Volume XIX, Number 1 Monday, January 9, 2012

TDR 2011 TOP TEN

2011's Top Ten Lab Stories

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

Integration of Clinical Care and the Lab Industry

DURING 2012, THE HEALTHCARE SYSTEM IN THE UNITED STATES will make measurable progress toward the goal of integrated clinical care. In my view, this will be a positive development for clinical laboratories, since it creates opportunities for labs to step up and add value to physicians, patients, and payers.

There is a bubbling stew of ingredients that will contribute to more integration of clinical care. Growing numbers of hospitals and office-based physicians are adopting electronic health records (EHR). As they do, they want their laboratories to interface the LIS to their EHR systems. This is a significant development. Once all of a patient's data can flow seamlessly across the care continuum—accompanied by computer prompts and reminders to physicians and the care team—the gaps in medical care begin to disappear.

Other ingredients include the advent of accountable care organizations (ACO), the expanding number of health information (HIE) exchanges that are becoming operational, and greater transparency on provider outcomes and prices. All of these forces for change are in motion today. How quickly we see today's predominately fee-for-service healthcare system transform into something different is difficult to predict. It will be a multi-year process and is likely to be more evolutionary than revolutionary.

Within every laboratory, there are administrators and pathologists who are tasked to be the strategic thinkers for their organizations. My recommendation to these individuals is that integration of clinical care should be a key element in their labs' strategic priorities.

In particular, the product that every laboratory creates is information. Thus, integration of healthcare informatics—whether from the use of a common electronic medical record (EMR) system within an integrated healthcare system, or provider support for the regional HIE—has the potential to disrupt the long-standing relationship that a laboratory has traditionally enjoyed as a primary source of lab testing to its client physicians.

But, this same disruptive force will open a door for those lab organizations that understand how to deliver added value to each group of stakeholders: physicians, patients, and payers. With the trend toward clinical care integration in its earliest stages, there is an ample amount of time for innovative clinical labs and pathology groups to develop the value-added services that will anchor long-lasting and profitable relationships with physicians and their patients. TDR

2011's Top 10 Lab Stories Point to a Busy 2012

Few "earthquake news events" during a year when many were anticipating ObamaCare reforms

CEO SUMMARY: Given the specific news stories that make up THE DARK REPORT's list of the "Top Ten Lab Stories for 2011," it might be said that 2011 was a rather quiet year overshadowed by anticipation of the coming reforms mandated by the Accountable Care Act of 2010. For the clinical lab testing industry, 2011 was a year where much of the news was about government and payer proposals. The biggest lab acquisitions of the year were done by major corporations buying their first lab companies.

IN FUNDAMENTAL WAYS, at the end of 2011, the laboratory testing industry looked much as it did at the end of 2010. Seen from this perspective, 2011 was a relatively calm year for most clinical laboratory organizations and pathology group practices.

But that belies the fact that a number of important trends moved forward during 2011. As these trends play out in coming years, their individual and collective impact on the laboratory testing industry will be significant.

These trends are salted throughout THE DARK REPORT'S "Top Ten Lab Industry Stories for 2011." Lab administrators and pathologists will recognize that many of 2011's top lab industry stories are directly associated with major forces of transformation.

Certainly 2011 lacked the drama of a major laboratory acquisition that promised to reshape the competitive marketplace for laboratory testing services. Rather than making the biggest lab companies bigger, the important laboratory acquisitions involved major corporations buying their first—and important—stake in the lab testing market.

That is certainly true of the transaction that saw **Novartis AG** purchase **Genoptix, Inc.**, for $470 million in January, 2011. Similarly, with its purchase of **Caris Life Sciences, Inc.**, for $725 million in October, **Miraca Holdings, Inc.**, of Tokyo, Japan, gained a major foothold in this country's lab market. *(See Top Ten Story 3 on page 6.)*

For our number one lab industry story of the year, THE DARK REPORT selected the Medi-Cal whistleblower case that cen-

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).

tered around allegations that certain independent laboratory companies violated state laws by offering some providers discounted lab test prices that were not also extended to Medi-Cal, California's Medicaid program. *(See Top Ten Story 1 on page 5, opposite.)*

THE DARK REPORT believes the $300 million collected in the various settlement agreements in the Medi-Cal case may encourage other laboratory whistleblowers to file *qui tam* actions that focus on controversial lab industry marketing practices, including the use of deeply-discounted lab test prices.

Big changes lie ahead in how both government health plans and private payers will reimburse clinical laboratories. At least three stories on the 2011 Top Ten list involved developments in such areas as reforms to code stacking for molecular tests, first steps by Medicare and private payers to implement value-based reimbursement, and the advent of accountable care organizations (ACOs). This latter model of clinical care may evolve to include lab testing as part of a bundled reimbursement. *(See Top Ten Stories 2, 4, 8, on pages 5, 6, and 8, respectively.)*

➤Make Way For Informatics

The rapid evolution in information technology and the Internet is a contributing factor in several of the 2011 Top Ten stories. During the year, mobile computing became the hot growth trend in healthcare. With smartphone use accepted and growing, the advent of iPads and similar tablets over the past 24 months has loosed a torrent of demand by physicians to incorporate these devices into their clinical practice. *(See Top Ten Story 6 on page 7.)*

A new factor in the lab testing marketplace is the growing demand by consumers for lab testing that is provided by an Internet-based provider. Economics is fueling this source of consumer demand. These are price-shopping patients who lack health insurance or are required to pay high deductibles. They are actively turning to the Internet to find the lab tests they need at affordable prices. *(See Top Ten Story 7 on page 8.)*

Of course, EMR adoption by hospitals and providers, stimulated by federal incentive payments for meeting "meaningful use" requirements was one of 2011's big stories. Across the nation, clinical labs and pathology groups are being stretched by the requests of office-based physicians to interface their EMR system with the LIS. *(See Top Ten Story 10 on page 9.)*

➤Government Budget Battles

Another noteworthy development in 2011 was national recognition that government spending has finally outrun revenue. Budget battles in Washington, DC, revealed the intensity of the problem at the federal level.

But what is equally significant is that this same intense budget process is happening at the city, county, and state levels. How this affects healthcare generally—and clinical laboratories specifically—will be seen in coming years. What made 2011 a watershed year is that elected officials now struggle in the normal budget approval process to meet spending demands. *(See Top Ten Story 9 on page 9.)*

It is our recommendation that laboratories and pathology groups use these "Top Ten Lab Industry Stories for 2011" as the basis for a strategic planning session. The list provides a good foundation to evaluate current business plans against changes in the laboratory marketplace.

➤Events That Influence Labs

In compiling this year's list of "Top Ten Lab Stories for 2011," the goal was to draw attention to the news events that would be expected to have great influence on the management and operation of clinical laboratories and pathology groups. As an ancillary service, laboratory testing is influenced and shaped by a wide range of trends and market forces. TDR

TDR 2011 TOP TEN 1 Big Medi-Cal Settlement Sets Stage For More *Qui Tam* Lab Test Price Suits

ONE GREAT SCHISM in the clinical laboratory industry centers around the use of deeply-discounted laboratory test prices by a select number of lab testing companies. That is why settlement of the Medi-Cal *qui tam* lawsuit in California got lots of attention.

During 2011, all of the defendant laboratories are reported to have finalized settlement agreements with the California Attorney General. In the case of **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**, each vigorously denied the allegations of the whistleblower lawsuit. Quest Diagnostics paid $241 million and LabCorp paid $49 million to end their respective roles in the case. *(See TDRs, February 7; June 13; and September 26, 2011.)*

It is known that similar *qui tam* suits, filed in at least six other states, are challenging discounted lab test prices that are alleged to violate Medicaid laws in those states. Meanwhile, in August, a group of lab industry executives filed a whistleblower lawsuit in federal court that accuses LabCorp of offering lab test prices discounted below the Medicare Part B fee schedule to managed care companies in violation of federal inducement and anti-kickback statutes.

Thus, across the nation, multiple legal challenges are winding their way through state and federal courts that accuse some lab firms of offering discounted lab test prices in violation of certain state and federal laws. In this sense, one genie is out of the bottle. A surprise court ruling could change the status quo.

TDR 2011 TOP TEN 2 First Payers Poised to Reform/Change Code Stacking for Molecular Claims

GOVERNMENT HEALTH PLANS and private payers are concerned about the increased utilization of expensive genetic and molecular tests. Another related issue is the ever-increasing use of code stacked claims that labs submit to payers.

So it was that 2011 marked the first steps by a payer aimed at addressing the issues caused by the use of code stacking when labs submit claims for certain genetic and molecular tests. For the Medicare Region J1, Medicare carrier **Palmetto GBA** proposed two local coverage determinations (LCD) and a molecular test registry process (MolDx) that it intends to implement on February 27, 2012. *(See TDRs, November 7 and November 28, 2011.)*

Meanwhile, private payers want to institute pre-authorization requirements for expensive genetic tests and molecular diagnostic assays. Progress on this front has advanced enough to motivate **Laboratory Corporation of America** to incorporate a new business it calls **BeaconLBS** (for lab benefit solutions). *(See TDR, December 19, 2011.)*

In parallel with these developments, some 100 new CPT codes for molecular assays were released by the AMA with an effective date of January 1, 2012. At this point, the national Medicare office has not priced these new codes for 2012 and will leave it up to each local Medicare carrier to determine if they want to accept and pay the new codes in 2012.

TDR 2011 TOP TEN 3 Several Corporate Giants Buy Their First Stakes in Lab Test Marketplace

ALTHOUGH THE NUMBER OF SIGNIFICANT LABORATORY ACQUISITIONS was limited during 2011, several important new players spent heavily to buy stakes in the laboratory testing market.

The year opened with **Novartis AG**, the pharmaceutical giant, acquiring **Genoptix, Inc.**, for a purchase price of $470 million. That deal was announced in January 2011.

The other big transaction saw Japan-based **Miraca Holdings, Inc.**, pay $725 million to purchase **Caris Life Sciences, Inc.**, of Irving, Texas. That announcement came in October 2011.

It is worth noting that, in October 2010, **GE Healthcare** purchased **Clarient, Inc.**, for a price of $570 million. It has been long expected that General Electric Corporation—which is one of the world leaders in imaging and radiology products—would buy its way into *in vitro* diagnostics (IVD).

Thus, in the 12 months between October 2010 and October 2011, three corporate giants spent a total of $1.8 billion to buy into the clinical laboratory testing marketplace.

Further, each of the acquired lab companies has a primary focus on anatomic pathology testing, particularly cancer. The strong prices paid by the buyers of these companies demonstrate how Wall Street continues to view laboratory testing in general—and anatomic pathology specifically—as a sector of healthcare that will continue to see strong growth in revenue and specimen volume.

TDR 2011 TOP TEN 4 Medicare and Private Payers Ready To Implement Value-Based Payment

IN THE UNITED STATES, the end is coming to the era dominated by fee-for-service reimbursement. During 2011, the Medicare program took its first steps to formally launch demonstration projects that utilize value-based reimbursement.

Meanwhile, some major health insurance companies have quietly begun to negotiate contracts with providers that include value-based reimbursement for selected healthcare services. These arrangements typically link improved patient outcomes with greater reimbursement for the provider.

This transition will not happen quickly. It will require years before value-based reimbursement becomes the dominant form of payment from payers. *(See TDR, May 23, 2011.)*

While accountable care organizations (ACO) and medical homes garnered most of the headlines during 2011, less attention was focused on Medicare demonstration projects that center upon bundled reimbursement and value-based reimbursement. The draft requirements for participation in these Medicare demonstration projects were published during 2011.

It was noteworthy that, in the four different models of bundled reimbursement defined by Medicare officials for that demonstration project, two models specifically required that laboratory test costs were to be included in the bundled price. Alert lab administrators will want to track these developments.

TDR 2011 TOP TEN 5 First Wave of Lab Professionals Retires As Oldest Baby Boomers Turn 65

ON JANUARY 1, 2011, a major milestone was reached in American society. That was the day that the oldest baby boomers marked their 65th birthday.

It also marked the beginning of a major demographic trend. During the next 20 years, each day 10,000 of the nation's 80 million baby boomers turn 65 years old. That makes them eligible for Medicare and Social Security benefits.

This retirement wave also has a direct effect on clinical laboratories and anatomic pathology groups throughout the United States. It means that labs will see their most experienced professionals retire in greater numbers than at any time in the past.

Unfortunately, few laboratory organizations have implemented effective succession planning programs. This is particularly true of many smaller anatomic pathology groups, where the number of physicians can range from three to six.

The impending retirement of one or two of these pathologists—and the inability of the pathology group to recruit replacement pathologists—means that these smaller group practices begin to look at consolidation with other local groups, or even outright sale. *(See TDR, April 11, 2011.)*

For clinical labs, the coming retirement of senior administrators and experienced lab managers will come with its own set of challenges. For that reason, all lab organizations should have succession planning strategies in place.

TDR 2011 TOP TEN 6 Mobile Computing Poised to Find Wide Acceptance Within Healthcare

MOBILE COMPUTING IN HEALTHCARE was a big story in 2011, although the full impact of this trend has yet to diffuse across the clinical lab industry.

The big driver in this trend is the expanding use of smartphones and iPads by physicians. Often purchased for personal use, many doctors quickly become interested in using these devices to support their clinical activities.

Essentially, as users of smartphones and iPads, physicians began pressing hospital information technology (IT) departments to allow them to access relevant clinical and administrative information via these mobile devices. Thus, physicians are "pulling" demand for more mobile computing solutions from hospitals.

The other element in this story is that new information technology makes it simple and fast to design and deploy mobile computing applications. This was the case at **Holy Name Medical Center**, in Teaneck, New Jersey. The IT department there took just three weeks to write "MicroHIS," a mobile computing app that allows physicians to use their smartphones to view patient information, including laboratory test data. *(July 25, 2011.)*

In response to these developments, a number of early-adopter lab organizations are working to deploy mobile computing applications that will allow client physicians to access the lab test data of their patients. Expectations are that physicians will welcome these solutions.

TDR 2011 TOP TEN 7 Internet-Based Lab Test Companies Grow by Serving Price-Shopping Patients

THERE ARE NEW TYPES OF CONSUMERS for clinical laboratory tests and first to tap this market segment are Internet-based lab testing companies.

These consumers are motivated primarily by lower cost and generally fit into one of three situations.

One group of these patients are uninsured. A second class of patients are what some health policymakers characterize as "underinsured." Typically, this means that these individuals have a health insurance plan that offers limited benefits.

The third group is comprised of people who have high deductible health insurance plans. That includes folks covered by a PPO, a POS, an HMO, and a fee-for-service plan, where employers now commonly require annual deductibles of $1,500 or more. (Those with health savings accounts [HSA] may have a 100% out-of-pocket annual deductible of as much as $3,100.)

It is access to the lowest price for lab testing which motivates these consumers. Often they are encouraged by their physicians to use these Internet-based lab test companies, since the physicians recognize their patients might skip the clinical lab tests completely if required to pay the "patient bill" prices charged by established clinical labs. *(See TDR, February 28, 2011.)*

The importance of this trend is that a growing number of patients now have a motivation to shop for labs, using lowest price as a primary selection criteria. For this reason, it may be timely for labs to revisit their test pricing strategy.

TDR 2011 TOP TEN 8 Welcome to ACOs and Medical Homes: Goal Is to Integrate Clinical Care

HOSPITALS, HEALTH SYSTEMS, AND PHYSICIANS spent all of 2011 preparing for the advent of accountable care organizations (ACO). This triggered the largest wave of provider consolidation since the mid-1990s.

ACOs are one of the major healthcare reforms in the Accountable Care Act (ACA) of 2010. Starting in 2012. the Medicare program will contract with ACOs in an effort to improve patient outcomes while better controlling the cost of care. Savings that result from improved patient outcomes will be shared with the ACO.

Most of the nation's hospitals and health systems are giving full attention to ACOs, as are office-based physicians. In particular, hospitals and health systems have been acquiring office-based physician practices at a stunning pace. Physicians—concerned about their future in a healthcare market expected to be dominated by ACOs—proved willing to sell their practices to local hospitals.

Even health insurers are acquiring ownership of physician practices. *(See TDR, July 25, 2011.)* This is a big story for the clinical laboratory industry, because it means there are fewer private medical group practices that can freely choose their lab testing providers.

Instead, the owners of these office-based physician groups will be hospitals, health systems, and health insurers. This will make it more difficult for competing labs to retain or expand their market share of office-based physicians.

TDR 2011 TOP TEN 9 Federal and State Budget Battles Are a Sign of Unprecedented Fiscal Stress

THROUGHOUT 2011, the financial crises in cities, counties, states, and the federal government dominated the national news headlines. It is a red flag that pathologists and lab administrators ignore at their own peril.

Two things are precipitating the financial melt-down of all levels of government in the United States. One is the direct impact of the longest-lasting depression since World War II (2008-2010), followed by a very weak economic recovery.

But the second is that the demand for government spending across all sectors—education, health, roads, social programs, and retirement benefits to government employees, to name a few—is growing at the same time that sources of additional taxes and government revenue are flattening or even shrinking.

Independent of the political solutions coming from the left and the right, the black hole of government finances is a fact that every clinical lab and pathology group must recognize in its strategic planning.

The year 2011 will be seen as a clear dividing line, separating relative years of plenty in the 1990s and the 2000s with the rancorous budget battles and inability of government at all levels to fully fund the level of healthcare, education, and social services that the American population has come to take for granted. Labs should budget very carefully, keeping these trends in mind.

TDR 2011 TOP TEN 10 First Year of EMR 'Meaningful Use' Ends for Hospitals and Physicians

DURING 2011, HOSPITALS AND OFFICE-BASED PHYSICIANS strived to adopt electronic medical records (EMR) on a timetable established by federal incentive programs.

To qualify for federal incentives, hospitals and physicians must meet "meaningful use" (MU) requirements. These incentives will be paid in response to providers meeting Stage 1 and Stage 2 meaningful use guidelines.

In response to these developments, throughout 2011, clinical labs were kept busy working to interface their laboratory information systems (LIS) to the EMR systems of their client physicians. This activity is part of the wider trend to achieve integration of healthcare informatics.

Clinical laboratories and anatomic pathology groups are having to upgrade their own information technology (IT) capabilities in order to fully integrate their LIS's with the EMRs of client physicians. The particular focus is for labs to support electronic lab test orders that come from the physicians' EMR, while transmitting lab test results directly back to the patient record in the EMR.

The transition by office-based physicians and hospitals to a fully-digital electronic medical record is a one-time event. That raises the stakes for clinical labs, because if they don't step up and meet the interface needs of their clients, those physicians are likely to switch and refer their laboratory tests to a competing lab that will meet those needs. **TDR**

'Salary Power' Helps Lab Recruit and Train New MTs

MT and MLT distance training programs help PeaceHealth Laboratories meet staffing needs

CEO SUMMARY: It was back in 2002 when THE DARK REPORT highlighted the innovative use of MT and MLT long distance training by PeaceHealth Laboratories (formerly Oregon Medical Labs). Distance training is part of a comprehensive program to attract individuals in the community with two-year and four-year degrees and give them an "earn while they learn" career path toward certification as medical laboratory technicians (MLT) and medical technologists (MT). Here is an update on this business strategy.

ACROSS THE NATION, demand for medical technologists (MT), medical laboratory scientists (MLS), and medical laboratory technicians (MLT) continues to exceed the annual supply of new graduates.

It is a problem that is further aggravated by the fact that an average of 10,000 baby boomers now turn 65 years old every day! This retirement surge began on January 1, 2011, and will continue for 20 years. It also means the clinical laboratory industry must now confront this long-predicted labor crisis.

Med Tech Training Programs

Because many cities lack even one established MT or MLS training program, lab administrators and pathologists in those regions are especially challenged to find adequate numbers of qualified MTs, MLSs, and MLTs to keep their labs at authorized levels of staff.

However, one sizeable laboratory organization in the Pacific Northwest has developed an effective strategy to tap its local labor market to develop its own med techs, despite the fact that the closest MT training program is located more than 100 miles away.

In Eugene, Oregon, **PeaceHealth Laboratories, Inc.** (formerly **Oregon Medical Laboratories**) now has eight years of success using distance learning programs to fill its needs for MTs and MLTs.

"The use of distance learning programs has played an important role in allowing us to attract and retain talented people," stated CEO Ran Whitehead. "If your lab is located in a community that doesn't have a local MT and MLT training program, then distance learning is an effective way to expand the supply of qualified staff by offering a career path to local residents who are often eager to work in your laboratory."

PeaceHealth Laboratories (PHL) has coined a phrase to describe how distance learning can help individuals improve their earning potential. "We use the term 'salary power' to describe this ongoing staff recruitment and educational development program," added Whitehead. "It is a message that resonates in our university town."

Eugene is home to the **University of Oregon** (UO) and has a population of about 156,000 people. "After graduation,

At PeaceHealth Labs, Distance Learning Is Effective Strategy for Recruiting New Lab Staff

FOR ALMOST A DECADE, THE USE OF DISTANCE LEARNING has been a key tool in recruiting, training, and retaining medical technologists (MT) and medical laboratory technicians (MLT) at PeaceHealth Laboratories, Inc. (formerly Oregon Medical Laboratories), in Eugene, Oregon.

One leader in this effort is Laura Lee Feiner, MT(ASCP), MPA, who is PeaceHealth's Human Resources Laboratory Educator. Feiner took on a master's degree in Public Administration, spent 25 years in the laboratory, and now has eight years' worth of laboratory training delivery where she has taught hematology, immunology, and blood banking.

Feiner views distance learning for clinical laboratory professionals as an ongoing, developing model. "Even as the student acquires scientific knowledge from the academic portion of the program, there is the need to gain hands-on training within the laboratory," she explained. "It is in the clinical laboratory that students learn the practical applications of laboratory medicine. This can range from understanding how laboratory automation developed and is used, to how the lab manages the results from automated equipment, and how functions such as QA/QC are handled in these settings."

One challenge is aligning the schedules of the distance learning student and the mentors within the laboratory. "Carving out time for both employees to meet simultaneously is sometimes difficult because of their individual daily workloads," said Feiner.

Using Distance Learning

The long distance training program for MTs and MLTs utilized by PeaceHealth is offered through the Georgia Health Sciences University (formerly known as the Medical College of Georgia). "Student employees in the laboratory go through an internship," noted Feiner. "Our primary MLT (associate's degree) distance training program is with Portland Community College in Portland, Oregon.

"For qualifying employees, PeaceHealth Labs offers scholarships of up to $1,200 for an MLT program and up to $3,000 for an MT/MLS program," stated Feiner. "Those seeking associate's, bachelor's, and/or master's degrees must make time for the internship between work and their studies.

"Every employee in any program, however—including distance learning—not only learns how to get laboratory test results, but also how to interpret them," she said. "We emphasize the original four basic areas of study—hematology, immunology, microbiology, and blood banking."

Role Of Advisory Committee

For annual feedback concerning all coursework for PeaceHealth Laboratories' distance learning curriculum, Feiner said she is the liaison as a member of an advisory committee that includes representatives from the medical laboratory industry, academia, and clinical advisors. When PeaceHealth Laboratories implemented automated immunology and molecular testing, for example, the advisory committee recommended changes in the curriculum.

"In our training program, molecular was first included in microbiology," recalled Feiner. "Then it was part of immunology. Now we have molecular as its own primary area of research and study.

"Less than 10% of distance learning programs for MTs and MLTs have a robust molecular program," continued Feiner. "But this is a fast-growing area of laboratory medicine and students need to know the theory of molecular testing, supplemented by hands-on experience so they fully understand it."

many students would like to get a job in Eugene so they can continue to live here. However, our community has limited job opportunities for graduates."

PHL recognized that the pool of recent UO graduates could be tapped as a source of new medical technologists. "It was back in 2002 that we realized we could offer Bachelor of Science (BS) graduates an employment package that incorporated their BS degree with an MT distance learning program offered through the **Georgia Health Sciences University** (formerly known as the **Medical College of Georgia**)," he explained. "They could work at PHL while they obtained their MT certification." *(See TDR, October 7, 2002.)*

At that time, PeaceHealth Laboratories was experiencing a wave of retirements even as its growth rate was accelerating. "These factors made it essential for us to maintain existing staff levels and be prepared to add more MTs and MLTs to support increased testing by our hospitals in tandem with our continuing growth in outreach specimen volume," recalled Whitehead.

Distance Learning For MTs

"At that time, the closest MT training program was at **Oregon Health Sciences University** (OHSU), 100 miles away in Portland," he continued. "OHSU did not offer distance learning opportunities. That is why we decided to use the distance training program offered by the Georgia Health Sciences University (GHSU), which is located in Augusta, Georgia."

PeaceHealth Laboratories created a comprehensive career path for prospective and current employees who had a Bachelor of Science degree. "We established a tuition reimbursement policy that pays up to $1,500 annually for a qualifying training program," noted Whitehead. "Our goal was to give employees a way to both live in Eugene and improve their earning power.

"Of course, there is the requirement that these students supplement the didactic online learning experience with hands-on clinical training in our laboratory," he said. "PHL managers help distance learning students with their internships and assign qualified staff to be mentors."

Grants From Lane County

Another effective business strategy that PHL used in 2002 was to apply for a training grant from the **Lane County Economic Development Corporation**. The first grant award totaled $127,824.

Since its inception in 2002, this staff development program has been successful for PeaceHealth Labs. "We have at least 16 to 18 program participants who stayed with our laboratory after completing their MT certification," stated Whitehead. "To date, 90% of the employees who went through the distance learning program continue to work in our lab.

"This demonstrates how distance learning creates 'salary power' for an individual who wants to achieve certification as a medical technologist," he added. "During the eight years that PHL has used distance learning programs, it has been quite effective at helping us recruit and retain talented people in a smaller community where such career opportunities are limited."

It was eight years ago when THE DARK REPORT first profiled this innovative use of long distance learning programs by PeaceHealth Laboratories. As noted above, this has been an effective business strategy to tap Bachelor of Science graduates in the community, and give them a defined career path to work in a good job while they earn their certification as a medical technologist. **TDR**

—By Carren Bersch

Contact Ran Whitehead at 541-341-8070 and rwhitehead@peacehealthlabs.org, Laura Lee Feiner at 541-341-8084 and lfeiner@peacehealthlabs.org.

9 Pennsylvania Hospitals Tackle Lab Specimen Errors

Errors in patient blood specimen labeling were reduced across the nine hospitals by 37%

CEO SUMMARY: In this unusual collaboration, the participating Pennsylvania hospitals dramatically reduced blood specimen labeling errors. This initiative to share best practices incorporated techniques that were refined in other projects designed to reduce medical errors and improve patient care. Another interesting feature of this multi-hospital quality initiative is that the participating institutions agreed to publish their rates of errors involving mislabeled patient blood specimens.

HERE IS AN UNUSUAL STORY for the clinical laboratory industry. It involves nine participating hospitals, the State of Pennsylvania, and the willingness to publicize error rates on the handling of laboratory test specimens.

"Working with the **Pennsylvania Patient Safety Authority** (PPSA), these nine hospitals reduced the rate of mislabeled blood specimens in the nine facilities by 37%," observed Barbara Booth, MT (ASCP), Laboratory Service Improvement Coordinator at **Geisinger Wyoming Valley Medical Center** in Wilkes-Barre.

"This project was initiated in 2009," she continued. "The goal was to improve patient safety by reducing one common source of errors—blood specimen labeling errors."

This program was organized by the PPSA. Hospitals that participated had to agree to:

1) Report blood specimen labeling errors through the authority's Pennsylvania Patient Safety Reporting System (PA-PSRS);
2) Submit monthly laboratory reports to an authority analyst; and
3) Investigate mislabeling events using a standardized event investigation tool.

This initiative is noteworthy because it shows how transparency in quality outcomes is advancing both for hospitals and for clinical laboratory services. It also demonstrates how government health agencies will step up and take a lead role in fostering cooperation across multiple healthcare organizations to pursue improved quality in patient care.

Further, this is an example of how cooperating institutions will increasingly be willing to share best practices that directly contribute to a reduction of medical and laboratory errors. Data from these initiatives will be available to the public and other health care providers.

For Booth, this project targeted an ongoing source of laboratory test errors familiar to every laboratory administrator and pathologist: blood specimen identification errors. "In 2009, PPSA (at *http://patientsafetyauthority.org*) recognized that blood specimen identification

errors occur at rates of 0.1% to 6.5%," stated Booth.

"Laboratory professionals know that misidentified specimens can lead to delays in diagnosis and cause providers to treat the wrong patient or the wrong disease, and contribute to severe transfusion reactions as well," added Booth. "Thus, to reduce blood specimen labeling errors, in 2009, the authority asked hospitals to address this issue in a collaborative project."

Booth was the leader of this effort at her hospital. She reported on the outcomes and lessons learned from this unique nine-hospital collaboration at the *Lab Quality Confab* that took place in San Antonio, Texas, in November.

"Nine facilities agreed to collaborate, even though most organizations do not like to air their dirty laundry," stated Booth. "All participating institutions recognized that this program offered a chance to review internal procedures and improve patient outcomes. The potential for improving patient care and patient safety clearly outweighed any disadvantages.

Goal: Cut Errors in Half

"The primary goal of the collaborative was to decrease blood specimen mislabeling events by 50% in 12 months," noted Booth. "We defined an event as unlabeled, partially labeled, illegible labels, or use of the wrong patient name or label. Point-of-care testing (POCT) was excluded from this project.

"At Geisinger Wyoming Valley, our initial thought was to make improvements hospital-wide," she said. "But this became our first lesson, as it was suggested that we focus on one department. This is consistent with the principle that, by starting small and achieving some success, we would build energy and momentum to take on larger quality-improvement efforts later.

"We launched our improvement efforts at Geisinger Wyoming Valley Medical Center with the medical intensive care unit," explained Booth. "As a 20-bed unit, it was relatively small and it allowed us to engage respiratory, laboratory, and nursing.

"At my hospital, our improvement team included staff from laboratory, nursing, respiratory, risk management, regulatory PI, and the medical director," she stated. "We launched a system-wide electronic educational course for all specimen collectors. Next, we observed the processes collectors used when obtaining blood specimens from a patient.

Consistent Observations

"To ensure that we were consistent in our observations, we developed an observation tool," she added. "We wanted to ensure that each observer knew what to look for and would gather similar information.

"The tool asked: 'Did the patient have an identification band?' 'Where was it?' 'What information was on it?' 'What identifiers were checked?'" commented Booth.

"Another lesson: observe procedures before and after process changes and include a variety of observers," she continued. "For our observations, we used staff crossover, meaning labs looked at respiratory, respiratory looked at nursing, and nursing looked at labs.

"Crossover is important," added Booth. "When your staff looks at its own procedures, the tendency is to see only the good aspects.

Differences In Collection

"These observations uncovered plenty of information: every department has slightly different procedures for collecting blood and identifying patients," she said. "Different processes existed because we had different staff (including respiratory, nurses, and sometimes physicians) collecting blood.

"When we observed the processes, we saw that laboratory tended to be more consistent and that staff from other

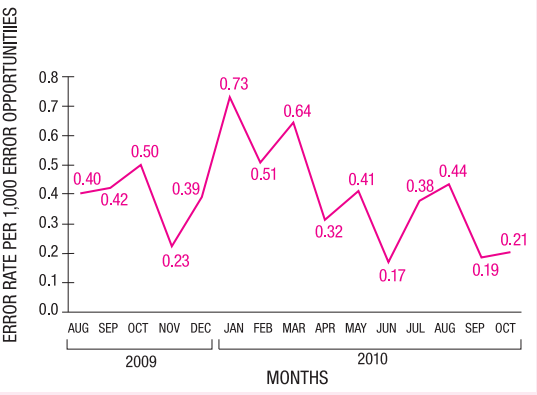
Project Harnesses the Efforts of Nine Hospitals To Reduce Blood Specimen Labeling Errors

Table 1. Reduction in Facility-Specific and Program-Wide Error Rates

FACILITY	BASELINE ERROR RATES (August through October 2009)			POSTINTERVENTION ERROR RATES (August through October 2010)			CHANGE	HOSPITAL-SPECIFIC CHARACTERISTICS
	Rate per 1,000	LCL	UCL	Rate per 1,000	LCL	UCL		
A	4.1	1.8	6.4	0.8	0.0	1.7	-81%*	One care area of focus; adequate leadership support; targeted interventions
B	0.6	0.4	0.9	0.3	0.1	0.4	-57%	Multiple care areas of focus; adequate leadership support; targeted interventions
C	0.1	0.0	0.2	0.0	0.0	0.0	-84%*	Multiple care areas of focus; adequate leadership support; targeted interventions
D	2.5	1.6	3.3	0.7	0.4	1.1	-71%*	Multiple care areas of focus; adequate leadership support; targeted interventions
E	3.2	1.5	4.9	1.3	0.2	2.4	-61%	One care area of focus; adequate leadership support; targeted interventions
F	0.3	0.2	0.4	0.5	0.3	0.7	67%	One care area of focus; inadequate leadership support; targeted interventions
Pooled Mean	**0.44**	**0.36**	**0.52**	**0.28**	**0.21**	**0.34**	**-37%***	

*p<0.05. Test of two proportions (z-test).

Chart 2: Collaborative Aggregate Specimen Labeling Error Rate



Source: Pennsylvania Patient Safety Authority © 2011

IMPRESSIVE RESULTS WERE POSTED by the nine hospitals that participated in the Pennsylvania Patient Safety Authority's project to drive down the rate of blood specimen labeling errors.

Table one (above) demonstrates how two hospitals reduced error rates by as much as 84% and 81%. The overall error reduction—measured across all nine hospitals in the collaboration—was 37%.

Chart two (at left) shows how the aggregate rate of specimen error rates declined during the 15-month period of the error reduction program. Some participating hospitals have been able to sustain a reduced rate of errors in specimen labels since that time.

departments had more variation in their collection processes," recalled Booth.

"Our findings may not surprise experienced laboratory professionals," noted Booth. "The observations showed that collectors were not doing all things we thought they should be doing to collect blood properly and identify the patient!

"Seeking to standardize blood collection, we listed the steps that a collector would follow to conduct the best process each time," said Booth. "Then we taught

this process by having team members go out to each clinical service, including the lab, respiratory, nursing, and the ICU.

"Initially, our efforts to standardize the process were not well received, and so here's another lesson," she added. "Interactions always included more than one team member, and the focus was always on patient safety. Whenever someone complained, it was explained that the program was designed to improve patient care. At that point, there was no further discussion because staff recognized the value of eliminating errors and thus improving patient care.

Post-Error Interviews

"Despite our efforts, we continued to have some errors in blood specimen identification," she said. "Therefore, we conducted post-error interviews to improve the process. The nine teams developed a standardized event investigation tool that is available online from the Patient Safety Authority (*http://tinyurl.com/7nrcf8s*).

"Using this form, we interviewed collectors in a non-punitive manner and encouraged them to be honest," Booth explained. "At first, it was a struggle, particularly with nurses. This was another lesson. The interviews gave our laboratory staff an opportunity to break down barriers and build relationships with the nurses.

"The data from this tool showed that the most significant factors contributing to errors were: a) procedures not followed; b) interruptions or distractions; c) emergencies; and d) significant workload increases," she said. "This data helped us identify reasons why collectors did not use the standardized process we developed.

Procedures Not Followed

"The number one source of errors for misidentified blood specimens was that procedures were not followed," recalled Booth. "We next began to dig into the reasons why procedures were not followed.

Reducing Label Errors Was Goal of Project

FOR THE PATIENT SAFETY collaborative in Pennsylvania, nine hospitals participated in the effort to reduce the number of blood-specimen labeling errors. The hospitals were:

- **Allied Services Rehabilitation Center** (Viewmont Medical Laboratories), Scranton
- **Berwick Hospital Center**, Berwick
- **Easton Hospital**, Easton
- **Geisinger Medical Center**, Danville
- **Geisinger Wyoming Valley Medical Center**, Wilkes-Barre
- **Lehigh Valley Health Network**, Allentown
- **Sacred Heart Hospital**, Allentown
- **Pocono Health Systems**, Stroudsburg
- **Wyoming Valley Health Systems**, Wilkes-Barre

"Three causes jumped to the top of the list," she said. "There was a need to improve the lab test requisition. Issues with the printing of labels required a fix. There was also the failure of collectors to properly identify patients when drawing blood.

"Over the course of this improvement program, the nine facilities decreased identification errors by 37%!" noted Booth. "Error rates at our facility did increase after the project was completed, however, they did not rise to the previous levels. Most importantly, we now had tools and a structure to address this increase.

"The authority published an article about the collaborative on its website and the article details all of the steps we took to solve the various problems we encountered," Booth concluded. "Its title is: 'Reducing Errors in Blood Specimen Labeling: A Multihospital Initiative' and the URL is *http://tinyurl.com/7nrcf8s*." TDR

—By Joseph Burns

Contact Barbara Booth, MT (ASCP), at babooth@geisinger.edu or 570-808-7845.

Final Three Labs Settle California *Qui Tam* Case

Individual agreements with seven defendant lab companies lack guidance on future compliance

CEO SUMMARY: In recent months, the California Attorney General (AG) entered into settlement agreements with the last three defendant laboratory companies involved in the Medi-Cal discount pricing whistleblower lawsuit. The AG did not make this news public. In their respective settlement agreements, the three laboratory companies stipulated that the agreement was not an admission of liability. Overall, the California Attorney General collected more than $300 million from the seven defendant laboratory firms.

In California, three defendant laboratories disclosed settlements with the State Attorney General. Each settlement resolves allegations made in the long-running whistleblower lawsuit originally filed in 2005 by **Hunter Laboratories, Inc.**, and Chris Riedel.

The central issue in this *qui tam* case is the widespread practice of charging certain providers a lower price for a laboratory test than the price for which that lab bills the Medi-Cal program for that same test. It was alleged that this practice violated state laws. *(See TDR, February 7, 2011, and June 13, 2011.)*

Financial Penalties

The financial penalties associated with the three new settlement agreements were as follows: **Physicians Immunodiagnostic Laboratory, Inc.** (PIL), will pay the state $600,000; **Primex Clinical Laboratories, Inc.**, will pay $750,000; and **Whitefield Medical Laboratory, Inc.**, will pay $400,000. All three lab firms denied liability.

Earlier this year, both **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** entered into settlement agreements with the California Attorney General. Both companies vigorously denied the allegations described in the whistleblower lawsuit.

Quest Diagnostics agreed to pay $241 million (reported to be the largest amount ever recovered in a state enforcement action). As part of its settlement, LabCorp agreed to pay $49.5 million.

Additionally, in their respective settlement agreements, both Quest Diagnostics and LabCorp agreed to extensive reporting requirements for Medi-Cal claims through 2013, but no such reporting is required of the private laboratories. With the announcement of the private laboratories' settlement, it is believed that the California Attorney General's active cases related to laboratory charges have concluded.

When these three laboratory companies reached agreements to resolve pricing issues with the California Attorney General in November, the state released no details on the cases. All seven defendant lab companies have now resolved their part of the whistleblower case that

the California Attorney General's office announced in March 2009.

Co-counsel for the three laboratories during the settlement negotiations was attorney Dawn Brewer of Marina Del Rey, California. She is familiar with this lawsuit and the resolutions made public.

Settlement Agreements

"When these three laboratories entered into settlement agreements with the California Attorney General, they denied any wrongdoing and agreed to pay a specific sum with no reporting requirements," she said. "The California Attorney General reached similar settlement agreements with other laboratories named in the lawsuit."

These final three settlement agreements bring an end to the *qui tam* case filed back in 2005 by Hunter Laboratories, Inc., and Chris Riedel. Then-Attorney General Edmund G. Brown joined the lawsuit in 2009 and made the case public at that time. In his press conference, Brown said that the defendant laboratory companies violated state law and regulations. He stated that no provider can charge Medi-Cal—the state's Medicaid program for the poor—a price for any service that is more than they charge for the same service to other purchasers under comparable circumstances.

Labs Want Clear Guidance

What has disappointed the clinical lab industry in California is the lack of definitive guidance by the state on how to comply with the state laws that were central to the whistleblower lawsuit. Many lab industry executives expected that one outcome from the resolution of this whistleblower lawsuit would be objective guidance on how these state laws would be interpreted and enforced going forward. Brewer picked up this theme. She noted that state officials should offer labs more guidance on billing procedures.

"Part of the complexity of this case was Medi-Cal's seeming acceptance, for years, of different price structures for different purchasers," explained Brewer. "These three smaller laboratories asserted that Medi-Cal had known of the differences in charges for which they regularly reimbursed the labs, and they rejected Medi-Cal's claim that it provided clear guidance on reimbursement practices."

With the settlement of this *qui tam* lawsuit in California, the action shifts to six other states where it is known that similar whistleblower lawsuits are active. These lawsuits are in Florida, Georgia, Massachusetts, Virginia, Michigan, and Nevada. TDR

—By Joseph Burns

Contact Dawn Brewer at 310-666-2267 or dawn@dbrewerlaw.com.

Lab CEOs Comment On Their Settlements

COMMENTING ON THE LATEST SETTLEMENTS, Alfred Ramzi, CEO of Physicians Immunodiagnostic Laboratory, Inc., (PIL) said, "The 130 employees of PIL feel vindicated by today's agreement, and we are recommitting ourselves to maintaining the highest standard of conduct for our industry. We hope the conclusion of the case will now lead to a dialogue with regulators about what is needed to ensure a level playing field and open competition among laboratories of all sizes."

Erik Avaniss-Aghajani, CEO of Primex, said, "This resolution to the costly and disruptive detour from running our business demonstrates that, despite the competitive disadvantages of being named as a defendant in the case, we defended our practices as fair and in compliance with the dozens—if not hundreds—of billing instructions that govern our industry."

Jatin Laxpati, President of Whitefield Medical Laboratory, commented, "Our clients–and our competitors for that matter–understood that we vehemently denied that we had improperly charged Medi-Cal for testing. After reaching this resolution, we are anxious to return our focus to service to our loyal and valued clients."

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

China-based **Kindstar Globalgene Technology, Inc.** (Kindstar), of Wuhan, Hubei Province, entered into an agreement to acquire and use the web-based anatomic pathology laboratory information system (APLIS) developed and sold by **PathCentral, Inc.**, of Irvine, California. Kindstar intends to deploy the web-based APLIS service across its corporate laboratory facilities. It will also implement the PathCentral APLIS in the labs of its hospital clients across China. Kindstar's strategy is to use this pathology informatics "Software-as-a-Service" (SaaS) solution to automate some manual processes and create an integrated informatics network that connects its various lab facilities with those of its client hospital labs.

MORE ON: *Kindstar*

The other benefit of the PathCentral SaaS solution is a smaller up-front investment. It "...will allow us to integrate our laboratory facilities and connect electronically to our broad base of hospital clients without making a large capital investment," declared Shiang Huang, M.D., Kindstar Founder and CEO, in the press release. Kindstar reports that it has 2,000 of China's 20,000 hospitals as clients. Kindstar also has a multi-year laboratory testing agreement with **Mayo Clinic** that was announced in June, 2011.

TRANSITIONS

• Effective on January 23, 2012, Francisco (Frank) R. Velázquez, M.D., will become CEO of **Pathology Associates Medical Laboratories** (PAML), based in Spokane, Washington. Velázquez served with **Quest Diagnostics Incorporated** at both **Nichols Institute** and **Focus Diagnostics**. A pathologist, Velázquez has held positions at several academic institutions, including the **University of Texas Southwestern Medical Center**.

CORRECTION FOR DEC 19, 2011 ISSUE

In reporting the retirement of David G. Beckwith, M.S., Ph.D., as President and General Manager of **Health Network Laboratories, Inc.**, of Allentown, the name of the Beckwith's laboratory was incorrectly listed as "Health Line Clinical Laboratories," which some readers will recognize was the name of a now-defunct laboratory company that was located 3,000 miles away in California.

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 acquisition of **S.E.D. Medical Laboratories**, owned by **Lovelace Health System** of Albuquerque, New Mexico, by **Quest Diagnostics Incorporated**. Quest will also manage in-patient labs at four Lovelace hospitals

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, January 30, 2012.

Registration Now Open!

EXECUTIVE WAR COLLEGE

May 1-2, 2012 • Sheraton Hotel • New Orleans

*Preview–**Paul Mango**, McKinsey & Co. on...*

Understanding ACOs, Integration of Clinical Care, and Healthcare's Changing Landscape

Here's your opportunity to learn about the transformational potential of ACOs and the new models of integrated clinical care—and how they will fundamentally reshape the way physicians use lab testing services. Nationally-recognized for his strategic understanding about the healthcare market, Paul Mango—himself a veteran lab industry executive—will make surprising predictions about the growth of private Medicare plans, while recommending effective strategies for clinical labs and pathology groups. This is a "can't miss" session!

Check for program details and to register!
visit www.executivewarcollege.com

UPCOMING...

- ***Two Successful Hospital Regional Laboratory Networks Share Secrets of Building Outreach and Payer Contracts.***
- ***Regulatory Land Mines Ahead for Lab Testing Industry: Why 2012 Will Bring Unpleasant New Requirements.***
- ***How 262-Bed Hospital Laboratory Used ISO 15189 QMS to Slash Number of Lab Errors and Cut Lab Test TAT.***

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