Focusing on the Journey, Not the Destination

Clinical laboratories look to process-improvement methodologies to improve performance, quality, and revenues.

In British Columbia, Canada, a large physician-owned laboratory wanted to increase productivity. So in addition to acquiring new systems to run *Chlamydia trachomatis* and *Neisseria gonorrhoeae* (CT/GC) tests, the laboratory decided to review its processes as well. Using Lean and Six Sigma principles and tools, the team identified areas to remove waste and decrease variability. Two years later, the volume of CT/GC tests had increased by 22%, to more than 300 specimens a day. Today, the laboratory handles an additional 25% capacity while finishing daily runs 3 hours earlier than before. No staff was added during this time period.

Another laboratory, this one a large university core lab, is currently focused on reducing hands-on time. Again, using Lean and Six Sigma, the team managed to reduce specimen hands-on time from about 75 seconds per specimen to 40 seconds, a reduction of about one-half (53%, to be more exact). At the same time, their capacity and volume rose 15%.

These savings are impressive and representative of what organizations can achieve using process-improvement techniques. In fact, these stories do not even represent the most successful examples encountered by Adam Walter, a Lean/Six Sigma consultant in the Women’s Health and Cancer Group of BD Diagnostics, headquartered in Franklin Lakes, NJ.

The OpEx Service Group LLC, with corporate offices located in Medford, Ore, cites achievements on its Web site that include reducing lead time by up to 80%, reducing inventory and space by 50% to 70%, and improving productivity by 30% to 50%. “Typically, we have
direct benefits that have ROIs [return on investments] somewhere between 200% and 500% over a 3-year period,” says David A Stewart, an OpEx partner and implementation specialist.

A number of factors can impact how successful a process-improvement effort will be, and they vary with each laboratory. But in general, process-improvement efforts with proper buy-in from both staff and senior management have a much greater chance of success. “It’s really a kind of 2- or 3-year time frame for most organizations to adapt to the new processes, and any kind of wavering from the senior leaders can put the gains at risk,” Stewart says.

Laboratories can get derailed by not examining their processes closely enough, starting improvement projects too soon, and/or fiercely resisting change. For this reason, many recommend first efforts be undertaken with the assistance of an outside, and therefore objective, expert who can guide the laboratory through the process-improvement journey.

“Too often laboratories take these episodic small projects that may create a spot of brightness along their total value stream, but don’t really change the key performance indicators or quality levels. So it’s important that they’re meaningful and manageable and really tie to a journey,” says Rick Malik, worldwide director of ValuMetrix Services, a division of Ortho-Clinical Diagnostics Inc, a Johnson and Johnson company headquartered in Raritan, NJ.

First Steps

The StatSpin® Express 4 from Iris Sample Processing

“Any time you are going to go down a journey and commit to it, you really have to step back and develop a strategy,” Malik says. Malik believes it’s important to start by identifying where the laboratory is now, where it wants to go, and the types of projects that will get it to that future state.

One of the challenges to implementing process improvement within the laboratory is that no portion is isolated. “Wherever you start, the process before or after, many times, is impacted. For example, you can speed up the analysis of a specimen and get the result very fast, but if
specimens are held up in the preanalytical area, overall, it’s not going to really help performance,” says Anne Daley, senior consultant with Chi Solutions Inc, Ann Arbor, Mich.

As a result, most process-improvement programs will start with the big view, creating a high-level process map, illustrating major protocol steps in preanalytical (including collection and transport), analytical, and postanalytical areas. From this, projects can be identified that align with the organization’s goals, customers’ needs, and practicality.

Ideally, an initial project should tackle the most problematic area or areas identified by the high-level process map, but should not be so large in scope as to overwhelm the staff or be too complex. “You never want a project to go past 90 days. If you do, health care changes so rapidly, you may have to start all over,” Daley says.

A common starting point is the elimination of waste (a focus of Lean), which may help to address some other issues, such as variability (a focus of Six Sigma). “Once you start to eliminate obvious waste, you may find specific processes within your system where the predominant form of waste is variability. When you find those situations, you might dig into your Six Sigma tool kit,” Stewart says.

Many also recommend starting small. One success will get everyone excited and begin to transform the culture into one where process improvement becomes a way of life.

**Finding a Guide**

However, too often, a laboratory that lacks a systematic, organized approach to process improvement will choose the wrong project for a variety of reasons that can include an eagerness to get started or attempting to do too much. “Laboratories need to define what is the first step and the last step in the process that the specific quality-improvement initiative will address. So many labs do not do that and then fail miserably because they’ve tried to solve ‘world hunger’ in one project,” Daley cautions.

Instead, process-improvement teams, whether entirely in-house or led by a consultant, need to analyze until they’ve discovered the root cause of an issue. “People stop short in their analysis and end up with Band-Aids,” Daley says, attributing the error many times to discomfort with change.

“The job of whoever is running the project is to empower the staff to make changes and to ensure those changes are made. The value of a consultant is to get the project off the ground and running and really help the group to think in a Lean and Six Sigma mind-set. So once the project has started and the staff is thinking in that mind-set, the staff should be driving the project,” Walter says.

Daley suggests that 6 months is a good time frame in which a consultant or educator can work with a client to enable them to sustain a process-improvement program on their own. In addition, a full-time implementation team representing various disciplines with the facility—typically, operations, customer service, quality control, purchasing, and IT and other technical
departments—should be involved. “You have to dedicate a handful of folks to this so they can focus on the project area for the duration of the project because if the team is constantly diverted to other tasks, the implementation might suffer,” Stewart says.

The Path

A dedicated process-improvement team or committee can help to sustain gains and momentum. These programs are cyclic, moving from analyses to project implementation using appropriate tools and techniques. Occasionally, projects will go quickly, but more often they fall within a 10- to 16-week time frame.

Examples abound, and conferences have been organized to share these stories. Though every laboratory is different, some trends have been noted. One of the more common has been a move to single-piece workflow.

As laboratories have grown and expanded instrumentation, their workflow has encouraged batch processing. So when morning bloods are drawn in these situations, bottlenecks are created. All the specimens (or a large portion) tend to be collected and delivered to the laboratory at the same time. When they arrive, they must be spun and sent to the appropriate department.

In the past, laboratories typically used large-scale centrifuges, which spin up to 100 specimens at once, but can take 15 minutes to 20 minutes, not including time to load and unload. “The whole processing for about a hundred samples can take up to 45 minutes, while the analyzer is idle,” says Pamela Pasakarnis, vice president of sales and marketing for Iris Sample Processing in Westwood, Mass.

However, batching makes sense when laboratorians need to walk the samples from station to station. “In some organizations, I can almost tell in what order systems have been purchased based on their placement in the laboratory,” Daley says.

What’s good for one department—say, chemistry—will not necessarily work well for overall laboratory flow. “One of the things we try to do is solve the problems that lead to batching,” Stewart says. Some approach the solution with workcells, where the instrumentation is arranged to minimize travel distance and encourage flow.

Iris Sample Processing has seen an increase in orders for smaller, faster centrifuges as laboratories move sample processing closer to analyzers and away from batch processing. Customers have ordered 15 to 20 centrifuges at once to place one or two near each of their large analyzers, according to Pasakarnis.

“Our small centrifuges hold eight samples at a time and spin those samples down in only 3 minutes,” Pasakarnis says. Samples are sent directly to these stations and processed serially. “So samples are placed on the analyzer quicker, which means you will get your results sooner, process all your samples sooner, and eliminate bottlenecks,” Pasakarnis says.
**Mustering Supplies**

Culture is one of the hardest aspects of the work environment to alter. To facilitate a transformation, senior executives need to be seen at the work site, engaging. “You need leaders all the way through to CEO, who on a daily basis are there, every shift, showing staff that they have support and are being held accountable to a culture of continuous improvement,” Malik says.

Stewart estimates that it can take 2 to 3 years for organizations to completely adapt to the new philosophies. A successful project helps to drive the momentum.

“When people experience significant improvement, especially right away, everyone in the organization perks up and says, ‘Wow, this really works. How can we do this? How can we do that?’ And eventually, it has a domino effect, and the departments that aren’t doing it begin to feel left behind,” Daley says.

**The Destination**

Once process improvement fever has caught hold within an organization, resources may become easier to procure as more successful projects bring significant returns on investment (ROIs). Stewart frequently sees direct benefits with ROIs between 200% and 500% over a 3-year period. Daley estimates that most organizations undertaking process improvement should expect a three-to-one investment; those with experience and a culture of change can see returns of six to one or more.

“I’ve seen billing projects where they focus on revenue capture and realize a million-plus dollars. I’ve seen process improvement in specimen collection and processing result in a quarter-of-a-million dollars’ reduction in staff, all achieved through attrition,” Daley says.

Successful efforts give facilities both a competitive and marketing advantage. “It positions the organization to ultimately be able to better respond to the needs and values of their customers. And as their customers demand change, the organization will be much more able to quickly adapt,” Stewart says.

Specific results as well as the continuous effort to improve can be marketed both internally (to patients and physicians) and externally. “The outcomes of implementing a successful Lean-Six Sigma project are endless: faster turnaround times, better service, increased quality of results,” Walter suggests.

Calvert Memorial Hospital in Frederick, Md, pledges to begin treatment on emergency patients within 30 minutes. If it takes longer, the patient receives a letter of apology from the president and a free gift. Oakwood Hospital and Medical Center in Dearborn, Mich, offers a similar guarantee. Some patients might be willing to take their own journey to receive such service.
Managing Improvement with Software

Process improvement can bring great rewards to a clinical laboratory, but it can also be time-consuming. The proper support and resources can help to maximize any improvement effort. This includes using the right tools. Information systems, in particular, can help with the improvement effort directly, providing the means to analyze, measure, and report, but only if they integrate.

Seeking this synergy, Data Innovations in South Burlington, Vt, acquired Rhoads Associates last year. Rhoads is the developer of EP Evaluator, a method evaluator software package now in its ninth generation. As a result, Data Innovations’ middleware system, Instrument Manager, connects the laboratory information system, instruments, and quality control programs.

Quality control focuses on the consistency of results, whereas quality assurance ensures result reproducibility, distinguishes Hunter Bagwell, sales and marketing manager at Data Innovations. Quality control measurements are typically taken more frequently than quality assurance analyses.

“Six Sigma focuses on quality assurance,” Bagwell notes, adding, “Without quality assurance, the reliability, timeliness, and dependability of results is in question.” To remain accredited, laboratories have to periodically reevaluate, remeasure, and reverify both their quality assurance and quality control procedures and practices.

Quality assurance can be very time-consuming when handled manually. “[The laboratory] must go back and measure key components to make sure the accuracy and dependability between instrument one and two are the same,” Bagwell says. Software simplifies this process, particularly when it can integrate data from various sources.

“One of the hardest components of quality assurance is going out and gathering all the data and results—10,000, 20,000—and putting it into the program to look at the statistical analysis of how the laboratory is producing. With the acquisition of EP Evaluator by Data Innovations last year, we have the ability to integrate the two, so now the laboratory has reports to present to chief pathologists and others quickly and easily without having to spend weeks or months slogging through spreadsheets to rationalize and demonstrate lab-accurate results,” Bagwell says.

These reports can be invaluable in meeting regulatory requirements as well as implementing process improvement. “EP Evaluator allows laboratories to constantly measure and analyze the quality the lab is producing. If variances are found, they can go back and improve the design to improve quality,” Bagwell says.

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