

An Introduction to LEAN

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Cincinnati's Children's Hospital and The Children's Hospital of Philadelphia are large, urban, tertiary care pediatric hospitals, each with more than 400 in-patient beds that serve patients from throughout the world. Some of the specialized pediatric services and programs offered at our institutions include fetal diagnosis and surgery, metabolic diseases, solid organ transplant, and pediatric eosinophilic disorders. In addition, our pediatric systems include a patient care network of primary and specialty care centers that serve ambulatory patients. The extensive patient population served contributes to some unique clinical and laboratory challenges, including antimicrobial susceptibility testing (AST). Identifying a reliable, cost effective and efficient susceptibility testing regimen for our pediatric patient populations that also provided clinically useful data was necessary for both of our laboratories.

Introduction

LEAN thinking and Six Sigma have been utilized by manufacturing industries to decrease cost and improve quality and productivity by reducing variation and production defects. Because of the dramatic successes in manufacturing, there is rising interest in the healthcare industry about institutions implementing LEAN to accomplish such goals as decreased wait time in the Emergency Room, improved bed capacity, and decreased wait for patient phlebotomy and laboratory services. In this article, we will discuss the basics of LEAN, a bit of Six Sigma, and suggest how to apply the concepts to the microbiology laboratory in order to work "smarter", more cost-effectively, and provide timely clinically relevant accurate results.

History

Process improvement initiatives have been in existence for quite some time and include continuous quality Improvement (CQI), Process Improvement (PI), Quality Assurance (QA), Quality Management (QM) and Re-engineering. In the mid-1900s, the term Six Sigma was coined by a Motorola Engineer, Bill Smith, to describe a new quality control process that emerged from the Total Quality Management (TQM) strategy and was very successful in improving profits. LEAN was founded by Taiichi Ohno in the 1950s

and¹ arose from the Toyota production System with key aspects including the never-ending quest for perfection, continuous search to eliminate waste and the recognition and importance of employee contributions.

Why do we now care?

The 1999 Institute of Medicine report "To Err is Human" began much discussion on how to reduce errors in the healthcare setting and resulted in an increased focus on improving patient safety. In the clinical laboratory, the challenge to provide accurate and useful test results was compounded by a decreasing and aging medical technologist population and reduced provider payments. In the laboratory, we responded by creating core and STAT laboratories with consolidated services, cross-trained technologists and automated methodologies. What's left to do? To further increase quality and accuracy, and reduce expenses, process improvement is needed.

Implementing LEAN

Meeting the needs of the customer is a vital component of LEAN and Six Sigma. The goal is to reduce, if not eliminate, unnecessary, time-consuming steps that are not Critical to Quality (CTQ) for the customer (patient, family, physician, nurse, administrator). There is much overlap in LEAN and Six Sigma processes, but basically, Six Sigma is data driven and makes use of a structured, focused approach and statistical tools to find the root causes behind problems and to drive processes toward near-perfection. LEAN is meant to streamline processes and eliminate unnecessary, time-consuming steps or "waste" (see box below). LEAN standardizes work flow and as a result, decreases variation, a common cause of error. A hybrid between a Six Sigma project and LEAN combines aspects of both methodologies. Do LEAN first, then the process problems will be easier to identify.

Among the many methodologies offered in LEAN to collect and analyze data are control charts, Define, Measure, Analyze, Improve, Control (DMAIC), histogram, Kaizen, and Pareto charts. All help to diagnose problems, identify steps and duplication in a process, and recognize roadblocks to perfecting a

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process. Three key tools which are proving to work well in hospitals are 5S -- a process simplification and process cleanup tool, 7 Wastes of Lean, and Value Stream Mapping (VSM), which visualizes process flow (i.e. patient information and specimen flow). Let's take a look at these three approaches in more detail.

5S

The standardized system of 5S includes the following components and reduces "visual clutter" by creating and maintaining an orderly workplace: sort, set-in-order, shine, standardize and sustain.

- Sort (*seiri*) – tidiness; organization
- Set-in-Order – orderliness
- Shine – cleanliness
- Standardize – control and consistency
- Sustain – maintaining standards

For example, adding visual controls, such as color coding, labeling cabinets with contents, even removing doors from cabinets, allows for additional ease of inventory control and less accumulation of unnecessary items. Examine the equipment layout in the "work cell", or work bench. Are there ways to re-organize tools and equipment to standardize practice and decrease walking? Finally, set up mechanisms and controls to sustain practices. When 5S is successfully applied, the result is an efficiently organized and standardized work area where variation is minimized.

Seven Wastes of LEAN

The Seven Wastes of LEAN are at the root of all unprofitable activity. In addition to those listed below, underutilizing people's skills is considered a waste when talent is used for activities that are non-value added.

What are the 7 Wastes?

- Inventory
- Overproduction
- Waiting
- Transportation
- Defects (errors/repeats)
- Excess motion/walking
- Processing

Value Stream Mapping

Value stream mapping (VSM) is a LEAN tool that helps detail the flow of supplies and information as a product or service makes its way through a process. It also shows decisions that are made, the sequence of events and any wait times or delays inherent in the process. The main goals of VSM include identifying, demonstrating and decreasing

waste in a process. The creation of a value stream map can take many forms including a "pen and paper" diagram of the process with real-time measurements of the length of time an activity takes. Another common approach is for a workgroup to use post it notes with time taken and by whom, plus colored dots indicating whether an activity is value added, non-value added, or required for regulatory or compliance issues. When all notes are posted, it is then easier to identify duplication or unnecessary processes, and waste. The workgroup is then charged to brainstorm ways to streamline the process by minimizing non-value activities and optimizing flow of required steps.

Once 5S is applied to a work area, all processes can start to be systematically reviewed, possibly using a tool such as VSM described above. Start by looking at the flow of work and organize areas to maximize testing activities. Is there clinical benefit to performing testing by a more rapid, albeit expensive, methodology rather than batching? Evaluate workload and staffing levels - are changes needed to best meet demands of volume?

Change Management

One of the main initial challenges for a supervisor is to reassure staff that a LEAN/Six Sigma implementation does not mean staffing layoffs. The goal is to free up staff from performing non-value added activities in order to have the resources to optimize patient care services, implement new testing, attend continuing education programs, evaluate new products and participate in other hospital or professional activities. Put together workgroups to address specific projects. Critical to success is also allowing those who do the bench-work to be actively involved in the processes. Technologists are aware of what the roadblocks are and should help diagnose problems and implement change. Involve "those who know" and communicate with others at the institution, preferably at high levels, to gain the support of a champion. Often, a champion can help remove organizational barriers to change.

Keys to Successful Change

- Acknowledge that Lean/SS affects the organization and its goals
- Acknowledge that change is difficult and causes discomfort
- "Change Management" education critical for managers/supervisors
- Acknowledge that this is a new way of thinking and working
- "Buy-in" at all levels is critical for success
- Present an organized, common-minded leadership
- Celebrate Successes!

Benefits of LEAN Implementation

What are the laboratory and organizational benefits and outcomes of a successful LEAN/Six Sigma implementation?

- Increased productivity
- Improved quality and patient care
- Space utilization improved
- Reduction in order processing errors
- Reduced staffing demands
- Reduction in turnover and attrition costs
- Reduction in inventory control activities
- Greater employee job satisfaction

To summarize, LEAN/Six Sigma is a systematic approach that eliminates waste, increases productivity and quality of work by reducing complexity, improving process flow and removing unnecessary or non-value added activities!

LEAN and Susceptibility Testing

- Don't duplicate systems
- Streamline
- When appropriate, get the results out as soon as possible
- Focus the technologists' time on tasks that require their training and expertise

Now that we have introduced you to the basic concepts of LEAN, let's look at susceptibility testing as an example of an important function where the laboratory that can benefit from LEAN. Remember that although we are focusing this discussion on susceptibility testing, the basic ideas apply through out the microbiology laboratory.

The hardest concept to get away from is the idea that we need multiple back up systems and that we often need to keep conventional or "old school" reagents and tests available "because we may need them." There are times when back up systems are important or even critical but most of the time laboratories simply keep outmoded stuff around because they are emotionally attached or they remember once, many years ago, when they needed some conventional test like "Hugh-Liefson fermentation tubes". System duplication should be minimized. As one can see in Figure 1., the microbiology laboratories at Cincinnati Children's and Children's Hospital of Philadelphia both suffered from too many systems for susceptibility testing. It seemed that Bauer Kirby offered an inexpensive methodology that we were all comfortable with, the commercial broth dilution system was the gold standard of the time, the Vitek system offered speed and efficiency and the ETest system was used for a small number of fastidious organisms. This practice involved multiple quality controls and set up process-

es, various supplies and manufacturers as well as different technical procedures that required ongoing training and competency testing of staff. We knew we had to "think smarter" and do things differently. That said, we wanted to be LEAN, but knew we couldn't transition to a single methodology for AST and still produce consistently accurate results, because of course, it is not LEAN to be wrong! An incorrect result puts patient care at risk by extending in-patient stay, using inappropriate therapy, and may result in more expensive antibiotic use, repeat laboratory testing in the laboratory, etc. We needed to get the right answer the first time.

Let's take a closer look at how and why we changed our AST algorithms:

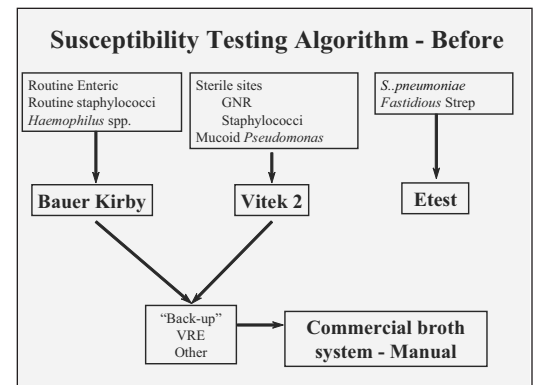


Figure 1 represents the susceptibility testing algorithm for CCHMC and CHOP prior to LEAN implementation.

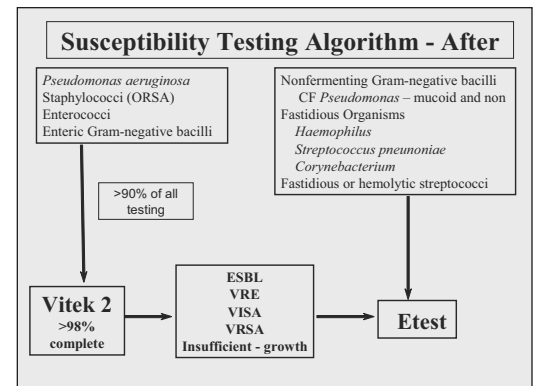


Figure 2 represents the susceptibility testing algorithm for CCHMC and CHOP following LEAN implementation.

There are several important considerations in why one set of organisms can be tested by one method or the other. The main analyzer in this new scheme is the Vitek 2 system. It has been validated and works well for a number of groups of organisms (see figure 2) and has the positive characteristics of high throughput, low hands-on time and rapid results. The strengths of Etest, our secondary system,

lie in its flexibility, full dilution MIC, and application for difficult organisms or clinical situations. The following example illustrates these points.

Pseudomonas aeruginosa

Although validated susceptibility testing methods exist for *P. aeruginosa*, there are reports of minor to very major errors for *P. aeruginosa* when comparing Vitek 2 to Etest [piperacillin/tazobactam (6.2%) and cefepime (13.7%)]. In addition, Jorgensen et. al. compared Vitek 2 with broth microdilution and found minor to very major errors for cefepime (23.6%) and piperacillin/tazobactam (10.0%). Also, the Vitek 2 and Microscan systems demonstrated inaccuracies for a variety of agents including amikacin, imipenem and piperacillin/tazobactam when testing pan-resistant *P. aeruginosa* samples distributed through the College of American Pathologist Proficiency Testing Program. Despite the weaknesses of automated systems described above, we converted testing for *P. aeruginosa* isolates (excluding those from patients with cystic fibrosis) from disc diffusion to Vitek 2 for cost, efficiency and workflow adaptability, while continuing to monitor results to determine if testing by Etest is required.

Role of Cystic Fibrosis Foundation Guidelines

Cincinnati's Children's Hospital and The Children's Hospital of Philadelphia provide care to a total of approximately 550 families with cystic fibrosis (CF). The Cystic Fibrosis Foundation (CFF) actively contributes to developing laboratory, treatment and infection control standards for patients with CF. The Foundation supports the use of automated susceptibility testing methods for rapidly growing Enterobacteriaceae and staphylococci, but recommends agar-based diffusion methods for pseudomonads and other multiply resistant organisms commonly recovered in this patient population. One confounding difficulty with all methodologies for *P. aeruginosa*, is conversion of the non-mucoid phenotype into the mucoid (biofilm mode) phenotype associated with the development of chronic lung infection and subsequent decreased lung function. There are no testing methods available for the clinical laboratory that simulates growth in a biofilm, yet research demonstrates some agents, such as beta-lactams, excluding meropenem, are less active when grown in a biofilm, whereas others such as aminoglycosides and ciprofloxacin appear unaffected. In several studies, Vitek2 and MicroScan Walkaway systems were evaluated and found to have a high rate of very major errors for susceptibility testing of CF *P. aeruginosa* isolates, an organism particularly difficult to eradicate, yet

Etest and disk diffusion testing were shown to correlate with reference MIC testing. Due to the complex nature of testing pseudomonads and other resistant Gram-negative bacilli, we follow the CFF guidelines for "best practice" and test these organisms by Etest.

Benefits of Algorithm Changes

Once the new AST algorithm was put in place, the following laboratory and organizational "downstream" benefits were soon realized;

- Quality Improved
- Fewer repeats or confirmatory testing
- Infection Control Impact
- Therapeutic agent changes (cost/toxicity)
- Inventory and receiving activities reduced
- QC reduction
- Productivity increased
- Space Utilization reduced
- Increased flexibility of testing
- Staff assigned where needed

Anti-Fungal Susceptibility Testing In-House vs. Sending to Reference Laboratory

During this process, we identified another important area that took our technologists away from tasks that utilized their expertise and cost our laboratories a significant amount of money. In the immunocompromised patient, providing timely antifungal susceptibility testing is paramount to treatment. According to a recent CAP Proficiency Surveys, increasing numbers of laboratories are performing testing in-house (currently approximately 42 %), most following CLSI Standard M27-A2. Sending testing to a reference laboratory creates a time delay as well as makes the process cumbersome if additional agents are requested or consultation with the clinician regarding methodology or interpretation is needed. Our hospitals serve a large number of transplant recipients, oncology patients and neonates; therefore, having a quantitative result plus category interpretation in a timely manner is critical. After adding this to our test menu, result turn around time was reduced by 4-8 days, an institution specific antibiogram was created, and we established standardized reflex testing protocol for positive normally sterile body fluids. In addition, the cost per test was reduced from \$183 to \$17 for reference laboratory and in-house, respectively. The decision to bring testing in-house depends on many factors including clinical impact, formulary, cost, test volume, required turn-around time, staffing resources, reference ranges, and methodology; however opportunities exist to evaluate options for streamlining and improving the process and quality of testing.

Before – sendout

- Packaging costs of \$8.50
- Shipping costs ~ \$50.00
- Ordering time as much as 5 minutes
- Resulting time as much as 5 minutes
- Cost of send out test \$155.00
- Total cost of ~ \$213.50
- Time to results was 7-10 days

After – in house

- Susceptibility set \$15.50
- Time to set and read 5 minutes
- Report out drugs as needed
- Create an antibiogram (quality)
- Turn-around time 1 to 3 days

What to do next?

The process of evaluating quality and effectiveness should never end for the microbiology laboratory. Once a laboratory has analyzed every process, it is time to start again; there are changes in technologies, personnel, methodologies, and in the needs of patients and physicians. LEAN is never satisfied - we shouldn't be either!