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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

"Here's to Plain Talk and Clear Understanding!"

"WELL, SIR, HERE'S TO PLAIN TALK AND CLEAR UNDERSTANDING." That's a well-known line in the classic 1941 detective movie, "The Maltese Falcon." It's spoken by the Kasper Gutman character, played by Sidney Greenstreet, to San Francisco private eye, Sam Spade, played by Humphrey Bogart. Gutman thinks Spade has the priceless Maltese Falcon statue and he wants to get to the answers quickly.

I've been reminded of that line during the past seven months, every time the **Centers for Medicare & Medicaid Services** (CMS) has stepped into the public arena and discussed the impending Medicare Clinical Laboratory Competitive Bidding Demonstration Project or released documents about the pilot demonstration it plans to conduct in the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical area). Officials from CMS have absolutely failed to meet the standards outlined by Kasper Gutman, when he asked for "plain talk and clear understanding."

To the contrary, officials from CMS and its minions at **RTI International, Inc.** (the contractor which has done development work for the past 12 years on the laboratory competitive bidding project) have done the opposite of "plain talk and clear understanding." They refuse to speak in a clear, understandable manner. They decline to offer objective, frank, and easy-to-understand insights about the requirements of the laboratory competitive bidding demonstration project. What makes this doubly insulting to the laboratory profession is that these same officials are public servants, chartered by the Constitution and various statutes to serve in the interest of the American public, with due process, and respect for the concepts of fair play that make this Republic an example of freedom and the rule of law.

Against the morass of obfuscation, complexity, and deliberate negative bias that marks the way CMS is proceeding with the lab competitive bidding demonstration, I think it is refreshing how at least one leader in the lab industry is willing to boldly use "plain talk and clear understanding" to state the obvious. As you will read on the following pages, Alan Mertz, President of the **American Clinical Laboratory Association** (ACLA) in Washington, DC, declared that the laboratory competitive bidding demonstration is "*coerced* bidding to force labs to bid below the true cost of providing the service... and that's not a bid demonstration which is objective and competitive." Kudos to Mr. Mertz. Let's hear more plain talk and clear understanding from our lab industry leaders! TDR

Labs Face "Coercive" Bid, Not Competitive Bidding

Lab coalition plans next strategy to change most egregious aspects of Medicare Bidding Demo

CEO SUMMARY: In the weeks since the December 5 bidders' conference in San Diego, where Medicare officials took the wraps off the complete requirements for the Laboratory Bidding Demonstration Project, the Clinical Laboratory Coalition has begun to consider strategies to delay or cancel the project. Options include litigation in court to stop the submission of bids on February 15, as well as continued education of members of Congress about the poor design and bias of the bidding demo.

ONE NATIONAL LABORATORY LEADER has a blunt and concise way to describe the Medicare Clinical Laboratory Services Competitive Bidding Demonstration project, moving toward implementation in the San Diego-Carlsbad-San Marcos MSA (metropolitan statistical market).

"This is not really competitive bidding. This is coerced bidding to force labs to bid below the true cost of providing the service," declared Alan Mertz, President of the **American Clinical Laboratory Association** (ACLA), in Washington, DC. "This is like what happens when someone holds a gun to your head!"

In recent weeks ACLA and other members of the Clinical Laboratory Coalition have met to develop strategies to to delay or stop the demonstration project in the San Diego MSA. "Litigation is one option," said Mertz. "As well, the coalition is working to get Congress to repeal the project by adding language to any bill that Congress passes about Medicare this year."

The federal **Centers for Medicare & Medicaid Services** (CMS) released the specific requirements for the project at a bidders' conference in San Diego last month. Labs are scrambling to submit bids by the CMS deadline of February, 15. *(See TDR, December 31, 2007.)*

"We are seriously exploring litigation to try to raise strong objections to the competitive bidding demonstration proceeding forward," Mertz explained. "I can't discuss any specifics at this time.

"But I can tell you the Clinical Lab Coalition has agreed to move forward with a full court press to try to get

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Congress to repeal this project early this year," he noted. "Congress will have to pass a Medicare bill in early summer, and we expect to address the bidding project in that bill. So, we are going back to all the key members of Congress and the champions we met with last year to tell them the clock is ticking, but it's not too late to stop the laboratory competitive bidding demonstration project. Those efforts are already underway up on Capitol Hill.

Grassroots Organizing

"In addition, we are doing grassroots organizing to encourage people in San Diego, including lab professionals, other providers, and Medicare beneficiaries, to lobby their members of Congress on this issue," Mertz added. "We also urge all labs across the country to participate in this grassroots effort.

"Labs should not in anyway give up," he continued. "Laboratorians should be contacting their congressmen and senators to ask Congress to stop this project before July. We have to keep the pressure on Congress. If we do, we have a good chance of stopping this through congressional action.

"Of course, it would be best to stop this project before CMS sees any bids," he warned. "If they see the bids on February 15, and even if we succeeded in getting a repeal after February 15, the damage will be done because CMS will have the bids that they covet. We would like to stop CMS from getting that bidding data because of its stated intention to use these bids as a prototype for a new national lab fee schedule.

"However, keep in mind that, for CMS to make wholesale changes in the fee schedule for those 303 tests listed in the bidding project, we believe it would require congressional action," said Mertz. "They have some authority to make recommendations on what's fair and reasonable regarding fees for a few tests. But for CMS to use the bids to make broad changes in the fee schedule—based on those 303 tests—would first require congressional action.

"Further, this Congress is likely to be suspicious about any information they will get from CMS on lab fees," continued Mertz. "I don't think it's possible for CMS to slip all these numbers over the transom and then have Congress change the national fee schedule based on this data. Many key players in Congress understand that the laboratory competitive bidding demostration designed by CMS is not a fair, objective, and transparent process.

"They know this because the lab industry laid the groundwork for this push last year," Mertz said. "We had intensive and numerous meetings with all the key members of Congress as part of the advocacy campaign by ACLA and the Clinical Laboratory Coalition.

"As a result of this lab-advocacy work, a number of influential members of Congress understand that what CMS is doing is not really competitive bidding," he added. "This is coerced bidding to force labs to bid below the true cost of providing the service. CMS is coercing them almost as if it had a gun to their heads and was saying, 'CMS will ban your lab from serving Medicare beneficiaries for three years if you don't give us these low prices.' What the government is doing is more like bank robbery than it is 'competitive bidding!' It's the equivalent to someone walking into a bank, putting a gun to your head and saying, 'Give me your money or you're dead.' That's not competitive bidding and many in Congress understand that."

Benefits Of Lab Advocacy

THE DARK REPORT observes that the Clinical Laboratory Coalition's advocacy efforts in Congress during the past year are proving to be most timely. If enough members of Congress truly understand the important role labs play in healthcare, that increases the odds that Congress will make informed decisions about competitive bidding and similar issues affecting the laboratory medicine profession. TDR

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FDA Approves New Test For Respiratory Viruses

Using non-invasive specimens, multi-analyte assay can detect 12 viruses and viral subtypes

CEO SUMMARY: Respiratory viruses are responsible for 75% of all visits to physicians and yet physicians struggle to identify whether an infection is viral or bacterial. Now there is a new molecular assay with FDA clearance that allows physicians to test for 12 common viral infections. It is the xTAG Respiratory Viral Panel (RVP) from Luminex Molecular Diagnostics. Beaumont Hospital in Royal Oak, Michigan, is one of the first hospitals to offer this test.

MULTIPLEX TESTING IS POISED to make another advance in clinical care. This time it's a non-invasive, multi-analyte test designed to detect 12 viruses and viral subtypes that are responsible for more than 85% of respiratory viral infections.

Pathologists at **William Beaumont Hospital** in Royal Oak, Michigan, are preparing for a dramatic change in how they test for respiratory viruses. By this time next month, the laboratory at the 1,061-bed major academic and referral center, will begin using the xTAG Respiratory Viral Panel (RVP) from **Luminex Molecular Diagnostics** to test for 12 respiratory viruses and viral subtypes.

This test is the first to use molecular technology to target respiratory viruses. Luminex announced 510(k) clearance for this assay on January 3, 2008. The test will be available for use by physicians practicing in the hospital. Beaumont Hospital's laboratory outreach program will also offer the assay to office-based physicians.

Specimens are collected from a patient by the use of a nasopharyngeal swab. After multiplex PCR amplification of the specimen's nucleic acid with target-specific primers, the xTAG RVP test can detect a respiratory virus (if present) within eight hours. This method is a significant improvement over current viral testing methods, which can take four to seven days.

"This test represents a fascinating transition in laboratory medicine where we go from doing cultures of viruses to actually detecting the viral genetic makeup," said Mark D. Kolins, M.D., Chair of Clinical Pathology at Beaumont Hospital, Royal Oak, and Medical Director of the **Beaumont Reference Laboratory**. "This is an example of how new assays based on molecular techniques can offer clinicians faster and more precise results.

Results In Eight Hours

"The big advantage is in terms of time," Kolins explained. "Culturing a viral sample can take four to seven days. The xTAG RVP can produce a result in eight hours, which could be the same day for a patient in the hospital.

"The concern about viral infections is not so much when a patient is at the beginning of a cold or respiratory infection, because we have all been taught to wait a few

days before seeing the doctor," continued Kolins. "This technology is useful when a patient has progressively worse symptoms over a number of days and is at a point where we are considering treatment. That patient may need to be hospitalized with respiratory insufficiency. At that point, this test can help guide the physician because we can distinguish certain viruses, and we can decide if the virus is susceptible to certain antiviral therapy.

Bacterial or Viral?

"If a bacterial infection is detected through bacterial culture, that patient needs to be treated with antibiotics," Kolins said. "If no bacteria are present, it is inappropriate to use antibiotics for a viral illness. Such inappropriate use leads to bacterial resistance, which is a major problem in healthcare. This multiplex test can put a dent in our use of inappropriate antibiotics by identifying the patient's condition accurately and guiding selection of the right therapy.

"During the past year, we were one of four laboratories that helped Luminex validate the test," he explained. "Now, we are acquiring additional equipment to go live with this test in the clinical setting.

"From the patients' perspective, this is a non-invasive test and they can be seen in any office, an emergency clinic, outpatient clinic, or in the hospital," Kolins added. "We will also use it in our Emergency Center for those patients who come in with more severe respiratory disorders. We are planning to introduce this test to our laboratory outreach program, which performs 4.5 million tests per year and is one of the largest in the nation. We think it will give us a competitive advantage in our outreach market."

THE DARK REPORT observes that this new multi-analyte assay demonstrates the speed with which molecular technology can suddenly give laboratories new tools that increase diagnostic accuracy and produce a faster answer. TDR

Multiplex Test Can Detect 12 Different Viruses & Subtypes

COLOR-CODED MICRO BEAD TECHNOLOGY LIES at the heart of the new multi-analyte xTAG Respiratory Viral Panel (RVP), recently cleared by the FDA and offered by Luminex Molecular Diagnostics of Toronto, Canada.

A sample containing viruses from a patient's nasal cavity, throat, sinuses, or bronchi is collected. Nucleic acid is extracted from viruses in the sample and amplified using PCR (polymerase chain reaction).

The amplified DNA is mixed with short sequences (TAG primers) of DNA specific to each viral target. If the target is present, the primer will bind and be labeled. Color-coded beads are added to identify the tagged primers. Attached to each bead is an anti-TAG sequence specific to one of the extended TAG primers.

Samples are placed in a Luminex xMAP instrument where lasers identify the color, then read the reaction of the bead (specific to a virus or subtype). xTAG RVP tests for:

- **Influenzas A, A-H1, A-H3, and B**
- **Adenovirus**, responsible for about 10% of respiratory infections and multiple deaths
- **Respiratory syncytial virus (RSV) A and B**, the most common cause of bronchiolitis and pneumonia in infants and children
- **Metapneumovirus**, a virus that causes flu-like symptoms and a leading cause of respiratory infection in children
- **Parainfluenza 1, 2, and 3**, source of upper or lower respiratory infections in adults and children, such as croup, bronchiolitis, and bronchitis
- **Rhinovirus**, a cause of the common cold.

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CMS Spotlights AP as It Delays Anti-Markup Rule

Anti-Markup rule implemented on January 1 targets one specific type of anatomic path lab

CEO SUMMARY: When Medicare officials postponed implementing a new anti-markup rule late last month, it did so because of questions about how the new rule will be applied. However, the Centers for Medicare & Medicaid Services (CMS) did implement an aspect of the anti-markup rule on January 1, 2008, that affects one anatomic pathology laboratory model. Attorney Rick Hindmand offers fives steps to help pathologists comply with the newly implemented anti-markup rule.

FEDERAL OFFICIALS ARE CONCERNED that physicians who send anatomic pathology (AP) specimens to clinical laboratories may be gaming the system, says a lawyer who follows federal healthcare reimbursement issues.

"Last month, the federal **Centers for Medicare & Medicaid Services** (CMS) announced it would delay implementation of new anti-markup rules, originally scheduled to take effect on January 1, 2008, with respect to a broad range of diagnostic testing services," stated Rick Hindmand, a attorney in Chicago for **McDonald Hopkins**, a national law firm. "In response to questions about how the new rules would be applied, CMS will conduct further review and may revise these rules prior to their implementation on January 1, 2009. This delay, however, generally does not apply to condo/pod labs and similar anatomic pathology arrangements maintained offsite by group practices.

"These actions show that CMS now has anatomic pathology in the spotlight," Hindmand said. "That spotlight is no longer shared with imaging centers and various other types of diagnostic testing. Of course, CMS has long-standing concerns about other services that referring physicians purchase. But, for the moment, CMS is focusing its attention on anatomic pathology.

"This year, CMS will look closely at anatomic pathology operations within group practices of referring physicians. In recent years, CMS has expressed its concern about AP arrangements that allow physicians to profit from the anatomic pathology work generated by their patients," he noted. "For example, CMS is concerned that some ordering physicians may have a financial incentive to order more tests, meaning they could be gaming the system in some way.

AP Arrangements

"The Stark Rule restricts the ability of physicians to refer work to facilities they own, but some physicians have gotten around the Stark Law limitations in various ways," noted Hindmand. "Because CMS is turning the spotlight on physicians who use anatomic pathology services, both pathologists and referring physicians should thoroughly understand the rules.

"Keep in mind that the new anti-markup rules were put in place in addition

to the Stark Law," Hindmand continued. "Therefore, physicians seeking to be in compliance with all federal rules will need to comply with both the Stark Law and the anti-markup rule."

It was on November 1, 2007, that CMS issued the 2008 Medicare Physician Fee Schedule final rule. Included was an expansion of rules that prohibit physicians from marking up diagnostic tests that outside suppliers perform. The revisions to this regulation were scheduled to become effective on January 1, 2008.

CMS Decides To Delay Rule

But on December 28, CMS delayed implementing the anti-markup revisions in the fee schedule. It wanted more time to study the location standard and issue clarifications. In a statement, CMS cited arrangements involving AP diagnostic testing as a "core concern." As a result of this concern, CMS did not delay the rule with respect to anatomic pathology diagnostic testing services furnished in a group practice's centralized building that does not qualify as the "same building" under the Stark regulations. This statement is widely viewed to apply to anatomic pathology condo/pod laboratory arrangements.

The final 2008 Medicare Physician Fee Schedule rule that CMS was prepared to implement included specific anti-markup requirements. These requirements would apply whenever a physician practice or other supplier bills the Medicare program for the technical or professional component of a diagnostic test that the supplier or a related party ordered and the diagnostic test was either: 1) purchased from an outside supplier; or, 2) performed at a site other than the office of the billing supplier. In either of these situations, payment to the billing supplier for the service that is subject to the anti-markup rule and may not exceed: 1) the lowest of the performing supplier's net charge; 2) the billing supplier's actual charge; or, 3) the Medicare fee schedule amount.

Hindmand advised that pathologists and their practice administrators should take five steps to understand the implications of these new regulations. "First, it is important to recognize that the one-year postponement does not apply to anatomic pathology tests that are performed at an offsite group practice location used by the group practice of the ordering physician, for example in condo/pod labs," Hindmand explained. "Thus, physicians who operate these types of AP laboratories need to recognize that this arrangement is now subject to the anti-markup rule which became effective on January 1, 2008. Pathologists who provide services to these types of AP laboratories must also recognize how the anti-markup rule governs their relationship with the referring physicians.

"The rule which became effective on January 1 doesn't apply to everyone," he added. "For example, if an orthopedic surgeon has an imaging center in his office, the orthopedist may not have to worry about the anti-markup rule. But a physician who uses pathologists may not be off the hook and so should learn more about the rules.

Review With Legal Counsel

"Second, because of how the newly implemented and the pending anti-markup rules will alter existing anatomic pathology referral and billing arrangements, it would be wise for referring physicians and the pathologists serving them to conduct a detailed review with their legal counsel," advised Hindmand. "If it is determined that the existing AP arrangement is covered by the anti-markup rule, then changes in billing practices may be required to bring the arrangement into compliance.

"Third, those pathologists who order anatomic pathology tests need to be aware of how the rule applies," Hindmand added. "If the pathologist orders a test that is performed offsite, that test may be covered under the anti-markup rule as it applies now. For example, you may have a

Did Physician Questions About Lab Locations Cause CMS to Change Course?

QUESTIONS AND COMMENTS from pathologists, lab directors, and referring physicians apparently caused the federal Centers for Medicare & Medicaid Services (CMS) to delay implementation of the anti-markup rules, said Rick Hindmand, an attorney with McDonald Hopkins.

"CMS was confronted with a number of details that need clarification, particularly on location issues," he explained. "That's why they postponed the implementation.

"Many physicians and their attorneys were concerned about the application of the location requirement—particularly for tests performed in the same building," Hindmand added. "For example, to avoid the anti-markup restriction, the rule specified that the test had to be performed within the same space where the group provides medical services.

"That raised questions," he noted. "What if a group practice has an imaging center on the first floor and a medical practice on the second? How does the rule apply to that situation? CMS decided to look at the location requirement more closely, because it was concerned about the unintended consequences that might result from the rule."

"Physicians asked how the rule would apply depending on whether a patient can get to a test without going through a common hallway in the medical office building, for example," Hindmand said. "Let's say a physician practice is on two floors of the same building and the practice has a common stairway leading from the medical clinic to the pathology lab. Is that deemed to be in the same space or a different space? CMS realized that it would need to refine the rule to clarify its interpretation."

Hindmand noted that under the anti-markup rule as currently in effect with respect to anatomic pathology, the physical location where the diagnostic test is performed needs to satisfy the "same building" standards under Stark regulations in order to avoid the anti-markup rule. "Group practices that currently have condo or pod labs offsite, in order to comply with the Stark regulations, will now be subject to the anti-markup rule," he said, "Only if the group maintains a substantial medical office in the same building where the condo or pod lab is located would it be allowed to mark up its Medicare claims."

pathologist who orders a follow-up test or who uses the services of another pathologist in a subspecialty and then bills globally for that work. The pathologist who ordered the test may be covered under the anti-markup rules.

"Fourth, the location where the test is performed is a crucial part of the anti-markup rule," he explained. "If the test is performed in a centralized building offsite [like a condo/pod lab complex], then it will be covered by the anti-markup rule, unless in that same building, the billing supplier (meaning the group practice) maintains a medical office. The key issue is whether the physicians of the group practice see patients in the same building. If not, the group practice may be subject to the new rule.

"Fifth, pathologists and lab directors should follow CMS' actions closely this year because CMS will make clarifications regarding the anti-markup rule and perhaps issue amendments with regard to their location tests," Hindmand said. "CMS probably will make clarifications regarding other issues, such as how the price limitations come into play.

"CMS is likely to make these clarifications and amendments in advance of the new rule going into effect on January 1, 2009," he added. "When they do make the clarifications, the clarifications will apply to anatomic pathologists as well as to other specialists." TDR

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CEO SUMMARY: A new study provides powerful evidence that laboratories using Lean, Six Sigma, and similar process improvement methods consistently outperform conventionally managed laboratories. Using data sets from 100 laboratories, including 14 Lean/Six Sigma laboratories, consultant Thomas P. Joseph, of Management Insight, LLC, demonstrated that Lean labs have dramatically improved turnaround times and consistently produce common results in less than an hour. They also have significantly fewer defects per million opportunities and operate with 40% less technical staff in key testing work cells, when compared with conventional labs. THE DARK REPORT provides a first look at some of the significant findings of this study.

Analysis shows Lean labs consistently do better than conventional labs

New Study Demonstrates How Lean Labs Outperform Peers

POWERFUL NEW EVIDENCE DEMONSTRATES that labs using Lean, Six Sigma, and similar process improvement systems enjoy superior performance compared with laboratories using traditional management systems.

This is the finding of a pathfinding new study conducted by Thomas P. Joseph, Managing Partner of **Management Insight, LLC**, of Ann Arbor, Michigan. Joseph unveiled his study at *Lab Quality Confab* in Atlanta last September in a presentation titled "Benchmarking the Best: Comparing the Performance of the Nation's First Lean Laboratories."

"Working from a database that includes more than 18 million performance measurements from more than 100 laboratories, the findings are unmistakable," stated Joseph. "When Lean/Six Sigma labs are compared with conventional labs, dramatic differences appear in operational performance across a wide variety of measures. The contrasts are striking in almost every area of laboratory performance!

"To my knowledge, this is the first direct comparison of Lean labs versus conventional labs that's been conducted in the lab industry," Joseph explained. "There have been numerous case studies from laboratories that *have* introduced Lean processes into their workflow. In every case, these labs report impressive improvements in turnaround time (TAT) and error reduction. It has been unclear, however, if these labs improved their performance, for example, from the lower quartile to the upper quartile or if they improved beyond levels of performance seen elsewhere in the industry."

In Joseph's view, the data support a clear conclusion about the value of Lean to the nation's clinical laboratories. "The study results tell us that Lean is having significant effect on how laboratories perform," he observed. "Of course, pathologists and managers running Lean labs are not surprised by these results.

"But for anyone not convinced of the value of Lean processes, these numbers close the case," declared Joseph. "So, why don't more labs use Lean processes? One of the challenges is that Lean represents a cultural change. Not every lab manager wants to undertake the highly disciplined method of working that requires standardized work processes. But, clearly, Lean has taken hold and will continue to make inroads into the lab industry."

Joseph, who has a long career in laboratory consulting, is working with a database of 100 laboratories of various sizes. During 2007, with the help of THE DARK REPORT, he approached a number of laboratories using Lean and Six Sigma about providing data that would be used to assess what types of differences could be revealed in a statistical comparison of conventional labs and those labs using Lean and similar process improvement methods. Curious about how their performance would compare to a representative cross section of conventional labs, the Lean laboratories readily agreed to provide data. They also provided details about the work processes in their labs.

Of the 100 laboratories in the database, 14 are among the early adopters using Lean processes. Most of the Lean laboratories are in teaching or academic medical centers, and as such are full-service hospital labs. One of the Lean labs is a rapid-response laboratory and two are core labs. Most of the laboratories do not use track-based automation, although two have **Siemens** Advia WorkCells. Most of the labs in the study use pneumatic tubes to transport morning draws to the lab.

➤ Lab Performance Database

Joseph's laboratory performance database contains data covering every aspect of clinical performance from test order to verification of results. It includes a number of specialty labs affiliated with emergency departments (ED), oncology, surgery, and point-of-care testing.

"Regardless of size, labs face similar challenges managing work flow," Joseph said. "There are spikes in specimen volume from morning draws and, often, courier drop-offs of outpatient specimens at other times of the day. One challenge involves managing those volume spikes. Conventional labs have fewer ways to manage work flow. Thus, during these volume spikes in many conventional labs their TAT suffers, as you might expect.

"Lean labs have implemented a very effective strategy," he added. "The typical approach in Lean labs is to level the work flow, guided by the principle of single piece or small batch work flow. Thus, particularly for morning draws, they have phlebotomists send down one, two, or three patient draws at a time—rather than 10 to 20 at once, as is a common practice in conventional labs.

Improving Efficiency

"With respect to in-lab performance differences (receive to verify) between Lean and conventional labs, Figure 1 (*see page 13*) provides a dramatic illustration," Joseph explained. "This figure shows TAT for STAT complete blood counts (CBCs) for Lean labs versus conventional labs. Because most cell counters have similar lead and cycle times, this represents a pure comparison of worker processing efficiency. The results show that 89% of Lean labs have a stat CBC TAT of 12 minutes or less, but only 16% of conventional labs achieve that level of performance! As a group, the Lean labs are substantially better.

"There is a similar difference for routine CBCs," he said. "Lean labs typically have a routine CBC TAT of 20 minutes or less and only 30% of conventional labs achieve that level of performance.

"For morning draws, the database shows that 75% of Lean labs have a collect-to-receive time in the lab of under 20 minutes," he said. "Lean labs reduce turnaround time in this segment of the value stream primarily by reducing batch size. In a typical conventional lab, a phlebotomist will go out for an hour or more and bring all the specimens down at once. But some Lean labs send batches of two or three draws at one time, and many have phlebotomists send specimens after each patient draw."

Batch Size and TAT

Joseph has developed a model of the effect of batch size on TAT and staffing that corresponds closely with observed performance by Lean and conventional labs. "Labs realize over 90% of the potential gain in improved TAT by reducing batch size from 15 to three patients at a time," Joseph explained. "However, if the phlebotomist is sending specimens after each draw, it means he/she walked back and forth to the pneumatic tube three times as often. It also means the lab opened up three times as many pneumatic tubes.

"My model and data from the study both indicate that single piece flow will improve collect to receive TAT by four minutes (versus batches of three)," observed Joseph. "For many labs, processing in batches of three may be the best compromise between a four-minute improvement in TAT and a 200% increase in non-value added work.

Opportunities With Couriers

"The same opportunity to level workload is often possible with courier deliveries," he noted. "I worked with a lab that had couriers picking up from several large collection sites, then making five or six additional stops at low volume locations requiring an additional hour of driving before delivering specimens to the lab. This lab had virtually no specimen deliveries while the courier was finishing the route. Using Lean methods to review their courier routing we were able to level the workload. We developed improved routing with a more even flow of specimen deliveries. This eliminated acute spikes in the volume of specimens arriving at the lab. These changes triggered a substantial reduction in TAT.

Comparing Performance of Lean Labs With Conventional Labs on Turnaround Time

Figure 1: STAT CBCs

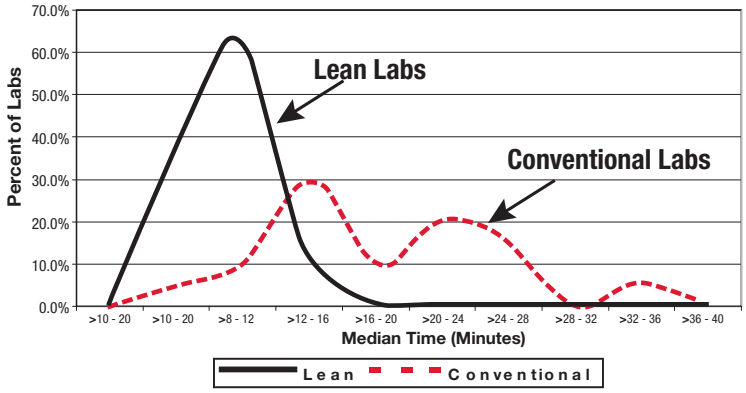
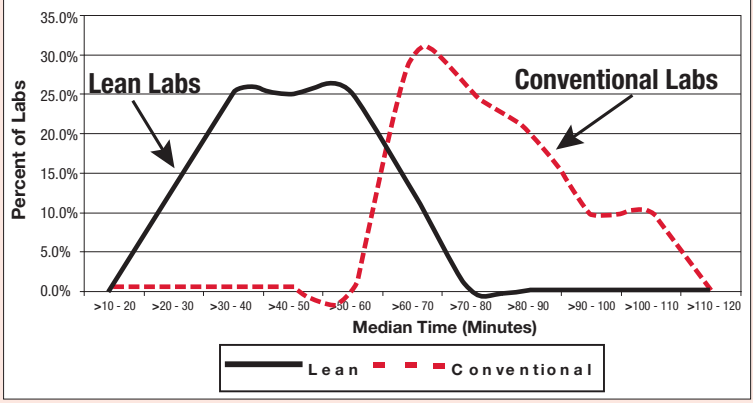


Figure One (above): 89% of lean labs have a STAT CBC TAT of 12 minutes or less. Only 16% of conventional labs achieve that level of performance.

Figure Two (below): 88% of lean labs have a collect to verify time of under 60 minutes for morning draws. Conventional labs average up to 120 minutes.

Figure 2: AM Draws (Collect to Verify)



Graphs courtesy of Management Insight, LLC ©2008

"As we examine a greater portion of the value stream, for example, from collection to verification of results from morning draws we see a huge difference," added Joseph, "in that 88% of Lean labs have a 'collect to verify' time of under 60 minutes for morning draws. *(See Figure 2.)* By comparison, no conventional labs had TATs under 60 minutes. The median TAT for Lean labs was 45 minutes versus 80 minutes for the conventional lab. The more process steps involved in the comparison, the greater the performance difference between Lean labs and conventional labs.

"Lean labs seek to eliminate waste at each step in the process," he explained. "So the difference with in-lab TATs (receive to verify) for CBCs between Lean and conventional labs is only about 10 minutes because it's a straightforward process. An examination of more of the value stream from collection to verification, as in the example of morning draws—with the need for more processing steps—reveals how striking the differences are between Lean labs and conventional laboratories.

"The traditional process improvement approach in industry is to focus on the equipment and the value-added processes by improving machine uptime and cycle times. The result is improvement in value added processes, but little effect on the overall value stream," Joseph explained. "Conversely, the Lean approach recognizes that most benefits derive from reducing or eliminating waste in the non-value added steps. In this way, the entire value stream is improved dramatically. For example, lead times are reduced, and often value-added processes are improved, resulting in a dramatically reduced TAT.

➤Volume & Turnaround Time

"Another way to look at differences is to compare the effect that volume has on TAT for Lean and conventional labs in Figure 3," he said. "When volume peaks, labs have turnaround problems, which stands to reason. Volume causes congestion and increases the wait time between processes.

"But when you examine Figure 4 (*on page 15*), you see that this Lean lab handles the volume and produces results in under 20 minutes on average," Joseph commented. "The results show a dramatically improved management of workflow irrespective of volume. The CBCs are processed in the lab quickly and efficiently.

"After seeing these results, I wanted to determine if turnaround time increases in labs as a function of their annual test volume. *(See Figure on page 17.)* My expectation was that as labs get larger, workflow problems are compounded and TAT suffers. In fact, there is a relationship between increased volume and higher TAT with conventional labs, as shown in the scatter diagram and regression line for conventional labs.

"But when you examine the regression line for the Lean labs, you see that there is no relationship between volume and TAT (the regression line is flat), indicating that Lean labs are managing workflow regardless of volume," he said. "Work processes in Lean labs allow them to handle increased workload without the increases in TAT experienced by conventional laboratories.

➤Minimizing Outliers

"While average TAT is important, lab managers also pay close attention to outliers," stated Joseph. "Outliers (excessive TATs) result in phone calls from medical staff demanding test results. Reducing outliers is perhaps more important than average TAT. When the outlier data of top conventional labs is compared to the outlier data of Lean labs, it can be seen that Lean labs have about 1.0% to 1.9% outliers (beyond 45 minute TAT from receipt to verification). By comparison, the top conventional labs had 2.6% to 6.4% outliers beyond 45 minutes as shown in Figure 6. (*See page 17.*) These results show that Lean labs not only perform better in terms of overall TAT, but have a dramatically reduced proportion of outliers.

"An additional distinction between Lean labs and conventional labs is in staffing requirements," commented Joseph. "On average, Lean labs operate their Lean workcells with 40% less technical staff versus equivalent workstations before the conversion to Lean processes."

➤Foward Thinking

Joseph plans to expand his groundbreaking studies into how and why Lean/Six Sigma laboratories operate differently

Workflow Differences Are Significant Between Conventional Labs and Lean Labs

Figure 3: Conventional Lab - CBC Workflow vs. TAT

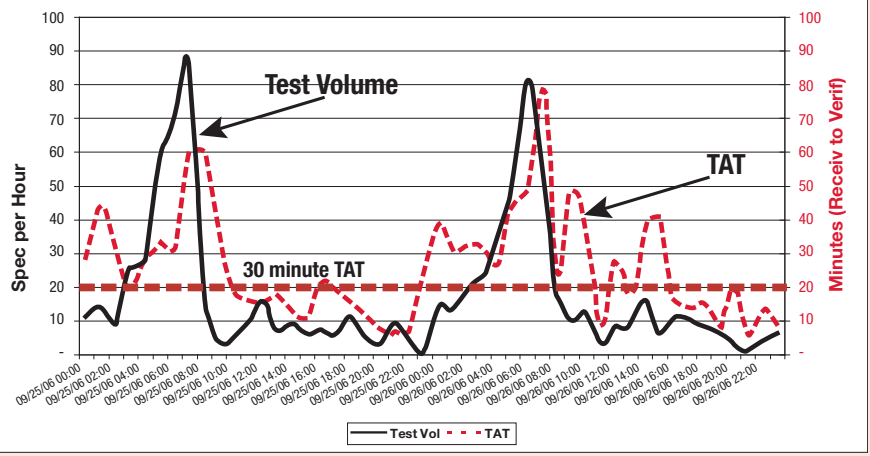
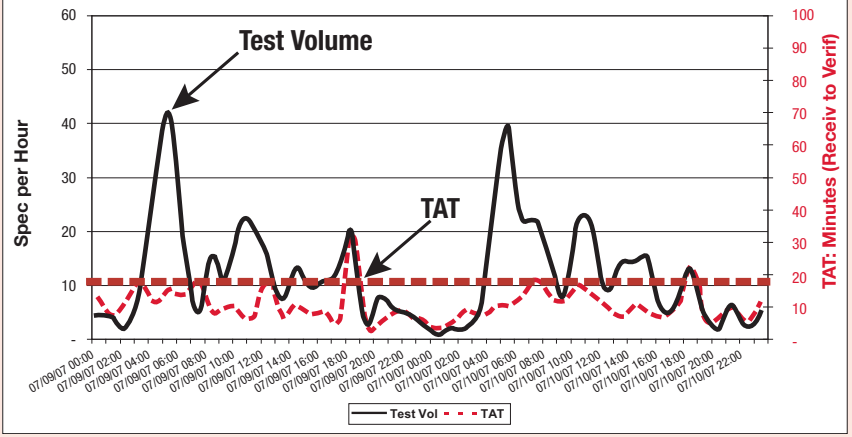


Figure Three (above): Conventional lab's two days of volume vs. TAT illustrates the lack of flow during peak periods. Periods of high volume see a corresponding increase in average test TAT.

Figure Four (below): Lean Lab's workflow rarely exceeds average TAT of over 20 minutes, regardless of test volume.

Figure 4: Lab Lab - CBC Workflow vs. TAT



Graphs courtesy of Management Insight, LLC ©2008

than conventional laboratories. His next effort is to include data on lab quality measures and satisfaction levels among lab employees and physicians. Later, Joseph may analyze the correlation between lab performance and clinical outcomes by studying, for example, the results of ED treatment of cardiac patients as it relates to troponin TAT results.

How Batch Size Affects Lab's Turnaround Time

ONE APPROACH THAT PATHOLOGISTS AND LAB DIRECTORS CAN USE TO UNDERSTAND the performance of their laboratories is to analyze how specimens are processed with respect to batch size. An illustration of lab performance developed by Thomas P. Joseph, Managing Partner of Management Insight, LLC, in Ann Arbor, Michigan, shows that, as batch size decreases, TAT (turn around time from collection to verification) is dramatically reduced.

"Consider what happens when morning samples come down from an inpatient floor," Joseph explained. "It's not unusual for phlebotomists to return to the lab with batches of 15 to 20 patient collections at once. Figure 7 (below), shows results of a model of performance that closely corresponds to data in the study of Lean early adopters.

"As batch size decreases, there are dramatic improvements in TAT. Decreasing batch size from three to one yields additional improvement, but at the same time requires more effort," he said. "If a lab is processing work in single piece flow, there is a price to pay in the amount of additional non-value-added work because, for example, the phlebotomists walk back from the patient rooms to the pneumatic tube after every draw instead of every third draw and open up three times as many pneumatic tubes."

Joseph explained, "In my view, processing morning draws in batches of three patient draws represents the sweet spot, balancing TAT gains against increases in non-value added work."

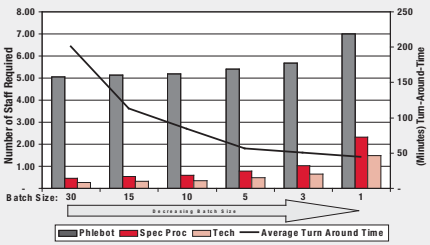


Figure Seven: The effect of batch size on TAT and staffing: As batch size decreases, TAT (collection to verification) is dramatically reduced.

THE DARK REPORT observes that Joseph's database affords pathologists and lab managers a thorough analysis of the performance of Lean labs versus conventional labs. In that way, it is a significant and important resource for all laboratory administrators and pathologists. Further, by incorporating Lean and Six Sigma management systems into their laboratories, lab administrators are positioning their labs to serve several important healthcare trends.

Quality Management Systems

These are the trends of: 1) patient safety and reducing medical errors; 2) helping clinicians reduce variability of care from one patient to the next and be more consistent at following approved clinical treatment guidelines; 3) supporting improvement in clinical outcomes; and, 4) participating in pay-for-performance programs. Each of these four primary healthcare trends requires providers, including laboratories, to better measure work processes and outcomes in real time. Fundamental to Lean and Six Sigma methods is the rigorous, real-time measurement of these activities.

In efforts to boost operational productivity and support these and other trends, many laboratories have turned to automation and middleware. Both such approaches deliver operational improvement and a good return on investment. However, Joseph's study of Lean laboratories versus conventionally-managed laboratories demonstrates that automation and middleware can only provide limited productivity gains. That is because of the long-standing adage among industrial engineers, which says "never automate bad work processes."

Lean Versus Conventional

What Joseph's study reveals is that Lean labs, using the same automation and integrated workcell equipment, consistently generate superior performance metrics compared to their conventionally-managed peers.

When Lean labs are shown to have dramatically better results than even the best performing conventional labs, perhaps it's

Looking for Relationship of TAT to Lab Size, Outlier Comparison Shows Striking Difference

Figure 5: TAT vs. Laboratory Size

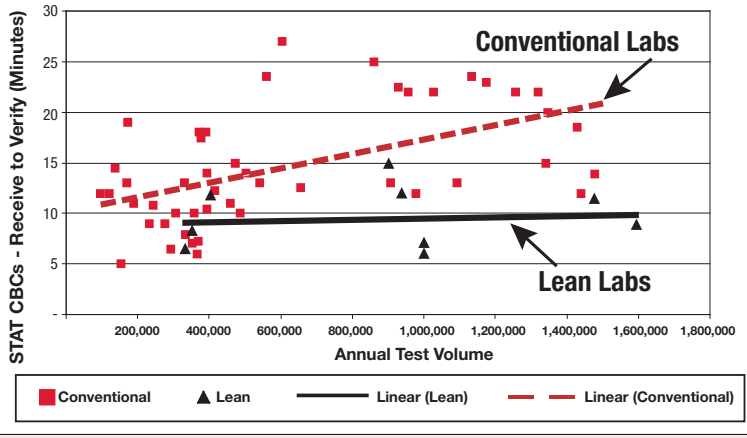
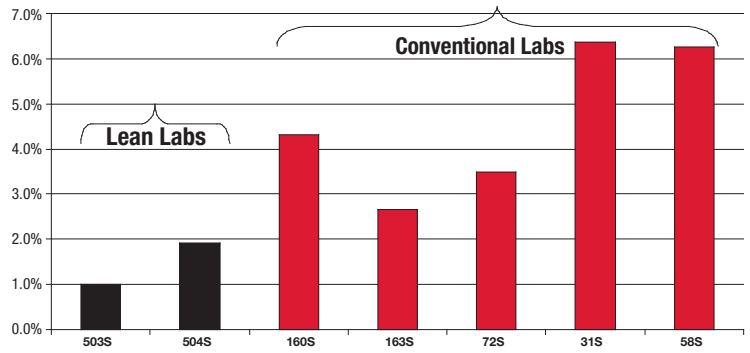


Figure Five (above): Lean labs define the highest level of performance and also seem to be unaffected by increasing volume.

Figure Six (below): Lean labs have a lower proportion of outliers than the better performing conventional labs.

Figure 6: Outliers Percentage (TAT above 45 minutes)
(STAT CBCs – receive to verify)



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time for more labs to convert to Lean processes. Two results from Joseph's Michigan database probably sum it up best: First, the quality of results from Lean labs is significantly better than that of conventional labs. The TAT is much shorter and there are far fewer errors. Second, Lean labs do it with 40% fewer staff members. TDR

Contact Thomas P. Joseph at 734-741-0356 or tpjoseph@umich.edu.. Visit www.management-insight.us.com for more information about laboratory performance benchmarking.

Healthcare Trends

Total Health Spending Rises 6.7%, Tops $2.1 Trillion during 2006

HEALTHCARE COSTS totaled $2.1 trillion in 2006, according to the January/February issue of *Health Affairs.* That is an increase of 6.7% over total spending in 2005, wrote researchers in an analysis titled "National Health Spending In 2006: A Year Of Change For Prescription Drugs."

Outside of a big, 8.5% jump in spending on prescription drugs, there was a slowdown in the cost of most of the major healthcare services and a 0.2 percentage point slowdown in personal healthcare spending. In fact, when higher costs for prescription drugs are excluded, growth in personal health spending declined from 7.0% in 2005 to 6.3% in 2006, noted the study's authors.

Trend In Coming Years

These facts raise a question for pathologists, lab directors, and all healthcare providers. What can they expect in the coming years about healthcare cost trends? In an analysis in the same issue, Paul B. Ginsburg, President of the **Center for Studying Health System Change** in Washington, D.C., explains the factors driving costs. His analysis, "Don't Break Out The Champagne: Continued Slowing Of Health Care Spending Growth Unlikely To Last," shows that about 50% of the growth in 2006 reflects rising healthcare prices, 16% reflects population growth, and the remaining 34% reflects real per capita growth in spending.

Several factors that are difficult to manage are causing this rise in costs, Ginsburg explained. "Increasing incidence of obesity is a major factor behind rising costs," he said, adding that, "The influence of the economic cycle on health spending, which has lowered the trend in recent years, is likely to reverse its impact shortly."

Another factor that encourages growth in spending is how entrepreneurial physicians are seizing opportunities to increase the number of outpatient procedures, such as surgery, imaging, endoscopies, and cardiac testing. These physicians recognize the high returns from facility fees—as opposed to professional fees.

"Physicians also have brought capabilities to perform profitable ancillary services into their offices," wrote Ginsburg, who noted that physician self-referral is another factor causing costs to rise. Research shows much higher referral rates for procedures when physicians have an ownership stake in the facilities they use.

Hospitals have also contributed to increased costs. Ginsburg observed that hospitals have expanded specialized facilities (such as adding operating rooms and imaging facilities) to serve patients with the latest technology.

Alert readers will note that several of the factors driving up healthcare spending have hit the radar screen at the federal **Centers for Medicare & Medicaid Services** (CMS). In particular, CMS has stated concern about how office-based physicians are establishing ancillary services within their group practice, particularly referencing in-house anatomic pathology and radiology.

One CMS effort to curb physician self-referral is the implementation of anti-markup rules affecting physician-owned pathology laboratories. *(See pages 7-9.)* CMS has stated it will seek to curb what it considers to be physician overutilization in several clinical services. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

It's a laboratory acquisition that shows the importance of anatomic pathology in today's competitive laboratory marketplace. **Carilion Labs** of Roanoke, Virginia, acquired **Innovative Pathology Services** (IPS), an anatomic pathology and cytology lab in Knoxville, Tennessee. The deal closed last year. Carilion Labs acquired the laboratory and entered into professional service contracts with the 13 pathologists at Innovative Pathology. IPS serves 10 hospitals, five surgery centers, physician offices in Tennessee, and pathology practices nationwide. Carilion Labs is a subsidiary of **Carilion Clinic**, also in Roanoke.

MORE ON: Carilion

Carilion Labs is embarked on an expansion strategy and is becoming an active acquirer of laboratories. In December, 2006, it purchased **Presbyterian Reference Laboratory** in Charlotte, North Carolina. Earlier it had acquired the consulting company now known as **Chi Solutions.**

PRIVATE INSURERS FOLLOW CMS, STOP PAYING FOR ERRORS

Refusing to pay hospitals for treatment associated with preventable medical errors is gaining traction among the nation's private health insurers. In separate announcements recently, **Aetna, Inc.**, **WellPoint, Inc.**, and other insurers have declared that they will cease to pay for errors, such as operating on the wrong limb or giving a patient incompatible blood. These payers are following the example of Medicare, which published a new policy last fall that denies payment to hospitals for eight conditions recognized as preventable events.

ADD TO: No Payment

THE DARK REPORT predicts this trend will spread. It is based on the work done by the **National Quality Forum** (NQF), in Washington, DC, to publicize its list of 28 "never events" that are widely agreed to be medical and operational errors that should never happen to a patient. "Never events" range from errors that include surgical-site infections and urinary-tract infection from a catheter, to bedsores and falls. Refusing to pay for "never events" and similar medical errors raises the performance bar for hospitals, physicians, and other providers. This trend is likely to favor laboratories, because lab testing is a key tool, particularly in programs to control the spread of infections in hospitals.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

... how a saliva test is under development at the **Johns Hopkins Kimmel Cancer Center** in Baltimore to detect head and neck cancer among heavy smokers, heavy drinkers, and other high-risk populations.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 11, 2007.

Preview #1

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UPCOMING...

- ***Disruptive Changes Ahead–TDR's Biannual List of Anatomic Pathology's Top Trends.***
- ***What's Unfolding in Laboratory Mergers & Acquisitions? A Look at Surprising Events.***
- ***First Report from Molecular Summit 2008: Experts Discuss* In Vivo/ In Vitro *Integration.***

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