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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

Patient Satisfaction Has New Significance for Labs

ONCE AGAIN, THE DARK REPORT IS FIRST TO CALL YOUR ATTENTION to a national trend not previously recognized. Specifically, I refer to how the focus by hospitals on patient safety and and patient satisfaction has surfaced the dissatisfaction most patients have with phlebotomy and, by extension, with the representatives of hospital labs who draw blood. Surveys in recent years show that hospital patients have expressed significant dissatisfaction with phlebotomy.

With satisfaction scores trending low like this, hospital CEOs are paying attention and devoting new resources into improving how patients view phlebotomy services. In this issue, we report national data from **Press Ganey Associates, Inc.**, that shows how patients consistently rated their lab experience among the least satisfactory in the hospital. Clearly, labs have a significant opportunity to help improve the patient satisfaction rankings of their hospital.

Seeing an opportunity, some pathologists and lab directors are getting in front of this trend. One strategy is to return phlebotomy to a centralized service in their hospital as a way to reduce errors and improve patient satisfaction numbers. *(See our article, "Phlebotomy Gets Heightened Attention for Improving Patient Satisfaction," in TDR dated October 29, 2007.)* Another strategy being used by hospital administrators is to invest in equipment and products designed to improve the patient's venipuncture experience. *(See page 10, "Improving Phlebotomy Lifts Satisfaction Scores.")* I think it's a noteworthy fact that hospital CEOs are willing to spend money on products to make patients more comfortable with phlebotomy collections. That shows a keen interest in lifting patient satisfaction scores in their hospital, for a very good reason: reimbursement will soon be linked to patient satisfaction.

Next year, the **Centers for Medicare & Medicaid Services** (CMS) will take patient satisfaction to new levels when it links reimbursement to survey scores. Beginning July 1, CMS will require HCAHPS (the Hospital Consumer Assessment of Healthcare Providers and Systems survey) for use in general acute care hospitals to maintain eligibility for full reimbursement updates.

Matt Mulherin of Press Ganey told us that, within the next year, patients' perceptions of the care they receive in hospitals will be publicly reported. Mulherin says that HCAHPS is a new and formal process to give patients more power and help them make informed decisions. By linking these scores directly to reimbursement, patient satisfaction will get even more scrutiny. TDR

Medicare Rules Tighten Anatomic Path Mark-ups

Federal healthcare regulators issue rules that limit how physicians can mark up AP services

CEO SUMMARY: Effective on January 1, 2008, new rules take effect that restrict the circumstances under which physicians can mark up the anatomic pathology services provided to their patients. However, ambiguities in how the rules are written are likely to make the intent of the new rules difficult to apply to all the types of TC/PC arrangements and anatomic pathology condominium laboratories that exist in today's marketplace.

On November 1, the federal **Centers for Medicare & Medicaid Services** (CMS) issued its 2008 Medicare physician fee schedule and final rules, which become effective on January 1, 2008. One section of the new rules will significantly change the status quo in certain types of anatomic pathology (AP) service arrangements.

In its press release, CMS described the new rules as "imposing an anti-markup restriction on the technical component (TC) or professional component (PC) of diagnostic tests (other than clinical lab tests) that are ordered by the billing supplier, if the TC or PC is purchased by the billing supplier, or the TC or PC is performed outside of the office of the billing supplier."

At the national law firm of **McDonald Hopkins** in Cleveland, Ohio, attorneys Jane Pine Wood and Rick Hindmand have studied the new rules. They believe that the new rules will directly affect AP condo/pod laboratories and several types of TC/PC arrangements involving anatomic pathology services. If the new rules prevent referring physicians from marking up AP services when billing Medicare, the economics of these types of AP service arrangements will change.

"For those new regulations which affect anatomic pathology services, the intentions of federal regulators are clear," stated Wood. "However, there are individual examples of AP arrangements provided by the federal Office of the Inspector General (OIG) where the appropriate application of these rules to each scenario is not clear.

"The obvious recommendation is that pathologists, lab directors, and referring physicians should be aware of the effect of

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

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these regulations on AP condo/pod labs or any scenario in which a physician is marking up the price for services provided to Medicare beneficiaries and performed outside of the physician's primary office," advised Wood.

'Mark Up From What?'

"But the question is: mark up from what?" she asked. "That's one of the issues involving the new regulations that we would like to understand better.

"Let's say you have a typical condo/pod lab arrangement, where a urology group in Virginia, for example, has a condo/pod lab in Florida," she continued. "The urologists could pay the condo/pod lab management company a monthly fee for leased space, leased technicians, leased pathologists, and leased equipment. That's an easy example. Under the regulations issued as part of the 2008 physician fee schedule, the urology group would *not* be able to mark up any bills from the condo/pod lab in Florida in this case.

"But consider a different arrangement for a urology group," Wood said. "Then the question becomes: What do they pay that outside supplier to do? What if the pathology work is performed at an offsite location, but the urology group leases the space itself, employs the techs directly, and owns the equipment? In that case, the language is open to some interpretation. And, in this scenario, what does the urology group use as the charge that it can't mark up when submitting claims to Medicare? The regulations can be interpreted to limit the charge to the amount paid to the techs to perform the technical processing, without any amounts for office or equipment overhead."

Hindmand agreed, saying, "That is a big issue under this particular rule. Stark regulations have allowed physician group practices to have a centralized location that is offsite to do their designated health services. And, now with the exception of some clinical laboratories, which are essentially excluded, you can't have a centralized location for the group without being subject to this anti-markup provision—unless, at the centralized location, you also do a full range of services, such as having a physician office and seeing patients there."

"The new rules definitely affect condo/pod labs that are offsite, meaning outside the referring physician's office," added Wood. "Also, it should be noted that these new rules only affect pathology services provided to Medicare beneficiaries at condo/pod labs. Referring physicians can continue to mark up services provided to self-pay and privately insured patients, to the extent permissible under state law.

"Pathologists should be aware that the new rules don't seem to limit some types of arrangements involving the technical component and professional component," Wood added. "Often, labs will do the technical component (TC) and bill Medicare directly, and the referring urologists will hire a local pathologist to sit in the urologists' office and do the professional component (PC). Because this PC work is being done in the urology group's office, the rules don't seem to affect these arrangements."

New Rules Start On Jan. 1

CMS will publish the physician fee schedule and new rules in *The Federal Register* on November 27. On November 1, CMS posted The Medicare Physician Fee Schedule (MPFS) and associated regulations on its Web site (*www.cms.hhs.gov/center/physician.asp*).

The fee schedule and new rules contain 1,481 pages. The portions that are most relevant to pathologists and lab directors include examples of laboratory contracts that may help pathologists and lab directors understand the issues involved, said Hindmand and Wood.

THE DARK REPORT observes that this is likely to be the first round of a continuing effort by federal healthcare regulators to address a variety of issues triggered by physicians establishing their own, in-practice ancillary services. This current round of rule-making includes rules that alter existing radiology arrangements.

Feds Provide Seven Examples to Explain Appropriate Billing for Anatomic Path Services

HERE ARE SEVEN EXAMPLES provided in the federal guidance on how to properly bill for anatomic pathology services as directed by new rules in the CMS 2008 physician fee schedule and regulations.

Example 1: A urology group practice contracts with a leasing company that supplies a technician and a pathologist to perform testing on prostate samples. The technician performs the tissue sampling and the pathologist reads the slides. All work is done outside of the office of the billing group practice, and instead is performed in space that is rented exclusively "24/7" by the group practice (thus meeting the definition of a "centralized building" at §411.351) for the sole purpose of providing pathology services for the group's patients. Because the centralized building does not qualify as "the office of the billing physician or other supplier," the anti-markup provisions apply to both the TC and the PC, and the group may bill Medicare the lowest of the following: (1) the leasing company's net charge to the group; (2) the group's actual charge; or (3) the fee schedule amounts for the TC and interpretation that would be allowed if the leasing company were enrolled in and billed Medicare directly.

Example 2: Same as Example 1, except that the TC and PC are performed by the group practice's employee technician and a pathologist who is an independent contractor of the group practice, respectively. Here, the anti-markup provisions again apply to both the TC and the PC because the work was not done in the "office of the billing physician or other supplier" (that is, the office of the group practice). It does not matter that the technician is an employee and the pathologist is an independent contractor because the work was not performed in the office of the billing group practice.

Example 3: A physician in a group practice orders a diagnostic test and a technician who is a part-time employee of the group performs the test in the group's office. A physician who is an independent contractor of the group performs the PC in the group's office and reassigns his or her right to payment to the group. The anti-markup provisions do not apply to the group's billing of the TC or the PC.

Example 4: Same as Example 3, except that the independent contractor physician performs the PC in his or her home and reassigns his or her right to payment to the group. The group's billing of the TC is not subject to the anti-markup provision, but the group's billing of the PC is subject to the anti-markup provision because the work was not performed in the office of the billing supplier.

Example 5: A group practice purchases both a diagnostic test and its interpretation from a laboratory and bills the TC and PC to Medicare. The anti-markup provisions apply to both the TC and the PC. Because the TC and the PC were purchased, the location(s) at which the TC and the PC were performed does not matter.

Example 6: A group practice orders a diagnostic test from an independent laboratory. The laboratory performs the test and contracts with a physician to perform the PC. The laboratory bills Medicare for both the TC and the PC. The laboratory is not subject to the anti-markup provision for the PC, because the laboratory did not order the test.

Example 7: Same as Example 6, except that a physician orders a diagnostic test from an independent diagnostic testing facility (IDTF). The IDTF bills Medicare for both the TC and the PC of the test. The anti-markup provisions do not apply because the IDTF did not order the test.

In recent years, as physician groups established in-practice radiology and pathology services, the year-to-year increase in use of these services has caught the attention of Medicare officials. Federal healthcare regulators will watch how these new rules alter existing business arrangements in radiology and pathology. If these rules do not achieve the outcomes intended by Medicare regulators, it is likely that they will propose additional rules.

This result is consistent with the efforts Medicare officials have taken in recent years. Within the pathology sector, AP condo labs and TC/PC arrangements have gotten lots of scrutiny. It is reasonable to expect further federal action on these arrangements. TDR

Contact Jane Pine Wood at 508-385-5227 or at jwood@mcdonaldhopkins.com; Rick Hindmand at 312-280-0111 or at rhindmand@mcdonaldhopkins.com.

Market Update

PAML and HCA Agree to Start New Lab Joint Venture in Utah

When the new laboratory joint venture between **MountainStar Healthcare Network** of Salt Lake City, Utah, and **Pathology Associates Medical Laboratories** (PAML) of Spokane, Washington, was announced on November 1, most people were not aware of an important fact. *(See Dark Daily, November 5, 2007.)*

MountainStar Healthcare Network is owned by **Hospital Corporation of America** (HCA), of Brentwood, Tennessee. That brings the nation's largest for-profit hospital corporation directly into the laboratory outreach business. That has interesting implications for the laboratory industry in the long term.

Motivating HCA To Expand

One, if this laboratory joint venture proves to be a financial home run, it could motivate HCA to enter into additional laboratory joint ventures in other regions where it owns hospitals. Since HCA owns 179 hospitals in the United States, Switzerland, and the United Kingdom, it has plenty of opportunities to exercise this option. If this were to occur, there are several cities where HCA owns multiple hospitals and would have a strong position from which to build a laboratory outreach program.

Two, it positions PAML to be a preferred joint venture partner with HCA. After all, if the marriage works in Utah, that augers well for joint ventures with HCA in other regions of the country.

Three, as this laboratory joint venture unfolds successfully, it will give PAML additional credibility whenever it approaches other hospitals and health systems to engage them in joint venture discussions. Not that PAML needs more credibility on this front. Over the past decade, it has managed multiple joint ventures with hospitals throughout the Northwest, with impressive financial success in more than one case.

Before any of this happens, however, the new laboratory joint venture must prove its mettle in Salt Lake City. It will be called **MountainStar Clinical Laboratories LLC**. Two of MountainStar's eight hospitals will participate in the joint venture. They are 297-bed **St. Mark's Hospital** of Salt Lake City, Utah and 116-bed **Lakeview Hospital** of Bountiful, Utah. PAML will build the joint venture around its existing laboratory operations in Salt Lake City.

Two elements make this joint venture announcement intriguing. First, it has always been a mystery to THE DARK REPORT as to why HCA never gave more emphasis to laboratory outreach programs, which can be profitable if run effectively. Beyond two large ventures with **MDS Laboratory Services** in the late 1990s, HCA has never made laboratory outreach programs much of a priority. *(See TDR, April 5th, 2004.)*

Another ICL In The Making?

Two, this may be the "break out deal" for PAML as a desired laboratory joint venture partner with other hospitals and health systems. Not since **International Clinical Laboratories** (ICL) of the mid-1980s has an independent laboratory company managed to establish so many lab joint ventures with different hospitals and keep them running for a decade or longer. TDR

Labs in U.S. and Australia Learn from Each Other

Laboratory management meeting in Sydney brings together innovators from four continents

CEO SUMMARY: Australia just conducted its first summit meeting on laboratory management and a near sell-out crowd showed up to learn the best and latest. For the Americans in the audience, there were several surprises. First, Australia has a highly-competitive laboratory sector, comparable in many aspects to the private sector here in the United States. Second, several states are far along at creating a single, statewide regional laboratory network with a single lab data repository.

When it comes to trends in healthcare and laboratory management, Australia and the United States have much in common. That was the consensus of attendees at *The Business of Pathology* (TBOP) conference conducted November 8-9, 2007 in Sydney, Australia.

Speakers from laboratories in Australia, Singapore, United States, and United Kingdom covered a range of topics in laboratory management, ranging from early successes with Lean and Six Sigma methods and regional lab consolidation to solutions to the shortage of skilled workforce and how labs can best support the electronic medical record (EMR) systems used by office-based physicians.

Laboratory Management

This event was co-produced by the **Association of Australasian Clinical Biochemistry** (AACB) and The Dark Report and, like the *Executive War College*, focused on issues in laboratory management. Emphasis was given to how innovative lab leaders in Australia, the United States, and several other countries are developing solutions to problems common to all labs, including inadequate reimbursement, shrinking workforce, and the creation of regional laboratory networks and organizations to better align laboratory resources with the healthcare needs of the local communities.

Lab executives and pathologists in the United States may be surprised to learn that the Australian healthcare marketplace has much in common with the healthcare market in the United States. There is a flourishing independent laboratory sector, with lots of competition. Also, just as in the United States, in recent years public and private hospital laboratories have begun to develop outreach programs to compete against commercial labs for specimens originating from physicians' offices and clinics.

The reason for these similarities is the Australian healthcare system, which has several common characteristics with healthcare in the United States. It is a system with universal coverage provided by the government that can be supplemented by private health insurance. There is a network of public hospitals. Private physician groups and private hospitals provide serv-

ices and are generally reimbursed by fee-for-service arrangements. Independent commercial laboratories compete for the lab test referrals of office-based physicians and may also provide services to private hospitals. Thus, just as in the United States, there is continual competition for laboratory testing business.

Ahead Of U.S. Laboratories

That's one reason why several laboratory initiatives are pushing Australian laboratories past their American cousins. For example, the government health plans in several states are creating regional hospital laboratory networks which standardize testing, consolidate work into primary lab facilities, and support a common laboratory test data base.

The obvious goal with a single lab test data repository in states such as Western Australia and Queensland is to support a central electronic health record (EHR) for every patient. Progress on this goal is relatively swift because public hospital labs form the backbone of the universal health system and take their strategic direction from the government health authority.

One interesting development related to controlling utilization of healthcare services is a recent law enacted in Queensland. It requires a physician to access and view the results of every laboratory test he or she ordered. The electronic system keeps a record of the time that the physician accessed the results.

Controlling Test Utilization

This is a relatively new development and the consequences of this legislation have yet to be fully determined. However, it is a different approach to the same problem seen in the United States: are physicians ordering tests which are unnecessary? If so, how can a system be developed to encourage them to improve the effectiveness of their test ordering patterns?

One area of laboratory operations that is progressing in Australia is the acceptance and use of quality management techniques, such as Lean and Six Sigma. TBOP organized an entire day around this subject and it drew almost an equal number of attendees as the full two-day conference.

From the Australian side, case studies were presented by **Sullivan Nicolaides Pathology** (a **Sonic Healthcare Ltd.** lab division) of Brisbane and **Pacific Laboratory Medicine Services** (PaLMS) of St. Leonards, near Sydney. From the U.S. side, **Fairview Health** of Minneapolis and **Ortho-Clinical Diagnostics** provided case studies of Lean and Six Sigma.

One fascinating difference surfaced in how Australian and American labs implement their Lean and Six Sigma projects. The Australian labs take a "do it yourself" approach while the American labs frequently engage experienced consultants to come in and run the first projects while training lab staff in quality methods.

Quality Programs

This revealed that American hospital administrators seem to be ready to invest money in quality management that they knew would be recouped from the savings generated by the improvement projects. Australian hospital administrators are more conservative about hiring consultants. Thus, their laboratories tackle process improvement projects which are smaller in scope and generate proportionally less gains than their American counterparts.

Another interesting difference is that Australian hospitals, clinics, and laboratories are using different software products than the most common products sold in the United States. Efforts to integrate clinical data repositories and enable patient healthcare information to flow across the continuum are progressing at rates that are faster than in the United States.

It was an informative week in Australia and one key lesson emerged: Australia's mix of public hospitals and private lab companies are just as progressive as their counterparts here in the United States. TDR

Lab Compliance Update

Federal Whistleblower Suit Settled by Dianon Systems

IT'S A REMINDER THAT WHISTLEBLOWERS continue to look for opportunities to turn in laboratories, even if the violations are relatively minor.

Last month, **Dianon Systems Inc.**, of Stratford, Connecticut, agreed to pay $1.5 million to settle a federal false claims action originally filed by pathologist James J. Tiesinga, M.D., who once worked for Dianon in its Connecticut facility. Tiesinga will be paid $300,000 from the $1.5 million settlement.

Medically Unnecessary Tests

According to the settlement agreement, Tiesinga worked for Dianon as a hematopathologist from July 2001 until June 5, 2002. On Sept. 6, 2002, Tiesinga filed a *qui tam* action against Dianon. The federal government entered the case on behalf of Medicare and Tricare, the healthcare program for military personnel and their families.

From January 1, 1996, to December 31, 2003, Dianon submitted claims to Medicare and Tricare for flow cytometry services, billed under CPT code 88180, that were not medically necessary, the settlement agreement says. Also, from January 1, 1996, to August 30, 1997, Dianon submitted claims to Medicare and Tricare for 26 units of flow cytometry services while performing only 22 units of flow cytometry services.

The amount of the settlement, compared to other past lab settlements with the federal government, shows that the business practices in dispute did not involve high volumes of tests. Further, these Medicare claims originated in the years before Dianon Systems was acquired by **Laboratory Corporation of America** in early 2003.

Tiesinga's attorney, Joseph Maya, of **Maya and Associates**, of Westport, Connecticut, told THE DARK REPORT that neither he nor Tiesinga could comment on the case. A spokesman for U.S. Attorney Kevin J. O'Connor, the U.S. Attorney in Connecticut, also declined to comment. Since federal attorneys usually like to talk about the details of successful legal actions, it is likely that this settlement was based on relatively minor infractions or operational processes that failed to meet compliance requirements.

What this case represents is a reminder to laboratories of their exposure to whistleblowers among their employees and staff. The interesting question raised by this case is how Dianon's internal compliance system responded if whistleblower Tiesinga—who worked there less than 12 months—followed the company's compliance policies. One of the primary purposes of a lab's compliance program is to create communication channels that employees can use to alert the company to practices that may be non-compliant. Then the company has the opportunity to address and correct those practices. It also should then notify government health programs of any improper claims so that corrective action can be taken.

Qui Tam Exposure

Whistleblower Tiesinga's $300,000 payment as his share of the $1.5 million settlement illustrates what continues to motivate employees to become whistleblowers. It is a timely reminder that labs should review their compliance program and how employees use it. TDR

CEO Summary: Based on patient satisfaction surveys done across the United States, Press Ganey Associates, Inc., reports that "lab" is ranked near the bottom of 10 clinical services. Source of these low satisfaction rankings is phlebotomy, since most patients find needle sticks uncomfortable and some even have a fear of needles. To raise patient satisfaction scores, hospital CEOs are now willing to spend money on phlebotomy products that improve patients' experience with blood collection.

Press Ganey Data Puts Labs Near the Bottom in Satisfaction

Phlebotomy Is Closely Linked To Hospital Satisfaction Scores

PHLEBOTOMISTS IN THE HOSPITAL have often felt like the late comedian Rodney Dangerfield, who regularly complained that "I don't get no respect!" However, phlebotomy services are gaining new attention from hospital CEOs and administrators.

This turnabout in recognition for phlebotomy's contribution to hospital care is due to the twin trends of improving patient safety and measuring patient satisfaction. As hospitals measure their performance against specific patient safety and patient satisfaction measures, phlebotomy services have surfaced as a major source of improvement.

This is particularly true in the area of patient satisfaction. National surveys consistently show that patients rate their lab experience, including phlebotomy, among the least satisfactory in the hospital and that millions of patients are highly uncomfortable about having their blood drawn. Many have blenophobia, a fear of needles.

Discomfort From Needle Pain

Further, it is an area ripe with opportunity for improvement. More than 350 million blood samples are collected annually in the United States. One study found that about 40 million patients experience high discomfort because of needle pain.

As hospital CEOs and administrators pay closer attention to patient satisfaction surveys, they are recognizing phlebotomy services as an area that holds great potential to improve how the patient views his or her total experience at the hospital. **Press Ganey Associates, Inc.,** of South Bend, Indiana, which provides measurement and improvement services to hospitals across the country, notes that dissatisfaction with phlebotomy is often highlighted by patients in these surveys.

"In today's healthcare environment, competition among hospitals is increasingly fierce and the patient's opinion is becoming much more prominent," said Matt Mulherin, Director of Corporate Communications for Press Ganey in an interview with THE DARK REPORT. "We have national data related specifically to outpatient procedures such as blood work, which is so common in healthcare. In fact, blood work is critical because of the sheer volume and frequency that it happens. Most patients will need to have blood drawn at some point, either during an outpatient visit or during a hospital stay.

"But while a blood draw might be routine for hospital and lab professionals, among patients there's a lot of fear and anxiety," added Mulherin. "Many patients are uncomfortable with needles, and these factors make the interaction between clinicians and patients critical."

Recent analysis by Press Ganey shows that patients rated their experience with the laboratory, which includes phlebotomy, as being the least satisfactory among outpatient procedures. Among 10 areas of care, patients rated satisfaction with laboratory services lowest, Press Ganey analysis shows. Press Ganey reports that, on average, only 72.8% of patients perceived their care from the laboratory as "very good."

Hospital CEOs and administrators are recognizing the role that phlebotomy can play in lifting the overall patient satisfaction scores of their institutions. One strategy is to centralize phlebotomy services so that trained phlebotomists have responsibility for blood draws. *(See TDR, October 29, 2007.)*

A second strategy finding favor is to spend money to purchase products designed to help patients undergoing venipuncture. The willingness of hospitals to invest in such products is another sign of how phlebotomy's connection to patient satisfaction has caught the attention of hospital CEOs and administrators.

This product category is growing rapidly, and many lab directors and pathologists are unaware of this phenomenon. Companies are selling products and tools that aid the phlebotomist in the actual venipuncture, as well as topical anesthetics and similar pain-relieving products. These products all have the same goal: to improve the phlebotomy experience of patients.

The VeinViewer, manufactured by **Luminetx Corp.**, of Memphis, Tennessee, shines a light on a patient's vascular system.

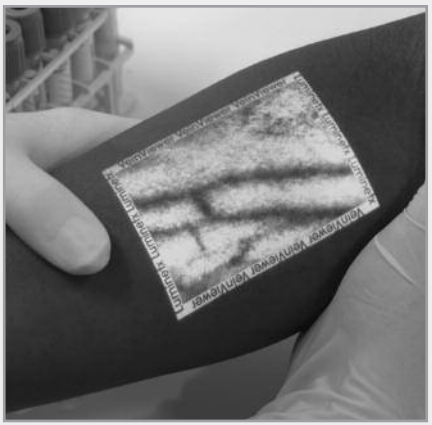
According to Luminetx, VeinViewer allows medical professionals to locate subcutaneous vasculature and project real-time images directly onto the surface of the patient's skin.

Using VeinViewer, a phlebotomist or other clinician can map a patient's vasculature regardless of age, body type, or skin tone. Luminetx claims the technology is a safe, non-invasive adjunct technology for clinical treatments and procedures including, but not limited to, IV insertion, routine venipuncture (for blood sampling), and PICC-line insertion.

Used to Help Phlebotomist Locate Patient's Veins

DESIGNED TO HELP PHLEBOTOMISTS see a patient's vascular system, the VeinViewer is a product manufactured by Luminetx Corp. of Memphis, Tennessee,

VeinViewer helps healthcare professionals locate subcutaneous vasculature and project real-time images directly onto the surface of the skin. Luminetx says that phlebotomists can keep their hands free during procedures while the system maps the patient's vasculature regardless of age, body type or skin tone.



Here is the VeinViewer in use, showing the patient's vascular system prior to drawing a blood sample.

Some hospitals now use LidoSite, a fast-acting topical anesthetic from **Vyteris Inc.**, of Fair Lawn, New Jersey, that works in as little as 10 minutes. Introduced in 2005, LidoSite delivers lidocaine and epinephrine to the puncture site through a skin patch boosted by electrical current from a battery-powered device.

Another product designed to improve the experience of venipuncture is Synera, manufactured by **Endo Pharmaceuticals**, of Chadds Ford, Pennsylvania. It is a self-warming, "peel and stick" skin patch containing lidocaine and tetracainea, designed for use by patients three years and older.

It was recognition of patients' fear of needles that encouraged the **Barbara Davis Center for Juvenile Diabetes at the University of Colorado Health Sciences Center** to take active steps to improve venipuncture. Michelle Hoffman, R.N., Clinical Coordinator for the Daisy Study and the Teddy Study at the center, said, "In our work, we do a lot of needle sticks and almost all of them involve children. We have used VeinViewer since August (2007). In our research studies, we have about 1,600 patients ranging in age from 3 months to 18 years.

➤ Phlebotomist's Skill

"We use the VeinViewer with a patient sitting in a phlebotomy chair or in a bed," Hoffman said. "The light source can be used on either side of the body and it shows the vasculature. Also, the phlebotomist sees what direction the veins are going in and whether there might be a bifurcation or a sudden change in direction. Seeing the veins in this way helps the phlebotomist discern the best stick point and the best angle. Our experience is that this device enhances the phlebotomist's skill.

"In the center, our research involves children and young adults who have Type 1 diabetes. We are also conducting multiple research studies on other autoimmune diseases related to diabetes, such as

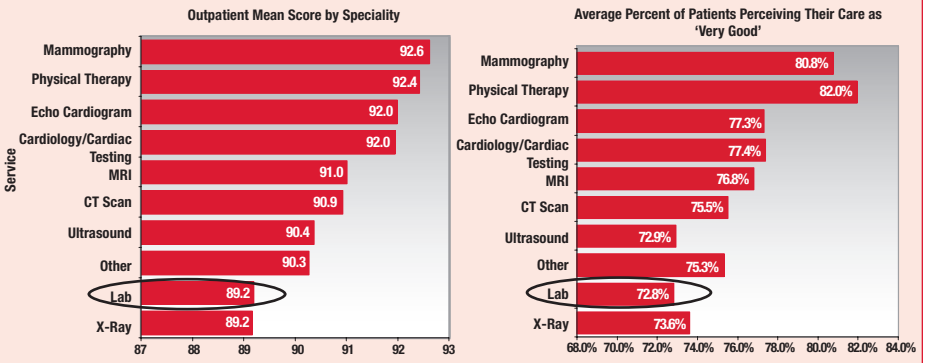
Press Ganey Survey Results Demonstrate Effect of Phlebotomy on Patient Satisfaction

PATIENT SATISFACTION SURVEYS CONSISTENTLY RANK LABORATORY NEAR THE BOTTOM of 10 clinical services, notes Press Ganey Associates, Inc., of South Bend, Indiana. That's because phlebotomy services are included in the questions about laboratory services. Often, patients are uncomfortable with venipuncture, and many have blenophobia—a fear of needles.

To raise patient satisfaction scores, hospitals are taking steps to improve phlebotomy services, even investing in products designed to make patients more comfortable during venipuncture.

Below are charts provided by Press Ganey Associates, which says, "to illustrate the differences in patient satisfaction among several common outpatient services, data were collected and analyzed from the Press Ganey outpatient facilities who received reports between January 1 and December 31, 2006. The graphs below represent these differences."

Patient Satisfaction Survey Data Place "Labs" Near Bottom



Courtesy of Press Ganey Associates, Inc.

rheumatoid arthritis, lupus, and heart disease," she said. "We've revised our phlebotomy procedures to improve the experience for the patient.

"First, we use a lotion that is a topical anesthetic," described Hoffman. "Next, the VeinViewer is used because that guides the phlebotomist to the location of the vein and allows us to stick most patients only once. Little children have small veins, which sometimes makes it difficult to find a vein by feel or by sight. Using the VeinViewer lets us see the best veins quickly.

"In our research studies, this tool is invaluable because our studies are based on doing repeated blood tests throughout the year," Hoffman added. "For some patients, we have to do the tests one to four times each year and we want families to keep coming back each time to continue in the study. Some of the children in the study don't have diabetes, but they are at risk. So it's invaluable to us to make each of the blood draws fast and easy and less traumatic.

Positive Patient Reaction

"So far, reaction from the patients has been positive," she said. "Kids think it's cool because they can see their veins, which makes taking a blood sample almost like a science lesson. They think it's awesome. Also, parents appreciate that we are using technology like this to make it easier for their children to participate. We

know that if their kids are unhappy, parents won't bring them back. If kids are happy and if the parents see that we're doing everything we can to make this easier for their kids, then they're more likely to trust us long term."

The Barbara Davis Center does not yet have data on what effect the VeinViewer has had on patient satisfaction. Nonetheless, Hoffman recognizes the value of having high patient satisfaction scores. "Patient satisfaction is incredibly important because the more satisfied the patients are, and the more satisfied the families are, the more likely they are to continue to participate in our long-term studies," she explained. "Long-term data is what's important to us. But patient satisfaction data is important to any hospital because once you have patients, you want to retain them."

Boosting Satisfaction Scores

THE DARK REPORT observes that as hospitals focus more on patient safety and patient satisfaction, they recognize the value of having the highest levels of customer service for every patient encounter. In some hospitals, the importance of phlebotomy can be overlooked, but it is, in fact, an opportunity to reduce specimen rejections and improve patient satisfaction while also reducing liability risk and improving patient care.

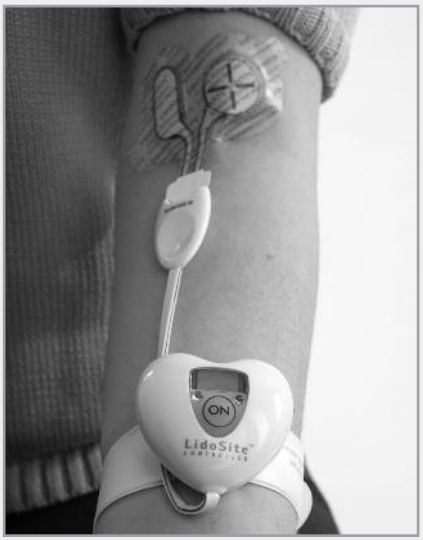
The increased attention that hospital administrators now give to phlebotomy is an unexpected consequence of the patient safety movement. On the other hand, it shows the power of measuring outcomes and patient satisfaction to drive improvement across all areas of healthcare. Who would have predicted, earlier in this decade, that one consequence of patient satisfaction surveys would be projects and investments to improve the quality of phlebotomy services! TDR

Contact Michelle Hoffman at 303-724-7555 or Michelle.hoffman@uchsc.edu; Matt Mulherin 574-234-8493 or mmulherin@pressganey.com.

New Product Helps Ease Pain of Venipuncture

TO REDUCE THE PAIN OF A NEEDLE STICK, Vyteris, Inc., of Fair Lawn, New Jersey, sells a product called LidoSite, a patch that delivers local anesthesia for use before venipuncture and routine blood draws.

The LidoSite product actually was developed as a drug delivery system and has found acceptance as a way to deliver anesthesia to the site of a needle stick. The company says, "Vyteris' active patch patented technology works by applying a positive charge to the drug-holding reservoir of the patch. As most drug molecules are positively charged, the two like-charges repel, forcing the drug molecules out of the reservoir and into the skin. By controlling the intensity and duration of the positive charge applied, the smart patch controls whether the drug delivery is topical, or whether the drug molecules are pushed deeper into the skin, where they enter the body's circulatory system directly."



Lidosite in use for a blood collection. The system releases lidocaine and epinephrine in measured doses to the site of the needle stick.

ARUP, Motoman Automate Thawing and Mixing Steps

Two companies collaborate in the design of customized, modular automation solution

CEO SUMMARY: Laboratory automation continues to develop in unexpected new directions. Recently, ARUP Laboratories and Motoman, Inc., collaborated to develop an automated thawing and mixing solution that integrates with ARUP's existing automated line and replaces manual processes. Put into operation earlier this year, the automated work cell has improved the standardization of specimen preparation, directly contributing to a better quality test result.

LABORATORY AUTOMATION CONTINUES to make leaps forward, but not in the way envisioned by the pioneers who developed the first TLA (total lab automation) systems 20 years ago. Lab automation is evolving in a task-targeted manner, as illustrated by the latest breakthrough now in operation at **ARUP Laboratories** in Salt Lake City, Utah.

Earlier this year, ARUP installed two highly customized workcells that fully automate thawing and mixing. Running side by side, each workcell processes 1,000 specimens an hour. The first one was installed in February, the second in September.

These workcells were a design solution to meet ARUP"s unique needs. As one of the nation's major sources of esoteric and reference testing, its mix of specimen types and test menu require different work flow solutions to maximize quality, service, and operational efficiency. Recognizing the benefits that would result from automated thawing and mixing, Charles Hawker, Ph.D., Scientific Director for Automation and Special Projects at ARUP worked with **Motoman, Inc.,** of West Carrollton, Ohio, to create an automated system. Motoman designs and builds robotic systems. It has customized robot solutions for a number of clinical laboratories in recent years. Since 2004, Motoman has provided robotic solutions to ARUP.

Specific Work Flow Need

"The development of this automated workcell evolved over time to meet a specific need in our laboratory," Hawker explained. "As an esoteric and reference lab, our conveyor system transports and sorts specimens—just as other hospitals and labs do for sorting and processing specimens. In most settings, these conveyor systems connect equipment such as centrifuges, aliquotters, cappers/decappers, and sorting machines. They then transport specimens to analyzers.

"However, our large volume of esoteric and reference tests make it challenging to automate work flow in ways that support our needs," continued Hawker. "As a reference lab, we get a substantial portion of our referrals as secondary specimens, compared with a primary lab that

Lessons Learned About Thawing, Mixing of Specimens Are Important for All Labs

WHEN DEVELOPING THE INNOVATIVE workcell with Motoman, Inc., ARUP Laboratories learned two critical factors about thawing and mixing specimens, said Charles Hawker, Ph.D., Scientific Director for Automation and Special Projects at ARUP.

"For clinical labs, this information about freezing and mixing specimens is critical," he said. "First, everyone knows that when a specimen freezes, it expands. If the tube is too full, critical parts of the sample can be lost. Most lab technicians think they lose only a portion of the specimen, but the reality is different. Important components of the specimen are concentrated in the solutes that are lost. That's because, as the tube starts to freeze, water molecules freeze first, pushing the solutes toward the center and out the top. For most testing purposes, we've determined that the specimen is ruined.

"We wanted to determine how full a tube could be and still go through the machine and be mixed effectively," continued Hawker. "In our experiments, we overfilled and underfilled tubes. Then we measured thaw times and whether the samples were getting adequately mixed. As part of these studies, we did chemistry and albumin tests on these tubes. We consider the results to be important and want to share them with other laboratories.

"Labs are overpouring tubes all the time and freezing them for shipment," he said. "They need to know the risk associated with freezing an overfilled tube. Even though this result was published in the 1970s, we wanted to share this information because there's been a complete turnover of staff in laboratories since then.

"The second observation involved mixing," he added. "As laboratorians, we are taught to mix specimens by inverting a tube 10 or 20 times. We wanted to know the minimum number of mixes the robot would need to mix the sample adequately. To our surprise, we learned only two mixes are required!

"We don't recommend that laboratories change their mixing procedures, however," he advised, "because a human doing the mixing is not necessarily mimicking how the robot does the mixing. The robot is timed to a specific speed and goes to a precise angle as it raises and lowers the tube for mixing."

gets front-line specimens. Our assays are more complex and esoteric. Typically, we do our tests on platforms because these tests cannot be performed on analyzers connected to track systems.

Standardizing Processes

"ARUP has another work flow requirement unique to a reference lab," stated Hawker. "We receive a large proportion of frozen specimens that must be thawed before processing. These specimens must be thawed and mixed before they can go on the analyzers in our high volume laboratory. That is why we wanted an an automated solution for thawing and mixing.

"Half the specimens we receive must be thawed and all specimens must be mixed," noted Hawker. "Having a well-mixed specimen to deliver to an analyzer is a standard process in every laboratory.

"It was about two years ago that we launched design and development efforts with Motoman," he added. "The first design concept was abandoned because we didn't think it would blow enough room temperature air at each tube to thaw the tubes quickly and uniformly.

"That was the point when we engaged the College of Engineering at the **University of Utah**," Hawker added. "The university owns ARUP. and engineering has collaborated with us regularly. One of our ideas was to design a nozzle that would aim air directly at individual tubes to speed thawing and make the process more

uniform than blowing air across an entire rack of tubes.

"The first design from Motoman had a general flow of air blowing linearly down the deck so the air would pass all of the tubes," he explained. "But with this design, the air did not blow directly at each individual tube. That's when we decided to use the individual nozzle design. Terry Ring, Ph.D., a professor in the Department of Chemical and Fuels Engineering, designed high-velocity brass nozzles, which proved to be a successful solution. Using this design positioned each specimen in front of one of these nozzles for thawing."

Achieving Uniform Quality

The goal of the design team was to achieve uniform quality in specimen processing. "It is important to know that the goal in developing this customized automation solution was to enhance the existing work flow and support a high quality of thawing and mixing," observed Hawker. "Our primary objective was not labor savings or a rapid return on investment (ROI). We wanted to use an automation solution that would produce uniform specimen quality and support existing work flow through our laboratory.

"Prior to this automation, the manual process involved putting blocks of 100 specimens on a benchtop and aiming a household electric fan at them for 60 or 90 minutes. That's a common method of thawing specimens in esoteric and reference labs. With a fan, there is some certainty that all the specimens are thawed before mixing. However, there is no absolute guarantee that each tube will be thawed thoroughly because each tube is not individually inspected after the manual thawing process.

Complete Thawing Required

"Then, to mix specimens, a lab technician would put a piece of cardboard or similar material over the top of a block of specimens and mix them by inversion back and forth 10 or 12 times," Hawker said. "Anecdotally, we knew that on rare occasions a client would call and say our results were not what he or she expected on a particular patient. They would ask us to repeat the test.

"We would repeat the test and get the results that matched the physician's expectations," he continued. "From this experience, we thought perhaps the explanation was that we had not completely thawed that specimen or mixed it well. In such situations, when the analyzer took a sample from the top of that specimen tube that was either not completely thawed nor completely mixed, it might get more water and not enough actual specimen, including the analytes, proteins, and the other serum constituents that are needed for a good test result.

"When a specimen is thawed, a layer is created based on the density of the elements in the serum," Hawker added. "The proteins are on the bottom, and the top part is watery. That is why all tubes must be mixed before testing. But because thawing and mixing was a manual process, it was beyond our control to guarantee that we would never have an unmixed specimen Now, our automated thawing and mixing solution gives us confidence that every specimen is completely thawed and adequately mixed.

"Standardization is the key," he noted. "It would be difficult for us to quantify the improvement in standardization. But we expect a decline in client calls to repeat any test results, as happened with manual thawing and mixing. Our automated mixing and thawing system now eliminates any chance of such errors, which is one reason we developed this machine.

"Each of our four main delivery tracks in our automation system transports a maximum of 2,000 specimens per hour," he said. "One of these four tracks serves our highest volume laboratory section–the Automated Core Laboratory–the section for which we wished to implement

automated thawing and mixing. In February, we installed the first thawing and mixing workcell, with the capacity to thaw and mix 1,000 specimens per hour. At that time, this was adequate to handle the peak flows on the automated testing line.

"By the beginning of the summer, ongoing growth in specimen volume justified the installation of a second automated thawing and mixing system," he continued. "That unit was installed in September. With our two automated thawing and mixing systems running, we can handle considerable additional volume on our automated line now.

Consistent Processing

"Today, there's no question that lab staff are happy to have these two thawing and mixing units running side by side," he concluded. "They know the outcome is consistent thawing and mixing of specimens. Also, the machines have reduced the manual labor that formerly was spent thawing and mixing on the benchtop. And, we have removed the fans from the processing area."

Craig Rubenstein, the sales manager for Motoman's Lifesciences division, commented, "To our knowledge, this process has never been automated in such a flexible way. This flexible approach allows a lab to choose its own parameters, such as the length of time that a specimen is exposed to the air for thawing or the number of mix cycles performed on each tube before being returned to the conveyor. The lab can change these parameters as needed.

Guarantee Of Consistency

"For labs, the level of consistency it provides guarantees that every specimen is thawed and mixed according to a predetermined set of parameters," Rubenstein added. "When it's done manually, there are no guarantees of consistency, and labs accept that there is a wide range in variety of results. That is a significant development for the lab industry."

Steps in Automated Thawing and Mixing

With a throughput of 1,000 specimens per hour, the automated thawing/mixing workcell developed by ARUP Laboratories and Motoman, Inc., has a six-axis, robotic arm that gathers samples as they travel across an automated transport and sorting system.

For thawing, the robot places specimens in front of high-velocity, brass nozzles. The array of 760 nozzles blow room-temperature air at two liters per minute at each specimen. Air enters the standardized tube carriers (STCs) through a slit normally used to read bar codes. Each specimen is thawed from all sides in as little as 20 minutes. There are no detrimental effects on any analytes to be tested.

During mixing, the robot can hold 10 specimens at once and uses pneumatic, pressure-pin cylinders that clamp tightly on the tube caps, preventing leakage. It then rotates the samples through a 270-degree pattern, designed to thoroughly mix the specimens without air bubbles. After mixing, the transport returns the specimens to a sorter where they are arranged for testing to be performed.

To ensure that no aerosolized, infectious-viral particles could enter the laboratory's air supply if a specimen spilled, an exhaust hood uses four high efficiency particulate air (HEPA) filters to displace air from the workcell at a rate that is approximately double the rate of air dispersed through the nozzles.

THE DARK REPORT observes that what ARUP and Motoman have developed is like the Holy Grail for esoteric and reference labs: a way to automate labor-intensive processes. This machine undoubtedly will lead to other, more sophisticated machines, thus leading to improvements in efficiency at all levels of processing in these labs. TDR

Contact Charles Hawker at 801-584-5261 or hawkercd@aruplab.com or Craig Rubenstein at 949-263-2640 x2648 or craig.rubenstein@motoman.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Readers of THE DARK REPORT may want to check out the November issue of *MLO Magazine*. It profiles the experiences of four scholarship winners to the *Executive War College* last May in Miami, Florida. Winners were Pervez A. Mirza of **State University of New York** (SUNY) in Brooklyn, New York; Gary Maluf, Ph.D., **Benson Hospital**, Benson, Arizona; Cynthia J. Kelley, **Children's Mercy Hospitals & Clinics**, Kansas City, Missouri; and, Susan Clark, **Memorial Regional Hospital**, Hollywood, Florida. Their information can also be found at *www.mlo-online.com*.

MORE ON: Scholarships to Executive War College

Prior to last year's *Executive War College*, THE DARK REPORT, in collaboration with *MLO Magazine*, offered full scholarships, including air fare and hotel, to applicants who responded to a notice published in the magazine. The goal was to give up-and-coming laboratory managers an opportunity to expand their knowledge and network. Scholarship winners were enthusiastic about the experience and THE DARK REPORT and *MLO Magazine* will be repeating the scholarship program for the May 13-14, 2008 *Executive War College*. Watch *MLO Magazine* for details. As thanks for years of support, THE DARK REPORT is funding the scholarship program as a way to help aspiring laboratorians add to their management skills and help them advance their careers.

URINE TEST HELPS IN EARLY DIAGNOSIS OF KIDNEY DISEASE

How about a non-invasive urine test that can be used for early diagnosis of kidney disease? **Nephrocor**, a nephrology laboratory in Richmond, Virginia states that its RenalVysion test identifies and measures urinary sediment findings not detected in routine urinalysis. The results allow anatomic localization of injury in the kidney and the severity of disease. Nephrocor says the technology is 91% accurate in diagnosing kidney disease when compared with diagnosis using kidney biopsies. RenalVysion allows a pathologist to distinguish categories of renal and bladder lesions by integrating urine cytopathlogy and quantitative and qualitative urine chemistries. About 26 million Americans, or 13% of the U.S. population, have chronic kidney disease, according to a new estimate published in November 7 issue of the *Journal of the American Medical Association*.

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...

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That's all the insider intelligence for this report. Look for the next briefing on Monday, December 10, 2007.