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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

CLIA's Catch-22 Involving Proficiency Testing

THERE'S A REGULATORY TRAP awaiting the unwary laboratory organization. It involves language in CLIA rules for proficiency testing (PT). All medical directors and lab administrators will want to fully understand the implications of what appears to be an emerging trend in CLIA laboratory enforcement.

In recent years, an ever-greater number of labs have unwittingly found themselves in a classic Catch-22 situation. In simplest terms, CLIA regulations call for a proficiency test specimen to be handled according to the lab's "normal/standard" procedures. That often means that a positive result may be sent to another laboratory for confirmation. Yet CLIA rules also state that PT specimens are not to be sent to another lab.

Therein lies the Catch-22. If the med tech handling the PT specimen follows the lab's protocols and sends it out for confirmation, CLIA regulators are deeming that to be a violation which puts the laboratory's CLIA license at risk of suspension or revocation. But, if the med tech did not follow the lab's procedures by sending out the PT specimen in the same manner that a patient specimen would be handled, that can also be a violation.

This is a high stakes situation. Medical directors can face a two-year ban from being medical director of any CLIA-licensed laboratory. As you will read on pages 6-8, a New Hampshire hospital laboratory has a one-year CLIA license suspension due to this situation and a major laboratory organization has been forced to change its ownership for two years.

We asked attorney Jane Pine Wood to provide an overview of this Catch-22 situation in this issue of THE DARK REPORT. She has represented multiple laboratories that found themselves enmeshed in this exact situation.

Until now, almost nothing has been written about this growing problem. One reason for this is the fact that most laboratory organizations caught in this situation try to keep that news out of the public eye. That is understandable. Having a CLIA license suspended or revoked is certainly not something any lab wants made public. On the other hand, this Catch-22 cannot be fixed or resolved unless labs that find themselves victims to this contradiction in CLIA rules speak out about the injustice of the situation.

It is important to remember that sunshine is the disinfectant to regulatory problems. That is why I encourage any of you experiencing this Catch-22 to contact us here at THE DARK REPORT and allow us to tell your lab's story. TDR

Exec War College Looks At Threats to Lab Industry

Speakers identify specific market forces that portend a very different future for clinical labs

CEO SUMMARY: Taken collectively, the speakers at the opening session of the 17th Annual* Executive War College on Lab and Pathology Management *had a powerful message to the nearly 700 attendees. After years of slow movement, a rapid transformation of the American healthcare system is about to unfold. There will be opportunities for clinical labs and pathology groups to prosper, but it will require new business strategies and good management execution.

WITH ALMOST 90 SPEAKERS over the course of three days, this year's *Executive War College on Lab and Pathology Management* provided a detailed window on the trends and technologies unfolding in the lab marketplace.

One of the most important sessions took place on the first morning of this year's conference. A series of speakers looked at the dominant forces actively reshaping both healthcare and the lab testing industry.

There is only enough space in this issue of THE DARK REPORT to bring out the essential points of three speakers. Additional insights from the other presentators will be provided in upcoming issues.

The opening speaker was Robert L. Michel, familiar to readers as the Editor-in-Chief of this publication. His primary message was that the long-standing business model of the independent clinical laboratory is poised to change in significant ways.

Michel called attention to the fact that, over the past four decades, office-based physicians have been the source of 80% or more of the lab test specimens referred to independent laboratories. He noted that, during this time, the dominant business model for office-based physicians has been one of physician ownership, either in the form of a partnership practice or a professional corporation.

However, the era of physicians as owners of their medical practices is ending. Doctors are moving from partners and equity-owners in their medical groups to employees. The pace of this transformation is moving quickly. *(See TDR, March 12, 2012.)*

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

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

"In 2010, **Department of Labor Statistics** noted that 691,000 physicians were practicing in this country," stated Michel. "Data from the **Center for Studying Health System Change** (HSC) show that approximately 73%—or 504,400 physicians—practice in office-based settings. It is this 500,000 physicians who represent the source of the vast majority of specimens and revenue handled by independent laboratories.

"In recent years, a sizeable proportion of physicians have moved from partner/owners to employees," he continued. "Data published by the **Medical Group Management Association** (MGMA) show that hospital ownership of medical practices moved from about 20% in 2002 to more than 50% by 2008!

New Criteria For Lab Tests

"Of course, the pace of hospital and payer acquisition of medical groups has accelerated since 2008," noted Michel. "This shift in the business model of the office-based physician means that the new owners of these medical groups will use different criteria when choosing their laboratory provider.

"Independent laboratories will need to develop a strategy to retain the lab test referrals from these office-based physicians," advised Michel. "Obviously, if hospitals and health systems are buying medical groups, then the labs of those hospitals and health systems have the inside shot at getting and keeping that business.

"The point here is that the fundamental change in who owns office-based physician groups is a trend which can create new winners and new losers among the nation's independent laboratories," concluded Michel. "The shorthand strategy hook is to answer the question: How can our lab best serve doctors who are employees versus doctors who are owners?"

Paul Mango had the challenging task of explaining the transformation of the American healthcare system and how laboratories should respond with strategies to emphasize their value proposition to physicians, patients, payers, and employers. Mango is a Director at **McKinsey & Company**.

Pricing Health Insurance Risk

Mango's first point was that reforms and similar changes within the healthcare system are altering the way health insurance risk is priced. "In particular, employers and private payers are now reallocating the financial accountability for medical risk," he said. "Further, the price bands imposed by the Accountable Care Act (ACA) will further narrow and socialize medical risk.

"An example of this is how employers are raising the deductibles and the out-of-pocket requirements for employees," continued Mango. "This can be seen in the increased enrollment in high-deductible health plans (HDHP). In 2012, it is estimated that 21 million people have HDHPs, compared to just 4 million people in 2006."

Mango next discussed the types of reimbursement initiatives underway. He identified four different care models that incorporate payment bundling. They are:

- Full capitation
- Accountable care organization
- Episodes of care
- Patient-centered medical home
- Basic pay-for-performance (P4P)

Two Drivers To Use of IDNs

The integrated delivery network (IDN) is another form of reimbursement reform. "On one side, payers are driving this," observed Mango. "Payers are affiliating or acquiring health systems and supporting full clinical and operational integration to reduce costs, improve member experience, and manage referral volume. In Pennsylvania, the **Highmark/West Penn Alleghany Health System** relationship is one example.

Mango Looks at How Hospital Laboratories Should Transform in Their Role as Providers

AMONG THE ISSUES TO BE ASSOCIATED accountable care organizations (ACO), Paul Mango of McKinsey & Company, highlighted the fact that the existing economic basis for ACOs will be misalignment between medical risk in the health economy and the way it is financed. In his view, this will be exacerbated by the Accountable Care Act of 2010 (ACA). However, this will open the door for hospital laboratories to support the transformation in the three dimensions he describes below.

Implications of ACOs for Lab Service Providers:

Role transformation along 3 dimensions

1) OUTREACH

- Within a hospital-led ACO, an effective outreach program becomes much more important. This includes not only the logistics of specimen transport and test result delivery, but of specimen draw as well.
- A more likely development is the formation of physician-led ACOs, in which case the hospital will need to have a competitive offering along many dimensions with the national laboratory service companies.
- Where insurers induce ACO-like formation, their benefit and reimbursement designs will likely guide patients and doctors away from using the hospital lab.

2) LABORATORY BENEFITS MANAGEMENT

- Establishing laboratory formularies and testing algorithms, and then enforcing them will be a new, value-enhancing role.
  - Adherence to evidenced-based standards of testing.
  - Substituting advanced diagnostics for other factor inputs (e.g., companion diagnostics and costly biologics).

3) FROM INFORMATION TO INSIGHTS

- At the individual patient level, using laboratory data to derive insights into early onset of disease, or broader practice patterns.
- At the population level, discerning incidence of disease, trajectory of health status.

"On the other side, provider systems can build a health plan specifically to leverage the brand name and to drive volume to the provider system," he explained. "**Intermountain Healthcare** in Utah is pursuing this strategy."

At a minimum, clinical laboratories and pathology groups need to pay increased attention to developing bundled payment models of care that will eventually change how laboratories are reimbursed for lab testing services. The different care delivery models described by Mango show the breadth of employer and payer interest in moving away from fee-for-service payment and toward other models, particularly bundled payments.

The next area of healthcare transformation that Mango discussed involved the Medicare program. He first identified the strategic drivers that the **Centers for Medicare and Medicaid Services** (CMS) will use to improve patient care and lower the growth in Medicare spending. There are three goals:

- Better care for individuals.
- Better health for populations with respect to educating beneficiaries about the upstream causes of ill health.

- Lower growth in expenditures by eliminating waste and inefficiencies while not withholding any needed care that helps beneficiaries.

He then explained the two Medicare ACO gain-sharing models; a one-sided version and a two-sided version. "The important thing to understand is that for primary care providers (PCP), there is worthwhile upside potential from achieving total cost of care savings," noted Mango.

Primary Care Bonus

"Assume a 10-physician PCP ACO with 5,000 Medicare beneficiaries (500 patients per doctor)," he began. "Currently, the median PCP annual salary in this country is $183,000.

"Should this PCP achieve just a 2% total cost of care savings with a shared savings of 25%, that would equate to a bonus per physician of $15,000 (or about 14%)," said Mango. "Raise that to a 5% savings on total cost of care and a 90+ percentile on quality. In this instance, each physician could receive more than $100,000 of bonus."

Mango also noted that Medicare Advantage plans are likely to gain favor with Medicare beneficiaries. CMS data shows that enrollment in Medicare Advantage is 12.8 million in 2012. That is a jump of 10% from enrollment of 11.7 million in 2011. This number represents 32.3% of the 39.3 million seniors enrolled in Medicare in 2012.

For clinical laboratories and pathology groups, a shift in enrollment by seniors away from Medicare Part B and over to Medicare Advantage plans will not be an auspicious development. That's because private health insurance companies administer the Medicare Advantage plans and these private payers tend to purchase laboratory services based on the commodity mindset; that is, all lab tests are equal, so why not pay the lowest price per test?

In fact, the danger of commoditization was one major point made by the speaker who preceded Paul Mango during this session. Marc Grodman, M.D., Chairman and CEO of **Bio-Reference Laboratories, Inc.**, spoke to the need for laboratories to work cooperatively to address the two "Cs" of the lab market. One C is competition and the other C is commoditization.

"Everyone in today's audience has a stake in seeing that vigorous and healthy competition continues in the lab testing marketplace," noted Grodman. "However, the growing size and clout of the national lab companies is approaching the tipping point where it will become very difficult for smaller lab companies to compete in a financially-sustainable way."

Grodman links competition with commoditization. He explained the connection between these two dynamics. "Reduced competition for laboratory testing will be a bad outcome for all stakeholders in the American healthcare system, " he observed. "It makes it easier to cut reimbursement if just a handful of very large lab companies remain. At the same time, smaller labs are consistently at the forefront of innovation and delivering a higher level of service to physicians and their patients. Yet it is this group of laboratories that will disappear if competition skews in favor of larger national laboratory companies.

Lab Test As A Commodity

"Similarly, all labs should be concerned about the steady drive by payers to commoditize laboratory testing," explained Grodman. "Laboratory tests are not a commodity. Every laboratory offers a unique combination of quality, accuracy, and clinical expertise that lie behind the results printed on the lab test report.

"Market forces currently are working to reduce today's level of competition and drive down the price of lab tests," he concluded. "That is why the lab testing industry should find ways to work more effectively together to preserve competition and prevent commoditization." TDR

Inadvertent PT "Errors" Trigger CLIA Sanctions

Confusing rules for proficiency testing lead to harsh penalties, including change in ownership

CEO SUMMARY: Despite taking appropriate steps to complete proficiency testing (PT), in recent years an unknown number of labs were determined to be in violation of CLIA requirements. Federal regulators are enforcing penalties ranging from suspension of the labs' licenses to transition to new lab ownership for two years. A lawyer involved in several of these cases says labs are confused about how to follow proper procedures without violating proficiency test rules.

IN RECENT YEARS, an unknown number of labs have found that taking all the proper steps to complete proficiency testing (PT) led to violations of federal CLIA rules and suspension of their laboratory licenses. In extreme cases, federal officials have required new lab ownership for two years.

Earlier this month, *Foster's Daily Democrat* reported that the CLIA certificate was to be revoked for the laboratory at 178-bed **Wentworth-Douglass Hospital** (WDH) in Dover, New Hampshire, effective May 31, 2011, but that action was deferred by government officials.

As reported by the newspaper, the laboratory at WDH followed proper protocol when conducting a PT and sent the sample to a laboratory at a sister facility for confirmation. But because the sample was for PT, the federal Centers for Medicare & Medicaid Services (CMS) ruled that sending out the sample was a violation of CLIA rules.

The hospital paid a fine of $60,000 and has operated under an agreement with CMS since January. Under the agreement, WDH voluntarily surrendered its CLIA license for one year, beginning January 1, 2012. Now the lab sends out tests to a lab it does not own or operate. *(See sidebar on page 9 for more details.)*

Other labs that have inadvertently violated CLIA's PT rules have been forced to transition to new ownership for two years, stated Jane Pine Wood, an attorney with **McDonald Hopkins**. One large regional laboratory incurred costs of about $2 million for such a transition.

"That is money that could have been put to much better use, such as for patient care," observed Wood. "It's hard to argue that this $2 million is money well spent.

New Owners Required

"In the past five years, I have seen several PT-related settlement agreements with CMS and laboratories and/or lab directors that I represent. Two such agreements were signed in recent weeks," she explained. "To preserve the confidentiality of these settlements, I can discuss only the general terms of these agreements.

"In the cases I've seen, there are variations on a theme—that theme being that all instances were relatively inadvertent," observed Wood. "The CLIA regulations

say that for proficiency testing, labs should treat the PT the same way they treat a patient specimen. But this rule is problematic if your lab's procedure says you should send out certain tests. If you can't send out a PT, there may be situations in which there is a conflict.

"One penalty is given out repeatedly as a result of protocols used in most labs," Wood said. "Let's say it's a test for HIV. Most labs do not do their own HIV antibody test in house. Instead, they send these out.

"So, if they get a PT that is positive for HIV, they record the result, and then check the lab protocol on how to handle a positive HIV test. At most labs, a positive result for HIV requires sending out the test for confirmation," she said.

"I know of cases where there are email messages from the clinical lab scientists who run the PTs," she added. "They ask their superiors, 'Am I supposed to send this out or not? It's PT and so I'm confused about the regulations.' Unfortunately, these PT sample were put in boxes for referral to other laboratories and went out.

"Generally, CMS takes the position that the definition of intentional referrals is that you intended to send it out—not that you intended to do something wrong," commented Wood. "That definition of intent is different from the definition used to define intent under any law with a substantial penalty. Under the law, usually 'intent' means you intended to violate the law.

Defining 'Intentional'

"In the various CMS regions, there are differences regarding interpretation of 'intent' and therefore differences in how penalties are applied," she added. "But CMS generally has recognized that there is no improper intent; a case like this with HIV was simply a misunderstanding. In fact, at least one CMS official has been quoted as saying that the agency recognized there is legitimate confusion in this area.

"Usually, CMS takes one of two general approaches with these cases," observed Wood. Each approach is not related to the seriousness of the violation but with the region where the problem arose.

"One approach involves having the lab pay a fine and invest in retraining staff," she continued. "The other approach is to require a new owner of the laboratory for two years.

Inadvertent PT Error

"I have a client that will transition the laboratory to a new owner in the next week," she added. "Again, this ownership change came after an inadvertent error in PT involving an HIV test. However, the estimated cost to convert this lab to new ownership will approach $2 million. A friendly pathology group will run the lab for two years. The clinical laboratory is significant size, involving multiple hospitals, nursing homes, and a sizeable outreach business.

"This laboratory organization must change every contract it has and revise all documentation to reflect the new name," she said. "That's a lot of contracts because the lab needs new provider numbers, new tax identification numbers, new benefit plans, and new retirement plans. For this large regional lab, the transition affects everything, including new policies, procedures, letterhead, requisitions, leases, and reagent and equipment contracts.

"Such a transition can be extraordinarily costly and those costs run counter to the goal of cutting healthcare spending," Wood commented. "Some officials at CMS recognize that this extreme measure doesn't make sense. But, to be honest, this is not the only case.

"In recent years, we had a similar case at a rural critical access hospital where a laboratory worker mistakenly put a PT sample in the bin to be sent out," she said. "It was the weekend and the laboratory was cited for violating the PT rules. But the clinical lab didn't even have that test available on its testing menu, so how could it have cheated?

Proficiency Test Issue Causes NH Hospital Lab To Voluntarily Surrender CLIA License for One Year

OVER THE PAST FIVE YEARS, attorney Jane Pine Wood of McDonald Hopkins has seen several cases in which labs have been penalized severely for inadvertent errors when conducting proficiency tests (PT). She believes an inadvertent PT-procedural error may have been the cause of trouble for the laboratory of Wentworth-Douglass Hospital, located in Dover, New Hampshire.

"Looking at this case, it's difficult to know actually what happened, but my first reaction was that any violation of the PT rules could easily have been inadvertent," she said.

"Fortunately, in the Northeast region, the penalties from the Centers for Medicare & Medicaid Services (CMS) in these cases are not as severe as they are in other regions," Wood commented.

A news story published last week in *Foster's Daily Democrat* reported that the laboratory at WDH was informed in a letter from CMS in March 2011 that it violated the PT procedures. Federal officials conducted a "complaint survey" at the WDH lab in February 2011.

The inspectors found the lab out of compliance with CLIA for "reporting proficiency testing results obtained from another laboratory," the newspaper reported. "The state claimed that WDH had sent its proficiency assessment samples to another lab and turned in the results as their own," the newspaper reported in an article May 9.

A hospital spokeswoman denied the accusation. State officials referred the case to CMS. Wentworth-Douglass Hospital appealed the decision and then settled with federal officials, the newspaper reported. The hospital paid a fine of $60,000 and put $126,000 in an account to pay for expenses related to quality improvement initiatives. It also surrendered its lab's CLIA certificate for one year, on a voluntary basis. The effective date of the surrender was January 1, 2012. WDH has complied with all of the components of the settlement agreement, the newspaper reported.

THE DARK REPORT contacted officials at the laboratory at Wentworth-Douglass Hospital for comment. As of press time, there has been no response from anyone at WDH.

In the view of attorney Wood, Wentworth-Douglass Hospital's agreement with CMS avoided much harsher penalties often resulting from laboratory proficiency testing violations in other areas of the country. "Compared to what they would have had to pay in legal fees and everything else if this case had occurred in another region, that's not too bad," concluded Wood.

"There is some interest in Congress about how substantial the penalties should be for something that has not resulted in real patient harm," offered Wood. "We have seen cases where a mistake was caught before testing was done or where there was confusion over which procedures to follow for PT. In both cases, there were severe penalties. That seems harsh when there was no threat of patient jeopardy. We have laboratory clients that have signed settlement agreements as a result of these situations."

Medical directors of clinical labs should take note of how the handling of proficiency testing specimens is tripping up a growing number of lab organizations in the United States. The consequences are severe for any laboratory which inadvertently mishandles a PT specimen along the lines described in the case of the lab at Wentworth-Douglass Hospital and the examples cited by attorney Jane Pine Wood. **TDR**

—Joseph Burns

Contact Jane Pine Wood at 508-385-5227 or jwood@mcdonaldhopkins.com.

Lean improvement project saves $3.5 million

Sarasota Hospital Lab Reduces Number of Hemolyzed Specimens

CEO SUMMARY: Seeking to improve turnaround time for stat lab tests, the laboratory at Sarasota Memorial Health Care System identified high rates of hemolysis as the chief reason for less than ideal TAT. Because 32% of blood draws were handled by the lab's phlebotomy staff while 68% of blood draws were performed by nurses and emergency department technicians, the lab's performance improvement team implemented standardized blood draws facility-wide. Hemolyzed specimens fell below 2% hospital-wide and $3.5 million in savings were realized.

HEMOLYZED BLOOD SPECIMENS are the bane of every clinical laboratory. Each hemolyzed specimen can delay appropriate patient care and is an unnecessary increase to the cost of laboratory testing.

It is a universal problem, with many root causes that often fall outside the clinical lab's ability to address. Thus, it is notable when any laboratory tackles the problem of hemolyzed specimens and can lower the rate by a dramatic amount and sustain those gains. Such was the case for the laboratory at **Sarasota Memorial Health Care System**, in Sarasota, Florida.

Following a series of Lean and process improvement projects launched in 2009, the rate of hemolyzed specimens—as high as 11% in one department—was driven down to less than 1% in most departments in the hospital.

The direct benefits to patient care are obvious. But equally significant is that this quality improvement initiative has saved the hospital $3.5 million since its implementation.

As is true at most other hospitals, the problem of hemolyzed specimens was particularly acute for blood specimens collected in the Emergency Care Center (ECC). "Further, the hemolysis rate across the entire hospital was much higher than the hemolysis rate for the lab's phlebotomy staff," explained Laboratory Director Charlene H. Harris, FACHE, MT(ASCP).

"Hemolyzed specimens not only delay patient care because of the need to redraw the patient, but hemolyzed specimens are also a major source of patient dissatisfaction," she said. "Patients invariably are unhappy about the need to be stuck with a needle a second time. It is also true that these same patients often recognize that someone on the hospital staff did not properly collect or handle their original blood specimen."

At 806 beds, **Sarasota Memorial Hospital** is the second largest acute care public health system and hospital in Florida. It has specialized expertise in heart, vascular, cancer, and neuroscience services. "Our clinical lab runs about 2 million billable tests per year," noted Harris. "Our lab's phlebotomists collect only 32% of all specimens in the facility. Nurses and medical technicians collect the remaining 68%.

"One thing that distinguishes Sarasota Memorial Health System is its culture of quality," continued Harris. "**HealthGrades** has named us as one of the top 50 best hospitals in the United States for five consecutive years. We are one of only five hospitals in the United States to earn this recognition."

During a presentation at the *Lab Quality Confab* in San Antonio last November, Harris pointed out that this "culture of quality" across the entire health system played a role in the lab's effort to reduce hemolysis rates. "There is support at the highest levels for these types of continuous quality improvement efforts," emphasized Harris.

"For example, one favorite expression of our CEO, Gwen MacKenzie, is 'The relentless pursuit of quality,'" noted Harris. "That message is understood by everyone working within our health system. It helped our lab gain the active support of nurses, physicians, and other staff for our efforts to reduce the rate of hemolyzed specimens across the entire hospital.

Reducing Lab Test TAT

"It was 2009 when we started our improvement project with the goal of reducing lab test turnaround time (TAT)," stated Dana J. Rickard, the lab's Pre-Analytical Manager. "Of course, hemolyzed specimens are one source of delayed TAT. To help us, we turned to Charlotte Damato, who is the Lean/Six Sigma Quality Coach at our hospital."

"The lab team analyzed all the processes involved in testing," noted Damato. "Five significant processes had the greatest impact on turnaround times for stat testing. Some of these processes are unique to our facility, but most of these will be familiar to anyone working in a hospital laboratory.

"The first of these five issues centered upon how the pneumatic tube system was involved in causing TAT delays," she

recalled. "Nurses on the floors would send specimens through the tube system—including stool and urine samples. Sometimes the collection cups were not sealed properly or they were not placed in the correct transport container.

Improperly-Sealed Samples

"When sent through the pneumatic tube system, improperly-sealed samples would sometimes leak outside the carrier," explained Damato. "At that point, the staff would immediately shut down the entire pneumatic tube system for cleaning and sanitizing. This can take an hour or more. That happened at least once a week and often more than that.

"A second source of delay was how lab specimens collected in the Emergency Care Center (ECC) were handled," she said. "All stat tests from the ECC dropped into a lab pneumatic tube station with lab specimens from other units in the hospital. That made it impossible to tell stat lab specimens from any other specimens in the bin. This source of delay was fixed by having ECC staff use only red canisters for stat specimens.

"The third source of turnaround time delays for stat lab specimens involved the ECC nurses," noted Damato. "They often drew blood before they got an order to do the draw. By sending specimens to the lab without an order, these stat tests would sit in a holding pen awaiting an order.

"Our root cause analysis showed that, whenever the ECC drew the blood before getting an order, it took an average of 34 minutes longer to get a lab result than if the lab had taken the order and performed the blood draw," she observed.

"Four was a common problem in many hospital labs: frequent phone calls to the preanalytical department," commented Damato. "There could be 30 calls an hour and some were for ridiculous requests. Someone would call and say, 'I need a red tube' or 'I need a baggy.' We revised the process for answering these calls so that work in the preanalytical department was not continuously interrupted.

"Five was high rates of hemolysis, and this factor had a big impact on TAT," stated Damato. "At the time, we noticed, of all groups and departments involved in collecting lab specimens, our phlebotomists had the lowest hemolysis rates.

"Of these five sources of delays in lab test TAT, we believed driving down the number of hemolyzed specimens had the potential to generate the biggest improvement," noted Damato. "The hospital-wide hemolysis rate was over 2%, but the rate for specimens collected by our phlebotomy staff was 2% or less. We believed that we could get the entire facility down to this 2% rate.

"Keep in mind that, back in 2009 the rate of hemolyzed specimens was about 10% for the ECC," she added. "We established the 2% rate as the stretch goal for this improvement project."

The Source of the Problem

Damato noted that the hemolysis rate data from across the entire hospital showed which units had the greatest potential for improvement. "We could see that the highest hemolysis rates were from the ECC," she said. "The ECC is divided into pods and even the best ECC pod was at 5.8%; the worst pod was 11%. This told us where we had to start implementing solutions."

At about this time, the lab tapped a new vendor for help in its quality improvement project. "We are always looking to find the best value and so I asked this vendor—**Becton Dickenson** (BD)—about our hemolysis rates," recalled Rickard. "BD offered to help with the staff education.

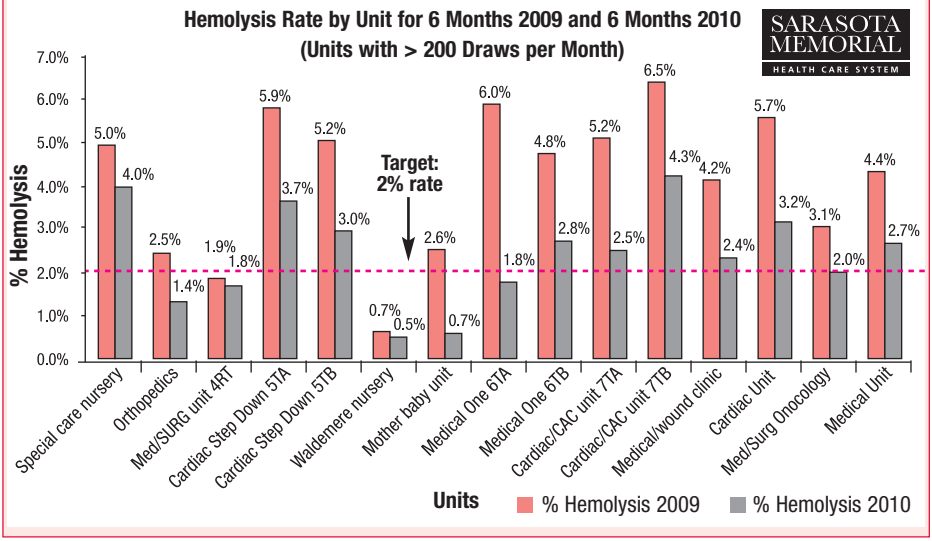
"Our strategy was to have BD—as an outside expert in this field—send its trainers to all areas where nurses draw blood on the floor and where multi-skilled techs draw blood in the ECC," she said.

"These trainers used a non-confrontational approach in each department," recalled Rickard. "They didn't observe

Lab's Lean Project Engages 15 Hospital Units In Effort to Reduce Hemolyzed Specimens

IT WAS AN AMBITIOUS GOAL TO REDUCE the rate of hemolyzed specimens across many different units of 806-bed Sarasota Memorial Hospital. The Lean project was orginated by the clinical laboratory and the improvement plan focused on the Emergency Care Center (ECC).

An assessment of current state was conducted. After several of the implementation strategies were presented to the nursing units, all 15 units also reduced their hemolysis rates. The table below shows the before and after performance of each unit that participated in this Lean project. The goal was for each unit to reduce the hemolyzed specime rate to under 2%.



over anyone's shoulder. Instead, they handed out the collection supplies and asked how they were used.

"These outside trainers found that there were different blood collection procedures and supplies used throughout the hospital," she said. "In fact, they identified 11 different procedures for drawing blood! It wasn't pretty. The BD trainers even found that the phlebotomists did not consistently follow all 'Best Practices.' At that point, they made a number of recommendations to us.

"Our next step was to have BD provide the necessary education throughout the hospital," Rickard said. "That meant explaining the proper procedures, making sure there were standardized collection supplies available on all the nursing floors, and explaining how and why hemolysis occurs when the incorrect collection process is used. We had not done a good job explaining the reason 'Why' previously.

When Hemolysis Occurs

"In fact, the nursing staff and the ECC MSTs thought that the lab caused hemolysis," she said. "They didn't realize that most hemolysis occurs at the point of collection. That was a major insight for them.

"Having BD do the best practice education helped hospital staff more readily accept this information," added Rickard. "After that, the lab staff was seen as experts in blood draw, which was much improved from how we were viewed pre-

viously and now our interactions are much more collaborative."

"Once we had the data, we met with the nursing coordinator and the education coordinator to identify the minimal procedures we have the staff follow," Damato added. "The procedures included letting the alcohol dry, keeping the tourniquet time to less than a minute, and gently inverting the tube.

Blood Collection Tip Sheet

"We developed a tip sheet that we put on the back of the procedure and put the procedures all over the hospital—wherever blood collection supplies were kept," she said.

"By 2010, we were measuring significant improvements in the rate of hemolyzed specimens," continued Rickard. "But in the ECC, that rate of hemolyzed specimens continued to be above 2%.

"Among the different ECC pods, these rates were at 3.1%, 3%, and 2.3%," she added. "It was challenging to drive those rates below 3%. At that point, an ECC Director suggested we have phlebotomists do the draws in the ECC to see if hemolysis rates can go down to 2% in a fast-paced environment like the ECC.

"We agreed. For a six-week period beginning in October 2010, two phlebotomists were assigned to the ECC for 12 hours a day, seven days a week," she said. "With phlebotomists doing the collections, hemolysis rates went down to under 2% in the two pods. Blood culture contamination rates also declined by a significant amount.

"There were impressive outcomes from the hospital-wide improvement project to reduce hemolyzed specimens," explained Rickard. "The emergency care center (ECC) achieved a reduction of 93% for hemolyzed specimens.

"Hospital-wide, we reduced hemolysis by 67%," she said. "Even the phlebotomists—who had the lowest rates at the start of this improvement program—reduced their hemolysis rates by over 70%!"

During the course of the improvement project, workflow changes within the laboratory itself contributed to a higher rate of hemolysis. "In the middle of this project, we saw an upward tick in the hemolysis rate," recalled Rickard. "The lab had installed new analyzers.

"The change was that hemolysis was no longer being detected visually," she continued. "These new lab instruments were detecting hemolysis spectrophotometrically and the equipment was more precise than the lab techs at detecting hemolysis."

It has been almost two full years since this improvement project was completed. Sarasota Memorial Health System has sustained its performance in lowering the rate of hemolyzed specimens.

"A new procedure was implemented as part of this project," stated Damato. "Each month, every department gets a report of hemolyzed specimens. It allows them to monitor the performance of their team.

"We are proud of these improved outcomes," she noted. "As of last year, the ECC was 0.88%, housewide was 0.86%, and phlebotomy was 0.13%. These rates are significantly below the national average for hemolyzed specimens. Unit-specific hemolysis rates are reported monthly."

The Cost-Savings Model

Every performance improvement project needs to estimate cost savings. "Our lab's improvement team started by looking at what was saved in supplies and the reduced turnaround time for stat testing," stated Damato. "The value of having outside experts from BD help us is that they showed us other criteria to measure that represent important sources of savings and improved patient outcomes.

"BD gathered data on length of stay and the number of patients in the ECC who left without being seen," she explained. "BD put that data in a cost-savings model that included: 1) the costs of supplies not used; 2) the time not wasted for redraws; and, 3) the reduced turnaround time.

Exposing Common Myths about Source of Hemolyzed Specimens Played a Key Role

EVERY HOSPITAL LABORATORY WAGES AN ONGOING BATTLE to help keep the rate of hemolyzed specimens at the lowest possible level. As part of a Lean project to achieve and sustain substantial reductions in the number of hemolyzed specimens, Sarasota Memorial Hospital's laboratory team decided to explode the three big myths associated with hemolyzed specimens. It was called the "Myth Busting Education Program" and was conducted prior to implementation of best practices to reduce the rates of hemolyzed specimens in different units.

Myth One: We are saving the patient a venipuncture if we draw from the IV start.

Myth Buster: *If hemolysis occurs, the patient has a longer wait and the patient must have a venipuncture anyway.*

Myth Two: Collecting blood at the time of IV start, before the test order is in the computer, saves time.

Myth Buster: *Actual data showed that collecting blood before a test order is placed, increased turnaround time for blood test results by 30 minutes, plus more blood was collected than needed.*

Myth Three: Nurses are as good or more skilled than phlebotomists for blood collection.

Myth Buster: *Hemolysis rates of specimens collected by phlebotomists are consistently below 1% in all settings. Phlebotomists are trained for all types of blood collection, even the most difficult ones. After phlebotomists worked in the ECC, nurses respected their ability and called on them to help with difficult sticks.*

"Taken together, all of these sources represent a total savings of $3.5 million," added Damato. "This resulted from significantly reducing rates of hemolyzed specimens and sustaining these reductions across the entire hospital since the inception of this performance improvement project."

Damato shared three key lessons that can be used by other hospital laboratories. "First and foremost, quality improvement across the entire institution requires time," she observed. "Processes must be changed, along with the culture of the institution. Taking time to engage and develop collaboration ensures downstream success.

"Second, don't be afraid to tap your lab vendors on the shoulder and ask for their help," continued Damato. "They have expertise and resources that can help your improvement project. Further, they have the experience of working with hundreds and thousands of their lab customers. So they bring deep knowledge and hands-on experience to the project.

"Three, celebrate success and keep the numbers visible throughout the hospital," she concluded. "People like to be part of a winning effort. Posting on-going performance reports helps them stay focused to continue doing the steps necessary to sustain that level of achievement and improve further."

Probably the best outcome of all is that patients are happier. Not only do they avoid unnecessary needle sticks and the collection of a second specimen of blood, but their lab test results are reported more quickly, and that contributes to faster diagnosis and treatment. **TDR**

—By Joseph Burns

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HIPAA Update

Patient Service Center Theft Highlights Labs' Need to Protect Paper Records

LABS PUT SO MUCH EFFORT INTO SECURING electronic health records, that it's easy to overlook the need to protect paper records. **St. Joseph's Medical Center** in Stockton, California, learned this lesson the hard way recently when thieves stole more than 700 paper records from one of the hospital's 23 patient service centers (PSC).

The theft showed that paper records and PSCs can be difficult to secure, stated Teresa Bryant, the lab's Administrative Director, who added that "many of the hospital's PSCs are in rented facilities where the landlord is responsible for maintaining security." She stated that, when a window at one PSC was locked—but unmonitored by the security system—thieves broke in and stole three boxes of patient records.

St. Joseph's Medical Center is a 350-bed hospital that is part of **Dignity Health** (formerly **Catholic Healthcare West**-CHW). Its laboratory does reference testing for the entire DignityHealth organization and processes 2,000 requisitions per day.

The theft took place in March and the hospital staff notified each affected patient by mail and posted information on the hospital's web site. "On February 2, 2012, we discovered that a storeroom window had been broken at the **HealthCare Clinical Laboratory** (HCCL) Patient Service Center located at 89 W. March Lane, Stockton, and that two storage boxes containing HCCL lab requisition forms were missing from the center," the hospital said in its notice to patients.

"We were able to determine that the missing lab requisition forms related to certain laboratory services provided between December 13, 2011, and January 5, 2012, and between January 17, 2012, and January 31, 2012.

"During our ongoing investigation, on March 16, 2012, we discovered that an additional box of requisition forms was also missing related to services provided between October 24, 2011, and November 18, 2011," the statement continued. The hospital recommended that patients check their credit ratings and offered free enrollment in a credit monitoring service.

"Since then we moved all the boxes and rechecked all PSCs to ensure they are secure," Bryant said.

The breach was a violation under the Health Insurance Portability and Affordability Act (HIPPA), requiring the hospital to notify patients and federal and state officials and post an explanation on its website, Bryant added.

Bryant explained that the staff scanned all test requisition forms each day and then stored the paper records onsite in boxes by date of service. "Because we knew which dates were stored in which boxes, we pulled the list of all patients seen on those days and contacted them all," she said. "The problem was that the records included Social Security numbers, insurance policy numbers, dates of birth, addresses, guarantors' names, and patients' names." Bryant believes the thieves may have used the information to apply for credit cards under the patients' names.

THE DARK REPORT observes that lab directors should recheck the security at all locations, including rented and leased space, and do not overlook paper records. TDR

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Magnets to Move Tubes On ARUP's Testing Line

Electro-magnetic powered transport line could raise capacity to about 15,000 esoteric tests per hour

CEO SUMMARY: In Salt Lake City, Utah, work is underway to pioneer use of an electro-magnetic conveyor system to automate the movement of large volumes of lab test specimens throughout the testing facility of ARUP Laboratories. Within two years, this new lab automation technology could allow the reference lab to accommodate a 60% increase in lab test volume over current levels. The transport system uses magnets and is capable of moving up to 15,000 specimens per hour.

As test volumes rise, all labs seek increased efficiency to boost throughput in every way possible. That makes lab automation a subject of high interest and no lab is a bigger user of lab automation than **ARUP Laboratories** of Salt Lake City, Utah.

In response to current and projected increases in specimen volume, ARUP is expanding its laboratory automation infrastructure. It is also preparing to pioneer a new lab automation technology that uses a magnet array to move specimens on the transport line.

"ARUP's automation project seeks to increase its specimen-handling capacity by 60% within two years," declared Charles D. Hawker, Ph.D., MBA. He is ARUP's Scientific Director of Automation and Special Projects, and is internationally-recognized for his expertise in clinical laboratory automation.

ARUP's automation expansion is ambitious. "Design of this new automation system will accommodate an increase in capacity of 300% above current levels—should the need arise," noted Hawker. The heart of the project is a new automated conveyor [specimen transport] system that uses electro-magnetic technology to move specimens along the line."

A Professor (Adjunct) of Pathology at the **University of Utah School of Medicine**, Hawker explained that, as ARUP adds specimens, it has a critical need for more efficiency in workflow throughout the laboratory. "Everything we have is custom designed for our particular needs for high volume reference esoteric testing," he noted. "Because we serve only hospitals and do not perform routine testing or serve physician offices, everything in our lab automation layout is custom.

Custom Lab Automation

"For example, we operate a two-story storage freezer that is all-robotic," noted Hawker. "It rapidly retrieves specimens for repeat or additional testing. We also have unique technologies, such as the world's only automated workcells for thawing and mixing.

"Use of laboratory automation at ARUP helped us to more than double the productivity of our technical workforce," he added. "Other important benefits are a

30% reduction in turnaround time and a decrease in the incidence of lost specimens to Six Sigma levels."

According to Hawker, one big jump in capacity will come from the installation of the new automated specimen transport system. "We began testing the new MagneMover LITE system manufactured by **MagneMotion** and the goal is to implement this system by June 2014," he said.

Reduced Maintenance Costs

"This automated line is between 50% to 100% more expensive than a more traditional conveyor system," explained Hawker. "The increased acquisition cost is justified by its expected life cycle and substantially lower costs for electricity and maintenance.

"Electric power consumption will be lower because the electro-magnetic field technology uses less power than conventional motor-driven chain-type conveyors," he continued. "Also, we concluded that costs will be much lower over the MagneMover's lifetime of 20-plus years because of lower maintenance costs. This conveyor system has virtually no moving parts.

"Over the next 24 months, we will test the MagnaMover system together with other new lab automation components," stated Hawker. "These include new robotic sorters, a thawing and mixing workcell, a pick-and-place robot, and another robot that inspects specimens to see if they're mislabeled.

Routing Management

"We will observe how the MagnaMover transport system interacts with these other systems," added Hawker. "Our programmers can program it for routing and puck management. We'll use dummy patient names and tubes filled with water. If problems are observed, we'll have time to make corrections."

Since the second half of the 1990s, ARUP Laboratories has been one of the world's largest users of clinical laboratory automation. Hawker and his colleagues have repeatedly worked with vendors to design customized solutions to automate specific workflow tasks.

Thus, ARUP's decision to invest in an electro-magnetic transport system is likely to be studied and copied by other clinical laboratory organizations. TDR

—By Joseph Burns

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Electro-Magnetic System Can Move Lab Specimens

FOR ARUP LABORATORIES, one way to efficiently increase capacity to handle steady growth in lab test specimens is to expand its use of laboratory automation.

Already one of the world's largest and most-automated clinical laboratories, ARUP was challenged to find an automated specimen transport system that would allow it to handle the projected increase in lab test specimens. It is turning to a new automation technology to address this challenge.

ARUP is preparing to install a new electro-magnetic automation line manufactured by MagneMotion of Devens, Massachusetts. MagneMotion's electro-magnetic field conveyor systems use linear synchronous motors (LSMs) to move items.

MagneMotion says that, "LSMs generate propulsive force by creating an electro-magnetic field that interacts with a set of magnets on a vehicle to create thrust. The magnets and vehicle are propelled by the moving electro-magnetic field, traveling along as electric current is applied to the stator beneath the vehicle."

When ARUP's MagnaMotion automated lab specimen transport system becomes fully operational in June 2014, it will be one of the first times that an electro-magnetic conveyor system has been used in a clinical laboratory to move lab test specimens.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Mayo Clinic is taking steps to more fully integrate its laboratory informatics. In a press release dated April 27, 2012, it stated that it had completed a multi-year implementation of a new laboratory information system (LIS). The new LIS supports both the Department of Laboratory Medicine and Pathology and **Mayo Medical Laboratories** (MML) and "connects Mayo laboratories in Arizona, Minnesota and New England." The vendor on this project was **SCC Soft Computer** of Clearwater, Florida.

MORE ON: *Mayo's LIS*

Mayo describes its LIS as "the most advanced laboratory information system in the world" and noted that this single system makes it possible to "manage testing in multiple locations, provides real-time location of a specimen, and enables continuous improvement in turnaround times and processes." Significantly, the LIS has client-friendly features, which are described as "broader ordering and resulting configurations (e.g., partial results, flagging, and richer test result details)." Mayo's emphasis on these client-focused features shows how it wants to differentiate itself from other labs in the marketplace.

VA LAB WORKER DIES OF INFECTION

In San Francisco, health officials are looking into the death, on May 2, of a laboratory worker at the **San Francisco VA Medical Center** who was infected with the *Neisseria meningitidis* bacterium. He was a meningitis research associate involved in a project to develop a vaccine.

US CLINICAL LABS BUYS HOUSTON LAB

In Houston, Texas, the acquisition of **Prestige Laboratory** by **US Clinical Laboratories, LLC**, was announced on April 23. US Clinical Labs was founded in 2010 by CEO Rodney R. Proto and several other executives. It has acquired a number of smaller laboratories across the Southeast United States and says it currently operates six laboratories and 16 patient service centers.

TRANSITIONS

• Martin Steffanelli has assumed duties as CEO of **Bostwick Laboratories**, based in Glen Allen, Virginia. Steffanelli has held executive positions with **Aurora Diagnostics**, **Asterand**, **AmeriPath**, and **Dianon Systems**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 4, 2012.