In a clinical laboratory, reliability cannot be achieved through the control of accuracy in the analytical phase of the testing process alone because studies have shown 70 to 85% of laboratory errors occur before that—in the preanalytical phase.¹

Analytic standards are set by established quality control criteria, but no such standards exist for defining the quality of the preanalytical phase—an important component of total laboratory quality consisting of specimen procurement, accessioning and transport.

Accessioning is a registration process. It occurs when the information in the paper requisition that accompanies a sample is entered into the lab information system, and a label is generated and placed on the sample tube.

North Shore-Long Island Jewish (LIJ) Health System, headquartered in Great Neck, NY, launched a Six Sigma project last year to reduce the number of accessioning errors at its core laboratory, which performs more than 3.5 million tests annually.

Created in 1998, North Shore LIJ’s laboratory model consists of a strategically located core laboratory using total laboratory automation, a rapid response laboratory in each of the system’s 18 hospitals, a standardized laboratory information system, standardized laboratory instrumentation and consolidated testing at the core laboratory.

Work for the core lab comes from hospitals, long-term care facilities, clinical trials, physician offices and reference testing (complex tests). The lab performs approximately 65% of the routine testing for the North Shore-LIJ network as well as all the network’s microbiology, special tests, molecular diagnostics and reference testing.

As part of the laboratory’s ongoing performance improvement process, accessioning errors had been measured historically for years. It was a chronic problem for which consultants had previously been engaged without arriving at a successful resolution.

At the core lab, a multidisciplinary team of technical, compliance, marketing, quality and accessioning management staff was assembled to tackle its first Six Sigma project using the define, measure, analyze, improve, control (DMAIC) approach.

The accessioning project aligned with the core laboratory’s strategic plan of increasing market share in the region and becoming number one among its competitors on measures of customer satisfaction. The lab’s customers include patients, hospitals, private physician offices and private nursing homes.

**Defining and Measuring the Process**

During the define phase, the team developed a high level process map (see Figure 1, p. 24) beginning with the initial step of the physician’s filling out the requisition and drawing the specimen to the end, when the result and chart for lab work is produced for the patient.
After conducting a survey to obtain the voice of the customer from physician practices, the Six Sigma team developed an *ICD-9 Common Diagnosis Codes Pocket Guide* to help physicians supply the correct diagnosis code for each laboratory test. ICD-9 codes are one of the required fields on a laboratory requisition.

Through careful data collection and analysis, the team found 5% of the specimens accessioned at the core lab were inaccurate or incomplete. This defect rate was in line with historical data. These inaccuracies cause delays in reimbursement and decreased customer satisfaction.

The Six Sigma team then used change acceleration process tools, such as the threat/opportunity matrix, during the define phase to obtain buy-in from the laboratory staff for the necessity of pursuing this project.

If successful, the lab would be able to increase productivity and customer satisfaction while decreasing the number of incomplete or inaccurate requisitions. If unsuccessful in the long term, the core lab’s reputation would be diminished, leading to a loss of revenue.

In the measure phase, the first order of business was to determine the operational definitions. The team defined a defect as a laboratory requisition with missing or inaccurate demographic, test or ICD-9 information.

The team performed a measurement system analysis by giving the requisition checking staff a test of 25 requisitions—some good, some bad. The gold standard was the accessioning manager, who knew which were good and which were defective. Each requisition was rated as good or bad depending on whether all seven

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**Figure 1.** *High Level Process Map*

- Critical to quality procedures
  - Physician supplies demographic information.
  - Physician’s office draws specimen.
  - Verify specimen with requisition.
  - Register patient in LIS.
  - Order test.
  - Label specimen.
  - Specimens placed on clinical laboratory automated system or delivered to department.
  - Result.
  - Chart.
  - Bill.

**Figure 2.** *Vital X’s*

<table>
<thead>
<tr>
<th>Type</th>
<th>Count</th>
<th>Percentage</th>
<th>Cumulative percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defects</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social Security</td>
<td>226</td>
<td>49.8</td>
<td>49.8</td>
</tr>
<tr>
<td>Name</td>
<td>71</td>
<td>15.6</td>
<td>65.4</td>
</tr>
<tr>
<td>Date of birth</td>
<td>58</td>
<td>12.8</td>
<td>78.2</td>
</tr>
<tr>
<td>Test</td>
<td>44</td>
<td>9.7</td>
<td>87.9</td>
</tr>
<tr>
<td>Doctor</td>
<td>39</td>
<td>8.6</td>
<td>96.5</td>
</tr>
<tr>
<td>Others</td>
<td>16</td>
<td>3.5</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Note: Initials are code for specific employees.
Purpose was not punitive but to develop a best practice.
Business Results

North Shore-Long Island Jewish Health System headquartered in Great Neck, NY, is the third largest nonsectarian health system in the country, comprised of 18 hospitals. The system is currently in its fifth wave of Six Sigma training, having completed more than 40 projects. The Six Sigma institute is part of the health system’s corporate university, known as the Center for Learning and Innovation.

Since the program began, the Center for Learning has trained 24 Black Belts, 70 Green Belts and three Master Black Belts. In conjunction with Six Sigma training, employees acquire valuable change management skills by taking classes in change acceleration process and fast track decision making.

Change acceleration process is a philosophy and tool set designed to help overcome cultural barriers to change by creating a shared need, shaping a vision and mobilizing commitment. Fast track decision making (North Shore’s version of General Electric’s Work-Out process) is a rapid problem solving approach with team involvement and in-meeting decisions.

It is a catalyst for change focusing on the process to drive improvement and empowering the people closest to the process to develop and implement appropriate solutions.

For additional information on the system, go to www.northshorelij.com.

fields were entered in the laboratory information system correctly. If any field was incorrect, the requisition was considered defective.

The team gave the test to the staff on two separate occasions. The gauge demonstrated repeatability, reproducibility and accuracy were more than 90% in all cases. A review of 5,607 laboratory requisitions collected over a one-week period revealed a defect rate of 283.

There are seven opportunities for defects in each requisition (name, Social Security number, date of birth, gender, physician, test and ICD-9 code):

\[
D = \frac{283}{(5,607)(7)} = 7,210
\]

The calculated DPMO of 7,210 was a 3.9 sigma score. The team also measured staff productivity by calculating the number of mean requisitions processed per hour as 17, with a standard deviation of seven requisitions per hour.

The team completed stakeholder analysis to aid in determining a strategy to move those individuals who were moderately against the project to a more supportive position. It also helped identify those individuals who were likely to touch the process and thus could be a resource to the team.

Analyzing and Improving Procedures

In the analyze phase, the team benchmarked the core laboratory’s performance against other reference laboratories throughout the country.

The core laboratory is a certified member of the College of American Pathologists. This certification entails peer review inspections of the facility and quality benchmarking study participation to compare the performance of laboratories throughout the country.

The sponsor of this project and chairman of the department of laboratories for the health system aided the team by putting it in contact with other large reference laboratories on the West Coast.

The core lab’s accessioning error rate of 3.9 sigma was comparable to industry standards. The productivity of the accessioning staff showed the current process had a large variation in the number of requisitions processed per hour and was below industry standards.

The goal was to decrease our DPMO by 50% as well as increase staff productivity to the industry standard.
Toward Error Free Lab Work

of 20 requisitions per hour with a decrease in variation to two requisitions per hour.

Graphical analysis using Pareto charts (see Figure 2) indicated 50% of the accessioning errors were due to incorrect entering of the Social Security number for skilled nursing facility patients. This discovery was an enlightening observation, or "ah ha"! Before the analysis, the team members had been convinced the culprit would be the handwriting of physicians when they fill out the name on the requisition.

This "X" proved statistically significant utilizing the chi-square test. The null hypothesis that all types of demographic errors are the same was rejected because the p-value = 0.002 was less than 0.05, and thus the team could conclude a statistical difference in the number of defects existed among the different demographic fields.

As the team drilled down utilizing the five why tool, it found the skilled nursing facility used addressographs for patient demographic information. Addressographs have multiple identifiers, making interpretation difficult for the accessioning staff.

In addition, addressographs tend to be illegible when run through an addressograph machine. Peel-off bar code labels located on the bottom of the core lab’s patient charts (which already existed) could be placed on the laboratory requisition and scanned in accessioning for the pertinent demographic information, thus eliminating the need for addressographs with multiple patient identifiers on laboratory requisitions (see Figure 3).

Each accessioning bench was already equipped with a bar code wand that could be used for scanning the codes. Graphical analysis using Pareto charts determined a small percentage of the staff (five out of 24 full-time employees) was making the majority of the errors. This again proved to be statistically significant with the chi-square test.

After the team’s review of the data to determine cause and effect for why a small percentage of staff was making the majority of errors, a new training program for staff was developed in the improve phase.

The team also created desktop reference guides to be positioned at each accessioning station. This helped make all the information new hires were supplied with at orientation and training readily available. The manual was broken into user-friendly tabs using the voice of the customer from the accessioning staff.

Ongoing competency assessment was achieved by using blind proficiency specimens throughout accessioning. The team modeled the assessment on the proficiency testing programs performed in the technical areas of the laboratory that are required for licensing. Box plots of accessioner (those who do the labeling of specimens) productivity showed the core lab lacked established best practices. Through analysis, the team concluded it was the process—not the people—driving the error rate for accessioning (see Figure 4).

Fast Track Session

Specimen movement within the lab was a “heartburn issue” for lab staff. To address the problems, a fast track decision making (FTD) session was held. The issue presented to the frontline supervisors and employees of the accessioning and technical departments was how to facilitate the movement of specimens from the nontechnical to technical area of the lab.
The productivity of the accessioning staff showed the current process had a large variation in the number of requisitions processed per hour and was below industry standards.

The session led participants to propose three recommendations:

1. A runner position—someone to move specimens around the accessioning department.
2. A color-coded book that lists all lab tests and which department performed the analysis.
3. Color-coded signs throughout the lab matching the color coding in the book so accessioning staff knows where to deliver specific specimens in the laboratory.

The empowered staff implemented recommendations two and three within the 90-day FTD timeframe. The employees designed the signs and books. The project was a huge success and generated buy-in for the Six Sigma team’s improvement strategies.

The response from the employees was so favorable the idea was translated to other key areas within the laboratory, such as marketing and information services.

Using lean and Six Sigma principles, the team was able to streamline specimen movement within the accessioning department, resulting in increased capacity (see Figure 5). Instead of each accessioner retrieving his or her work from the receiving sample bins and then delivering work to the clinical laboratory automated system, a lead accessioner position was developed. This role was given to an experienced person who would deliver 20 requisitions per hour to each accessioner, pick up completed work, place it on the robotics and answer technical accessioning questions when making rounds.

The Six Sigma team performed a design of experi-

Figure 5. Specimen Movement

CLAS = clinical laboratory automated system.
Aliquot = smaller sample created from the original specimen sample.
To determine whether the use of barcodes on the laboratory requisitions, distribution of specimens and expertise of the accessioning staff had any effect on the number of accessioning errors and the productivity of the staff per hour, a full factorial design of three factors and two different levels using analysis of variance, main effects and interaction plots, was employed. The team was able to prove that the use of barcodes and distribution of specimens was statistically significant (see Figure 6). The p-value of 0.047 also demonstrated that the variation was not caused by random chance.

The team developed an elevator speech that was presented to the accessioning and marketing staff and
to outreach clients to stress the importance of using the barcodes provided on the patient’s charts for patient demographics on laboratory requisitions.

The DOE helped prove to the staff that the new lean workflow helped increase productivity and the bar codes reduced accessioning errors.

**Controlling Results**

In the control phase, the Six Sigma team implemented a plan that incorporated individual and moving range charts for monitoring accessioner productivity. The DPMO for accessioning errors is now monitored on a monthly basis. The Six Sigma metric has become part of the laboratory quality management program. Blind proficiency testing is performed on a monthly basis and is also incorporated into the laboratories’ quality monitors.

At the end of the control phase, the process went from a 3.9 sigma to a 4.2 sigma. The accessioning department was able to increase its capacity and handle the 43% increase in outreach specimen volume that occurred in the first quarter of 2003 without additional full-time employees. The improvements from this project resulted in a combined financial impact of $339,000 a year due to increased revenue and cost reduction.

The Six Sigma team turned the project over to its process owner in May 2003 and disbanded. Currently, the productivity of the accessioning staff is more than 23 requisitions per hour, with a standard deviation of two requisitions per hour. The DPMO for accessioning errors is 1,387 with a 4.5 sigma level (see Figure 7). The proficiency score for the accessioning staff is 99%.

Six Sigma, lean and change management gave the team the tools it needed to fix the process and sustain the improvements.

**REFERENCES AND NOTES**

2. For definition of the five why tool, go to www.asq.org/sixsigma/terms/index.html.
3. For more information on individual and moving range charts, see *How To Use Control Charts for Healthcare* by D. Lynn Kelly (ASQ Quality Press, 1999).