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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

A Pricing Strategy Soon to Boomerang?

HAVE NATIONAL LAB COMPANIES CREATED A REIMBURSEMENT BOOMERANG that will erode financial stability for the entire laboratory industry in the United States? I ask that question because the Medicare Competitive Bidding Demonstration Project for Laboratory Services has selected San Diego to be its first site. It was ready to conduct a bidder's conference until last week's wildfires in Southern California forced a change in plans. In taking these steps, CMS is likely to open a Pandora's box of unintended consequences.

Most of us are familiar with how national lab companies, beginning about 15 years ago, decided on a strategy of bidding for managed care work using marginal cost pricing. The underpinnings of this strategy was a belief that gaining exclusive contract access to a private health plan's beneficiaries would make it easier to access the discretionary, fee-for-service work referred by physicians. This was the "pull through" concept, and Medicare Part B fee-for-service reimbursement, representing 30% to 40% or more of a large laboratory's payer mix, was a necessary component to provide the reimbursement dollars needed to offset the losses from private payer contracts bid by the lab at marginal cost. The national contracts based on marginal cost lab test pricing that **UnitedHealth**, **WellPoint**, **Aetna**, and other large health insurance companies currently enjoy are widely believed to be falling below 50% of Medicare Part B reimbursement levels.

So imagine this scenario. In the San Diego-Carlsbad-San Marcos SMA (statistical metropolitan area), the competitive bid demonstration successfully meets three goals: 1) the lowest bids Medicare accepts for the test mix in the SMA save considerable amounts of money for what Medicare would pay for Part B lab tests when extrapolated across the entire United States, 2) patient access is not affected in negative ways, and 3) at least a few small labs in the demonstration site could provide some testing at the lower prices. Based on these outcomes, Medicare administrators then encourage Congress to enact fee-for-service reimbursement levels comparable to what national laboratory companies currently offer as contract pricing to the nation's largest private health insurers.

That would be a pricing boomerang with devastating financial consequences across the lab industry. As the Medicare program finally insists on paying the same amount that national lab companies have voluntarily bid to private insurers, it would be an economic shock that many labs may not withstand. TDR

San Diego MSA Selected For Medicare Lab Demo

Site selection has interesting advantages to success of Lab Competitive Bid Demo Project

CEO SUMMARY: Earlier this month, CMS revealed its selection of the first of two sites for the Medicare Competitive Bidding Demonstration Project for Laboratory Testing Services. It will be the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area). An assessment of this MSA reveals a number of reasons why it is likely that CMS believes it can move expeditiously to implement the competitive bidding demo in the San Diego MSA.

LABORATORIES IN SOUTHERN California will soon learn more details about the Medicare Competitive Bidding Demonstration Project for Laboratory Testing Services. Before wildfires spread across the area last week, the **Centers for Medicare and Medicaid Services** (CMS) was planning to hold a bidder's conference this week in San Diego specifically to brief laboratories about the bidding process.

CMS is expected to announce a new date soon for the demonstration project in the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area) which is to be the first site for the Medicare Competitive Bidding Demonstration Project.

Before wild fires forced the postponement, CMS had expected the bidding process to be concluded and the winning laboratories to be determined by year end. It would then implement the demonstration project in the San Diego MSA by mid-year 2008.

The selection of San Diego-Carlsbad-San Marcos MSA may turn out to be a shrewd move by CMS and its contractors, for a number of reasons.

First, neither the congressional representatives from this area nor the two California senators sit on any of the committees in the House and Senate that have direct responsibility for oversight of the Medicare program and implementation of the Medicare Competitive Bidding Demonstration Project for Laboratory Testing Services. One can speculate that Medicare bureaucrats would be aware of the political ramifications of selecting a demonstration site that had members

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

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from Congress sitting on such committees. Thus, the choice of the San Diego MSA ensures that CMS officials in charge of competitive bidding won't have to deal with Congressional delegates who are in a position to wield power over the relevant committees.

San Diego Is A Duopoly

Second, it is not likely that independent laboratories serving the San Diego-Carlsbad-San Marcos MSA will be able to exert much opposition or influence in the bidding demo implementation. That's because San Diego County is dominated by the two national laboratories. Together, **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** hold the lion's share of the lab testing market in this region.

Outside of the two blood brothers, there are no independent lab companies of size in the MSA. In fact, only a handful of other independent lab companies have clients in San Diego County.

Third, the San Diego-Carlsbad-San Marcos MSA has little hospital laboratory outreach activity. Two of the largest health systems, **Scripps Health** and **Sharp Healthcare**, do some outreach testing. But their activities are oriented primarily to serving physicians owned or associated with the respective health systems. Thus, CMS will not have to deal with hospitals or health systems that have sizeable lab testing outreach programs and a willingness to challenge any unfair aspects of the demonstration project.

No Change in PSC Numbers

Fourth, in terms of patient access and how the demonstration project could cause a deterioration, San Diego MSA offers CMS an interesting benefit. As noted above, other than Quest Diagnostics and LabCorp, there is not much existing laboratory infrastructure in this region in terms of rapid response labs and patient service centers (PSCs). Thus, were the bidding process to lead to such low prices that other labs are discouraged from providing services to Medicare beneficiaries in the San Diego MSA, the result would not be the closure of many existing PSCs. For this reason, CMS has little exposure to criticism or patient complaints about reduced access.

Fifth, independent physician associations (IPAs) are a significant factor in the San Diego-Carlsbad-San Marcos MSA. Since the mid-1990s, IPAs throughout California have had a major role in directly contracting for laboratory testing services. IPAs have often negotiated lab testing contracts at rock bottom capitated rates and deeply discounted fee-for-service prices. The ability of IPAs to consistently negotiate deeply-discounted pricing is a significant reason why overall lab prices in California are lower then they are in many other states.

CMS May Have Head Start

Certainly CMS recognized that lab prices in California are often lower than prices in many other regional markets across the country. That fact would argue in favor of selecting the San Diego MSA as the first demonstration site. It gives CMS a head start on delivering an array of bids that would be measurably below the existing Medicare Part B fee schedule for laboratory tests.

Sixth, the specific menu of tests involved in the competitive bid demo project likely will make it easier to implement. CMS has identified 303 specific tests that represent 99% of the lab tests reimbursed under Medicare Part B. Because these are relatively high volume assays, it can be expected that the two blood brothers have good information on their costs to perform these 303 assays. Further, the two national labs probably have a substantial average cost-per-test advantage relative to that of other labs.

Both points would be useful to CMS administrators in implementing this competitive bidding demo for three reasons. First, because the two blood brothers

already hold major market share in the San Diego MSA, CMS knows it reduces the number of other labs in a position to complain, to challenge, and to file legal action that could delay or derail the competitive bidding demo at this site.

Medicare Savings Potential

Second, the two national labs can be expected to have a significantly low average cost per test relative to other laboratory providers, thus increasing the odds that the competitive bids will deliver savings when compared with existing Medicare Part B fees. Third, over the three-year course of the San Diego site demonstration, CMS will have to deal only with the two blood brothers and a small number of lab companies and hospital lab outreach programs, since the prices accepted as part of the bid process are likely to make it uneconomical for smaller laboratories to continue serving Medicare beneficiaries.

This assessment of reasons why CMS found it desirable to select the San Diego-Carlsbad-San Marcos MSA assumes that CMS and its contractors actually recognized and based their decision on these factors. Many times, decisions are made based on unpredictable human elements.

Might Demo Succeed?

What becomes clear, however, is that multiple factors exist and could play a role in helping the San Diego MSA demonstration site succeed. That conclusion is certainly not what most laboratory administrators and pathologists want to acknowledge.

On the other side of the ledger, the Medicare program still remains a "command and control" bureaucracy, with all of the attendant hurdles, obstacles, and political influences that are part of this world. The need to comply with a host of statutes, regulations, and due process of law often leads to a complicated and convoluted solution that collapses of its own complexity.

Basic Features of Medicare Demonstration Project

LABORATORY TESTS PERFORMED for Medicare patients enrolled in fee-for-service Medicare plans and living within the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area) will be covered by the Medicare Competitive Bidding Demonstration Project for Laboratory Testing Services. Some relevant facts about the demonstration project are:

- It includes 303 tests representing 99% of all Medicare Part B payments.
- It excludes Pap smear and colorectal cancer screening tests.
- It excludes tests provided by entities that have a "face to face" encounter with patients (such as physicians with office-based laboratories).
- Multiple winning laboratories will be selected, using criteria that includes bid price, quality, capacity, and geographic coverage.
- The demonstration project sets out rules that define which laboratories must bid, how the winning bids will be used to establish reimbursement levels during the three-year course of the demonstration, and which laboratories will be excluded from providers once the winning bids have been announced.

Lab directors and pathologists can track the progress of the demonstration project on this CMS Web page: http://www/cms.hhs.gov/center/clinical.asp (click on "Demonstration").

If the project does collapse as a result of its own complexity, it would answer the prayers of many lab executives and pathologists. However, as noted earlier, multiple factors exist in San Diego that improve the potential for this demonstration site to succeed. TDR

Docs Want EMRs to Match Lab Orders and Results

➤Physicians become more sophisticated in how they use EMRs to advance clinical care

➤➤CEO SUMMARY: At a national EMR users meeting, physicians indicated a growing interest in having their EMRs do more than electronically accept lab test results. On the want list are direct electronic ordering of lab tests and automatic matching of lab test orders and lab test results. Physicians are rapidly learning how to use EMRs to boost their productivity and generate operational efficiencies and cleaner claims that are paid quicker.

UPON IMPLEMENTING ELECTRONIC MEDICAL RECORD (EMR) SYSTEMS in their practice, physicians invariably approach their laboratory to request an electronic interface for transmitting laboratory test results directly into the EMR.

"That has consistently been true, but now physicians have begun to ask more of their laboratory provider," stated Pat Wolfram, Vice President of Marketing and Customer Services for **Ignis Systems Corporation**, in Portland, Oregon. Ignis Systems helps independent labs and hospital laboratory outreach programs provide bi-directional electronic test ordering and lab test reporting integrated within the EMR workflow of the physician."Now physicians want to electronically order lab tests and they want their EMR lab-interface systems to match lab orders and results seamlessly.

"Today, few EMR systems do both of these functions well," Wolfram explained. "Physicians want EMR systems that, by design and function, support the way the physician practices medicine. The EMR must handle all functions, even the most complex, in ways that compliment and enhance the clinical and operational flow in the practice."

These developments are based on Wolfram's participation in a national meeting of EMR users which took place in Chicago last month. "This meeting attracts users of **General Electric's** Centricity EMR—some of whom have used this EMR for more than 10 years," he said. "It's a great place to identify emerging trends in how physicians use EMRs."

➤Informal Survey Results

"During my presentation, I polled the physicians in attendance and determined that 95% required direct electronic reporting of lab results as part of their EMR implementation," noted Wolfram. "Notably, about 30% of respondents have more than one lab sending electronic results directly into their EMR. These results are telling.

"Next, there was high interest by physicians to enable electronic lab test orders directly from the EMR and to have lab test orders automatically matched with test results," continued Wolfram. "This is for three reasons.

"First, when both orders and results match, the physicians are guaranteed to have a patient identification match and a physician identification match," explained Wolfram. "This step is accomplished without manual intervention and the associated additional costs of staff time. That intervention is needed when, in the absence of an electronic order, the paper requisition is manually keypunched into the lab's LIS, and simple spelling mistakes are made. A paper result is forgiving when this happens since a nurse will take the result off of the printer/fax and file it manually, recognizing the intended patient name. An electronic system (EMR) is less forgiving because it needs a match.

Second Benefit To EMRs

"The second benefit to electronic matching of lab orders and lab results is that the system automatically updates the test status, which further increases efficiency," noted Wolfram. "Up until now, physicians had to manually 'complete' all test orders in the EMR. Once you close the order loop, you know which order was completed. That's a significant benefit for physicians because they have to track the results of every test they order.

"A third important reason physicians want an EMR to initiate orders is for accurate and automated routing and billing. Insurance or location-based routing will always send the tests to the right test provider," he explained. "As a physician, if I have a pass-through billing arrangement with one of my labs, I want the system to route tests to that lab as a preferred lab. Further, it should send an HL7 billing message to my practice's practice management system, automating my billing process.

ABNs Handled By EMRs

"Physician groups associated with hospitals also want EMRs to handle advanced beneficiary notices (ABNs) to help ensure that providers will get paid," added Wolfram. "If the EMR system doesn't handle ABNs well, then there is a risk the provider will not be paid for a lab test—usually when there is no diagnosis on the lab test order. Attendees at this EMR conference who cared most about having an EMR that can handle ABNs were those who represent hospitals and clinics together. If there's no ABN, then the hospital often ends up writing off the loss. Conversely, if the EMR handles ABNs well, there may be incentive packages to the physicians if they abide by rules and have clean claims throughout the year."

Wolfram's observations demonstrate why physicians are rapidly becoming more sophisticated in how they utilize EMRs. These software systems can expedite the flow of clinical services and improve the productivity of the physicians and their office staff. For that reason, physicians place a high premium on the ability of their laboratory service provider to support electronic ordering of laboratory tests and direct reporting of lab results through the EMR. TDR

Contact Pat Wolfram at 971-255-9282 or pat.wolfram@emr-link.com.

Certified EMRs Must Handle Electronic Lab Orders in 2009

"Currently, the **Certification Commission for Healthcare Information Technology** (CCHIT) has certified 32 different EMR products," said Pat Wolfram, Vice President of Marketing and Customer Services for Ignis Systems Corporation, in Portland, Oregon. "In 2009, CCHIT certification standards will require an EMR to be capable of electronically handling laboratory test orders."

"This requirement may reduce the number of EMRs that are certified by CCHIT," predicted Wolfram. "During 2006 and 2007, CCHIT set the bar relatively low for certification. That made it easier to qualify as a certified EMR. However, because of the complexities of supporting electronic lab test ordering, along with other criteria, there could be a reduction in the number of EMR systems which meet CCHIT certification requirements."

Full Pathology Digitization Is Becoming Feasible

➤Pathology Visions 2007 Conference attracts pathologists, biotech, and pharma executives

➤➤CEO SUMMARY: Advances in computer hardware, software and support systems such as scanners are bringing the era of full pathology digitization closer to reality. Last week, in San Diego, California, an enthusiastic crowd of several hundred gathered to learn how laboratories, hospitals, and researchers are taking the first steps to digitize different areas of pathology services and laboratory operations. No single path toward digitization emerged from the more than 39 sessions.

DIGITIZATION OF PATHOLOGY IMAGES AND INFORMATION has long been recognized as a necessary achievement if the pathology profession is to maintain pace with the drive to create a universal electronic health record (EHR).

Two decades ago, it was Bruce Friedman, M.D.'s annual meeting in Ann Arbor, Michigan on laboratory informatics (now called **LabInfoTech** and held each winter in Las Vegas, Nevada) that provided a forum for innovation in laboratory and pathology information systems. Last decade, it was Michael J. Becich, M.D., Ph.D.'s annual meeting on pathology imaging and informatics that heightened attention on pathology imaging (called **Advancing Practice, Instruction and Innovation through Informatics** [APIII] and conducted each fall in Pittsburgh, Pennsylvania).

In this decade, it is Dirk Soenksen's Pathology Visions conference in San Diego, California, which is becoming an additional resource for advancing the cause of digitization and informatics integration in anatomic pathology. Soenksen is CEO of **Aperio Technologies, Inc.**, which manufactures a digitized pathology imaging system.

At Pathology Visions 2007 last week, there was a fascinating spectrum of topics and presentations on the digitization of pathology images and information. These talks ranged from using digital pathology images for standardization and remote consultations to how the evolution of PACS (picture archiving and communication systems) might be a model to predict how digital pathology will develop and the use of telepathology to make primary diagnoses of frozen sections.

➤General Electric's Views

One speaker who captured the close attention on many in the crowd was Giri Iyer, General Manager of Strategic Relations of **General Electric Healthcare**. Because GE is a major player in radiology, its views on digitization of pathology images were of keen interest. Iyer outlined a market adoption curve that identified the pharmaceutical industry as being the first to implement and use digitized pathology images. He stated that this process is underway now.

Digital Information and Digital Images Change the Learning Habits of Today's Medical Students

WHAT MAY INTRIGUE pathologists and laboratory directors are the learning habits of the current generation of medical students. These students use digital information in unique ways that they will carry with them into clinical practice.

At Pathology Visions 2007, Andrew J. Connelly, M.D., Ph.D., Assistant Professor of Pathology at the **Stanford School of Medicine** in Palo Alto, California, discussed these new study patterns in a presentation called "Experience with Virtual Slides at Stanford Medical School."

Major reforms in how medical students are taught in each year of their education is occurring in tandem with a switch away from paper-based educational materials (like course synopses and textbooks) in favor of digital media. Connelly discussed how digital pathology images plays an important role in supporting these new study patterns of medical students.

"Our experience is that virtual [digitized] slides are uniform, high quality, and easily distributed," noted Connelly. "They can be linked in useful ways to other digital content that is relevant to the medical student. One consequence of our increased use of digitized pathology images is that we find students are less proficient with a microscope. However, we don't anticipate this will be a problem as digitized images gain wider use."

According to Connelly, medical students are using digital information in the Internet as a basis of study in the following order:

1) First resources are the course content Web site, which includes objectives, syllabus, and problems.
2) On-line textbooks, which must be free.
3) Google to hunt for the best content, which must be free and, if a log-in is required, they are likely to pass up the page.
4) *Wikipedia.org*.
5) Send instant message (IM) to fellow students who are also on-line.
6) Go to *library.med.utah.edu/WebPath/-webpath.html* as suggested by course materials.
7) Visit *www.path.uiowa.edu/virtualslidebox*.

Iyer predicted the next step in adoption would be as technology reduced current scan times and produced a digital image of a quality that had parity with that of glass slides. In his view, this is likely to be achieved in 2008 and 2009.

This would be followed by FDA approval of technology and systems which are designed to support the workflow of pathologists and which offer useful algorithms. This would occur in 2009 and 2010 and reference laboratories would likely drive the use of such systems in clinical applications.

In Iyer's view, it is not until 2010 and beyond that digitized pathology systems would go mainstream. In order for this to happen, not only do such systems need to enhance pathologists' workflow, but they must also have a demonstrated return on investment (ROI) and a documented clinical capability.

Iyer stated that "evolution in the industry will be driven by image digitization in a way that has a common denominator: If physicians do not have to look for a piece of paper, a glass slide, or a piece of film—if all this information is in one computer in digital form, then short term gains in clinical value and efficiency will drive acceptance and adoption."

Progress in pathology informatics and digitization is happening at accelerated pace. Strong attendance at LabInfotech, APIII, and Pathology Visions demonstrates the widespread interest in this topic. TDR

Decentralized Phlebotomy Fails to Deliver Improved Quality and Patient Satisfaction

"IT WAS A MOVE TO CUT COSTS that motivated many hospitals to shift phlebotomy to the nursing staff in the 1990s," said Dennis Ernst, Director of the **Center for Phlebotomy Education, Inc.**, in Ramsey, Indiana. The center develops educational materials for healthcare professionals responsible for blood specimen collections.

"Today, hospitals recognize that laboratorians and trained phlebotomists are better suited to collecting blood samples from patients," Ernst commented. "But back in the 1990s, there was a trend of moving responsibility for blood draws to the nursing staff. That trend has proven to be a miserable failure because of poor patient satisfaction scores.

"Unfortunately, it has taken five to 10 years for hospital administrators to realize that decentralized phlebotomy was a mistake," noted Ernst. "Starting in 2000, laboratories began fighting to get back responsibility for phlebotomy.

"When phlebotomy is decentralized, hospitals have customer service problems," he continued. "Research shows decentralized phlebotomy results in more mislabeled laboratory samples reported and an increase in unacceptable specimens, including hemolysis.

"When non-laboratorians draw blood, they often don't pay as much attention to detail because they don't appreciate how the accuracy of the test result is a function of collecting the sample properly," explained Ernst. "Since it is widely known that patients are less satisfied when non-laboratorians are drawing specimens, there are many reasons why a lab manager would want to reclaim responsibility for phlebotomy services."

program in 1996. "Because of these classes, we saw immediate improvement in many areas," reported Ogden-Grable.

"Our training program runs for seven weeks. Each participant needs 80 hours of didactic classroom training and 120 hours of clinical rotation," Ogden-Grable explained. "During the rotations, the phlebotomist in training is never alone with a patient. Each one works with a mentor and must do 100 observed venipunctures before he or she can work independently."

Improving Technique

To measure patient satisfaction, NCH Health Systems uses survey company, **Press Ganey Associates, Inc.**, in South Bend, Indiana. "We mail surveys to patients following their hospital stay," said Ogden-Grable. "On these surveys, the hospital lab is graded on two factors: the technique of the person taking the blood sample and their level of customer service, meaning their communication with the patient. We consistently score very high on both measures.

"What's more, the patient satisfaction scores reflect on the entire laboratory because the people in the laboratory never meet a patient," Ogden-Grable explained. "Our phlebotomists are the ambassadors for the laboratory. They make a positive impression on the patient and that's what the patient remembers about his or her lab experience.

"It sounds simple to take a blood sample and put it in a tube, but there is much more to it than that," she said. "It involves establishing rapport with the patient, having compassion, treating every patient the same, and following all the required procedures, including identifying the patient properly, using the correct technique, and taking the sample from the proper vein. The patients are going to let us know through our satisfaction surveys when we don't deliver the best patient care.

"We also go one step beyond the mail surveys," Ogden-Grable added. "We utilize an internal random patient survey system. Our lab directors, the phlebotomy supervi-

sor, the lead phlebotomist, or the clinical educator can meet with patients and go through a checklist. This lets us know how they feel about blood collection.

"By doing these random surveys, we discovered important issues that help us coach the staff to do a better job," Ogden-Grable continued. "We can use the information from the patient when we meet with the phlebotomist and explain how they can improve.

Reflecting Lab Quality

Since implementing a centralized phlebotomy service in 2002, other responsibilities have been added. "Here at NCH, we have an IV Start Phlebotomy Team," Ogden-Grable said. "We have nine senior phlebotomists, any of whom can be asked to do IV starts. It's unusual to have a team like this, but any patient getting an IV wants someone who knows what they're doing. Nurses were happy that we implemented this start team because our senior phlebotomists are experts at finding veins.

"Some of the best hospitals in the country, such as the **Mayo Clinic**, have vascular access teams or a team of phlebotomists who do IV starts as we do," she added. "We have very high patient satisfaction scores as a result of our IV start team and the trained phlebotomists."

New Guidelines Get Results

THE DARK REPORT observes that it is no accident that phlebotomy services are getting increased attention by hospital administrators. This is a direct result of the changing accreditation guidelines, which, themselves, are steps to reform the American healthcare system.

It shows that, not only are some healthcare reform efforts catching the attention of hospitals and other providers, but they are triggering responses that lead to improved care and greater patient satisfaction. Hospital administrators are paying closer attention to phlebotomy services and devoting more money and resources to improving the performance of phlebotomy because it directly improves the patient experience. This is not news to laboratories, because they recognize how many people are uncomfortable with venipuncture. Labs also know how angry doctors can become if the patient complains about a poor or painful blood draw.

The next intelligence briefing on phlebotomy services will profile a booming sector of phlebotomy and laboratory medicine that represents an unlikely range of products attracting hospital dollars—and all designed to improve the patient's experience during venipuncture. TDR

Contact Keith Nelson at 815-740-1234 x7809; knelson@silvercross.org; Helen Ogden-Grable at 239-436-5103 x2173 or helen.ogdengrable@dsilabs.com; Dennis Ernst at 812-633-2346 or phlebotomy-@phlebotomy.com.

Predict that Phlebotomists Will Help Point-of-Care Testing

THERE IS A SIGNIFICANT TREND developing in point-of-care (POCT) testing that is likely to affect phlebotomy technicians.

"In the next five to 10 years, phlebotomists will start to get involved in point-of-care testing because more tests will be done at the bedside and that's a perfect role for the phlebotomist," said Keith Nelson, Administrative Director of Laboratory and Dialysis at Silver Cross Hospital in Joliet, Illinois.

"This is likely to be a natural opportunity as point-of-care testing becomes more cost-effective and bedside testing kits for a greater number of conditions become available," noted Nelson. "The phlebotomy profession is well-placed to perform point-of-care testing, under the supervision of the laboratory. Among other reasons, phlebotomists are trained to collect a quality specimen. They understand how the sensitivity and specificity of the test can be affected by the quality of the specimen."

ISO 15189 Gains Favor For Lab Accreditation

CLSI works with government in Tanzania to accredit five regional labs in African nation

CEO SUMMARY: Volunteers for the Clinical and Laboratory Standards Institute (CLSI) are in the midst of an 18-month project to help five state-run medical labs in Tanzania gain ISO 15189 accreditation. The project shows how labs in Africa and other countries are moving to adopt international accreditation standards. A growing number of countries, including Australia, Germany, France, and Canada, already use ISO 15189 in their accreditation requirements.

IN VARIOUS NATIONS across the world, laboratories are pursuing accreditation based on ISO 15189. That's because a growing number of countries are adopting ISO 15189 as the basis for their national accreditation standard.

Use of ISO 15189 for laboratory accreditation is an important example of the convergence of laboratory operations now occurring across the globe. A number of laboratory professionals from the United States and Canada are actively involved in this trend.

"Volunteers from the **Clinical and Laboratory Standards Institute** (CLSI) in Wayne, Pennsylvania, have been working since August 2005 to help five of the largest state-run medical labs in the United Republic of Tanzania gain ISO 15189 accreditation," said Sheila Woodcock, President and Principal Consultant for **QSE Consulting, Inc.**, in Rose Bay, Nova Scotia.

Woodcock traveled to Tanzania twice this year to help officials from these five zonal labs as they work to earn accreditation by 2010. "Zonal labs are operated by the Ministry of Health and Social Welfare in Tanzania, which initiated the ISO 15189 accreditation program," explained Woodcock. "In Tanzania, the zones are regional districts with a number of hospitals offering different levels of service and centered around a main hospital.

Strong and Growing Trend

Acceptance of ISO 15189 in laboratory accreditation internationally is a trend not well known to American laboratory professionals. That's because laboratories here have different accreditation and licensing requirements which pre-date the creation of ISO 15189, which is a quality management system customized to medical laboratories.

Since its creation in 2003, however, ISO 15189 has found growing acceptance as the basis for laboratory accreditation and licensure in industrialized countries and developing nations across the globe. For example, ISO 15189 is used as a standard for laboratory accreditation in Australia, Canada, France, and Germany, among other large industrialized nations.

"The world is moving toward ISO 15189," said Glen Fine, Executive Vice President at CLSI. Last month, Fine trav-

eled to the African nation of Namibia month to advise the government there on ISO 15189 accreditation. CLSI is also working with Nigeria and Côte d'Ivoire.

"The rest of the world doesn't have the same laboratory licensure and accreditation requirements as currently exist in the United States," Woodcock added. "So, one by one, the nations of the world are adopting international standards. In many cases, they are working toward the ISO 15189 standard. ISO 15189, of course, was developed specifically for medical laboratories. Across Canada, this standard is being implemented province by province.

"Within the United States, there are a couple of organizations using ISO 15189 as the basis for medical laboratory accreditation," Woodcock said. "One is COLA (**Commission on Laboratory Assessment**), in Columbia, Maryland, which is using ISO 15189 accreditation with medical laboratories in Taiwan, and the other is the **American Association for Laboratory Accreditation** (A2LA), in Frederick, Maryland. A2LA has just launched a new international accreditation program for clinical laboratories using ISO 15189.

"Globalization of the lab industry is a trend which is reinforced by the common technology used in laboratories around the world," Woodcock continued. "No matter where you go in the world, you see the same equipment in all these different labs. By using ISO 15189 as an accreditation standard, these labs are demonstrating that they meet the same standards as other labs around the world. That was the reason the Tanzania government choose ISO 15189 for its state run labs."

Working in Tanzania

In recent years, THE DARK REPORT has pointed out that laboratories across the world are evolving toward common organizational models and operations. "Accreditation plays a role in encouraging convergence," said Lucia Berte, Founder of ***Laboratories Made Better!*** of Broomfield, Colorado. Berte spoke last month at the *Lab Quality Confab* in Atlanta and is a member of the international committee responsible for updating ISO 15189 standard. "ISO 15189 is becoming a framework around which many countries are choosing to design their lab accreditation programs. Thus, a common standard for accreditation from one country to the next plays a role in encouraging common forms of laboratory organization and operation." TDR

Contact Sheila Woodcock at 902-766-4295 or swoodcock@qseconsulting.com; Glen Fine at 610-688-0100 x116 or gfine@clsi.org; Lucia Berte at 303-487-1135 or lmberte@comcast.net.

Resident Lab Mentors Wanted in Tanzania

TO SERVE AS RESIDENT VOLUNTEERS in Tanzania, the Clinical Laboratoory Standards Institute (CLSI) in Wayne, Pennsylvania, is seeking five qualified and dedicated laboratory professionals.

Each resident mentor will reside in Tanzania for two to three months to coordinate, support, monitor, and continuously assess the development of a quality assurance system in each assigned medical laboratory facility. This is the next phase of the project to advise five zonal labs in the West African nation on ISO 15189 accreditation.

The zonal laboratories involved in this effort are: 1) **Kilimanjaro Christian Medical Centre**, in Moshi; 2) **Bugando Medical Centre** in Mwanza; 3) **Muhimbili National Medical Centre** in Dar es Salaam; 4) **Mnazi Mmoja Hospital**, in Zanzibar; and, 5) **Mbeya Referral Hospital** in Mbeya.

Candidates selected as resident volunteers will receive formal training in specific quality management systems, the ISO 15189 standard, and how to introduce and establish a quality management system for the Tanzanian laboratories. More information can be found on the CLSI's Web site. (*www.clsi.com*).

Health Guru Predicts End to Medical Errors

Patient safety expert Lucien Leape, M.D. says hospitals and physicians can achieve zero defects

CEO SUMMARY: One of the most exciting developments in patient safety is that it is now possible to begin eliminating adverse events in healthcare, declared Lucien Leape, M.D., Professor of Health Policy at the Harvard School of Public Health. Leape bases his prediction on how pioneer hospitals have achieved a zero rate of infection in ICUs and other specific areas of care. He believes the U.S. healthcare system is poised to achieve new breakthroughs in the quality of care.

IMPROVEMENTS IN PATIENT SAFETY are coming so quickly that zero defects are possible. That's the view of Lucien Leape, M.D., Professor of Health Policy at the **Harvard School of Public Health** in Cambridge, Massachusetts.

"The most exciting thing that has happened recently in patient safety—something that has truly changed our agenda—is that it is now apparent that we can use perfection as a benchmark," declared Leape in an interview published by the policy journal *Health Affairs*.

"We now have convincing demonstrations that when the effort is made and new practices are implemented, we can actually eliminate certain adverse events," explained Leape. "There is no reason to think that this cannot be expanded to the whole universe of adverse events."

Leape is enthusiastic about the potential to use quality management tools in healthcare to achieve three goals: 1) zero defects, 2) teamwork training, and, 3) the development of tools to identify and fix potential problems and the sources of error before they cause harm to patients. He believes these three developments (zero defects, team training, and trigger tools) are transforming the way healthcare is delivered.

These developments are significant for lab directors and pathologists because Leape recognizes that healthcare is on the verge of pursuing performance goals and quality outcomes that are common to non-healthcare industries around the world.

Following Protocols

THE DARK REPORT has regularly discussed the steady introduction of national goals, accreditation guidelines, and pay-for-performance programs that measure the results of hospitals and physicians in improving patient safety and raising healthcare outcomes. Leape is assessing the results of these early efforts and programs. He believes these early demonstrations validate the goals of zero defects, quality improvement, and will help lower the overall cost of care.

Leape explained how previously unthinkable results are possible. When Peter Pronovost, M.D., a physician in the intensive care unit at **Johns Hopkins Hospital** in Baltimore, Maryland, demonstrated the

ability to eliminate central-line infections, the event was significant, noted Leape.

"Let's put this in perspective," he commented. "Thirty-six million people are hospitalized in the United States every year. Approximately 11% receive care in an ICU, so the total number of ICU days is 18 million or so. Approximately half of the patients in ICUs have a central venous catheter, so the best estimate is that there are 9.7 million catheter days per year, and 48,600 central-line bloodstream infections. Approximately one-third of those patients die because of those infections. The figures for ventilator-associated pneumonia—another major cause of morbidity and mortality—are similar.

"The team at Hopkins was able to eliminate both of these types of infections by implementing protocols and rigidly enforcing them: ensuring that the five or six things that needed to be done every time were done and done right. The secret was a major team effort and commitment," Leape explained.

Then, another exciting development occurred when Pronovost used the protocols in hospitals in Michigan, got the support of **Blue Cross and Blue Shield**, and reported that 100 hospitals had reduced central-line infections to zero. "For more than six months, 68 hospitals had no central-line infections and no ventilator-associated pneumonia," Leape observed. "I call this 'getting to zero.'

"What Pronovost has shown is that this [achieving zero infections] is not just something that one or two 'safety nuts' can do, but, rather, anybody can do it if they put their mind to it," he stated. "If 68 hospitals in Michigan can achieve these results, then so can all 5,000 hospitals in the United States. We have a new ball game and a new benchmark, and it is a very exciting development."

One key to Pronovost's success was the use of teamwork. "Indeed, my second hot topic is team training, an idea that has finally caught on and has been greatly facilitated by simulation," Leape said. "Although simulation is expensive, it is a very powerful teaching tool. Everyone likes the idea of doctors, nurses, and anesthesiologists experiencing their first crisis on a plastic patient as they learn how to put a tube in, tap a chest, or give a medication.

"Simulation is sweeping the country and with it a new emphasis on increased sophistication in team training," he noted. "Many of us in healthcare think that this is second only to implementing new practices in terms of its power to create a culture of safety and reduce accidental injuries.

Using Trigger Tools

"The third important new development, in my opinion, is the use of more sophisticated ways to identify adverse events," he added. The **Institute for Healthcare Improvement** (IHI) in Cambridge, Massachusetts, has developed a trigger tool that is very effective. The tool is a list of approximately 50 elements that can be found in the patient record, many of them laboratory tests or simple clinical observations.

"One searches for these, either in the electronic record or by going through a paper record, reviewing lab tests and so forth," he explained. "You identify abnormal findings and investigate whether a patient has suffered an adverse event. We are moving away from looking at deaths (which is a rather crude measure)—in fact, even away from errors, because injuries are what count. It does not make any difference if we are preventing errors if we can't prevent the injury."

THE DARK REPORT observes that Leape has identified how medical errors can be eliminated and healthcare outcomes improved by the use of these proven quality management methods. Previously, the thinking was that medicine was as much art as science and so it was impossible to predict adverse events. By focusing on eliminating defects, it is possible to prevent injuries and death. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Microsoft Corporation is the latest company to offer a digital health record (DHR) aimed at consumers. Called "Healthvault," it can be found at *www.healthvault.com*. This secure Web site allows consumers to manage and monitor their personal health information, including weight loss and disease management information, such as for diabetes. The Web site also includes a search tool to allow consumers to view and organize articles and other information on health.

MORE ON: Health Vault

Microsoft's strategy is to get other organizations to build services that allow consumers to upload and store data on Healthvault. According to Microsoft, 40 organizations, ranging from the **American Heart Association** and the **American Lung Association** to **New York-Presbyterian Hospital**, along with such medical device companies, such as **LifeScan Inc.** and **Omron Healthcare Inc.**, have announced their intention to build features that will allow consumers to interact with Healthvault.

PROBE LIGHTS UP CANCER MOLECULES

Seeking to improve the diagnosis and treatment of cancer, pathology researchers at **Stanford University Medical Center** have discovered an *in vivo* marker with unique properties. The probe's main ingredient is a molecule that labels active proteases—protein-destroying enzymes—that run amok in cancerous cells. The molecule is normally invisible to the naked eye but it carries a fluorescent tag that lights up when it binds to the protease. The tag beams out near-infrared light that passes through skin and is detectable with a special camera. This novel imaging technique was described in the September issue of *Nature Chemical Biology*. "We think these probes may ultimately provide a less harmful, noninvasive method of detecting cancer," said Galia Blum, Ph.D., a postdoctoral scholar in the pathology laboratory. Blum was lead author of the study.

ADD TO: New Probe

"Unlike other enzyme-targeting molecules, it's very specific, sticks to where it binds and does it all very rapidly—in 30 minutes or less," noted Matthew Bogyo, M.D., Assistant Professor of Pathology at Stanford University Medical School. Another characteristic sets this marker apart from other molecular probes. This type identifies only active enzymes. "We went one step beyond just telling if the enzymes are there. We can answer the question, 'Are they active.' That's important because an accumulation of inactive enzymes doesn't necessarily indicate disease," explained Bogyo.

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DARK DAILY UPDATE

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...the number of physician pay-for-performance (P4P) programs has almost quadrupled in the past 5 years, going from 39 in 2003 to 148 in March of this year, with more payers embracing this approach.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, November 19, 2007.