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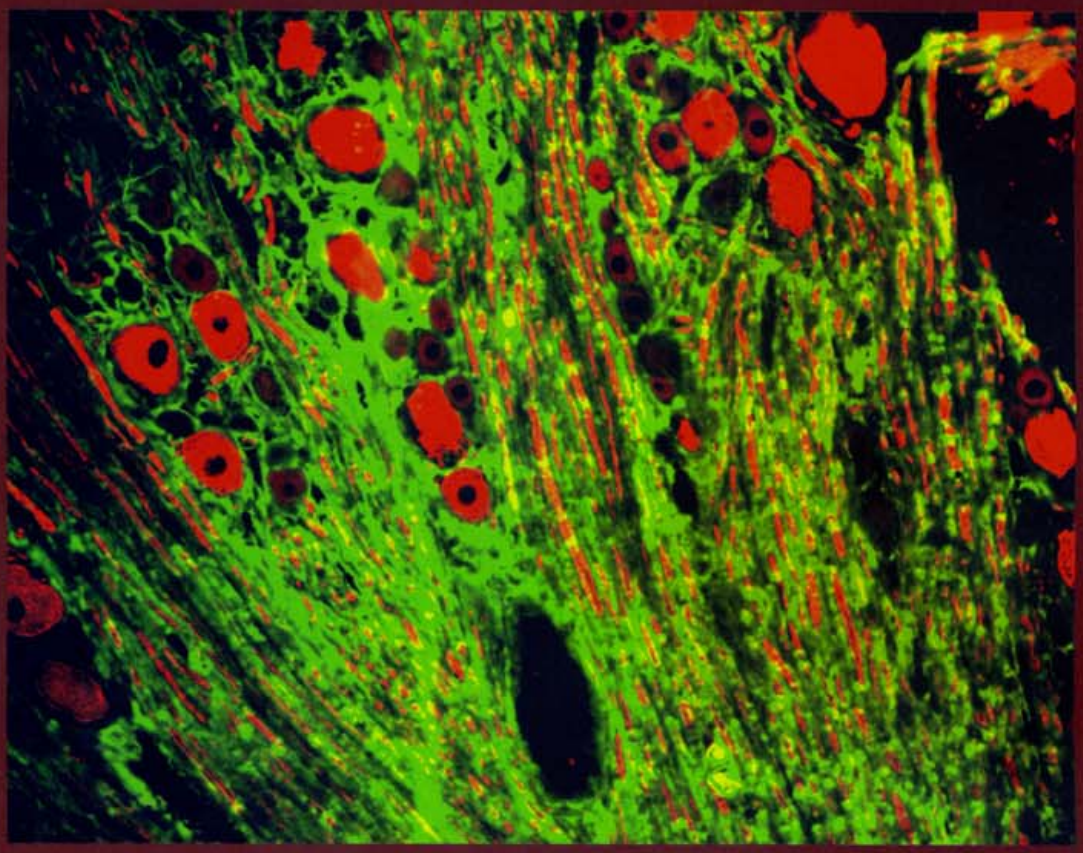

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Laboratory transformation through Lean enterprise

Current situation faced by laboratories

The demand for increased test volumes, higher-quality processes and lower costs have become the standard and are placing constant pressure and added stress on laboratory staffs worldwide. As laboratories look for solutions to this growing situation, companies continue to introduce solutions that include a variety of process improvement techniques and various levels of automation.

While automation solutions provide a great incentive on the surface, there can be a tremendous price tag and long-term Return on Investment (ROI) before the laboratory can truly achieve the cost benefits demonstrated by many companies. What is often overlooked in many of these automation conversions is the large amount of process improvement that actually occurs as a direct result of implementation.

To achieve the greatest ROI, the laboratory must understand the current process, what opportunities exist, and what must be done to implement efficient processes. Over the past several years, many healthcare organisations have begun to turn to any number of process improvement techniques, from in-house developed programs to mainstream initiatives such as Lean and/or Six Sigma (see RCPath *Bulletin* 2006;131:25).

By focusing on process improvement first and foremost, it is possible to create efficient processes and set the stage for technology and automation solutions that provide maximum efficiency. Approaching laboratory modernisation from this perspective, as opposed to jumping to conclusions on automation solutions, it is possible to avoid the, "automating a bad process only gives you a bad automated process" trap.

The common thread to all of these process improvement techniques is the underlying premise that for success to be sustained, the approach must be one of continuous improvement. As interest in this approach gains ground within an organisation, the question turns to methodology. What approach should be used to improve processes? What tools and techniques will transform the laboratory into an efficient laboratory responsive to the needs of the customer?

The methodology behind Lean enterprise

Lean enterprise, as a continuous improvement initiative, continues to gain acceptance within the laboratory environment. The power and speed at which Lean produces results rests in the methodology itself. Lean attacks the very issues that stagnate many organisations each and every day: complacency, time and money.

Instead of accepting the status quo, or looking for one big all encompassing solution, Lean creates a culture where process improvement lives in a continual improvement environment within all employees. Lean focuses on responding to customer demands and expectations, as well as creating an environment receptive to change. And Lean accomplishes these goals by involving all employees to drive waste out of the process, something that is often times very easy to identify and address.

A textbook and often used definition of Lean enterprise is, "...identifying and eliminating waste through continuous improvement at the pull of the customer in pursuit of perfection". The definition itself while somewhat long and cumbersome is quite effective at communicating the message when it is broken down into segments.

Identifying and eliminating waste: Using all employees to provide in-depth review of processes looking for non-value-added (NVA) tasks (anything that the customer is not willing to pay for) and eliminating this waste when found. If the task is NVA and cannot be eliminated, every effort should be made to simplify the task so that it is as small a piece of the process as possible.

Continuous improvement: A never-ending journey. Once an organisation begins utilising continuous improvement, to stop relegates the effort to that of a mere program, and is often viewed by the workforce as just another 'flavor of the month'.

Pull of the customer: Listening and responding to customer expectations and demands. This means responding in a fast and effective manner to what the customer wants, when the customer wants it. For the laboratory, this can be challenging since the consultant pathologist is a customer, the doctor is a customer, the patient is a customer, and the National Heath Service (who pays the bill) is also a customer.

In pursuit of perfection: The ultimate goal – perfection. This is what keeps the organisation listening to customers, attacking process opportunities and working as a team to drive waste out and improve quality on a daily basis. The organisation that seeks perfection, and provides the means to attempt to reach this goal daily can achieve great efficiencies.

Lean enterprise has come to the forefront as a continuous improvement initiative, not because it is the latest and greatest business management tool that has been embraced by highly-skilled professionals, but because it has been proven as an effective methodology for process improvement over many decades. Lean is the Toyota Production System brought to the masses. The concepts and tools are not new, just implemented in a different manner.

The Toyota Production System has evolved from basic industrial engineering concepts over the past 50 years. After World War II, Toyota and many other Japanese manufacturing firms were looking for ways to compete in the global marketplace. Embracing the concepts brought to Japan by Dr W Edwards Deming, and improving upon these concepts and ideas over the years, Toyota created a business model that went beyond the manufacturing floor. The team-based, and *muda* (waste)-focused philosophy seeks out imperfections in all processes, removes this NVA whenever it is found, and continues – seeking perfection on an on-going basis.

Focus of Lean efforts

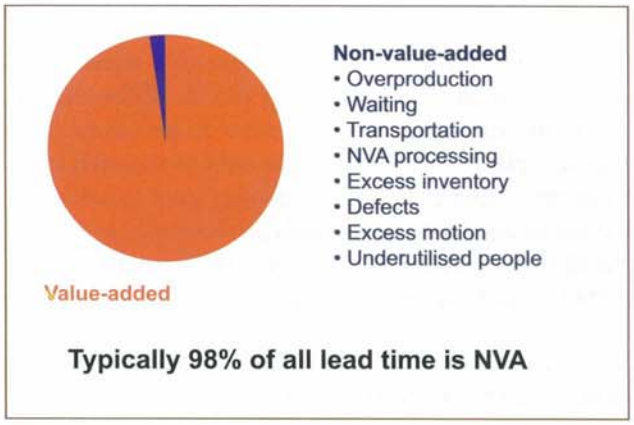
Toyota categorises waste into the *Seven Deadly Mudas*:

1. Defects.
2. Overproduction.
3. Excess inventory.
4. Unnecessary processing.
5. Excess motion.
6. Unnecessary travel or transportation.
7. Waiting.

Many Lean practitioners and professional organisations working with Lean techniques have added an additional waste, something that is quite a foreign concept to many Japanese organisations: *People waste*. This is not utilising the knowledge, skills and physical abilities of the employee. While Japanese culture embraces the role that the employee plays within the process, for many organisations in other parts of the world the employee's role has been greatly diminished due to business politics, culture, etc.

Why does the Toyota Production System, and more importantly Lean, focus so much effort on identifying and eliminating waste? There is one simple reason: As much as 98% of all process lead time found in transactional processes is (NVA)[1] (see table 1). If a laboratory were able to eliminate even half this NVA, turn-around time (TAT) would significantly improve. Costs would also be reduced, and employee job satisfaction and customer satisfaction would also increase due to the elimination of tasks viewed by the employee and customer as non-essential.

Table 1: Process lead-time in transactional processes



Toyota has successfully proven this continuous improvement methodology year-in and year-out for decades and is now positioned to be the largest and most successful automotive manufacturer in the world. But the techniques that combat waste on the production floor are just as powerful when applied to transactional processes throughout the organisation. This far-reaching, flexible and universal continuous improvement methodology is being proven in a variety of industries and sectors as the popularity and success of the methodology continues to grow.

As waste is identified, and customer expectations are gathered, analysed and understood, improvements must be initiated quickly to respond to customer expectations before the marketplace changes. The speed at which Lean is implemented allows practitioners to respond to the marketplace, protect and grow market share, and proactively take the lead in quality improvement and cost reduction.

Lean tools and techniques

As waste is identified, project teams must move swiftly to eliminate this waste in a methodical manner utilising a series of tools or techniques. The tools of Lean enterprise are not new by any stretch of the imagination – the manner in which they are used, however, is. Lean improvements are made by running projects comprised of staff from all levels of the organisation. Management team members join forces with all levels of the workforce to implement Lean change. The most effective teams include not only subject matter experts from within the area of focus, but also include engineering and/or maintenance staff to assist in physical and mechanical changes to equipment and facilities. In addition to workers within the process, subject matter experts, and engineering support, teams focusing on transactional processes often include internal customers and internal suppliers.

The primary Lean tools utilised are often displayed as a block, or toolkit, of techniques used as the situation and opportunities dictate. Unlike many other continuous improvement initiatives, Lean does not use a standardised implementation plan where each tool is always used in a certain order. Lean is very similar to an effective Six Sigma implementation, where the right tool is used at the right time. Lean requires each project team to assess the situation, determine which tools are necessary to address the identified waste, and then using the strengths of each team member, implement change.

The Lean toolbox, as shown below in table 2, can be broken into three primary groups of tools: foundational, creation and maintenance of flow, and advanced or focused improvement tools. Organisations wishing to maximise their improvements through a Lean methodology should also understand the importance of other continuous improvement tools. Successful organisations such as Toyota are continually looking for additional tools from other disciplines that might assist them in eliminating waste. Quite often defect and variation issues that are not improved through Lean techniques require more sophisticated techniques such as those used by Six Sigma practitioners. The successful Lean implementation will not be constrained by staying within the core toolkit.

The foundational tools of Lean provide maximum improvement in a very short time frame and address the basic organisational, layout and flow problems encountered by most organisations today. The use of these tools is generally found throughout a Lean transformation. Project teams find themselves returning to these basic concepts throughout the Lean transformation – looking for additional opportunities regardless of the number of times Lean technique is applied to an individual area within the organisation.

Table 2: Continuous improvement core toolbox

Continuous improvement tool box				
Lean tools	Pull Systems	Work Cells	TPM	Performance Measurement
	Setup Reduction	Quality at the Source	Continuous Flow	Batch Size Reduction
	Standardised work	Teams	POUS	
	Visual Controls	Value Stream Mapping	5S System	Layout
Six Sigma tools				
Other continuous improvement tools				

The only commonality most project teams find from project to project is the use of value stream mapping and 5S System implementation (outlined below). These two concepts are generally used early in a Lean project cycle, and used extensively throughout the project as well as during the sustainment of improvements. As cultural changes occur, and adoption of the Lean philosophy becomes the new culture of the organisation, these two concepts become a part of every day life.

Value stream mapping: A process mapping technique used to demonstrate both the current state and the future, or ideal, state through a map set (see table 3). Unlike traditional flowcharts or process maps, value stream maps are drawn with the process (product or service) flow always moving left to right on a single page. Subtasks or parallel tasks are drawn below and lined up with the main flow. All communication (both formal and informal) is included, as are all employees seen working within the process. Data such as workload observed, cycle times, labor content time, observed non-value-added time, and travel distance are included. Additional information that may be of importance can also be included in the data boxes that accompany each process step.

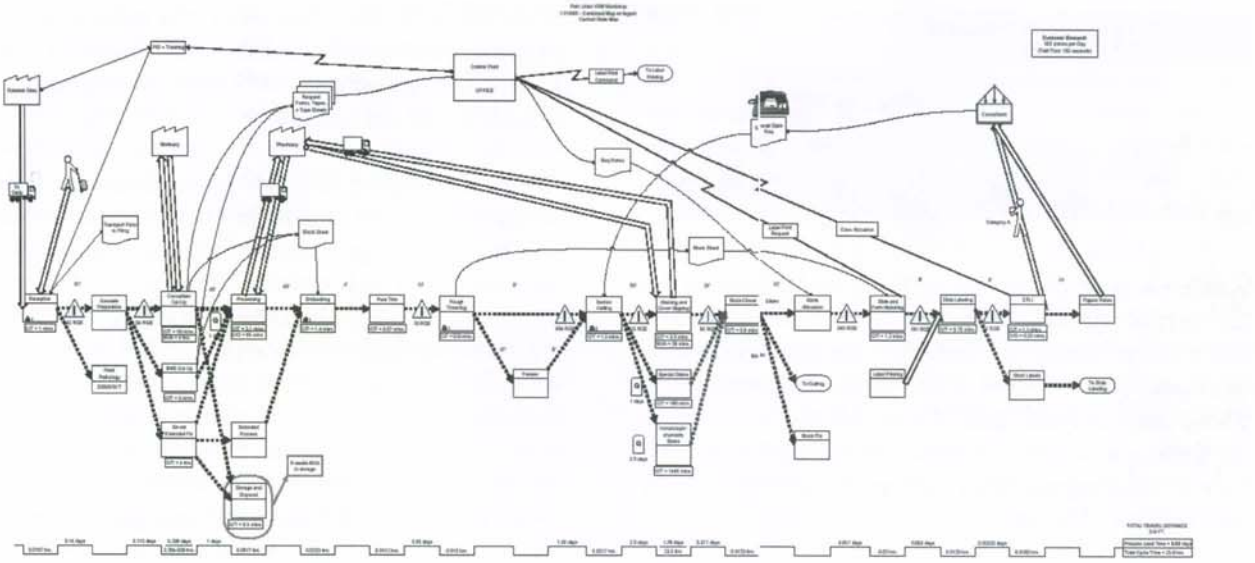
5S System: An organisation and housekeeping system used to create and maintain order within an environment. The system relies heavily on visual aids and controls, as well as placing a strong emphasis on training and a cultural change to create order over controlled chaos. The five S' as translated from the Japanese who developed the system, are:

1. Sort: Sort through and sort out. Eliminate the obvious trash and then remove all items within the area that do not belong. The structure of the system provides for removing questionable items and returning them into the environment if necessary.

2. Set in order: A place for everything and everything in its place. Relying heavily upon visual aids and controls, set in order creates designated positions for all tools, supplies, etc. and controlling the quantity of all such items positioned in the area. The primary benefit from this technique is the efficiency created which allows quick location of all necessary items when they are required to complete a task.

3. Shine: The act of thoroughly cleaning the entire area inside and out. The purpose is

Table 3: Typical current state map from a healthcare facility



not only to make the area look spotlessly clean, but also to provide an extensive inspection of all equipment, supplies, cabinets, etc. looking for potential problems and defects in a proactive manner. Often problems can be identified before they shutdown a process due to total failure.

4. Standardise: Setting rules to enforce the first three S'. The creation of standardised rules, by the employees working within the area, accomplishes both a methodology of 5S housekeeping and ownership in the 5S initiative. It is much more difficult for employees to avoid maintaining the clean and orderly environment when they themselves establish and own the rules by which they must live.

5. Sustain: Changing the culture to embrace and live 5S each and every day. Perhaps the hardest of all the S' to implement and maintain, sustainment requires strong and continual training, auditing, team meetings, communication through newsletters, wall signs, memorandums, etc. Since many cultures emphasise 'work' over 'order', it can sometimes be difficult to embed the concept of more productive work through order.

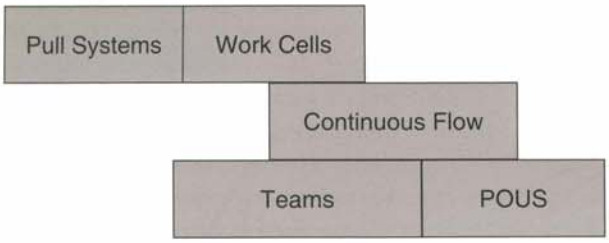
Visual controls: Simple signals that provide an immediate understanding of a situation or condition. They are efficient, self-regulating and worker managed. Visual controls and aids come in many shapes and forms: kanbans (a Japanese word, translating as a sign or system and used to mean a signaling system in English), or replenishment signals, used to inform staff that supplies, forms, reagents, etc., are replenished in an efficient and proactive meaning with minimal communication: colored lines on floors, or colour-coded signs to designate work areas, or direct employees and customers to designated areas: colour-coded bins, trays etc., used to identify certain conditions and marked and labeled areas for placement of tools, supplies or work-in-process.

Standardised work: Perhaps the most basic of all Lean tools, standardised work focuses on doing the same thing the same way every time. In regards to employees completing assigned tasks in this manner, the benefits are threefold: higher productivity over time since repetition will increase speed and throughput of task; improved quality through the natural tendencies of humans to check their work if they are using standardised work and then complete something out of order - if it doesn't feel right, check it – and the ability to estimate the amount of time required to conduct each task (as explained through Fredrick Taylor's *Theory of Time and Motion* which was established in the 1890's). This concept also makes it much easier to train new employees since anyone can train the new employee if everyone is doing the assigned job in the same manner every time the job is done.

Layout: The efficient and orderly physical placement of equipment, workstations, tools and supplies to allow work-in-process to flow through the facility in the shortest and fastest possible travel path. This often requires the elimination of physical walls and departmental barriers.

The second group of Lean tools employed during a Lean transformation focus on creating and maintaining flow. These tools work together in many combinations to develop flow within the process so that work may move through the process in as efficient a manner as possible without stopping or waiting on the next step in the process (see table 4).

Table 4: Creating and maintaining flow



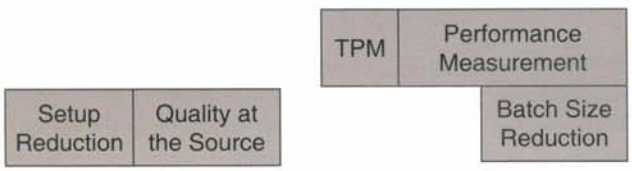
Teamwork is at the center of these tools, looking for the creation of a well-coordinated team working in synchronised fashion to evenly flow the work. Teams use ***continuous flow*** to move product/materials through the process uninterrupted (unit of work by unit of work), or synchronous flow (moving items as far through the process without stopping) when the demand is extremely low or indeterminate in nature.

To assist teams in reducing or eliminating NVA tasks, ***point of use storage (POUS)*** is implemented to place materials, supplies and tools at the point where they are used. Combining POUS with kanbans and other visual controls, it is possible to provide immediate knowledge of the process to both workers within the process and management.

Pull systems establish a condition where the demand of customers tells employees when to work. Once again visual signals are used to communicate to the process that action is required. The goal of this technique is to move required work through the process as fast and efficiently as possible. By calculating 'takt time' (the speed that the work center or cell must operate at to meet customer demand without creating a backlog or bottleneck), and working at or slightly faster than this calculated time, it is possible to level the workload and apply the proper level of workforce and equipment to always meet customer demand. Combining each of these techniques together can create an extremely efficient process.

However, to be truly efficient and effective, all related tasks, both manual and automated need to be combined into a single ***work cell***. By creating work cells it is possible to maximise the throughput while minimising the labor content required to accomplish the task. The optimal design of a work cell is a U-shaped layout where employees work inside the cell. This allows for reduced travel time by the workforce and the ability to float quickly from task to task to assist others or add value to the process where it is needed at any given time.

Table 5: Advanced Lean tools



The final grouping includes more **advanced or highly-focused Lean tools** which are used to address or control specific issues or opportunities that often require significant data collection and analysis (see table 5). The principal tool in this group is ***performance measurement***. This is the creation, analysis and utilisation of a set of metrics designed to provide insight into the improvements made through Lean projects. Lean metrics generally break away from traditional management metrics and focus on such things as cycle times, travel distance, on-time delivery, cycle time versus takt time, and first pass quality. While this is not an all-inclusive list, it demonstrates a new way of thinking, as opposed to the more traditional mind-set of measuring just productivity and throughput.

Setup reduction provides a technique to reduce the amount of time necessary for equipment setups and changeovers. Separating the setup or changeover into internal and external activities, employees can change the setup process to get equipment into a productive state as quickly and efficiently as possible.

Quality at the source is a structured method of providing basic quality guidelines to the employees to ensure that the work handed-off to them meets acceptable minimum quality standards before they begin the process of adding value to the item. Since there is no value in working on a defective product, this is a proactive way to bring all employees into the quality system of the organization, building quality into the process as opposed to working to the point that a defect stops the process, or relying on inspection at the end of the process to catch the error.

Batch Size Reduction aims to reduce the batch size to its optimal size to a) move the work through the process as fast as possible, b) take advantage of one-piece flow when possible, and/or, c) take advantage of equipment capacity when a batch process is required by the equipment. Many Lean practitioners seem to focus on the concept of one-piece flow, but each and every environment will dictate how small the actual batch size can be.

And finally, ***total productive maintenance (TPM)*** is intended to bring the concepts of preventive maintenance, predictive maintenance, and operator involved maintenance together to create a maintenance system that encourages teamwork between operators, engineers and mechanics. The goal is to eliminate equipment downtime as a

waste factor. Management may also elect to incorporate overall equipment effectiveness (OEE) into their TPM system to provide a capacity analysis metric for each piece of equipment. OEE provides a dashboard showing availability, performance efficiency, and rate of quality for the piece of equipment measured. Using this concept, management can make intelligent decisions about how to use, purchase, and/or maintain each piece of equipment in the facility.

Lean applications in healthcare

As interest in Lean enterprise has gained ground in healthcare, there is a growing need to understand how Lean fits in with Six Sigma, Total Quality Management (TQM), and other quality and process improvement initiatives already being used within the industry. But how does Lean work in healthcare, and how and where does it work?

The most basic and obvious use of Lean in healthcare to date has been in the laboratory. Many laboratory staffs have begun to vocalise the similarities between what takes place on the manufacturing floor and what happens in a healthcare laboratory. Specimens (raw materials) are received in the laboratory, work is sent to the floor for production (testing) and a final product (test report) is created and provided to the customer (doctor).

While this may appear to be simplistic in nature, it very clearly demonstrates the ability of Lean to address waste in a laboratory setting. All laboratories focus on turn-around-times (TAT) and quality of results. Lean attacks the waste that causes delays in TAT. Lean methodologically helps laboratory staff eliminate specimens waiting on accessioning of requisitions. It provides basic fundamental concepts to move specimens quickly through the receiving process, centrifugation and on to test analysers.

Using visual controls, laboratory staff can provide an immediate signal when work needs to be undertaken. Additionally, the creation of work cells allows as little as 20% of the staff to complete as much as 80% of the work, freeing up biochemists to work on more demanding tasks.

But just as important, Lean can assist the laboratory in bringing specimens into receiving faster. By focusing on the courier system utilised by the laboratory and applying Lean technique to routes and delivery patterns, work can be received much faster throughout the day leveling the workload to provide a more constant work flow within the laboratory.

Applying similar techniques to phlebotomy can bring work down from the wards in a hospital or draw room to the laboratory with the same end result of level work flow. And using pull systems and kanbans on the wards and in the draw rooms can place the required supplies on-hand for nurses and phlebotomists. When a replenishment signal appears, the card, bin, etc. can be sent back to the laboratory or supply room to replenish before the supply is exhausted.

The tools and techniques of Lean are not new, and they are definitely not new to the healthcare industry. Lean is nothing more than industrial engineering concepts mandated through a top-down initiative and implemented from the bottom up. Management encourages and directs, while staff identifies opportunities and implement them. An industrial engineering technique has existed within the healthcare industry for decades. After all, it was an industrial engineer that first suggested arranging surgical tools on a tray and having the surgeon ask for the specific instrument, which a nurse then placed firmly in the surgeon's hand in the correct position. This was only the beginning of Lean in healthcare, but it certainly will not be the end.

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