

►► **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.**

ries 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.

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

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 laborato-

“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

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 conven-

tional 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

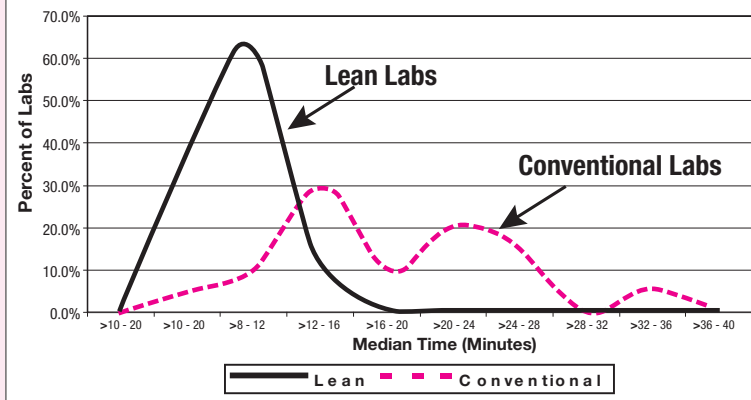
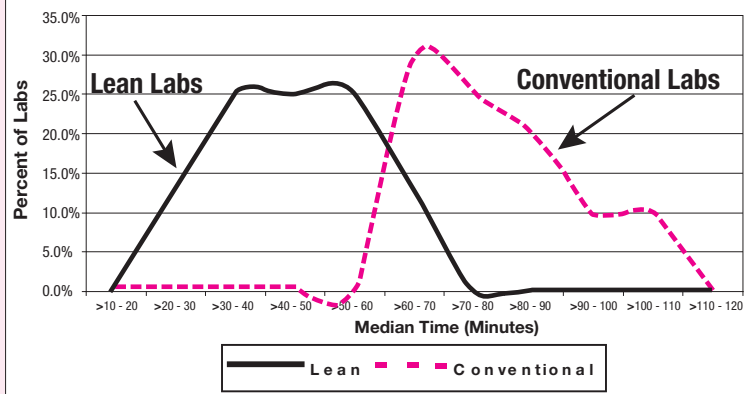


Figure One (above): 89% of lean labs have a STAT CBC TAT of 12 minutes or less. Only 16% of conventional labs achieve that level of performance.

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)



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“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 com-

parison, 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 vol-

ume. (*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

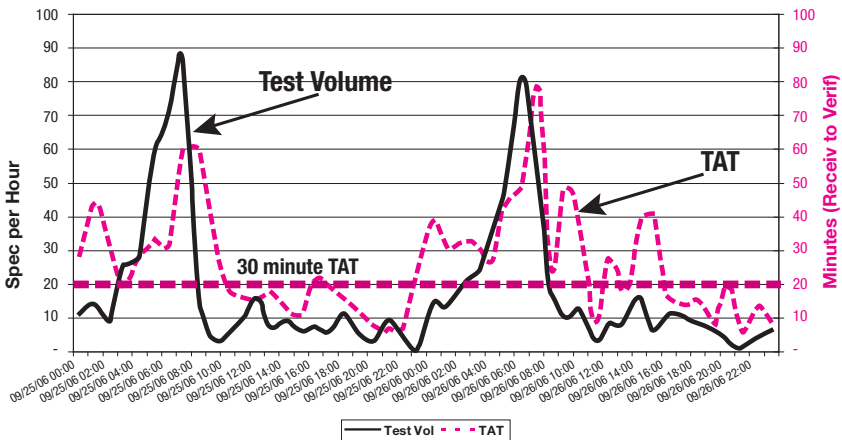
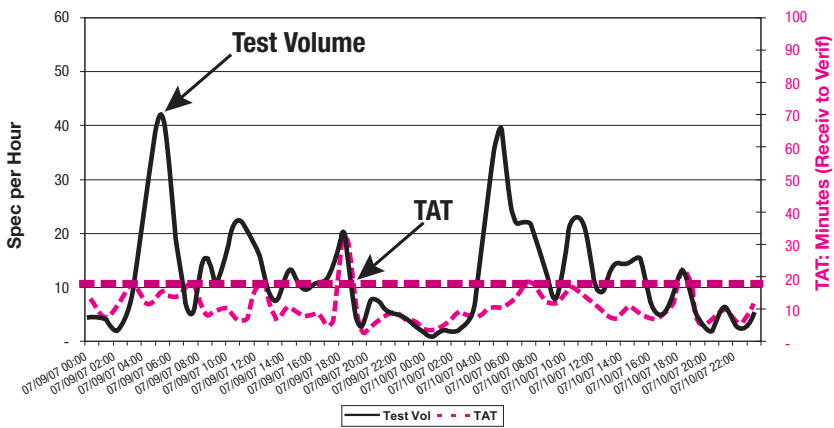


Figure Three (above): Conventional lab's two days of volume vs. TAT illustrates the lack of flow during peak periods. Periods of high volume see a corresponding increase in average test TAT.

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



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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."

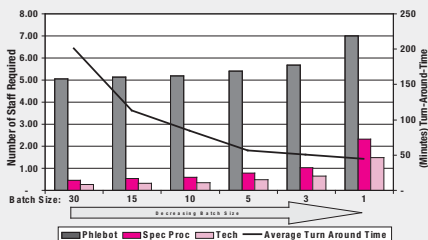


Figure Seven: The effect of batch size on TAT and staffing: As batch size decreases, TAT (collection to verification) is dramatically reduced.

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

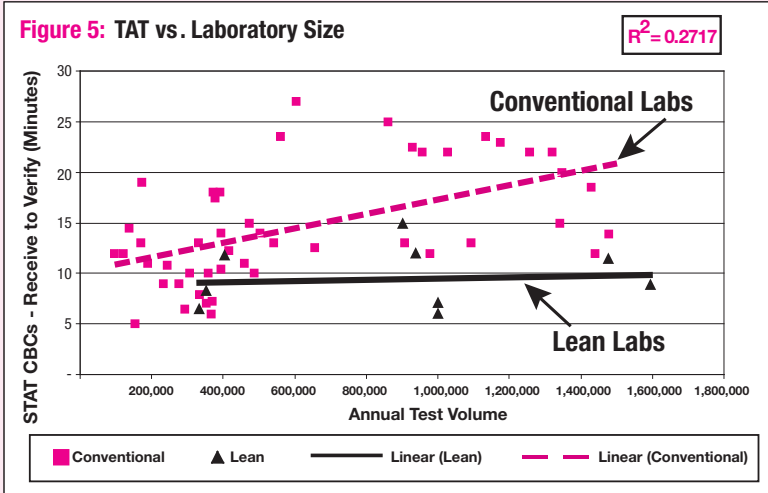
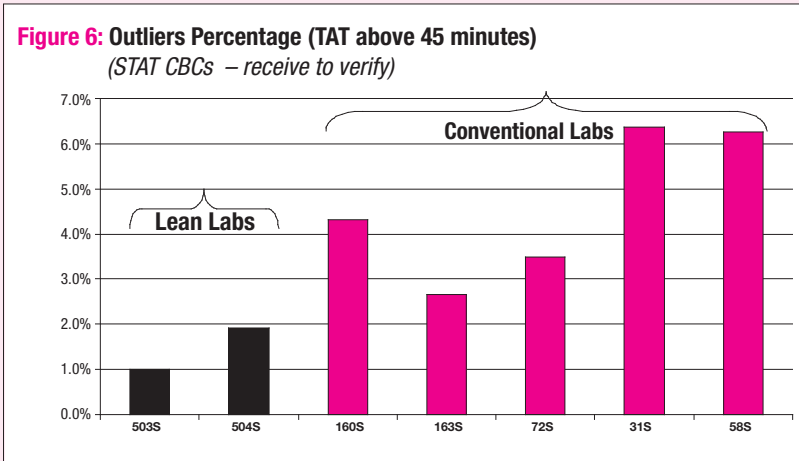


Figure Five (above): Lean labs define the highest level of performance and also seem to be unaffected by increasing volume.

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



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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

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