

From the Desk of R. Lewis Dark...

THE **RD** **DAIRK** **REPORT**

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

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R. Lewis Dark

Founder & Publisher



Changing the Way Laboratories Do Business

I HOPE BOTH PATHOLOGISTS AND LABORATORY ADMINISTRATORS pay close attention to our coverage of early-adopter hospital laboratories and how they are using “Lean” quality management methods to boost performance of their laboratories. These labs are harvesting productivity gains in the range of 30% to 50%, following a training and implementation schedule requiring as little as 12 weeks.

It’s my belief that Lean—and other quality management systems like it—are about to drive deep and profound changes to the organization and operation of both clinical laboratories and anatomic pathology groups. In this issue of THE DARK REPORT, we’ve identified the handful of early-adopter laboratories which are just now completing their first major Lean projects. This is timely and useful business intelligence, since it allows our clients and readers to be first to understand and investigate these developments.

Although this first round of Lean projects were targeted at the clinical laboratory, histology is next in the queue. When efforts to apply Lean to the histology laboratory are finished, I would encourage anatomic pathologists to give time and attention to the outcomes. The post-Lean histology laboratories of these early-adopter hospitals will provide a fascinating peek at the direction histology operations will take during the next 36 months.

For one thing, I’ll bet that the first Lean make-overs of histology labs demonstrate that a fair amount of automation and “must-have” technology are not as important as an effective redesign of work processes in the pre-analytical stage. If true, that means our clients and regular readers of THE DARK REPORT will be able to avoid investments in certain technologies because they’ve seen how post-Lean histology laboratories boost quality and productivity without them.

Seven years ago, THE DARK REPORT was first to identify and articulate the reasons why there was a wave of hospital laboratory consolidations—and that it would pass within 24 months. Now, I believe we are first to identify that the introduction of quality management systems into clinical laboratories is underway—and that this will be a long-lasting phenomenon because of Lean’s power to change the operational status quo by as much as 50% in its initial deployment in a laboratory.

How “Lean” is Benefiting Early-Adopter Laboratories

One major goal is to slash turnaround time for critical testing of hospital inpatients

CEO SUMMARY: *First steps toward a radical change in clinical laboratory operations are under way in a handful of early-adopter laboratories. This movement is so new that little information about their successes can be published. But the early evidence is compelling. For those labs willing to take the plunge, implementation of quality management systems such as “Lean” and Six Sigma generates major benefits.*

By Robert L. Michel

IN SEISMIC TERMS, there’s a tectonic shift of great magnitude unfolding in the clinical laboratory industry. It centers around the earliest efforts to apply the latest generation of quality management systems to clinical laboratory operations.

Since January, a handful of hospital laboratories have introduced “Lean” techniques into their lab testing operations. In every case, early results confirm the potential of these techniques to transform laboratory operations in ways that generate substantial and rapid improvements.

The benefits are multiple. When Lean methods are introduced into laboratory operations, quality and pro-

ductivity go up. Errors and costs go down. Turnaround time and service levels improve. Morale and enthusiasm zooms among the lab staff empowered to use Lean methods to revamp their laboratory.

It is my firm conviction that quality management techniques, ranging from Lean to ISO-9000, Six Sigma, and others, are on the verge of widespread acceptance and adoption by the clinical laboratory industry. Other parts of the healthcare system are embracing them as well. For clients and regular readers of THE DARK REPORT, this is no surprise. In recent years, the pressure on healthcare providers to improve the quality of health services while reducing the cost of care has increased. These pages regularly chronicle such developments.

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In fact, on pages 9 to 14 of this issue, you will read how **DSI Laboratories** of Ft. Meyers, Florida became the first major laboratory organization in the United States to implement and complete a Lean-driven reorganization of a high-volume hospital core laboratory. However, even as DSI Labs was first to complete such a project, four or five other major hospital system laboratories were launching similar Lean initiatives in their lab facilities.

The list includes some prestigious institutions. **Fairview Health Services** of Minneapolis, Minnesota, **Middle Tennessee Health System** of Jackson, Tennessee, **Evergreen General Hospital** of Kirkland, Washington, and **MedTox Laboratories, Inc.** of St. Paul, Minnesota currently have major Lean/Six Sigma projects unfolding in their laboratories.

Pathologist and laboratory administrators are urged to pay close attention to this development. As each early-adopter laboratory introduces Lean into its organization, it reports major improvements in critical measures of quality, performance, and cost. These improvements come with another significant benefit: laboratory directors who've deployed Lean say it reduces the stress on everyone in the lab, while allowing them to constantly improve their performance.

It is worth noting that the leaders in this infant trend are hospital laboratories, not commercial laboratory companies. This may reflect the increasing pressure on hospital laboratories to respond to the changing needs of clinicians for laboratory testing services which are delivered ever-faster, with greater accuracy, from a test menu that is becoming increasingly complex.

Further, this first wave of Lean projects is targeting improvements in

clinical laboratory operations, particularly collection, transport, accessioning, and testing. The goal is to squeeze down the average time from test order received to test result delivered.

Next in the queue is the histology laboratory and anatomic pathology. Several early-adopter hospital laboratories have plans to tackle histology as a second or third phase of their Lean deployment. Outcomes from these efforts will be closely watched, since they represent the first efforts to apply Lean methods to the basic work flow in most anatomic pathology operations.

New, Different Approach

It is important to understand that quality management systems like Lean, Six Sigma, and ISO-9000 represent a very different approach to operational management. They attack the root cause of systemic problems with the goal of improving quality, reducing turnaround time, and eliminating waste. They measure work processes in a different way and use customer expectations as the guide for ongoing improvement.

What sets Lean apart from earlier quality management systems, like Total Quality Management (TQM) and Continuous Quality Improvement (CQI) is the speed with which it can generate results. As you will read in the following pages, laboratories are taking only 12 to 16 weeks to implement major Lean projects in their high-volume testing operations. This includes the time necessary to train the Lean team and have them begin training the lab staff.

These are reasons why I believe Lean management methods will find a welcome place in laboratory operations. As you will read on these pages, early-adopter labs enthusiastically endorse Lean and the way it is transforming their laboratories' performance. It is these real-world successes which will speed the introduction of

Middle Tennessee Healthcare Generates Major Gains From Deploying Lean in Lab

“BEFORE WE STARTED OUR LEAN PROJECT, average turnaround time (TAT) between specimen collection and lab test result was 71 minutes,” stated Leo Serrano, Administrative Director of Laboratory Services at **West Tennessee Healthcare** in Jackson, Tennessee. “After our first major Lean project, average turnaround time fell to 41 minutes. That’s a reduction of 42%!

“This surprised us, because we had already installed lots of automation, but the automation had contributed only modest improvements in our average TAT from order to result,” he added. “By contrast, we were able to use Lean methods in our existing laboratory to recast work flow and substantially shrink our average time from order to test result. It was a powerful lesson and confirmed the adage that ‘you don’t want to automate bad processes.’”

Having seen how Lean attacks bad work processes and creates efficiencies, Serrano decided to put Lean to work in another practical way. “Earlier this year, we finished the design for a new laboratory facility,” he explained. “We believed we needed 65,000 square feet to meet our requirements. But administration was not willing to invest the capital required to build a facility that large.

“This left our laboratory with two strategic challenges,” explained Serrano. “First, we cannot hire enough med techs in our market to fully staff our laboratory, so we were already shopping for any management solution which would boost the productivity of labor in our laboratory.

“Second, we needed to pare down the cost of building a new laboratory facility, to meet the budget requirements established by our administration,” he added. “Strategically, we believed the new laboratory was one way to improve productivity.

“Originally, we decided to introduce Lean into our laboratory because we believed it would show us how to run our lab more efficiently and help us meet both of those strategic challenges,” said Serrano. “But we were totally unprepared for the magnitude of gains we experienced.

“In phase one, our Lean project targeted the front end—collection, transport, and accessioning. It also included the blood bank. It took only 14 weeks to reduce average TAT by 42%,” he noted. “That was a major win for us. But it didn’t stop there. We created four work cells and freed up three FTEs. These three people now form an internal mini-Lean team that continues to develop and complete additional Lean projects. This gives us the ongoing ability to continue boosting quality, eliminate waste, and reduce costs.

“Armed with this experience, we then applied Lean methods to the design of our new lab facility,” he continued. “The results were astonishing. Lean methods allowed us to shrink the building by one-third, to 40,000 square feet. Lean methods allowed us to budget \$4.4 million less for the new lab. Moreover, we have space to include the blood bank, which, under the original architectural design, was not planned to go into the new laboratory building.”

Lean, and similar quality systems, throughout the laboratory industry.

In particular, hospital labs are learning that Lean management principles can generate substantial improvements in an unexpected area: reduced turnaround time for inpatient laboratory testing.

Evidence to support this tentative conclusion comes from early results posted by the first three hospital laboratories to complete a significant Lean project. The magnitude of reduction in average turnaround time from order to result is between 30% and 50%.

Perceptive lab directors and pathologists will recognize the profound significance of this fact. “Job One” at hospital labs is to enhance inpatient care by delivering accurate and speedy test results. During the past decade, neither innovations in diagnostic technology nor new management strategies in laboratory operations have demonstrated the ability to reduce a hospital lab’s average turnaround time by a factor of 25% to 50%. Now the real-world experience of several major hospital laboratories indicates Lean quality systems can not only slash average lab test turnaround times by as much as 50%—but that such gains can be realized in as few as 12 weeks of operational restructuring.

Most people believe that eliminating waste and boosting productivity are the primary benefits from deployment of Lean and similar quality management systems. The fact that Lean also reduces cycle time in work processes has gone unrecognized by most laboratory managers.

Goal Of More Productivity

Yet laboratories are information factories and the test results they produce are time sensitive. Thus, it may be Lean’s ability to radically reduce the time from test order to result that becomes the primary motive in its adoption by clinical labs.

Even though the first Lean project in histology has yet to be completed, it holds equal potential to transform the work processes of anatomic pathology (AP). Anatomic pathology groups should track this still-nascent trend.

Effective deployment of quality systems will change long-standing operational practices in two primary areas. First, histology labs will undergo fundamental changes in their form and structure. The outcomes will be higher productivity, more work preci-

sion, and a better match of services to customer needs.

Second, the process of handling, evaluating, and reporting anatomic pathology specimens will undergo deep change. The methods and techniques of Lean, Six Sigma, and ISO bring every step of the work process under scrutiny, with the goal of eliminating systemic sources of errors and waste. For anatomic pathologists, this means the way cases are presented, diagnosed, and reported will be improved as quality techniques are implemented.

New Lab Management Tool

Lean is the management tool that lab directors and pathologists lacked during the laboratory consolidation wave of the 1990s. During this time, most laboratory consolidation projects cut costs through one primary method: reducing labor.

Not only were layoffs as the primary cost-cutting method a miserable process that caused much human suffering, but the productivity gains were relatively minimal because basic work processes remained unchanged. The fewer people who remained still needed to process the same volume of work—using the same basic work processes.

The good news about Lean and similar quality management systems is that they stimulate positive operational changes in a way that preserves human dignity and enlists the creativity and enthusiasm of both staff and management. The next few years in laboratory management will be much more fun than the last decade. For the first time in a generation, lab administrators and pathologists have potent management tools that can radically improve the status quo, while allowing them to do more for users of laboratory data. **TDR**

Contact Leo Serrano at 731-425-6049; Rick Panning at 612-672-2751.

Fairview Health System's Lab Division Rolling Lean into Several Different Hospitals

FOLLOWING THE SUCCESS of its first Lean project, the laboratory division of **Fairview Health Services** in Minneapolis, Minnesota is preparing to introduce Lean into the labs of other hospitals in the system.

"Our first Lean project was in the laboratory at **Southdale Hospital**," stated Rick Panning, President of Laboratory Services for Fairview Health Services. "We are closely monitoring performance measures in two categories as part of that project.

"First was average turnaround time (TAT) from order to result," he said. "Our previous goal was 60 minutes (from order to result) and our Lean goal was to meet a 30 minute TAT 95% of the time for routine chemistry, hematology, coagulation, and urinalysis. Currently, our overall average is down to under 45 minutes. But we've greatly reduced variability. For Troponins, the goal will be 45 minutes from order to result."

The second monitor is labor productivity. "Originally, our automated testing and processing required six to seven professional/technical FTEs during the day shift (Monday-Friday)," Panning noted. "Post-Lean, we now staff three, plus a floater. One handles processing, one manages the primary work cell, one is responsible for the manual test cell, and one floater is available to supplement where needed and to process send-out testing."

"We are most satisfied with these outcomes from our first Lean project," he added. "Next, starting in October, we intend to do two 12-week Lean projects. One will involve histology at Southdale Hospital. The other is a Lean makeover in the clinical laboratory on the Riverside campus of **Fairview University Medical Center**. The Riverside project is tied to a planned remodeling project. In addition, the laboratory at Fairview Northland Hospital has been designed with Lean concepts in mind."

Panning did note that his team underestimated the human side of the change process

in preparing to deploy Lean. "We thought we were aware and ready for the human issues. But Lean triggers rapid and dynamic changes," he observed. "It allows you to accomplish in weeks what often takes a year or more under other management philosophies. So the lesson is to devote plenty of resources to communication and strongly encourage employee involvement in the change process. The ability to maintain the degree and speed of change while paying attention to employee engagement is the most significant challenge."

Another valuable lesson learned is to incorporate hospital staff from other departments into the first laboratory Lean team. "We invited an individual who is part of Fairview's 'Performance Excellence' Division to be part of the Lean team," stated Panning. "We wanted her perspectives and input to balance our views. In fact, this worked out great, just as we had hoped. In addition, it provided an opportunity for the rest of the organization to learn, first-hand, about the concepts of Lean.

Trained And Ready

"It was only later that we recognized the unexpected benefit. Once other departments and sites in the organization saw the success of Lean in transforming our laboratory work processes, they clamored for a Lean team in their area. Because a non-laboratory individual was trained in Lean during our first project, Lean concepts are more easily transferable to other departments, such as surgery. That allows us to keep our trained laboratory Lean team working on projects in our laboratory division," Panning said.

Panning had interesting advice for other lab directors and pathologists. "Lean works extremely fast and delivers substantial benefits," he said. "However, if it is done slowly and stretched out over time, it won't generate comparable benefits. Any laboratory which goes forward with Lean should be fully prepared to implement it on the rapid time-line it requires."

Lab Crisis Planning

NY Labs Had Unique Problems During August Power Outage

Traffic disruptions, inability to gas courier cars prove toughest challenges during blackout

WHEN THE POWER OUTAGE on August 14 hit states from New York to Michigan, the crisis plans of laboratories throughout the region were put to the test.

For the most part, laboratories across this region were prepared and continued to deliver the most critical testing services. Even where operations were disrupted, once power was restored, most labs worked through the backlog within hours.

In executing their crisis plans during the power outage, unanticipated consequences revealed vulnerabilities. In the New York City area, the power outage had a particularly devastating effect on regular courier and logistics activities.

The experience of New York labs during this recent blackout demonstrates the challenges of preparing, in advance, emergency plans that anticipate the full range of disruptive events during a crisis. In particular, it was just two years ago that laboratories in this area had to cope with the impact of the terrorist attack on 9/11 and its aftermath. Following this event, labs in the New York City area revised their logistics plans.

Not surprisingly, the August 14 blackout introduced new variables. Among them was traffic congestion as people walked home, traffic lights that were inoperable, and the inability to fuel vehicles during their routes, since gas stations lacked power.

Two labs in Greater New York City shared their experiences with THE DARK REPORT. On Long Island, most of the courier fleet operated by **Sunrise Medical Laboratories, Inc.** was in the process of completing afternoon pickups and heading back to the lab when the blackout hit just after 4:00 p.m. EDT.

“At our main lab, the generator kicked in immediately and we kept right on going,” stated Larry Siedlick, CEO of Sunrise Medical Laboratories. “With the fuel we keep on site, we can run on our own for quite some time. Our most pressing problem was getting gasoline for the courier cars in our fleet. The blackout started at a time when many of our cars had been on the road for several hours already and would be refueled later in the evening.

Continued Efforts

“Our response was to reschedule courier stops based on vehicles that had adequate fuel to cover their route and parts of others,” explained Siedlick. “While power was out that evening, we managed to get to 75% of our stops.

“Power was restored on our locality by 5:00 a.m. on Friday. We had staff waiting at ready to refuel our courier cars. The cars were refueled and on the road by 6 a.m. to pick up missed stops. By 10 a.m., all of these specimens were in our laboratory. As part of our emergency planning, we had additional staff in the lab. By 2 p.m. all of this work was completed and results had been reported.”

Across the Hudson River from New York City, **Bio-Reference Laboratories, Inc.** (BRLI) turned the generators on in its main lab facility and laboratory operations continued without much incident. However, because its service area covers six states and goes as far south as Washington, DC, it faced more complex problems.

"In contrast to the smooth response in our central lab, our network of 160 full and part-time couriers had major challenges," stated Marc Grodman, M.D., Chairman and CEO of BRLI, located in Elmwood Park, New Jersey. "Throughout the New York and New Jersey areas, the lack of traffic lights, the failure of the cell phone network, and the disruption of normal train and subway schedules created chaos on the roads.

Maintaining Service

"We developed an ad hoc contingency plan to deal with these circumstances," he noted. "Couriers did routes on foot, used land-line based telephones where possible, and reached every client location that was accessible.

"Because gas stations did not have electricity and couldn't pump gas, BRLI sent vehicles out with gas containers to refuel courier vehicles that were on long routes, allowing them to complete their runs and get back to the laboratory.

"By 7:00 p.m. on Thursday night some areas of New Jersey were getting power back," noted Grodman. "Throughout the night our logistics department responded to maintain the flow of specimens into the laboratory. Specimens were picked up from every provider and, by mid-morning on Friday, test results were reported out on virtually all the prior day's work." **TDR**

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Labs in Western NY Fare Much Better

IN WESTERN NEW YORK, the power outage did not last as long as in Michigan, Ontario, Canada, and New York City. Most laboratories reported few problems in transitioning to emergency operations.

"In our central laboratory, the switch-over to emergency power went without incident," stated Jack Finn, CEO of **Centrex Laboratories**, located in New Hartford, New York. "About 60% of our equipment remained operational. Because air conditioning is not on the emergency power system, we had to rotate use of our instruments.

"Power was restored around 9:00 p.m. on Thursday. We had all our work caught up by the next morning," he noted. "It's an amazing thing to see the lab staff pull out all the stops during a crisis like this. Everyone worked together and our emergency plan handled just about all the circumstances of this power blackout."

In the Syracuse area, **Laboratory Alliance of New York** also took the blackout in stride. "Our lab system serves three hospitals with 1,400 beds," noted Frank Kearns, CEO. "The power in all labs was out as long as six hours. Critical testing was maintained throughout this episode and all testing was current by the next morning."

The blackout did expose some overlooked issues in emergency planning. "In recent years, we had remodeled our building and moved sections of the lab," Kearns said. "But we had not reassessed our emergency power assignments in the remodeled areas. Thus, we learned that some locations did not have emergency power outlets in the right places after the remodel. The pump that serves our de-ionizer was not on emergency power."

There was another practical lesson. Kearns noted that "new employee orientation has just been expanded to include pointing out locations where flashlights and extension cords can be found."

It's a National Lab Management First For DSI Labs

“Lean” Quality Methods Transform Core Lab In Florida Hospital

CEO SUMMARY: DSI Laboratories of Fort Myers, Florida became the nation's first hospital laboratory to apply the “Lean” quality management system to a high volume core laboratory. In just 13 weeks, DSI's Lean team created a work cell which performs 80% of the test volume in a 400-bed hospital and is staffed by just two medical technologists! Turnaround time in the lab fell 51%, to an average of 35 minutes. In conjunction with its “Lean” project, DSI was also able to double the productivity of its phlebotomy team, with corresponding improvements in quality and turnaround time from collection to receipt in the lab.

THERE'S AN EXCITING EXPERIMENT in clinical laboratory management unfolding at **DSI Laboratories, Inc.** in Fort Myers, Florida.

Earlier this year, the decision was made to implement the quality management systems of Six Sigma and Lean. DSI Laboratories is a for-profit division of the not-for-profit **NCH Healthcare System**. It serves two hospitals, 400-bed **Naples Community Hospital** and 100-bed **North Collier Hospital**, and maintains a thriving outreach testing program.

As noted on the pages of **THE DARK REPORT** in recent years, a growing number of laboratories are introducing quality

management systems such as ISO-9000, Six Sigma, and Lean into their lab operations. What sets DSI Laboratories apart from their peers is an important decision: lab administrators at DSI decided to apply Lean and Six Sigma methods in a comprehensive reconfiguration of the high volume portion of laboratory testing at Naples Community Hospital.

Most laboratories introducing Six Sigma and Lean select a first project which, by definition, won't disrupt critical testing operations if things don't go right. By contrast, Lab administration at DSI waded right in. Its first Lean project tackled the high-volume testing core laborator-

ry of its 400-bed hospital. DSI lab administration made this decision confident that: 1) Lean methods would deliver significant improvements in a relatively short time; and 2) its lab staff could learn and implement its first Lean project without any detrimental impact on daily testing operations.

Both assumptions were validated by the project's outcomes, although the planned eight-week project actually took 13 weeks to complete. The Lean team designed a primary work cell that performs 80% of the lab testing which passes through the hospital's lab. Upon implementation, average time to result

(from receipt in the lab) improved by 51%, to 35 minutes.

This work cell, covering chemistry, hematology, coagulation, and cardiac enzymes, among others, is comprised of nine instruments. Because of the efficiency of design, this primary work cell can be run by one medical technologist at peak hours. In fact, every med tech in the laboratory has been trained to run the primary work cell alone. For practical reasons, the cell is generally staffed with two med techs.

At the *Executive War College on Lab and Pathology Management* in May, attendees got an early peek at the first outcomes from this ground-breaking effort to “Lean” the laboratory at Naples Community Hospital. Martha Sunyog, DSI's Administrative Director, presented a case study about the project, the process of change, and its impact on the laboratory's customers.

Ambitious Goals

“Planning for this Lean project began in the summer of 2002,” said Sunyog. “It was designed to generate downstream improvements from a Six Sigma project that tackled specimen collection and transport within the hospital.

“Within DSI, there is an off-site core laboratory that does routine testing for the two hospitals. This central lab is located about 30 miles north of Naples, in Fort Myers,” she explained. “We call the labs at the two hospitals ‘immediate response labs.’ Naples Community Hospital does lots of open heart surgery, oncology, orthopedics, and has a busy emergency department.

“We decided to tackle the central laboratory at Naples Community Hospital for a simple reason,” observed Sunyog. “Everyone was working hard, but there was this sense that we could achieve a higher level of efficiency. Our objective was to eliminate the root causes of daily problems found in every laboratory—those recurring issues which frustrate and stress the lab staff.

Why DSI Labs Chose To Plunge into “Lean”

“OUR MOTIVATION TO INTRODUCE Six Sigma and “Lean” techniques into our laboratory was rooted in the need to meet the needs of our clinicians throughout the hospital,” stated Paul Gotcher, CEO of DSI Laboratories.

“We recognized the contradictions. On one hand, our lab staff works at a relentless pace day after day to do the best they can,” continued Gotcher. “On the other hand, when we surveyed our customers—the emergency department, the ICU, and other areas of the hospital, we were told that turnaround times were inconsistent and their perception of the lab didn’t always reflect the hard work we put in on our side.

“We recognized that Six Sigma reduces variation and that, by removing variation, our lab’s quality would improve,” Gotcher explained. “Lean thinking is about removing waste, streamlining processes, and moving work through the system as fast as possible.

“Our first Six Sigma and Lean projects have delivered exactly these types of benefits. If our laboratory looks different, that’s because it was designed by people who come from non-laboratory environments. But these folks, and the techniques of Six Sigma and Lean, helped us create a lab that is much better at meeting the expectations of our customers,” declared Gotcher.

“These early projects have transformed the culture of our laboratory,” he observed. “We see everything from a new perspective. It’s exciting to implement changes which push us toward goals that we once could only envision—but now are within reach.”

“We wanted tighter control over work processes, a better way to measure outcomes, and management tools that would allow us to continuously

refine and streamline our lab operations,” she continued. “We were looking to break out of our status quo and boost our lab’s performance by a significant amount. Our Lean project was not about doing 5% or 10% better. It was about doing 30% and 50% better. Our goals were ambitious.”

To teach the principles of Six Sigma and Lean and guide the initial projects, DSI engaged the Process Excellence team from **Ortho-Clinical Diagnostics**, a division of **Johnson & Johnson Company**. “Their role was two-fold,” Sunyog explained. “First, they were to train our lab managers and staff in the philosophies, methods, and tools of Six Sigma and Lean. This training is designed to allow us to successfully design and complete Six Sigma and Lean projects on our own.

Coaching And Training

“Second, they were to guide us through the first projects to insure that evaluation, planning, implementation, and measurement were carried out properly and in a timely fashion,” she said. “We wanted both pieces, because the strategic objective for our laboratory is to create a management knowledge base that allows us, without consultants, to continuously improve lab quality and productivity into the future.”

With Sunyog as “champion,” the Lean team included Sunyog, two candidates working on their Six Sigma black belt designation, two med techs, a histologist, and a lab assistant. These individuals were released from normal duties and assigned, full-time, to the Lean project until its completion.

“Without this full-time effort, we could not have accomplished what we did,” observed Sunyog. “For a lab our size, this was a considerable investment of human resources. But it allowed us to achieve a substantial management breakthrough in our laboratory.”

All the Six Sigma and Lean efforts in the laboratory were designed to improve how the laboratory supported critical care in the hospital. A Six Sigma effort had earlier tackled the challenge of reducing the time from test order to receipt of specimen in the laboratory. This effort involved phlebotomy and: 1) shortened the average time between order and receipt of specimen in the lab by 30%; while, 2) generating an even flow of specimens into the laboratory.

Value Map Of The Lab

The Lean project's objective was to improve the lab's performance in receiving the specimen and reporting the result. "Our first step was to diagram the existing work flow and map our existing value stream," Sunyog noted. "In our lab, it was possible for tubes of blood to go in all sorts of directions. That increases the possibility for mis-handling, misplaced tubes—all the types of mishaps we deal with daily.

"Along with mapping our existing work flows, our consultants came into the laboratory to take photographs and videotape work processes," she said. "Talk about an eye-opener! The photographs and the videotape showed us why everyone was so stressed handling the daily workload. In viewing our lab through the perspective of Lean, we realized how unstructured our laboratory actually was.

"Boxes and supplies were stored in inappropriate places. Different med techs had different ways of handling the same work. The power of the photographs and the videotape is that you cannot deny the conclusions, because the film so graphically demonstrates the inefficiencies and waste that were part of our laboratory at that time," observed Sunyog.

"Two guiding principles of Lean are eliminating waste and establishing stan-

dard work," she added. "Photographs and video tape let you see precisely how the existing layout and work processes of your lab impede productivity and quality. More importantly, to be successful with Lean, one has to be willing to recognize waste, call it waste, and take steps to eliminate waste. That requires courage from lab managers, because it means they must literally acknowledge that much of the operational activity in their lab, for which they are responsible, needs corrective work.

"We certainly had to confront that dynamic. The Lean project proposal was to create two work cells. The primary work cell would handle 80% of the lab's test volume. The secondary work cell would handle the remaining 20%. Histology was not involved and will be addressed in a separate Lean project.

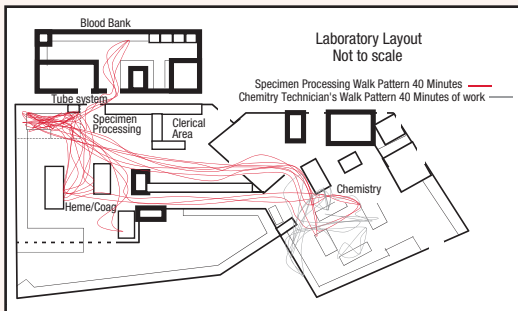
"...to be successful with Lean, one has to be willing to recognize waste, call it waste, and take steps to eliminate waste."

"Initially, it was a leap of faith to commit 80% of our lab's testing into a single work cell," she stated. "Everyone in the laboratory likes to see redundancy and we were going to change many of our long-standing work practices. But redundancy is an integral part of Lean. As we learned more about this management system we better appreciated how it boosted quality and productivity even while improving back-up capabilities.

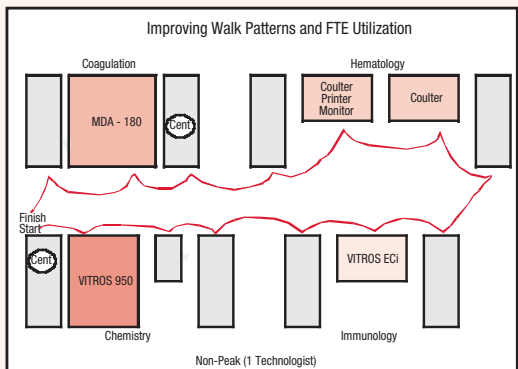
"With limited space, I'd like to describe some of the key design elements that make our primary work cell successful," said Sunyog. "First, all the instruments in the work cell are automated. So it doesn't make sense

DSI Labs Meets Patient Care Goals While Improving Lab Productivity

In a 16-week "Lean" project, the team at DSI Laboratories, Inc. of Fort Myers, Florida created a primary testing cell to do 80% of the lab test volume at 400-bed Naples Community Hospital. Below are diagrams which show the configuration of the laboratory work cell before the Lean project and after its completion. Using Lean quality management principles, specimens flow continuously into the work cell. The cell, with nine high-volume instruments, can be operated by just one medical technologist, although it is generally staffed with two med techs.



Lab Layout: Pre-Lean



Lab Layout: Post-Lean

Results from First Lean Project:

- Overtime declined 60%
- Technologists reduced from 19 to 15.5
- Reduced total lab staff by 7.6 FTEs
- Product travel (tube of blood) reduced by 92%
- Labor travel reduced 92%
- Total TAT (from request to result) reduced by 49%, to 66 minutes
- TAT (from receipt in lab) reduced by 51% to 35 minutes
- Floor space in lab reduced by 20%
- Phlebotomy productivity increased by 300%
- Total savings exceed \$360,000

DSI
LABORATORIES

for a med tech to load the instrument, then stand by waiting for results.

"To resolve this, the work cell is laid out so that the med tech moves, in an orderly fashion, around a circuit, sequentially loading or unloading instruments," she explained. "This means the med tech is moving continuously and results are generated continuously from all the instruments.

"The second concept is continuous flow of testing, not batch," added Sunyog. "This is counter-intuitive to most lab managers. Batch is considered efficient. But in a hospital lab, faster turnaround time (TAT) for critical testing is the goal and TAT is better served by continuous flow. We changed several elements of our work processes to encourage continuous flow.

“In phlebotomy, the Six Sigma project taught phlebotomists to complete a draw, then use the pneumatic tube system to send that patient’s specimen directly to the lab. As each specimen reaches the lab, it doesn’t sit in accessioning, because we decentralized that function. As both lab assistants and phlebotomists walk through the lab, they pick up specimens just arrived in accessioning and carry them to color-coded racks at the primary work cell.

Continuous Test Flow

“The third concept is that everyone must take responsibility to maintain continuous flow of specimens through the lab,” offered Sunyog. “For example, anyone who walks by and sees a tube in a rack waiting to be loaded into a centerfuge will stop. They will unload/load the centerfuges.

“Not only does this accelerate a single tube’s journey through the lab, it avoids that familiar problem of accessioning spending 45 minutes loading 300 tubes into racks, then dumping them on the techs, who then rush to meet TAT deadlines,” explained Sunyog. “This is the type of stress I mentioned earlier. Under our old system, people worked hard to do a good job. But it was flaws in that old system which generated the stress.

“With Lean tools, we are reconfiguring our work flow in ways that reduce stress on the lab staff, while allowing them to do a better job meeting goals for quality and turnaround time. In turn, this improves patient care in our hospital.”

These details are just a sampling of the radical transformation that occurred in the laboratory at Naples Community Hospital. Not only did the principles of Lean management touch every aspect of laboratory operations, but the laboratory has made huge improvements in a variety of operational measures.

“In support of critical care for our patients, we’ve cut average turnaround time for tests by significant amounts,” Sunyog said. “Total TAT from request to result declined from 129 minutes to 66 minutes, a 49% reduction. TAT from receipt in lab to result declined 51%, from 70 minutes to 35 minutes. Because of speedier time from collection to test result, specimen quality is enhanced. We’ve reduced product travel of tubes by 92%. These changes boosted the quality of our test results.

“Overall, we reduced the number of medical technologists from 19 to 15.5,” stated Sunyog. “However, the real impact can be seen on different shifts. On our day shift, we had six to seven techs per day. We can now do it easily with four even during our busy season. Overall, our post-Lean lab operates with 7.6 fewer FTEs.”

As the results posted by DSI Laboratories demonstrate, effective application of the principles Lean can trigger substantial improvements in a wide variety of laboratory performance measures. Moreover, DSI Laboratories, because it invested in training, has established a knowledge base within its laboratory that can perpetuate these projects.

Lab Quality Measures

THE DARK REPORT will track subsequent Lean projects at DSI Laboratories, because the story is not in a spectacular one-time gain from a single project. DSI Labs is undergoing a management and operational transformation. It is learning—and mastering—a new perspective on laboratory operations, along with a new set of management tools to continuously harvest quality and productivity gains. Their success will be both the inspiration and the example for other laboratories to emulate.

TDR

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The Dark Index

IMPATH Delisted by Nasdaq, Under Investigation by SEC

Onetime high-flying pathology company now faces incredible scrutiny on almost all fronts

EFFECTIVE AUGUST 27, **Nasdaq Stock Market, Inc.** delisted the stock of **IMPATH, Inc.** Less than a week earlier, IMPATH had disclosed that it was under investigation by the **Securities and Exchange Commission (SEC)**.

IMPATH can truly be described as a company under siege. It is short of cash, under regulatory investigation, and defending itself from at least 13 class action shareholder lawsuits.

The financial community attributes much of IMPATH's woes to its oft-criticized accounting for account receivables and other policies on how to allocate income and expenses. There are strong reasons to believe this to be true.

Other Undisclosed Issues?

However, **THE DARK REPORT** suspects there may be another troubling dimension to IMPATH's existing problems. There may be Medicare compliance problems of notable magnitude. Known facts support this speculation.

First, for many years, IMPATH has aggressively coded and billed for its diagnostic services. Compared to most laboratories, IMPATH has been willing to perform and bill for substantially more test markers per case—by a factor of two or three. For example, if common practice in the laboratory industry was to perform and bill for, say, five to seven markers on a breast cancer case, IMPATH was known to often bill more than 20 markers. This was common practice in other areas of its

oncology testing menu. Second, Medicare revenues are a significant component of IMPATH's payer mix. If one holds an opinion that IMPATH, by deciding to perform high numbers of tumor markers per case, was performing procedures that could be challenged as medically unnecessary, then the act of billing Medicare for those markers would possibly violate several compliance laws and regulations.

Assume that the above is true. Then the following scenario is a possibility. Since IMPATH sacked its long-time Chair and CEO, Anu Saad, Ph.D., earlier this year, a new CEO has undertaken a comprehensive review of IMPATH's legal and regulatory compliance. If its outside experts identified that IMPATH's practice of performing two and three times the number of tumor markers per case (compared to the rest of the lab industry) to be excessive, then IMPATH's current executive team has a much greater problem; one that eclipses its problems with accounting issues and shareholder lawsuits.

It is possible that IMPATH believes it has potential exposure with Medicare for a portion of its past billings. Because these practices go back as far as ten years, potential exposure might amount to tens of millions of dollars, along with exposure to civil and criminal penalties. If this speculation is accurate, then what may be giving IMPATH's new executive team pause is the daunting amount of money that would be needed to settle with Medicare.

20% Medicare Co-Pay A Blow to Regional Labs

Threat exists that Medicare's 20% co-pay might be copied by private health insurers

CEO SUMMARY: *Informed speculation indicates that private health insurers are likely to adopt some form of laboratory test co-payment if the proposed Medicare 20% lab test co-pay legislation becomes law. For hospital laboratory outreach programs, the resulting reduction of reimbursement and associated higher costs of billing small amounts to patients would prove to be financially devastating.*

IMPOSITION OF A 20% CO-PAYMENT for Medicare Part B laboratory testing will have the greatest negative impact on regional laboratories, particularly hospital laboratory outreach programs.

But there is a double-indemnity aspect to the proposed 20% co-pay legislation now pending in Congress. If Medicare were to impose a lab test co-pay, there is credible evidence that some of the nation's biggest health insurers would move to institute similar lab test co-payments by their beneficiaries.

This would wreak financial havoc among regional laboratories across the United States. There are several reasons for this. First, except for the two blood brothers, the remaining independent commercial lab companies providing laboratory tests for office-based physicians generally run on razor-thin profit margins.

Many of these small labs will move into the red. The combination of reduced reimbursement because of a laboratory test co-pay implemented by

Medicare and private payers, along with the higher costs of billing and collecting small amounts of money from patients, will spell the difference between survival and sale or bankruptcy for numerous small labs.

Lack Economies Of Scale

Second, a large number of surviving regional laboratories are owned and operated by not-for-profit hospitals and health systems. These lab operations lack the buying power and economies of scale of their commercial lab competitors. They also have a specific mission of furthering health-care to their local communities.

For these types of laboratories, a switch to a laboratory test co-pay by both Medicare and private payers would prove a financial disaster. Most such laboratories operate at financial breakeven, passing along the economic benefits of the outreach testing to their parent hospital in the form of lower average cost-per-tests for inpatient testing.

Many hospital-based laboratories operating lab outreach programs are

attempting to gauge the financial impact of the proposed Medicare co-pay. In the Northeast, Stan Schofield, President of **NorDx Laboratories** in Scarborough, Maine is studying the problem. “This summer, we’ve run all sorts of financial models on the impact of the Medicare 20% lab test co-payment,” he said. “The projections are uniformly discouraging.

Prediction About Impact

“In the first year of the co-payment, we estimate 20% of our Medicare patients will go to bad debt,” Schofield revealed. “With patient education, that may level off at about 10% in year two and beyond. I should add that this is a best-case scenario for us, and we are very good at billing and collections. Our days sales outstanding (DSO) is consistently at 39. Not many hospital outreach programs do billing as well as us, so the impact on them would be greater.”

NorDx studied the secondary insurance held by Medicare patients in its outpatient lab testing operations. “In this community, a consistent 65% to 75% have Medi-gap or similar type of insurance,” noted Schofield. “Our financial models assume that Medi-gap would pay first dollars for the lab test co-payment. But one response to the 20% lab test co-pay may be for Medi-gap types of insurance plans to exclude it from their coverage in subsequent years.”

Private Insurer Lab Co-Pays

Schofield is also one of those who believe private health insurers will follow Medicare’s lead and institute their own lab test co-payments. “In Maine, the three big insurers are **Anthem Blue Cross, Aetna, and Cigna**. I’ve spoken to executives at all three companies. They acknowledge they are aware of Medicare’s proposed lab test co-pay, and without saying so directly, their comments indicate a likelihood

that they would study that situation and institute their own types of lab test co-pays or deductibles.

“The Medicare 20% lab test co-pay, if enacted, will be a hammer blow for smaller regional labs,” observed Schofield. “Those of us who operate as a break-even laboratory, in support of a not-for-profit hospital system, already struggle with the Medicare’s low reimbursement for Part B laboratory testing. Were private payers to follow with their own laboratory test co-pays and deductibles, the cumulative effects would be a financial knock-out blow to many of these community-based laboratories.”

Schofield’s observations carry credibility. He is a past president of the **Clinical Laboratory Management Association (CLMA)**. He continues to be actively involved, at the national level, in a variety of laboratory industry leadership initiatives.

Erosion of Reimbursement

Since 1988, the Medicare program has not been kind to the clinical laboratory industry. Adjusted for inflation, reimbursement for Part B laboratory testing is flat when compared to the mid-1980s. The 20% co-pay, if imposed by Congress, maintains an established pattern whereby Medicare Part B lab test reimbursement is continually pruned back, leaving labs with inadequate money to cover the basic cost of providing lab testing.

Further, this co-pay, if enacted, will have a disproportional financial impact on the nation’s regional laboratories. At best, their year-to-year financial survival is precarious. And if imposition of a Part B laboratory test co-pay is followed by similar laboratory test co-pay requirements by private health insurers, the level of financial stress will be substantial.

TDR

Contact Stan Schofield at 207-885-7888.

INTELLIGENCE

LATE & LATENT
Items too late to print,
too early to report



Early last week, **Laboratory Corporation of**

America announced an out-of-court settlement in its lawsuit involving its subsidiary, **DIANON Systems, Inc.** As plaintiff, DIANON had sued five former DIANON employees and their new company, **DiaPath LLC**. The claims involved “unfair trade practices” by DiaPath representatives, who had approached DIANON customers and encouraged them to switch their business to DiaPath. Among other things, as part of the settlement, defendants agreed to discontinue use of the name DiaPath.

Privately-owned **Esoterix, Inc.** of Austin, Texas continues to enjoy rapid growth. It recently reported that revenue for the first six months of 2003 increased 32% over the first six months of 2002. Although it doesn’t release its financials to the public, Esoterix is known to have annual sales in excess of \$100 million. Thus, 32% growth in the first six months represents at least \$17 million in new revenues.

VACCINATED BOOMERS HAVE SMALLPOX IMMUNITY

In the war against terrorism, many people working in laboratories have justifiable concerns about how an attack with biological agents such as anthrax and smallpox might put them at risk. Now comes good news for that generation of baby boomers and older folks who were vaccinated for smallpox decades ago. Researchers at **Oregon Health Sciences University** (OHSU) in Portland, Oregon conducted a study of 300 volunteers who were immunized against smallpox between 25 and 75 years ago. Their conclusion? More than 90% of the subjects retained “substantial immunity” to smallpox.

ADD TO: Smallpox immunity

OHSU researchers discovered that antibody defenses were still ample in people vaccinated as long as 75 years ago. But anti-viral T-cells became undetectable in volunteers after about 30 years. Because of the lack of specific T-cells, some experts caution that smallpox immunity, decades after vaccination, may not be

strong enough to fully defeat an infection. However, OHSU researchers Mark Slifka, Ph.D. and Erika Hammarlund believe that, because antibodies are a first line of defense, vaccinated people have “essentially lifelong immunity” against a smallpox infection.

CAREER MOVES

- **Diagnostic Laboratory Services, Inc.** (DSL) in Honolulu, Hawaii has a new President. Richard I. Okazaki, formerly Senior Vice President and General Manager, assumed his new duties earlier this month. Long-time DSL President John Edwards, Jr., M.D. retired at the end of August and is rumored to be looking for a retirement home on the Carolina Coast.

- After four years as CEO, Roy H. Trucks has resigned from his position at Valdosta, Georgia-based **Doctors Laboratory, Inc.** During his tenure, Doctors Laboratory became one of the first labs in the United States to be certified as ISO-9000 compliant.

*That’s all the insider intelligence for this report.
Look for the next briefing on Monday, September 29, 2003*

PREVIEW #3

PATHOLOGY INCOME & EQUITY

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Topic—Everything You Must Know About Pathologist Employment Contracts

In a growing number of situations, pathologists are employed and under contract. Experts in law and negotiations will share the do's and don'ts of effective employment contracts from the perspective of the employee-pathologists and from the pathology company or group. Learn how to develop win-win contracts, along with unique regional quirks and new developments in legal theories that affect existing contracts.

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