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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Lean Six Sigma Takes Root in Labs & Hospitals

LAST WEEK, MORE THAN 300 ENTHUSIASTIC LAB AND HOSPITAL PROFESSIONALS from 11 different countries around the globe crowded into Atlanta for the Second Annual *Lab Quality Confab*. They were gathered to hear the latest success stories and breakthroughs in how laboratories and hospitals are using quality management methods like Lean and Six Sigma.

If anyone remains skeptical about the value of Lean and Six Sigma to improve outcomes and workflow in healthcare, more than 50 presentations and case studies by some of America's first rank laboratories, hospitals, and health systems demonstrated the remarkable gains that well-executed process improvement projects generated for their organizations.

Evidently I am not alone in believing in the value of Lean and Six Sigma management methods to play a role in meeting the healthcare system's challenges of improving quality, reducing errors, and lowering costs. The demand for experienced Lean and Six Sigma professionals to work in the nation's hospitals and health systems is so great that management recruiters are struggling to find candidates to fill these positions. Healthcare magazines are writing stories about this staffing gap.

Our Editor, Robert Michel, tells me that this year's speakers at *Lab Quality Confab* displayed much more sophistication as they discussed improvement projects in every area of clinical laboratory and pathology laboratory operations. I take that as an early warning for those laboratories and pathology groups which have yet to implement Lean and Six Sigma. The competitive bar is being raised by your peers and colleagues! Just as **General Motors**, **Ford**, and **Chrysler** found themselves outcompeted by Japanese car manufacturers (using these quality management methods) in the 1970s and 1980s, so also will those labs and hospitals who are slow to understand the power of Lean and Six Sigma to lift their performance—and their profits—find themselves at competitive disadvantage in the laboratory services marketplace.

Across the American healthcare system, the pace of change and reform seems to be intensifying. Adoption of Lean and Six Sigma by labs, hospitals, and health systems is playing a major role in this transformation. In coming weeks and months, THE DARK REPORT and *Dark Daily* will bring you "the best of *Lab Quality Confab*" so you and your management team can learn from these top-performing laboratories, hospitals, and health systems. TDR

iTunes Business Model For Digital Path Scans

Things heat up in digital pathology market as BioImagene introduces 99¢ per slide pricing

CEO SUMMARY: If BioImagene's CEO is to be believed, the company is ready to deliver a digital pathology system that is robust and affordable, even in settings with just two or three pathologists. One key to the BioImagene strategy is "per scan" pricing that avoids the need for upfront capital to acquire its system. Confident investors just pumped $26 million into BioImagene and, as of this month, its new CEO is a 20-year veteran of Siemens, who was leader of its Image and Knowledge Management business.

ITUNES PRICING COMES TO anatomic pathology. Imagine purchasing digitized pathology images based on the iTtunes pricing model of 99¢ per scan!

That's the business strategy of **BioImagene Inc.** (*www.bioimagene.com*), of Cupertino, California. BioImagene intends to make digital pathology affordable to hospitals and pathology groups of all sizes—even groups with just two or three pathologists.

Evidently professional investors are impressed with both BioImagene's digital pathology systems and its unorthodox pricing model. This summer, BioImagene closed a $26 million round of financing, with **Burrill & Company** of San Francisco, California as a lead investor. Rounding out the investors were **Acension Health Ventures**, **National Healthcare Services**, **Artiman Ventures, and ICCP Ventures**.

Further evidence of BioImagene's potential are two additions to its management team. At the closing of the $26 million financing package, Steven Burrill, CEO of Burrill & Co., assumed responsibilities as Chairman of BioImagene's Board of Directors. He issued the confident statement that, "the company has established itself as a clear innovation leader in digital pathology over the past years, and is well positioned to lead the market."

The strength of BioImagene's digital pathology technology and its market strategy helped it recruit another executive heavyweight. On September 17, BioImagene announced that Ajit Singh, Ph.D., was its new CEO. Singh comes to BioImagene from Erlanger, Germany, where he was CEO of the Image and Knowledge Management business of

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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).

Siemens Healthcare. He worked at Siemens for nearly 20 years in various roles.

Founder and former CEO of BioImagene, Mohan Uttarwar, is now Chief Strategy Officer. In discussing his company's future with THE DARK REPORT, Uttarwar explained that his company has ambitions to change the current business model for digital pathology. "The first step is to change the thinking of most pathologists, who believe, because of cost and other considerations, digital pathology systems are just for large pathology groups and hospitals," he stated. "That thinking is no longer accurate!

"We believe our current generation of digital pathology systems are compelling, comprehensive, and affordable—even for groups with only two or three pathologists," declared Uttawar. "We are working to change the paradigm. Our mission is to make digital pathology the standard of care, just like what happened in radiology. Our system is designed by pathologists for pathologists and we believe market forces are already in motion that will make digital pathology systems a necessity for all pathology groups."

➤Good Timing For Growth

Uttarwar and BioImagene may also benefit from good timing. As clients and regular readers of THE DARK REPORT know, momentum behind digital pathology is building. For example, **Aperio Technologies, Inc.**, (*www.aperio.com*) in Vista, California, is marketing its digital pathology systems in the United States, Australia, and other countries. Tucson, Arizona-based **DMetrix Inc.**, (*www.dmetrix.com*) is developing highly sophisticated digital scanners for pathology applications. *(See TDR, July 7, 2008.)*

However, probably the biggest boost to the future of digital pathology systems was the entry of imaging and radiology giant **General Electric** (GE) into the field of pathology imaging last June. That was when GE and the **University of Pittsburgh Medical Center** (UPMC) announced a new joint venture, called **Omnyx, LLC** (*www.omnyx.com*). The two partners will invest $40 million to develop and market digital pathology systems for primary diagnosis.

➤Two Years To Market

At the press conference last June, Omnyx executives stated that their goal was to have their products cleared by the FDA and into the pathology marketplace within two years. Omnyx promises that its system will perform whole-slide scanning in 30 seconds. *(See TDR, June 16, 2008.)*

Gene Cartwright, CEO of Omnyx, caused quite a stir with one prediction when he stated, "We envision the market [for digitized pathology systems] will expand to be about a $2 billion market in several years. We will be addressing the market on a global basis, and we expect it to be adopted at about the same rate that digital radiology was adopted."

Another indication of how fast things are changing in the market for digitized pathology systems is a milestone achieved by BioImagene. "We have already placed 40 systems since January and will be the first company to introduce a new digital pathology system and have 100 of those systems deployed within one year," declared Uttarwar. "That will happen later this year and it will be a feat unmatched by any existing company selling digital pathology systems today.

➤Enterprise Software

"That market acceptance underscores what we consider to be a fundamental difference between our company and the others in this market," Uttarwar said. "We believe that digital pathology is built on enterprise software, which we have. Yes, of course you need instruments and scanners. But you also need software to analyze digital images. Over the years, we have partnered with almost all the companies in this field. That means our software works with all the systems. We believe this

Apple's iTunes 99¢ Pricing Model Inspires BioImagene's Per-Scan Pricing Strategy

MOST PEOPLE KNOW ABOUT THE PRICING MODEL FOR APPLE'S ITUNES. Open an account at the online iTunes store and pay 99¢ cents for each song you download. That was the inspiration for executives at BioImagene, Inc., who were looking for marketing strategies that would encourage pathologists to acquire and use digital pathology systems.

Despite the significant differences between downloading a song and digitizing a slide of human tissue, BioImagene's executives saw parallels in using the iTunes pricing policy in digital pathology. "Can you beat that price of 99¢ per scan?" asked Mohan Uttarwar, BioImagene's Chief Strategy Officer. "We know that laboratories make 200 million slides every year. But the number of pathology slides currently scanned is quite small—only a couple of percentage points of that 200 million number.

"So, we asked ourselves, 'What does it take to jump start the digital pathology market?' We were inspired by the iTunes example, where the Apple iPod, in combination with the 99¢-per-song download at the iTunes store, became the most successful online music business in history," he said.

"BioImagine knew its digital pathology technology was robust and affordable," recalled Uttarwar. "But technology alone would not accelerate market acceptance by hospitals and pathology groups. We wanted to combine our innovative technology with an innovative business model. These two elements would work together to accelerate market acceptance.

"The up-front investment in an integrated, fully-digitized pathology system is significant, because most companies in this market sell large systems that cost about $200,000 each," noted Uttarwar. "When a pathology group puts all the pieces together, buys the software, and does the integration, total costs can approach $500,000. Because of these costs, typically it is academic groups and larger hospitals and pathology groups that acquire and use an integrated digital pathology system.

"On the other hand, much of pathology is performed in lower-volume settings," he added. "For example, two or three pathologists work together in a group or a smaller hospital, and these sites are often part of a multi-hospital health system or integrated pathology group practice.

"Most pathologists work in these types of settings, yet there was no digital product for that segment of the pathology market," observed Uttarwar. "That is why BioImagene developed a digital pathology system that has a small footprint, a lower price point, is compact, and integrates easily with other laboratory systems.

"To appeal to this rather large segment of the pathology profession, we designed a pricing structure which requires no capital expenditure. That's a paradigm shift!" he enthused. "BioImagene's pricing model is 99¢ for each slide scanned. If the pathologist wants to add diagnostic tests, that's about $10 per test. We have some minimums, such as we expect 1,000 slides to be scanned each month. However, that volume is something that is commonly generated by a couple of pathologists with no problem."

feature gives BioImagene a recognizable competitive advantage in the digital pathology market."

That's not to say that Uttarwar underestimates his competition. "Aperio is aggressively putting marketing dollars behind its products," he noted. "DMetrix challenges all of us with its scanning innovations. Everyone is waiting to see what GE and UPMC develop at Omnyx.

"We welcome these companies, because the pathology imaging industry is growing at a pace where no one company can be the dominant player," explained Uttarwar.

"Digital pathology will probably be much like the radiology market in that it will have three or four solid players. As demand for digital pathology products expands, all these digital pathology companies will help each other by growing the national and global market for pathology imaging."

➤Fast-Moving Developments

THE DARK REPORT recommends that pathologists and their practice administrators recognize the importance of these developments in digital pathology, as well as the unique nature of BioImagine's iTunes per-scan pricing strategy. First, it demonstrates how steady advances in information technology, including hardware and software, are rapidly changing both the capabilities and the economics of digital pathology. Costs are coming down, even as functionality and speed improves.

Second, the field of competitors offering digital solutions to pathology groups is growing. BioImagene, Aperio, and DMetrix have entered the market in recent years. Certainly established vendors selling microscopes and other imaging systems will not cede this market and have their own solutions to offer pathologists.

Third, THE DARK REPORT observes that BioImagene's adoption of iTune's pricing model, offered to pathologists at 99¢ per scan, shows how longstanding business practices in anatomic pathology will be upended. Pathologists are going to see disruptive marketing strategies and disruptive clinical technologies tumble into the profession as aggressive vendors borrow what works outside healthcare and bring it into laboratory medicine.

➤Digital Pathology Era Is Here

Finally, the accelerating number of placements and sales successes of Aperio, BioImagene, and DMetrix, among others, should be convincing evidence that the pathology profession has crossed the threshold and is now squarely in the early stages of an era of digital pathology. TDR

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Will Digital Pathology Lead To Outsourcing to India?

IN THE UNITED STATES, MANY PATHOLOGISTS are concerned that digital pathology will create opportunities to outsource pathology to lower-cost countries, such as India and China. But one digital pathology expert believes this is wrong thinking, for a surprising reason.

"Not likely to happen!" said Mohan Uttarwar, Chief Strategy Office for BioImagene Inc. "This phobia is rooted in a belief that digital pathology, computers, and the Internet will take jobs outside this country because pathologists in China and India will soon do the work of pathologists here in the United States. Yes, digital pathology gives us a way to work across borders. But it can also enable work to flow into the United States.

"The benefits of digital pathology are significant because it allows a pathologist to work remotely," he noted. "You can get a second opinion or an informal review at the click of a button. Your colleague could be around the corner or around the world. All of this work can be done easily. And doing so is simple and affordable. In fact, our goal is to have no barriers to get onto the digital pathology platform.

"But contrary to what some pathologists think, we find that pathologists in Mexico, China, and India want to get second opinions from pathologists here in the United States!" Uttarwar explained. "This is particularly true for those pathologists who treat patients at the higher end of the spectrum. They want to tap the expertise of the well trained and well educated pathologists here.

"We find keen interest from pathologists in many countries to refer cases to the United States," stated Uttarwar. "Yes, outsourcing of pathology will happen, but is is likely to be pathologists in other countries outsourcing to pathologists here in the United States."

Illinois Pathologists Dodge Medicaid CP Payment Cut

Illinois Medicaid Program was prepared to end payment for clinical pathology professional services

CEO SUMMARY: Pathologists in Illinois acted swiftly to this month's announcement that the Illinois Medicaid program would cease to directly pay pathologists directly for clinical pathology professional services. The new policy was to take effect on October 1, 2008. As this issue of THE DARK REPORT goes to press, there is breaking news that educational efforts by the Illinois Society of Pathology have led the state's Medicaid program to rescind implementation of the announced cuts to CP professional services.

ONCE AGAIN, clinical pathology professional component reimbursement is under attack by a payer. However, swift action by pathologists appears to have forestalled efforts by one state's Medicaid program to cease direct payments for these services.

It was September 9 when the **Illinois Department of Healthcare and Family Services (DHFS)** said it would no longer reimburse providers for the professional component (PC) of automated laboratory services, effective October 1, 2008. The net effect for individual pathologists in Illinois was predicted to be a loss of about $25,000 for the year. For pathology groups in Illinois, the loss could have been as much as six figures annually.

Now comes news that the Illinois Medicaid program has decided not to cease payment for clinical pathology professional services. The decision was made following meetings that took place last week between pathologists and representatives from the **Illinois Society of Pathologists** (ISP) and officials from the Illinois Department of Healthcare and Family Services.

"IDHFS said on Friday, September 26, that it would reduce its base rate for automated lab services by 25% for the professional and the technical component rather than eliminate the professional component fees," stated ISPs Executive Director Pamela Cramer today in an interview with THE DARK REPORT. "The change will be effective October 1.

"Pathologists are waiting for IDHFS to issue its fee schedule so they can determine the net effect of the change in reimbursement," she added. "What the IDHFS has done is change the formula. They are leaving in the professional component and instead the department will reduce its base rate. They are recognizing the professional component, which is good for pathologists. But it's still a 25% cut for the professional and the technical component.

"One positive outcome triggered by this issue is that, we have developed a good relationship with the IDHFS now and they recognize what pathologists do," stated Cramer. "Following numerous meetings and phone calls, IDHFS now better appreciates pathology services.

"Previously, IDHFS was simply making a blind cut based on how other state Medicaid programs reimburse for pathology. They didn't realize that the rates in Illinois are different than they are in other states.

"Pathology is such a small percentage of total state spending and IDHF officials didn't have a precise understanding of what pathologists do," continued Cramer. "Now, this issue has given the Illinois society an opportunity to have a relationship with IDHFS. After meetings last week, IDHFS officials said, 'Thank you for enlightening us. We had no idea.' So, in that respect, it was a win-win."

When it announced this no-payment policy on September 9, DHFS stated that the change would affect CPT codes 80000 through 85999. Any claim submitted with a 26 modifier would also be rejected.

While news that the Illinois Medicaid program will continue to pay for clinical pathology professional component services is welcome, the trend of payers targeting reimbursement for these services remains worrisome. "Over the past past 10 years, a number of public and private payers have ceased payment for clinical pathology professional component services," said Mick Raich, President and CEO of **Vachette Pathology**, a company in Blissfield, Michigan, that provides business services to pathology groups nationwide. "Any time a payer establishes a policy of non-payment for clinical pathology professional services, it undermines the long term financial solvency of pathology groups."

Clinical Pathology Services

Since Medicare instituted Diagnosis Related Groups (DRGs) for hospital payments in the 1980s, fees for clinical pathology (CP) professional component services have been under attack by payers. Starting about five years ago, **Aetna**, **Humana**, and **United Healthcare** stopped paying for CP professional services," noted Raich. "This recent attempt by the Illinois Medicaid program shows that this trend has momentum. That's not auspicious for the pathology profession."

According to Attorney Jane Pine Wood of **McDonald Hopkins**, the attempted action by the Illinois Medicaid program action continues a trend established many years ago. "The Medicaid program in Illinois is one of the few that continues to pay pathologists directly rather than paying the hospital for these services," she explained. "The Arizona Medicaid program stopped paying pathologists for the clinical pathology professional component about eight or more years ago. Since then, we have seen that Medicare and many state Medicaid programs do not pay pathologists directly for these services.

Experts have warned against the use of arbitrary cutbacks to provider compensation as a way to balance state Medicare program budgets, declaring that this is a short-sighted policy. At some point, these arbitrary reductions in provider reimbursement will fall so far below the cost of providing such services, that physicians, including pathologists, will find it impossible to provide services to Medicaid patients.

Stepping from the Illinois state level to the national level, pathologists and laboratory administrators should recognize that a growing number of states are no longer able to fund their Medicaid programs at an adequate level, given three factors. The first is the year-to-year increase in the cost of health services.

The second factor is the increased utilization of health services by the beneficiaries covered by state Medicaid programs. These individuals often have multiple, chronic diseases and conditions and their healthcare needs can be both complex and expensive. The third factor is the increased number of beneficiaries who enroll in Medicaid each year. That raises the overall cost of a state's Medicaid program from one year to the next. **TDR**

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Lab Briefs

MED TECH SHORTAGE CAUSES DEVRY UNIVERSITY TO OFFER MT DEGREE

IN RESPONSE TO THE GROWING SHORTAGE of skilled lab scientists and medical technologists, **DeVry University** of Phoenix, Arizona, is offering a new bachelor's degree program in Clinical Laboratory Science (CLS). What is notable about this development is that DeVry is a private, for-profit organization and believes it can make money training students in clinical laboratory science.

A large, private training enterprise, DeVry is likely to spend money marketing its program and advertising the availability of jobs for MTs. Devry's new MT degree program also demonstrates that the shortage of MTs and MT training creates a business opportunity, one that many academic centers have been slow to address.

Significantly, DeVry named Naomi P. McMillan, M.S.A., to be its Academic Program Director for the new CLS degree program. Previously, McMillan served as chief of the Applied Technology Center of the **U.S. Air Force Institute for Operational Health** in San Antonio, Texas. She has 20 years of experience in clinical laboratory operations and management.

ANALYSIS DETERMINES WALK-IN CLINICS DO MEET NEEDS OF PATIENTS

WHEN IT COMES TO RELATIVELY MINOR HEALTH ISSUES, retail walk-in medical clinics are filling a consumer need for predictable, speedy, reliable healthcare services. Also, because clinics located in retail stores help patients avoid traditional medical settings, they are attractive to patients who want to avoid obstacles to care for minor ailments.

An analysis of these clinics was published in the journal *Health Affairs.* In the study, data was analyzed from 1.35 million patient visits at more than 300 clinics, including those operated by eight different companies in such stores as **Wal-Mart**, **CVS**, and **Walgreens**. Researchers determined that 67% of retail clinic patients have insurance and 60% do not have a primary care physician. About 90% of patients sought treatment for relatively simple treatments that don't generally require a physician's care, such as ear and upper respiratory infections, immunizations, and blood pressure checks. Essentially, these patients had minor conditions, were basically healthy, and wanted easy access to rapid treatment.

In his blog, *Lab Soft News,* pathologist Bruce Friedman, M.D., has said retail clinics are an attractive new model for healthcare delivery based, in part, on price transparency. But also they could become a significant venue for lab testing, he added. Laboratories could capitalize on this trend by implementing patient-friendly features and providing information for patients to make lab tests easy for consumers to find, access, and use. Labs could work with walk-in clinics to offer point of care testing at these clinics, for example.

VOLUME GROWTH IN MOLECULAR TESTING BOOSTS TWO PUBLIC LABS

INCREASED UTILIZATION OF MOLECULAR TESTS for certain cancers is fueling increased specimen volume and revenue at two public laboratory companies. Both **NeoGenomics Inc.**, in Fort Myers, Florida, and **Clarient Inc.**, of Aliso Viejo, California, reported similar gains on their most recent financial statements.

Molecular testing volume is growing by about 25% per year, according to Robert Gasparini, President and Chief Scientific Officer of NeoGenomics. He notes that this growth is driven, in part, by demand from an aging population and by

an increase in the number of new tests being introduced into clinical practice.

NeoGenomics describes itself as a high-complexity clinical laboratory that specializes in molecular and genetic testing for cancer. For second quarter 2008, Neogenomics reported a 108% increase in revenue, to $4.9 million. The company also said requisitions increased 69% and average revenue per requisition increased 24% to $835.

Clarient (formerly **ChromaVision Medical Systems Inc.**) said its revenue for the second quarter increased by 71%. It was $16.9 million compared with $9.9 million in the same quarter last year. Clarient has now reported 16 consecutive quarters of increased revenues. Testing volume for the second quarter rose by 60% over the second quarter of 2007. Clarient attributed this growth to a 30% increase in breast prognostics and solid tumor tests, an 86% increase in leukemia and lymphoma volumes, and a 98% increase in PCR/molecular testing.

Despite enjoying similar rates of growth in specimen volume and revenue, both companies had different financial outcomes. The smaller NeoGeonomics, which has funded its growth through its cash flow and retained earnings, posted net income of $72,000 in Q2-08, compared to a Q2-07 loss of $973,000. The much larger Clarient, which has been primarily funded by professional investors, reported a net loss of $4.3 million for the quarter. That was larger than the company's net loss of $3.3 million for Q2-07.

LAB FINDS RARE CASE OF BUBONIC PLAGUE

ONCE AGAIN, A LABORATORY IN THE UNITED STATES HAS DEMONSTRATED THE ABILITY to accurately detect a rare and often fatal disease. Pathologists at **Clinical Laboratory Partners** in Newington, Connecticut, identified an unusual disease-producing pathogen earlier this month: *Yesina pestis*, or bubonic plague.

Jaber Aslanzadeh, M.D., the lab's Director of Microbiology, said it was the first time he had identified the rare—and potentially deadly—specimen. The patient is believed to have contracted the infection while visiting Wyoming and was expected to make a full recovery.

CANCER LAB CLERK FACES CHARGES IN PATIENT ID THEFT

IT HAS HAPPENED AGAIN. An employee in a clinical laboratory is accused of patient identification theft. Police in Houston, Texas, issued an arrest warrant for a clerk in surgical pathology at the **University of Texas M.D. Anderson Cancer Center** in Houston. The clerk is accused of using patients' data to apply for credit.

Harris County prosecutors issued a warrant on Sept. 5 for Angelina Cloud-Equam, a 26-year-old former clerk at the cancer center who was wanted on charges that she stole identities of hospital patients. A spokesman for the cancer center said Cloud-Equam was fired after an investigation revealed that the clerk's home computer contained personal information on three patients at the center.

M.D. Anderson acted swiftly. In a public statement, it said it was in contact with the three individuals affected by Cloud-Equam's alleged crime to assist them in appropriate ways. The cancer center is also offering 12 months of free credit monitoring for any patients whose personal data might have been compromised by this laboratory clerk.

This case is a reminder for pathologists and lab directors. It demonstrates that labs are vulnerable to patient identify theft crimes. Every laboratory should be reviewing its protections against such crimes. In 2005, THE DARK REPORT published detail coverage about the nation's first successful prosecution under HIPAA laws of a phlebotomist who stole a dying patient's information and used it to steal almost $20,000 *(See TDR, April 18, 2005).* TDR

Implementation Date For ICD-10 Is Proposed

Department of Health and Human Services publishes ICD-10 launch date of October 1, 2011

CEO SUMMARY: Even though the transition from ICD-9 to ICD-10 will not be required until 2011, laboratories and pathology groups should have a transition plan in place. ICD-10's 155,000 seven-digit codes will replace the 17,000 five-digit codes of ICD-9. Because of major changes in the design of ICD-10, extensive training of laboratory coders will be necessary to ensure a smooth implementation. Referring physicians and their staff must also be trained and ready for ICD-10 if labs are to minimize denied claims.

THIS SUMMER, the **Department of Health and Human Services** (HHS) proposed to make the International Classification of Diseases, Tenth Revision (ICD-10) code sets (ICD-10) effective on October 1, 2011.

This proposal was met with considerable opposition by the payer community. Effective lobbying may lead to a further delay in implementation of ICD-10. But that does not change the fact that laboratory administrators and pathologists should have ICD-10 implementation on their radar screen. There are powerful forces at play that encourage U.S. adoption of ICD-10.

For example, since ICD-10 was finalized in 1992, most developed nations already use it. That puts the United States behind in producing the type of healthcare data that is useful in advancing evidence-based medicine (EBM) and other important health data sets.

Also, work is progressing on ICD-11. As early as next year, the first draft of the ICD-11 system may be released. Expectations are that ICD-11 will be published by 2015. As a side note, the **World Health Organization** has already announced that Web 2.0 principles and capabilities will be incorporated into ICD-11.

These facts illustrate why health policymakers are under pressure to introduce ICD-10 in the United States. This country is as much as 15 years behind other countries in its use of ICD-10. And, every year that it delays implementing ICD-10, the United States faces the possibility that it could be two generations behind, once ICD-11 is ready for adoption.

Complications Expected

"Labs can expect a variety of complications when implementing the systems required to comply with ICD-10," noted Lâle White, Founder and Executive Chairman of **XIFIN, Inc.**, a company in San Diego, California, that specializes in laboratory accounts receivable and financial management operations. "We fully expect to see a wave of claims rejections when the new system goes into effect.

"Lab administrators and pathologists must address this issue in three dimensions," continued White. "One, every laboratory's information systems must be

changed to account for the new format (3 to 7 characters) and associated editing functionality for medical necessity, CCIs, and OCEs. Two, coding staff will need training in how to use the new ICD-10 codes. Three, labs must help referring physicians prepare for ICD-10 implementation. Physicians and their staffs will require training in how to use the new code sets and how to comply with updated medical necessity rules.

"One caution about the new ICD-10 system," observed White. "It is designed to be a richer set of data. That means carriers will have more tools for monitoring fraud, because the system allows for better edits for diagnosis/CPT code combination errors. Also, because much more information is associated with each code, ICD-10 coding can be used to implement pay-for-performance criteria.

Initial Problems For Labs?

"Although there is much discussion about better, cleaner, and faster reimbursement because of ICD-10, I see more problems for labs in the initial phases of implementation because more claims are likely to be rejected," she commented. "As medical necessity and coding edits become more complex, the number of rejections increases. That means laboratories will have to work harder to clean up rejected claims and to do more physician training.

"In the past, when coding changes were implemented, the level of denials increased. Further, labs have struggled for years to lower the denial rate from missing and incomplete diagnoses provided by physicians," White warned. "That is why moving to ICD-10 could be a perfect storm for some period of time. Payers currently use more edits. Because IDCl-10 makes it possible for enhanced edits, and because ICD-10 requires more complicated diagnosis information, these factors are likely to result in more denials of laboratory claims.

"With ICD-10, labs will also be challenged to ensure that both laboratory staff and referring physicians are prepared for the new codes," added White. "Labs will need to determine if they have sufficient data to accurately translate physicians' narrative diagnosis descriptions into the proper ICD-10 code. The complexity and increased specificity of the new codes will not facilitate effective coding by lab staff and will likely require software solutions at the source of the information.

A Challenge for Labs

"Implementation of ICD-10 codes is scheduled to go live in 2011," noted White. "Today, this seems like plenty of time. However, these things seldom go as planned. Plus, human nature is to wait until the last minute to prepare. We know from experience that the system always encounters problems. For example, during the transition to the new National Provider Identification (NPI) numbers that took place earlier this year, most labs experienced plenty of problems getting accurate, timely payment for claims they submitted."

White observed that the Medicare program has a significant amount of work to do before it is ready to implement ICD-10. "For its part, the federal **Centers for Medicare & Medicaid Services** (CMS) needs to make a number of changes before ICD-10 can be successfully implemented," she said. "For a starter, CMS will need to revise its national coverage determinations (NCDs) just as local Medicare carriers will need to revise their local coverage determinations (LCDs).

"Next, CMS must update its outpatient code edits. These identify inconsistencies between the gender of a patient and a diagnosis to accommodate the new diagnoses and new more specific codes contained in ICD-10," explained White. "The Correct Coding Initiative (CCI) also will need revisions."

New HIPAA Standards

"Another important issue is the serious systems changes required to accommodate ICD-10 codes under the Health Insurance Portability and Accountability Act (HIPAA)," she stated. "Under HIPAA standards, we will move from what are

Transition from ICD-9 to ICD-10 Will Require Extensive Preparation by Labs and Path Groups

REGARDLESS OF WHETHER THE IMPLEMENTATION DATE for the new ICD-10 codes remains 2011 or is moved back to 2012, laboratories and pathology groups have plenty of work ahead.

"ICD-10 codes will bring plenty of benefits once implementation is achieved," predicted Lâle White, Founder and Executive Chairman of XIFIN, Inc., based in San Diego, California. "But it will take much preparation and training for laboratories to make a successful transition from ICD-9 to ICD-10."

"ICD-10 codes offer more precision," she said. "There are 17,000 codes in ICD-9. By contrast, ICD-10 contains more than 155,000 codes. These new codes are seven digits, rather than the current five digits.

"This enriched set of 155,000 codes will initially complicate coding for physicians, despite the insistence by some observers that coding will be easier," White advised. "It also explains why re-education is required for everyone who does coding—from the ordering physician's office all the way to the coders within a lab.

"Currently labs don't actually code the disease states," she explained. "They translate verbiage provided by an ordering physician into an ICD-9 code. Once ICD-10 is implemented, doing that translation will be more difficult because a more extensive amount of narrative will be needed for a lab to do the proper translation.

"In fact, moving to ICD-10 may end the practicality of their being able to do this translation," she added. "Because of this complexity, it may turn out that the onus on providing the right diagnosis code will be on the referring physician.

"Since it will be more difficult to do these translations, lab coders will have to be more knowledgeable about anatomy, disease states, and diagnoses than they are today because ICD-10 is more complex," she said.

"The complexity and the increased number of codes available in ICD-10 means that both physicians' offices and labs will need to rely more heavily on electronic tools to do diagnosis translations instead of looking up codes in manuals as they do now," she predicted. "That is a likely outcome and, of course, using electronic tools will make this work easier for some people and over time it should contribute to coding that is more accurate and more consistent."

called the HIPAA 4010 transaction standards to HIPAA 5010.

"Federal officials have worked for some time on the transition to HIPAA 5010, yet it is still not fully ready," observed White. "At the same time, some payers have yet to implement all of the 4010 transaction standards, despite regulatory compliance requirements. Many payors still do not provide a fully compliant electronic 835 remittance file, claims status files, or standard eligibility transactions.

"For all these reasons, our healthcare system has plenty of work to do before a successful implementation of ICD-10 can take place," said White. "This holds true for laboratories and pathology groups. Therefore, it makes sense that labs should join other providers in requesting that the implementation date be pushed back into 2012."

THE DARK REPORT observes that, while October 1, 2010 is more than 36 months away, the work required to ensure a smooth transition is extensive. Not only must labs train staff on the details and nuances of ICD-10 coding, But labs must also ensure that all referring physicians have the requisite systems, a thorough understanding of the new code sets, and training in how to use them properly. **TDR**

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Regulatory Update

Current Review of CLIA Standards Intended to Address Laboratory PT

EFFORTS ARE UNDER WAY TO REVIEW existing requirements for laboratory certification under the federal Clinical Laboratory Improvement Act (CLIA). CLIA legislation was a response by Congress to widely-publicized failings in the quality and performance of certain cytology and office laboratories during the 1980s. It has been 16 years since the existing requirements took effect.

It was 1992 when these CLIA laboratory certification standards were published by the **Centers for Medicare & Medicaid Services** (CMS) and became effective. Since that time, laboratory medicine has seen new technologies, new assays, and new laboratory practices become accepted into clinical practice. The objective of this unfolding review and revision to CLIA laboratory certification requirements is to reflect these changes in laboratory practices in the CLIA laboratory standards.

In a recent intelligence briefing on the subject of quality management systems (QMS), THE DARK REPORT commented that it was likely that the "impending reform and updating of CLIA standards will include a requirement that, to maintain status as a CLIA-licensed laboratory, the candidate laboratory must demonstrate its effective use of quality management systems in its daily operations." *(See TDR, August 18, 2008.)*

No Plans For QMS Standards

"That is simply not the case," stated CMS Director of Laboratory Services, Judy Yost, in a recent telephone interview with THE DARK REPORT. "There is no plan to review and incorporate the principles of quality managment systems into current CLIA standards any more than what currently exists."

Yost further noted that the ongoing review is neither a reform nor a major overhaul to existing CLIA requirements. "What is intended is to update the proficiency testing (PT) standards for laboratories, PT programs and the list of analytes for which PT is required to better align with the current practice of laboratory medicine," she stated. "At its core, CLIA is a program to ensure quality testing in laboratories covered under these regulations."

CLIA Licensure Standards

One factor that increases the complexity of developing appropriate CLIA laboratory licensure standards is that the requirements must be appropriate to support accurate testing in a variety of laboratory types and settings. More than 206,000 CLIA certified laboratories operate in this country. These labs can be small and located in physicians' offices, clinics and a multitude of other sites. They include the various laboratory testing sites in hospitals, integrated healthcare systems and reference laboratories.

Since introduction of the CLIA laboratory certification program in 1992, CMS' inspection and proficiency testing (PT) data indicate improved performance over time. As well, there have only been isolated examples where a laboratory has systematically failed in ways that put patients at risk because of inaccurate or false test results. TDR

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Phlebotomy Automation Likely To Be Next Trend

Goal will be to reduce variation in outcomes and raise the quality of individual work processes

CEO SUMMARY: Here's a prediction that automation of work processes for phlebotomy, specimen collection, and specimen transport may be the next trend. Unfolding developments in the United States are creating a situation parallel to what was seen in Japanese hospital laboratories more than two decades ago—and led to the world's first automated solutions for clinical laboratories. Another factor to enable this trend are recent advances in technology and miniaturization.

By Robert L. Michel

Is phlebotomy and specimen collection the next area of laboratory work flow to undergo automation? There are several reasons why one can answer this question with a "yes."

First, one consequence of the use of automation, particularly in accessioning/pre-analytical and in the high volume core lab, is recognition of how automation contributes to reducing variation in outcomes, including more consistent turnaround times as well as overall improved quality.

Second, once laboratory staff has used automation to improve work flow in both the pre-analytical stage and the analytical stage, they want to identify other sources of errors in the laboratory work flow. This sets up the use of automation as a tool to reduce these errors.

Third, the growing use of Lean, Six Sigma, and similar process improvement methods reinforces an operating mind set of continuous improvement. Staff in Lean labs constantly seek ways to reduce the source of errors and identify opportunties to lessen variability produced by individual work processes.

The Dark Report believes that each of these three factors, as they become rooted in an increased number of clinical laboratories here in the United States, will collectively act to create a demand for products that automate specific work processes in phlebotomy, specimen collection, and transport of specimens into the laboratory.

Automation Path Of Labs

This is a natural outcome from the automation path most laboratories have taken. Typically, the first automation solution implemented involved the high volume core laboratory. Often it was creating an automated track to transport specimens from one instrument to another. Another approach was use of a consolidated analyzer that put chemistry and immunochemistry into an integrated instrument system.

Whatever specific automation solution was used in the high volume core laboratory, two improvements were quickly confirmed by data. One, the automation

reduced errors often related to manual handling of individual specimens. Two, there was a notable reduction in variability of quality and turnaround times.

It is a similar story for laboratories that next used automation in accessioning and pre-analytical work flow. Again, automation contributed to fewer errors and less variability in how each specimen was handled and processed.

Demand For Automation

Here is where the future of the lab industry becomes interesting and leads to a demand for automated phlebotomy and specimen collection solutions. What does a laboratory do next to improve quality if it has already installed automation in both accessioning/pre-analytical and the high volume core laboratory?

To continously improve, this lab must next identify the largest source of errors. Invariably, the process improvement teams look at the work steps upstream of accessioning. This puts phlebotomy, specimen collection, and specimen transport on the radar screen. Because these work processes remain manual and few phlebotomists adhere to standard work, data on the existing state generally reveal that errors and variability in outcomes typically fall far short of a Six Sigma level of performance (only 3.4 million errors per million events).

Going Upstream To Improve

This sequence of developments, as it occurs in the United States, supports the prediction that a demand for automated phlebotomy and specimen collection solutions is likely to emerge. How many years are required for an active market to develop is uncertain. What can be said, with a high degree of confidence, is that laboratories—using process improvement methods in tandem with automation solutions—will eventually go upstream in the pre-analytical work flow. They will identify phlebotomy and specimen collection as having high potential for improvement.

Of course, some of this is happening already. Automated systems to aid in patient identification and to help phlebotomists produce labels for specimen containers are already in the marketplace. But the level of phlebotomy automation that is typical in Japan, Korea, Taiwan, and other asian countries has yet to occur in the United States.

Following trips to Korea (2006) and Japan (2008), THE DARK REPORT has alerted clients and regular readers to the rather remarkable and widespread use of automated phlebotomy systems in hospital laboratories. *(See TDRs, May 5, 2008, and May 1, 2006.)* In fact, this extensive use of automated phlebotomy systems by hospital labs in Japan and Korea is one aspect that makes them different from hospital labs in the United States.

Differences In Japan

As I puzzled over why this difference exists during this year's trip to Japan, I recognized two reasons why—in this operational aspect—labs in Japan have evolved differently from labs in the United States. One reason has to do with mind set. The other reason has to do with volume. Both reasons worked together in Japan to create an opportunity to improve laboratory operations in ways that have not existed in our country.

Reason One: Japanese people understand and respect the concept of "kaizen", loosely translated as "continuous improvement." This is the reason why, when several innovative pathologists began to develop the world's first laboratory automation systems early in the 1980s, they were inspired and guided by the continuous improvement mind set. This caused these pathologists to constantly look for the next source of improvement in their labs' workflow and individual work processes.

For example, once they had designed automated solutions for the analytical stage in their laboratories, they quickly looked upstream in the work flow and saw

Labs in Japan and South Korea Take Two Paths To Automate Phlebotomy & Specimen Collection

By Robert L. Michel

DURING VISITS TO HOSPITAL LABORATORIES in Korea (2006) and Japan (2008), I saw automated phlebotomy/specimen collection systems being used in two ways.

The first approach was automation in the patient service center. When a patient presented at reception with the test request, this information was either entered into the information system, or, if an electronic test order, confirmed against that order in the computer.

Here is where the automated phlebotomy system takes over. That patient's order is received by an automated system that selects the collection materials and evacuated blood collection tubes needed, prepares and applies the correct identification labels, then assembles these items into a small collection tray.

Next, this collection tray is sent out, via a transport line, to the phlebotomist's work station where the specimen collection will take place. Commonly, the transport line runs under the bench tops of the draw stations.

Transporting Specimens

Once the collection is completed, the phlebotomist puts the collection materials back in the collection tray and places the tray on a different transport line. This transport line takes the specimens directly into the laboratory, where automated systems process the specimens, then send the specimens to the correct analyzers.

Two comments about this arrangement. First, in sites where I observed this method of phlebotomy/specimen collection automation, the hospital stood next door to a large outpatient clinic. The patient service center was a central site and was often drawing between one and two thousand patients each day. That volume helps generate a return on investment from this automation solution. Also, by collecting specimens directly next to the central laboratory, it is possible to utilize an automated transport line that takes specimens directly into the laboratory and supports automation in pre-analytical and analytical stages.

During a Korean hospital laboratory site visit, the automated phlebotomy equipment in use for this type of arrangement was manufactured by **Astech Corporation** of Osaka, Japan. Its products can be found at: *http://www.astech.co.jp/e/products/index.html.*

Automated Phlebotomy

The second approach involved an automated phlebotomy unit that stands in the central laboratory. When a test request is received, it is entered in the automated system. The automated system then selects the correct collection materials and evacuated blood collection tubes. These are labeled and inserted into a collection tray. This collection tray is transported to the correct location in the hospital by a pneumatic tube or other automated system. The phlebotomist uses these collection materials with the patient, then sends the collection tray back to the laboratory using the same transport system. Upon arrival back at the laboratory, the specimens go right on the pre-analytical line.

Our Japanese and Korean laboratory hosts, in discussing these automation solutions in phlebotomy and specimen collection, pointed out how automation reduced manual handling errors and reduced the chance of the phlebotomist selecting the wrong collection supplies. Automation of the labels eliminated the possibility that the phlebotomist would either use the wrong patient label or apply the labels incorrectly, leading to problems on the automated line in the laboratory.

One system used in this arrangement that I saw on my lab tours is made by **Techno Medica Co., Ltd** of Yokohama, Japan. Its phlebotomy automation solutions can be viewed at: *http://www.technomedica.co.jp/t02/en/products/bc-robo.htm.*

the improvement opportunities that existed in accession and specimen processing. Once those improvements were harvested, these pathologists looked further upstream and recognized that phlebotomy, specimen collection, and specimen transport—if automated properly—could deliver further improvements in quality, turnaround time, productivity, decreased variation, and reduced costs.

Reason Two: Phlebotomy automation has flourished in Japan and is non-existent in this country because of a characteristic of laboratories in larger Japanese hospitals. The size of these laboratories generates economies of scale not seen in hospital laboratories in the United States.

Many hospitals in Japan are larger than the largest hospitals in the United States. For example, only a handful of hospitals in the United States exceed 1,500 beds. Japan has many hospitals larger than 1,500 beds. This means the large Japanese hospital laboratory tests large numbers of patients daily. This volume of specimens triggers economies of scale that make it easier to realize benefits from using automation in many work flow steps within the laboratory.

Another difference in Japan from the United States is that the larger hospitals commonly have an outpatient clinic attached to the hospital building. This outpatient clinic may see between 2,000 and 5,000 patients per day. Specimens from these patients are often drawn by the hospital lab at a central patient service center that is located next to the core laboratory.

Automation Adoption Curve

This means that a hospital laboratory in Japan may draw blood from 1,000 to 2,000 patients per day—with a large number performed at the single draw site next to the core laboratory. Such large volumes of specimens contribute to economies of scale that are difficult to match for an American hospital laboratory.

Not only did Japanese pathologists have the mind set of continuous improvement, they had economies of scale to support automation solutions that did not exist in the United States or countries in Europe. It was only natural that, as these pathologists first automated the high volume laboratory, and next, accessioning and specimen processing, they would then look upstream in the work flow and apply the same continuous improvement techniques to phlebotomy and specimen collection.

Labs In Japan And The U.S.

Simply said, one major difference between hospitals laboratories in Japan and hospital laboratories in the United States is the daily volume of patients serviced and specimens collected. The combination of a large hospital—of greater than 1,500 beds—with a large outpatient clinic next to the hospital, handling several thousand outpatients daily, creates a volume of specimens not seen by large hospital labs in this country.

Despite the fact that Japanese labs dived into automation in the 1980s, and notwithstanding the significantly fewer specimens handled daily by hospital labs in this country versus their counterparts in Japan, the adoption of laboratory automation has strong parallels. Labs in both countries began by using automation in the analytical stage. They then went upstream in the work flow and began using automation in accessioning and specimen processing.

Thus, just as Japanese labs next looked upstream in work flow and applied automation to phlebotomy and specimen transport work processes, it is reasonable to expect that American laboratories will start to do the same. Lacking the daily specimen volume common to labs in Japan, Korea, and other Asian countries, laboratories here will likely struggle to find cost-effective approaches to phlebotomy automation. But creativity and innovation are likely to resolve those issues. As that occurs, it will trigger a growing use of automated phlebotomy by hospital labs in the United States. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

It's been a productive year for **Michigan Co-Tenancy Laboratory** (MCL) of Ann Arbor, Michigan, which performs reference and esoteric testing for its members. During 2008, four hospital systems have come aboard as new co-tenants. They are: **Baptist Health**, Montgomery, Alabama; **Bay Medical Center**, Panama City, Florida; **Mercy Memorial Hospital**, Monroe, Michigan; and **Northeast Alabama Regional Medical Center**, Anniston, Alabama. Michigan Co-Tenancy Laboratory now has 26 tenants in common representing 80 hospitals in seven states.

MORE ON: Co-Tenants

The Michigan Co-Tenancy Laboratory was created in 1997 by the hospital owners of **Warde Medical Laboratories**. Co-tenancy is a well-established business concept where owners share assets as tenants-in-common. The objective of MCL is to deliver high quality lab testing to its owners at a lower cost than other sources. *(See TDR, October 28, 2002.)*

NANO BIOSENSORS CAN DETECT MICROORGANISMS

Here's a new research breakthrough that may lead to sophisticated, reliable point-of-care (POC) testing systems. NASA researchers are using carbon nanofibers, manufactured with a similar process as silicon computer chips, to create a nano-size biosensor capable of detecting trace amounts of up to 25 different microorganisms. This system is designed to detect life on other planets. NASA recently licensed the technology to **Early Warning, Inc.** of Troy, New York.

ADD TO: Biosensors

Early Warning's first application of this nanoscale biosensor is water-quality monitoring for municipal water systems. This lab-on-a-chip tests for multiple microrganisms in parallel and can alert operators in just 30 minutes if contamination is detected in the water supply. NASA's chief researcher on this project, Meyya Meyyappan, Ph.D., predicts that this technology will find ready application in medical diagnostics.

TRANSITIONS

• Mark Johnston recently resigned his position as Chief Information Officer at **PAML** in Spokane, Washington, and will take a new position at **Microsoft Corporation** in its healthcare information systems division.

• James Santucci is back in Seattle, Washington. He is now TBFI of XYW at **Swedish Hospital**. Formerly, Santucci had held an executive position with **Dynacare-Laboratory Corporation of America** in the Northwest.

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...

...how **St. Göran's Hospital** of Stockholm, Sweden, is using Lean methods to transform laboratory operations and create integrated clinical services that are patient-friendly and patient-focused.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, October 20, 2008.