

Reducing Errors in the Clinical Laboratory: A Lean Production System Approach

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Why Do We Have Such Difficulty Preventing Errors?

Sometimes we make mistakes in the laboratory. The media has been diligent in reminding us of this. A few years ago, laboratory errors discovered at Maryland General Hospital provided

what seemed to be a bottomless source of copy for *The Baltimore Sun*.¹ Since then, laboratory errors have been the subject of feature articles in *The Los Angeles Times*, *The New York Times*, *The Wall Street Journal*, and *Good Housekeeping*,²⁻⁵ to name a few. Consumers want to know why we have such difficulty in preventing our errors.

Are we not smart enough? Are we lazy? Do we just not care? I don't think it's any of these reasons. I believe the Institute of Medicine provides the answer. Its reports in 1999 ("To Err is Human"),⁶ 2001 ("Crossing the Chasm"),⁷ and 2006 ("Preventing Medication Errors")⁸ all came to the same conclusion: it's not the people. Health care seems to attract some of the brightest, most dedicated, most hard-working people in any industry. Rather, it's the system. We have created a health care delivery system that allows failure, facilitates failure, encourages failure. In fact, our system may make it impossible to function without failure.

Consider the errors that have occurred in your own laboratories. Did they result because people didn't know what they were doing, because they were lazy, or because they didn't care? Or did the causes of those errors have something to do with the system—say, communication or production? Maybe the system abandoned them altogether. Maybe there was no safety net, no component in the system to catch and correct the errors before the consequences of those errors left the laboratory to visit patients.

How Has Our System Failed Us?

In my view, the system upon which we have relied to reduce errors in our laboratories is rooted in benchmarking. Benchmarking requires that we first define measurable indicators of quality for the services we provide, collect data on those indicators, and perform statistical analysis on the data to determine benchmarks of performance. At the same time, we catalog the clinical practices by which we deliver those services. Stratifying

performance benchmarks by clinical practices allows us to deduce which of those practices we believe to be "best." Logic tells us that employing best practices should reduce errors.

Of all the health-based organizations in the United States, the College of American Pathologists (CAP) probably has the most experience with benchmarking.⁹ Since the late 1980s, the CAP's Q-Probes and Q-Tracks programs have conducted scores of benchmarking studies. Participants in these programs claim that these benchmarking programs assist them in identifying weaknesses in their laboratories and help them decide where to invest their error-reducing dollars. Studies have shown that in certain instances, laboratory service providers who monitor quality indicators over the course of years, implementing what they believe to be best practices, do show continuous improvement beyond what might be expected from the Hawthorne effect alone.¹⁰⁻¹³

Two Q-Probes studies dealing with transfusion practices illustrate how benchmarking is intended to reduce errors.¹⁴ In these studies, participants representing more than 650 health care institutions audited almost 16,500 transfusions to measure what the CAP believed to be 2 key quality indicators. The first indicator was the frequency with which health care workers completed 4 key steps in matching patients with their proper units of blood. The second indicator was the frequency with which transfusionists checked patients' vital signs at 3 critical intervals during the transfusions. **Figures 1 and 2** show the results. While participants gathered benchmarking data, they also recorded information about their practices: who transported blood to the bedside, who performed the transfusions, what sort of training programs were available to the transfusionist, etc. **Table 1** lists those practices associated with better performance determined from the data of both studies. Shouldn't setting performance goals based on these benchmarks and employing these best practices result in fewer errors in the laboratory? Not necessarily.

Ideally, we would like our benchmarks to reflect clinical outcomes. For instance, if we are examining transfusion errors, we'd like to measure transfusion reactions or transfusion deaths. However, these events are so rare that it can take years to accrue enough data on their outcomes to draw any conclusions or produce recommendations about them. It might take a lifetime to gauge the effectiveness of interventions designed to make those rare outcomes even more rare.

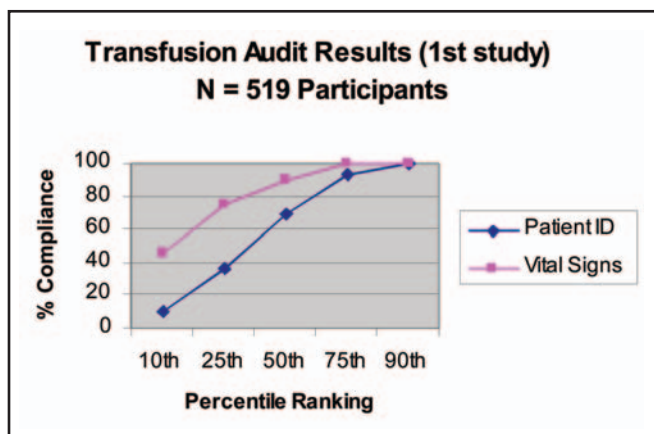


Figure 1_Q-Probes. Percentage of transfusions in which health care workers at 519 health care institutions completed all 4 required steps in patient identification and all 3 required steps in recording patients' vital signs (first study).

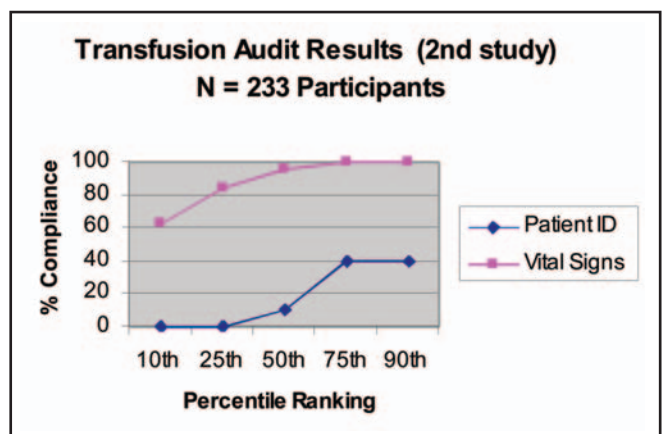


Figure 2_Q-Probes Study No. 2. Percentage of transfusions in which health care workers at 519 health care institutions completed all 4 required steps in patient identification and all 3 required steps in recording patients' vital signs (second study).

Determining Best Practices

Completing all four patient ID procedures
Performing required three VS procedures

- ✓ Routine monitoring of transfusions
- ✓ Nursing/couriers receive transfusion/ID training
- ✓ Transfusionists use checklists
- ✓ Two transfusionists read ID aloud
- ✓ Transporting blood directly to patient bedsides
- ✓ Having only one person handle blood units in route

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Table 1 Practices associated with greater compliance in performing required steps in identifying patients and performing vital sign measurements determined in 2 College of American Pathologists Q-Probes studies.

Instead of measuring outcomes, we measure operational processes—the frequencies with which people perform the tasks they are paid to perform in the first place. Whether or not these specific tasks improve outcomes may be quite another story.

In general, we designate the results achieved by the top performing 5 or 10 percent (95th and 90th percentiles) to be the “benchmark” performance. This is not necessarily the best performance possible, just the performance achieved by the top 5 or 10 percent of participants. In the first of 2 Q-Probes transfusion studies cited above, the 90th percentile performance was indeed perfect and worth emulating (Figure 1). However, if all we had to go on was the second study (Figure 2), we might not be so enthusiastic. It is unlikely that anyone would be content with having their staff perform required identity checks in less than half the transfusions.

To paraphrase the words of Richard Zarbo, MD, Chairman of Pathology and Director of Medical Laboratories at Henry Ford Hospital, who directed the CAP’s benchmarking program for many years, benchmarking may encourage mediocrity. Service providers aim for the 95th, 90th, and perhaps even the 75th percentile rather than settle for nothing less than perfect performance. This mentality seems to be acceptable in health care, but if we were discussing the performance of the braking system in the automobile that delivers your children to soccer practice, it is unlikely that the 90th percentile would be good enough.

Benchmarking encourages intervention retroactively. We tend to question our performance only when it dips below a certain threshold or is triggered by some catastrophe. That’s like having automobile companies examine breaking systems only after, rather than before, we suffer a critical number of collisions.

Improvement under a benchmarking system tends to be painfully slow. We recognize problems, and then monitor their occurrences. We enter cycles of monitoring and intervention that seem to go forever. During those intervals, whatever rotten environment precipitated the problem may fester.

Finally, interventions are often idiosyncratic. Just because “best practices” work for some of the participants in a Q-Probes study doesn’t mean that they will work in your laboratory. In fact, some of the “best practices” employed in the top-performing laboratories were also employed in the bottom-performing

laboratories. It is not always so clear why some laboratories do or do not function well.

Is There Another System Worth Looking At?

Given the shortcomings of relying solely on a benchmarking system to keep us out of trouble, it may be worth our while to investigate other systems that operate to reduce errors. One system that deserves our attention is that developed by the Toyota Motor Corporation. It is perhaps the most copied production system on the planet, copied not just by manufacturing companies, but by service providers, including those in the health care industry.

Applying industrial techniques to the delivery of health care services does not imply turning health care workers into robots and patients into engine blocks. Activities involving people—a hematology technologist identifying a leukemic cell on a peripheral smear or a microbiology technologist identifying a pathogen on a culture plate—must be differentiated from activities involving systems—properly labeling peripheral blood slides and obtaining uncontaminated microbiology specimens. Eliminating medical errors is a matter of improving systems, not people.

Pickup trucks or peripheral smears, the goals of these systems are the same. They all aim to deliver services at low cost, high quality, and in a safe manner (safe both for those using and for those providing the service). These goals should sound familiar. Third-party health care payors have been extolling them for decades. Toyota is worth our study because it achieves these objectives so well. Toyota vehicles are rated among the top in quality, safety, and reliability.^{16,17} What does Toyota know that we don’t? What ideas can the laboratory industry borrow from this car maker?

The success of Toyota is built on a pyramid constructed of 4 blocks.¹⁸ First, at the base of this pyramid, is a sound business philosophy. Second, the philosophy is operationalized by Toyota’s unique production system. Third, the system is driven by Toyota’s most valuable resource, its people. Fourth, at the top of the pyramid, is a culture of continuous improvement that is grown and nurtured by Toyota’s employees. Companies that have not achieved success implementing the Toyota model failed most likely because they tried to build their system on only 1 of the blocks, probably the production system. They did not appreciate that duplicating the success of this car company required building the pyramid using all 4 blocks.

The supporting block, Toyota’s philosophy, is a commitment to sacrificing short-term profitability in order to achieve long-term growth. For instance, companies that deliver TV infomercials for machines that will develop Olympian abdominal muscles or send Internet e-mails for products that will enhance sexual performance are likely focusing on short-term profitability. Those companies might not be around in a year or 2. Contrast the activities of the Chief Executive Officers (CEOs) of these companies with those of hospital CEOs who purchase primary care practices. When a hospital CEO purchases a primary care practice, short term, profitability suffers. However, these CEOs know that unless they purchase these practices, their hospitals may not survive the long term. Commitment to this philosophy at the very top level of management, the hospital CEO and trustees, is essential in successfully driving the other elements of the system.

Toyota’s philosophy is operationalized by the Toyota Production System (TPS). The TPS was developed for Toyota by Taichi Ono, who borrowed heavily from the lessons of W. Edwards Deming and Henry Ford. The TPS was subsequently coined generically as the “Lean” production system.¹⁹ A discussion of the TPS

with all its many components and techniques is beyond the scope of this short article. With regard to reducing errors, 2 principles stand out: eliminating all waste in production and building quality directly into the product as it rolls down the assembly line.

Preventing Errors—Getting Rid of the Waste

Toyota describes 7 cardinal wastes in industrial production, to which Jeffery Liker, author of the classic explanation of the TPS, *The Toyota Way*, has added an eighth²⁰:

1. **Overproduction.** Considered to be the single greatest source of waste in industry, overproduction is characterized by having more inventory presented to a work station than can be processed efficiently. Upstream, work backs up as assemblers toil feverishly to move inventory. Downstream, workers are idle waiting for inventory. This may be not unlike some clinical laboratories at 6 AM when buckets of specimens arrive from patient care units throughout the hospital. Upstream, work backs up as technologists labor to generate test results. Downstream, doctors and nurses are idle waiting for the results so that they can advance the care of their patients.
2. **Unnecessary movement.** Figure 3 demonstrates the flow of work in one laboratory recorded from the time specimens arrived to the time when reports were released. It doesn't take a laboratory or Lean expert to appreciate the unnecessary movement that this spaghetti represents.
3. **Overprocessing.** Reading 1 or 2 admitting notes prior to performing an autopsy on a patient who expired shortly after admission makes sense. Reading a half-dozen notes by the emergency room doctor, house officer, hospitalist, specialist, etc, all of which say the same thing, is overprocessing.
4. **Overstocking.** Stocking an entire shelf of size large gloves in a laboratory in which there are no size large hands is wasteful, excess inventory.
5. **Unnecessary transport.** Shipping specimens from the emergency room at one end of the hospital to the laboratory located at the other may be sending them farther than they need to travel.
6. **Unnecessary waiting.** Waiting for a patient to return from X-ray in order to draw blood wastes phlebotomists' time.

7. **Defects.** Erroneous laboratory reports require repeating the tests and investigating the errors.
8. **Unused employee creativity.** Failing to solicit ideas on how to improve operations from the people who are in the very best position to provide that information is, in my view, the most egregious waste in any industry.

Our most common reactions to waste are “workarounds” and “camouflage:” work around or hide the waste rather than eliminate it. Running out of space in the laboratory? Build a bigger laboratory rather than look for ways to reduce the need for all that space. Short on inventory? Purchase more and clutter the aisles with it rather than reduce the volume of it by timing delivery to meet consumption. Not getting tests out fast enough? Hire more technologists and pay more overtime rather than look for ways to reduce the need for manpower.

How might Toyota-style production engineers deal with waste? First, they would remove all the silos from the laboratory. In general, the laboratory operates in silos: phlebotomy, receiving, processing. Silos only serve to put more distance and steps between operations. In fact, whenever we step into someone else's silo, we represent something of an intrusion. The engineers would tell us that we should all be operating in 1 silo, each of us doing 1 piece of the same job.

With the silos removed, the engineers would next diagram the flow of production from the time specimens enter the laboratory to the time reports are released (Figure 4). They would examine each step of the process and determine which ones do and which do not provide value to patients. For instance, drawing blood, recording specimen information, processing tests, and putting test results in the hands of physicians all provide value to the patient. Moving the specimen from one point to the next, waiting for instruments to be available for testing, and rewriting test results provide patients with no inherent value. Finally, the production engineers would eliminate as many nonvalue steps as possible. They would not attempt to truncate any of the value-producing steps. Indeed, technologists would like to spend more time looking at blood smears and culture plates. The benefits to efficiency and profitability of reducing wasted steps are obvious, but what does it have to do with reducing errors?

Every wasted step removed from the process takes with it another opportunity to make an error and generate a defect. For instance, in the transfusion audit study cited above, removing wasted

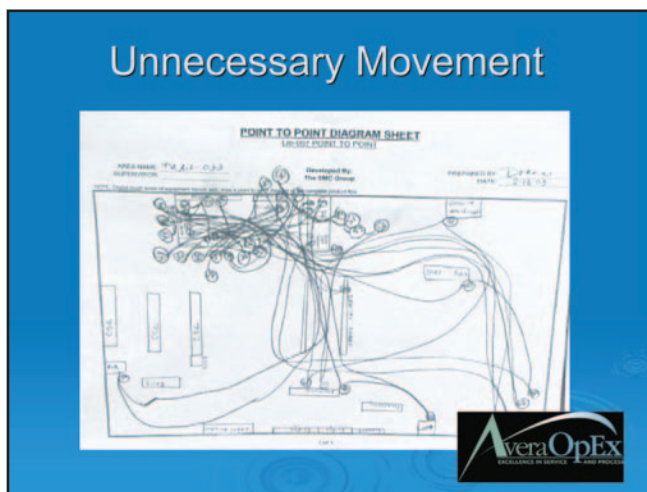


Figure 3_Movement of specimens in a laboratory.

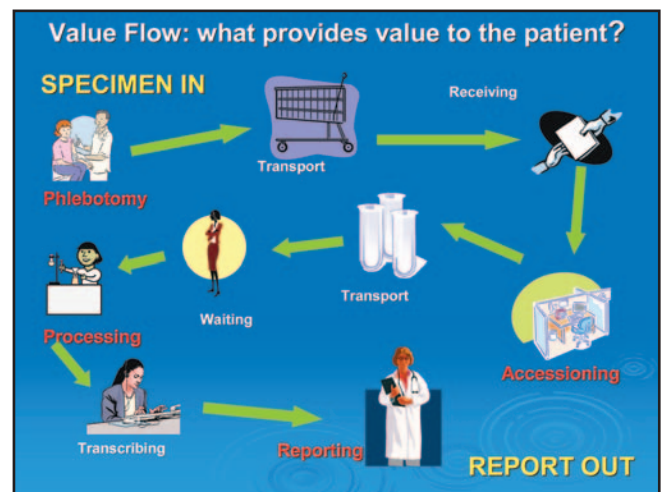


Figure 4_Value flow in the laboratory.

steps—transporting blood directly to patients' bedsides rather than allowing the courier to make several stops along the way, and having only 1 person handle the products rather than allowing units to pass through multiple sets of hands—was associated with fewer processing errors.

A more dramatic example of how elimination of wasted steps reduces errors is provided by investigators at the University of Michigan. They attacked inefficiencies in the process of inserting percutaneous intravenous catheter (PIC) lines. Prior to their intervention, the intervals necessary to complete insertion of PIC lines, measured from the time physicians wrote orders to place the lines, ranged from 1.5 to 4 days. After wasted steps were removed, order-to-insertion time dropped to 7 to 10 hours. Even after cutting the total procedure time dramatically, the amount of time spent on value-laden activities, that one-on-one time that doctors and technicians spent with their patients, increased by 10 percent. To gauge the frequency of errors, the researchers measured "first time quality," that is, the frequency with which the procedures went without any hitches. The measurement of first-time quality went from getting it right 1 out of 3 times to performing error-free procedures almost 9 out of 10 times.

Preventing Errors From Reaching Patients—Making Errors Visible

Removing waste from production reduces the potential to make errors. Building quality into the product directly as it rolls down the assembly line prevents errors from reaching patients. This is accomplished by making errors visible as soon as they occur. Once identified, defects cannot be ignored. They must be corrected immediately before they are passed on to the consumer.

This principle emanated from Sakichi Toyoda, whose inventive vision fueled the development of the Toyota Motor Corporation.²¹ At the beginning of the 20th century, Toyoda was in the textile business. He invented a loom that shut down if a thread broke. Perhaps not Nobel Prize-winning technology today, but in 1929 this was a giant step forward in mistake-proofing. Until that time, the thread would break, the loom would keep running, and it would take the rest of the afternoon to sort out the mess.

In today's modern production, this mistake-proofing is achieved through 2 principles: standardization and redundancy. Standardization means doing the same job, the same way, every single time. The assembler is not allowed to improvise because idiosyncratic improvisation is a virtual land mine for errors. Redundancy of tasks as described here means catching defects that sneak past standardization before those defects can be passed on to customers. This is essential because no matter how tightly we standardize our procedures, no matter how hard we try to get things right, something is bound to go wrong. A system that does not expect, recognize, and prepare for this, or a system that attempts to reduce defects only by trying to build better assemblers, will never duplicate the quality level achieved by this automobile company.

In the factory, standardization means parts that are color-coded and that fit together one way and one way only. It means protocols that describe a worker's every movement right down to the details of how many degrees torsos may turn and how many centimeters arms may reach. Chassis fit on the conveyor in only one position. It is easy to see that if the music of the assembly line becomes dissonant, the dancers are immediately thrown out of step, must stop, and correct whatever is not right.

In the clinical laboratory, instruments also have color-coded parts that fit together one way only. Laboratory professionals are

perhaps the masters of protocol and procedures in the health care industry. Certainly there are areas for improvement, such as in the application of standardized reporting templates, but with regard to standardization, at least in the laboratory we "get it." Redundancy is another story.

For those errors that get past standardization, the goals of redundancy are to decrease the intervals between when errors occur, when they are detected, and when they are corrected. Building redundancy into a production system is a matter of taking a step back, looking at what we've done, and determining whether or not our work has provided the consumer with value.

One way to build redundancy into the system is through inspections. Inspections have been divided into 3 types: judgment, informative, and source.²² Judgment inspections are postmortem exams. A disaster occurs, after which data is collected in order to perform root-cause analysis. Root-cause analysis is certainly an important technique in eliminating errors, but as the only technique employed, it is not adequate. First, intervention is too late. The damage has already occurred. Second, the intervals between when errors occur and when all the doctors, nurses, and administrators can find time to sit down and talk about the error are likely to be quite long. During those intervals, rotten environments persist.

Finally, the targets of repair tend to be overly focused. Medical disasters almost never result from just 1 mistake. They result from the perfect alignment of all the holes in the sliced Swiss cheese. We end up writing protocols for a confluence of occurrences that we may not see again for another decade. The manufacturing industry has long recognized that of all types of inspections, judgment inspections have the least value in reducing defects. In the health care industry, judgment inspections seem to be the type of inspections that we employ most commonly in our attempts to get a handle on errors.

Informative inspections are designed to decrease the intervals between when errors occur and when they are corrected. Preferably, informative inspections correct defects before they are passed on to consumers. There are 3 types of informative inspections: statistical quality control, self-checks, and successive checks. Statistical quality control is what occurs every day in laboratories. If test controls are not in range, results are not reported. No report, no error. Reports are not issued until controls are back in range. Statistical quality control works well, but only on those tasks in which numbers are generated. They don't work with the sorts of subjective tasks that many of us deal with routinely in health care.

Self-checks are what we learned from our third-grade teachers, "remember to check your work before you hand it in." Self-checks are effective, but are useless if we forget or won't make time to do them. Moreover, we may not be the most unbiased critics of our own work.

Successive checks require workers to inspect somebody else's work. Before we start turning wrenches on the assembly line, we make sure that the last person who worked on the chassis did her job and did it correctly. Successive checks have been shown to reduce manufacturing defects by 90%.²³ There are a few, and only a few, reported examples of successive checks used in the laboratory. In the transfusion study cited above, the use of checklists (an example of both successive check redundancy and standardization), and having 1 transfusionist read patient identification information to another before starting transfusions were associated with fewer process errors. Several investigators have shown that having one pathologist check the work of another before tissue diagnoses are released to clinicians results in fewer diagnostic errors.²⁴⁻²⁷

Source inspections are the ultimate goal of redundancy. They represent standardization so complete that retrograde inspection

itself becomes unnecessary: workers detect errors before defects can occur. For instance, a radio frequency device (RFD) may be placed into a machine part. If the part is not installed, or not installed correctly, electrical circuits are completed, whistles blow, production stops, and the defect must be repaired before the conveyor resumes operation. There are a few, and again very few, examples of source inspections in the laboratory. Radio frequency devices are finding their way into wristbands. Electronic circuits will not allow point-of-care glucose instruments to operate unless quality control has been performed and the controls are in range.

From Factory to Laboratory

Toyota's model has changed production techniques in many industries. In order to see how things are now different, it is necessary to see how things used to be, at least since the beginning of the industrial age. Although the examples that follow deal with manufacturing of cars and television sets and widgets, the message they bring is universal: production in laboratories can mirror production in factories.

Traditionally, work has been organized in a "push, queue, and batch" system (Figure 5). Suppose a manufacturer receives an order for 20,000 television sets. He borrows money from a bank

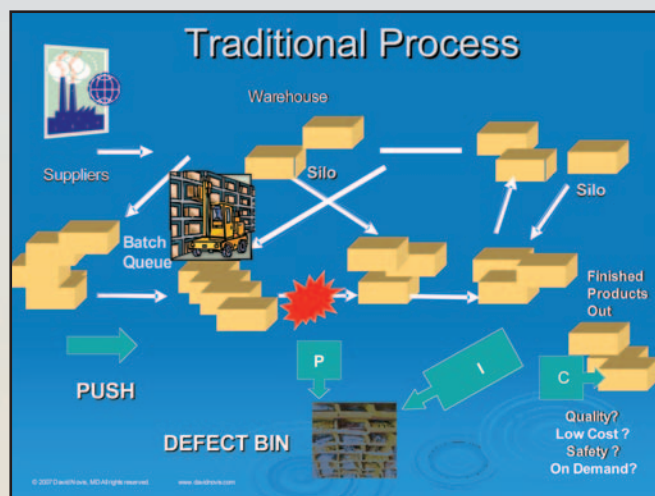


Figure 5 Traditional manufacturing. P: production; I: inspection; C: consumer.

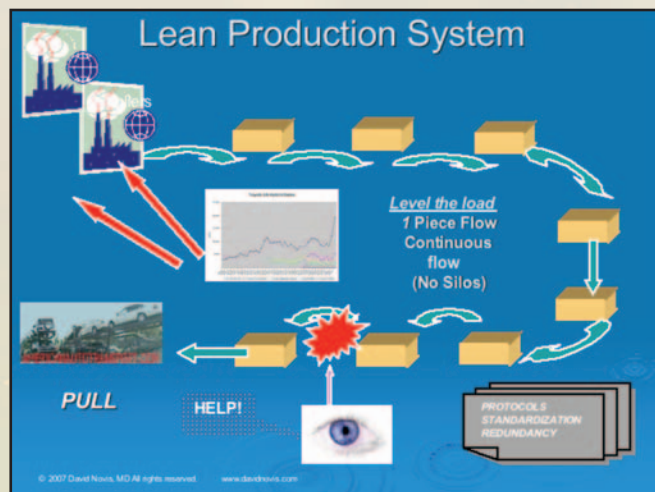


Figure 6 Lean manufacturing.

to purchase parts from suppliers, rents a warehouse to store the parts, and hires workers to assemble them. Interest accrues as the warehouse fills and workers wait for all the parts to arrive so they can begin production. Finally, everything shows up, perhaps late as they so often do in manufacturing. Workers now gear up for the tsunami of inventory that waves through the plant. Upstream, workers toil madly as batches of inventory queue up at their workstations. Downstream workers are idle waiting for inventory to arrive. Because so much work is done in silos—bending in 1 silo, welding in another, painting in a third—waste and inefficiency are compounded. As the inventory takes a scenic tour of the factory, it backs up at each silo. This is not unlike what occurs in many clinical laboratories at 6 AM.

This system does not allow workers much time to deal with defects. They have inventory to move. They toss their mistakes into defect bins. Not only does this waste resources, the cause of the defects remains unsolved and assemblers can expect to see similar defects throughout the day. If defects are not spotted during production or inspection, they go out to customers. Bottom line: low quality (defective products are released to customers), high cost (tossing inventory and backing up at silos wastes effort and inventory), poor safety (unsafe for workers toiling overtime and unsafe for consumers receiving defects), and late deliveries (start late, end late).

Toyota uses a "pull, single unit flow" system (Figure 6). Their production starts several years in advance. Working with their distributors and customers, Toyota estimates what it expects demand for its cars will be. This is not a static number. Estimates are redrawn yearly, monthly, weekly, right up to the time of production. The information is not kept a secret. It is shared with Toyota's suppliers and with their suppliers. Everyone gears up together in a deliberate, orderly, efficient manner—1 big silo.

What might this system look like in a hospital? Perhaps the laboratory staff might have continuous access to patients' presenting complaints as those patients register in the emergency department. True, presenting complaints are not always so accurate, but over the course of time, statistics will work in the laboratory's favor. Experience will tell laboratory workers what sort of work they can expect that day and plan accordingly. The alternative? The alternative is having a bushel of specimens dumped onto the receiving desk, mobilizing people and resources precipitously, working frantically to process the work, hoping that errors are not being generated in the rush, and all the while trying to keep at bay impatient doctors calling for results.

Once Toyota knows how many cars it needs and the period of time over which it must deliver them, it becomes a matter of simple division to determine how fast to set the speed of the conveyors in order to produce 1 vehicle at a time in a safe, controlled, orderly fashion. What makes this a "pull" system is that as the last car is loaded onto the delivery vehicle, the last worker pulls the almost completed chassis forward for that last inspection. The next worker, seeing that chassis disappear, pulls forward the next one for the final turns of wrench. And so on right up to the front of the line, back to the suppliers, and back to their suppliers—1 single, continuous chain of work processing 1 unit at a time. The system is facilitated by the absence of silos in the factory. If 5 drill presses, or for that matter 5 glucose analyzers, are required to make this happen, 5 drill presses or glucose analyzers are purchased. If extra factory deliveries, or extra couriers, are required to keep the flow of specimens arriving into the laboratory in a steady unit flow, then extra couriers are engaged. This is sacrificing short-term profitability in order to achieve long-term goals

Defective inventory is not thrown into defect bins. Workers are given time to spot and correct defects, but if a chassis migrates past a critical point on the conveyor, the worker pulls a cord to stop the line. The stoppage summons a supervisor. If the 2 of them cannot solve the problem, engineers are brought onto the floor. They perform the necessary root-cause analysis, but root-cause analysis on a problem that occurred 5 minutes ago, not 5 weeks ago. As inventory is exhausted upstream and downstream, additional conveyor segments come to a halt. Any assembler is empowered with the ability to shut down the entire line. This is not just a matter of salvaging 1 part. The engineers want to diagnose the cause of the problem so that there will be no more surprises later in the day.

If any assembly worker is allowed to shut down the line, how does the factory ever get any work done? Anyone who has ever worked the night shift in a busy laboratory probably knows the answer to this. Problems encountered but ignored at 2 AM don't go away by themselves. They have a nasty habit of reappearing at 8 AM, only now more disruptive. Any supervisor who's had to discuss a "lost" specimen with an irate doctor knows it's a lot easier to track down and repair the damage if the incident occurred 10 minutes ago than if it occurred 10 weeks ago.

Maximizing the Effort of Your Most Important Resource

The system works because the people on the assembly line make it work. Toyota goes to great lengths to maximize the effort of its No. 1 resource, its people. Toyota starts with getting the right employees on board. Candidates for employment do not show up for interviews on Monday and receive locker assignments on Wednesday. Applicants are not hired indiscriminately just to fill holes in schedules. They must undergo months of interviews and testing. Toyota endeavors to hire only people it believes will be committed to the ethic and culture of the company.

In turn, Toyota makes a commitment to its employees. No one is fired because of economic downturns or automation. Workers are cross-trained as necessary. Technology is used to support workers, not replace them. Candidates are not passed up for promotion. Toyota grows leaders from within rather than hire from the outside.

Once the right people are on board, secure in their employment, and empowered to initiate improvements in the jobs they do every day, management does not have to instill in them a culture of continuous improvement. The employees instill that culture themselves. The military analogy depicted in **Figure 7** demonstrates the philosophy.²⁸ Before the battle starts, it is the general who transmits orders regarding strategy and goals down through the ranks to the enlisted men and women. After the shooting starts, the triangle flips. Now, the enlisted men and women transmit their needs up through the ranks to the general, who can supply them with whatever they need to achieve the goals.

Hypertherm, a company in New England that manufactures arc welders, provides a stunning example of this culture and how it works. Hypertherm employs 700 people, makes its products in the United States, and commands 3 quarters of the world market for the type of welder they manufacture. For several hours every month, workers are pulled off the line and paid not to make arc welders, but to brainstorm ways to improve the operation. They design experiments to improve safety, reduce errors, be more efficient, and reduce overhead. They develop outcome metrics to test their hypotheses. They don't have to convince top management

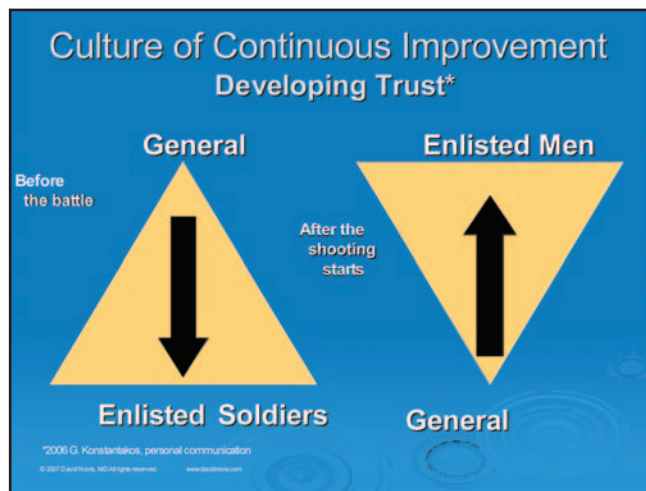


Figure 7 Empowering employees, developing trust, and building a culture of continuous improvement.

to allow them to perform the experiments, they just need to convince the people sitting around the table. This is a culture of error reduction that is proactive (nobody waits for errors to occur before thinking about how they can eliminate them), blameless (no error, no blame), and perpetual (just because they improved some aspect of production last month does not mean they can't try to improve it further still this month).

The system required rigorous leadership, organization, and discipline to sustain it, but the results have been impressive. In 2005, these 700 employees offered 2,500 suggestions to improve production, 1,800 of which were incorporated into factory operations. In 2004, the numbers were about the same, as they were in 2003. This merits asking the question: last year, how many of your laboratory employees came forward with how many ideas to improve safety or reduce errors?

How Do You Get Started in the Laboratory?

Implementing this system in the laboratory starts with commitment from top management, namely the hospital CEO and trustees. They must appreciate the necessity of sacrificing short-term profitability in order to achieve long-term growth. They must be willing to abrogate tactical decision making and leave it to those employees who exercise those tactics every day. If top management is not sold on the system, then convincing them of its value is the place to begin.

Once top management is on board, the staff must be educated. The process of education serves not only to familiarize the staff with the application of TPC techniques, it also provides an opportunity to identify "change agents." Change agents are those bright lights who grasp the vision, become passionate about what it can accomplish, and will work hard to see it succeed. They are the "right people" to have on board.

Change agents provide the leadership. They select areas of the laboratory to improve and form teams of employees to execute the improvement. The teams diagram the current states of work flow, identify those processes that do and do not provide value, devise plans to remove wasted steps, and build methods to catch and eliminate errors. The teams also formulate outcome metrics and set performance goals by which to evaluate their success. Once

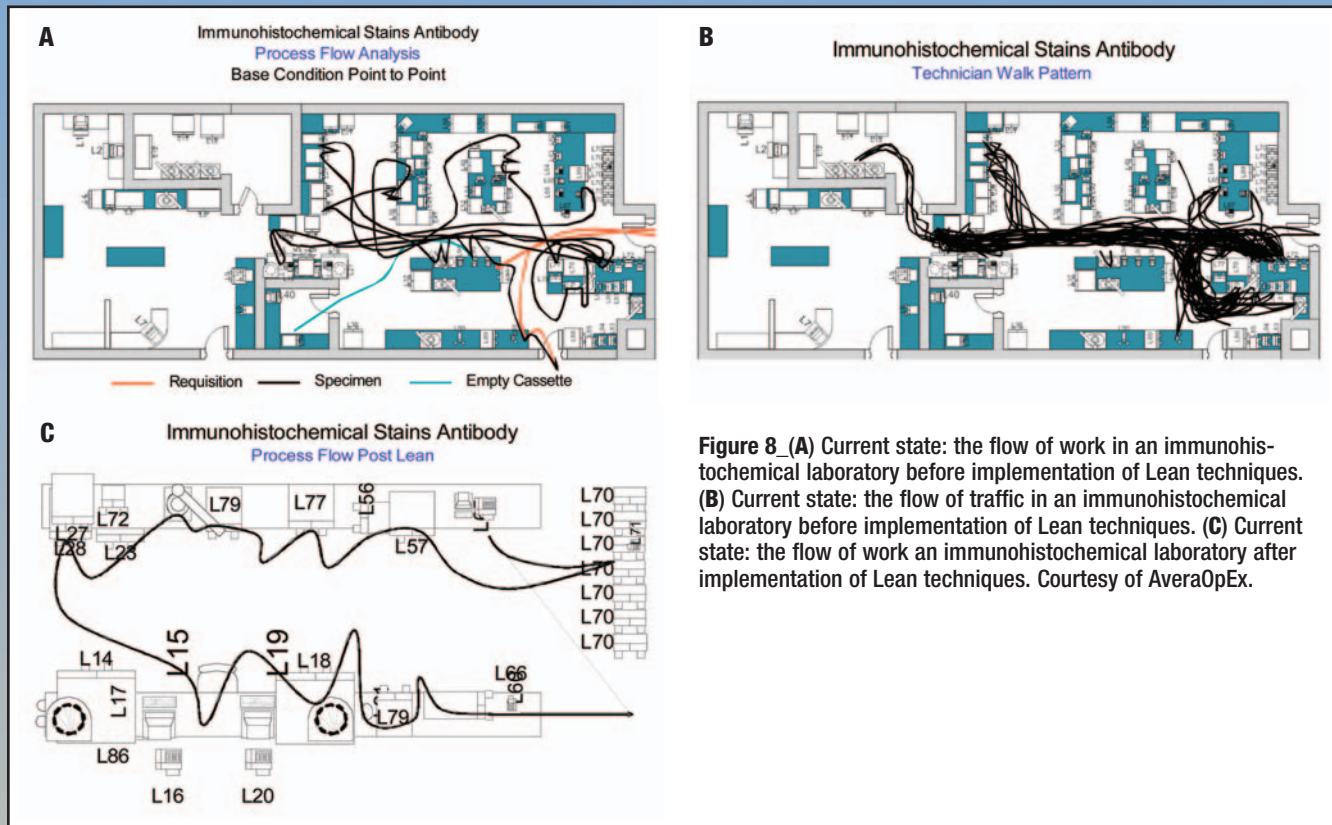


Figure 8 (A) Current state: the flow of work in an immunohistochemical laboratory before implementation of Lean techniques. (B) Current state: the flow of traffic in an immunohistochemical laboratory before implementation of Lean techniques. (C) Current state: the flow of work in an immunohistochemical laboratory after implementation of Lean techniques. Courtesy of AveraOpEx.

everyone agrees to allowing the data and not their presumptions to drive their actions, the teams implement their plans. **Figure 8** shows the diagrams of work and traffic flow before (**8A** and **8B**) and after (**8C**) waste-reducing measures were instituted in an immunohistochemical laboratory.

Perhaps the biggest mistake that hospital and laboratory managers can make is to assume this is a 1-time event, some science project that has a beginning and an end. There is no end. As dramatic as the improvement may be, there is always room to improve on it further. There is always room to extend the silo to encompass other areas of the laboratory, and then extend it again beyond the laboratory walls to other departments in the hospital.

Unfortunately, most data demonstrating the value of implementing Lean production techniques in reducing laboratory errors is proprietary and has not made it into the literature. Perhaps not everyone wants to share their error rates with their competitors or every malpractice attorney in their state. Raab and colleagues reported reduced error rates in reaching diagnoses on Pap smears and thyroid aspiration smears following institution of Lean production techniques.²⁹ Zarbo and coworkers applying Lean techniques in a large tissue laboratory reduced the rate of defects (the potential to generate errors in surgical pathology reports) by 55%.³⁰ A CAP Q-Probes study showed reductions in pathology tissue reporting errors among laboratories implementing successive inspections.³¹

Our patients are demanding that we do a better job reducing errors in our laboratories. Medicare says it will no longer reimburse hospitals for medical errors.³² Third-party payors³³ and state hospital associations^{34,35} have followed suit. We need to think of other ways to mistake-proof our laboratories. The system developed by Toyota seems to be one that is worth our attention. LM

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