Financial Times Ahead for Lab Industry

THE YEARS 2008 THROUGH 2010 WERE TOUGH ECONOMIC TIMES for all healthcare providers, including clinical laboratories and pathology groups. Moreover, although the deepest recession in 30 years was declared over by mid-2009, many hospitals continue to struggle financially and the national unemployment rate still hovers at about 9%, meaning that millions of Americans cannot find work.

It is my belief that the entire healthcare system will face daunting financial challenges in the next few years. For example, hospitals are worried about the potential negative impact of accountable care organizations (ACO) and value-based reimbursement.

For physicians, the Medicare sustainable growth rate (SGR) formula specifies that their fees should be reduced by 29.5% during fiscal 2012. Over the past decade, Congress has overridden the formula and funded an annual increase in the physician fee schedule. But outside forces will make that tougher for Congress to do during the current budget talks. Moreover, as noted earlier in THE DARK REPORT, the Obamacare bill, when scored as revenue neutral by the Congressional Budget Office in 2010, included this 29.5% cut in Medicare physician fees for 2012 and future years.

Now the laboratory testing industry has its own growing list of potential financial hits. For starters, the Accountable Care Act specifies an annual reduction in Medicare Part B lab test fees in coming years. And don't forget the 2.3% medical device tax, which is expected to include *in vitro* diagnostics equipment purchased by medical laboratories. This tax takes effect in 2013.

As you may already know, the newest financial threat that can significantly undermine the finances of the laboratory testing industry involves restoration of the 20% Medicare patient co-pay for lab tests. The lab industry faces this threat on two fronts. First, this proposal is part of the federal debt ceiling negotiations. Second, the lab test co-pay is back on the table within Congress as part of the annual budget planning process.

These examples serve as an early warning to lab administrators and pathologists. It won't be smart to develop strategic plans based on the assumption of "business as usual." Since the federal government pays more than half of the $2.5 trillion in healthcare costs annually, its budget problems alone are likely to lead to more dramatic declines in reimbursement than have been seen in recent years. The message for lab leaders is simple: "Be ready to do more for less money." TDR

Why Insurers Are Buying Office-Based Physicians

UnitedHealth Group is quietly expanding its ownership and services to physician groups

CEO SUMMARY: Four of the five largest health insurance companies in the nation have expanded their ownership of physician groups over the past 12 months. Some experts believe that private payers are preparing to do more acquisitions of physician groups as a way to expand their role in the integrated clinical care models that include medical homes and accountable care organizations (ACO). If this happens, it will alter how labs market their services to office-based physicians.

WHEN THE NEWS BECAME PUBLIC earlier this month that **UnitedHealth Group** was quietly purchasing physician groups in selected areas of the country, there was a flurry of news articles recognizing this as a new trend.

These news stories came after July 1. That's the date when *Kaiser Health News* published an analysis of UnitedHealth's strategy involving management and ownership of physician groups. The story focused on **OptumHealth**, a subsidiary of United that is "buying doctors' groups, building management companies to organize physicians, fostering new partnerships with medical groups and hiring doctors at a group it already controls."

Because UnitedHealth is one of the giants of the health insurance industry, its business strategies are closely followed by financial analysts and healthcare policy makers.

Other news accounts chronicled situations where health insurers own and operate physician groups or medical clinics. Such examples include the **CareToday** medical groups in Arizona that are controlled by **Cigna** (launched in 2006) and **Concentra**, which is an urgent-care system in Addison, Texas, that was recently acquired by **Humana**. Just eight weeks ago, **WellPoint** purchased 26-clinic **CareMore Health Group**, which is based in California.

In fact, four of the nation's five largest health insurance companies have increased their physician holdings during the past 12 months. The exception is **Aetna**. Its CEO, Mark Bertolini, has publicly stated that Aetna will not participate in this trend.

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For clinical laboratories and pathology group practices, there are implications to this trend if it gains momentum. Here is yet one more health industry sector that is ready to acquire independent physician groups and bring them under corporate management.

Operating Physician Groups

What happens if health insurers were to begin buying and operating physician groups on a large scale and throughout the nation? For clinical and pathology labs, this is an important strategic question.

Currently, independent physician groups have wide latitude in their choice of a primary clinical laboratory and/or pathology laboratory. It can be speculated that, once a physician group came under the ownership of a health insurer, that health insurer would want to control where that physician group sends its lab testing specimens.

It could be argued that payers owning physician groups would use the cheapest price per lab test as the primary criteria when selecting a laboratory to serve its physician groups. If that proves to be the case, that is positive for the two blood brothers. Their huge volume gives them a pricing advantage that local laboratories and hospital laboratory outreach programs cannot match.

Benefits Of The Outreach Lab

On the other hand, hospital laboratory outreach programs—particularly those at hospitals and health systems which provide inpatient services to these same physician groups—could argue persuasively that performing inpatient, outpatient, and outreach lab testing on the same patient has significant benefits, particularly in settings where integration of clinical care is the goal.

This would be the classic economic choice between "lowest price" versus "added value." Historically, the major health insurance companies have demonstrated a clear preference for contracting with laboratories that offer the lowest price.

However, it is not likely that health insurance companies will become a major force in the ownership and operation of physician groups in the United States, at least in the near term. That's because another class of buyers is acquiring physician groups at a much faster pace.

Over the past 24 months, a large number of hospitals and health systems have been aggressive buyers of physician groups in their communities and regions. How aggressive?

"There is definitely a land grab over primary care physicians," declared Ted Schwab. He is a Partner in the Health and Life Sciences Practice at **Oliver Wyman**. His assessment is mirrored by Paul DeMuro, an attorney at **Latham & Watkins** who represents physicians. DeMuro told *Kaiser Health News* that the prices buyers are paying for physician groups have spiraled upwards to "absurd" levels.

Health Market Is Evolving

The key point here is that it means something when hospitals, health systems, and now health insurers want to acquire and operate physician groups and medical clinics. It is the market speaking loudly.

Heightened activity to purchase physician groups also means something else. For every interested buyer, there must be a physician group that is willing to sell.

Thus, it is important for lab administrators and pathologists to understand what changes are unfolding in the American healthcare system that motivate ever more physicians to sell their medical groups and become—for all intents and purposes—employees of either the local hospital or a health insurance plan.

After all, traditionally, office-based physicians have had strained working relationships with hospital administrators and health plan medical directors. Yet,

Remember the Tidal Wave of "PPMs" in the 1990s? That Business Model Proved to Be a Total Failure

THERE IS SOME IRONY in the current land rush by hospitals and health systems to purchase and operate physician groups. That's because private practice physicians went down a similar road during the decade of the 1990s.

It was the time of physician practice management companies and "PPMs" were the darlings of Wall Street. One after another, private medical groups lined up to sell ownership in their medical practice to PPM companies.

PPMs Would Increase Profit

Private equity companies pitched doctors with a game plan that said "Let us buy an equity share of your medical practice. You practice medicine and let us manage the business operations and sales to increase revenue and profits. The result will be a larger pot of profits to split at the end of each year." *(See TDR, July 14, 1997.)*

The story of **MedPartners, Inc.**, graphically illustrates the roller coaster ride experience by physicians who sold their group practice to a PPM. It was 1993 when MedPartners was founded by **HealthSouth Corporation** (during the time that Richard Scrushy was CEO).

Growth was rapid. MedPartners went public in 1995. It merged with **Caremark** in early 1996. The combined company, at its peak, had 238 practices, 7,250 physicians, and contracts for the care of 1.5 million patients. By 1998, MedPartners' revenues totaled $7 billion. It was the nation's largest physician practice management company.

But things unraveled just as quickly. A proposed $8 billion merger of MedPartners and **PhyCor Inc**., fell apart and share prices of PPMs collapsed.

In November 1998, MedPartners changed its name to Caremark Rx, began divesting its ownership of physician groups, and shifted its business mission to pharmaceutical services. That marked the end of the PPM era as other PPM firms disbanded.

Pathologists with good memories of the 1990s will recall that "single specialty PPMs" were sprouting up during those same years. *(See TDRs, November 4, 1996; April 21, 1997; June 19, 2000.)*

Pathology saw its share of these start-ups. The names of pathology PPMs included:

- AmeriPath, Inc.
- American Pathology Resources, Inc.
- Inform Dx, Inc.
- Pathology Consultants of America
- Pathology Partners, Inc.
- PathGroup, Inc.
- Path Source, Inc.
- USLabs, Inc.

By 2002, only AmeriPath continued to operate as a single specialty PPM, focused on pathology. USLabs had abandoned the PPM business model to offer reference testing services focused on cancer. It was acquired by **Laboratory Corporation of America** in 2005.

PPM Era Lasted 10 Years

In hindsight, the concept of having business people take an equity position in a private physician group practice and contribute to improved revenue and net profits through better management and sales development proved ineffective in the real world. The PPM era lasted only about 10 years.

Because of the poor outcomes for the PPM business model, important questions are yet to be answered as hospitals, health systems, and health insurers acquire growing numbers of physician groups. At the same time, one difference in the 2010s from the 1990s is the movement toward integrated clinical care, supported by electronic health records and informatics technologies unavailable 20 years ago.

once these physicians sell their medical groups to hospitals or health insurers, they will be managed by these same individuals!

So what is changing in today's healthcare marketplace that motivates growing numbers of physician groups to sell to organizations they often considered to be hostile to their interests as office-based physicians?

At the same time, how are these changes also motivating hospitals, health systems, and health insurers to pay premium prices to purchase physician groups, then operate these groups moving forward?

THE DARK REPORT believes that the answer to these questions lies in the pending arrival of several significant new care delivery models, along with specific changes in how reimbursement will be paid to providers. Credit for these developments goes to the Obamacare legislation of 2010, which mandates these changes.

➤Changes Are Coming

Thus, providers are reading the tea leaves. They understand that accountable care organizations (ACO) and medical homes will require a tighter integration of clinical care—along with the need to better track the patient and to proactively work with the patient to achieve both early detection of disease and active management of chronic health conditions.

As ACOs become operational, hospitals and office-based physicians recognize that Medicare and private payers plan to incrementally increase the number of basic health services covered by the ACO reimbursement model. In future years, ACOs are expected to evolve into the primary channel for reimbursement for both hospitals and physicians.

To make money in future years, hospitals and physicians understand that they will need to interact more closely with each other than at any time in the past. This requires infrastructure to support a real time electronic health record (EHR). It also needs a mechanism to foster closer adherence to evidence-based medicine practice guidelines, and a way to collect outcomes data to allow providers to deliver better quality care to patients at a lower cost.

All of this requires capital investment and collaborative services, which office-based physicians do not have—but hospitals do! This is probably why so many physician groups have allowed themselves to be acquired by hospitals and health systems in their communities during the past 24 months.

➤Bundled Reimbursement

All of these same pending changes in integrated clinical care and bundled reimbursement that now bring hospitals and physicians groups together, represent a threat to private health insurers. Executives at the payers recognize these threats.

Integration of clinical care—in the form of medical homes and accountable care organizations (ACO)—has the potential to greatly diminish the current role provided by health insurance companies.

Many experts believe that ACOs will assume many of the functions and roles currently delivered by private health insurance plans. So it should be no surprise that private managed care companies recognize this possibility. Acquiring and operating physician groups is one strategy they are willing to pursue to protect their healthcare business interests.

➤Develop A Strategy

Thus, the booming demand to acquire office-based physicians is a warning flag to all lab administrators and pathologists. It would be timely for clinical labs to develop effective strategies that can help them maintain access to these office-based physicians, regardless of whether they are acquired and operated by hospitals or health insurers. TDR

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Quest Diagnostics and LabCorp Report Second Quarter Earnings

Financial reports open window on direction of lab testing marketplace for past six months

JUST ONE DAY APART, the nation's two largest laboratory testing companies reported second quarter and half-year earnings for 2011. Each financial report opened a window into marketplace developments for the first six months of this year.

First to release its earnings report was **Quest Diagnostics Incorporated**. On July 20, it announced that quarterly net revenue was $1.9 billion, up 1.5% from Q2-10, when revenue was $1.87 billion. For the first six months of 2011, revenue was $3.72 billon compared to $3.68 billion in 2010, an increase of 1.2%.

Quest Diagnostics said that clinical testing volumes declined by 0.9% for second quarter, compared to Q2-10. Its revenue per requisition increased by 1.6% over the same quarter last year.

The company is in the process of integrating its acquisitions of **Athena Diagnostics** and **Celera**. It said that 2.5% of second quarter revenue growth came from these business units.

For operating income in second quarter, Quest reported $316.8 million. This was a decline of 14% over the operating income of $365.9 million in Q2-10.

LabCorp's Net Revenue

The following day, on July 21, **Laboratory Corporation of America** released its earnings report. In the second quarter, it posted net revenue of $1.4 billion, an increase of 13.3% over Q2-10, when net revenue was $1.2 billion.

For the first six months of 2011, LabCorp posted net revenue of $2.8 billion, compared to $2.4 billion in 2010. This was an increase of 13.9%.

LabCorp said that its testing volume, as measured by requisitions, grew 4.8% for Q2-11 versus Q2-10. Revenue per requisition increased by 8.1% at LabCorp over the same time period.

LabCorp's Lab Acquisition

Operating income at LabCorp declined during the second quarter due to special charges. It was $225.7 million in Q2-11 versus $270.5 million in same quarter last year. Without the special charges, LabCorp said its operating income for second quarter was $279.6 million.

LabCorp is also integrating recent acquisitions. It attributes some of its increased numbers to the contribution of **Genzyme Genetics**. In fact, it identified Genyzme as accounting for 7.6% of its 13.3% increase in revenue growth.

For many years, the earnings statements and the market performance of Quest Diagnostics and LabCorp tracked relatively closely to each other. Divergences in growth rates and other measures were generally not great.

However, over the past 18 months, the quarterly growth in specimen volume at Quest Diagnostics has sometimes declined even as the same numbers at LabCorp have increased. For example, in second quarter, Quest Diagnostics' clinical testing volume declined by 0.9% while LabCorp's

testing volume increased by 4.8%. LabCorp CEO David King told analysts that organic growth in test volume was 2% for his firm during the second quarter.

This divergence in the ability to grow specimen volume organically between Quest Diagnostics and LabCorp has caught the attention of analysts. In the case of Quest Diagnostics, its executives explained the second quarter volume decline as partially due to a drop in patients' visits to physician offices during second quarter.

Growth In Lab Test Utilization

By contrast, when asked this same question by financial analysts during its second quarter conference call, LabCorp executives attributed the company's 2% organic growth in volume to physicians utilizing more laboratory testing. Mentioned were demographics, new test offerings, and "better understanding of utilization of tests by physicians."

As well, at least three other public laboratory companies that serve the physicians' office marketplace enjoyed robust growth in net revenue during the second quarter of 2011. The sidebar at right provides the numbers reported by **Bio-Reference Laboratories, Inc.**; **Enzo Biochem, Inc.**; and **MedTox Scientific, Inc.** Each lab reported double-digit growth in net revenue from their clinical laboratory testing operations.

Business Priorities

During their respective conference calls with financial analysts, the executives from Quest Diagnostics and LabCorp discussed very different business priorities and market strategies. Laboratory administrators and pathologists competing against the two blood brothers will see these differences play out in the competitive marketplace.

At Quest Diagnostics, one ongoing priority has been to expand the sales team—by hiring as many as 100 new sales reps—and to add more patient service centers and phlebotomists. Labs that compete against Quest Diagnostics will recognize that the company is restoring sales staff and draw sites that were probably removed during prior years' cost-cutting efforts.

$500 Million in Cost Cuts

In fact, cost-cutting will be a major priority at Quest Diagnostics in coming years. It is making a commitment to eliminate $500 million in costs during the next 36 months. On 2010's annual revenue base of $7.4 billion, this goal represents a 6.75% reduction of costs.

Moreover, it was back in January 2007 when Quest Diagnostics, responding to the loss of the **UnitedHealth** managed care contract, pledged to cut $500 million in costs by the end of 2009. So this is the second time in less than five years that Quest Diagnostics wants to trim $500 million in costs in a 36-month period.

Quest Diagnostics is also placing an emphasis on building its "genetic, esoteric, and anatomic pathology revenues." The company wants to increase the percentage of esoteric testing, which it currently says is 36% of revenues.

Over at LabCorp, the business priorities are described as the "Five Pillar Strategy." Pillar number one is deploying cash to "enhance our footprint and test menu." The Genzyme Genetics acquisition was part of this strategy.

More Use Of Informatics

Pillar number two is to enhance capabilities with information technology. LabCorp was boosting its Beacon product, which it says, for the first time, allows its customers to use a single web portal to electronically place orders for every LabCorp brand and service.

Pillar number three is to improve efficiency to increase service levels and customer value. This focuses on operational improvements and better use of automation, among other things. LabCorp says that these initiatives have allowed it to raise "per employee output in our core laboratories by 30% over the last four years."

Pillar number four is to use innovation in science to deliver new lab tests that deliver value at "reasonable and appropriate pricing."

Pillar number five is to consider alternative delivery models. LabCorp executives say they are holding talks with managed care plans to identify how healthcare reform and new reimbursement initiatives may change existing payment arrangements.

LabCorp did mention that it has an agreement in principle with the State of California and the *qui tam* relators to settle the Medi-Cal lawsuit, "without an admission of liability." The amount of the settlement is expected to be $49.5 million.

Stock Buyback

If there was one common strategy that both laboratory companies are using over the course of 2011, it is buying back their own shares. Since January 1, Quest Diagnostics says it has paid $835 million to re-purchase shares. LabCorp has used $335 million to re-purchase shares since the beginning of the year.

One way to better appreciate the magnitude of the cash flow that is generated by these two lab testing behemoths is to consider the stock repurchases in light of the Medi-Cal settlement amounts that each has agreed to pay. In the case of Quest Diagnostics, its settlement agreement called for it to pay $241 million. This is the largest settlement in the history of California, the nation's largest state. Yet that amount is just 29% of the $834 million that Quest used to purchase back its stock during the first half of 2011.

For LabCorp, its $49.5 million settlement amount with California represents 14.8% of the $335 million it has spent to repurchase its stock since January 1. These two examples show how much cash is being generated by each company. It is a reminder that they both have ample capital which they can use to improve their market share. TDR

Other Public Labs Report Q-2 Earnings

ONLY A HANDFUL OF PUBLIC LAB COMPANIES provide routine testing to office-based physicians. But their second quarter earnings reports help provide understanding about trends in the lab testing marketplace.

Bio-Reference Laboratories, Inc. (BRLI), of Elmwood Park, New Jersey, uses a fiscal year ending on October 31. For its second quarter ending April 30, 2011, it said that net revenue increased by 24.5%, from $110 million the previous year to $137 million in this year.

Growth was equally strong in BRLI's number of requisitions. That increase was 23%. It served 1.7 million patients in its Q2-11 versus 1.4 million in Q2-10.

At Enzo Biochem, Inc., of New York, New York, growth in clinical laboratory testing revenue was equally robust. For its second quarter, Enzo said clinical laboratory revenues grew 28%, from $10.8 million for Q2-10 to $13.8 million in Q2-11.

In St. Paul, Minnesota, MedTox Scientific, Inc., released its earnings report on July 14. It said that clinical laboratory revenue was up by 20.5%. For Q2-11, clinical lab revenue totaled $9.1 million versus $7.6 million in Q2-10.

In percentage terms, each of these three public laboratory companies reported significant increases in their net revenue for clinical laboratory testing operations during the second quarter of 2011. Individually, each public company is demonstrating its ability to compete effectively in the physicians' office market against the national lab firms.

Vendors rush lab equipment to 60-bed field hospital

Destructive Tornado Hits Joplin Hospital, Lab Rebuilds Swiftly

CEO Summary: One week after one of the worst storms ever to strike a hospital in the U.S., St. John's Regional Medical Center in Joplin, Missouri, was back treating patients. Surprisingly, the hospital's lab was one of the first departments to get up and running again. Within hours of the storm, the lab staff was doing point-of-care testing in an emergency triage center. By the next morning, lab equipment vendors had begun sending lab equipment so that the lab was able to operate as a high-complexity facility within about two weeks without making many changes to its test menu.

IN 45 SECONDS IT WAS OVER. One of the worst tornados in U.S. history tore through Joplin, Missouri, on May 22 and **St. John's Regional Medical Center** took a direct hit. In less than a minute, the hospital went from a normal Sunday evening shift to total chaos as the category EF5 tornado hit Joplin and the surrounding area with winds exceeding 200 miles per hour.

Caught in this disaster were the seven staff members on duty in the clinical lab at St. John's, which is part of the **Mercy Health System**. "But this lab team knew precisely what to do," stated Connie Wilkins, MSHA, MT(ASCP), Administrative Director Laboratory Services at St. John's. "Our lab drills at least once a year for this type of emergency."

Damage from the tornado was immediate and immense. It broke nearly every window in the hospital building, knocked out power, damaged the backup generator, and broke water pipes. The tornado sucked mattresses, chairs, curtains, and other debris out the windows. The building was later condemned amid unconfirmed reports that it had been knocked off its foundation.

Alert Issued Ahead Of Tornado

"A code gray alert in advance of the tornado directed everyone to move to a safe place away from the windows and wait it out," stated Wilkins. "Unhurt, the hospital lab staff moved quickly to help evacuate the 183 patients and did so in 90 minutes."

This natural disaster is a reminder to all laboratory administrators and pathologists that attention must be given to reviewing and updating emergency plans. Regular drills for the laboratory staff are essential to prepare the laboratory to cope with emergencies and still be able to serve physicians with accurate and timely laboratory testing services.

Such emergency preparation made the difference for the laboratory team at St. John's Regional Medical Center. With little advance warning, and in just a few minutes, their 367-bed, nine-story hospital facility suffered extensive damage and it became impossible to use the building for patient care. However, the laboratory team reacted with effective responses to this natural disaster.

"Since the storm, the hospital and our laboratory have worked steadily to restore a full laboratory testing service, with the complication that we are caring for our patients in a mobile hospital set up in our parking lot," noted Wilkins.

Widespread Devastation

In Joplin, devastation from the tornado was widespread. More than 150 people died. It was reported that among the dead were four patients and a visitor at St. John's Medical Center. However, support from the community and vendors is helping both the hospital and its clinical lab restore clinical testing services.

In an interview with THE DARK REPORT, Wilkins said, "The lab staff had to execute a condition gray. That sent them to designated areas where they rode out the storm. As the storm hit, the power immediately went out.

"After the storm passed, the lab team determined that they were okay," she continued. "They went to help evacuate patients. As well, some off-duty members of our lab staff managed to get to the hospital. They also assisted in moving the patients. All 183 patients were evacuated from the damaged hospital building in 90 minutes!

Patients Were Transferred

"The most critical patients went across the street to **Freeman Hospital**," she noted. "Other patients were taken to Memorial Hall, a civic center here in Joplin where we did the initial triage. A local Catholic school was also used for triage and to handle arriving patients.

"From these initial locations, patients were then transferred to other hospitals, such as **St. John's Mercy Hospital** in

Springfield," Wilkins stated. "Patients were also transferred to St. Louis and other cities.

"With the power out and the emergency generators damaged, we were unable to perform testing in our hospital laboratory," continued Wilkins. "However, the lab staff immediately secured a significant capability to perform point-of-care (POC) testing.

"This allowed us to provide testing for patients at Memorial Hall," she added. "Our POC test menu included chemistries, H&H [hemoglobin and hematocrit], several types of kit tests, and selected POC cardiac tests. If physicians needed more complex testing, arrangements were in place to send those tests to another lab.

"The point-of-care tests allowed us to offer moderate complexity testing," she said. "We did that for about a week at Memorial Hall and then the field hospital opened the following Sunday (May 29), exactly one week after the storm hit.

"Right now, we operate a laboratory in this field hospital," commented Wilkins. "It is not yet a full, high-complexity lab. But, we are working toward that goal.

"Right now, we operate a laboratory in this field hospital," noted Wilkins. "It is not yet a full, high-complexity lab. But, we are working toward that goal."

"We now have a hematology analyzer up and running," stated Wilkins. "Freeman Hospital, across the street, supplies us with the blood products we need. Any testing we cannot do here at the hospital we can send out to other Mercy hospitals. With these arrangements, we are currently able to provide our patients with all the testing that's required.

"Remarkably, of our entire lab staff of about 80 FTEs, all have been able to work, despite the fact that some lost their homes," she continued. "They either work here or we arranged for some staff to work in the labs of the other Mercy hospitals because of the increased workload going to their labs.

"At the field hospital laboratory, we currently staff each of the three daily shifts with about six people," stated Wilkins. "Our laboratory is open 24 hours every day, seven days a week. We also have some lab staff at Memorial Hall, where some patients continue to get care. In a normal routine, our lab would staff about 27 people for an eight-hour day shift.

"The entire 60-bed field hospital is about 5,500 square feet and we have 20 emergency department beds," she explained. "Our laboratory is located right in the middle of the emergency department (ED) because that's our busiest area. Specimens collected are processed onsite.

Referring Tests To Labs

"For any lab test that we cannot perform in our field hospital laboratory, we have arrangements that allow us to refer that test to another facility," noted Wilkins. "All of this testing is performed by laboratories located within Joplin. Currently we are referring esoteric tests and non-urgent tests to our sister hospital in Springfield."

As was true following the natural disasters of the multiple hurricanes in Florida in 2004, and Hurricane Katrina in Louisiana in 2005, Wilkins' laboratory received immediate and substantial support from key suppliers. "The reason our laboratory can function at this high level of service is because our vendors stepped up with incredible support," praised Wilkins.

"Our lab's two biggest vendors are **Sysmex America** and **Beckman Coulter Corporation,**" she added. "Sysmex delivered a hematology analyzer here before I even had a place to put it! This analyzer was in place before we opened our field hospital.

"I also asked Beckman Coulter if there was a way to put a chemistry and immunoassay analyzer in a van for me," noted

Lab Equipment Vendors Moved Quickly to Support St. John's Medical Center Laboratory

IT TOOK JUST 24 HOURS AFTER THE TORNADO struck Joplin, Missouri, for **Sysmex America, Inc.**, to deliver a new hematology instrument to the temporary laboratory facility at St. John's Medical Center.

"Upon hearing of the disaster, our account manager Tim Dillon secured a hematology analyzer from Sysmex America's demo equipment storage site and personally drove it to St. John's in Joplin," stated Ron Walczak, Director, Market Research & Communications for Sysmex America. "In Joplin, Tim met Ken Danowski, Sysmex's field service representative, who assisted with the installation and calibration.

"St. John's laboratory was equipped with the Sysmex XE-Alpha and used an XE2100 as a backup," noted Walczak. "This equipment was destroyed as a result of water damage from the tornado. We replaced these instruments with a Sysmex XT-2000i automated hematology analyzer. We also immediately shipped reagents and other consumables to replenish the laboratory and help ensure its full operation."

Team Sent To Joplin

"Along with the testing instruments, Sysmex sent a team to install, implement, and perform correlation studies to ensure the automated hematology analyzer was operating appropriately and reporting results," he added. "Our employees—from senior managers and technical service representatives to our customer service department—quickly engaged once they realized the acute needs of St. John's. We are happy to have supported St. John's return to community service."

Mary Luthy, a spokesperson for Beckman Coulter, Inc., said the company had a demonstration van configured for chemistry and immunoassay testing that was sent to St. John's Medical Center. To help the laboratory restore its testing services, Terry Elder, Beckman Coulter's regional sales manager for the Joplin area, was working closely to ensure that the lab equipment operated properly.

Speedy Response

"Everyone at **Diagnostica Stago, Inc.**, worked quickly to help out," explained Robert Bachkosky, Director of Marketing for Diagnostica Stago. "We immediately shipped a STA-Compact analyzer from our facility in New Jersey to help the laboratory at St. John's restore its coagulation testing.

The St. John's laboratory even got help from an unlikely source—the shipping company that delivered the Stago instrument! "When we learned the equipment was to replace a damaged machine at the hospital lab in Joplin, we waived the shipping charges," recalled Jeff Rossier of **Trade Show Technologies** in West Caldwell, New Jersey.

"It requires a specialized carrier to transport diagnostic equipment," noted Rossier. "Anything our company could do to help the people in Joplin is well worth it. The news pictures of the destruction from the tornado are heart-rending."

Wilkins. "They made it happen by Saturday, June 4.

"The Sysmex hematology analyzer arrived just days after the storm and **Diagnostica Stago** sent a coagulation system," commented Wilkins. "These lab testing instruments gave our laboratory a relatively complete test menu for hematology and coagulation testing.

"By the following week, we had serology testing and urinalysis," continued Wilkins. "This means, that, since the tornado, our laboratory's test menu has not changed much, except for microbiology.

Once I secure a site for microbiology we will put that in place."

Immediate help also came from other hospital labs in the **Mercy Health System**. In nearby Springfield, Missouri, the lab team at **St. John's Mercy Hospital** sprang into action. "When the tornado had passed, we mobilized our blood bank and called people in because we knew we would be called on to assist," stated Edwina L. Cook, MS, MT, SM(ASCP), Director, Laboratory Services, at St. John's Mercy Hospital in Springfield, Missouri. "These steps were taken as part of our clinical laboratory's disaster planning preparations.

"We notified our blood supplier about the emergency," said Cook. "Our laboratory immediately sent point-of-care testing units and supplies to Joplin. This included iStat instruments and glucometers.

"We also sent them supplies that were already prepared and had been quality controlled," she added. "Our laboratory sent controls and we sent procedures because, although that lab might have had the same device, it may not have been running the same tests as we do in this lab."

Lab Testing Capabilities

All this support helped the laboratory at St. John's Medical Center regain much of its testing capabilities. "By Monday, June 6, our laboratory had regained almost all of the capabilities that we had before the storm," stated Wilkins. "With the exception of our microbiology department, we have a full-functioning high-complexity laboratory.

"Our various vendors have been very gracious to send lab test equipment in as fast as they can get it here and so our rebuilding has been a work in progress," praised Wilkins. "We have equipment arriving from everywhere and we are validating, calibrating, and doing our correlations. This lab is going forward."

The response to this devastating tornado, by the laboratory teams at St. John's Regional Medical Center in Joplin, and other hospital labs in the region, demonstrate the value of good disaster planning. Both Wilkins and Cook agree that people are ready to respond following a natural disaster or similar crisis. What allows them to do so in a timely effective manner is a well-designed disaster plan, combined with regular drills and similar training.

When asked about the lessons learned from the response to the Joplin tornado, Wilkins said that there was not much she would do differently. Her message was that good preparation is the primary lesson. However, she did want to emphasize a couple of important insights.

"For our laboratory here at St. John's Medical Center in Joplin, there are two key points from disaster planning that made the biggest difference," Wilkins commented. "First, know the other laboratory testing resources in your community because, in a worst-case scenario, you may have to re-direct lab work if your laboratory is not functional.

"Keep in mind that this re-direction of lab test work may include another element," she explained. "It is equally necessary to have a plan to train your staff to help with the increased workload in other laboratories.

Disaster Recall List

"Second, for all the staff in your laboratory, maintain an up-to-date disaster recall list," recommended Wilkins. "Communication is critical after a disaster. Following this destructive tornado, we needed to send our lab staff to many different locations. Our disaster recall list allowed us to stay in touch with all of our staff.

"When I look back, there is nothing signicant that I think our laboratory would do differently," she concluded. "Further, I especially believe St. John's in Joplin is a place of grace and I am honored to work with this amazing team of healthcare providers and laboratory professionals."

THE DARK REPORT observes that the Joplin tornado and the damage it did to

Lesson Learned from the Joplin Tornado: Keep Electronic Patient Records Offsite

ONE LESSON LEARNED from the Joplin tornado involves the importance of storing electronic patient records in a protected site. Because its patient records were stored at another location, St. John's Regional Medical Center in Joplin, Missouri, was able to access the complete medical record for every patient evacuated the night of the storm.

"Our hospitals have the **Epic** electronic medical record (EMR) system, and Joplin went live on May 1, just three weeks before the storm," said Edwina Cook, MS, MT, SM(ASCP) Director of Laboratory Services of **St. John's Mercy Hospital** in nearby Springfield, Missouri. "Within minutes of the tornado hitting Joplin, our command center here in Springfield became operational.

Health System's EMR

"Because we are all one Mercy system, the Epic EMR is being rolled out to all Mercy facilities," Cook added. "Mercy has 30-plus hospitals and more than 200 physician offices across four states. Eventually all these hospitals will be connected to the Epic system.

"At this time, our hospital and clinics here in Springfield and its surrounding region are all on this common EMR system," she stated. "There are Mercy hospitals in the St. Louis area, Arkansas, Kansas, and others that are also already on our EMR system.

"Therefore, for a patient in one facility, it is possible for physicians and those who need to know in other facilities within the Mercy system to access that patient's records from other facilities," observed Cook. "This connectivity comes through a computer facility in St. Charles, Missouri, that is rated to withstand earthquakes and major tornados.

"Because of this integration of the EMR system, our command center here in Springfield could pull the patient roster from the Joplin hospital in a matter of minutes," she explained. "It was immediately known that there were 183 patients in that facility.

Viewing The Patient's EMR

"As patients of St. John's Regional Medical Center in Joplin were transferred to other Mercy hospitals, we could view those patients' electronic medical records with a few keystrokes," continued Cook. "For patients sent to facilities outside the Mercy family, the command center in Springfield printed the medical records and faxed them to those facilities.

"Following the tornado, patients from St. John's Regional Medical Center were sent to Freeman Hospital in Joplin, and hospitals in Springfield, Arkansas, Oklahoma, and Kansas," she noted. "For each of these patients, fast access to their EMR was invaluable.

"This was important," stated Cook. "Wherever those patients went—whether it was to Tulsa, Fayetteville, Freeman Hospital, or here in Springfield—physicians had each patient's medical reports and could treat them appropriately.

"This demonstrates the value of having an EMR system at one hospital, and keeping back-up records in another hospital," Cook explained.

hospitals and the community is a reminder that clinical laboratories in every region should re-visit and update their disaster plans. Such preparation makes the difference in coping with the unexpected. **TDR**

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Doctors Use Mobile Apps To View Lab Results

Era of mobile applications commences and lab test ordering/results reporting is on the menu!

CEO SUMMARY: By sending lab test results and other data from the hospital's electronic health record system to physicians' smartphones, Holy Name Medical Center in Teaneck, New Jersey, is empowering physicians to manage patient care more efficiently. Today, few hospitals send information directly from the electronic health record (EHR) system to a smartphone (meaning an Apple iPhone, Rim Blackberry, or Android device). But the number of physicians interested in this feature is increasing.

GROWING NUMBERS of physicians, nurses, and other health professionals are flocking to smartphones, iPads, and similar high-touch/high-function mobile devices. Because clinical laboratories produce information, this is a trend with important implications for all labs and pathology groups.

Another notable aspect of this trend is that physicians and nurses are pushing their hospital IT (information technology) departments to make clinical data and patient health records accessible on smartphones and iPads. This is an important development.

In response to this trend, first-mover hospitals are seizing the opportunity to help their physicians use mobile computing devices for an expanded number of clinical and operational purposes. In Teaneck, New Jersey, these were the goals of **Holy Name Medical Center** (HNMC).

Earlier this year, it rolled out an application that enables physicians to view results and patient information on smartphones. In an interesting twist to this story, HNMC's app was developed by its own IT staff!

Holy Name Medical Center's 12-member software development team wrote the programming code over three months earlier this year, then launched the mobile app in June. Called MicroHIS, it allows physicians and staff to use mobile devices to order procedures and view results and patient data. Their home-grown application works seamlessly with HNMC's home-grown EHR, called Web Health Information System (or WebHIS).

Lab Test Data on Smartphone

"It handles lab data very well," stated Michael Skvarenina, the medical center's Chief Information Officer, in an interview with THE DARK REPORT. "Not only does it show laboratory test data, but it also shows radiology reports and interpretations, EKG data, and vital signs—such as the patient's temperature and blood pressure.

"Currently these are text-only views," he explained. "However, this application can be adapted to show graphics, such as a trend line chart.

"Our mobile app also has the patient's demographic information," commented

Lab Director Gets News Via Smartphone, Just As the Docs Get Their Lab Test Results

VACATIONING IN ITALY LAST MONTH, Edward A. Torres, MPA, used his cellphone to check his e-mail. At that moment, the Administrative Director, Pathology & Laboratory Medicine, at Holy Name Medical Center (HNMC) learned that his hospital in Teaneck, New Jersey, was now sending laboratory test results to physicians' smartphones with a home-grown mobile application.

"It's a great advance that allows our physicians to view laboratory test results on their smartphones and similar mobile computing devices," Torres commented. "We knew CIO Mike Skvarenina and the IT Department were working on sending lab results from the hospital's health information system, the WebHIS, to physicians' smartphones. But we did not know when he would launch this exciting new service for our physicians. I found out by e-mail when I read *Dark Daily* while on vacation." *Dark Daily* is a daily e-mail news service from THE DARK REPORT.

"At Holy Name Medical Center, our laboratory test data is stored in our LIS, which has long been interfaced with our hospital's electronic health record (EHR) system, which is called WebHIS," noted Torres. "It was surprisingly easy for our IT department to create the interface needed to make laboratory test data available on MicroHIS, which is the name of the mobile phone application."

HNMC is located to the west of the George Washington Bridge, which is a major gateway into New York City. The lab staff numbers 93 full-time equivalent workers (130 total employees) and performs 1.5 million billable lab tests annually.

"The launch of MicroHIS helped our lab improve how we deliver data and lab information," concluded Torres. "We see this as an example of how the clinical laboratory must be innovative and help physicians access laboratory test results using all the latest technology that becomes available."

Skvarenina. "This includes the patient's in-room telephone number, an emergency contact name (meaning next of kin) and that person's phone number, as well as the name of the patient's nurse for the current shift."

The system is free to physicians affiliated with HNMC, and the data are available immediately when posted to the medical center's system. On his or her mobile device, the physician simply clicks on the MicroHIS icon to then log onto the secure network, thus ensuring patient privacy. After logging on, the physician sees a list of his or her patients and each patient's essential medical information. Any data that has not been viewed previously is highlighted and abnormal test results are flagged.

"Physicians also can search for a patient by unit, then add that patient to his or her list of patients to follow," noted Skvarenina. "MicroHIS allows a physician to call the patient's room, the patient's nurse, or a next of kin directly from the physician's mobile phone.

Tap Screen, Call the Nurse

"In our hospital, every nurse takes a wireless phone when signing in for the day," he said. "The physician can then use that telephone number to call the patient's nurse from anywhere. Because phone numbers are hyperlinked, the physician could be at home or out to dinner and call the nurse just by tapping the number on the screen.

"During the week of July 18, we introduced the latest version of the MicroHIS," he added. "This new version includes the operating room schedule for our surgeons and the ability to search the master patient index, including outpatients.

"We created the outpatient feature in response to requests from our physicians," noted Skvarenina. "This useful feature allows physicians treating one of our patients to look up any patient in the database—whether an inpatient, an outpatient, or an outreach patient who only had their clinical laboratory tests drawn and performed by our hospital lab.

"Originally we built the MicroHIS so that physicians could have data when doing inpatient rounds," recalled Skvarenina. "But once they tried it, they wanted data on outpatients as well. Now they can get each patient's history, physical, discharge summaries, progress notes, operation reports, and any transcribed report on the MicroHIS."

Skvarenina also explained why HNMC created its own electronic health records system. "Over the past 25 years, we have continuously developed and improved our own EHR. This included building interfaces to other clinical software systems," he said.

EHR Interfaces With LIS

"For example, our EHR, which is called WebHIS, interfaces with our **Sunquest** laboratory information system (LIS) for laboratory data and with **IDX** for radiology data," Skvarenina noted. "WebHIS is the repository for all patient data. That means physicians can also track new results. In fact, some of our physicians use MicroHIS as their only form of EHR access outside of their offices.

"When the doctor logs onto MicroHIS, it presents his/her rounding lists," he said. "A counter on the screen may show 5L and 1R to indicate that five lab reports and one radiology report are available that the physician has not previously seen.

"If the physician taps that 5L icon, it brings up those results on screen," Skvarenina explained. "Normal results show up in blue. If any lab tests results are abnormal, the data will show as red. Once a physician views these results, that item is marked as 'read.' It will no longer appear on the home screen unless the physician goes back and gets it from the patient's data file.

"Having lab test data available during a patient's stay is significant because that's how physicians manage most patients," he continued. "We give them the name of the test; the date and time the sample was taken; and the date and time the test was done. If it's a complete blood count, it will say 'CBC' and show the component results for white blood count (WBC), red blood count (RBC), and any other component laboratory test results the physician ordered.

"Next to the lab value is the reference range. Most doctors know what the reference range should be, but it's there if they want it," noted Skvarenina. "We also show an H or L for each component, meaning high or low. Any text-based data, such as readback documentation that lab personnel entered, or a critical value, also will appear with the result.

"To date, we haven't had any requests to show trends for lab data on the MicroHIS," he said. "However, we do show trends on the WebHIS in numerical form and also offer a graphical format.

"The MicroHIS system is designed to do—on a smartphone—all the functions that were expected to be handled by a tablet PC," added Skvarenina. "The tablet is a handheld laptop. The benefit of smartphones is that they are always on the owner's hip or in his/her pocket. By contrast, a tablet is too big to fit into a pocket, and physicians are more likely to have their smartphones with them."

THE DARK REPORT observes technology makes it easier for in-house IT departments to develop smartphone applications like MicroHIS. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In a play to expand its presence in cervical cancer testing, **Roche Holdings** announced an agreement to acquire **mtm laboratories AG**, based in Heidelberg, Germany. Roche will pay U.S. $180 million, plus another U.S. $85 million if performance milestones are achieved. mtm laboratories will become a division of **Ventana Medical Systems**. In its press release, Roche noted that mtm has proprietary test solutions based on the p16 biomarker, which is associated with cervical cancer.

MORE ON: *Roche*

In recent years, mtm has gained approval in Europe to market its CINtec Plus Cytology kit, which identifies over-expression of p16 in cervical Pap test samples to detect pre-cancerous lesions.

Roche stated that it believes this test "could aid in the classification of patients with abnormal Pap or positive HPV results into those with and without significant pre-cancer or cancer, reducing unnecessary biopsies and ensuring patients are treated appropriately." Financial analyst Andrew Weiss of **Vontobel** told a *Reuters* reporter that Roche may want to pair up mtm's CINtec Plus Cytology test with its own HPV test as a way to define a new standard of care for cervical cancer testing. Because tens of millions of Pap tests are performed annually in the United States alone, this represents a huge market. It is why Roche and other competitors would like to develop a more accurate diagnostic test panel for detecting cervical cancer in its earliest stages.

WALTER REED ARMY HOSPITAL READY TO CLOSE

After more than 100 years of operation, **Walter Reed Army Medical Center** in Washington, DC, will close next month. On September 15, the Army will transfer the facility to the State Department and the District of Columbia, who will become the new tenants. Over the years, a steady number of pathologists worked at Walter Reed and the **Armed Forces Institute of Pathology** (AFIP). AFIP will dis-establish in September 2011. It ceased accepting case referrals on March 31, 2011.

TRANSITIONS

- Earlier this month, **Puget Sound Institute of Pathology** in Seattle, Washington, appointed Stu Adelman to be its new CEO. Adelman was formerly General Manager of **PACLAB Network Laboratories**, a position he held for almost 14 years.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 15, 2011.