Volume XX, Number 3 Monday, March 4, 2013

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Predicting the End of Fee-for-Service Medicine

HOW DISRUPTIVE WILL THE END OF FEE-FOR-SERVICE MEDICINE be to the lab testing industry? I ask this question because we are about to leave the era of fee-for-service (FFS) medicine and move into the era of value-based and bundled reimbursement.

Since World War II, FFS has been the overwhelmingly dominant payment model for the healthcare system in the United States. Yes, there is Medicare's Diagnostic-Related Groups (DRGs) for Medicare Part A services (introduced in 1983) as a different payment model. And don't forget, during the 1990s, we were all guinea pigs in healthcare's short-lived experiment with capitated, full-risk payment arrangements during the heyday of the closed-panel HMOs.

Now we are at the birth of a new era for rewarding providers. Employers, private health insurers, and officials managing the Medicare and Medicaid programs are all telling hospitals, physicians, laboratories, and others the same thing: you will soon be paid in a way that recognizes the better outcomes you deliver to patients and factors in your contribution to reducing the overall cost of healthcare.

This is a radical development and I don't believe that most pathologists and laboratory administrators have thought about what life will look like as the proportion of their labs' revenues that comes from fee-for-service shrinks and the proportion of revenues that is due to value-based and bundled reimbursement increases. Yet it is important to consider this issue.

On this point, the question that I ponder is how labs will organize themselves differently to meet the needs of customers who pay them with a value-based reimbursement or ask them to provide lab testing services as part of bundled reimbursement scheme.

For example, FFS reimbursement encourages consolidation of lab test volumes because a greater volume of tests means lower average cost per test. That maximizes the lab's profit when the lab is paid on a fee-for-service basis. So, when FFS goes away and value-based reimbursement takes its place, will it be more important for a lab to be nearer to the patient and the physician—despite the lack of economies of scale that drive down the average cost per test?

This is just one example of how evolving reimbursement models for medical lab testing may encourage labs to organize themselves in new ways. For that reason, lab testing may look quite different in 10 years than it does today. TDR

Urologists Weigh In on Prostate Biopsy Testing

Findings of a newly-released study claim to support a 10- to 12-core standard of care

***CEO SUMMARY:** Based on an impressive number of 4,230,129 vials collected from 437,937 biopsies, the new study is expected to add fuel to the fire of the ongoing debate about the appropriate number of prostate biopsies physicians should collect and refer to pathology labs for cancer testing. The researchers compared the number of prostate biopsies sent to a national reference laboratory with the number collected by urologists and self-referred to their own in-office pathology labs.*

UNDER ATTACK FROM MANY QUARTERS because of alleged patterns of utilization from their in-office pathology labs, researchers collaborated with the **Large Urology Group Practice Association** (LUGPA) to conduct their own study into this matter. The results, endorsed by three urology professional associations, were announced last month.

If numbers matter, then the study, titled "Utilization and cancer detection by U.S. prostate biopsies (2005-2011)," should have credibility. It involved 4.2 million specimens collected from 440,000 prostate biopsies.

The study's findings were presented at a poster session during a symposium conducted last month in Orlando, Florida, by the **American Society of Clinical Oncology Genitourinary Cancers**.

In their abstract of the study, the authors boldly concluded, "The increased cancer detection rate correlated significantly with the increased number of specimens examined. Segregation of prostate biopsy cores into 10-12 unique specimen vials has been adopted by urologists across sites of service and can be considered the *de facto* national standard of care."

At the heart of the matter is the 20-year debate over what number of prostate biopsy cores represent a standard of care that contributes to optimal diagnostic accuracy. Community pathologists, national pathology lab companies, and urologists have all weighed in at different times on this issue. The debate has often been rancorous because of the differing opinions.

"Identifying the proper number of

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. **(ISSN 1097-2919.)**

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

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

cer appropriately is a patient care issue that is at the heart of the dispute," stated Deepak A. Kapoor, M.D., in an exclusive interview with THE DARK REPORT. A board-certified urologist, Kapoor is President of the Large Urology Group Practice Association, and Chairman and CEO of **Integrated Medical Professionals (IMP),** in Melville, New York.

Integrated Medical Professionals is a multispecialty practice serving Long Island, parts of New York City, and Westchester and Rockland counties in New York. One of the largest practices of its kind in the United States, IMP runs one of the nation's largest in-office pathology laboratories. It has 106 physicians and six multi-purpose outpatient treatment facilities.

At the 2013 Genitourinary Cancers Symposium last month in Orlando, Florida, Kapoor and other experts on this issue presented research they conducted to assess the positive biopsy rate and core sampling pattern in patients. The researchers collected data on prostate biopsies from a national reference laboratory and from pathology laboratories integrated into urology group practices. The research produced two significant results, Kapoor said.

Number Of Specimen Vials

"The first significant result involved the relationship between positive biopsy rates and the number of specimen vials per biopsy (sv/b)," observed Kapoor. "In a subsequent analysis of similar data, our research team hopes to determine the appropriate number of specimen vials per biopsy needed to identify cancer in prostate patients.

"We believe our study is the largest of its kind ever done," he declared. "It involved more than 2,000 urologists who collected 437,937 biopsies and 4.2 million cores over six years."

In addition to Kapoor, the researchers included three of his IMP colleagues: Carl A. Olsson, M.D., Lattimer Professor and Chairman of Urology, emeritus, at the **Columbia University Medical Center**; and two pathologists, Savvas E. Mendrinos, M.D., and Ann E. Anderson, M.D. Also participating and providing data from a national lab company was David G. Bostwick, M.D., Chief Medical Officer of **Bostwick Laboratories** in Uniondale, New York.

The researchers collected data on the total number of specimen vials submitted per prostate biopsy and the final diagnosis for each case from urologists and urology practices referring samples to a national reference laboratory (NRL). Over the same period, they also collected similar data from urology practices with in-house laboratories performing global pathology services.

Positive Biopsy Rates

For each year studied, the positive biopsy rate and number of specimen vials per biopsy were calculated in aggregate and separately for each site of service, according to an abstract presented at the symposium.

The results showed that from 2005 to 2011, 437,937 biopsies were submitted in 4.2 million vials (meaning 9.4 specimen vials per biopsy or sv/b). The overall positive biopsy rate of 40.3% was identical at both the NRL and in-office pathology labs, the abstract said. Interestingly, the results showed urologists tended to collect more specimens in the last three years of the study, when the sv/b rate increased sharply from a mean of 8.8 during 2005 to 2008 to 10.3 from 2009 to 2011, the researchers reported.

"The reason urologists collected more specimens per biopsy over the last three years studied than they did in the previous four years resulted from changes in urologists' practice patterns," explained Kapoor. "This is after they saw a correlation between a positive biopsy rate and sv/b.

"In 2005, the average number of cores per biopsy sent to the NRL was 7.2 cores, and the positive biopsy rate was 38%," he continued. "By 2011, the number of cores per biopsy was about 10 to 11 cores, and the positive biopsy rate was 42.5%.

"When doing a prostate biopsy, the goal is to optimize the yield while minimizing costs and complications," added Kapoor. "Therefore, it is significant that there was a near linear correlation between the number of biopsy cores collected and the positive biopsy rate.

"When the physician collects seven to eight biopsy cores, the positive cancer rate is about 38%," he noted. "The collection of 10 to 11 cores is associated with positive cancer rates of about 41% to 42%.

"That is a difference of about 10%, which is significant in terms of patient care because it may help us identify the appropriate rate of biopsy specimens to collect," Kapoor explained.

"This issue will be the subject of another study," he said. "Through extrapolation, we want to determine that a specific number optimizes the yield in terms of positive biopsy versus cores collected. I believe that number will almost certainly be somewhere between 10 and 12."

More Research Needed

Kapoor pointed out that there was a second significant result from the study. This result involved the number of specimens sent to the national reference laboratory compared with the number of specimens reviewed at in-office laboratories. "From 2009 to 2011, the sv/b rate for samples sent to the NRL was 10.0, which was statistically identical to the rate of 10.6 sv/b done at in-office labs. The notion that physician ownership drives utilization of pathology services is not sustainable since positive biopsy rates as well as numbers of sv/b are so similar across sites of service," Kapoor said.

Research by Kapoor and colleagues was reported only in abstract form at the symposium. But a peer-reviewed medical journal is reviewing the full study and Kapoor hopes the full manuscript will be published soon. TDR

—Joseph Burns

Contact Deepak Kapoor, M.D., at 516-931-0041 or dkapoor@imppllc.com.

Battling Studies Over Biopsy Utilization Rates

FOR PATHOLOGISTS AND LAB EXECUTIVES watching this ongoing battle over what number of cores is appropriate for prostate cancer testing, the release of this study by three national urology associations is the urologists' turn at bat.

This study, more than 10 times larger and covering over twice as long an interval, is designed to answer the findings of a study published last year in the journal *Health Affairs*. Titled, "Urologists' Self-Referral For Pathology Of Biopsy Specimens Linked To Increased Use And Lower Prostate Cancer Detection," the *Health Affairs* article reported that self-referring urologists billed Medicare for 4.3 more specimens per prostate biopsy (s/pb) when compared with the adjusted mean of six s/pb that non-self-referring urologists sent to independent pathology providers—a difference of almost 72%.

In *Health Affairs*, the study authors wrote that, "Additionally, the regression-adjusted cancer detection rate in 2007 was 12 percentage points higher for men treated by urologists who did not self-refer. This suggests that financial incentives prompt self-referring urologists to perform prostate biopsies on men who are unlikely to have prostate cancer. These results support closing the loophole that permits self-referral to 'in-office' pathology laboratories."

The *Health Affairs* study had its critics who pointed out that the funding for the research had been provided by the **College of American Pathologists** (CAP) and the **American Clinical Laboratory Association** (ACLA), two organizations which represent those pathologists who would prefer to see the in-office pathology laboratories owned by specialty physicians go away.

As well, there were criticisms about the Medicare data sets chosen by the study's author, as well as criticisms about the design and the methodology of the study itself. (*See TDR, April 23, 2012).*

Payer Update

Palmetto's Prostate Biopsy Policy Removed after Talks with CMS

Action is a welcome development for labs, but uncertainty remains about unpaid claims

THERE IS SOME POSITIVE LAB INDUSTRY NEWS that has not been widely reported yet. It involves a decision to change an unwelcome Medicare policy that limited the number of prostate biopsy specimens per case that would be reimbursed.

After discussions between lab industry groups and the federal **Centers for Medicare & Medicaid Services** (CMS), **Palmetto GBA** removed a policy that limited the units of service that a provider could bill for a prostate biopsy.

This policy was instituted in August 2012 by Palmetto, the nation's largest Medicare contractor, for prostate biopsy claims originating from regions J1 (California, Hawaii, and Nevada) and J11 (North Carolina, South Carolina, Virginia, and West Virginia).

The impact of this policy was to reduce reimbursement for a 12-core prostate biopsy claim by about 50%. Reimbursement for prostate biopsy specimens in these seven states may now rise, a lawyer representing the **American Clinical Laboratory Association** (ACLA) said.

Discussions About Policy

ACLA officials met with representatives of CMS recently to discuss the policy implemented by Medicare contractor Palmetto GBA last year. This policy reduced the reimbursement it paid for prostate biopsies in regions J1 and J11.

Last August, Palmetto changed its rules on how pathologists bill for regular prostate biopsies and saturation biopsies. The rules appear to have begun with a change in the National Correct Coding Initiative (NCCI) manual, which was effective on January 1, 2012.

Even though Palmetto changed the policy on August 7, 2012, it said the new policy was retroactive to January 1, 2012. The net effect was estimated to be a cut in revenue of as much as 50% for a 12-core urology biopsy. *(See TDR, August 27, 2012.)*

Clarifying The NCCI Edit

"There was some ambiguity about the NCCI edit," explained Peter Kazon, a lawyer with **Alston + Bird** who represents ACLA. "CMS has clarified the edit to ensure that the code for saturation biopsies should be applied only to saturation biopsies and not to regular prostate biopsies. Subsequently, Palmetto removed the policy."

In January, Palmetto reported on its website that claims "submitted with CPT 88305 for prostate biopsy frequency were denying incorrectly. The claims affected were processed on November 14, 2012, for dates of service on or after January 1, 2012. Mass adjustments will be performed on the claims which denied incorrectly once the system fix is complete. There is no need to submit an appeal for these claims." The claim adjustments were completed on January 10, Palmetto added. Palmetto offered no other explanation. TDR

Contact Peter Kazon at 202-239-3334 or info@clinical-labs.org.

Two MTs Launch New Lab In Aberdeen, North Carolina

Start-up laboratory company growing steadily, expects to reach breakeven at end of first year

CEO SUMMARY: Although located in the same region as two of the nation's largest laboratory companies, newly-created Triune Laboratory, Inc., is reporting steady growth and acceptance by physicians in the community. Founded by two medical technologists and partially funded by a pathologist, this new lab company demonstrates that many physicians are ready to support an entrepreneurial lab company that provides personalized service as a local provider within their community.

CONVENTIONAL WISDOM in the clinical lab industry is that one must enter the business by acquiring an established lab company rather than start a new lab company from scratch.

Start-up labs are considered high risk because of the substantial up-front cost of equipping the lab, tough competition in the marketplace, and declining reimbursements. However, over the past decade, THE DARK REPORT has chronicled the successes of entrepreneurs who did start their lab companies from scratch and succeeded.

In Aberdeen, North Carolina, a new laboratory company is about to reach its first anniversary and its owners are optimistic about their lab's future. **Triune Laboratory, Inc.**, launched in March, 2012. Sylvia Small, MT (ASCP) and Rhonda Outlaw, MT (ASCP) own and operate the lab.

It is a familiar story. Motivation to launch their own lab company came after **Laboratory Corporation of America** acquired their employer's lab company in Aberdeen in 2011. "Having worked together for 20 years, we decided to venture out on our own," stated Small.

"It took us just a few months to raise most of the capital we needed," she said. "Our lab facility is 2,200 square feet and is located in an industrial park in Aberdeen.

"Our primary investor is a pathologist from South Carolina, whom we've both known for some time," explained Small.

Start-Up Money

Starting up a medical laboratory costs an estimated $300,000 to $400,000. Laboratory vendors often help start-up labs by offering discounts on equipment, knowing they will make up the loss over time with reagent sales. But this didn't happen in the case of Triune Laboratory. "While acquiring equipment, we were not offered special discounts or help," Small noted. "However, we did shop carefully for lab equipment that would meet our needs and was affordable."

In preparing to organize and operate their laboratory, Small and Outlaw took the time to consult with the experts at the small business and entrepreneur development programs at **Fayetteville State University**, the **University of North Carolina** at Pembroke, and **Richmond Community College**. "We both worked at a small inde-

pendent lab for almost two years. However, these experts helped us understand that there was much we didn't know," recalled Small. "We learned from these experts and they helped us focus on the right issues in developing our business plan."

Since opening their lab, Small and Outlaw have not looked back nor had any regrets. "We are on track to break even during the first quarter of 2013," noted Small. "Our partnership works well. I handle daily operations and the business side. Outlaw runs the sales development part of our business and runs the patient samples."

Their comfort with the decision to become business owners stems from confidence in their own technical skills, understanding of their customers' needs, and the relationships they've built over the years with lab users throughout the region.

Securing credentials "was perhaps the easiest part of our journey," said Small. "Triune has both CLIA and COLA accreditations. Between the two of us, we have more than 50 years of laboratory experience, with a large portion of it in management."

Outlaw has a bachelor's in biology and a master's in public health administration. She previously served as manager of a small reference laboratory and director of two physician office laboratories. Small has a bachelor's in business administration and previously owned a business. Additionally, both women have worked in management positions in hospital labs.

Needs Of Customers

"We understand that our clients have a choice when choosing a laboratory," Small continued. "Our focus will always be on creating long-lasting relationships with our customers. Understanding the needs of our clients is the very core of our business."

Their lab currently services clients in both North and South Carolina. Triune has lots of competition from independent labs, including LabCorp, **Solstas Lab Partners** and **Quest Diagnostics Incorporated**. Triune's owners estimate that these three labs combined have about 40% of market share. The remainder goes to hospitals.

She believes Triune has an advantage in being able to offer clients personalized service. "Our message is that, at the large corporate labs, their customers are just numbers," observed Small. "But when physician offices call Triune, they are speaking to one of the owners."

Two Full-Time Sales Reps

Triune currently employs 14 full and part-time laboratory professionals and support staff. "We have two full-time sales reps and our marketing has been low key," explained Small. "So far, word-of-mouth, face-to-face, local newspaper stories, and participation in community health fairs have generated most of our lab's business."

Nursing homes constitute about 20% of Triune's business. The lab accepts all insurance plans and offers competitive self-pay rates for uninsured patients. However, Small and Outlaw chose to only contract with four of the region's health insurance providers: **Blue Cross Blue Shield**, **Wellpath/Coventry One**, Medicare, and Medicaid.

Triune offers a full range of blood and diagnostic tests, including hematology, blood chemistry, immunology, immunochemistry, serology, coagulation, and microbiology, which are done in-house. The lab also secures specialty-testing services from an anatomic reference laboratory partner. Triune offers clients specimen pick-up service twice daily and provides same-day turnaround for 90% of test results.

Offering advice for others considering taking the leap from lab employee to owner, Outlaw pointed out, "Be sure to estimate correctly how much money you will need to get to the point of breaking even. Also, when you hire sales people, make sure they have experience in sales and a working knowledge of the lab." TDR

—By Patricia Kirk

Contact Sylvia Small at 910-944-0595 or sylvias@triunelaboratory.com.

Dark Index

LipoScience Completes IPO, Raises $44.9 Million from Sale

Success with this stock placement may encourage other lab firms to pursue a public stock offering

IT HAS BEEN A WHILE since a laboratory company has successfully completed an initial public offering (IPO). Thus, it is notable that **LipoScience Inc.**, of Raleigh, North Carolina, recently accomplished that feat.

On January 24, 2013, Liposcience closed its IPO and raised $44.9 million. It now trades on NASDAQ under the stock symbol LPDX. The company sold 5,750,000 shares at $9 per share. It had hoped to place these shares at between $13 and $15. Since the IPO, LipoScience shares have traded above $11.

Founded in 1994 as **LipoMed**, LipoScience is best known to pathologists and laboratory administrators for its first diagnostic test, the NMR LipoProfile. This assay measures the number of low density lipoprotein (LDL) particles in blood and is used by physicians to manage a patient's risk for heart disease.

NMR Test In Development

In its prospectus, the *in vitro* diagnostics company said it is developing a new field of personalized diagnostics based on nuclear magnetic resonance (NMR) technology. The technology will make it possible to analyze lipoproteins and small molecule metabolites from blood serum, plasma, and other bodily fluids without sample preparation, LipoScience said.

The lab testing company plans to use the proceeds from the stock sale to expand its sales force nationally. It will also step up marketing awareness campaigns, and improve relations with health insurers and managed care plans.

Another development at LipoScience is that the FDA recently cleared the company's automated clinical analyzer, the Vantera system, the prospectus said. The analyzer became available commercially in December 2012, allowing the company to sell this instrument system directly to clinical laboratories.

Growth In Lab Test Volume

LipoScience has grown at a rapid pace. Between 2006 and 2011, the number of NMR LipoProfile tests ordered increased at a compound annual growth rate of about 30%, the prospectus said. Test volume in 2011 was more than 1.5 million.

However, this growth in test volume has only recently allowed the company to show a net profit. Revenue at LipoScience was $41.2 million for the first nine months of 2012 and the net income was $1 million. In the prospectus, the company reported that it had an accumulated deficit of $48.2 million as of September 30, 2012.

This cumulative loss shows the value of investor capital to start-up lab companies such as LipoScience that want to introduce a proprietary diagnostic test into clinical use. There are few examples of emerging lab companies that have built market share using internally-generated cash flow.

As long as the stock market remains favorable, other lab companies may be encouraged to follow LipoScience's example and attempt their own IPOs. TDR

➤➤ ***CEO SUMMARY: Probably the most challenging infections for hospitals to control and reduce are methicillin-resistant* Staphylococcus aureus *(MRSA) and* Clostridium difficile *(C. diff). The laboratory at one New York hospital introduced algorithms to screen for the presence of each infection. In the past five years, the hospital not only cut costs by almost $3 million and improved quality, but also did fewer tests for these two infectious diseases. The contribution of the laboratory at John T. Mather Memorial Hospital demonstrates how labs can leverage lab testing to deliver increased value.***

Long Island hospital cuts costs while reducing hospital acquired infections

Leveraging Testing Technology To Identify MRSA, C. Difficile

EVER SINCE BEING NAMED one of Medicare's original "Never Events" in 2008, hospital acquired infections (HAIs) have become a high-profile target for early detection and prevention in hospitals throughout the United States.

No one disputes the size of the problem. The **Centers for Disease Control and Prevention** estimates that, each year, there are 1.7 million hospital acquired infections causing about 100,000 deaths annually. On average, a single case of HAI incurs costs of up to $38,000. Moreover, each year, one in seven Medicare beneficiaries experiences a "never event" such as an HAI.

These are huge numbers. In 2008, innovative hospital labs recognized the potential to help their parent hospitals and health systems reduce and prevent HAIs. That's because of the essential role that laboratory testing plays in helping clinicians identify patients with HAIs and then guide the selection of appropriate therapies.

One first-mover in this regard was the 248-bed **John T. Mather Memorial Hospital** in Port Jefferson, New York. During 2007, its laboratory leaders had put a plan on the table to use state-of-the-art rapid molecular technologies specifically to improve detection and treatment of methicillin-resistant *Staphylococcus aureus* (MRSA). In 2010, a similar plan was implemented for *Clostridium difficile* (C. *diff*).

"Every hospital laboratory has the opportunity to improve those statistics," stated Denise Uettwiller-Geiger, Ph.D., DLM(ASCP), Director of Laboratory Services and Clinical Trials at Mather. "At the same time, new diagnostic technologies are giving us faster and more accurate ways to identify these infectious diseases. It is why the lab is well-positioned to collaborate with other departments to cut these infection rates."

The lab at the Mather Hospital runs 2.3 million tests annually. It has 72 FTEs including clerical staff, accessioners, and phlebotomists. Among those 72 FTEs are about 30 clinical laboratory scientists who work in three shifts, 24 hours a day, seven days a week.

The program that Geiger's lab team implemented addressed two HAIs that are among the most vexing for hospitals. One interesting benefit of this program was that it led to reduced testing, even as costs declined by almost $3 million and patient outcomes improved for these two infectious diseases. For this reason, the success of the Mather lab provides a road map for boosting the contribution of lab testing to achieving more effective HAI control that other labs will find useful.

Pathologists and lab administrators understand why MRSA and C. *diff* were made a priority. Treatment of MRSA is becoming ever tougher, making early detection essential. In the case of C. *diff*, incidence of this disease is at historic highs in the United States, according to the CDC. The diarrhea it causes is linked to 14,000 deaths annually nationwide.

"Of course every hospital has protocols to address both of these infections, which is why, over the last few years, we wanted to improve our test results for MRSA and C. *diff* by providing actionable information more rapidly to our clinicians," recalled Geiger. "For MRSA, we started by seeing what technology was available for screening patients. There are many different approaches, including universal screening and targeted screening for high-risk patients. Some hospitals screen everyone with nasal swabs, but this method can be costly.

"Instead, we thought it might be more cost effective to do targeted rapid MRSA screening for high-risk patients," she explained. "These would be patients in intensive care and critical care units, nursing home patients coming to the hospital, and surgical patients needing hip or knee replacements.

"Not only is it important to screen patients to improve patient care, but also

(Continued on page 14.)

Mather's Outcomes for C. *difficile* and MRSA Control

New Laboratory Algorithm Generates Substantial Benefits for C. *difficile* Testing

Costs

Total Testing Volume

- **2009:** 275/mo = 3,107/yr
- **2010:** 148/mo = 1,774/yr
- **2011:** 160/mo = 1,919/yr
- **2012:** 122/mo = 1,522/yr

- Simultaneous EIA- $12 per test
- PCR Assay ~ $40 per test

- **Cost 2010:** $ 26,968
- **Cost 2011:** $ 33,108
- **Cost 2012:** $ 26,384

Total Testing Cost: $86,460

NO ADDITIONAL FTES

C. diff testing performed 24/7

Savings

248 bed hospital

82,373 patient days/91% occupancy

Rate of Infection/1000 Patient Days

- 0.95/1,000 = 70.0 infections **(2009)**
- 0.57/1,000 = 46.0 infections **(2010)**
- 0.65/1,000 = 50.0 infections **(2011)**
- 0.34/1,000 = 26.0 infections **(2012)**

(2009 vs 2012)

Difference = 44.0 infections @ $35,000
Decrease in 2010 hospital costs = $840,000
Increase in 2011 hospital costs = $140,000
Decrease in 2012 hospital costs = $840,000

$1,540,000 cost avoidance
Net Savings Due to Prevention
$1,453,540

At John T. Mather Memorial Hospital in Port Jefferson, New York, the lab's program to support testing for *Clostridium difficile* (C. *diff*) has made a signficant contribution to reducing the costs associated with testing, as well as a decrease in the number of hospital infections for this disease.

- **Improved services for C. *diff* detection and treatment by providing simultaneous testing for GDH and Toxins**
- **Implementation of reflex to PCR for Ag+/Toxin-**
- **Increased Awareness of HAIs**

Achieved Best Practices in:

Decreased Infection Rate	Cost Reduction	Testing Volume
-63%	-63%	-51%

Collective savings since 2010 for C. *diff* control total $1.5 million!

Reduced cases of MRSA at Mather Mean Better Outcomes, Reduced Costs

Costs

- **Screened high risk patients**
- **2008:** 88/mo = 1,050/yr
- **2009:** 139/mo = 1,663/yr
- **2010:** 176/mo = 2,107/yr
- **2011:** 182/mo = 2,181/yr
- **2012:** 164/mo = 1,967/yr

- **PCR Assay ~ $50 per test**

- **Total Screening Cost $448,400**

- **NO ADDITIONAL FTES**

- **MRSA testing performed 24/7**

Savings

248 bed hospital

82,373 patient days/91% occupancy

Rate of Infection/1000 Patient Days

- 0.90/1,000 = 74.0 infections (2007)
- 0.59/1,000 = 48.0 infections (2008)
- 0.29/1,000 = 23.0 infections (2009)
- 0.25/1,000 = 19.0 infections (2010)
- 0.17/1,000 = 13.0 infections (2011)
- 0.23/1,000 = 18.0 infections (2012)

(2007 vs 2012)

Difference = 56.0 fewer infections @ $35,000
Decrease in 2008 hospital costs = $910,000
Decrease in 2009 hospital costs = $875,000
Decrease in 2010 hospital costs = $140,000
Decrease in 2011 hospital costs = $210,000
Increase in 2012 hospital costs = $175,000

$1,960,000 cost avoidance
Net Savings Due to Prevention
$1,511,600

Launched in 2008, the MRSA testing program at Mather Memorial Hospital has helped cut the number of patients infected with MRSA. The savings since 2008 for the MRSA initiative total $1.5 million.

- **Implementation of an Active MRSA High Risk Screening Program**
- **Improved services by bringing molecular testing in-house**
- **Increased Awareness of HAIs**

Achieved Best Practices in:

Decreased Infection Rate	Cost Reduction
-76%	-76%

Collective savings since 2008 for MRSA control total $1.5 million!

one MRSA infection can cost upwards of $35,000," Geiger noted. "And we know that, starting in 2006, the New York State Department of Health commenced collecting data on HAIs. Also, two years later, the Medicare program stopped paying hospitals to treat patients with HAIs. All of these reasons made it imperative that we had an effective screening program here at Mather.

"We track our MRSA and C. *diff* infection rates using typical benchmarks," added Geiger. "We gather the number of infected patients per 1,000 patient care days and we report this rate as a percentage of hospital occupancy.

"If we compare the infection rate from our base year of 2007 to 2012, we had a dramatic reduction in MRSA infections of 76% and we also had an associated cost-avoidance that dropped our costs by 76% as well," observed Geiger.

"Before our MRSA program began, we had 74 MRSA infections in 2007," she said. "That gave us an infection rate of 0.90 per 1,000 patient care days, based on 91% occupancy.

"In March 2008, we worked with infection prevention specialists, infectious disease clinicians, nursing, and the information technology department to track and reduce infections," noted Geiger. "In that first year of 2008, the number of MRSA infections went down to 48, which reduced our rate to 0.59 per 1,000 patient care days, representing a 35% decrease in MRSA infections.

"From there, it continued to decline significantly," she stated. "If we compare the infection rate from our base year of 2007 to 2012, we had a dramatic reduction in MRSA infections of 76% and we also had an associated cost avoidance that dropped our costs by 76% as well," observed Geiger. "You can see that the savings potential is significant if the hospital can avoid just one case of MRSA.

"In the case of C. *diff*, our program was a bit different," she continued. That is because the primary testing was not molecular and we didn't need an algorithm to identify which patients would be screened.

"But, for C. *diff*, we did need to identify a rapid-screening method," observed Geiger. "We decided to use an enzyme immunoassay (EIA) because it is convenient and easy to use.

"The EIA incorporates a rapid flow membrane technology that allows us to do the analysis of both the glutamate dehydrogenase (GDH) and toxin A and B simultaneously," she said. "This testing can be done on demand in 60 minutes or less.

"Before we started using the EIA to identify C. *diff* in May 2010, we had an algorithm that involved performing three sequential tests on samples that came from all patients experiencing symptoms of C. *diff* infection. The previous test identified toxin A and B but not the GDH. Because of the improved sensitivity and specificity of our new test methodology, we immediately recognized that we did not need to do three serial samples.

C. *diff* Testing Approach

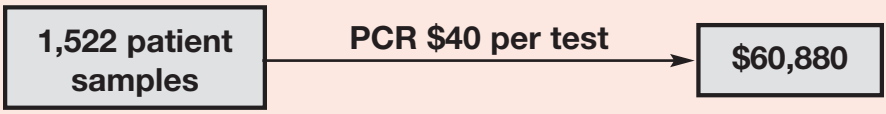
"Another approach to C. *diff* testing is with polymerase chain reaction (PCR)," added Geiger. "But this method is costly when applied to each sample. Our decision was to reserve PCR testing for a specific subset of patient samples.

"In our base year of 2009, we had 70 C. *diff* infections. Last year we had 26 infections, which is 0.34 per 1,000 patient care days (compared with 0.95 per 1,000 patient care days in 2009). These numbers show that, when you compare the base year of 2009 to 2012, we had a decrease in C. *diff* infections of 63%," she explained.

Understanding Mather Lab's Simultaneous Two Test Algorithm for C. *diff* Diagnosis

Original C. *difficile* Algorithm

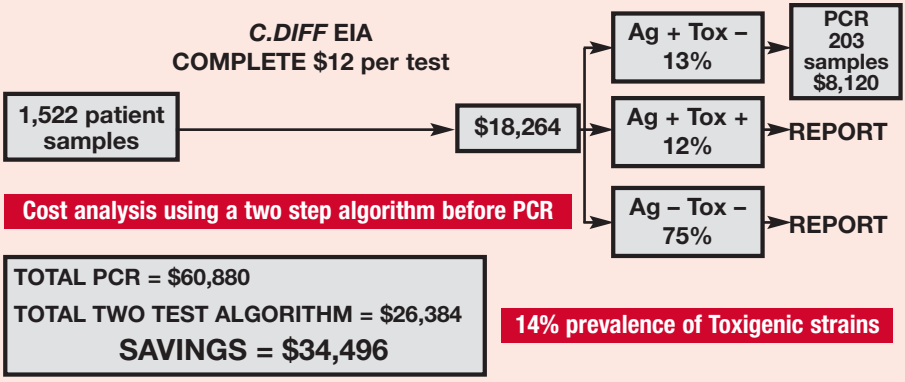
100% of patients tested with PCR



Some experts recommend using molecular testing for all *Clostridium difficile* (C. *diff*) infections. If the laboratory at Mather Memorial Hospital performed PCR testing on 100% of the specimens, the cost would be more than $60,000 per year.

The *Clostricium difficile* Algorithm Incorporating Two Simultaneous Tests

Simultaneous Two Test Algorithm



For the same volume of specimens, use of the simultaneous two test algorithm eliminated the need to run PCR tests on 87% of the specimens. This initiative contributed to a savings of about $1.4 million. The savings from the two initiatives totaled almost $3 million.

"In 2012, we screened 1,522 samples, and 75% were reportable immediately as antigen and toxin negative. We also had 12% that were reported immediately as antigen and toxin positive," Geiger said. "The remaining 13% of specimens represented a subset of patients who were antigen positive, meaning they were GDH positive but toxin A and B negative.

For this 13% (which was 203 samples) we used PCR testing," Geiger commented. "So now we can calculate how much was saved using this stepwise approach in our lab testing algorithm.

"If we did 100% of the samples with PCR, which is what the molecular testing experts recommend, that would have cost $40 per test on 1,522 samples for a total of

$61,000," she calculated. "But because we use EIA to stratify those 87% of the specimens that did not require PCR testing, we saved almost $35,000. By using EIA testing for most of the samples, the costs totaled just $18,000.

"However, this story gets even better!" she added. "In 2009 we ran three sequential tests on each sample. In that year, we did 3,300 C. *diff* tests," noted Geiger. "Then, in 2010, we implemented our algorithm and eliminated serial sampling. That cut the number of samples tested down to 1,774. For 2012, we did only 1,522 of these tests, representing a drop of 51% from the base year.

"These data show that we are doing less testing, even as we cut our hospital's infection rates and reduced its costs as well," she stated. "Our lab performs less testing even as our hospital achieves a reduction of more than 63% in the infection rate.

Hospital-Wide Initiative

"All of this was done as part of a hospital-wide initiative started in 2008," added Geiger. "It is called the 'Voyage to Excellence' and it is our mission to be the best community hospital in New York State. This rating is measured in different ways by such metrics that include our infection rates and patient experience scores. Notably Mather is ranked second on Long Island, according to one report.

"Overall, our lab's engagement with the program to reduce hospital acquired infections is a compelling story because it shows what is possible when our laboratory collaborates with other departments," emphasized Geiger. "It also shows that the lab can play a bigger role in managing care when it becomes more effective at using the data and the new diagnostic technologies we have in our clinical laboratory." TDR

—Joseph Burns

Contact Denise Geiger at 631-473-1320, ext. 4137, or dgeiger@matherhospital.org.

Mather Lab Shares Lessons Learned

OVER A MULTI-YEAR PERIOD, the laboratory at John T. Mather Memorial Hospital has made significant contributions to reducing hospital acquired infections (HAIs), including MRSA and C. *difficile*. There are several useful lessons learned during this time.

"First, we showed that the lab can and should play a vital role in the reduction of hospital acquired infections," observed Denise Uettwiller-Geiger, Ph.D., DLM (ASCP), Mather's Director of Laboratory Services and Clinical Trials. "Second, our lab delivered substantial value in a performance-driven health care system by helping to control total costs. Even though the lab represents only 2% to 3% of total healthcare costs, we have a significant role in controlling spending as we showed with this infection control effort.

"A third lesson is that—to be successful in an effort like this—the lab needs the support of clinical leadership within the hospital," she continued. "For the MRSA initiative, in particular, that leadership was important. To develop the MRSA screening program, our lab team worked closely with the chief medical officer and we made a presentation to the board of directors. In that way, the program had a lot of visibility.

"Similarly, we needed that support from leadership to acquire new equipment, which included a molecular testing platform," said Geiger. "This was essential if we were to deploy new diagnostic technology.

"Fourth, in addition to getting leadership support, our lab needed to work collaboratively with staff from a number of departments," she concluded. "After all, infection control programs require interdisciplinary team effort. Our lab team worked closely with senior hospital leadership, infectious disease professionals, pharmacists, nursing management and staff, physicians, environmental services, information technology, and finance."

EHR Donation Ruling in WA Raises Questions for Labs

State AG issues ruling that donations of money to physicians for EHRs is illegal under state law

CEO SUMMARY: When the Washington State Attorney General issued an Attorney General Opinion last fall, he created confusion among pathologists and lab directors whose labs have paid to have EHR software installed in physicians' offices. The Washington AG's ruling not only conflicts with federal law, which allows labs to donate EHR software, but raises questions within Washington State about other lab industry marketing and business practices that federal regulations permit.

PATHOLOGISTS AND CLINICAL LAB DIRECTORS in Washington State are wondering what effect—if any—the November 2012 ruling by former state Attorney General Rob McKenna has on any donations of electronic health record (EHR) software made to physicians in full compliance with federal law.

The broad language of this Attorney General Opinion also gives rise to additional uncertainty in Washington State about other common laboratory business practices long deemed appropriate by the federal government.

This opinion is consistent, however, with a trend of state-level regulations getting tougher on the types of activities common in the marketing practices of clinical laboratories and other providers.

In the opinion, McKenna writes: "A clinical laboratory's donating money to a physician to be used for a portion of the cost of an electronic health record, when the donations are made only to those physicians who maintain or create arrangements for the physician's referral of specimens to the laboratory, would violate the anti-rebate provisions in RCW 19.68.010."

RCW 19.68.010 generally prohibits the payment or receipt of rebates when medical professionals refer patients to others to obtain services or supplies, he added.

Opinion, Federal Law Differ

"The Washington State Attorney General's opinion is confusing and likely to be troubling to pathologists and lab directors whose labs already have paid for 85% of EHR software installed in the offices in their physician customers, in full compliance with the federal regulations," said David W. Gee, a lawyer with **Garvey Schubert Barer** in Seattle. "As envisioned by the federal laws, such EHR software likely serves as the labs' principal mode of receiving lab test orders and reporting lab test results into the EHR systems of those customers.

"Another practical dilemma is that, as federal law permits, the labs likely have undertaken contractual obligations with the software vendor to support and maintain the software. Those vendor agreements now

need to be terminated or assumed by the physician groups," Gee added.

Federal Law Undermined

"It's hard to understand why the attorney general would take the view that donating EHR software is illegal because that position directly undermines the federal government's statutory efforts to promote physicians' electronic health information connectivity," he said. "Likewise, the AG's opinion talks about a 'cash donation,' but the EHR software donation permitted by the federal laws does not contemplate monetary donation to a physician," noted Gee. "In fact, EHR software donation is expressly excluded from the Stark law definition of 'remuneration.'

"The AG Opinion also seems to overlook some of the key safeguards of the federal law. For instance, the AG's principal objection to donation of EHR software is that lab donations are limited to those physicians who refer patients to the lab. However, under the federal statutes, laboratories may not condition their donation of EHR software on where the physicians refer their lab tests," Gee explained.

"Instead, the federal law requires that the software be interoperable. That means physicians must be able to use donated EHR software to send lab tests to any lab," he said.

Challenges for Labs

"Another challenge for labs, hospitals that run labs, and other healthcare providers generally is that the AG's reasoning in the opinion is so broad that it arguably extends the prohibitions of the Washington anti-rebate statute to a variety of other common practices between healthcare providers that have long been permitted under federal law. For example, labs are permitted under federal guidelines to provide supplies and equipment to their physician customers, as long as those items are used by the physician solely for ordering and receiving lab testing results," Gee explained.

"Supplies and equipment viewed as permissible under federal law include fax machines or other communication interfaces dedicated to ordering and reporting lab tests. It is not clear if the AG's interpretation of the Washington state anti-rebate law would include or exclude donation of such items, even if used solely for transmission of lab orders and reports," he said.

Clinical lab companies doing business in Washington State should be aware of this Attorney General Opinion. It creates different compliance issues and labs will want to establish compliance policies that are consistent with this opinion. Further, this opinion is a reminder that a growing number of states are getting tougher on business practices used by many labs. TDR

—By Joseph Burns

Contact David Gee at 206-464-3939 ext. 1351, or dgee@gsblaw.com.

State Representative Asked About EHR Donations

TO ANSWER A QUESTION from a state representative, Washington State Attorney General Rob McKenna stated the following:

"A clinical laboratory's donating money to a physician to be used for a portion of the cost of an electronic health record, when the donations are made only to those physicians who maintain or create arrangements for the physician's referral of specimens to the laboratory, would violate the anti-rebate provisions in RCW 19.68.010.

"RCW 19.68.010 generally prohibits the payment or receipt of rebates when certain licensed medical professionals refer patients to others to obtain services or supplies. The state legislature enacted the law in 1949 during a period when the Federal Trade Commission and the Justice Department were cracking down on rebate or kickback schemes."

The ruling is available online at: *http://www.atg.wa.gov/AGOOpinions/Opinion.aspx?section=archive&id=30767#.UPGx6uR9Le6.*

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Even if not billion-dollar transactions, there are some interesting deals unfolding in the *in vitro* diagnostics (IVD) marketplace. Last month, **HYCOR Biomedical, Inc.**, of Garden Grove, California, sold its Kova urinalysis system and business "to an affiliate of **One Rock Capital Partners**, **Laurel Crown Partners**, and **StoneCreek Capital**," according to a Hycor press release. As a side note, Hycor's Chairman is Rick Novak. He has held executive positions at **Laboratory Corporation of America** and **SmithKline Beecham Clinical Laboratories**.

ADD TO: *IVD Mergers*

It was in January when **StatLab Medical Products**, of McKinney, Texas, acquired **Mossberg Labs** of Kalamazoo, Michigan. StatLabs is a manufacturer and distributor of histology and cytology consumable supplies. Mossberg develops and manufactures histology, cytology and hematology stains and related reagents.

LAB ACQUISITIONS IN INDIA CONTINUE

It is estimated that thousands of small medical laboratory companies operate in India today. This makes it a prime market for the nation's larger lab companies to grow by acquisition. Recently, **Dr. Lal PathLabs** announced that it had purchased five independent medical lab companies in the western and southern regions of India. Two investors in Dr. Lal Pathlabs are **Sequoia Capital** of Menlo Park, California, and **TA Associates** of Boston, Massachusetts.

MORE ON: *India Labs*

Recently other U.S. firms invested in an Indian lab company. The **International Finance Corporation**, a World Bank investment arm, and **NYLIM Jacob Ballas India Fund** provided R370 million (US$ 6.7 million) to **Super Religiare Laboratories**, of New Delhi, India.

TRANSITIONS

• Judd Jessup will retire this month as CEO of **CombiMatrix Corporation**, based in Irvine, California. He was formerly CEO of **USLabs** at the time it was sold to **Laboratory Corporation of America** in 2005.

• Mark McDonough will become the new CEO of **CombiMatrix Corporation**. He is currently the firm's Chief Commerical Officer. His prior experience includes positions with **Pathwork Diagnostics**, LabCorp, and US Labs.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...the prediction of **Aetna, Inc.'s** CEO, Mark Bertolini, that health insurance premium rates could climb by 25% to 50% in 2013. He described it as "premium rate shock," and attributed the cause to a variety of a factors.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 25, 2013.

Registration NOW OPEN!

EXECUTIVE WAR COLLEGE

April 30-May 1, 2013 • Sheraton Hotel • New Orleans

Preview–Trisha Brown on...

Payer's Goals for Pricing, Pre-Authorization, & Medical Necessity for Molecular/Genetic Tests

Here's a rare opportunity to get an insider's perspective on how and why health insurers are taking aggressive steps to implement pre-authorization requirements for a growing number of molecular assays and genetic tests. In her time at DNA Direct, Trisha Brown was part of the team that signed the first national contract with a major health insurance corporation to establish and manage a process of pre-authorization and medical necessity that doctors were required to use when ordering expensive molecular tests and genetic assays. **Learn how labs can deliver value in these arrangements.**

For program details and to register, visit www.executivewarcollege.com

UPCOMING...

- ***Digital Pathology's Market Adoption Curve: Steady Progress Because of New Work Flow Solutions.***
- ***Innovative Ways to Serve Cash-Paying Patients to Build Specimen Volume and Increase Revenue.***
- ***Unique Insights into Mass Spectrometry's Growing Role in Clinical Diagnostics.***

For more information, visit:

www.darkreport.com

Sign Up for our FREE News Service!

Delivered directly to your desktop, ***DARK Daily*** is news, analysis, and more.

Visit www.darkdaily.com

DARK Daily
Clinical Laboratory and Pathology News/Trends