SESSION 38: IMPROVING HEALTH CARE USING SPC AND QUALITY ENGINEERING: BILLING AND LABORATORY CASE STUDIES

This case study illustrates the use of TQM, statistical process control (SPC), and quality engineering to continually improve an enrollment and billing process, as well as the resultant cost savings.
INTRODUCTION

Quality Engineering, Inspection Planning, and SPC in Health Care

This paper illustrates the general application of quality management, statistical process control (SPC), and other quality engineering methods to study and improve any health care process. This approach is based on the management philosophy of the late quality pioneer, Dr. W. E. Deming, and his contemporaries, who emphasize the need to develop an understanding of a system, statistically and otherwise, in order to improve quality and reduce costs. For example, the applicability and value of using SPC in health care has been discussed by Benneyan (1995, 1996), Finison et al (1993), and others.

Additionally, a very simple and widely-applicable method exists to help health care managers determine when and where it is - and it is not - cost effective to inspect or audit process output. In fact, improper quality and inspection methods often can account for as much as 5% of net operating costs and significantly increase clinical liability. For example, considerable savings often are possible by changing from a 100% inspection mentality to a quality control philosophy based on statistical process control (SPC).

This method, most often associated with Dr. Deming, helps determine the appropriate inspection policy in order to minimize the total expected costs of poor quality (CPQ). This model also illustrates that anything but 0% or 100% inspection never results in a lower cost policy, despite continued widespread partial sampling practice to the contrary. After some background and a brief review of this method, case studies in an Enrollment and Billing department, clinical laboratories, and other examples illustrate the application of these concepts.

The paper concludes with brief mention of several other health care applications of this approach and references for further exploration. By following the general approach outlined in this paper, readers can identify similar opportunities for savings in their own processes.

Enrollment/Billing Case Study

When new members join or leave a particular HMO, all member applications, terminations, and re-enrollments are manually entered into a computer system in an Enrollment and Billing department. Due to a high rate of data entry errors, these transactions traditionally then are 100% checked for data entry errors. This inspection activity consumes time, increases costs, and delays the process until a newly enrolled member can book an appointment in the computer appointment systems. A macro flow chart of this process is shown in Figure 1.

Figure 1: The Data Entry Process

This data entry process was significantly improved by using quality management, various basic SPC tools, and Deming's "k1/k2" inspection rule. During this 18 month "CQI" process, the accuracy of data entry improved from approximately 8% errors to less than 0.5% errors. Additionally, as a result of this improvement, the costly end-of-the-line quality control inspection was removed, together saving approximately $120,000 per year and helping reduce turn-around-time.

USE OF TQM, QUALITY ENGINEERING, AND SPC

An interdisciplinary quality improvement team was formed, consisting of data entry personnel, inspectors, line managers, member service representatives, and a statistical quality management consultant. Data entry errors were identified as the highest priority problem, based on customer dissatisfaction and the belief that these errors were one contributing root cause of long turn-around-times.

Training was provided in the philosophy of quality management (TQM). During the course of the project, additional training was provided on an as-needed basis in various quality and statistical tools. These included process flow analysis, Pareto charts, scatter plots, histograms, statistical control charts, and others. The project then followed a simple data-driven scientific problem solving approach, as embodied in the classic Plan-Do-Study-Act (PDSA) cycle of Shewhart and Deming.

Process data were used throughout the project to study the performance of the process and to check for improvements. For example, the Pareto chart in Figure 2 illustrates the primary types and sources of errors during a thirty month time period. Note that the "critical few" categories include the phone, street, and name data fields, whereas relatively fewer errors were associated with the
address, zip code, and town data fields.

Scatterplots and regression analyses also were used to investigate possible causes of data entry errors. For example, Figure 3 examines whether the frequency of errors increased during periods of time when higher volumes were processed. In this case, note that higher volumes do not appear to have significantly increased the rate of errors, which was contrary to the common intuition. (The notable exceptions in this figure are the points corresponding to months in which temporary labor was hired, as discussed further below; otherwise, very little relationship appears to exist between volume and error rates.)

In fact, the correlation coefficient between monthly data entry volume and monthly fraction of errors was only $r = 0.23$, which is insignificantly different from $p = 0$ at an $\alpha = 0.05$ significance level. The results from this simple data analysis saved the expenditure of considerable effort on a part of the process which in fact was not a “root cause” of data entry errors.

Statistical control charts indicated that the data entry error rate initially was not in a state of statistical control and that no standard predictable process seemed to exist, both overall and between employees. By then focusing on the primary types of errors indicated in the earlier Pareto chart, using simple process flow techniques, and providing training and other information as to how to improve, the error rate first was brought into statistical control and then significantly reduced, as illustrated in Figure 4.

A possible exception to this improved and in control process is the high error rates corresponding to the months of 12/93 and 1/94. Additional data analysis determined that these high error rates were attributable to temporary labor used every December in order to handle extremely high enrollment volumes due to companies and major employer groups re-enrolling or switching their employees between health plans. A special quality assurance process and a more advanced control chart, therefore, were designed for this infrequent situation.

Additionally, temporary employees also now are given further training then previously thought necessary.

A self-directed work team continues to work on further improvements. For example, recent Pareto analysis indicated that the two data fields with the most errors are numerical (telephone and social security numbers), and special training in keying numbers is being pursued in order to further reduce these “critical few”. Additionally, now that the team has gained some comfort with the SPC approach, control charts also are being used to further understand and reduce turn-around-time.

COST OF POOR QUALITY AND INSPECTION

When to Inspect, When Not to Inspect?

“Cease dependence on inspection to achieve quality. Eliminate the need for inspection on a mass basis by building quality into the product in the first place.”

- Dr. W. E. Deming

The stabilized and improved data entry process meant that the end-of-the-line quality control inspection now probably was less justified by its time, expense, and questionable effectiveness. A simple type of cost of poor quality (CPQ) study therefore was performed. Deming’s $k_1/k_2$ inspection cost model (1982), briefly summarized below, revealed that significant savings now were possible by eliminating this inspection altogether.

Dr. Deming’s $k_1/k_2$ minimum cost rule (1982) helps determine where inspection steps should and should not exist in any process, based on the costs of poor quality and the impact on the customer. The method selects the least expensive inspection policy between the three general approaches summarized in Figure 5. In many processes, either adding or eliminating inspection steps can result in significant savings.

Without going into mathematical detail, another very important result is that, given certain reasonable assump-
tions, either 0% or 100% inspection always will be optimal. For this reason, the rule sometimes also is referred to as the “all-or-nothing” quality inspection rule. Additional information can be found in Anscombe (1958), Papadakis (1985), Gitlow et al (1989), and Benneyan (1994). Partial sampling, while intuitively very appealing, never will have a lower expected cost than the optimal policy! One basic reason is that historical quality control sampling plans do not account for the total cost, including the impact on the customer.

Although this result may be counter-intuitive, it is nonetheless a statistical fact which in some cases can significantly reduce costs and liability. This result is based on several general assumptions and is fairly robust and applicable in a wide range of settings. For example, it has been successfully applied in service, finance, manufacturing, administration, and distribution functions of biomedical, automotive, plastic, machining, shipbuilding, and computer industries, to name just a few.

The expected costs of the three general policies are based on the inputs and notation listed in Figure 6. Using this notation, the minimal expected cost inspection policy then easily is determined by comparing the ratio of $k_1/k_2$ to $p$, as shown in Figure 7. The expected costs of each inspection policy also are shown in Figure 7. In the present data entry example, the fraction of data entry errors had decreased to approximately $p = 0.005$ and the average cost to inspect a single invoice was estimated at $k_1 = $0.52. Due to a recent merger, approximately 12,500 transactions may be processed monthly, or approximately $N = 150,000$ per year.

Note that the exact cost of not detecting a data entry error is tougher to estimate due to intangibles such as customer inconvenience and dissatisfaction. However, a lower bound on the tangible costs (e.g., reprocessing time, postage, materials) was estimated at $k_2 \geq $0.58. Using these estimates, then

$$\frac{k_1}{k_2} = \frac{$0.52}{$0.58} = 0.897 \geq p = 0.005.$$  

The criteria in Figure 7 therefore indicates that 0% inspection is the optimal policy. As the $k_2$ cost of a data entry error is not known with certainty, Figure 8 plots the annual cost of each of the three inspection policies (0% inspection, 100% inspection, and partial sampling) for a
Quality Policy: Possible Intuitive Reasoning

100% Inspection: Inspect every item for being nonconforming, to try to ensure that no errors are passed on to an external or internal customer.

0% Inspection: Inspect no items, thereby saving inspection time and money.

Acceptance Sampling: Inspect a partial and random sample and based on the number of nonconforming found in this sample, either inspect every remaining item or accept them all with no inspection, thereby trying to balance between the above costs.

Figure 5: Three Possible General Approaches to Quality

Inputs to Deming’s k1/k2 Inspection Planning Cost Model

\[ p: \text{ Process fraction nonconforming (assumed “stable” over time);} \]
\[ k1: \text{ The cost to inspect an item (including labor, time, equipment, overhead, amortization, etc.). These costs usually can be estimated fairly easily; } \]
\[ k2: \text{ The cost of passing on an undetected error (including the cost of a nonconforming item centering the stream of commerce, disassembly, shipping, replacement, rework, dissatisfied customers, liability, etc.). Usually these costs are difficult to estimate; and } \]
\[ N: \text{ The total number of items under consideration in the given time period.} \]

Figure 6: Inputs to Deming’s k1/k2 Inspection Rule

<table>
<thead>
<tr>
<th>Minimal Cost Criteria</th>
<th>Optimal Inspection Policy</th>
<th>Long-Term Expected Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>k1/k2 ≤ p</td>
<td>100% Inspect</td>
<td>( \frac{N \times k1}{1 - p} )</td>
</tr>
<tr>
<td>k1/k2 ≥ p</td>
<td>0% Inspect</td>
<td>( \frac{N \times p \times k2}{1 - p} )</td>
</tr>
</tbody>
</table>

Figure 7: Simple Rule for Identifying The Least Total Cost Inspection Policy

Range of possible k2 costs. As this figure shows, supposing that a reasonable range for k2, including customer dissatisfaction - might be anywhere less than $104.00, eliminating the end-of-line inspection clearly could save considerable costs.

In fact, the possible savings achieved by switching policies quickly can be obtained by computing the differences between these cost functions. For example, using the above estimates and the formulas given in Figure 7, the annual cost of keeping versus removing the end-of-the-line 100% inspection are:

Cost of 100% Inspection = \( \frac{N \times k1}{1 - p} \)

= \( \frac{150,000 \times 0.005}{1 - 0.005} \)

= \$78,391.60

Cost of 0% Inspection = \( \frac{N \times p \times k2}{1 - p} \)

= \( \frac{150,000 \times 0.005 \times 0.58}{1 - 0.005} \)

= \$437.19

The annual savings which would be possible by removing this inspection step therefore is:

Savings by Switching Inspection Policies =

= 100% Inspection Cost - 0% Inspection Cost

= \$78,391.60 - \$437.19

= \$77,954.77 per year.

In this case, the immediate savings of almost \$78,000 annually equates to approximately 5% of the net operating cost of the process, which is not uncommon in a variety of settings and industries. Moreover, recent dramatic increases in membership and market share, as well as the
increased capacity now to handle volumes from other divisions of the health care network, suggest that the eventual annual savings could more than double.

Finally, Figure 9 summarizes the annualized combined savings of approximately $120,000 due to the improvements depicted in the earlier control chart and the later elimination of the costly end-of-line inspection. Note that even before removing the 100% inspection, this improvement trend resulted in approximately $42,000 savings per year, demonstrating that incremental continual improvement increased quality and reduced costs, as Dr. Deming theorized.

**Financial Control Charts**

It is important to note that the selection of 0% or 100% inspection is for the purpose of controlling the quality of processed items. Even if 100% inspection is eliminated, periodic small random samples should be plotted on a statistical control chart in order to detect if the process deteriorates and to ensure that 0% inspection remains the minimum cost policy.

Control charts such as that shown earlier in Figure 4, in fact, can now serve as financial control charts to ensure minimal cost. That is, SPC serves as a very effective (in fact, the most effective) financial control, audit, and monitoring policy.

**OTHER HEALTHCARE AND LAB APPLICATIONS:**

**Pap Smears and Mammography**

Based on the success of this project, the approach and results were presented to various managers and used as a "TQM/SPC" training tool, asking the question "Where else?". As a result, similar possible applications have been identified in several other departments, with the total company-wide potential annual savings simply by switching to optimal inspection (0% or 100%) policy exceeding $500,000 per year.

Some of these other identified potential applications are shown in Figure 10, as well as some non-health care examples. These include medical records, internal audit,
cash handling, accounts receivable, and outside utilization authorization. Several clinical applications also have been identified, including the accuracy of pharmacy prescriptions, radiology, mammography, and Pap smear laboratory results. In these cases, the cost of an error includes patient health and liability, with savings including significant reductions in unnecessarily lost lives.

All of these laboratory or diagnostic procedures can be thought of as inspection-type of activities which could question when, and how many times, to review ("inspect") a specimen for indications of a particular medical condition. For example, mammograms sometimes are screened by a technician with subsequent radiologist verification of results. Additional possible diagnostic applications include testing for colorectal cancer, prostate cancer, breast cancer, and others.

Another important example is the reading of Pap smears to detect cervical cancer. Although the cure rates for cervical and breast cancer generally are high if detected in early stages, treatment is considerably less successful when allowed to progress undetected. For example, breast cancer is the number one cancer-related cause of death among females in the U.S., and over 200,000 preventable cervical cancer related deaths occur per year worldwide.

Benneyan and Kaminsky (1996) therefore recently developed similar methods to that described in the preceding section in order to help identify the optimal number of rescreenings and the optimal partial rescreening rate in these laboratory settings, although somewhat more complicated mathematically than the simple \( k_{1}/k_{2} \) rule. Using these results, analysis somewhat similar in concept to that above recently has shown that significant improvements are possible via alternative quality inspection policies than those currently mandated by the Clinical Laboratory Improvement Amendments Act (CLIA) of 1988. For example, Figure 11 illustrates one situation where four multiple evaluations of every Pap smear actually results in the minimal total cost, due to a high cost of not detecting cervical cancer.

Similar to Deming’s result, Benneyan and Kaminsky (1996) also show that the optimal policy always will employ either 0% or 100% rescreening by one or more lab technicians. That is, in no case will any amount of partial rescreening ever result in the best possible laboratory policy. This is a very significant result in light of current practices and requirements to the contrary. Related methods also are being used to determine optimal cutoff points in testing for HIV and hepatitis.

Although not the primary focus of the current paper, the application of SPC and other tools of statistical quality control to clinical laboratories is discussed and illustrated further by Benneyan and Kaminsky (1995). In mammography and other radiology procedures, for example, the ability to discriminate between various tissue mass densities is critical to accurate diagnoses. The control chart in Figure 12, however, indicates that this mammography film process is not in a state of statistical control, exhibiting several trends and spikes, and at one point shifting quite dramatically. Similarly, the Pareto chart in Figure 13 illustrates that the primary reasons that chest x-rays are repeated involve patient positioning, lighting, and movement.

Although several individuals have suggested that additional quality control programs only will further increase overall laboratory costs, this view tends to reflect a traditional quality assurance approach to health care management, rather than a quality management orientation. For example, contrary to Deming’s philosophy, Dr. Inhorn (1995) recently stated

> "The reality if that (quality control procedures) increase the workload of the laboratory and the cost of cyto logical analysis. Many studies have shown that Total Quality Management systems add at least 25% to overall laboratory costs."

Mango (1995) also echoed this traditional pre-TQM management concept, stating “In my opinion, there are no

<table>
<thead>
<tr>
<th>Health Care Applications</th>
<th>Non-Health Care Applications</th>
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<tbody>
<tr>
<td>Medical Records</td>
<td>Accounts Receivable Department</td>
</tr>
<tr>
<td>Internal Audit</td>
<td>(5.5M - 1M/year savings)</td>
</tr>
<tr>
<td>Cash Handling</td>
<td>Bank Payroll Department</td>
</tr>
<tr>
<td>Accounts Receivable</td>
<td>($4.75 per transaction)</td>
</tr>
<tr>
<td>Outside Utilization Authorization</td>
<td>Integrated Circuits in TV sets</td>
</tr>
<tr>
<td>Prescription Accuracy</td>
<td>($24/set = 15% of manufacturing cost)</td>
</tr>
<tr>
<td>Radiology and Mammography</td>
<td>Automobile Engine Testing</td>
</tr>
<tr>
<td>Pap Smear Readings</td>
<td>($47/motor x 4,000 motors/day = $185,000/day)</td>
</tr>
<tr>
<td>Other Laboratory Results</td>
<td>(* see Deming, 1982; ^ see Benneyan and Chute, 1993)</td>
</tr>
</tbody>
</table>

Figure 10: Other Health Care and Non-Health Care Empirical Applications of \( k_{1}/k_{2} \) Inspection Rule
Minimal Cost Policy versus Number of Repeated Screenings

Figure 11: Example of Optimal Laboratory Quality Policy Identification

Control Chart for "Step 12" Optical Density Data

Figure 12: Statistical Control Chart of Mammography Optical Density QC Data

Reason for Repeated Chest X-Rays

Figure 13: Pareto Chart of Reasons the Chest X-Rays Need to be Re-Taken
known quality control procedures that do not impact workload or cost. As shown by the above examples, however, the effective use of quality engineering methods can result in significant reductions in total costs and increases in overall quality.

CONCLUSION
Statistical quality management is an effective technique which should be used to complement traditional quality assurance procedures. Sound methods should be designed and implemented which ensure the ability to detect errors, of any kind, at minimum cost. For example, the manager of the Enrollment and Billing department believes they have eliminated unnecessary work, streamlined key processes, replaced frustrating work with more meaningful work, and significantly reduced cost and turn-around-time with less resources.

Traditional approaches that attempt to “inspect quality in” are difficult to defend against arguments that better quality control methods should be used. This is especially true in clinical laboratories, where ensuring the earliest detection of disease, both at minimum possible costs and accounting for the possibility of human error, is critical. For example, significant improvements in ability to detect cervical cancer and in total costs are possible by changing the current mandated Pap smear inspection policy.

Statistical process management, as illustrated herein, is a much sounder approach to health care quality assurance, be it for administrative, clinical, non-clinical, or laboratory processes. Additional information on the application of statistical process control to health care and clinical laboratories can be found in several of the listed references or by contacting the author.

REFERENCES


