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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Lean, Six Sigma and Laboratory Errors

IT IS TOUGH TO IGNORE THE STEADY DRUMBEAT about patient safety. In every sector of healthcare, accrediting bodies, state legislatures, private insurers, and federal health administrators are instituting programs designed to focus providers on eliminating the sources of medical errors and reducing the variability in care provided to patients.

As you will read on pages 17-18, just last week two medical errors commited by national lab companies triggered newspaper headlines and coverage on television news programs. In both cases, simple errors in specimen handling at the laboratory caused a woman to get an inaccurate diagnosis of cancer. Only after undergoing life-changing surgery and other procedures, did these women's physicians learn about the lab errors. It was the post-surgery pathology review which uncovered the original laboratories' errors.

These types of errors are unusual and uncommon—but they do occur with some regularity, given the large volume of specimens handled annually by the nation's laboratories. All lab directors and pathologists know stories about how a lab error caused a patient to receive inappropriate care. Although most of these stories escape the notice of journalists and television news reporters, they do represent an area of lab medicine that does not get the attention it deserves.

However, as more laboratories actively incorporate quality management systems, like Six Sigma and Lean, into their operations and clinical services, they are discovering effective tools that will further drive down the already-low rate of medical errors that occur in laboratories. That was one clear theme at last month's Lab Quality Confab, where the profession's first mover and early adopter labs shared their case studies and successes with improvement programs and projects. *(See pages 3-5.)*

I can foresee the day when laboratories will cease to report the performance of laboratory functions using decimals and percentages and will use either a Six Sigma scale or a defects-per-million figure. Those two measurement terms were a common *lingua franca* at Lab Quality Confab. By effective use of quality management techniques and methods, laboratories at this conference are achieving a notable reduction in error rates within their lab operations. That is a positive omen for the future of laboratory medicine. It represents early evidence that the laboratory profession can achieve paradigm-shifting gains in quality and reduction of medical errors. TDR

More Labs Actively Adopt Quality Management

Lab Quality Confab draws global audience to share improvement breakthroughs, successes

***CEO SUMMARY:** With almost 300 speakers, attendees, and vendors in attendance from seven countries, Lab Quality Confab was a significant milestone for the global lab industry. On one level, it was a sign that the quality improvement trend has come of age. On another level, it provided ample and powerful evidence that labs using Lean and Six Sigma are actively raising the benchmarks for measuring the quality of laboratory testing services.*

By Robert L. Michel

IF ANYONE STILL DOUBTS THAT THE ERA OF QUALITY MANAGEMENT has reached the laboratory profession, 300 speakers, attendees, and vendors at the *Lab Quality Confab* in Atlanta last month would vociferously argue otherwise.

The list of participants at this first annual event was a Who's Who of the nation's most prominent laboratories, including hospital/health system labs, independent laboratories, pathology group practices, and industry vendors. That so many respected laboratory organizations have active and thriving quality management programs is powerful evidence that quality management systems—such as Lean, Six Sigma, and ISO 15189—have achieved mainstream status in this country.

A common theme linked the 50 presentations and sessions, conducted over the four days of September 18-21. This theme is the universal success laboratories experience as they use quality management methods to implement improvements in all aspects of services and operations.

That's a remarkable statement about the use of quality management methods by clinical laboratories, pathology group practices, and hospitals. When these techniques are applied with a basic level of expertise and effort, the consistent outcome is improvement in the targeted objective. Not every project generates spectacular increases in quality and productivity. However, quality management methods invariably deliver enough gains to motivate the laboratory or hospital to continue their use.

This theme of common success is an important milestone for the laboratory industry. It demonstrates that the paradigm in laboratory management is shift-

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

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $13.10 per week in the US, $13.70 per week in Canada, $14.85 per week elsewhere (billed semi-annually).

ing. That has implications for all laboratories and pathology groups.

New Management Paradigm

It means that a gulf is forming between labs and pathology groups now using Lean–Six Sigma and those that continue to operate using the old management paradigm. Over time, that gulf will continue to widen and create both clinical and competitive advantage to those labs which adopt and use quality management methods. Labs holding onto the traditional management paradigm will find themselves falling behind in a variety of key performance and financial measures.

Along with the universal success experienced by labs now using quality management methods, another common theme emerged at *Lab Quality Confab*. Laboratories utilizing Lean, Six Sigma, and similar principles are forging stronger links throughout the clinical continuum. Since improvement efforts must be organized to meet and exceed the needs of laboratory testing users, these labs actively engage their users and customers as collaborators in improvement projects.

More Lab Involvement

Such interaction helps the laboratory become a more involved clinical contributor. *Lab Quality Confab* featured several examples of this development. At **Harris Methodist HEB Hospital** in Bedford, Texas, having completed multiple Lean projects in accessioning and the core lab, the laboratory is now working with the gastroenterology department and nursing on an improvement project. Similarly, at **Mobile Infirmary Medical Center** in Mobile, Alabama, a one-week long Kaizen event was conducted with the emergency department (ED), the laboratory, and other hospital service areas to shorten average lab test turnaround times for tests requested by the ED.

From a strategic perspective, **Lab Quality Confab** demonstrated several other important developments beyond the two common themes just described. There are at least five.

First, the fact that this event could be conducted and draw almost 300 participants is a sign that the quality improvement movement has established deep roots within the laboratory industry. This is further indicated by the fact that many of the nation's most influential laboratory organizations are actively using some type of ongoing improvement program, often based on Lean and Six Sigma methods.

Second, *Lab Quality Confab* attracted attendees from across the globe. People came from Argentina, Australia, Brazil, Canada, Sweden, and the United Kingdom. The willingness of these individuals to travel across oceans to learn and network with other quality management practioners indicates the depth of commitment that Lean and Six Sigma engenders.

Vendor-Attendee Interaction

Third, individuals actively using Lean, Six Sigma, and other improvement techniques are ardent learners. Sessions conducted by IVD manufacturers and lab management consultants were well-attended and the exhibition was a beehive of activity. One conclusion is that the shared interest in mastering the tools and techniques of improvement becomes a bonding element for lab vendors and their customers.

Fourth, collectively, the 50 presentations provide powerful evidence that the benchmark for acceptable laboratory performance will be radically increased. For example, At **PAML** (Pathology Associates Medical Laboratories) of Spokane, Washington, the performance of its 120-courier logistics department has been improved to 5.2 Sigma. That's about 80 defects per million events.

Similarly, after a negative incident with irradiated blood products, **Fairview Health System** of Minneapolis, Minnesota, initiated a Lean project that involved the laboratory and included all staff involved in

handling such blood products across eight hospitals. The resulting improvements, including standardized procedures, caused the number of incidents involving wrong blood products to drop to zero over the past 18 months.

My point here is that, as labs using Lean, Six Sigma, and other improvement methods achieve these kinds of remarkable improvements, it raises the bar for the entire laboratory industry. Thus, the ongoing adoption of quality management systems by labs and pathology groups will put pressure on lab competitors to do the same—or fall behind in the drive to increase quality, improve outcomes, and better satisfy patients.

Fifth, laboratory accreditation is about to be transformed by the performance of the techniques of Lean, Six Sigma, and other quality management methods. ISO 15189–Medical Laboratories is already gaining international stature as a platform on which countries are basing licensure and accreditation. There was keen interest in ISO 15189 at *Lab Quality Confab* for that reason.

First To Learn About Quality

Clients and long-time readers of THE DARK REPORT have been first to learn about quality management systems and the early applications of Lean and Six Sigma in laboratories and hospitals in this nation, going back to the early years of the decade. This is still a trend which is not fully recognized across the laboratory industry.

That is about to change rapidly. At *Lab Quality Confab*, most of the laboratory consulting companies and *in vitro* (IVD) diagnostics manufacturers participating at the conference reported that a growing number of their customers are taking active steps to introduce Lean and Six Sigma techniques.

THE DARK REPORT predicts that Lean, Six Sigma, and similar quality management systems will become ever more common with each passing year. The consistent gains in quality and productivity enjoyed by labs using these methods will likely accelerate adoption of Lean and Six Sigma. TDR

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How to Develop Your Lab's Quality Management Program

AT THIS YEAR'S *LAB QUALITY CONFAB*, the majority of attendees were experienced and active practitioners of quality management systems such as Lean and Six Sigma. Also in attendance were laboratory managers who have yet to launch a quality management program in their laboratory organization.

For labs and pathology groups preparing to develop a quality management program, there was consistent advice from speakers. To implement a successful and self-sustaining Lean or Six Sigma program, it is necessary to have the understanding and the support of senior administration.

As part of administration's buy-in, every quality program should have agreement in how improvement will be measured and a specific cost savings target or return on investment (ROI) that will be used to determine if the improvement project achieved its objective.

Lab managers and pathologists interested in Lean, Six Sigma, and similar improvement methods for their lab can find plenty of experts to advise and help them. A number of laboratory consulting companies now have certified practitioners in Lean and Six Sigma. Further, most of the nation's largest *in vitro* diagnostics (IVD) manufacturers now offer Lean, Six Sigma, and improvement consulting services.

A good starting point to learn about these resources is *www.labqualityconfab.com*, where the program speakers and their companies are listed. Also available is another resource. Audio recordings and presentation slides are also available for the 50 sessons, covering a wide range of Lean and Six Sigma projects in clinical labs and pathology groups.

Shiel Medical Lab Grows In Tough NYC Market

➤Flying under the radar screen, lab firm builds market share to achieve yearly sales of $50 million

➤➤CEO SUMMARY: There's a new lab player emerging in the New York metropolitan market. Shiel Medical Laboratory of Brooklyn, New York, is growing steadily and now reports $50 million in annual revenue. It is taking full advantage of the managed care contracting turmoil and adding new clients at a surprising rate. During the first 12 weeks of 2007, Shiel Medical Laboratory says nightly specimen volume increased by 50%.

PROVING THAT IT IS POSSIBLE to profitably grow even in a challenging market for laboratory testing services, **Shiel Medical Laboratory** has quietly experienced strong growth in New York City over the past 10 years.

Shiel is a thriving regional laboratory located within the city limits of New York. It is posting impressive rates of growth in specimen volumes and revenue. Shiel Medical Laboratory went from 600 specimens per night in 1998 to 5,000 per night today. "In that time, we also went from about $6 million in revenue to about $50 million in revenue today," said Tod Schild, Shiel's Senior Vice President.

Recent turmoil in the New York market is helping a number of regional laboratory companies in the area grab increased market share from the national laboratories. THE DARK REPORT has chronicled the successes of several, including **Sunrise Medical Laboratories** in Hauppauge, New York, and **Bio-Reference Laboratories, Inc.**, in Elmwood Park, New Jersey. *(See TDR, July 16, 2007.)*

Shiel Medical Laboratory can be added to this list. While working off the radar screen of the lab industry and many financial analysts, Shiel Medical Laboratory, based in Brooklyn, New York, boosted its nightly specimen volume from 3,000 to 4,500 just in the first quarter this year!

That 50% increase in nightly specimen volume in just three months is attributed to two factors. First is a direct mail campaign linked to unfolding events in the New York markets. Second is Shiel's announcement on January 1 that it would continue to be a contract provider for the **United Healthcare** and **Oxford Network**. It was on that date, of course, that **Quest Diagnostics Incorporated** lost the United Healthcare and Oxford Health Plans business. *(See TDR, February 19, 2007.)*

➤Contract Provider For Aetna

In July, Shiel announced that it would provide lab services to all of **Aetna, Inc.'s** HMO and PPO patients. Its sustained growth and provider status with key managed care plans are signs that this regional lab, in business since 1919, is becoming an important competitor for lab testing business in New York City and surrounding areas.

"Shiel's success is based on three key elements," Schild explained. " They are fast

turnaround times, good customer service, and strong information systems. These strengths help us differentiate ourselves in the market."

Strategic Hiring Philosophy

Another point of differentiation, according to Schild, is that Shiel Medical Laboratory has developed its staff in a strategic manner. The goal is to bring in skilled staff that have experience in the local communities. This helps Shiel build close working relationships with its referring physicians.

"We provide laboratory testing services to physician practices, nursing homes. and some institutional accounts," noted Schild. "We had a significant spurt in growth over the last year as a result of some key hires, and from the consequences of Quest Diagnostics being de-selected from the UnitedHealth network.

"Upon news of the UnitedHealth decision, we did a mass mailing to physicians in the New York metropolitan area, followed by a second mailing several weeks later," he continued. "The response was positive for us as many physicians clamored for other lab options for their UnitedHealth patients besides **Laboratory Corporation of America**." *(See sidebar at right.)*

Effective Sales/Marketing

"The key to any lab's success, besides providing good laboratory service, is a stable and effective marketing organization," Schild continued. "In the nine years that I have been with Shiel, we have retained all of our top-performing sales people. Retention of key employees is critical. With few exceptions, we tend to hire only mature, seasoned laboratory reps with strong relationships.

"Several of our sales reps have many years of service with us and have built strong books of business," added Schild. "Their ongoing success has made Schiel Medical Laboratory look attractive to

Direct Mail Campaign Generates New Clients

RECOGNIZING THAT THE MANAGED CARE CONTRACTING WARS in New York would create a major opportunity for regional labs, Shiel Medical Laboratory of Brooklyn, New York, turned to direct mail to help it jump start its sales and marketing offensive.

"We knew that Laboratory Corporation of America would be stretched thin as it built up its infrastructure and staff in the Northeast," explained Shiel's Senior Vice President Tod Schild. "We expected that there would be dissatisfied physicians and they would look for alternative laboratory providers.

"Late last year, we did a direct mail campaign to physicians across the New York metropolitan market. A follow-up mailing was sent to these same physicians several weeks later," stated Schild. "Responses from these physicians opened the door for our sales team to call on them. We had a flood of physicians interested in opening accounts with us. As a result, our volume went up significantly, almost to the point where we would not have been able to handle the increased volume.

"We sent the mailing to our entire service region," Shild continued. "This included the five boroughs of New York City, the New York counties of Nassau, Suffolk, Westchester, and Rockland, as well as to northern New Jersey. Each mailing was about 15,000 pieces and was sent to every physician in about 12 medical specialities, including cardiologists, pediatricians, gastroenterologists, endocrinologists, urologists, general practitioners, and internal medicine specialists.

"Timing for the direct mail campaign was perfect," recalled Schild. "We got a tidal wave of calls. In some cases, our sales reps actually opened new accounts over the phone! We added about 1,500 specimens per night in just 12 weeks, which was a dramatic increase for us!"

experienced sales reps from other laboratories. It makes it easier to recruit top talent as we expand our sales team."

Schild arrived at Shiel Medical Laboratory in 1998, at a time when CEO Jack Basch, as the new owner, was reorganizing the lab at all levels. "That year, I left one of the national laboratories to become Shiel's sales manager. At that time, I was actually the only one on the sales team," Schild related. "When I arrived, most of the $6 million in annual revenue was from nursing home business. As a district sales manager for my former laboratory, I covered Brooklyn, Queens, and Staten Island. Thus, I was familiar with the local market, as well as the sales people who were competing for business in these communities.

Developing Client Services

"At the time of my arrival, Shiel had no client service department," he continued. "In those days, lab techs answered the phones. And, we had no information technology department either. In fact, I served as the IT department along with some outside help.

"The strategic plan was to sell accounts and build the infrastructure needed for Shiel to evolve into a full service laboratory," Schild explained. "As specimen volume and revenue increased, we beefed up our sales, administrative, and technical staff.

"Earlier this year, we hired a new Medical Director, Patricia Romano, M.D., formerly of Quest Diagnostics and **Clinical Diagnostics Services** (CDS)," Schild added. "We now employ more than 300 people, have implemented client automation solutions, and have successfully inked managed care contracts that many of our regional competitors have not been able to secure. The recent growth in specimen volume and market share now makes Schiel one of the major lab players in the New York metropolitan market.

"Today, we are a full service clinical and pathology laboratory serving private physicians, group practices, union and industrial accounts, long-term care facilities, and home care agencies in the five boroughs of New York City," Schild said. "We also serve Nassau, Suffolk, Westchester, and Rockland counties in New York, and northern and central New Jersey. We will expand geographically as we continue to grow.

Differentiation Strategy

"Many factors contribute to a lab's growth, including quality customer service and strong customer relationships," observed Schild. "However, a regional laboratory needs to clearly differentiate itself from competitors to achieve ongoing success.

"Use of technology can be one way to differentiate your lab from competition," he added. "All labs today sell technology. But often they only offer their most advanced information technology to new clients. That ignores their existing client base—who may be on an older system or no system at all. Our sales team often targets these types of competitor accounts.

"To help us differentiate ourselves in the technology area, Shiel recently upgraded our physician interface. It is robust and packed with features," noted Schild. "It has the ability to interface to most EMR, billing, and practice management systems. We made it a priority to deploy this advanced technology to our existing client base. They like having the latest technology and it protects us from eager competition. Our system is homegrown and tailored specifically to the needs of our clients.

Connecting To EMRs

"To respond to the trend of physicians adopting electronic medical record (EMR) systems, we created an interface gateway that is simple, and it is driving sales right now," observed Shiel. "We believe enhanced information technology will increasingly drive sales in the labora-

Shiel Wants to Create Competitive Differentiation By the Use Of Proprietary Reference Assays

TO FURTHER DIFFERENTIATE ITSELF from competing laboratories, Shiel Medical Laboratory of Brooklyn, New York, wants to add selected reference and esoteric tests to its menu. Cardiology testing is a starting point for this strategy.

"At this time, we are unique in our ability to offer the Oxidized LDL/HDL Ratio Test (OxLDL/HDL)," explained Tod Schild, Shiel's Senior Vice President. "This test is pending FDA approval. A number of credible clinical studies offer evidence that this is an effective indicator of cardiac risk. A major pharmaceutical company is interested in oxidized LDL and is engaging us to perform clinical trial testing.

"We introduced this test early last year," he continued. "It was available for research use and recently Shiel Medical Laboratory got this OXLDL/HDL test validated by the New York State Department of Health. We are launching a marketing campaign to educate clinicians about its appropriate use.

"Our evidence demonstrates that the Oxidized LDL/HDL Ratio Test is a powerful biomarker for distinguishing patients with coronary artery disease (CAD) from non-CAD patients," explained Shild. "Currently, we believe we are the only lab in the world offering a combination of oxidized LDL with an HDL ratio.

"Other labs offer the oxidized LDL test, which is a commercially available kit, but we have two additional features that distinguish how our assay is used," Schild said. "We have automated the platform for processing these results—and we believe no other lab has yet to automate this assay. Further, we have been fortunate to work with Dr. Harold Bates, Ph.D., a researcher who is known for developing tests that later became standards of care. Over the course of many years, Bates introduced a number of tests to MetPath/Corning/Quest. Now he's working with Shiel and has developed a way to couple oxidized LDL with an HDL ratio.

"The resulting test produces a coronary risk assessment factor based on those two values," Schild said. "We have a study that shows the combination of oxidized LDL and the HDL ratio is better as a risk assessment factor than using the traditional lipid biomarkers. We're excited about the growth possibilities for this test and how it is likely to advance the standard of care in the assessment of coronary risk."

tory services market in coming years. Every physician using an EMR system in his or her practice quickly realizes the benefits of having both lab test results and lab orders flow seamlessly between the EMR and the laboratory provider. Labs which offer that connectivity—and make it easy for the physicians—will have an advantage in the market.

"We try and do another thing to outcompete the national laboratories," he continued. "These labs make great efforts to take care of their client physicians, but it is difficult for them to maintain a comparable ongoing presence as a local laboratory like us. We are in the neighborhood and we staff specifically to build personal relationships with our clients at all levels of the laboratory. Plus, because our turnaround time is faster on the routine work and Pap smears than most of our competitors, we play that card to its maximum advantage."

Developing Client Services

Shiel Medical Laboratory's achievement in reaching annual sales of $50 million is evidence that there is plenty of opportunity for regional labs to compete and succeed. The fact that Shiel Medical Lab has done this in the Greater New York City market area—one of the nation's most challenging—further reinforces that message. **TDR**

Contact Tod Schild at 800-553-0873 ext. 1167 or ts@shiel.com.

Lab Briefs

NEW CEO NAMED AT ROCHE DIAGNOSTICS, VENTANA OFFER EXTENDED

LAST WEEK, **ROCHE HOLDINGS AG** announced the appointment of Jürgen Schwiezer to become CEO of Roche Diagnostics, effective January 1, 2008. He succeeds Severin Schwan, who will take over for Franz B. Humer as Roche Group CEO on March 4.

Schwiezer is currently President of Roche's regions for Europe, the Middle East, Africa, and Latin America. Previously, Schwiezer held managemanagement sales positions at **Boehringer Mannheim**, which Roche acquired in 1997. He has extensive experience in the diagnostics business and a long track record in Europe, which is Roche's largest market region.

In a separate announcement, Roche extended, until November 1, its hostile takeover offer for **Ventana Medical Systems, Inc.** The offer was scheduled to expire on September 20. This is the third time Roche has extended its tender offer for Ventana. In June, Roche offered to acquire all of the 34 million outstanding common shares of Ventana, based in Tucson, Arizona, for $75 per share, representing 44% premium over Ventana's close of $51.95 on June 22. *(See TDR, July 16, 2007.)*

AETNA OFFERS TOOL FOR COST COMPARISON

CONSUMER PRICE TRANSPARENCY takes another step forward. Starting next month, **Aetna, Inc.'s** members will have a new Web-based tool to help them determine how much they can expect to pay for specific procedures done in hospitals and ambulatory surgical centers.

The tool, accessed through Aetna's password-protected member Web site, provides information for facilities in all or parts of 11 states and the District of Columbia. The "Medical Procedure by Facility Cost" program will include charges for the facility, the physician, and ancillaries such as lab and anesthesia services. It allows members to compare different providers for all costs—from admission to discharge—for 30 common procedures.

The tool is the third instrument from Aetna as it seeks to make more price and quality information available to members. In 2005, Aetna started its Physician-specific Price Transparency program to give members access to physician-specific prices for 30 common in-office procedures. Last year, Aetna launched its Physician-specific Clinical Quality and Efficiency Transparency program to provide members with physician-specific indicators based on adverse events, 30-day hospital readmission rates, and overall efficiency in use of services.

BILL WOULD REPEAL LAB BIDDING DEMO

THREE SENATORS introduced a bill to repeal the Medicare competitive bidding demonstration project for clinical lab services. Titled "Preserving Access to Laboratory Services Act of 2007" it was introduced on September 26.

The Senators are Ken Salazar (D-Colorado), Pat Roberts (R-Kansas), and Maria Cantwell (D-Washington) and all three serve on the Senate Finance Committee, which has jurisdiction over Medicare. Similar legislation, HR 3453, was introduced by Small Business Committee Chairwoman Nydia Velazquez (D-New York) in August.

After a basic introduction to the competitive demonstration project was made public earlier this year, Congress has heard a steady stream of comments from the laboratory profession in opposition to the planned demonstration. TDR

CDC Convenes Institute To Leverage Lab Testing

"Summit" brought healthcare leaders together to explore how lab testing can play a bigger role

CEO SUMMARY: In convening the 2007 Institute "Managing for Better Health," in Atlanta last week, the Division of Laboratory Systems of the CDC invited a broad spectrum of healthcare experts and policymakers to participate. The ambitious goal was to facilitate discussions involving stakeholders such as employers, payers, policymakers, clinicians, and others to identify ways that laboratory medicine could more effectively leverage outcomes and patient care.

IT IS WIDELY RECOGNIZED THAT LABORATORY MEDICINE can play a more effective role in helping the American healthcare system improve the quality of care, reduce medical errors, and improve patient satisfaction. Yet laboratory medicine seldom has a place at the table when policymakers develop new plans and programs.

To help change this situation and give laboratory medicine wider recognition and involvement in achieving national health policy goals, the **Division of Laboratory Systems of the Centers for Disease Control and Prevention** (CDC) convened the 2007 Institute "Managing for Better Health" in Atlanta on September 24-26. By invitation, approximately 80 people participated to identify strategies and opportunities for laboratory medicine to improve collaboration and involvement.

"Groundwork was laid to lift the profile and contribution of laboratory medicine within the American healthcare system," stated D. Joseph Boone, Ph.D., Acting Director, Division of Laboratory Systems, NCPDCID at the CDC. "This 2007 institute brought together a group of national healthcare leaders specifically to interact with laboratory professionals. The goal was to identify ways that the American healthcare system could leverage laboratory testing services to make faster progress on such goals as reducing medical errors, improving clinical outcomes, and increasing patient satisfaction."

Different Health Stakeholders

The 2007 institute was organized around three theme groups: collaborations, measures, and futures. In a series of facilitated sessions, participants worked to identify healthcare priorities in which laboratory medicine had the potential to contribute to significant improvements in healthcare outcomes and patient safety in ways that are cost effective for the American healthcare system.

Because of the cross section of healthcare interests represented, there was intense discussion across a wide range of topics and opportunities. "The hard work was to take a priority that has broad consensus, like 'improve health outcomes,' and drill down into specific areas of care where there was both a major opportunity to advance

and improve, and where laboratory medicine would be an essential element in triggering those gains," observed Boone.

Emphasizing Lab Medicine

"Over the course of these individual sessions, there was repeated recognition that laboratory medicine's greatest contribution, particularly in the short term, was at two places in the clinical continuum," stated Elissa Passiment, Ed.M., who was Chair of the Institute Committee. She is also Executive Vice President of the **American Society for Clinical Laboratory Science** (ASCLS) in Bethesda, Maryland.

"The first place is that moment when a clinician must decide whether to order a laboratory test and, if so, what the right lab tests should be," explained Passiment. "The second place is when the laboratory results are reported to the clinician and it is time for the clinician to use these lab test results to decide an appropriate course of action for the patient.

"Many laboratory professionals recognize these points as the pre-pre-analytical and post-post-analytical steps," she noted. "It was also recognized at the institute that it is not common for laboratory professionals to regularly consult, as appropriate, with clinicians at these stages in the clinical continuum. Yet, if laboratory medicine expertise can become part of the clinical consultation at these points, it was agreed that significant improvement in care outcomes could result for many high-profile diseases and chronic health conditions."

Action Items Identified

Working from this framework, participants developed agreement that three or four action items would be worth pursuing as a direct result of the institute and the interaction of individuals who participated. "One action item is to develop a framework with which to review, catalogue, and create evidence-based measures and practices in laboratory medicine that emphasize the added value of these services and produce quality patient outcomes," stated Passiment. "These evidence-based guidelines would then form the basis for collaborative efforts. Physicians, payers, policymakers and laboratory professionals would work together to educate and encourage appropriate clinical use of these evidence-based guidelines.

"Another actionable recommendation was to implement models of patient care that integrate clinical consultation provided by laboratory medicine professionals in the selection of laboratory services and the interpretation of test results," she continued. "A third action item—and a logical complement—was to develop courses and programs to train and educate clinicians to better utilize evidence-based guidelines, including laboratory tests, in a patient-centered care model."

Under the aegis of the CDC, the 2007 institute committee is preparing a summary of the proceedings for public release. A major objective of the institute was that the findings of the participants be translated directly into actionable projects, pursued by a collaborative task force made up of interested organizations and individuals. It is expected that several *ad hoc* working groups will be assembled to accomplish this task.

Call For Resources

As part of this effort, the institute committee will call on the laboratory profession for two needed resources. One is the active involvement of qualified individuals from all parts of healthcare to collaborate on pursuing the action items. The second is sources of funding to enable these teams to meet, to conduct necessary studies, and to publish findings. Anyone with an interest in contributing to this effort and funding these teams can contact the individuals listed below. TDR

Contact Elissa Passiment, Ed.M.,at 301-657-2768 or elissap@ascls.org; D. Joseph Boone, Ph.D. at djb2@cdc.gov.

Medicare Soon Won't Pay Hospitals for Errors

Private payers may be encouraged to adopt similiar policies of no pay for "preventable errors"

CEO SUMMARY: CMS issued new rules, effective in October 2008, that it will no longer pay the extra cost of treating patients after preventable errors, infections, or injuries that occur in hospitals. It continues Medicare's transformation from a "passive payer simply processing claims" to an "active purchaser with a stake in quality and efficiency." Many experts believe that private payers will follow Medicare's lead and also cease to reimburse for conditions related to preventable errors.

SAYING IT WILL NO LONGER PAY for the extra costs of treating preventable errors and injuries that occur in hospitals, the federal **Centers for Medicare & Medicaid Services** (CMS) is setting a new standard of accountability in healthcare.

In adopting this new policy, Medicare is making a significant policy shift. It is raising the profile of medical errors to a higher level, by making hospitals directly responsible for the financial consequences of "preventable errors"

At least eight conditions are included in the new rule book published by CMS late last month. The rules are in response to a 2005 law passed by Congress and will take effect in October 2008.

After implementation of the new rules, Medicare will no longer reimburse hospitals for treatment that resulted from nosocomial infections, surgeries performed to retrieve objects—including sponges or instruments—left in a patient, reactions when transfusion patients get the wrong blood type, bedsores that develop during hospitalization, and injuries from a fall sustained in the hospital.

Upon initial implementation of the new rules, hospital laboratories will be directly involved in how hospitals respond, particularly in programs to improve protocols for use of blood products. It is likely that hospitals will increase testing of newly-admitted patients to identify if there is an existing infection and, if so, what type of infection it is.

Long-Term Implications

However, these short term consequences and their impact on hospital laboratories are only a small part of this story. THE DARK REPORT believes the new Medicare policy will have long-term policy implications in healthcare. After all, Medicare's coverage and reimbursement guidelines tend to be adopted by private payers. Thus, Medicare's declaration that it will not reimburse hospitals for preventable errors sets the stage for private payers to adopt the same policy.

Further, the new Medicare rules are implementation of Medicare's evolving stance as a purchaser of healthcare. "We

are transforming Medicare from a passive payer simply processing claims to an *active purchaser with a stake in quality and efficiency [TDR's emphasis]*," said Tom Valuck, M.D., J.D., who is a Senior Advisor to CMS and Director, Special Program Office of Value-Based Purchasing. Valuck was discussing the new rules on preventable errors.

Downstream Benefits

Valuck observed that downstream savings would result if hospitals are able to significantly reduce the number and cost of complications. "You could have less home health care, less nursing home care and less ambulatory service care, as well as less physician follow-up," he observed.

Valuck also recognized how Medicare frequently influences private payers. He specifically identified **HealthPartners** of Minneapolis, Minnesota as already having such a policy. Instituted in 2005, HealthPartners doesn't pay for "never events" or clear medical mistakes. *(See sidebar on page 15.)*

Private payers have multiple incentives to adopt policies similar to the new Medicare rules and HealthPartners. Some of our readers will point out that, by denying payment for conditions associated with preventable errors, private payers stand to benefit financially by reducing the amount of money paid out for claims. Certainly those financial consequences will be considered as private payers establish policies on non-payment for avoidable errors.

Patient Expectations

However, another motivation is likely to override economics: the public perception about whether private payers are willing to "take a stand" on preventable errors. A policy of not paying providers for preventable errors or "never events" sends a powerful signal to employers (who select plans and pay the premiums) and patients. It is a statement that the insurance company is committed to raising the quality of care and supporting provider's efforts to reduce and eliminate medical errors.

Take this point from the opposite perspective, with a patient asking "why does my insurance company reimburse (reward) my hospital and doctors when they fail to follow established guidelines in my treatment—and Medicare and other insurance plans won't pay for these same types of medical errors?"

By adopting this policy, Medicare is establishing a new precedent and paradigm. It won't take long for patients to develop a new expectation about the care they receive from hospitals and physicians. Medicare is quietly in the process of raising the expectation of patients about the quality of healthcare provided to them.

Nosocomial Infections

Further, among the eight conditions covered by Medicare's new rules, the inclusion of nosocomial infections signals an escalation in the effort to reduce hospital-acquired infections. Although CMS has provided an estimate of $20 million in annual savings from the new rules, it is estimated that 2 million patients suffer from hospital infections every year and nearly 100,000 of them die. Costs associated with hospital-acquired infections are estimated to total as much as $27.5 billion annually.

CMS's move to stop paying for errors raises some interesting questions for pathologists, lab directors, and other providers. First, does the new rule mean that physicians and hospitals will order more laboratory tests for each patient upon admission? If so, the hospital's cost for Medicare patients will increase, although the DRG reimbursement is a flat fee. Interestingly, the trend to test all newly-admitted patients for MRSA infections is already gaining momentum and is a useful part of infection control programs at hospitals which have already adopted this policy.

Minnesota's Efforts on Patient Safety Support HealthPartners' 2005 Policy on "Never Events"

HOSPITALS IN MINNESOTA have been at the forefront of the patient safety movement. HealthPartner's policy on avoidable errors is consistent with the statewide effort to improve patient safety.

Taken directly from HealthPartners' Web site, here are the key points on its hospital payment policy for medical errors:

On Jan. 1, 2005, HealthPartners implemented a policy that witholds payment to hospitals for extremely rare medical errors identified by the National Quality Forum as things that should never happen to a patient. These events, called "never events" include errors such as surgery performed on the wrong body part or on the wrong patient, or leaving a foreign object in a patient after surgery. We believe that patients should never pay for "never events."

*The **Minnesota Hospital Association** and its member hospitals have been leaders in advancing patient safety in Minnesota. They led the way in establishing pioneering legislation on "never events." The new policy builds on that legislation by stopping payment to a hospital and does not affect individual physicians.*

We applaud the hospitals that already waive costs associated with never events and will continue to work with our hospital partners to ensure that this is the case for every patient, every time.

Answers to Frequently Asked Questions

What are "never events"?

The National Quality Forum, a nonprofit national coalition of physicians, hospitals, businesses and policy-makers, has identified 27 events as occurrences that should never happen in a hospital and can be prevented. They include surgical events such as performing the wrong surgical procedure, product or device events such as contaminated drugs or devices and criminal events such as abduction of a patient. See a complete list of "never events." More information can be found on the NQF Web site.

What is HealthPartners policy?

On Jan. 1, 2005, HealthPartners implemented a policy that stops payment to hospitals for "never events". The policy states that:

- *HealthPartners will not pay for services associated with a never event or permit providers to bill members.*
- *If a provider bills HealthPartners or a member, the provider must notify HealthPartners.*

Do hospitals already waive charges related to "never events?"

Some hospitals already waive charges related to "never events." The Minnesota Hospital Association and its member hospitals deserve credit for leadership in advancing safety initiatives in Minnesota. They lead the way in sponsoring the "never events" legislation. It is through a partnership with hospitals that we can ensure that patients in Minnesota experience the safest care in the country.

Won't this lead HealthPartners to not pay for other medical errors?

This policy applies to hospitals only and is limited to 27 "never events." It is based on state law that is supported by Minnesota hospitals and it reflects standards established by a national coalition on heath care quality. HealthPartners policies will continue to be consistent with state and national quality standards. (Statements are at: http://www.healthpartners.com /portal/866.htmlite)

The noteworthy aspect of HealthPartner's policy on non-payment for "never events" is that it is compatible with statewide efforts in Minnesota to improve patient safety. It is also based on widely-accepted national standards.

"To Err Is Human" Contributor Says Policy is Wake-up Call

NEWS THAT MEDICARE WILL NO LONGER PAY hospitals for "conditions that could reasonably have been prevented" is an overdue wake-up call for American hospitals, according to Lucian Leape, M.D., an expert in healthcare safety and hospital infections.

Leape is a member of the **Institute of Medicine** (IOM) committee that issued the report, "To Err is Human: Building a Safer Health System," the landmark 2000 report that estimated between 44,000 and 98,000 patients die in hospitals each year as a result of medical errors that could have been prevented. He is also a Professor at **Harvard Medical School**.

Writing in an article in *The Boston Globe*, Leape observed that CMS is simply reflecting the rising indignation among members of the public about the high rate of harm they experience when hospitalized.

"Since our Institute of Medicine committee issued the report "To Err is Human" eight years ago, patient safety leaders have been calling on hospitals to get serious about safety, to make a commitment to eliminating preventable injuries, and to implement known safe practices that will prevent them," Leape wrote. "Some have. Most have not. It was as if the safety folks were speaking a foreign language. Now the hospitals are being spoken to by people with authority and in a language they understand: the language of money.

"Hospitals have had the opportunity for some time to help their patients and save money by implementing a number of proven safe practices—bar coding of medications, computerized ordering, prevention of blood stream and ventilator-associated infections, to name a few—and most have ducked it. The 'business case' for safety has been well-established. Now it is the payers, not the hospitals, who will save the money—and, if we're lucky, the public—in the unlikely event that savings get passed on in reduced premiums," concluded Leape.

Second, there will be intensified efforts to improve how blood products are ordered, processed, and administered. This will directly encourage more laboratories to begin using process improvement techniques, including Lean and Six Sigma, since the goal is zero adverse events.

Third, Medicare now posts information about the performance of hospitals on its Web site. As it gathers data on preventable error rates by individual hospitals, CMS is likely to make that data accessible to the public within a few years.

Strategic Implications

THE DARK REPORT suggests that laboratory directors and pathologists view this new policy as a development with both short-term and long-term strategic implications for their laboratories and hospitals. The decision by an influential payer like Medicare to cease paying providers for conditions related to preventable errors marks a major escalation in the patient safety trend.

Remember, it was only in the early years of this decade that patient safety became a priority that required providers to establish programs with measurable goals in such areas as patient identification and nosocomial infections. Next, Medicare and certain private payers began to institute pay for performance programs and collect specific data on outcomes. Now, Medicare is ceasing payment for conditions directly linked to preventable errors.

Changing Expectations

This step-by-step escalation of the patient safety trend was predicted by THE DARK REPORT about the time that the **Leapfrog Group** publicly announced its first initiatives to improve healthcare. *(See TDR, January 28, 2002.)* Policy makers, employers, CMS, accrediting bodies and private payers have instituted new policies and requirements. Publicity about these developments has educated consumers and raised their expectations. Labs should be prepared to serve the higher expectations of today's healthcare consumer. TDR

Laboratory Error Results In Mistaken Mastectomy

NY Dept. of Health determines that lab tech cut corners with tissue samples, causing wrong diagnosis

CEO SUMMARY: In New York, because of a laboratory error and wrong diagnosis, a woman underwent a needless double mastectomy. In reporting the case, New York newspapers discovered another case of lab error and both women are suing the labs involved. Each case is a reminder that the public and state healthcare regulators are becoming increasingly intolerant of preventable laboratory errors.

ONCE AGAIN, AN ERROR IN AN ANATOMIC PATHOLOGY LABORATORY is generating national media attention with the news that, acting on a mistaken laboratory diagnosis, a New York woman underwent unnecessary and life-altering surgery.

In a lawsuit filed by the patient this summer, **CBLPath, Inc.,** of Ocala, Florida, is accused of mislabeling tissue samples resulting in the misdiagnosis. As a result of the misdiagnosis of invasive lobular carcinoma (breast cancer), Darrie Eason, 35, a single mother from Long Beach, New York, had a double mastectomy in May 2006. Two months later, Eason learned that she was incorrectly diagnosed because of a laboratory error.

"Cut Corners By Batching"

A report issued by the **New York Department of Health** in August 2006 said a CBLPath technician in the company's Rye Brook, New York, laboratory, had handled Eason's test and admitted to supervisors that he "occasionally cut corners by batching," samples, meaning processing more than one tissue sample at a time, and did not always verify patients' initials when labeling them.

"This is a system failure," said Eason's attorney James Baydar. "Somewhere along the line—because someone cut corners—Darrie has to live with the consequences of the scars and the emotional turmoil that she continues to go through." Baydar was quoted in *The Journal News*, a newspaper in White Plains, New York. Eason filed a suit last month in State Supreme Court in Mineola seeking undisclosed damages.

New York newspapers also reported the case of another woman who underwent a needless mastectomy as a result of a laboratory error. According to *New York Newsday*, a newspaper in Melville, New York, Lynne Yurosko, a 57-year-old consultant in Garden City, New York, was told she had cancer and had a lumpectomy and 25 radiation treatments in 2005 before she learned that she never had cancer. *Newsday* said the misdiagnosis was the result of a mistake at a laboratory of **Quest Diagnostics Incorporated**.

Both women have brought suits in State Supreme Court in Mineola. Eason is suing CBLPath and Yurosko is suing Quest Diagnostics and her doctors. Yurosko's case is scheduled for trial next year.

While such errors are limited in number, they are, nonetheless, very high profile

cases when the public learns the details. Inevitably, the facts of these cases and the names of the laboratories involved get reported in newspapers nationwide.

Another High Profile Case

Long-time clients and readers of THE DARK REPORT will remember the national media uproar caused by the Linda McDougal case in February 2003. In May 2002, McDougal, a 47-year-old accountant and mother of three, responding to a pathology report which diagnosed her as having an aggressive form of breast cancer, underwent a double masectomy at **United Hospital** in St. Paul, Minnesota (owned by **Allina Hospitals and Clinics**).

When no malignancy was found in the amputated breast tissue, an investigation revealed that McDougal's diagnosis of breast cancer was inaccurate—the result of a laboratory error. While reading McDougal's slides, the pathologist mismatched the specimen slides and paperwork of McDougal and another female patient, both of which were kept in the same folder. The pathology group admitted it was common for several patients' slides and paperwork to be placed in a single folder to be read by a pathologist. *(See TDR, February 10, 2003.)*

In the New York cases, CBLPath and Quest Diagnostics cited patient confidentiality when they declined to comment to newspaper reporters. William Curtis, CBLPath's CEO, did issue a statement saying, the "case involving Ms. Eason is one we have taken very seriously." When the mistake was reported more than a year ago, Curtis added, the company "completed a thorough investigation in cooperation with New York State authorities to confirm all appropriate training, protocols, and procedures were and are in place to ensure patient care and safety."

In its August 2006 report, the New York Department of Health said a technician admitted cutting corners while labeling tissue specimens. Even though the state report found "no systemic problems" at CBLPath, Eason's attorney, Steven E. Pegalis, said the lab must be held accountable. "You kind of assume that if a lab diagnoses you as having cancer, you've got it," Pegalis told *Newsday*. "How do you have faith and trust in systems that are supposed to be infallible?" Pegalis also told *Newsday* that he and his client chose not to sue Eason's doctors because the physicians were working with flawed information from CBLPath.

At the time of the McDougal case, THE DARK REPORT noted that the national publicity was a sign of the ongoing evolution in public opinion toward medical errors and physician incompetence. Increasingly, news of any type of serious medical error has consequences for the provider responsible for making the mistake.

Quality Bar Is Rising

For clinical labs and anatomic pathology groups, such failures raise the bar on quality. The consequences of laboratory errors and misdiagnoses can literally put a laboratory out of business.

It is for this reason that progressive laboratories and pathology groups are turning toward quality management systems such as Lean and Six Sigma to error-proof workflow and clinical practices. These quality management systems are based on a "system of prevention" mindset—that individual work processes are organized so that they can produce the desired outcomes.

That is why the laboratory errors in the cases of Eason and Yurosko are a timely warning for the lab profession. Many patients, working in companies that use Lean and Six Sigma, now understand how these methods—when used in labs—can reduce errors. The result is that the public and healthcare regulators have little tolerance for the types of preventable lab errors that brought distress to Eason, Yurosko, and McDougal. **TDR**

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Evidence is accumulating that the **Leapfrog Group** is getting the attention of the nations hospitals. It reports that just over half (52%) of hospitals have adopted the Leapfrog Groups' "Never Events" policy, a list of actions hospitals pledge to take whenever a rare medical error occurs that should never happen to a patient. In its Leapfrog Quality and Safety Survey, the Washington, DC-based organization said that, during this year, 1,285 hospitals reported for the first time on their adherence to the policy. The policy requires that hospitals apologize to the patient or family affected by the error, report the event to one of three patient safety agencies, do a root cause analysis to identify the source of the error, and waive all costs directly related to the event.

NYC HOSPITALS PUBLISH INFECTION RATES ONLINE

The New York City Health and Hospitals Corporation is publishing infection and death rates at its 11 hospitals. Responding to concern about hospital-acquired conditions, the nation's largest public health system now posts mortality, mortality heart attacks, preventable bloodstream infection, and pneumonia rates, among other data, on its Web site (*www.nyc.gov/hhc*). The 11 hospitals in the system treat 1.3 million patients annually. In a separate action, the **New York State Assembly** passed a law this year requiring hospitals to report infection rates to the state Health Department, which will issue hospital reports in 2009.

MORE ON: Infection Rates

In 19 states, hospitals are required to report information to the public about hospital-acquired conditions such as bloodstream infections. Pennsylvania, Michigan, Florida, and Vermont are among the states that mandate reporting of hospital data. The New Jersey State Legislature has passed a bill that requires hospitals to publish infection rates. It is awaiting Governor Jon Corzine's signature.

TRANSITIONS

• **Emory Univerisity** named Fred Sanfilippo, M.D., Ph.D., to be Executive Vice President for Health Affairs, CEO of the Woodruff Health Sciences Center and Chairman of the Board of **Emory Healthcare**. He is currently senior vice President and Executive Dean for Health Sciences at **Ohio State University**, and CEO of the **OSU Medical Center**. He also has served as President of the **American Society of Investigative Pathology** (ASIP).

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 29, 2007.