

Reducing Errors in the Practices of Pathology and Laboratory Medicine

An Industrial Approach

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Abstract

The use of quality benchmarking and performance tracking techniques has been successful in reducing errors in the practices of pathology and laboratory medicine. However, techniques developed in the manufacturing industry, specifically those pioneered by Toyota Motor have been more efficient and effective in reducing errors than those developed in the health care industry. We discuss some of those techniques and draw analogies as to how they might be applied in the laboratory.

Traditional Approach to Error Reduction: Benchmarking and Best Practices

For more than a decade and a half, the College of American Pathologists (CAP) has defined the nature of quality in the practices of laboratory medicine and anatomic pathology through its quality benchmarking Q-Probes program. By using these data collection tools, voluntary participants representing heterogeneous groups of hospitals and practice environments located in all geographic regions of the United States have measured standard parameters of quality. In each of these studies, enormous amounts of data were collected during periods lasting weeks to months. From these data, CAP statisticians have established benchmarks of laboratory performance. Participants have been able to gauge their performances relative to those of the national benchmarks determined in these studies and those of their peers participating in the studies. In each study, participants also have provided general information describing how laboratory services are provided in their institutions. CAP statisticians have used these data to determine which laboratory and professional practices are associated with superior outcomes.¹⁻⁵

For example, 2 Q-Probes studies examined the frequencies of the following: (1) completion of 4 standard components of patient and blood unit identification before performing blood transfusions and (2) performance of required vital sign monitoring during the transfusions.⁶ Participants representing a total of 600 hospitals audited 16,494 transfusions. The median frequencies with which health care workers performed all patient identification and monitoring procedures ranged from 10.0% to 69.0% and 90.2% to 95.0%, respectively, in both studies. Individual practices and/or institutional policies associated with greater

frequencies of completed patient identification and/or vital sign monitoring included having patients wear identification tags (eg, wristbands) before transfusions, using written checklists to guide the administration of transfusions, and having health care workers routinely audit the administration of transfusions. At the time of this writing, more than 120 Q-Probes studies conducted in thousands of hospitals and independent laboratories located mostly in the United States, as well as elsewhere in North America and abroad, have established scores of performance benchmarks.⁷

Several Q-Probes studies have examined the occurrence and prevention of errors in the practices of laboratory medicine and anatomic pathology.⁸ For example, 1 Q-Probes study examined the frequency of errors appearing in surgical pathologic diagnoses. Pathologists representing 359 institutions calculated their amended surgical pathology tissue report rates, defined as the rates with which second reports were issued for the purposes of correcting errors present in reports released previously.⁹ Of the 1,667,547 surgical pathology cases reviewed, the aggregate mean amended report rate was 1.9 per 1,000 cases. Lower amended report rates were associated with routine review of all cases by second pathologists before rather than after finalization of pathology reports.

That this approach to improving performance and reducing errors is successful has been documented in the CAP's companion Q-Tracks program. In this voluntary subscription program, participants collect during a period of years data on selected performance indicators. During their enrollment, participants track improvement in their performance of these indicators following whatever quality improvements they choose to implement. The results of these studies have shown quality metrics to improve continuously throughout the entire period during which participants were enrolled.¹⁰⁻¹⁴

Shortcomings of the Traditional Approach

As successful as it has been, the benchmarking and tracking approach to performance improvement, specifically with regard to reducing errors, is not perfect. First, improvement often proceeds at a snail's pace. Because catastrophic outcomes resulting from errors occur relatively infrequently, quality outcome data must be accrued during protracted periods to determine whether practice interventions have improved outcomes. Worse, environments that may breed errors are allowed to persist as health care workers labor deliberately to alter them. Progress is painfully slow.

Second, the system allows health care workers to set targets that are suboptimal—usually at the 90th or 95th

percentiles—rather than tolerate nothing less than perfect performance. For example, in the Q-Probes study of compliance with transfusion safety practices,⁶ participants in the top performing 10% of the 660 participating institutions (90th percentile) adhered to their own standardized patient identification protocols during 93% of the transfusions. In other words, in 7% of transfusions administered in the “best” performing hospitals, protocols designed to prevent misidentification of patients (and, hence, transfusion reactions) were not followed.

Another confounding circumstance in our efforts to reduce error is consumers' equation of errors with malpractice.¹⁵⁻¹⁷ Customers of health care services tend to connect dots between untoward events and individual culpability. Such notions may lead laboratory directors to think that they should be building better products, say pathology reports, by building better, smarter pathologists. This may not work. At least it has not been shown to work well in other industries.¹⁸ More reliable ways to reduce errors may be to create work protocols that are designed not only to prevent mistakes (such as incorporating diagnostic checklists)^{19,20} but also to provide redundancies and safety nets to catch and correct them when they do (such as prospective review of surgical case material).²¹⁻²⁴

An Industrial Approach to Error Reduction: The Toyota Production System

It may be time to turn the page on systems that attempt to reduce errors retrospectively and that settle for anything less than perfect performance. The manufacturing industry provides such models. In discussing these models, we distinguish between what constitutes provision of health care services, for which we believe manufacturing models may be applied, and the practice of “doctoring,” for which we believe they may not. For example, selecting tissue to submit for histologic sections, examining tissue under a microscope to arrive at a diagnosis, and discussing the implications of diagnoses with clinicians is doctoring. Sending tissue that is well fixed and ready for examination from the operating room to the laboratory, delivering well-stained histologic sections in a timely manner from the histology laboratory to pathologists, and supplying pathologists with all the necessary patient histories and other data by which to make diagnoses are essential components of providing health care services.

Manufacturing models that may be applied to the health care industry are those provided by Toyota Motor. Why Toyota? Toyota has made a science of analyzing and optimizing processes. The vehicles it produces are among the

highest quality in the industry.²⁵ Toyota's factories are among the most productive and safest while achieving the lowest defect rates in the automobile industry.²⁶ Toyota attributes its success to the implementation of its unique Toyota Production System (TPS), also known as the "lean production system," which it began developing in the 1950s. Other companies and industries that have embraced the TPS have been able to duplicate Toyota's success.²⁶

There is no reason to believe that the principles of the TPS cannot be applied to reducing product defects or errors in the practices of pathology and laboratory medicine. Processes of any industry share commonality. The organization and development of a process by which a factory produces engine transmissions is not fundamentally different from that by which a laboratory produces blood glucose results or by which a pathology department produces surgical pathology reports.

The cornerstone of the TPS's lowering of product defects is its relentless focus on the elimination of waste in its processes. As former Toyota honorary chairman Shoichiro Toyoda said during the height of the 1973 energy crisis, "Waste is anything other than the minimum amount of equipment, materials, parts, space, and worker's time which are absolutely essential to add value to the product."²⁷ Every unessential step in the production of goods or the provision of services that can be eliminated removes with it opportunities to make errors or generate defects. Indeed, the longest duration of time spent on any process is consumed by wasted time, space, and energy. The duration of the process that contributes to actual value provided to and/or perceived by the "customer" using the product—be it an efficient automobile for a commuter or a cogent pathology report for a surgeon—is relatively short.²⁸

Implementation of the TPS uses 2 principles by which waste and, hence, opportunities to make errors are eliminated: "Just in Time" (JIT) production and *jidoka*. JIT production means supplying a product or service, one at a time, just as it is needed by the customer. When a customer demands and receives a product or service, production of its replacement begins, flows, and does not cease until the product or service is available to the next customer. In other words, a customer driving a Camry off the dealership lot triggers the construction of another Camry at the factory. Once construction of the new vehicle is initiated, the automobile and all of its subcomponents progress down the assembly line in nonstop sequence. All parts and subassemblies arrive on the production line moments before they are consumed. The chassis and its parts are never allowed to stop moving until the entire car is completed. Bottlenecks caused by accruals of unfinished inventory are not allowed to occur. There is no wasted motion or material. JIT production has been successfully implemented in the production of daily

surgical case material and has been shown to reduce errors in diagnoses of gynecologic case material.²⁹

Jidoka refers to building quality directly into products as they are manufactured. At Toyota, this means the immediate detection and correction of errors. Standardization of parts and rigid operational protocols make deviations from desired outcomes obvious. Workers are able to detect errors and product defects immediately. When errors are too large for single workers to repair, the workers are empowered with the authority to shut down production assemblies altogether and to engage other work team members to correct the problems. Root cause analysis and problem solving take place minutes after errors occur. Long-term fixes are implemented immediately. Once all contributors are satisfied, work resumes.

In laboratories and pathology departments, standardization and rigid operational protocols may be accomplished with checklists and pathways. Error detection may be improved by redundant procedures such as reviewing critical laboratory values or surgical pathology reports before they are released to clinicians. Error correction may be accomplished by root cause analysis performed immediately, rather than at some time after erroneous results have inadvertently instigated therapeutic misadventure.

Detecting and Reducing Errors Through Inspection Process in the Lean Enterprise

Inspecting processes and outcomes for the purpose of eliminating errors requires an understanding of inspection techniques and an understanding of how workers may be empowered to temporarily suspend operations when inspections detect errors. At Toyota, inspections are classified into 3 types: *judgment inspections* find defects, *informative inspections* reduce defects, and *source inspections* eliminate defects.

Judgment inspections determine when an error is made and what impact the error has on products or services. Judgment inspections have relatively little value in reducing errors and lowering defect rates. This inspection is a post-mortem examination. It is conducted after defects occur and are caught by some screening process. Their only usefulness is to provide information for subsequent root cause analysis.¹⁸ In the practice of laboratory medicine, such inspections and root cause analyses might be performed weeks or months after the occurrence of a blood component labeling error. During those protracted intervals, uncorrected defects present in transfusion protocols may allow for similar errors to occur. This approach to inspection and error reduction is not uncommon in the health care industry.

Informative inspections are performed as soon as defects occur. Information concerning defects is fed back into the

work process immediately so that they can be corrected before they have opportunities to generate mischief. Informative inspections are effective in permanently reducing defect rates over time.¹⁸ There are 3 types of informative inspection: statistical quality control, self-check systems, and successive check systems.

As in the clinical laboratory, statistical quality control charts call attention to production metrics and tolerances that drift out of range. Workers use this information to correct offending processes. Statistical quality control is applied to processes that are measurable by specific analytic tools, such as assaying high and low serum glucose standards. They are not applied to processes in which inspections must be sensory, such as visual inspections of phlebotomy sites.

Self-check systems describe inspections that are conducted immediately following the conclusion of single operations. They allow instantaneous correction of offending operations. However, because they are performed by the workers who also performed the operations, the assessments may be biased. Self-check systems also depend on workers to remember to perform the inspections. In the clinical laboratory, technicians may forget to verify critical value results before calling them to the clinicians. In the pathology laboratory, pathologists may not be objective in reviews of their own case material.

Successive check systems describe the inspection of all critical characteristics or outcomes derived from previous steps of the production process. This inspection becomes the first step in the subsequent operation. If defects are detected, the process stops, information is fed back immediately to those responsible for the offending operation, and countermeasures are instituted to correct this and subsequent defects. Successive inspection has been shown to reduce defects by 80% to 90% within the first month after being initiated.³⁰ For example, in the clinical laboratory, successive check systems are used to verify patient identities before transfusing blood components or calling critical values. In the practice of pathology, similar redundant systems may be used to verify patient and slide identities before making diagnoses.

Source inspections detect errors, or at least the possible causes of errors, *before* they have the opportunity to generate product defects. Detection of error conditions allows workers to modify systems immediately to prevent defects from occurring¹⁸; with successive defects, inspection of the process and errors takes place before rather than after the completion of manufacturing. For example, at Matsushita Electric, a unique electronic device accompanies each item (eg, component, manual, warranty document) placed into the product's package that will eventually go to the consumer. At the site where the package is sealed, the electronic devices trigger indicator lights on a control

board. If the box does not contain all of its proper components, corresponding indicators will fail to light, the automatic box sealer is deactivated, and a bell sounds. The missing components are added before defects (missing parts or manuals) are passed on to customers. For several years after installing this source inspection, Matsushita's packing operation remained free of defects.¹⁸ In the hospital, point-of-care glucose analyzers will shut down and not function unless operators perform required quality control functions.

Challenges of Implementing the Toyota (Lean) Production System

Some company managers are unsuccessful in their attempts to implement lean production systems. Possibly, they believe that lean production is solely about implementing improvement tools and protocols. In reality, the science of creating lean processes is actually quite simple. But lean production is more about learning and building culture than it is about turning wrenches. Managers who fail at lean production may not be committing themselves to the rigorous and persistent education that is so essential to implementing the TPS. Improving services and reducing errors cannot be sustained without the understanding that the success of the TPS in driving process improvement requires respecting the human dignity of the workforce. Hospital administrators will achieve partial but not maximum success in implementing lean production with anything less than total commitment to the people who are operating that production. In the words of Taiichi Ohno, cocreator of the TPS, "People don't go to Toyota to 'work' they go there to 'think.'"³¹

Another possible cause of failure is that corporate leadership may expect immediate bottom-line results. It is not wise for laboratory directors to tell their administrators that overhead can be lowered profoundly and instantly by instituting 1 or 2 changes in laboratory processes. Senior management must be in it for the long term. True, modest bottom-line results may begin soon after adoption of lean techniques, but significant lasting improvements in profit likely take a year or more to realize.

Twelve Steps Essential for Developing a Lean Enterprise

How do laboratory managers and pathologists transform their laboratories into lean operations? Implementing lean production systems follows a sequence of 12 basic steps:

1. Commitment from top executives. The top executive and managing staff must commit themselves and their

- resources to the philosophy and implementation of the lean system. In the laboratory, this may extend beyond the technical and medical directors to the board of trustees, chief executive officer (CEO), and executive management team.
2. Training of executive management. People at the top of the management team, eg, technical and/or medical directors of the laboratory and section chiefs, must be visible, active participants in the transformation to lean production systems. They will require training in areas of communicating with, setting expectations for, and measuring the progress of their workforces.
 3. Selection of "change agents." Change agents, ie, the top individuals in each department who will be responsible for leading the implementation of lean production techniques, must be extricated completely from their functional roles for the duration of the project.
 4. Training change agents. The change agents must be trained and educated in the philosophy and techniques of lean production. They must oversee the education of their coworkers.
 5. Training of and communicating with the entire institutional workforce. Nothing may be done in secret. The hospital CEO, board members, executive staff, and other institutional health care workers not involved in the project must be kept current.
 6. Selection of "first areas" for improvement. All health care workers and administrative personnel participating in the project must decide as a group which area of the laboratory is most in need of help. This is where the project begins.
 7. Execution of the first projects. In general, the scope of projects is designed so that improvement in a specific process can be accomplished with 3 weeks of planning, 1 week of implementation, and 2 weeks of follow-up. Change leaders facilitate implementation, but it is the front-line bench workers who develop outcome metrics, formulate possible solutions, and execute changes. The success of the project is determined using standard foundational tools. The process by which the project is conducted, evaluated, and contributes to general learning among participants is termed *kaizen*.
 8. Selection and execution of the next round of projects. Projects or kaizen events are repeated at a rate of 8 to 12 per year per change agent.
 9. Regular on-site review of the lean implementation by the executive team. The successes of kaizen events, changes in culture, adherence to lean techniques, and improvements in safety and morale are determined following observations made in precisely the same locations where the specific lean techniques are implemented. It is the absolute responsibility of leadership at every level to participate in this review and

be visible where the change is occurring. This is referred to as *genchi gembutsu* (*genchi*, go to the actual scene; *gembutsu*, confirm the actual happenings or things).

10. Selection of a "master guide" from among the change agents. A master guide who shines among the change agents as an individual who best embraces the lean philosophy is selected by the leadership team to conduct all future training of and to coach and mentor administrative personnel, health care workers, and future change agents.
11. Redeployment of change agents into functional roles. People who formerly functioned as change agents resume their previous functional roles. They encourage others to embrace the lean philosophy and processes. This step documents the transformation of the organization to the lean production system.
12. Select and train new change agents. The process repeats itself.

Future Direction

The retrospective approach of pursuing quality to reduce errors in the practices of pathology and laboratory medicine has served our purposes, but only up to a point. Industrial models of error reduction, ie, those developed by Toyota, have made us rethink this approach. Specifically, it seems advisable to devise systems that find and eliminate the causes of errors before they can result in defects and, failing that, catch and correct defects before they are passed on to and are allowed to harm patients.

The challenge to installing lean systems is not just about developing the right protocols. It is about developing people and their commitment to excellence. Everyone, from the hospital trustees and CEOs, to laboratory directors and pathologists, to front-line technologists and phlebotomists, needs to be on board.

Bits and pieces of these systems already exist in our industry. However, there is no start-to-finish global system installed in any clinical laboratory or pathology department. At some innovative institutions, such as at Shadyside Hospital, Pittsburgh, PA; Henry Ford Hospital, Detroit, MI; and Good Samaritan Hospital, Dayton, OH, efforts to install lean production systems are under development. With their leads, we hope the laboratory industry can reduce defect rates similar to those enjoyed in many manufacturing and service industries.

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