Innovations in the Clinical Laboratory

An Overview of Lean Principles in the Laboratory

August 2007

This paper is based on the application of Lean principles within operations at Mayo Medical Laboratories.
Executive Summary

Mayo Medical Laboratories is committed to providing clients with high-quality laboratory testing which results in improving patient care and employee safety. One of the ways this is accomplished is with the implementation of Lean management principles.

Lean principles can be applied to any organization that has a defined set of process steps that it follows to produce an end product. Whether it is physical goods or a service, Lean has been successfully implemented in industries ranging from manufacturing to health care. Lean is a systematic approach to process improvement that focuses on the reduction and elimination of waste, variations, and imbalance in the process.

As this paper will describe, Mayo Medical Laboratories strived to accomplish the following goals by using Lean principles:

- Improved operational performance (faster testing turnaround time, decrease in costs and improved quality)
- Reduced variability in operational performance
- Operations management approach as an end-to-end discipline
- Improved patient and employee safety
- Improved employee morale
- Reduction in development time for new tests
- Reduction in testing defects and errors during new test development and implementation
History of Lean

In 1913, the first innovator to truly integrate a full production process was Henry Ford. Ford used the principles of standard work tasks performed on a moving assembly line to create what he termed flow production. Wherever possible in the work flow, Ford lined up special machines with stop/go gauges that delivered standardized pieces of equipment directly to the assembly line exactly when they were needed in the process. Ford revolutionized the manufacturing shop practices with this approach to assembly but his system lacked one essential component—variety in the end product. In the 1930s, Toyota perfected the Ford system by introducing more continuity in the flow of the process that allowed for a wide variety in product offerings. By introducing some simple innovations and revisiting Ford’s original process, the Toyota Production System was invented. In terms of overall sales, Toyota is the leading auto manufacturer in the world which lends credence to the success of Lean thinking.

The internet is overflowing with articles, Web sites and books about Lean thinking. Lean thinking has been embraced by many types of companies around the world. In summary, Lean thinking is the identification and elimination of waste which allows managers to pursue perfection through continuous improvement. Because of the quest for constant quality improvement, Lean principles are easily adaptable to the health care industry and have been applied by many health care systems.

Lean is a different way of viewing and approaching work. It is about developing a change in the management of the process and looking at process reorganization. This is done while intently concentrating on eliminating redundant motion, recognizing waste, and identifying what creates value from the client’s perspective. Lean is a continuous process improvement initiative and not an end destination. It is about allowing your process to flow and continually striving to improve the flow.

The main objective of Lean, when applied in the laboratory, is to deliver quality patient laboratory results, at the lowest cost, within the shortest time frame while maintaining client satisfaction.
The five Lean principles as they apply to the clinical laboratory are:

- **Value**: Define the value in the process from the client’s perspective; “value” is that which the patient or client would knowingly pay for or the attributes of a product or service (quality, speed of delivery, personal attention, etc.)

- **Value Stream**: Identify the value stream for each process providing that value, challenge the wasted steps, and eliminate all of the waste that you can

- **Flow**: Make the product or service flow continuously through the remaining, value-added steps

- **Pull**: Introduce a continuous flow of events between all steps of the process where continuous flow is possible. In a well-defined pull system, the process lets you know by inherent triggers when something needs to be done and the process manages itself

- **Continuous Improvement**: Manage toward perfection on an on-going basis so the number of steps, the amount of time, the scope of resources and the information needed to provide the service to the client and patient is constantly under scrutiny

Implementation of Lean principles can increase quality, throughput, capacity, and efficiency while decreasing cost, inventory, space and lead time. And, most importantly, it ultimately provides better patient care.

Lean is not an acronym. It is called Lean because it is a descriptive process that uses less of everything—space, time, investment in equipment, inventory, and staffing resources. Lean is also known by other names, most notably Operational Effectiveness, Business Process Redesign, Flow, or as the history section describes—the Toyota Production System (TPS).
Lean—Getting Started

Within Mayo Medical Laboratories, when initiating a Lean project, our emphasis is usually directed on the waste elimination. The first step is to perform a “waste walk” which entails direct observation of the process while in production in the laboratory. It takes this direct involvement of activity to be able to see and identify the waste in the process. This direct observation of the process is the simple part. The challenge is to have the courage to identify and call it waste and to instill the desire to eliminate it.

Below are some types and examples of waste that can be found in clinical laboratories:

<table>
<thead>
<tr>
<th>Types of Waste</th>
<th>Definition</th>
<th>Examples</th>
<th>Potential Causes</th>
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</table>
| Waiting              | Idle time created when material, information, people or equipment is not ready | Waiting for:  
- Tech or instrument to become available  
- Samples in a batch to complete testing  
- System to come back up  
- Client or vendor response |   
- Excessive WIP due to large batches  
- Equipment problems  
- Defects requiring re-work  
- Push system |
| Transportation/      | Movement of material or information that does not add value                  |   
- Samples traveling throughout the lab to be processed and tested  
- Carrying samples and documents to and from shared equipment  
- Taking files to another person  
- Moving patients for testing |   
- Inefficient workplace layout  
- Large batches and/or equipment  
- Islands of “like” machines instead of work cells |
| Material Movement    |                                                                             |                                                                                                                   |                                                             |
| Over-processing      | Efforts that create no value from the client’s standpoint                   |   
- Unnecessary testing due to overly sensitive instrument  
- Perform testing not requested  
- Repeated manual data entry  
- Excess paperwork  
- Redundant approvals  
- Over incubation or mixing of samples |   
- Work silos  
- No visual controls  
- No standard work |
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<tbody>
<tr>
<td><strong>Inventories</strong></td>
<td>More information or material on hand than what is needed at present</td>
<td>- Lab supplies</td>
<td>- Long lead time for supply replenishment</td>
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<td></td>
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<td>- Specimens waiting analysis</td>
<td>- Re-stock and re-order not consumption based</td>
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<td>- Paperwork in progress</td>
<td>- Large reagent lot sizes</td>
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<td>- Unused records in the database</td>
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<td><strong>Motions/Movement</strong></td>
<td>Movement of people that does not add value</td>
<td>- Techs need to reach to get more reagents or samples</td>
<td>- Layout of work area ill-planned</td>
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<td>- Tech leaves work area to find supplies</td>
<td>- Non-ergonomic or unorganized work cell design</td>
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<td></td>
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<td>- Extra keystrokes or clicks on computer</td>
<td>- Poor supply replenishment plan</td>
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<td></td>
<td></td>
<td>- Gathering tools</td>
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<td></td>
<td></td>
<td>- Handling paperwork</td>
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<td><strong>Defects</strong></td>
<td>Work that contains errors, rework, mistakes or lacks something necessary</td>
<td>- Failure to get the proper result on the proper patient to the proper physician</td>
<td>- Missing or inaccurate information</td>
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<td>- Re-test, redraw or result revision that could have been avoided</td>
<td>- Poor equipment maintenance</td>
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<td></td>
<td>- Data entry error</td>
<td>- Frozen sample thawed</td>
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<td>- Missing or inaccurate information</td>
<td>- Work not standardized</td>
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<td></td>
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<td>- Duplicate work</td>
<td>------------------------------------------------------------------------------------------------------</td>
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<tr>
<td></td>
<td></td>
<td>- Sample integrity compromised</td>
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<tr>
<td><strong>Overproduction</strong></td>
<td>Generating more information than what the client needs right now</td>
<td>- Upstream process step working at a faster pace than downstream testing or analysis process requires</td>
<td>- Unbalanced processes</td>
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<td>- Testing ahead of time to suit lab schedule</td>
<td>- No visual controls or management</td>
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<td>- More information than the next process needs</td>
<td>- Push versus Pull system</td>
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<td><strong>Re-prioritization</strong></td>
<td>Starting one task, being interrupted (phone, e-mail, page) and changing to another task before the first task is completed</td>
<td>- Stat or priority orders</td>
<td>- Equipment preventive maintenance lax</td>
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<td>- Trouble-shooting</td>
<td>- Batching model issues</td>
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<td>- Unexpected equipment failure</td>
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<td><strong>Mis-utilization of skills</strong></td>
<td>People seen as a source of labor and not work process experts</td>
<td>- Improvement ideas not solicited</td>
<td>- Work area is understaffed</td>
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<td>- No continuous improvement culture</td>
<td>- Top-down management</td>
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After the initial step of identifying the waste in the laboratory process, the second step is to examine and document the current system from start to finish. This is known as mapping the value stream. To scrutinize the “as is” system from end to end:

- Track the movement of an individual sample or patient through the entire process
- Track the movement of the people at each work station
- Observe where the value for the client is being created
- Highlight the wastes
- Break down the time spent in each of the process steps
- Document the current state with a map, work balance chart and “spaghetti diagrams”

Identifying, documenting, and reviewing the entire system for each testing process in the laboratory can be an extremely tedious process but one which is necessary and very effective because it almost always exposes enormous amounts of waste.

Mayo Medical Laboratories realized early on in the application of Lean principles that if they did not recognize waste and manage the value stream to eliminate the waste, the results of their efforts would be mediocre.

Figure 1. The Value Stream Map is a component of the Lean process that can identify, document, and review entire processes.
The third step in the application of Lean principles is to envision the future state for the process with the waste eliminated. A Lean laboratory optimizes the whole value stream, from the time it receives an order until the test result is deployed and the request is addressed.

![Diagram](image)

**Figure 2.**
A component of the development of the future state map is to find the right metrics to manage performance as the plan of action is implemented.

### A Typical Lean Project

At Mayo Medical Laboratories, a typical Lean project starts out with the establishment of a laboratory team. The laboratory team usually consists of a supervisor, a lead tech, two or three people from the front lines, a non-laboratory person and an experienced Lean leader. From the start, the commitment from administration and upper management to lend their administrative support to the project is required.

The team works with the service line or a process matrix that has been identified for the Lean project. Key performance indicators are developed and the baseline measurements are documented.

At this stage, the team is trained in Lean thinking and the numerous tools available for the project. Value stream mapping is performed to document the current state and as the project moves forward the team is trained in other Lean tools as needed (5S, change management, Pull/Kanban, flow layout, etc.). Once the current state is mapped out, a future state is documented and then implementation planning can begin. Execution of the plan is the next step with the measurement of the key performance indicators at the specified time intervals. Periodic follow up is performed which forms the basis for a continuous review of the process.
Overall, the reasons for applying Lean methodology within our laboratories are the same as what a client experiences. In the current health care environment, the number of potential patients continues to expand as the population grows older and space in the laboratories is needed to accommodate this growth. The clinical laboratory is facing a shortage of skilled professionals, and the laboratory service level expectations of clients remains high and is getting higher.

The improvement actions implemented from Lean projects have resulted in:

- Reduced batch sizes
- Staffing schedules matched to sample arrivals
- Standardization of work processes with visual cues to help people stick with the standard
- Reduced set up time for testing
- Root cause analysis and mistake-proofing to reduce defects due to human error
- Improved operational tracking management

At Mayo Medical Laboratories, we focus on continually optimizing quality, patient care, and employee and patient safety. We are committed to excellent client service. We accomplish this by utilizing Lean processes to make continuous improvements.
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There are various white papers available based on specific departments at Mayo Medical Laboratories. Please contact Mayo Laboratory Inquiry for laboratory specific Lean white papers.