The Positive Impact of Simultaneous Implementation of the BD FocalPoint GS Imaging System and Lean Principles on the Operation of Gynecologic Cytology

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Context.—Our cytology laboratory, like many others, is under pressure to improve quality and provide test results faster while decreasing costs. We sought to address these issues by introducing new technology and lean principles.

Objective.—To determine the combined impact of the FocalPoint Guided Screener (GS) Imaging System (BD Diagnostics–TriPath, Burlington, North Carolina) and lean manufacturing principles on the turnaround time (TAT) and productivity of the gynecologic cytology operation.

Design.—We established a baseline measure of the TAT for Papanicolaou tests. We then compared that to the performance after implementing the FocalPoint GS Imaging System and lean principles. The latter included value-stream mapping, workflow modification, and a first-in-first-out policy.

Results.—The mean (SD) TAT for Papanicolaou tests before and after the implementation of FocalPoint GS Imaging System and lean principles was 4.38 (1.28) days and 3.20 (1.32) days, respectively. This represented a 27% improvement in the average TAT, which was statistically significant (P < .001). In addition, the productivity of staff improved 17%, as evidenced by the increase in slides screened from 8.85/h to 10.38/h. The false-negative fraction decreased from 1.4% to 0.9%, representing a 36% improvement.

Conclusions.—In our laboratory, the implementation of FocalPoint GS Imaging System in conjunction with lean principles resulted in a significant decrease in the average TAT for Papanicolaou tests and a substantial increase in the productivity of cytotechnologists while maintaining the diagnostic quality of gynecologic cytology.

For each imaged slide, a cytotecnologist reviews all 10 FOVs selected by the instruments. If the cytotechnologist deems there are no potential abnormalities within any of the 10 FOVs and the slide is satisfactory for interpretation, full-slide manual screening is not required, unless the slide is selected for directed, quality-control (QC) rescreening. With no potential abnormalities in the 10 FOVs, the slide is reported as negative for intraepithelial lesion or malignancy and satisfactory for interpretation. Full-slide manual screening is required if one of the following conditions are met: (1) any potential abnormalities are identified in any of the FOVs, (2) no endocervical or transformation zone component is identified in any of the FOVs, (3) the specimen adequacy cannot be determined or is deemed to be unsatisfactory, or (4) the instruments undergo a technical processing failure. Full-slide manual screening is then performed immediately following the FOV review by the same cytotechnologist who performed the FOV review. According to the protocol, FPGS selects 15% of the highest scoring negative slides for full-slide manual screening as part of the QC. The QC rescreen is performed by cytotecnologists who have not previously reviewed the slides.

To take advantage of the full benefits of the improved operational efficiency and productivity offered by these instruments, laboratories must not rely on the workflow and processes that were status quo in the past. Instead, effective process and workflow redesign is necessary. When our laboratory implemented the FPGS to replace the FocalPoint Slide Profiler in May 2009, we also embarked on a makeover of our laboratory processes, based on the lean manufacturing principles.

Lean principles create a management- and process-improvement philosophy, which can be applied to reduce activities that are unnecessary or add no value to decrease total production time and effort. Lean management principles challenge the status quo in favor of simplified and standardized methods. Several studies13–23 have reported their experiences in applying the lean principles in clinical laboratory as well as in anatomic pathology laboratories. In this study, we evaluated the impact on the turnaround time (TAT), productivity, and quality in screening accuracy after the implementation of FPGS, along with the application of lean methodology in redesigning the workflow of the gynecologic cytology laboratory.

**MATERIALS AND METHODS**

**Background**

Since 2006, our laboratory has processed more than 80,000 Pap tests annually. The Pap tests were predominantly submitted by various obstetrics and gynecology practices in the surrounding community. The cytology laboratory was staffed by 40 full-time equivalent employees, including 7 cytopathologists, 15 cytotechnologists, and 18 support staff members.

**FocalPoint GS Imaging System**

Our laboratory implemented a FPGS in May 2009. After validation of the FPGS and the completion of cytotecnologist training, the FPGS was put into clinical use in June 2009. Before that, for more than 8 years, Focal Point Slide Profilers had been used as the primary screening tool for SurePath specimens; on average, 24% of SurePath cases were classified as no further review needed. Currently, the laboratory operates 2 FPGS imaging systems and 6 review stations. With FPGS, 100% of the imaged slides were reviewed by cytotecnologists using a review station that was limited to the 10 FOVs.

**Lean Methodology**

Figure 1 shows the pre-FPGS value-stream map, which is a frequently used lean tool for summarizing the step-by-step time requirements of a process. The goal was to identify and eliminate nonvalue-added activities. Value-added activities refer to steps that are actually valuable and contribute to the finished product, in this case, the cytology reports. On the other hand, nonvalue-added activities refer to steps that do not add value to, or are unnecessary for, the overall product, called the wastes. Some examples of nonvalue-added activities include rework and wait time. After creating the pre-FPGS value-stream map, we estimated the process time and the prestep queue time (ie, the wait time) for each step, based on our experience. The process times and wait times were added together to determine the total cycle time. In addition, total value and nonvalue-added times were estimated. We then visualized any opportunities where implementation of the FPGS and lean principles could affect the overall workflow. One way to think of value in delivering patient care—in this case, Pap test results—is to ask the question, “Would the patient be willing to pay for a certain step of the process?” For example, as far as the patients are concerned, slides sitting on a shelf waiting to be screened by cytotecnologists adds no value, whereas pathologists reviewing abnormal cases added value. After several brainstorming sessions, we identified and eliminated several key bottlenecks and nonvalue-added activities. Figure 2 shows the value-stream map after FPGS and lean principles implementation.

The laboratory layout before lean implementation, with a superimposed spaghetti diagram for processing of gynecologic cytology specimens, is shown in Figure 3. A spaghetti diagram is a lean tool that visually demonstrates the path taken by staff when performing their assigned duties; it was created based on direct observation. The laboratory layout was rearranged to make the path as streamlined as possible and to avoid wasted motions (Figure 4).

We also implemented a first-in, first-out policy, which describes the flow of cases that had been in the “inventory” the longest. In cytology, this was achieved by the orderly accessioning, processing, and screening of cases as they arrived so that they were completed in the order received, where possible. For example, one new tool was to organize the slides that were waiting to be screened and QC according to the date of accession, and the cytotecnologists were instructed to take the oldest cases first. In addition to these measures, we also made other minor changes, for example, installing a virtual private network on each individual pathologist’s laptop to enable him or her to sign out electronically even when away from the office.

**Outcome Metrics and Statistical Analysis**

Using the laboratory information system, information was retrieved to compile the metrics for the 2 periods, before and after FPGS and lean principles implementation. The metrics included the following: (1) mean TAT for all Pap tests, including SurePath, ThinPrep, and conventional preparations; (2) TAT for 90% of Pap tests; (3) workload of cytotecnologists expressed in slides per hour; and (4) the false-negative fraction. The TAT was defined as the time from specimen accessioning until results were verified electronically in the laboratory information system. We calculated the TAT using business days, that is, weekends and holidays were excluded. Cases classified as no further review by the FocalPoint Slide Profiler were not included in the calculation of cytotecnologists’ hourly workflow for the first period. The FNFs were estimated based on cases initially interpreted as negative that were rescreened because they were either among the mandated 15% direct QC review or were high-risk cases, which were reclassified as squamous intraepithelial lesions or higher grade lesions. The equation for calculating the false-negative fraction was false-negative cases/(false-negative cases + true-positive cases). The satisfaction of clinicians was measured indirectly by auditing the number of weekly phone calls received from physicians’ offices requesting cytotecnologic reports.
Statistical analyses were performed using the Student t test and the Mann-Whitney U test. P values of .05 or less were considered statistically significant. The statistics were calculated using Minitab software, version 16.0. (Minitab Inc, State College, Pennsylvania).

RESULTS

During the study period, a total of 234,616 Pap tests were processed and evaluated, 108,828 (mean [SD] = 6801 [490]/mo) and 125,788 (6620 [564]/mo) before and after FPGS and lean principles implementation, respectively. Both cohorts were derived from the same physician practices and same demographic patient population. SurePath preparation constituted about 80% of all Pap tests, followed by 17% ThinPrep preparation and 3% conventional Pap tests.

Before FPGS and lean principles implementation, the mean total cycle time was 158.48 hours; the value and nonvalue-added times were 12.48 hours and 146.0 hours, respectively. After FPGS and lean principles implementation, the mean total cycle time decreased by 79.9% to 31.9 hours. The value and nonvalue added time decreased by 8.7% to 11.4 hours and 86.0% to 20.5 hours, respectively.

The Table summarizes the overall TAT before and after FPGS and lean principles implementation. There were significant decreases in both the mean TAT (27%) and the TAT for 90% of the cases (37%) after FPGS and lean principles implementation. (P < .001; Figure 5). In addition, the difference between the mean TAT and the TAT for 90% of the cases was significantly reduced after FPGS and lean principles implementation (1.96 [0.62] days versus 0.82 [0.29] days; P value < .001). Significant reductions were also noted with the mean TAT and the TAT for 90% of the cases for cytotechnologists only after FPGS and lean principles implementation. In addition, the number of weekly phone calls from physicians’ offices requesting cytologic reports decreased from more than 10 to less than 1 after FPGS and lean principles implementation.

Also, there was a significant increase (17%) in cytotechnologist productivity as measured by the number of slides that were screened each hour by each individual cytotechnologist. For the first 19 months after FPGS implementation, the average false-negative fraction was 0.88% compared with 1.39% before FPGS implementation; this represents a 36% decrease, which was statistically significant. At the same time, there was an increase in the diagnosis of atypical squamous cells and squamous intraepithelial lesions by 52% and 7%, respectively, after FPGS implementation.

DISCUSSION

Lean refers to an integrated approach to process improvement by eliminating waste and maximizing value. Value is about delivering products and/or services that customers, in our case, physicians and their patients, want and need and not adding things that are superfluous to them, “wastes.” Because value is specified from the point of view of the customers, one of the key features of lean is listening to the voice of the customer. In the current study, one of the factors that triggered the initiation of the process-
Figure 2. Value-stream map for SurePath processing after implementation of the FocalPoint GS (FPGS) imaging system and lean processes (workflow for cases that required quality control [QC] is not shown). Abbreviations: CT, cytotechnologist; FOV, field of view.

Figure 3. Spaghetti diagram for processing of SurePath specimens before implementation of lean processes.
improvement project was the frequent complaint from our clinicians about the long TATs; the laboratory used to receive 2 to 3 inquiries every day from clinicians’ offices about Pap tests results because of long and inconsistent TAT.

As mentioned before, another goal of lean principles is to eliminate or minimize wastes. Lean principles describe 8 waste categories: defects (eg, screening errors), overproduction (eg, cytotechnologist overcalls resulting in unnecessary referrals to pathologists), transportation (eg, slides being processed and screened at different locations), waiting (eg, slides sitting on the shelf waiting to be screened by cytotechnologists), inventory (eg, excess supplies and kits), motion (eg, poor workflow design resulting in unnecessary movement by technicians), overprocessing (eg, performing unnecessary ancillary tests), and human potential (eg, cytotechnologist performing data entry).

**Figure 4.** Spaghetti diagram for processing of SurePath specimens after implementation of lean processes.

**Figure 5.** Average turnaround time before and after implementation of FocalPoint GS (FPGS) imaging system and lean processes. Individual values equal to turnaround time for 90% of cases, expressed in days. Observations expressed in weeks. Abbreviations: LCL, lower control limit; UCL, upper control limit.
Recently, Hassell et al\textsuperscript{14} reported similar experience with the combined positive effects of lean principles and the Ventana Symphony autostainer (Ventana Medical Systems, Tucson, Arizona) for TAT and productivity. Improving a single process often results in problems being shifted to adjacent processes; therefore, any positive impact may appear insignificant.\textsuperscript{26} On the other hand, lean principles emphasize a systemic, holistic view of process improvement. Although the initial application of lean principles may focus on single process, the desire to avoid shifting problems to adjacent processes will redirect attention to the entire value system. Our experience supported the argument that we were able to maximize the benefits of new technology when its introduction was combined with the implementation of lean tools.

One of the lean tools we used in the current project was the spaghetti diagram, which allowed us to visualize the path taken by the staff when processing SurePath specimens. The goal was to make the workflow pattern as streamlined as possible and to avoid any wasted motion. Although the workflow pattern after lean principles implementation was more streamlined than its prior counterpart, it was not ideal because the staff had to travel “upstream” after step 7 (recentrifugation) for step 8 (loading the slides for PrepMate; Figure 4). Because lean is a stepwise philosophy, the small changes made had positive effects and led to a goal of overall laboratory redesign. Despite a less-than-ideal redesigned workflow, we managed to reduce the cycle time for processing SurePath specimens by 16.7%.

Using value-stream mapping, we discovered that more than 90% of the cycle time was nonvalue-added time before FPGS and lean principles implementation. Before lean principles implementation, because most of our specimens arrived in the laboratory in late afternoon and early evening, at least half of the SurePath specimens were processed the next day. Therefore, the first change we made was to rearrange the schedule of the second shift of the laboratory staff. Because of this rearrangement, along with the improved workflow of SurePath processing, we were able to process all SurePath specimens into slides within the same calendar day we received the specimens after lean principles implementation. The most prominent nonvalue-added time event before lean principles implementation was having the imaged slides sitting on the shelf waiting to be screened by cytotechnologists. By taking advantage of the shorter screening time required when using FPGS and the first-in, first-out policy, we were able to gradually reduce this nonvalue-added time event by 86%; this contributed significantly to the overall reduction in lead time. Interestingly, this reduction in
lead time was also noted with ThinPrep and conventional preparations, which resulted in both total cycle time and non-value-added time being significantly reduced by 80% and 86%, respectively. The small difference between overall TAT and that of cytotechnologists could be attributed to the pathologists’ efforts to improve the overall TAT; for example, the use of virtual private networks to electronically sign-out cases remotely. On the other hand, one could safely conclude that the reduction in overall TAT was predominantly attributed to the implementation of FPGS and lean improvement project.

One of the secondary benefits of our current project was the improved productivity per full-time equivalent employee. The implementation of FPGS and lean principles made it possible for the laboratory to reduce the number of cytotechnologists positions from 15 to 13 (a 13% reduction); one employee left before FPGS implementation and another left 3 months after FPGS implementation. No staff were laid off—the reduction was achieved through attrition. Recently, the number of cytotechnologists has again increased to 15 because of the increase in the volume of nongynecologic specimens and the number of requests for cytologist-assisted fine-needle aspiration biopsies. The 2 new cytotechnologists were hired 7 months and 17 months after FPGS implementation, respectively.

At the heart of any process-improvement project is measurement. Measurement helps laboratories understand their current positions so that problems can be defined because it is difficult to improve what cannot be measured. Measurement also helps to determine whether the interventions have been successful, and continuous measurement is necessary to ensure the improvement is maintained. Because of the wide adoption of laboratory information systems, measurements are often readily accessible in cytology laboratories, provided the laboratory information system is managed effectively.

Perhaps the most crucial success factor for implementing lean principles was the involvement of the frontline workers in defining the problems, devising the solutions, running the improvement projects as trials, and gathering feedback to refine the projects. In many instances, after running the improvement projects as trials, and gathering feedback to refine the projects, in many instances, no staff were laid off—the reduction was achieved through attrition. Recently, the number of cytotechnologists has again increased to 15 because of the increase in the volume of nongynecologic specimens and the number of requests for cytologist-assisted fine-needle aspiration biopsies. The 2 new cytotechnologists were hired 7 months and 17 months after FPGS implementation, respectively.

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Perhaps the most crucial success factor for implementing lean principles was the involvement of the frontline workers in defining the problems, devising the solutions, running the improvement projects as trials, and gathering feedback to refine the projects. In many instances, the projects would be revised and adjusted based on feedback and suggestions from staff. Zarbo and D’Angelo22 also emphasized the importance of constant communication and the creation of a blame-free environment when reporting problems and mistakes. By engaging and empowering the frontline staff, we were able to sustain our improvement in performances for 18 months and beyond the time described in this article.

Our study demonstrated that the introduction of new technologies, such as FPGS, produced some small but significant improvements in TAT, productivity, and diagnostic quality. However, when these new technologies were implemented in conjunction with lean principles, we were able to achieve much greater improvements in TAT. One area was the reduction of the waste in many of the waiting times. By involving our frontline workers, we were able to sustain and yield further improvements. Although the benefits we have presented here are limited to gynecologic cytology, we believe that similar improvements can be achieved in other areas of the cytology laboratory, such as nongynecologic cytology, fine-needle aspiration biopsy, and molecular cytology, by applying lean principles and methodology, especially in conjunction with the introduction of new technologies.

References