Pursuing Perfection

through Continuous Improvement

An Introduction to Lean Healthcare Principles

You may wonder how a methodology pioneered by Toyota in the 1940s to optimize its assembly line could possibly apply to the modern diagnostic laboratory. But if you compare an automotive plant to a diagnostics lab, the parallels become quite evident. Both strive to bring people, processes, materials, and automated equipment together into an efficient and effective workflow. The distinction is that one uses steel to produce a shiny new car, and the other turns information into timely and accurate results.

Simply defined, Lean is a structured and common-sense approach to measuring and analyzing operations, standardizing and continuously improving processes, and eliminating inefficiency and waste to produce what the customer wants.

Just as Lean helped the auto industry increase speed, productivity, efficiency, and quality, while reducing costs and errors, a comprehensive Lean Transformation Plan can do the same for your lab. But before we delve into Lean terminology, tools, and techniques, and even before you begin to think about implementing such a plan, you can start making small, incremental changes that will produce immediate improvements.

At its core, Lean can be as simple as Observe, Think, Act, and Repeat. However, to expand beyond these basics, let's look at the foundation of Lean thinking, define core vocabulary and concepts, and discuss helpful tools to add structure to your methods.

Observe your processes in action, watching where people, tubes, supplies, and information go.

Think how these processes could be improved, reduced, or eliminated to make them faster, easier, and more consistent.

Act to put your ideas in place and observe again.
- If the process **does not** improve, try something new.
- If the process **does** improve, congratulations!

Repeat continuously, always looking for new ways to do things better.

The Principles of Lean Thinking

1. Define value from the customer's perspective and provide what they want.

2. Identify the value stream or step-by-step process for each product and reduce or eliminate steps that do not add value.

3. Align the value-added steps so they flow continuously.

4. Allow the level of customer demand to pull the process, i.e., produce only what is ordered.

5. Pursue perfection through continuous improvement.

Lean Concepts and Terminology

Value is what the customer wants, perceives as valuable, and is willing to pay for. But labs have more than one customer, each with different needs. The physician and the patient want timely and accurate results, but regulation and insurance policies define reimbursement and will pay only for a reportable result.

Value-added activities are those that improve the product (product herein can also refer to services) to increase value to the customer. They include the equipment, materials, and work essential to produce only what the customer needs. In reality, value-added activities represent less than 2% of process time.

Non-value-added activities are essentially everything not included above and are defined as waste. In Lean, the goal is to simplify, reduce, or eliminate wasted effort, time, and resources. However, there are necessary nonvalue-added activities that are enabling or incidental, such as maintenance, calibration, or quality control, so these should be integrated into the process. Many of these are time-consuming or labor-intensive tasks that are far more efficiently handled by automation, such as pre-analytical sample processing, specimen retrieval, inventory management, and manual dilutions and reruns.

Kaizen is a Japanese term for the process of continuous improvement. It begins by defining and documenting current best practices to establish a baseline. Everyone's work adheres consistently to this standard, while they continuously seek to improve it. As the process is refined, the new method becomes the standard, and the cycle continues. Standardization may not be possible or advantageous for all processes and should be implemented only if it produces improvements.

Lean metrics measure the improvements achieved through Lean practices and are defined as challenging but achievable objectives that are **SMART**: **S**pecific, **M**easurable, **A**chievable, **R**elevant, and **T**ime-based. Lean metrics should be motivating and not punitive, with the team recognized and rewarded for their achievements to encourage desired behavior. Turnaround time (TAT) is by far the most common metric used to evaluate a lab, but in the pursuit of continuous improvement, there are many objectives that can provide critical insight, such as billable results per paid hour, reduced overtime, or increased use of autoverification.

Tools to Guide Your Lean Transformation Plan

The Process Map is a high-level view of the activities required to take a product from sample collection through results to the physician. It serves as a best-practices checklist to ensure that a process is efficient, effective, reproducible, and predictable, ensuring that everyone is doing the right things the right way, with controlled variability. In nonautomated labs, common sources of variability include manual validation, inconsistent flow of samples to instruments, and varying skills and work methods among the staff.

The Process Map of an entire laboratory workflow can be too complex to be useful, so it is common to map subprocesses individually. However, it is important to keep the entire process in mind even when analyzing subprocesses to avoid inadvertently introducing problems in other areas.

For example, if a lab is having difficulty meeting its TAT goals, it might initiate a Rapid Improvement Event. Beginning with a Gemba walk through the lab to directly observe the processes in action, your Lean team may decide to focus first on the pre-analytical process, meeting to review and document the main steps, such as specimen receipt, initial sort, centrifugation, and transport to the analytical area. These become the headers for the process, which are then broken down further into individual steps. When the current state has been documented, the team looks at each step to determine its value. Examples of non-value-added steps include unpacking samples from transport bags and sorting, racking, decapping, recapping, reracking and transporting tubes to various discipline areas for processing.

During this analysis, your team would make recommendations to reduce or eliminate non-value-added steps, which could be something as simple as moving a bench to improve workflow or more complex solutions such as adding a dedicated bulk input module or moving standalone hematology to the core lab track. The Lean team uses its collected data to demonstrate potential savings in time, cost, and resources and propose its business case to laboratory management for consideration.

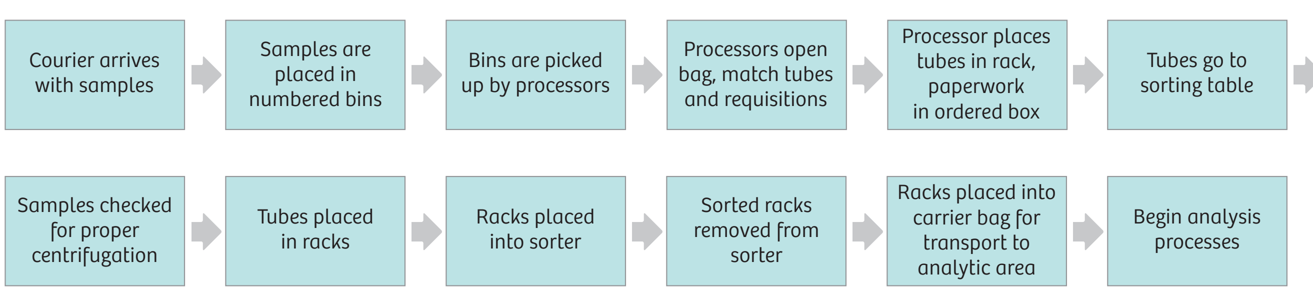
The Value Stream Map plots the interlinked flow of materials and information from accessioning to final results to the physician and is filled with data points gathered from direct observation, so it depicts what is actually occurring rather than what you may think is happening.

Since it may be too complicated to fit everything on one map, a typical appriach is to group similar processes together and approach each group individually, compiling them together as one complete workflow.

The Value Stream Map follows the route outlined by the Process Map, with each step quantified by touch time, batch size, and number of people required, as well as observed time, wait time, and cycle time. Touch time is how long it takes to process a single item, so if it takes 100 seconds to load 50 samples on the centrifuge, the touch time for one sample is 2 seconds.

From this data, you can calculate Takt time, which is the rate of production required to meet the customer's need (available time divided by customer demand). For example, if you see that production is backing up at the sort step, you can calculate that if 250 tubes must be sorted in 1 hour, the Takt time is 14.4 seconds (1 hour/250). If your Value Stream Map indicates that it takes one person 20 seconds to sort one sample, your analysis demonstrates that you need to assign more staff to keep up with demand or improve the process to take less time.

Pre-analytical Process Map for Nonautomated Lab

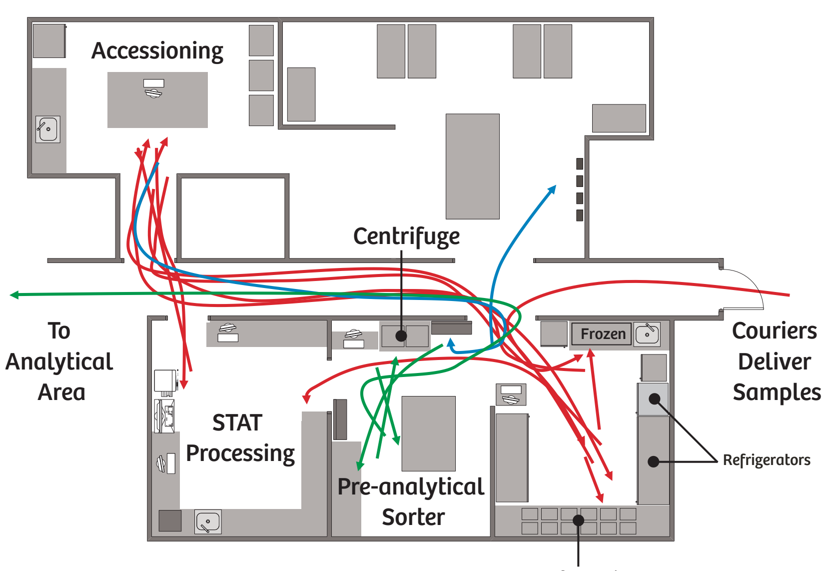


The Spaghetti Diagram is created by walking the actual path taken through the workplace by samples, supplies, people, or information (paper or digital) and drawing this path as a continuous line on a floor plan to illustrate a single cycle of a process. Each stop, such as transferring tubes to a centrifuge, is marked, numbered, and timed, and reasons for trips are indicated, such as obtaining supplies or signatures. Peak and off-peak workflows should be mapped separately.

When moving from your current state to an improved future state, such as when implementing new automation, the spaghetti diagram can be valuable for revealing poor space utilization and unnecessary movement of tubes, staff, or consumables. It becomes very clear where a lot of travel occurs and where travel is interrupted or stopped. Often, such steps can be improved or eliminated by changing their order, eliminating rework steps, or bringing supplies and equipment closer together. For example, if a centrifuge is moved 10 meters closer to the sorting bench, at 20 trips a day, it saves staff 52 kilometers (32 miles) a year. After addressing these issues, map the process again and compare results.

The Spaghetti Diagram

The pre-analytical process tracks the path taken by samples, supplies, people, and information in a typical lab before implementing automation. If this same process was mapped after implementing automation, many of these steps would be replaced by the single step of placing all incoming samples in the system's input-output module.



The 5S Method helps remove unnecessary items and place the necessary ones in a logical order in a clean and organized workspace. It helps identify problems, highlight opportunities for improvement, and nurture a culture of discipline.

A simple but effective application of the Sort step can reduce the overwhelming number of manuals and notebooks cluttering most laboratories. Working with one workbench at a time over a few weeks, ask staff to put a colored sticker on a book whenever it is used. In the end, any book without a sticker does not need to be taking up valuable laboratory space and can be relocated elsewhere.

5S Method

1. **Sort:** Remove items from workplace that are not frequently needed.
2. **Set in Order:** Improve ergonomics and place items in a logical sequence for how they are used.
3. **Sweep (or Shine):** Clean the area of clutter.
4. **Standardize:** Assign a place for everything.
5. **Sustain:** Repeat continuously to maintain order.

Key Issue Identification is performed by brainstorming to gather ideas and concerns and organizing them around common themes. Anyone who has experience with an issue and a vested interest in resolving it can be involved. These can be documented using two diagramming tools:

- **An Affinity Diagram** takes a large number ideas or facts that are not organized in a coherent manner and groups them into logical categories, drawing attention to previously unrecognized ideas. Grouping related issues together also helps your team rethink how issues are connected, which can suggest new ways to address a problem.
- **An Ishikawa (Fishbone or Cause and Effect) Diagram** helps determine the root cause of a problem by systematic modeling of contributing factors. Look to see how the problem is associated, caused, or worsened by each of the headings (people, process, equipment, materials, and information) and use the results to define how to resolve each issue.

Putting Lean into Action

From even simple applications of Lean principles, you can immediately begin to see improvements in productivity and quality. But when smaller incremental changes are not enough to achieve the performance goals you seek to achieve, your lab should consider a focused, carefully structured Lean Transformation project, which often is part of a plan to implement automation for the first time or replace an older automation system. While automation offers significant improvements in workflow and efficiency, you never want to automate a flawed process.

Whether undertaken with your own team or working with Lean healthcare consultants, this is the time to not only document and analyze your workflow and processes, but also to refine them with a keen eye on your strategic and operational goals.

The Eight Wastes:

Eliminating wasted effort, time, and resources (D.O.W.N.T.I.M.E.)

D

Defects: Errors or corrections due to work not being done correctly and requiring more time, resources, or cost to fix, such as performing tests on an instrument that is experiencing a QC violation.

O

Overproduction: Producing more, sooner, or faster than required, such as collecting more blood tubes from a patient than necessary for the ordered tests.

W

Waiting: When work stops due to insufficient staffing, long setup times, and mismatched production rates. Examples include waiting for tubes to be sent to the lab, samples to analyzed, reagent to be delivered, sendout results to be reported, or tubes to be centrifuged.

N

Not Using Staff Appropriately: Employees performing tasks that are not aligned with their education, certification, or expertise, such as a medical technologist manually checking samples into the lab or searching through refrigerated storage for a misplaced tube.

T

Transportation: Unnecessary movement of samples and supplies due to a poorly laid out lab space, an inconvenient lab location, or improperly placed instruments.

I

Inventory: Lack of required supplies (such as reagent) can halt production, while excess stock on hand increases operational cost, requires storage space, and can expire before use. Kanban is a process that signals the depletion of product or parts and ties inventory levels directly to rate of consumption. Automating your lab's inventory management is an effective step to reduce multiple wastes, including waiting, improper staff utilization, and inventory.

M

Motion: Excess movement of people, equipment, paperwork, or electronic information, often caused by poor laboratory layout.

E

Extra Processing: Putting more work into a process than required, such as sorting and resorting of samples, performing unneeded analyses, or overprocessing due to lack of sample-relevant information, such as collection time or serum indices flagging or performing more calibration or quality control testing than necessary.

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