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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 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Medicare To Publish Its Fees on the Web

IN A FEW WEEKS, the **Centers for Medicare and Medicaid Services** (CMS) will publish its reimbursement prices for common procedures on its Web site at *www.medicare.gov*. The objective is to allow consumers to see the fees Medicare currently pays to hospitals and physicians and allow uninsured patients to negotiate comparable discounts for services provided to them.

This is not the only step that federal healthcare officials will take to make the prices they pay for healthcare services accessible to the public. Within a few months, federal Web sites will publish the negotiated prices for healthcare services provided to the **Department of Defense**, the **Federal Employees Health Benefits Program**, and private health plans in six communities.

These actions have a common goal: to create transparency in the discounted prices federal agencies pay for healthcare and to allow consumers to use this information to make informed decisions about their care. **Health and Human Services** (HHS) Secretary Mark Leavitt has dubbed this initiative "payer power." During the next couple of years, his agency plans to require hospitals to publically report data on mortality and outcomes on a variety of diseases, ranging from heart attacks to infection. It is expected that consumers, including senior citizens, will use price and outcomes data to shop hospitals and physicians in advance of elective surgeries and other procedures.

I hope most of you grasp the implications of this development. Federal healthcare officials are irrevocably moving the American healthcare system towards a "consumer first" environment. As Leavitt told the press, the immediate goal is to give patients the same full range of information available to them as when they go out to buy a car or a refrigerator.

Consumer-directed health plans give patients a powerful economic motive to know all the costs of their care–and negotiate discounts in advance of elective services. In my view, as the federal government puts healthcare prices paid by Medicare, the Department of Defense and the Federal Employees Health Benefits Program into the public domain, it won't be long before labs and pathology groups get these types of phone calls from customers. For this reason, it is timely and smart for laboratories to develop policies and procedures to meet the needs of price-shopping consumers. TDR

CMS Defers MUE Edits Until After Jan. 1, 2007

Implementation date of July 1, 2006 changed, No action to occur before January 1, 2007

CEO SUMMARY: Medicare officials have granted a temporary respite on the troubling proposal to institute service restrictions per patient on some 80 pathology CPT codes and 1,100 clinical laboratory codes. These proposals are part of a new round of Medically Unbelievable Edits (MUEs). CMS has yet to answer questions about the rationale and motive behind these proposed edits.

UNDER PRESSURE from many fronts, the **Centers for Medicare and Medicaid Services** (CMS) extended deadlines for comment and implemention of a controversial and rather lengthy list of Medically Unbelievable Edits (MUEs).

For the pathology profession, the best advice may be former Yankee catcher and Mets coach Yogi Berra's famous malaprop: "It ain't over 'til it's over!" That's because, although CMS is extending the comment and implementation timetable for the contentious MUEs, it still plans to implement some form of new MUEs, stating that no implementation will occur before January 1, 2007.

It was THE DARK REPORT which first made public key aspects of the proposed MUE edits. A CMS contractor issued an extensive list of proposed restrictions of service to the **American Medical Association** (AMA) in mid-December 2005. This list included restrictions of service for approximately 80 pathology CPT codes and 1,100 clinical laboratory CPT codes. *(See TDR, January 16, 2006.)*

These MUE edits captured the full attention of anatomic pathologists when it was discovered that one proposed MUE targeted CPT 88305 (Level IV—Surgical Pathology, Gross and Microscopic Exam). The CMS contractor proposed to restrict the use of the 88305 CPT code to two units of service per patient per day.

Such a restriction on CPT 88305 would directly contradict accepted

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medical standards of care for a large number of diseases—many of which are life-threatening to affected patients. Restrictions to CPT 88305 would also have a devastating financial effect on anatomic pathology groups throughout the United States.

Apparent Lack Of Input

Equally disturbing to the pathology profession and the laboratory industry is the process used by CMS to develop the proposed MUEs and implement them. The subcontractor on the MUE project was a business unit of **Empire Blue Cross Blue Shield** in New York State. It apparently did its work in secret and isolated from expert sources. As it compiled a list of MUEs, it does not seem to have consulted with any medical specialty association.

Further, CMS was proceeding to implementation without using formal rule-making processes. It has also declined to make public the rationale and methodology that was used to create the list of proposed MUEs.

On both counts, critics are excoriating CMS. The **College of American Pathologists** has called upon CMS to: 1) utilize the formal rule-making process for proposed MUEs; 2) work closely with the provider communities to ensure that MUEs are aligned with accepted clinical standards of practice; and, 3) see that MUEs are only used for their intended purpose—to detect errors in claims submission.

Similar statements have been made to CMS by the **Practicing Physicians Advisory Council** (PPAC) and House Representative Nancy L. Johnson (R-Connecticut). On March 10, Johnson sent a letter to CMS Administrator Mark McClellan specifically calling attention to how pathology MUEs would negatively affect patient care.

The pathology profession and the laboratory industry must stay on high alert. Bad bureaucratic proposals tend to hang around year after year. Like the 20% lab test copay concept, restrictions on service for CPT 88305 are likely to threaten the profession for some time in the future. TDR

Who Was Behind Controversial MUEs?

Upon learning that the proposed list of Medically Unbelievable Edits (MUEs) restricts units of service for CPT 88305 to two per patient per day, many pathologists want to know who originated this proposal.

After all, the proposed 88305 restriction directly contradicts established standards of clinical care and has the potential to put the lives of patients at risk. The irrationality of this decision is clear to both pathologists and the clinicians who refer cases.

Medicare's list of proposed MUEs was developed under a subcontract granted to Empire Blue Shield Blue Cross in New York state. Knowledgeable sources tell THE DARK REPORT that the person in charge of this project at Empire was a medical director named Salvatore M. Moffa, M.D.

A cardiothoracic surgeon by training, Dr. Moffa left the employ of Empire Blue Cross Blue Shield during December 2005, around the time that the complete list of proposed MUEs for all medical specialties was delivered to the American Medical Association for distribution to specialty associations for their review and comment.

More than one source speculates that Moffa, who's resume was posted on the Web in December and who was known to be seeking another job, may have simply put ones and twos in the column of "units of service per patient per day" for pathology and clinical laboratory CPT codes as an expedient way to complete his work.

Sadly, this is a believable scenario. If true, it is another example of how a healthcare bureaucracy can generate an irrational proposal, which then takes on a life of its own. More astonishingly, such irrational proposals often prove impossible to stop–despite the negative consequences that can be seen in advance of implementation.

Geisinger's Coag Clinics Located in Docs' Offices

In-office coagulation clinics provide lab tests and consultations in 30 minutes

CEO SUMMARY: It was six years ago when Geisinger Health System pushed laboratory testing and pharmacy services closer to the patients and referring physicians. By establishing coagulation clinics in six multi-specialty clinic sites, Geisinger has allowed pharmacists to use point-of-care testing to provide coag consults, therapy, and patient counseling in real time—often in as little as 30 minutes from a physician's order.

KEEPING UP WITH COAGULATION MANAGEMENT is presenting new challenges for clinicians—and new opportunities for laboratories. One such opportunity is to more closely integrate pharmacy services with laboratory testing.

This is happening at **Geisinger Health System** (GHS) in Danville, Pennsylvania, where pharmacist-staffed coagulation clinics have been established throughout the Geisinger service area. The laboratory division's ability to support these coagulation clinics is a direct consequence of its integrated informatics capability, along with its rigorous program to connect all point-of-care testing devices to the LIS (laboratory information system). *(See TDR, November 14, 2005.)*

Close interaction and cooperation between pharmacy and laboratory has made a significant difference in patient care. One example of clinical improvement involves patients on anticoagulation therapy. For these patients, there has been a relative reduction in bleeding episodes of 79% during the six years that Geisinger Health System has operated its coagulation clinics. Another example of improved clinical outcomes is the relative reduction in recurrent thrombotic events of 89%.

Doing More With Lab Results

These two examples show how close interaction and collaboration between pharmacy and laboratory is making a big difference at Geisinger Health System. These coagulation clinics provide a powerful example of how laboratory test results can be used to significantly improve clinical outcomes even as the cost per healthcare encounter is reduced.

In such situations, everyone is a winner. Physicians see their efforts produce higher-quality outcomes. Patients benefit from more accurate care, delivered in a timely fashion. The health system enjoys a reduction in the cost per healthcare encounter, along with the long-term benefits that accrue from improved patient satisfaction.

Geisinger established these coagulation clinics in recognition of the complexity of treating patients with bleeding problems. "It's becoming increasingly difficult for clinicians to manage coagulation issues," stated Dean Parry, R.Ph., Director of Pharmacy Utilization Management for Geisinger. "The current armamentarium of anti-coagulants requires close management of the patient. Patients must be monitored frequently and dosages of anti-coagulant drugs adjusted immediately when indicated. Failure to appropriately monitor could expose patients to serious risks."

Integrated Health System

Geisinger is a physician-led, integrated health system. It serves 40 counties spanning 20,000 square miles in northeastern and central Pennsylvania. Approximately 2.5 million people live in Geisinger's service area.

"We're fortunate to have a stable, rural population as our service market," observed Dr. Parry. "It creates three interesting advantages to our healthcare system. First, we can more easily translate discoveries through research into actual patient care. Second, it allows us to more easily monitor patients. Third, these prior two advantages better allow us to improve patient care.

Models Of Care

"This fortunate set of circumstances creates benefits that extend beyond our system," said Parry. "We are able to create models of care that can be replicated nationwide, particularly in other rural areas."

That's exactly what GHS is doing with its pharmacist-run coag clinics. "Maintaining this vital interaction with patients is time-consuming for physicians," commented Parry. "Pharmacists can bring special expertise to drug therapy management.

"At Geisinger, we saw that, with the capabilities presented through our integrated POCT and informatics system, we could improve drug therapy management and reduce costs by setting up coagulation sites at multi-specialty clinics located throughout our service area," he explained.

Geisinger's goal was to bring pharmacists closer to the referring physicians by establishing coagulation clinics at key locations within the health system. Geisinger operates a hospital-based clinic in Danville, along with another 50 ambulatory clinics within its 40-county service area.

"We have six coag clinics," noted Parry. "These are located in Danville and five of the largest primary practice sites. Each Geisinger clinic site that includes a coagulation clinic also has a CLIA laboratory. Any testing performed by the coagulation clinic is integrated with the on-site laboratory and the lab owns all the testing equipment used in a coagulation clinic.

Managing Coag Therapies

"At these locations, pharmacists actively manage drug therapy," he explained. "Further, we use these clinic sites as hubs to serve anti-coagulation patients in the surrounding areas. Our staff includes 10 pharmacists and five clerical support personnel.

"Our coagulation clinics operate in a straight-forward manner," Parry noted. "The physician refers the patient to the pharmacist with three specific objectives: 1) drug therapy management; 2) patient education; and, 3) drug dosage adjustment.

"Additionally, the pharmacist—working in collaboration with the laboratory—provides two valuable services to the clinician," he explained. "One, the pharmacist makes recommendations to the clinician for the laboratory testing necessary for evaluation of ongoing concerns, for example, coagu-

lopathy. Two, the pharmacist coordinates and helps interpret laboratory test results for appropriate therapeutic interventions.

"Currently our coag staff is managing care for over 5,000 patients at our coag clinics," stated Parry. "These patients fall into three basic categories. In the first category are patients with atrial fibrillation. Blood clots are a big risk factor for atrial fibrillation. These patients are prescribed an anticoagulant—a blood thinner, such as Coumadin. In the second category are patients who have already had a clot.

Patients At Risk For Clots

"The third category includes patients who've had surgical procedures that put them at risk for a clot," stated Parry. "These are patients who had orthopedic surgery, spine surgery, hip or heart valve replacement, as well as pregnant women who are at high risk for clots. These women may be on Coumadin or heparin or low-molecular heparin. There is a constant process of dosage adjustment due to the ongoing weight gain during pregnancy. Age is another factor in coag management, since risk of a clot increases with age.

"Another significant risk group is the diabetic population," stated Parry. "About 30% of our coagulation patients are diabetic. One pharmacist now serves in the additional role of managing the medication of diabetic patients for physicians within the region of the health system for which she is responsible.

Diabetes And Heart Disease

"Diabetics must deal with a variety of crossover risk factors," he said. "For example, there is a tie between diabetes and heart disease. Physicians at Geisinger are taking a more proactive approach to evaluate diabetic patients for all these risk factors.

Coag Clinics Generate Benefits for Laboratory

For the past six years, Geisinger Health System (GHS) has reaped benefits at multiple levels by placing pharmacists in the field at coagulation clinics in the GHS service area in rural Pennsylvania.

"These coag clinics brought added value to Geisinger's laboratory operations in two unexpected ways," stated Jay B. Jones, Ph.D., Director, Chemistry and Health Group Laboratories. "First, these clinics made the laboratory a higher profile player. Establishing the coag clinics took us out of the factory environment of the laboratory and into the arena where the doctors, nurses, and patients are.

"For example, lab personnel had to train the nursing staff on the proper use of the point-of-care instruments, such as the i-STAT," he explained. "Training nurses became a high-value role for our laboratory personnel. This was a real culture change for us.

"Second, the need for POCT connectivity with the EMR (electronic medical record) and our LIS (laboratory information system) brought our lab staff directly into the information business," continued Jones. "Implementing the coagulation clinic project required advanced integrated informatics. As a result, we developed a better understanding of how remote devices hook in and of the specification software involved in connectivity."

"Each of the six multi-specialty clinic sites where we operate a coagulation clinic has three to 10 physicians and one pharmacist," explained Parry. "The coag clinic is located in a standard examination room, which houses the pharmacist's desk and computer. This exam room is large enough to accommodate the patient and one or two family members.

"Our coag clinics perform certain point-of-care testing (POCT) on site" he noted. "These include INRs (inter-

national normalized ratios) and normal monitoring tests. We use **i-STAT** instruments for Prothrombin time, for example. Lab test results are fed into the LIS and Geisinger's EMR (electronic medical records) system.

"Our pharmacist-run coag clinics bring added value to patients, clinicians and the healthcare system," observed Parry. "Patients receive more rapid and personalized care. Clinicians save time. The health system reduces costs through improved outcomes.

"At a minimum, the pharmacist meets personally with the patient for at least the first visit to provide education and start therapy," he continued. "Some patients are always seen in person by the pharmacist, others are then managed via the telephone. A stable patient is checked every four to six weeks.

Dosing Adjustments

"New patients are checked every few days until their levels are stable," noted Parry. "Each dosage adjustment does not require the prior consent of the physician. Part of the initial consultation request from the physician establishes parameters for dosing and authorizes the pharmacist to make adjustments. The physician receives an e-mail report of every encounter."

At three of the six coag sites, the pharmacist does the fingerstick. "This depends on whether the pharmacist has the time and capacity to take the specimen and phlebotomy doesn't," stated Parry. "It depends on the site, volume, and who has the time. At the hospital-based coag clinic, the pharmacist's office is located right next to phlebotomy. In this situation, it saves time for phlebotomy to do the sticks. It's very much a cooperative process."

Special pharmacological expertise puts the pharmacist in a position to stay abreast of current guidelines and to manage patients accordingly. The pharmacist's role includes identifying patients with coagulopathies and making recommendations for therapy and follow up tests.

"To come up with the best therapy, our pharmacists work with hematologists in the laboratory," observed Parry. "We then consult directly with the referring physician and recommend short-term therapy.

Preventative Medicine

"The objective is to recognize coagulopathy and start therapy *before* the patient has a clot," stated Parry. "The pharmacists work with hematologists in the laboratory and recommend a short-term therapy to the clinician. Prior to our coag clinic program, 80% of the patients who did not have a clear reason for their clot, were not evaluated for the possible underlying causative factors. As a result of the closer cooperation with our pharmacists through the coag clinics, there is a greater awareness of coagulopathy among our physicians.

"The major advantage of the pharmacist-run clinic is the ability to respond quickly and to immediately adjust dosage," stated Parry. "The critical objective in anticoagulation is to make the dosage adjustment proactively, before a high-risk scenario develops. As part of our monitoring strategy, the laboratory reports any unexpected values to the pharmacist around the clock. This allows for rapid response dosage adjustment.

Doing Lab Tests On Site

"Our coagulation clinics are able to perform about 85% of the need laboratory tests on-site," Parry noted. "Because some patients live as far as 220 miles from the Medical Center (up to 100 miles from the nearest coag clinic), their tests are sent to our main laboratory," he said. "As appropriate, all our clinics are able to send patients to the lab for venipuncture or POCT.

"On-site testing is an essential to the success of our coag clinics," Parry noted. "Typically, elapsed time from draw to a face-to-face consultation between patient and pharmacist is less than thirty minutes. For telephone encounters it's within twenty-four hours.

"By contrast, the lag time with physicians managing dosage can be as much as three to seven days," he added. "Effective use of POCT and pharmacists has allowed us to cut out all the middlemen and provide faster, more effective treatment to patients."

Significant Outcomes

Lab administrators and pathologists should pay particularly close attention to the substantial outcomes this six-year effort has generated. Here's a partial list:

- Relative reduction in recurrent thrombotic events by 89%.
- Relative reduction in bleeding episodes for patients on anticoagulation therapy by 79%.
- Comparative data shows that the percentage of INR's within the therapeutic range for the coag clinic is twice that of the rate prior to implementation of the clinics.
- Positive patient satisfaction ratings for the coag. clinic exceed 96%.
- The monitoring and followup provided by the coag clinic has allowed the average length of stay for patients with a DVT (deep vein thrombosis) to decrease from just under six days to about two days.
- Stable patients without significant co-morbidities can often be managed as an outpatient.
- This decreased length of stay has been accompanied by a reduction in cost of care for these patients of about 50%.

As these impressive results demonstrate, the effort to bring laboratory testing into the pharmacy at Geisinger Health System has contributed to significant improvements in patient care. The laboratory is supporting testing which is done closer to the patient and is producing lab test results in real time. Pharmacists are using this information to improve their patient's outcomes.

THE DARK REPORT predicts that this type of close interaction between the laboratory and clinicians will become more common in future years. Coagulation is just one clinical area where faster access to relevant test results can trigger major improvements in patient outcomes. TDR

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—By Pamela Scherer McLeod

United Kingdom Has Lab Testing in Pharmacies

IN THE UNITED KINGDOM, the **National Health Service** (NHS) has a pilot project under way to provide laboratory testing services in pharmacies. The goal is to provide pharmacists with real-time laboratory test results that allow them to better match the appropriate prescription to the clinical needs of the patient.

This pilot project is taking place in Manchester, England. The NHS has remodeled several pharmacies to include a phlebotomy drawing station and an on-site laboratory. The remodeled pharmacies have been in operation for more than a year, and the results have been favorable.

"I am aware of the ongoing project in Great Britain with regard to anticoagulation services by pharmacists," Dean Parry, R.Ph., Director of Pharmacy Utilization Management for Geisinger Health Systems, based in Danville, Pennsylvania. "I believe that the benefits of such a program have been clearly established in the literature and it is only a matter of time until this process becomes the standard of care."

CEO Summary: As part of a major restructuring program under way at Christian Hospital in St. Louis, Laboratory Administrator Bette J. Stanley decided to apply Lean quality management methods in projects to improve work processes in phlebotomy and the chemistry department. Using internal quality consultants from the parent health system, the laboratory staff applied Lean methods and significantly reduced average lab test turnaround time while posting major gains in productivity.

Used in Phlebotomy and Chemistry

Christian Hospital Laboratory Goes Lean with Solid Results

WHENEVER A NEW LAB DIRECTOR comes into a financially-struggling hospital with the goal of turning around laboratory operations, he or she invariably faces the classic list of clinical lab challenges: greater demands, fewer resources, and explosive changes in medicine and technology.

"That's certainly what I found when I became the Administrative Director of Laboratories at **Christian Hospital** (CH)," stated Bette J. Stanley. "The equipment was dated, the laboratory space was cut up, work flow and work processes were inefficient, and the laboratory's budget was limited."

CH, part of **BJC HealthCare** (BJC) in St. Louis, Missouri, is a two-hospital, non-profit, 493-bed acute care and outpatient facility. "The hospital was built in 1975," stated Stanley. "It was considered very modern at that time and was doing quite well."

But by the late 1990's the hospital was in the red. "In 2000 the hospital initiated 'Recovery 2000,' a major restructuring program to turn things around," recalled Stanley. "Part of the Recovery 2000 strategy involved cutting the Network Reference Laboratory's (NRL) nursing home business. This meant losing 175 nursing homes—and big layoffs in the phlebotomy staff. Upon my arrival in June 2002, I found a group of highly dedicated laboratory personnel in an atmosphere of very low morale."

"The first thing I did as administrative director was to involve the staff, from top to bottom, in creating a new vision for the lab," recalled Stanley. "Staff involvement in this process renewed the sense of empowerment that had been missing since the earlier layoffs. Morale started to recover.

"As a team, we studied the existing problems and jointly developed a strategy. Our themes became 'Renovate. Automate. Skinny down—Develop a Quality Management System (QMS)'," she explained. The management team was reorganized and we divided the lab into three divisions: Core Lab (24/7 testing), Special Procedures (those areas that were not open 24/7), and the Network Reference Lab (our outreach program)."

Prior to assuming leadership at the CH laboratory, Stanley had worked for 21 years at St. **Louis University Hospital**, moving from Chemistry Supervisor to Laboratory Director. "One of my references for quality standards and procedures was the **Clinical and Lab-oratory Standards Institute** [CLSI, formerly NCCLS]," Stanley stated. "Our blood bank supervisor, who had developed the blood bank's quality plan, became our team leader for our Quality System Team (QST). We devoted much effort into developing the Quality System Essential policies as the framework of our QMS."

Learning About Lean

In the spring of 2003, Stanley attended THE DARK REPORT'S *Executive War College on Laboratory and Pathology Management* in New Orleans. "It was the first time I was able to learn detailed specifics about the use of Lean and Six Sigma methods," she noted. "Although one of our hospitals' surgery departments had already undergone a Lean makeover, there was nothing at BJC to alert departments systemwide of the available in-house quality improvement programs.

"I was impressed with the information on Lean and Six Sigma presented at the *Executive War College*," recalled Stanley. "It was a new way of thinking—a new way of seeing what goes on in the laboratory. I knew I could use this knowledge as a platform for streamlining our entire laboratory operation."

Stanley began studying Lean and Six Sigma methods. In the fall of 2003, she attended a workshop on Lean and Six Sigma techniques offered by the ValuMetrix team at **Ortho-Clinical Diagnostics**.

As she gained more knowledge in these quality improvement methodologies, Stanley launched her staff into their first Lean projects. "Our goal was to eliminate waste and increase productivity in the lab," she said. "At CH, that meant further reductions in FTEs. To achieve that result, we agreed on five management tactics: 1) redesign the lab around central processing; 2) remove walls for better communication; 3) automate for efficiency and better TAT; 4) increase capacity and decrease need for more staff; and, 5) reduce staff through attrition and retirement.

"With assurances that every effort would be made to avoid any major layoffs, the lab team accepted the proposed cuts in personnel as essential to achieving the desired goal of a financially sustainable laboratory," explained Stanley. "The average age of our staff was around 50. We developed a strategic plan around natural attrition and redeployment of personnel to other areas of the hospital—instead of layoffs.

"At the time I came on board, the CH lab was in the middle of implementing a new **McKesson** LIS system, which caused us to rethink certain aspects of our business," she continued. "The outreach program, which had been established in 1985, had been going downhill. We decided that having the laboratory do its own outreach billing was a big part of the problems in our outreach program.

Outsourcing Billing

"We decided that, instead of administering a billing system on our own, we would choose an external billing company to do all our outreach billing and collections," explained Stanley. "We went live with Horizon LIS and an interface to **Quadax** (our external billing company) in November of 2002. The billing company would maintain the NCD and LCD updates. Therefore, we only needed to work the failed medical necessity and CCI edits on the back end. These new arrangements allowed us to reduce the billing staff from 10 FTEs to just two FTEs.

"Next, we needed money to make the necessary changes in the laboratory," noted Stanley. "We submitted a proposal for our Lean lab makeover to administration. It demonstrated savings of more than $3 million over a seven-year period. It took about five months of collaboration with the finance department and the architects to get approval to tap a BJC contingency fund for the $1.4 million project.

Lean Project #1
Phlebotomy

"Our first target for a quality improvement makeover was the phlebotomy department. This made sense for three reasons," said Stanley. "One, we needed to look at the laboratory's work flow in its entirety and phlebotomy is the first step. Two, we wanted to satisfy our physician-customers by having test results from all morning draws on the charts by 8:00 a.m.

"Three, we knew that improvements in phlebotomy would help the analytical segment," she continued. "Pre-analytical is generally the most time-consuming part of the overall work process. We knew that, by streamlining work processes in phlebotomy, we stood to achieve significant gains in turnaround time (TAT)."

With the help of the Lean/Six Sigma black belt trainer from BJC corporate, Stanley's Lean team studied phlebotomy's baseline work processes. "For one week, a Lean team member followed five different phlebotomists around—a different one each day—with a video camera and a stop watch," recalled Stanley. "Each phlebotomist wore a pedometer. We

Lean Makeover at Christian Hospital Improves Phlebotomy and Core Laboratory Processes

MULTIPLE CHALLENGES awaited the management team at the laboratory of Christian Hospital in St. Louis, Missouri. The turnaround strategy was to recognize and encourage people and apply Lean management techniques to improve the laboratory's work flow and performance.

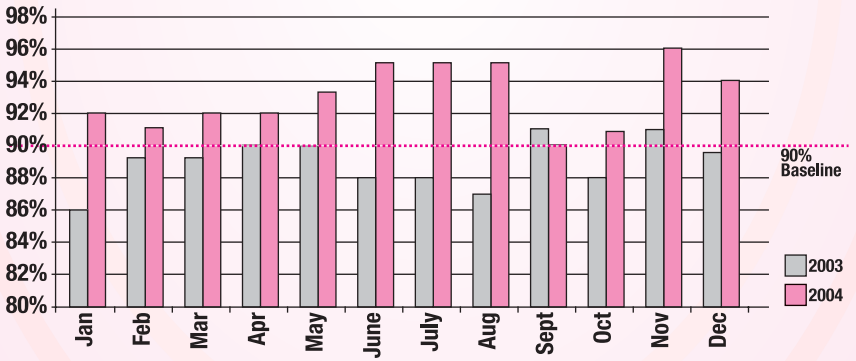
Lean project number one centered upon phlebotomy and had a simple, measurable objective: have 95% of lab test results from the morning draws on the patients's charts by 8:00 a.m. The phlebotomy Lean project focused on changing how supplies were utilized and re-directing work processes to support single piece and small batch production.

Lean project number two involved a make-over of the chemistry department. Because instrumentation was very old, it presented an opportunity to redesign work processes around latest-generation equipment.

Upon completion of the two Lean projects, the 95% goal for posting lab test results from morning draws was achieved. At the same time, 15.1 fewer FTEs were required to operate the chemistry department, allowing these med techs to be redeployed to other areas of the laboratory.

Phlebotomy Morning Pick Up–Collected by 7 a.m.

Comparing 2003 with 2004



Shown above is a chart that illustrates how the percent of phlebotomy collections before 7 a.m. increased over the course of the Lean project to streamline workflow and reduce turnaround time in the phlebotomy department. In the second year, 2004, no month was below the baseline of 90%.

timed every process and counted each footstep."

"We immediately identified three significant opportunities to eliminate waste: 1) supply trays: 2) batching; and, 3) personnel deployment."

Solution #1: Supply trays. "First, our baseline observation showed that some phlebotomists were placing the supply tray on the patient's sink. This one simple habit often doubled the number of steps required to perform

the draws. We switched to using standardized phlebotomy carts, instead of trays," explained Stanley.

"Second, our baseline observation showed that some phlebotomists spent additional time deciding what supplies to take into the patient's room," she continued. "We cut wasted time here by equipping each phlebotomist with a fanny pack containing the needed supplies for each patient."

Solution #2: Batching. "Prior to going Lean, the phlebotomists held collected tubes until they finished the draws for the entire floor, which is designed in an H configuration," stated Stanley. "Through our baseline analysis, we saw that we could smooth out this part of the work flow. We had the phlebotomist start at the farthest end of the floor and drop the completed batch of specimens at the tube station at the crossbar of the H. They then repeat this pattern. This new arrangement generates four smaller batches of tubes per floor, instead of one large batch. It has contributed to improved flow in the lab by leveling the volume of tubes recieved in accessioning."

Solution #3: Personnel deployment. "Our third improvement involved creating a 'visual management' board in the processing areas, showing a shaded box for every floor," noted Stanley. "Each phlebotomist carries a red tag, similar to a luggage tag. When all the specimens on that floor are collected, the phlebotomist tubes the red tag down to the processing area with the last batch of specimens. The red tag is placed on the bulletin board and the processing coordinator is alerted that collections on that floor had been completed.

"Any available phlebotomist can now be deployed via pager to a floor with specimens remaining to be drawn," added Stanley. "These innovations were simple and cost-neutral. They helped us achieve our FTE reduction goals—even before the capital improvements phase of our Lean makeover! We now consistently meet our goal of having test results from 95% of the morning draws available to the clinicians by 0800."

Lean Project #2
Chemistry

"Our lab's second Lean project—and our most extensive accomplishment—was the renovation and automation of our chemistry lab," noted Stanley. "When I arrived at the lab, techs had to feed 10 aging analyzers—including a 15-year old **Hitachi**—which were located in small, chopped-up rooms. There was little integrated capability among the machines. Workflow through these lines was ragged and discontinuous.

"As part of our makeover, we determined which specific tests needed to be up 24/7 and which tests could be moved away from the core lab," she said. "Next, we formed a selection team to decide which vendors to use.

Replacing 10 Instruments

"In keeping with our team strategy, members of the lab staff were on the selection committee," explained Stanley. "We replaced the 10 pieces of equipment in the lab with three: two LX20 analyzers and one DxI immunoassay system from **Beckman Coulter Inc.** We also bought a countertop for backup. We selected these instrument systems because it allowed us to have total automation from front-end centrifugation of the specimens to back-end storage and mapping of specimens for future retrieval.

"Our renovation and automation makeover in the chemistry lab eliminated time-consuming manual tasks and created an efficient work flow," observed Stanley. "One unexpected benefit was the attrition of some staff

members, who chose to retire rather than go through the learning process on the new equipment.

"In our proposal, we had committed to reducing 7.75 FTEs in the chemistry laboratory by the end of installation," observed Stanley. "Our actual reduction was 15.1 FTEs, representing about 9%. of the laboratory staff.

Employee Satisfaction

"One of the most important improvements in our laboratory has been in employee satisfaction," stated Stanley. "The value of viewing employees as internal customers cannot be overstated. Growing shortages of experienced, highly skilled med techs make retention a high-priority issue. Automation alone can only achieve so much. By adopting strategies that incorporate the concept of personnel as internal customers, our laboratory is positioning itself as an employer of choice for the future.

"Employee satisfaction in the CH laboratory is up to 80%, one of the highest ratings for any department in the hospital," she stated. "We attribute that outcome primarily to two strategies: 1) creating a Lean/Six Sigma work environment with strong employee involvement; and, 2) incorporating customer and employee satisfaction as a core management strategy.

Keeping Staff Involved

"One example of an employee satisfaction-based initiative at CH is our 'Compassionate Care' program," explained Stanley. "All departments at the hospital were given the opportunity to participate. The program involves a half-day training session and allows the staff, as a team, to participate in charitable projects and morale boosting activities for staff and patients.

"Under this program, money was raised on behalf of an employee's son who was diagnosed with cancer and two soldiers in Iraq were 'adopted' by the laboratory staff," stated Stanley. "This program contributes significantly to positive morale and a team environment in the lab."

All these management successes in the laboratory did not go unnoticed around the health system. "The CH laboratory's Lean/Six Sigma improvement projects now serve as models for the rest of the BJC system," noted Stanley. "As we initiated the "Five S's of CLEAN [Sort, Set in order, Shine, Standardize, Sustain] in generic areas of the laboratory, such as the storage room, we shared the experience with other departments. In the lab, we encouraged departments to take before and after pictures."

Inspired by these major successes, Stanley's team still has more to do.

Some Lessons Learned From Lean Projects

USING QUALITY MANAGEMENT CONSULTING RESOURCES WITHIN ITS HEALTH SYSTEM, the laboratory at Christian Hospital successfully conducted two Lean projects: one in phlebotomy and one in chemistry. These are some key lessons learned:

Things That Went Well:

- Reduced staff without layoffs. Staff was redeployed and some med techs opted to retire.
- Projects were completed on time and within budget.
- Boosted morale of lab. Staff was quite proud of the measured improvements.

Things That Didn't Go Well:

- Changed two important things at once. (Collection tubes and new methods, like troponins.)
- Should have given our reference lab clients more advance notice that reference ranges would be changing.

"We've accomplished a great deal, but we still face two significant challenges. First, we need to expand our outreach business and our 'Lean Lab' allows us to be more competitive on pricing. Second, we need to achieve a 5% increase in productivity each year to stay fiscally sound.

"To help us increase productivity, we are working with **Jim Shaw Resources**, a firm based in Seattle, Washington," she said. "Our goal is to perform to benchmarks that keep our laboratory at the leading edge in our market. "For example, we derive our productivity measures through comparison of hours-worked-per-test with other hospital labs that have similar volume, outreach, and send-out numbers.

25% Jump In Productivity

"These efforts are paying off," continued Stanley. "In 2002, we performed 7,500 billable tests per FTE. In 2005, we performed 9,400 billable tests per FTE. That's a 25% increase in productivity! During that same period we went from 179.7 FTEs in the laboratory to 145.4 FTES, for a 19% decrease—all through attrition and with only the one layoff involving the NRL billing group."

The CH laboratory is ready to tackle new challenges. "Next targets for Lean/Six Sigma projects are the blood bank and hematology. Our budget proposal was rejected for the next two years, but we continue to move forward on these projects," noted Stanley. "Our activities are capital-neutral at this time, such as developing architectural plans and selecting vendors. Once funding is authorized, we'll move into the renovation and automation phase."

Having enjoyed success with Lean and Six Sigma methods, Stanley is broadening the management tools she uses in the laboratory. "In addition to Lean and Six Sigma, we are aggressively pursuing continuous improvement initiatives based upon 'human technology'," she said. "**Herman Gyr**, a transformation consulting company, is working with us to increase business at the hospital by transforming the patient/family experience at our facilities. This is part of the 'customer pull' approach and is designed to generate repeat customers.

"Part of the hospital's strategy is to offer amenities that appeal especially to women," explained Stanley. "We are developing prototypes and doing observational research. Laboratory staff went through a customer service training program that emphasizes that the customer defines quality. Through process improvement and process reengineering, we can continually improve our processes and quality."

This customer service training in the laboratory is another intriguing aspect to the quality management journey at the Christian Hospital laboratory. It demonstrates how hospitals and health systems are taking proactive steps to improve the patient experience at their institutions.

Quality Management

Buoyed by the successes generated from its first two Lean projects, the laboratory at Christian Hospital is looking for other opportunities to apply quality management methods. Stanley's comments indicate that the laboratory staff is learning to understand how quality management methods like Lean and Six Sigma contribute to a more productive work environment. This is consistent with the experience of other hospital laboratories which have taken the time to educate the lab staff in these quality management systems. TDR

Contact Bette J. Stanley at 314-653-5630.

—by Pamela Scherer McLeod

Middleware Is Hot Topic At LabinfoTech Meeting

Labs are pushing for middleware solutions to support a variety of management objectives

CEO SUMMARY: Middleware is a growing component in the market for laboratory information services. Labs are asking vendors to provide targeted software solutions to address a growing list of needs and functions. To fill this demand, specialty software companies and IVD firms are introducing new middleware products. It remains unclear whether traditional LIS vendors will compete vigorously with their own middleware.

HOWEVER YOU DEFINE IT, middleware is the hot topic in laboratory informatics. That's one reason why middleware rated a special session at the third annual *LabinfoTech* meeting, held March 1-3 in Las Vegas.

In its simplest definition, middleware is software acting as an intermediary between systems software and an application. Clinical laboratories are using middleware to accomplish a wide range of functions.

Using Middleware

In some cases, middleware is used to supplement a hospital lab's LIS (laboratory information system) and provide the functions needed to support a laboratory testing outreach program. These range from courier/logistics and pre-analytical needs to post-analytical reporting, billing and collections. In other settings, labs are using middleware to support automation, direct specimens, manage operational services like QA/QC, and for autoverification.

Within the market for laboratory information services, there is a lack of clarity and consensus about how laboratories will use information technology in future years. Both informatics vendors and laboratory customers have differing views on this subject.

One reason for this confusion is the proliferation of companies selling middleware solutions to laboratories. In today's marketplace, laboratories can buy middleware from IVD manufacturers, from specialized software development firms, as well as the nation's largest healthcare IT corporations. In fact, this proliferation of middleware sources is a new phenomenon.

Speakers at LabinfoTech recognized this new development. "One way to view middleware is to classify it as a short-term path that plays a long-term role in a variety of laboratory functions," stated Rob Bush, President of **Orchard Software**. "From this perspective, middleware has emerged in recent years as a way for laboratories to solve a problem for which there was no prior solution.

"Laboratories are using middleware to serve a specific need that isn't

being met," he continued. "Most frequently, these solutions are tailored to specific instruments and specific LIS products being used by a laboratory."

As a provider of LIS products, Orchard is being asked to write software to address specific tasks within the laboratory. Labs want LIS manufacturers to provide software that can solve these same issues.

Helping MT's To Multi-Task

"Middleware is often needed because medical technologists are being asked to manage multiple processes during the same shift," observed Ron Berman, Worldwide Director of Automation and Information Systems at **Beckman Coulter Inc.** during his presentation. "Med techs may be also managing multiple types of testing. Middleware is one solution to helping med techs meet these multi-tasking needs."

Berman noted that Beckman Coulter offers middleware designed to help med techs in these types of situations. "Further, there is middleware available that labs can use to advance patient safety," he said. "Increasingly, labs need to implement systems that capture and document receipt of all tests ordered by clinicians, as well as the timely delivery of lab test results to referring physicians. Middleware can meet these needs."

Three Types Of Competitors

During a panel discussion that included Bush and Berman, *LabinfoTech's* Founder and Director, Bruce A. Friedman, M.D. observed that "I expect to see three types of firms compete in the middleware marketplace: LIS vendors, IVD manufacturers, and middleware vendors.

"With new competitors entering the field, some type of shake-out is inevitable," continued Friedman. "Also, the drive to develop an enterprise-wide EMR is likely to cause some traditional LIS functions, like lab test ordering and lab test resulting, to migrate from the LIS to the EMR."

Jaques Baudin, General Manager of **Technidata America Medical Software**, told the LabinfoTech audience that labs are turning to middleware as a way to generate and update information in real time. "To better manage work processes, laboratories want a single-screen view that incorporates all the data necessary for the operator to make decisions. They want this data in real time and in only two mouse clicks."

Baudin observed that, when laboratories test specimens in batches, the data needed to effective decisionmaking often comes too early or too late. "This is why labs want middleware to produce information in real time," he explained. "Rules-based middleware solutions, operating in real time, allow labs to make timely interventions while reducing the complexity of managing laboratory operations."

New Product Category

Collectively, speakers at this year's LabinfoTech recognized that middleware is already an established product category in the laboratory marketplace. The debate and differences centered around how experts predict that middleware will evolve.

Laboratory administrators and pathologists should recognize another fact about middleware. Laboratories are driving this new product category. As laboratories look for ways to make labor more productive, to automate manual work processes, and to guide med techs in their decisions, they are turning to middleware solutions.

This year's large crowd at *LabinfoTech* bears powerful witness to the growing importance of middleware. It should be no surprise that IVD manufacturers and specialty middleware vendors are stepping forward to meet this demand. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

On March 13, 2006, **American Esoteric Laboratories, Inc.** (AEL) of Brentwood, Tennessee announced the acquisition of **Physicians Medical Laboratory** (PML). Terms of the transaction were not disclosed. Located in Morristown, Tennessee, PML gives AEL a presence in east Tennessee. AEL has owned and operated **Memphis Pathology Laboratory** in west Tennessee since 2004.

VIRUS DISCOVERED IN SOME PATIENTS WITH PROSTATE CANCER

Using the same microarray technology that a scientist at the **University of California San Francisco** (UCSF) used to rapidly identify an unknown SARS virus back in 2003, researchers have discovered a virus in certain prostate cancer patients. Eric Klein, M.D., a researcher at the **Cleveland Clinic**, had sent specimens from 86 cancerous prostates he had removed to Joseph DeRisi, M.D. at USCF. DiRisi's microarray contains 20,000 snippets of DNA from every known virus in the world. These prostate tissue specimens were tested on DeRisi's microarray. Eight specimens, from 20 patients known to have a mutated gene, matched the DNA of a virus previously found only in mice. In contrast, only one specimen from the remaining 66 prostate cancer patients contained the virus.

ADD To: Virus in Prostate

This finding suggests that at least one form of prostate cancer could be caused by an infectious disease. That's because the mutated gene being studied is essential to the immune system since it codes for an enzyme that helps kill viruses that attack the body. Prostate patients with the mutated gene produce less of this enzyme than men with normal versions of this gene. Klein and his colleagues are developing a diagnostic test and will conduct further research.

Transitions

• Fredrick L. Kiechle, M.D., Ph.D. will be Director for Clinical Laboratories with **Laboratory Consultants of South Broward**, a pathology group affiliated with the **Memorial Hospital System** in Fort Lauderdale, Florida.

• At the start of the new year, Jim Fantus became CEO of **Clinical Laboratory Partners**, a laboratory company owned by the parent of **Hartford Hospital** in Hartford, Connecticut. Fantus was formerly CEO of **SED Laboratories** in Albuquerque, New Mexico. The CEO position opened up when Theophil (Ted) A. Begansky, Jr., M.D. retired after years of service with Clinical Lab Partners.

• Next week, Earl Buck joins **Chi Solutions, Inc.**, which is a successor company to **Chi Laboratory Services, Inc.**, the consulting firm he left in 1995. Until recently, Buck was part of the executive team at **Duke University Health System Laboratory** in Durham, North Carolina.

• **Specialty Laboratories, Inc.** reunited a long-running executive collaboration when it recently hired Robert Kisabeth, M.D. Kisabeth, formerly Senior Vice President of Medical Affairs at **Mayo Medical Laboratories** in Rochester, Minnesota, will again be working with Keith Laughman, another Mayo Medical Laboratory alumnus who is now President of Specialty Laboratories.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 10, 2006.

PREVIEW #4

EXECUTIVE WAR COLLEGE

May 3-4, 2006 • Intercontinental Hotel • Miami

New Legal Threats to Pathology and Clinical Labs

One of the *Executive War College's* highest-rated speakers returns again with an update on the hottest legal issues in anatomic pathology (AP) and clinical laboratory. Attorney Jane Pine Wood leads her list with the Medicare proposal to restrict use of CPT code 88305 to two units of service per patient per day. But that is not the only important legal threat facing the nation's laboratories. Client billing, deeply-discounted pricing, managed care contract practices, provision of pathology services by non-pathology specialists, and evolving legal concepts about inducement make this a "must hear" presentation for lab managers and pathologists alike.

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