Improving Preanalytic Processes Using the Principles of Lean Production (Toyota Production System)

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Abstract

The basic technologies used in preanalytic processes for chemistry tests have been mature for a long time, and improvements in preanalytic processes have lagged behind improvements in analytic and postanalytic processes. We describe our successful efforts to improve chemistry test turnaround time from a central laboratory by improving preanalytic processes, using existing resources and the principles of lean production. Our goal is to report 80% of chemistry tests in less than 1 hour and to no longer recognize a distinction between expedited and routine testing. We used principles of lean production (the Toyota Production System) to redesign preanalytic processes. The redesigned preanalytic process has fewer steps and uses 1-piece flow to move blood samples through the accessioning, centrifugation, and aliquoting processes. Median preanalytic processing time was reduced from 29 to 19 minutes, and the laboratory met the goal of reporting 80% of chemistry results in less than 1 hour for 11 consecutive months.

Laboratories are under constant pressure to improve their services. The mantra of “faster, cheaper, better” is heard in the laboratory world as loudly as in other sectors of society.1 Clinical chemistry laboratories have responded to these demands by acquiring analyzers with improved throughput to speed up the analytic process. The postanalytic process of reviewing results and distributing them to the appropriate providers has been largely automated by adoption of laboratory information systems (LISs) that use autoverification rules to reduce the number of results manually reviewed by laboratory scientists. The use of autoverification makes results available on-screen to clinicians much sooner. Less attention has been given to preanalytic processes. In this article, we describe our successful efforts to improve chemistry test turnaround time from a central (core) laboratory by improving preanalytic processes, using existing resources and the principles of lean production.

The basic technologies used in preanalytic processes for chemistry tests (centrifugation and aliquoting) have been mature for a long time. There is little financial or technological incentive to replace preanalytic equipment (centrifuges and pipetters) unless they fail and become uneconomical to repair. Operating the centrifuges, preparing sample aliquots, and distributing samples to analysis stations traditionally have been manual processes. Within the last decade, systems have been developed to automate these processes, but they require significant capital expenditures and long payback periods. Thus, improvements in preanalytic processes have lagged behind improvements in analytic and postanalytic processes.

Our laboratory supports a 763-bed acute care hospital, an emergency treatment and level I trauma center, and numerous general and specialty clinics located in the same physical structure. The clinical chemistry laboratory handles 1,000 to
1,500 samples per day and performs between 7,000 and 10,000 analyses per day. Our interest in improving the preanalytic chemistry test process was prompted by complaints from our customers about slow turnaround times and complaints from laboratorians about workplace stress. The word most commonly used by laboratorians to describe the environment in the preanalytic process work area was chaos. Interviews with laboratorians and direct observation of the workplace confirmed that the processes in place were no longer meeting the needs of the laboratory or its customers.

The laboratory’s traditional approach to resolving customer complaints about turnaround time was to establish an expedited process for that customer’s samples. Examination of workload data revealed that approximately 47% of chemistry tests were being ordered with the expectation of expedited processing—the meaning of the term stat. Some customer groups, particularly the emergency treatment center, were requesting that service be expedited even beyond the stat classification.

We believed that providing additional categories of expedited testing would result in additional chaos by adding even more processes and pathways to an already complicated environment. Additional processes and process complexity also contribute to cyclic propagation of error-generating behavior.2 Conversations with key customer groups revealed that all customer groups desired faster turnaround time for chemistry tests. Therefore, we chose to take a different approach to redesigning the processes. We believed that we could improve service for all customers by using the tools of lean production to create preanalytic processes that eliminated wasteful activities and delays. Our goal was to be able to report 80% of all chemistry tests (including therapeutic drug monitoring and thyroid hormones) in less than an hour, and we would no longer recognize requests for expedited (stat) testing.

The concepts of lean production were first developed by the Toyota Motor Corporation during the last half of the 20th century and since have become known as the Toyota Production System.3 The major goal of lean production is to reduce waste in 7 categories: overproduction, inventory, transportation, inspection, correction, motion, and waiting. Waste is defined as the elements of production that do not add value to the product or service being produced. Lean production has been adopted in many industries but has been applied to health care only recently and separation gel (Vacutainer, Becton Dickinson, Franklin Lakes, NJ). Tests were accessioned into an LIS (Cerner Classic, Cerner, Kansas City, MO) that assigned a unique accession number to each sample and printed barcode labels that were affixed to the parent sample tube and any child (aliquot) tubes.

For samples requiring serum or plasma for analysis, centrifugation of the blood collection tubes was performed at 3,000 rpm for 6 minutes (approximately 1,600g) with a Jouan C-412 centrifuge (Jouan, Winchester, VA) equipped with swinging bucket heads.

**Analytic Process**

Chemistry tests were performed on a Modular analyzer (Roche Diagnostics, Indianapolis, IN) consisting of 1 ISE1800 module and 3 P800 modules as the primary analyzer. The secondary analyzer initially consisted of a Hitachi 737 (Roche Diagnostics). The 737 was replaced with a Modular consisting of an ISE and 1 P module in April 2002. Immunochemical assays were performed on an Elecsys 2010 (Roche Diagnostics). No significant changes were made to the operation of the chemistry analyzers during the study period, other than replacing the secondary analyzer.

Analyzers were linked to the LIS via a computerized interface (Dawning Technologies, Fairport, NY). The LIS uses a rule-based system to verify results from the analyzers that meet defined criteria and transmit them to the hospital’s computerized medical record system. Results failing to meet the acceptability criteria are held until reviewed by a clinical laboratory scientist.

**Baseline Cycle Time Study**

To determine a baseline for benchmarking process improvement toward our goal, we conducted a chemistry test cycle time study before implementing changes. Adhesive labels were prepared with a time code that masked the arrival time to minimize the occurrence of the Hawthorne effect. A sample identification station was established approximately 50 ft from the laboratory sample drop-off window. As incoming chemistry samples were brought to the sample identification station, we affixed a label to each that identified the time the sample passed the station. The samples then were delivered and processed in the usual manner. As the samples reached the input rack of the main chemistry analyzer, we recorded the assigned time code as well as the LIS-assigned accession numbers. The time the accession number was assigned was obtained retrospectively from the LIS. From these data, we calculated the time delay before accessioning (time from sample delivery to accessioning) and the preanalytic cycle time (time from accessioning to delivery at the chemistry analyzer input rack).

**Performance Index**

Because significant resources are required to conduct a complete cycle time study, we sought to develop a simpler,
automated measure of chemistry test turnaround time that could be obtained on a daily basis. We determined that our LIS could provide us with a report listing the percentage of chemistry tests completed in an hour for hourly and daily intervals. Because our goal was to report 80% of tests in an hour or less, we subtracted 80% from each period’s percentage completion rate to arrive at a performance index (PI). A positive PI is the percentage of tests completed above the 80% goal, and a negative PI is the percentage below the 80% goal. We monitored hourly and daily PIs. The monthly PI was obtained by averaging the weekday PIs for the month.

**Process Map**

We observed the existing accessioning and preanalytic processes, with close attention to the process steps that might be wasteful, unnecessary, or inappropriate. Laboratorians involved in the process also were asked to describe the processes and environment in the preanalytic work area. These observations and descriptions were used to create the preintervention map of the process [Figure 1]. Like most clinical laboratories, our laboratory purportedly provided 2 levels of service, expedited (stat) and routine. However, the only distinction between the process for an expedited sample and a
routine sample was that the expedited sample would be moved to the front of whatever queue it was in at the time. With more than 40% of the samples being marked stat, this distinction was essentially meaningless.

**Intervention**

By using the information obtained from our observations and interviews, we redesigned the preanalytic process using principles of lean production and the Toyota Production System. In our process redesign, we were constrained to use the same laboratory space and human resources for preanalytic functions, although duties could be reassigned. The redesigned process was submitted to supervisors and laboratorians for comments, and their suggestions were incorporated. The process map for the redesigned process is shown in Figure 2.

**One-Piece Flow**

The redesigned process incorporates the concept of 1-piece flow. In a 1-piece flow system, all activities that constitute a process are performed on each object undergoing the process before the work is begun on the next object; there is no batching. For example, when a requisition arrives in the laboratory accompanied by multiple sample containers, the laboratorian handling each requisition accesses all tests and labels all containers associated with that requisition, including containers for aliquots not yet prepared. Only after accessioning is complete are the containers sorted based on the next process or destination.

In the 1-piece flow process, no distinction is made between stat and routine requests; rather, samples are handled on a “first in, first out” (or FIFO) basis.

**Toyota Production System**

In addition to redesigning the flow of work, we also redesigned how the work would be accomplished, using 4 rules of the Toyota Production System. The rules and an example application are given in Table 1.

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**Figure 2** Process map for the redesigned preanalytic process.
Redesigned Process

In the redesigned process, 5 new workstations were created, with specific descriptive titles. Table 2I describes the principal duties of each workstation. Laboratorians are assigned to workstations for 2-hour periods, alternating between sitting–cognitive task workstations (accessioner, exception handler, customer service/phones) and standing–physical task workstations (centrifuge operator, sorter-circulator) as much as possible. This rotation ensures that laboratorians are cross-trained on all tasks in the area, maintaining proficiency in these tasks, and experience task variety. In cases of staff shortage, this organizational structure can be collapsed to require fewer laboratorians by combining some duties.

To accommodate the new workstations, we made minor modifications to the laboratory workspace. A customer service workstation was established separate from the accessioning stations, and the primary telephone lines were configured to ring at this workstation. The accessioning workstations were configured to include a computer, label printer, rack containing clean aliquot tubes, and baskets for incoming samples and samples ready to be distributed to the next workstation. The centrifuge workstation included open bench space to load and unload centrifuge buckets, 2 centrifuges, biohazard waste containers, and above-counter bins for transfer pipettes and other consumables. The design of the centrifugation process called for a 6-minute centrifugation cycle at 1,500g followed by a 3-minute deceleration. The procedure for centrifuge operation called for starting a centrifuge batch every 6 minutes; thus, the centrifuge operator has 3 minutes from the time the deceleration is complete to empty the centrifuge and load the next batch. Aliquot preparation was performed when the operator was not loading or unloading.

Following a training period, the redesigned lean process was introduced. We conducted additional observations to monitor performance. Supervisors conducted daily evaluation

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| **Toyota Production System Rules**

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<th>Example</th>
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<tr>
<td>1</td>
<td>All work shall be highly specified as to content, sequence, timing, and outcome.</td>
<td>Samples needing centrifugation are loaded into waiting centrifuge bucket inserts in a specified pattern (tubes not requiring aliquots in the center, tubes requiring aliquots on the perimeter). A centrifuge batch is started every 6 minutes, regardless of the number of samples to be centrifuged or in the accessioning queue. When the centrifugation is complete, the tubes not requiring aliquots are removed and placed in a transport rack. The tubes requiring aliquots are removed from the buckets one at a time and the aliquots dispensed into prelabeled tubes. When the bucket inserts are empty, they are returned to the loading point.</td>
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<tr>
<td>2</td>
<td>Every customer-supplier connection must be direct, and there must be an unambiguous yes-or-no way to send requests and receive responses.</td>
<td>If a requisition is received without complete information, the accessioner does not accession, but completes an “exception ticket” citing the missing information, attaches it to the requisition, and places it in a basket. The sorter-circulator picks up exceptions and delivers them to the exception handler. The exception handler resolves the missing information issue, signs off on the exception slip, and returns the sample to an accessioner to restart the accessioning process.</td>
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<tr>
<td>3</td>
<td>The pathway for every product and service must be simple and direct.</td>
<td>The sorter-circulator delivers accessioned samples directly from the accessioners to the centrifuge workstation and delivers centrifuged samples directly to the chemistry analyzer loading workstation.</td>
</tr>
<tr>
<td>4</td>
<td>Any improvement must be made in accordance with the scientific method, under the guidance of a teacher, at the lowest possible level in the organization.</td>
<td>Laboratorians wanting to change a “best practice” submit their ideas to a supervisor or process engineer. An experiment is designed to test the effects of the change and conducted with appropriate measurements. If desired effects are achieved, the new information is incorporated into a best practice.</td>
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<th>Table 2I</th>
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<td><strong>Principal Duties for Each Workstation</strong></td>
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<table>
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<tr>
<th>Position</th>
<th>Principal Duties</th>
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<tr>
<td>Accessioner (1 to 3 workstations)</td>
<td>Unpack incoming samples; check for completeness of information; accession tests into LIS; affix labels to parent and aliquot containers</td>
</tr>
<tr>
<td>Sorter-circulator</td>
<td>Unload pneumatic tube carriers; distribute incoming workload to accession workstations; deliver accessioned samples to next workstation; deliver centrifuged samples to next workstation; restock supplies at accessioning workstations as needed</td>
</tr>
<tr>
<td>Centrifuge operator</td>
<td>Load and unload centrifuges (2); prepare aliquots as needed</td>
</tr>
<tr>
<td>Exception handler</td>
<td>Resolve problems with incoming workload (eg, lack of information, inappropriate samples); measure and aliquot 24-hour urine specimens; back up accessioners during busy periods</td>
</tr>
<tr>
<td>Customer service</td>
<td>Answer incoming telephone calls; accession requests for “add-on” tests</td>
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LIS, laboratory information system.
meetings with laboratorians to find additional process problems and reinforce the use of the lean process. As laboratorians became more familiar with the lean process, their comments were used to develop best practices for operating each workstation. These best practices were disseminated at the daily evaluation meetings and incorporated into the procedure manual and training for new staff.

During the study period, we experienced the usual amount of employee turnover but neither added nor reduced the number of budgeted full-time equivalent positions assigned to the preanalytic process.

**Results**

**Decreased Cycle Time**

The redesign of the preanalytic process in our laboratory significantly improved chemistry test turnaround time. The results of the baseline and postimprovement cycle time studies are shown in [Figure 3](#) and [Figure 4](#). The redesigned preanalytic process resulted in a 30% improvement in the 50th, 80th, and 90th percentiles of the cycle time distribution.

**Increased PI**

[Figure 5](#) and [Figure 6](#) show the daily PIs for November 2001 (before implementation of the lean production system) and November 2002 (6 months after implementation of the lean production system). The monthly PIs for the 18 months following the beginning of the project are shown in [Figure 7](#).

Following complete implementation of the lean production system in June 2002, the monthly PIs became positive and remained positive for 9 consecutive months. The monthly index became negative in March, April, and May 2003. Review of the daily PIs for these 3 months revealed that each of these months had 3 “bad days” on which the daily PIs were less than –10. Further investigation revealed that performance on these 3 days was suboptimal owing to failures of analytic instrumentation. When the data for the analytic instrumentation failure days were removed, the monthly PI became positive for March and April and less negative for May. The 12-month period of sustained improvement supports our conclusion that the performance improvements are the result of the improved preanalytic lean process and not a manifestation of the Hawthorne effect or the result of seasonal or periodic changes in workload. Workload increased by an average of 0.54% per month during the study period, or 6.5% per year.
Figure 4: Preanalytic process cycle time (lean production system).

Figure 5: Performance index, November 2001 (before lean production).
Figure 6: Performance index, November 2002 (lean production system).

Figure 7: Monthly performance index average.
Table 3 lists examples of the kinds of waste eliminated with the lean process. Reduction of mislabeled and missing tube errors was an additional benefit of the lean process. Under the old process, the batching and unbatching of tubes occasionally led to missing tubes, and laboratorians would spend considerable time locating the missing tubes. With the new lean process and 1-piece flow, there are few opportunities for a tube to be lost or misplaced, and these errors no longer occur.

The redesign of the preanalytic process also revealed some hidden wastes in the system. In 1 clinic, the phlebotomists had developed an unwritten and unapproved practice of obtaining an extra tube of blood from most patients in case the physician decided to order additional tests after the patient had left the clinic. Investigation revealed that only 10.8% of these tubes actually were used, and in nearly half of those cases, the additional tests could be done on specimens already in the laboratory. Changing the practice to obtain extra tubes only when specifically requested by the physician resulted in more than 1,000 fewer specimens being processed per month, with a concomitant decrease in the number of collection tubes used and amount of biohazardous waste discarded.

**Discussion**

We demonstrated that redesigning the preanalytic processes to incorporate the elements of lean production and the Toyota Production System can result in significant improvement in chemistry test turnaround time without the addition of automation or other resources. Laboratories that desire to improve their preanalytic processes but are not able to acquire preanalytic automation systems may benefit from this approach.

A key element in our success is the use of the Toyota Production System rules in the implementation of the redesigned process. All 4 rules impose a discipline on the process that results in consistency of output and quality. Convincing laboratorians that they needed to maintain this discipline was a major part of the change effort involved in the implementation of the lean process.

In addition to the process changes, the lean production process required a paradigm shift by laboratorians. Incoming workload would no longer be classified as stat or routine, because 1-piece flow and the lean process eliminated any distinction in the handling of these samples. It is interesting to note that the stat vs routine paradigm is still widely accepted in the clinical laboratory industry. Mohammad et al described the use of simulation modeling to determine the impact of increasing numbers of routine samples on routine and stat turnaround times for a chemistry analyzer. Their study presumed that there is a constant demand for stat testing and examined the effect of increasing routine workload on stat turnaround time. In our experience, requests for rapid turnaround time are increasing, requiring laboratories to improve their processes for these samples. Carried to its logical conclusion, this trend will result in no “routine” testing. Developing a process that improves turnaround time for all samples is a better long-term strategy for delighting laboratory customers than categorizing requests as stat and routine and trying to improve service for only 1 category.

Review of laboratory processes with the goal of improving them inevitably reveals wasteful practices, as we discovered when we looked at the use of extra tubes of blood obtained in 1 clinic. The informal initiation of this practice by front-line workers was well-intentioned—they wanted to reduce the number of patient call-backs and additional phlebotomies on a population of very sick patients—but it had the...
effect of reducing system throughput by adding additional specimens to the workload that ultimately were never used. As our efforts to improve laboratory service continued beyond the time described in this article, we discovered additional opportunities to reduce waste by changing practices. This also is consistent with the application of the Toyota Production System, in which every employee participates in continuous improvement efforts.

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