A Statistical Process Control Case Study

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Statistical process control (SPC) charts can be applied to a wide number of health care applications, yet widespread use has not occurred. The greatest obstacle preventing wider use is the lack of quality management training that health care workers receive. The technical nature of the SPC guarantees that without explicit instruction this technique will not come into widespread use. Reviews of health care quality management texts inform the reader that SPC charts should be used to improve delivery processes and outcomes often without discussing how they are created. Conversely, medical research frequently reports the improved outcomes achieved after analyzing SPC charts. This article is targeted between these 2 positions: it reviews the SPC technique and presents a tool and data so readers can construct SPC charts. After tackling the case, it is hoped that the readers will collect their own data and apply the same technique to improve processes in their own organization.

Key words: case study, control charts, quality management, SPC, statistical process control

One of Edward Deming’s quality principles is to make quality everyone’s job.¹ Health care organizations have always assumed that quality is everyone’s job and everyone knows the difference between quality care and substandard care. Yet health care by relying on individualistic definitions of quality without performance evaluation systems has never made quality everyone’s job. Consequently, quality management is left to quality improvement director, department, and/or committee, fails to achieve widespread support in the organization, and produces few tangible improvements in processes or outcomes.

Implementing Deming’s principle requires employees to understand what quality is, be capable of identifying substandard performance, and have the authority to make changes that will improve performance. According to Deming, it is the responsibility of management to suffuse this quality focus into their organizations. Of course, this is the problem in health care; other industries have developed rigorous systems to monitor quality and modify processes when output does not meet expectations. Berwick bluntly addressed this problem; doctors, nurses, receptionists, and other health care workers are not trained in or capable of changing how they work.²

Health care has been implementing quality improvement programs for decades but efforts to cross into the fertile fields of quality management always seem to flounder. The inability to apply the quality management techniques of other industries is due to the more complex nature of health care but part of the problem is the way health care has approached quality management. Berwick recognizes that health

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care workers have not been given the tools to systematically incorporate quality measurement in their work.

The following case was developed to demonstrate how statistical process control (SPC) can be applied to health care processes. The SPC is a tool that defines what quality is, how performance is measured, and when investigation and possibly correction must occur. The SPC, once understood, empowers the doctor, nurse, department manager, and other health care workers to enter into the quality management process on a more equal basis with those trained in quality management techniques. The initial audience for this article is health care managers, but as Deming and Berwick note, improvement occurs only when all employees understand and embrace these quality improvement techniques. Getting managers and opinion leaders on board is only the first step to institutionalizing quality practices throughout the organization.

This article does not assume that the reader is versed in statistics or quality management techniques, it does however assume familiarity with spreadsheet software. The goal is to demonstrate that quality improvement techniques can be used productively by all health care workers. At the end of this case it is hoped that the reader will be able to identify a use for the SPC in their area of responsibility, create SPC charts using Excel, and interpret these charts to improve outcomes.

QUALITY IMPROVEMENT IN HEALTH CARE

One of the greatest obstacles to quality improvement in health care is the belief of providers that quality management tools developed in other industries are not relevant to health care services. Not only are the initiatives of other industries deemed irrelevant to health care, many providers hold that quality improvement mechanisms developed in other health care organizations are not applicable to the institution they work in. This belief is the direct result of the second factor, and health care providers are not familiar with the purpose, operation, and interpretation of quality management tools. Without understanding quality management techniques and the ends to which they can be applied, it is understandable that health care providers would think these tools have little to offer them.

Health care quality management texts inform the reader that SPC charts should be used to improve delivery processes and outcomes often without discussing how they are created. Conversely, medical research frequently reports the improved outcomes achieved after analyzing SPC charts. This article is targeted between these 2 positions: it reviews the SPC technique and presents a tool and an application so readers can learn how to construct SPC charts and offers suggestions as to when they can be used to improve health care delivery processes.

A case study is developed and followed to conclusion to demonstrate one potential application of the SPC to health care. The intent is to provide the readers with a basic understanding of how to build SPC charts and encourage them to access and analyze the case data using Excel to evaluate performance on their own. The case question is: are medicines delivered in a timely manner to maximize medical effectiveness and patient comfort? The control charts developed are used to draw conclusions regarding the operation of the system, explore potential reasons for the performance observed, and speculate on system changes that could improve the timeliness of medicine delivery. After working through the case, it is hoped that the reader will be motivated to apply the principles and techniques to their own work.

One of the major difficulties in advancing health care quality is the lack of specificity in defining health care processes, establishing performance standards, and measuring compliance with standards after they are defined. Attempts to improve operations and outcomes are difficult if not impossible when standards and measures are ill-defined or absent. Efforts to define medical processes continue to be hotly debated, and opponents argue that there is too much variation in medical practice to establish one way of treating patients and dictating to physicians will not improve patient care and may hurt patients.\(^5\)
On the other hand, countless research has been done to define proper medical practice; much of this work is amendable to and should be tracked by the SPC to improve health care outcomes for patients. McGlynn et al found that patients received 54.9% of recommended care, more important than their conclusion was their technical supplement that provided the indicators of what should occur and when it should occur for 30 conditions.4

Other industries recognize that poor performance is the result of variation, that is, deviations from how things should be done that adversely impact outcomes. Controlling variation is the key to process improvement. Health care providers are arguably saddled with more sources of variation than producers of other goods and services but the issue remains; is there too much variation in treatment and will a more systematic approach to health care delivery processes improve outcomes? The SPC is a tool health care workers can use to determine when variation is a routine part of patient care, necessary and beneficial for patients and the health care system, and when variation is excessive and potentially harmful. Armed with this information, it is the duty of health care providers to reduce inappropriate variation.

**IMPROVING HEALTH CARE**

**Root cause analysis or routine monitoring?**

Current quality control efforts revolve around root cause analysis, that is, a comprehensive examination of an adverse event with the goal of reducing harm to patients by preventing the reoccurrence of the event. JCAHO-accredited health care organizations must conduct a root cause analysis focusing on systems and processes when a sentinel event occurs. Root cause analysis is limited by its initiating cause; it is undertaken after an adverse event has occurred and examines only those processes that were part of the care episode. In arguing for a broader approach it has been noted “when multiple sources of variation are present, isolated observations provide insufficient information on which to base objective decision making.”5

The SPC is a broader approach that continuously examines processes to identify undesirable trends in performance and institute corrective action before harm arises. Fasting and Gisvold used the SPC in anesthesia to study a range of adverse events that are less severe and more frequent than sentinel events that contained the potential for harm. As a result of their study, they were able to reduce anesthesia accidents.6 The SPC complements root cause analysis and extends process improvement efforts by adding ongoing monitoring of a broad range of events to quality management. JCAHO (LD.5.2) notes that sentinel event analysis is reactive and does not meet the intent of the JCAHO patient safety standard.7 The SPC is not concerned with particular cases but rather with the ongoing function of systems and thus is a proactive approach to operations that monitors performance to detect changes in system performance before problems arise.

**The 6 steps of SPC**

The goal of the SPC as envisioned by Walter Shewhart is to determine when a system is out of control and requires adjustment to improve its output. An in-control system simply indicates that it is operating close to its historical performance; this performance, however, may fail to meet generally accepted standards or customer expectations. A system that is out of control indicates performance that is significantly different from historical performance. The goals of the SPC are to identify when performance deviates sufficiently to endanger quality and improve in-control performance to improve outcomes.

Shewhart's second goal was to devise a quality monitoring and improvement system that could be operated effectively by workers whose expertise lies in areas other than statistics.8 Such a system required clear signals to indicate when system performance fluctuates too much and be easy to use. Shewhart created his system in a manufacturing environment for those trained in engineering and, as will be demonstrated, it is as applicable for service industries and those trained in medical sciences. The SPC is designed for ease of use; the technique can be described and completed in 6 steps.
The SPC can be used to monitor the behavior of any system that produces outputs that can be measured numerically. The SPC can monitor the percentage of defects in a sample (P charts), the number of defects in a sample (c charts), or output characteristics (average and variance, $\bar{X}$ and $R$ charts) among other things. These applications require employees to routinely collect simple performance measures to monitor quality: percent defective, number of defects, the average weight or length of a product, time required to deliver a product or service, and the variance in these characteristics. The case uses $\bar{X}$ and $R$ charts since the concern is the interval between prescribed medication time and the actual delivery of medicines to patients. An earlier article in this journal provides a concise explanation of when the different control charts should be used.9

**Step 1: Data collection**

Data collection is the most time consuming part of the SPC process. A manager wanting to assess performance using the SPC must determine the desired sample size, how often samples are to be drawn, procedures to ensure that the samples are random, and who is responsible for data collection. Managers must realize that they face a trade-off between the cost of collecting data (sample size and sampling frequency) and the accuracy of information obtained from the collected data. Larger samples typically produce more accurate information but are more costly and time consuming to collect. The events sampled must be randomly drawn to ensure that the sample is not biased; that is, the information gained from the sample must be representative of the larger population for it to accurately assess the performance of the nonsampled phenomena. The procedures and responsibility for data collection should ensure that the data collector has no incentive to collect either favorable or nonfavorable performance. After the data are collected, it should be recorded in a spreadsheet.

**Step 2: Calculation of descriptive statistics**

After the data are recorded, descriptive statistics must be calculated. Descriptive statistics provide the information necessary to understand how the system is operating, the first statistic is the mean. The mean is the measure of central tendency and reports “average” performance. The mean is used to determine whether performance meets the desired standard. The mean for a sample is calculated as follows: $\bar{X} = \frac{\sum x_i}{n}$, the sum of the sampled observations divided by the sample size. If Excel is used to record data, the mean is calculated as follows: =AVERAGE(range of observations). In medication management the mean can be used to determine whether patients received the specified dose—larger or smaller dosage is a problem. Likewise, science and common sense dictate that the most effective interventions are delivered proximate to a medical event; the case seeks to determine whether medicine is delivered to patients within (plus or minus) 2 hours of the prescribed time.

The second statistic, range ($R$), provides a measure of the variance in the sample. Range is the highest value in the sample minus the lowest value and is used to assess the variability in performance. Excel can be directed to scan a series of numbers and identify the maximum and minimum values and perform the subtraction by the command: =MAX(range of observations)-MIN(range of observations).

The need for both statistics is demonstrated by assuming that the average turnaround time for a laboratory test is 60 minutes. Those awaiting results prefer a process in which 50% of tests are available in 65 minutes and the remaining 50% in 55 minutes to a process where one half of results are available in 10 minutes and the other half take 110 minutes. Average turnaround time, $\bar{X}$, for each process is 60 minutes but the first process has a 10-minute range (65–55 minutes) while the second has a 100-minute range (110–10 minutes). Lack of predictability in the second process is a problem. The person awaiting results from the second process does not know whether he or she will receive them quickly or have to wait almost 2 hours. Processes with the narrowest range are generally superior; the process with a 10-minute range provides users with a clear idea of when results will be available and allows them to schedule work accordingly. The variance in the second process can lead to inefficiency if delays in the availability of
1. Collect data
2. Calculate descriptive statistics
3. Calculate control limits
4. Graph actual and expected performance
5. Interpret performance
6. Investigate when indicated and fix as appropriate

**Figure 1.** The 6 steps of statistical process control.

Information impacts the effectiveness of treatment or providers must repeatedly check for results because they do not know when they will be available.

Differences in system performance are the result of variance, and all systems are affected by variance. Variance is categorized as natural or special cause; natural variation is inherent to a process and is the result of noncontrollable forces such as the capabilities of labor and equipment, the impossibility of 100% accurate measurements, and/or environmental factors (ie, the weather). Special cause variation can be traced to a controllable cause(s) that should not be present in a properly operating system. Special cause variation may arise from system design, inputs used, fatigue, wear and tear, lack of equipment maintenance, lack of training, etc. Any of these causes could reduce performance below desired or achievable levels. When assignable variation arises, it is the responsibility of managers to identify its cause and control it to improve outcomes.

Process improvement is built on meeting a desired standard and reducing the variance in performance. Managers must monitor performance on an ongoing basis, using the mean and range to ensure that performance targets are met. The \( \bar{X} \) chart monitors how actual performance varies from historical performance while the \( R \) chart monitors uniformity—the difference between the best and worst performance in a sample. Both charts seek to identify when performance should be investigated, that is, when observed performance deviates significantly (is too high or too low) from historical performance.

**Step 3: Calculation of control limits**

The calculation of control limits requires 4 formulas and provides a quantitative answer to how much variance will be accepted before a process is investigated. The formulas for the upper control limit (UCL) and lower control limit (LCL) of the \( \bar{X} \) chart are as follows:

\[
\text{UCL} : \bar{X} \pm (A \times \bar{R})
\]

\[
\text{LCL} : \bar{X} - (A \times \bar{R})
\]

The new terms in these formulas are \( \bar{X} \), average performance across the samples collected (\( \bar{X} = \sum \bar{X}/\text{number of samples} \)); this is an average of averages, \( \bar{R} \), the average range across the samples (\( \bar{R} = \sum R/\text{number of samples} \)), and \( A \), the control chart factor. \( \bar{X} \) and \( \bar{R} \) establish the historical performance against which individual samples will be judged. \( \bar{X} \) specifies what average performance has been over a large number of samples or extended time period and \( \bar{R} \) defines how performance has varied across the samples or time period. The control chart factor is multiplied by the average range to determine the acceptable range of performance.

The magnitude of the control chart factor (A) is determined by sample size that is the number of items \( n \) in a sample. A larger sample size generally produces more accurate statistics, and consequently the control chart factor is reduced producing tighter limits (see Fig 2). When selecting a control chart factor, it is a common mistake for students of the SPC to confuse the number of samples taken with the sample size—control chart factors are determined by the

<table>
<thead>
<tr>
<th>Sample size (n)</th>
<th>A</th>
<th>( D_1 ) LCL</th>
<th>( D_2 ) UCL</th>
</tr>
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<tbody>
<tr>
<td>2</td>
<td>1.880</td>
<td>0.000</td>
<td>3.267</td>
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<tr>
<td>5</td>
<td>0.577</td>
<td>0.000</td>
<td>2.116</td>
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<td>25</td>
<td>0.153</td>
<td>0.459</td>
<td>1.541</td>
</tr>
<tr>
<td>&gt;75</td>
<td>( 0.75 \times 1/\sqrt{n} )</td>
<td>( 0.45 + (0.001 \times n) )</td>
<td>( 1.55 - (0.0015 \times n) )</td>
</tr>
</tbody>
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**Figure 2.** Control chart factors. \( \text{LCL} \) indicates lower control limit; \( \text{UCL} \), upper control limit.
sample size (the number of observations in the sample) rather than by the number of samples drawn.

The product of the control chart factor and the average range is added (or subtracted) from the historical performance (the average of the averages) to determine the upper (or lower) control limit. For example, when samples of 25 are drawn, the average output of a process is expected to routinely fluctuate around its historical performance by ±15.3% of its average range (±0.153 × \( \bar{R} \)). Investigation is required whenever the average for a sample varies by more than 15.3% of the average range.

The upper and lower limits for the \( R \) chart also require 2 formulas:

\[
\text{UCL : } D_2 \times \bar{R} \\
\text{LCL : } D_1 \times \bar{R}
\]

\( D_1 \) and \( D_2 \) are control chart factors and, similar to \( A \), these factors produce tighter control limits as sample size increases. When samples of 10 are drawn, a sample range could be up to 77.7% above or below the average range (1.000 ± 0.541 × \( \bar{R} \)) before investigation is warranted. Using a larger sample of 25, acceptable variation is reduced to 54.1% above or below the average range (1.000 ± 0.541 × \( \bar{R} \)). It is only when a sample range exceeds the control chart limits that investigation and potential corrective action are required.

Step 4: Graphing performance

Steps 2 and 3 provide all the necessary information to graph actual performance, the average, and the range between the highest and lowest values, against historical and expected performance. Sample averages (or ranges) are graphed as \( XY \) charts with the \( x \)-axis defining when the sample was collected (reported in a chronological order) and the \( y \)-axis recording the value of the sample average or range. The centerline (CL), \( \bar{X} \) or \( \bar{R} \), and the upper and lower control limits are also graphed to provide the baselines against which actual performance is measured. Routine monitoring of performance, after the control limits are established, requires the relatively simple task of collecting data, calculating the mean and range, and charting the values for new samples.

Step 5: Interpreting performance

Step 5 is the examination of actual and expected performance to determine whether the process is in control or out of control. An in-control or stable process is one where actual performance, \( \bar{X} \) or \( R \), falls within the control limits with data points lying on either side of the centerline, without exhibiting a pattern. Figure 3 presents 6 configurations to look for when examining control charts. Chart 1 shows an in-control process in which data points do not breach the upper or lower control limits and are randomly distributed around the centerline. Chart 2 presents the classic out-of-control process where multiple sample values (samples 2, 5, and 8) breach the established control limits. Charts 3–6 show no samples breaching the control limits but all have recognizable patterns that indicate instability in the process or a systemic change. Sample values fall only on one side of the centerline in chart 3, an upward trend beginning in period 5 is evident on chart 4, a cyclical pattern occurs on chart 5, and the lack of variance starting in period 6 on chart 6 suggests that none of these systems are operating as they have in the past.

Charts 2–6 suggest that the process has changed; it is the manager’s job to identify if and why performance has changed and the impact of this change on patients. SPC charts may record positive or negative changes to system performance. Once the change and its impact are understood, managers need to institutionalize those changes that improve outcomes or initiate corrective action for those that reduce the effectiveness of the health care process.

Step 6: Investigation

Steps 1 through 5 are necessary to identify when a process should be reviewed, control charts clearly indicate when a limit is exceeded or the starting point of a trend but they do not identify what has changed or the impact of the change on patients. Step 6 is the most challenging part of the process; does breaching a control limit or an identifiable pattern indicate that the process is out of control and requires
correction (or does it signal improved performance)? Correspondingly, in the absence of limit breaches or trend, is a process performing at a high enough level? The answers are not straightforward, and the nature of sampling ensures that occasionally nonrepresentative samples are drawn. A particular sample may include a disproportionate number of high (or low) values and breach an upper (or lower) control limit, indicating a process change when no change has occurred. The first task of an employee, after a control
When a sample exceeds a control limit (Fig 3, chart 2), the first step in the investigation is to increase the sample size to determine whether the out-of-range result holds as more observations are examined. If the expanded sample produces a mean or range that falls within the control limits, the manager can assume that the process is in control, resume monitoring, and avoid tinkering with a stable system. One of the primary goals of the SPC is to focus employee effort on areas that require correction by eliminating processes that do not need attention.

If the out-of-range results persist after the sample size is increased, the employee can assume that nonrepresentative sampling did not produce the control limit breach and the harder task of determining why performance has changed arises. Breaches of control limits are designed to be rarely occurring events so employees will not spend significant amounts of time or efforts investigating trivial variation in performance. The SPC can maximize the effectiveness of improvement efforts by concentrating employee efforts toward assignable variation and controllable causes and away from stable processes.

Given the rarity of breaches of limits or patterns demonstrated on charts 3–6 in Figure 3 that indicate processes are not functioning as they have in the past, the manager’s and employees’ job is to pinpoint the cause(s) of change and enact corrective action if the change has impaired outcomes. The SPC enhances employees’ ability to pinpoint causes by providing an early detection system to identify performance that is inconsistent with historical performance. Prompt identification of change may enhance employees’ ability to pinpoint the cause of change while the causes of change are still fresh in their mind.

The uses to which the SPC can be applied in health care are numerous: are generally accepted standards of care being followed, is health care provided differently to different populations, are waiting times appropriate, and does performance vary with the personnel delivering care, the location of service, or the time or day of service? The next section applies the 6-step process to a set of hypothetical data to illustrate the SPC technique. The readers are encouraged to calculate the descriptive statistics and control limits and create the control charts for themselves.

### A MEDICATION MANAGEMENT CASE

Effective and high-quality medical care requires that medicines be administered on a timely basis, and the performance standard expected in this case is that medicines should be administered within 2 hours of the prescribed time. Rather than examining every dose delivered, the SPC allows the use of a sample of a small number of drug administrations to determine whether the system is in control, is it meeting the 2-hour window, or is it out of compliance? A 100% sample may not be particularly informative as it is unlikely if 100% of drugs are delivered within 2 hours since natural variation is at work, that is, patients have the right to refuse medication and do so, the patient may be receiving other treatments and be unavailable for medication, etc. A 100% sample would also be arduous, if not impossible, to collect given that a 500-bed hospital may dispense 160,000 medications in a month. The 6-step SPC technique described above is followed to analyze medication management.

### Step 1: Collect data

A random sample of 50 medications was drawn for the day, evening, and night shifts every day for a month; a total of 4650 observations (50 medications × 3 shifts per day × 31 days) and recorded in a spreadsheet. The sample size of 50 was arbitrarily determined; it is hoped that a sample size of this magnitude would persuade skeptical employees that the data were valid. As the validity of the SPC process is demonstrated, the sample size could and should be reduced. Technical note: with a sample size of 50, an \( \bar{X} \) and SD (standard deviation) chart is recommended but this case will use the more understandable \( R \) chart. A copy of this data can be obtained at http://personal.ecu.edu/rossth/QMHCv15i4.xls and pasted into Excel.
Step 2: Calculate descriptive statistics

The first sample (Day 1, Day Shift, Monday) produced an average delivery time of 111.38 minutes, \( \text{AVERAGE}(B5:B54) \). The difference between actual and prescribed administration time was recorded as absolute values so medicines administered prior to and after the prescribed time are both recorded as positive values. Once the Excel formula is entered, it can be copied to the remaining columns (through column CP) to calculate average administration time for each shift each day. The performance of the first sample can be contrasted against the most timely average delivery time of 100.12 minutes (#52), and the least timely, 134.44 minutes (#71). The average time between the prescribed medication time and the actual administration of medicines for all 93 samples (3 shifts per day \( \times \) 31 days), \( \bar{X} \), is 115 minutes. The Excel formula is \( \text{AVERAGE}(B56:CP56) \). The centerline is thus established at 115 minutes on the basis of historical performance, as stated earlier an industry average or patient expectation, if known, could be used to establish expected performance.

Sample #1 has a range of 98 minutes between the most on-time delivery of medicine and the least timely delivery, \( \text{MAX}(B5:B54) - \text{MIN}(B5:B54) \). This formula must again be copied across to column CP to calculate the range for each shift each day. Sample #1’s range of 98 minutes can be contrasted with the low of 33 minutes (#41) and the high of 100 (#10). The average time between the most on-time and the least on-time administration for the 93 samples is 65 minutes. The average and the range indicate that average medication administration time is 115 ± 65 minutes or actual administration of medicine ranges from 82.5 to 147.5 minutes (115 ± 65/2) before or after the prescribed time.

A cursory review of performance, based on the descriptive statistics, provides a manager with a good idea of where she or he should devote her or his attention. For example, the highest mean delivery time occurs on the Monday through Friday evening shifts and the greatest variance occurs on the day shifts during the week. Is this performance acceptable? Should the manager devote his or her time and energy to investigating the delivery processes on these shifts? The SPC will answer these questions; at this point the high mean and wide range suggest that desired performance is not being achieved.

Step 3: Calculate control limits

\[ \bar{X} \text{ UCL}: 115 + \left( 0.75 \times \frac{1}{\sqrt{50}} \times 65 \right) = 121.9 \text{ minutes} \]
\[ \text{Centerline (the mean)} = 115.0 \text{ minutes} \]
\[ \bar{X} \text{ LCL}: 115 - \left( 0.75 \times \frac{1}{\sqrt{50}} \times 65 \right) = 108.1 \text{ minutes} \]
\[ R \text{ UCL}: (1.55 - (0.0015 \times 50)) \times 65 = 95.9 \text{ minutes} \]
\[ \text{Centerline (the range)} = 65.0 \text{ minutes} \]
\[ R \text{ LCL}: (0.45 + (0.001 \times 50)) \times 65 = 32.5 \text{ minutes} \]

Enter the \( \bar{X} \) control limits and centerline directly below the calculation of the average medication time in the spreadsheet and copy across all columns. Similarly, the \( R \) chart limits and centerline should be entered and copied below the range for each sample.

The control limits indicate whether the medication process is stable and subject to only natural variation, and average medication time for a sample of 50 should fluctuate between 108 and 122 minutes. Similarly, the range between the most and least on-time delivery should vary from 33 to 96 minutes. If these thresholds are exceeded, the SPC indicates an unstable process or a potential change in performance that requires investigation. Breaches of the upper limit in this case indicate deterioration in performance (less timely administration of medicines) while downward breaches may indicate positive changes in the process and improved performance.

Step 4: Graph actual and expected performance

Once the averages and ranges for each sample have been calculated and the upper and lower control limits and centerlines are entered, Excel can create control charts through the INSERT function. After INSERT is selected, the user selects CHART and LINE (type of chart) and enters the desired data range for the \( \bar{X} \) chart, the data range entered must include the mean for an \( \bar{X} \) chart (or the range for the \( R \) chart), the upper and lower control limits, and the centerline. In Figure 4, the x-axis reports the sample number, 1 though 93.
Step 5: Interpret graphs

The $\bar{X}$ chart demonstrates that medication is routinely delivered outside the desired 2-hour window. The sample means reveal that average performance ranges from 100 to 134 minutes. The $R$ chart demonstrates that there is only a 33-minute difference between the most on-time and the least on-time delivery of medicine on the most uniform shift (#41), on the other hand shift sample #10 shows a 100-minute difference in performance.

Given average performance of 115 minutes and the average range of 65 minutes, patients are receiving their medication on average a minimum of 50 minutes before or after their prescribed time (115–65) or up to 170 minutes before or after their prescribed time. At this point the reader should see we have a potent tool to evaluate how a process has and is operating. Is the process operated acceptably? In spite of the fact that the LCL is set at 108 minutes, the organization in this case should be striving to reduce its average medication time below the current 115 minutes. In addition, the control charts provide an early detection device for changes in system functioning over time, more (or less) on-time delivery of medication or more (or less) consistent delivery of medicines should be reflected in the sample average and range allowing a manager to recognize positive or negative changes in their operations.

In this case, we can clearly see that performance is unacceptable, and the $\bar{X}$ chart shows numerous breaches of the UCL and increasing delivery times on the last 3 days of the sampling period (samples #84–93). The manager should explore both of these issues.

The sample ranges on the $R$ chart generally lie within their control limits but there are many samples located around the upper and lower control limits. There are no data points substantially above or below the calculated control limits yet the multiple samples at or slightly beyond the UCL and the multiple consecutive samples clustering around 40 minutes suggest the need for investigation. Further investigation will reveal that there are systematic differences in average performance and the range between the most on-time and the least on-time administration times on various shifts.

Similar to the finding of the $\bar{X}$ chart, the range on the last 3 days of the month is significantly different from performance throughout the month. Contrary to the $\bar{X}$ chart, which showed an upward trend signaling a divergence between actual delivery time and the prescribed time, the $R$ chart shows a downward trend, that is, a reduction in the difference between the most on-time and least on-time delivery of medication. Simple calculations reveal that the average medication time and range were 114.3 and 69.4 minutes during the first 10 days of the month, during the last 10 days it was 117.2 ± 60.5 minutes. The conclusion is that medications at the end of the month were less likely to be delivered at the prescribed time but when they would be delivered they became more predictable.

The control charts demonstrate a wide fluctuation in performance across shifts and days, indicating an unstable medication management process. These
differences provide valuable information to understand system performance; which shifts provide the most on-time delivery of medicines, are there differences in performance related to the day of the week, and why is end-of-month performance different from that in the rest of the month?

Step 6: Investigate when indicated and fix as appropriate

Control charts do not judge performance, in this case, both charts indicate that investigation is required and suggest that the medication management system is out of control. The UCL on the $X$ chart shows that medicines are routinely not administered within the desired 2-hour window. Having received this signal, it is the responsibility of managers and employees to determine whether the system requires fixing. The first question that should be asked is: what factor(s) prevents the timely administration of medicines? This is an open-ended question but the SPC can make identifying the cause(s) easier by examining performance on different days or shifts. Diagnosing and improving a system are easier when substandard performance can be isolated to a particular shift, day, or unit; that is, can differences be detected between shifts, days, or units with high performance and those with low performance?

DIAGNOSING THE PROBLEM

Given that medication times are failing to meet the desired standard, what is wrong? Are there unique factors occurring on different shifts or days that prevent prompt administration of medicines? At this point the manager could decide to draw a larger sample to see whether the results persist, but we will assume that they are valid and proceed to diagnosing the problem.

Sorting the data allows the performance of individual shifts or days to be graphed against the established control limits. If the data are sorted by shifts (use the Excel SORT function: select DATA, SORT, OPTIONS, ORIENTATION, LEFT TO RIGHT, row 4, day, evening, and night shifts), the charts in Figure 5 can be created. The $x$-axis now reports the day of the month, 1 though 31, rather than the sample number since only 1 shift per day is graphed.

Day shift

Medications are routinely delivered in less than 115 minutes on the day shift, and there are only 5 (out of 31) samples in which the medication time is above the centerline, that is, the historical average. Performance according to the $X$ chart meets the established standard yet the $R$ chart raises concern. Although average administration time is within the established control limits, the variability in performance is troubling. The upper limit is 95.9 minutes; 12 samples breached this limit, suggesting a uniformity problem. The large range indicates that individual patients routinely receive their medications beyond the desired 2-hour window, thus violating the established standard. The greatest variation occurs Monday through Friday while performance on Saturday and Sunday is more uniform (the 2 data points clustering around 40 on the 6th, 7th, 13th, 14th... days of the month). What factors are different between weekdays and weekends, which could account for this difference in performance?

This finding demonstrates the need for both control charts; the $X$ chart may show performance within control limits but performance may be unacceptable if the range is large. Assuming that one half of patients received their medication within 1 hour and the other half in 3 hours of the prescribed time, the $X$ chart would report an acceptable average of 2 hours but the average of 2 hours with a 2-hour range clearly indicates that medications are not delivered within the 2-hour goal.

Evening shift

Analysis of the $X$ chart for the evening shift shows that the Monday through Friday shifts routinely produce samples above the UCL. Obviously, this should be the chief concern of employees, and graphing the performance of the second shift against historical performance reveals no samples falling under the mean performance time of 115 minutes and 23 samples breaking the UCL. The $R$ chart reinforces the concern as it shows a difference between the most
Figure 5. Performance by shift. UCL indicates upper control limit; LCL, lower control limit.
on-time and least timely delivery of medicines is 80 minutes. Twenty observations are above the centerline and these are in consecutive runs of 5, again emphasizing that employees working the evening shift Monday through Friday are less likely to deliver medications at the prescribed time and are less uniform in the delivery of medication than employees working on the weekend. As asked in the analysis of the day shift, what factors are at work that account for the different performance of the evening shift between weekdays and the weekend? After isolating evening shift performance, it is clear that performance on this shift is failing to achieve the standards set and further investigation is needed.

Night shift

The night shift has the promptest medication times with the majority of samples falling below the LCL and only 3 samples produce an average above the centerline. Breaking the lower limit may indicate superior performance but it could also reflect a broken reporting system—data may not be recorded or recorded properly. The 3 samples above the centerline were also above the UCL and occurred on the last 3 days of the month. This may be the result of a system change that requires rectification or perhaps it was due to an unplanned absence and performance will return to its previous level with the return of the absent employee. The R chart shows very consistent performance on the night shift, its range falls below the centerline indicating superior performance compared with the day and evening shifts. Once again, the pattern reflects strings of 5 and 2 showing that the weekend shifts are more consistent in their delivery times than those of the Monday through Friday shifts. It is interesting to note that the end-of-month change that indicated a movement away from the prescribed time reduced the variation in performance.

While on-time delivery of medication is the goal of the organization, the lack of consistency between the shifts indicates process instability. Unstable in this case means an inability to predict outcomes; the organization cannot predict when medications will be delivered given the differing performance across shifts. The manager should explore the reason(s) for inability of the evening weekday shift to deliver medicines within 2 hours of their prescribed time and the varying performance of the day shift. There appears to be at least 1 factor that accounts for the lack of on-time administration of the evening shift and wide range in delivery times on the day shift during the week, given the performance demonstrated on Saturday and Sunday. The difference between weekday and weekend performance may be due to patient volume, staffing, or the assignment of duties.

Comparing performance across shifts

The discussion above was based on analyzing performance on a shift; analyzing performance across shifts indicates that there are 1 or more factors that explain the different performance of the day, evening, and night shifts. Average medication time clusters around 110 minutes on the day shift, 125 minutes on the evening shift, and 105 minutes on the night shift. The night shift provides medicines 20 minutes closer to their prescribed times than the evening shift and 5 minutes closer than the day shift. Similarly, there are pronounced differences in the range between the shortest and longest administration times, 100 minutes on days, 80 minutes on evenings, and 60 minutes on nights. The night shift demonstrates consistently superior performance as in more timely delivery of medicines and more uniform delivery times than the other 2 shifts. Obviously the reasons for the differences in performance across shifts must be understood, whether it is wholly or partially due to the distribution of nursing and pharmacy duties between shifts, to improve performance.

The stratification of the control charts by shift makes it apparent that performance improvement efforts should begin on the evening shift. Managers and employees should embrace process improvement as an ongoing process (ie, continuous quality improvement [CQI]); hence, over time the goal should be administration of medicines at or at least closer to the prescribed across all shifts and days but the first step begins by analyzing the process on the shift with the widest gap between desired and actual performance.

The CQI is an ongoing process of striving for better performance; once an organization improves its
performance and SPC indicates these improvements are stable, it should attempt to reduce its control limits and institute tighter control over processes to produce even better patient outcomes. An institution that successfully implements the SPC can expect better patient outcomes, higher patient and employee satisfaction that accompany better outcomes, and more effective use of resources.

**Identifying the major causes of a problem**

The first task in improving outcomes is to identify an area for improvement; in this case, the SPC was used to recognize the untimely delivery of medications on the evening shift on weekdays. The next task is to explore and ultimately identify the potential causes of substandard performance. Why is performance failing to meet expectations? Fishbone or cause and effect charts are often employed to explore the potential causes of performance problems. Fishbone charts begin the exploration process by identifying the major reasons why unacceptable performance could occur and then exploring each reason to identify the specific organization practices that could contribute to the problem. Off-schedule medication may be the result of 4 or more major causes; for brevity 4 causes; staffing, caseload, process design, and pharmacy, are identified in Figure 6.

After the major causes are identified, employees should explore the issues within each major cause to identify if, why, and how it impacts the delivery of medicines. For example, examining staffing as a major potential cause affecting the timeliness of medication may lead the QI team to investigate staffing levels, employee qualifications and training, productivity of personnel, or any numbers of staffing issues. Examining caseload may lead the team to investigate whether the number of patients and/or the intensity of care required affects the timeliness of drug delivery. Similarly, questions of process design may explore job assignments and scheduling (admissions, surgeries, ancillary tests, discharges, and housekeeping duties), while pharmacy issues may include the delivery of medications from the pharmacy, medication errors (dosage and/or type), illegibility of orders, and adverse drug reactions and/or contraindications.

In this case the reasons for off-schedule medication may arise from too few employees and too many patients, communication problems, poor oversight, or any other factor suggested on the fishbone diagram. Any or all of these issues (plus others not identified) could impact the timeliness of the medication management process.

The role of manager, quality or process improvement director, and other members of the health
care delivery process is to evaluate and eliminate the causes identified on the fishbone diagram until the most probable factor(s) is identified and corrective action taken. The identification process may involve reaching consensus among the involved parties or running investigations and tests.

After the most likely cause is identified and corrective action taken, the team should determine whether the action produced the intended effect, and were medications delivered more timely? If timeliness does not improve, then further review is required. If corrective action is successful in improving performance, outcomes must continue to be monitored to ensure that the improvement is not lost over time and as a baseline for further improvement thus initiating a CQI cycle.

The SPC improves management by setting clear performance standards for employees, establishing a consistent evaluation standard for managers and employees to use, and providing a tool to monitor processes when managers are absent; that is, the head nurse has the ability to monitor evening and night processes in spite of the fact that she or he may generally work in the day shift (or weekend performance when she or he works Monday through Friday).

CONCLUSION

Improving patient care is a formidable task, which should not be hampered by a lack of or misunderstanding of quality management techniques. This article reviewed the SPC technique, demonstrated how a widely available spreadsheet package can be used to record and analyze data, and analyzed an SPC case. Readers were encouraged to access the case data, perform their own calculations, create their own graphs to complete the case, and consider how a comparable process could be used to monitor and improve care in their organization. This case demonstrates that the SPC can be used anytime timeliness is a factor affecting medical outcomes and/or patient satisfaction such as the timeliness of discharge, procedure time, test turnaround time, registration time, waiting time, and etcetera.

The SPC compliments and extends current health care efforts to improve health care processes and outcomes. Analysis of the case demonstrates that the SPC can provide a wealth of information to understand how current processes are performing and a basis to institute improvement. More important than the information generated however is how instilling this way of thinking into employees will change how they approach their work. The discussion shows that there can be multiple causes for substandard performance, these causes are not revealed by the SPC but rather provide employees with a starting point to apply their analytical and problem-solving skills. Employees will determine how successful the quality improvement process is and they must see themselves as stakeholders in the process. We know that health care workers are committed to improving the health of their patients; the SPC is simply a tool to assist them in these efforts by quantifying performance and signaling when a process has changed sufficiently to impact outcomes.

The SPC is a tool specifically designed for those not trained in management science or statistics to improve the quality of their work and remains underutilized in the health care field. Quality improvement in health care is not going to be the result of a top-down approach but will become only an integral part of the health care delivery system when all employees embrace quality improvement tools. The first step is to convince health care workers that quality improvement tools are relevant to their work and that they can measure performance themselves. It is only when employees begin to measure and analyze their performance that we can expect to see ongoing and widespread improvement in health care delivery processes and outcomes.

REFERENCES

3. Timmermans S, Maulk A. The promises and pitfalls of evidence based medicine; non-adherence to practice guidelines remains


