STATISTICAL PROCESS CONTROL: SEPARATING SIGNAL FROM NOISE IN EMERGENCY DEPARTMENT OPERATIONS

Laura Pimentel, MD*† and Fermin Barrueto Jr., MD†‡

*University of Maryland Emergency Medicine Network, †Department of Emergency Medicine, University of Maryland School of Medicine, Baltimore, Maryland, and ‡Department of Emergency Medicine, Upper Chesapeake Health Systems, Bel Air, Maryland

Reprint Address: Laura Pimentel, MD, Department of Emergency Medicine, University of Maryland School of Medicine, 110 South Paca Street, 6th Floor, Suite 200, Baltimore, MD 21201

Abstract—Background: Statistical process control (SPC) is a visually appealing and statistically rigorous methodology very suitable to the analysis of emergency department (ED) operations. Objective: We demonstrate that the control chart is the primary tool of SPC; it is constructed by plotting data measuring the key quality indicators of operational processes in rationally ordered subgroups such as units of time. Control limits are calculated using formulas reflecting the variation in the data points from one another and from the mean. SPC allows managers to determine whether operational processes are controlled and predictable. We review why the moving range chart is most appropriate for use in the complex ED milieu, how to apply SPC to ED operations, and how to determine when performance improvement is needed. Discussion: SPC is an excellent tool for operational analysis and quality improvement for these reasons: 1) control charts make large data sets intuitively coherent by integrating statistical and visual descriptions; 2) SPC provides analysis of process stability and capability rather than simple comparison with a benchmark; 3) SPC allows distinction between special cause variation (signal), indicating an unstable process requiring action, and common cause variation (noise), reflecting a stable process; and 4) SPC keeps the focus of quality improvement on process rather than individual performance. Conclusion: Because data have no meaning apart from their context, and every process generates information that can be used to improve it, we contend that SPC should be seriously considered for driving quality improvement in emergency medicine. © 2015 Elsevier Inc.

Keywords—statistical process control; control chart; quality improvement; special cause variation; common cause variation; emergency department quality improvement

INTRODUCTION

The Patient Protection and Affordable Care Act calls for “a national quality strategy,” including the development of measures of several dimensions of health care quality. Defining quality and designing the environment in which it can be achieved are more elusive than the goal. In the statistical world, a landmark text began with this quote: “In September 1960, a new definition of World-Class Quality was quietly introduced … ‘On Target with Minimum Variance.’” Wheeler and Chambers, the authors of Understanding Statistical Process Control, explain why statistical process control (SPC) is an excellent tool for studying and improving processes from which performance data can be measured accurately (1). SPC can be easily incorporated into the assessment and improvement of quantifiable and measurable emergency department (ED) operational processes. The results of using this powerful tool might greatly enhance quality improvement in emergency medicine.

SPC is a rigorous methodology for analyzing a process over time by measuring its key indicators; the individual data points are considered in the context of their dispersion
from the mean and variation from one another. Think of a histogram placed on its side and plotted over time. Process analysis is performed by plotting control limits on each side of the mean and studying the patterns of the data according to validated rules. More than this, SPC is a philosophy with the core concept of learning through data. It incorporates process thinking, analytic study, prediction, and the analysis of stability and capability through which one can achieve true continuous improvement (2). The control chart is the premier tool of SPC; it allows intuitive and visually appealing real-time understanding of any quantifiable process with a measurable outcome. Given the marked increase in data availability with the proliferation of electronic medical records, emergency physicians and directors are in need of readily available analytics to capitalize on this wealth of information. Our contention is that SPC capably meets this need.

**DISCUSSION**

*The Control Chart*

A control chart (Table 1) is a graph of a process on which statistical analytical tools are programmed (Figure 1). When evaluating an outcome measure such as door-to-physician time, the variable in question is plotted graphically against a unit of time. The optimal number of data points or subgroups for a statistically strong analysis is 20 to 30 (1). Control lines representing standard deviations of dispersion of the moving range among the data points are calculated and delineated on the graph. The upper control limit and lower control limit (Table 1) represent three standard deviations above and below the mean, respectively. The work of the control chart is to determine whether the process is in control and thus predictable, or out of control and therefore, unpredictable. A controlled process is predictable because it will continue to perform within the control limits until affected by an external force. In a controlled process, the variation in data points represents common cause variation (Table 1), referring to the normal daily variation (noise) in any measured process. With respect to door-to-physician time with a median value of 30 min, common cause variation is reflected in normal intrinsic process variations. One month, the median might be 32 min and the next, 27 min, even though no meaningful external factors changed or affected the process. If that process is achieving the

<table>
<thead>
<tr>
<th>Table 1. SPC Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Binomial distribution</strong></td>
</tr>
<tr>
<td><strong>Capable process</strong></td>
</tr>
<tr>
<td><strong>Common cause variation</strong></td>
</tr>
<tr>
<td><strong>Control chart</strong></td>
</tr>
<tr>
<td><strong>Control chart types</strong></td>
</tr>
<tr>
<td><strong>c Chart</strong></td>
</tr>
<tr>
<td><strong>p Chart</strong></td>
</tr>
<tr>
<td><strong>XmR Chart</strong></td>
</tr>
<tr>
<td><strong>Lower control limit</strong></td>
</tr>
<tr>
<td><strong>Poisson distribution</strong></td>
</tr>
<tr>
<td><strong>Rationally ordered subgroup</strong></td>
</tr>
<tr>
<td><strong>Run chart</strong></td>
</tr>
<tr>
<td><strong>Special cause variation</strong></td>
</tr>
<tr>
<td><strong>Type 1 error</strong></td>
</tr>
<tr>
<td><strong>Type 2 error</strong></td>
</tr>
<tr>
<td><strong>Upper control limit</strong></td>
</tr>
</tbody>
</table>
optimal or desirable level of performance, it is said to be capable. If the process is controlled but not achieving acceptable performance, it is incapable and requires directed process improvement.

When a process is out of control, it is affected by special cause variation (the signal) (Table 1) (1). Uncontrolled processes are unpredictable until control is restored. When special cause variation is identified, it means that an external factor(s) not inherent in the process has fundamentally altered the normal rhythm of the process (3). Special cause variation (signal) may affect a process negatively, in which case it should be identified and eliminated, or positively, in which case it should be identified and analyzed for incorporation into the process. Using the door-to-physician time example, the implementation of an electronic health record requiring physicians to document electronically might well constitute an external factor causing a fundamental change in the process. The result might be seen on a control chart as negative special cause variation if the door-to-physician time spiked to a new median of 50 min. It is very important to ensure that a process is in control before new initiatives are introduced.

**Approach to SPC In Emergency Medicine**

The first step in incorporating SPC into quality efforts in ED operations is to identify key quality indicators (Table 2). Many physician groups and hospitals already do this by tracking dashboard measures of flow metrics, core measure performance, and patient satisfaction.

![Figure 1. Sample control chart.](image)

![Figure 2. Special Cause Variation Rule 1: Any single data point beyond the upper or lower control limit.](image)
Hospital quality departments commonly track mortality rates, returns to the ED within 48 or 72 h, and, readmission rates. Whatever key indicators of quality are chosen, it is crucial to define the operational definition so that it can be measured the same way over time (3). For example, some EDs measure the time interval from admission decision to the patient’s arrival on the inpatient unit. It is extremely important that the definition and time stamp for the admission decision are concrete and used consistently.

The next step is to collect the data over a consistent time interval. Depending on data availability and the urgency of change, the pace of data collection can vary. Common practice is to collect and review data monthly. If 1 to 3 years of consistently collected monthly data are available, robust control charts can be constructed using standard spreadsheet software. Charts can be constructed manually, or inexpensive SPC software can be purchased and installed as add-ins to Microsoft Excel (Microsoft Corporation, Redmond, WA). These programs will construct control charts from the data and analyze stability. The examples in this article were constructed using QI Macros for Excel (4).

After the control chart is constructed, the next step is analysis. Is the process stable? The classic scientifically validated criteria for identifying special cause variation (signal) are referred to as the Western Electric Zone Rules, published by the Western Electric Company (5). These rules are listed below:

1. A single data point falls above the upper control limit or below the lower control limit (Figure 2).
2. Two out of three consecutive data points fall on the same side of the center line and beyond the two-sigma line (Figure 3).
3. A run of eight consecutive data points falls on the same side of the center line (Figure 4).
4. A trend of six consecutive data points steadily increases or decreases (Figure 5).

If the Western Electric Zone rules indicate special cause variation (signal), the process is not stable; an external force has affected it. If the force has negatively affected the process, it should be identified and eliminated. Root cause analysis is an effective technique (6). If the force has had a positive effect, it should be analyzed

Table 2. Steps in Incorporating SPC into Emergency Medicine Quality Improvement

1. Identify measurable key quality indicators (KQIs).
2. Collect time-ordered data reflecting KQIs.
3. Construct control charts.
4. Analyze the charts utilizing the Western Electric Zone rules.
5. If negative special-cause variation is identified, eliminate from the process. If positive special-cause variation is identified, incorporate into the process.
6. If the process is stable, assess capability. If it is capable, continue to monitor and work to decrease variation. If it is not capable, initiate performance improvement process.

SPC = statistical process control.

Figure 3. Special Cause Variation Rule 2: Run of two out of three consecutive data points beyond two sigma lines from the center.
for incorporation into the process. A new chart should be started after the process change.

If the process is controlled and thus predictable, two questions should be asked. First, is the process capable of achieving a result consistent with your goal or your definition of quality? The center line of your control chart answers that question. If your goal is a door-to-physician time of 30 min and your controlled process is yielding a mean time of 50 min, the process is controlled but not capable. Asking physicians and staff to work harder or monitoring the data with the hope of seeing improvements are ineffective responses. Your action should be a formal process improvement project. This may utilize Lean or other proven strategies (7). The objective is to introduce special cause variation into the process. As you implement changes, the control chart will tell you whether your changes have been effective, ineffective, or detrimental to the process. If you do nothing, although common cause variability will show fluctuation in data points above and below the mean, the overall process will not change.

The second question is the degree of variation in the process. Even a controlled and capable process (Table 1) might be improved by decreasing the amount of variation. Drilling down on your data and identifying conditions under which variation is high is the proper approach. Monthly data may indicate that overall door-to-physician time is 30 min on average and the process is under control. If you look at daily data, however, you might find that, on Mondays the average is consistently 40 min. Strategically adjusting your process on Monday

Figure 4. Special Cause Variation Rule 3: Run of at least eight consecutive data points above or below the center line.

Figure 5. Special Cause Variation Rule 4: Trend of at least six consecutive data points in the same direction.
will decrease variation and improve the entire process. Breaking down aggregate data to look at subgroups in this manner is called rational subgrouping (Table 1), a powerful analytic tool (6).

Dr. Walter Shewhart, the father of SPC, was a scientist at Bell Laboratory. One of his premier objectives in the development of the control chart was to prevent Type 1 and Type 2 errors (Table 1) when assessing process performance. A Type 1 error occurs when one treats common cause variation (noise) as though it was special cause variation (signal). For example, if the median door-to-physician time was higher one month than in the preceding 6 months but still within control limits, hospital administrators might unnecessarily request a performance improvement plan even though the fundamental process was unchanged. In traditional research, the parallel is mistakenly rejecting the null hypothesis. Silver would describe this as treating the noise as though it were a signal (8). The result is tampering with a controlled process.

A Type 2 error is failing to identify special cause variation and therefore not addressing a process change that requires attention and action. An example would be a sustained increase in the median door-to-physician time exceeding control limits after institution of an electronic health record, left unaddressed by the hospital. The three-sigma limits are designed to minimize the probability of committing a Type 1 error. Wheeler and Chambers noted that, “given a homogeneous set of data … approximately 99% to 100% of the data will be located within a distance of three standard deviation units on either side of the average” (1).

**Attribute Data Charts**

Various control charts calculate control limits differently, based on underlying assumptions about the distribution of the data. Discrete attribute data can be counted. The data might be binary, such as the number of patients leaving before treatment is complete (binary because a patient either left or completed treatment). Control limits for binary data are calculated based on the assumption that the data follow a binomial distribution (Table 1). This control chart, a p chart (proportion chart) (Table 1), reflects the occurrences of a binary event as a percentage. Counted data can also be derived from an underlying stable population such as the number of emergency admissions during the month of January. This type of chart is called a c chart (Table 1). Control limits for c charts are based on the assumption that the data follow a Poisson distribution (Table 1) (9). A Poisson distribution is depicted by a histogram demonstrating the probability of events occurring around a known mean when the events are independent of one another. A histogram of medication errors per month should follow a Poisson distribution.

**Moving Range Charts**

Measured data such as length of stay or door-to-physician time are analyzed by moving range, or XmR, charts (Table 1). The XmR chart is quite robust because its control limits are calculated solely based on the point-to-point variation in the data, with no assumption about the underlying data distribution (10,11). Wheeler stated that “the XmR chart uses both a measure of location and a measure of dispersion to give empirical limits that are actually based upon the way data behave” (12). Therefore, the XmR chart is ideal for analysis of the complex world of ED operational data.

An XmR chart consists of two components. The first is the individual values chart, which begins as a run chart (Table 1) of individual subgroup data, such as the monthly mean door-to-physician time in minutes (Figure 6A). A run chart is a record of measured data plotted over time. The second component is the moving range chart (Figure 6B), which consists of the variation in values from the first chart. Control limits are calculated by multiplying the mean value of the moving range by a constant: 3.27 for the moving range chart and 2.66 for the individual values chart. These constants are scaling factors used in process control to allow easy calculation of the three-standard-deviation limit. The resulting values are added and subtracted from the center line (mean value) of each chart to create the upper and lower control limits (12). In practice, many authors and practitioners of SPC use only the individual values XmR chart because it is simple and efficient; they note that all of the information on variation within the process is contained in this chart.

**SPC in ED Operations: Real-world Examples**

A few illustrations will demonstrate the proper use of control charts in the management of ED operations. The first example, depicted in Figure 7, uses SPC to evaluate the impact of a process change designed to reduce door-to-physician time in the ED of a community hospital. The physician group and hospital administration were dissatisfied with the ED’s performance in 2011. The first 11 data points demonstrate a mean door-to-physician time of 43 min, with a standard deviation of 6.4 min. In December 2011, the nursing staff implemented a “pull-to-full” strategy so that patients were never left in the waiting room if a treatment room was available. The control chart demonstrates immediate improvement in door-to-physician time, to a mean of 34 min, with a standard deviation of 3.2 min. The decrease in variation is as impressive as the reduction in waiting time. The chart reveals another marked improvement in November 2012, corresponding to the addition of scribes to the practice.
Both of these process changes, incorporated into the normal practice, are examples of the successful introduction of special cause variation (signal) resulting in improved metrics.

The second example of the use of SPC in emergency medicine operations illustrates the temptation to tamper with a capable process based on a single data point representing common cause variation (noise). Figure 8 presents a comparison of a dashboard of monthly left-without-being-seen (LWBS) data compared with a control chart for an ED with an annual patient volume of 21,000. In May 2012, the hospital administration, based on the dashboard number, became concerned when the LWBS metric reached 4.4%. The administrators requested an explanation and an action plan. The accompanying control chart created from the same data clearly shows that this response was treating the noise as a signal. The process is controlled and capable of achieving the target LWBS rate of 2.25% despite the fact that six data points exceeded the target based on common cause variation. A more appropriate response to the control chart would be to work on strategies such as a surge response to decrease the variation in the data.

**Advantages of SPC In Practice**

SPC complements other statistical analytic tools used in health care. The first strength is that the display of data

![Figure 6. (A) Calculation of the control limits on the XmR chart. The upper control limit is calculated by multiplying the mean on the moving range chart by a constant (2.66). The resulting product is added to the center line value on the XmR chart. The lower control limit is calculated by subtracting this product from the center line value. (B) Moving range (XmR) chart: data points reflect the values of the variances between the data points.](image-url)

![Figure 7. Statistical process control demonstrating the impact of emergency department operational changes; both changes created positive special cause variation.](image-url)
in graphic format is more intuitive and easy to interpret than data listed in tables (13). The statistical work of a control chart can be explained to and understood by people who are not statisticians or researchers. This makes control charts particularly useful for frontline clinicians and managers to use their own data in a meaningful way for performance analysis and improvement. Pfadt and associates noted that control charts conform to Yale University Professor Emeritus and statistician Edward Tufte’s principles of graphic excellence, as they “show the data and avoid distortions; make large data sets coherent; encourage the eye to compare relevant features; serve a reasonably clear purpose; and integrate statistical and verbal descriptions of the data set” (14).

Operational processes in the ED are complex and frequently inconsistent; they represent the interaction of diverse patients presenting in varying numbers and intervals to imperfect systems. This milieu does not lend itself to the controlled grouping ideal for randomized controlled trials. Controlled grouping refers to the ability to divide subjects into study groups and control groups meeting defined research criteria (15). SPC offers a simple and elegant tool to analyze processes with the sophistication of statistical rigor and the time sensitivity of performance improvement, allowing the voice of the process to guide operational change (16).

Because data are presented graphically as a time series or another rationally ordered subgroup, information is presented in context; it therefore preserves the evidence in the data, allowing predictions to be made about the performance of the process. Interpretation of the chart also guides whether and what action should be taken. If a control chart measuring the monthly percentage of patients leaving without treatment indicated a stable process with a mean of 5% (Figure 9), neither the ED director nor the hospital would find this performance acceptable. The chart tells them that the proper action is to initiate a directed performance improvement project with the objective of decreasing the percentage of patients who leave without being seen. Such a project will include the examination of other key performance indicators, such as door-to-physician time and the length of stay for admitted patients, which might offer clues about why so many patients leave without treatment. Because prediction and performance improvement constitute the essence of management, SPC is an important tool (12).

Effective quality improvement utilizes real-time data to monitor and analyze current performance rather than inspection or study of aggregated data after the fact. When managing operational processes and quality improvement, process stability is crucial. Decoding variation within the dataset to discern the meaning of monthly changes in performance and selecting the appropriate management response are necessary for effective management of clinical operations.

Because SPC expresses the voice of the process, effort and analysis surround process rather than individuals. The importance of this orientation in effective quality improvement cannot be overstated. Callahan and Griffen cited the

---

**Figure 8. Dashboard data compared with control chart. This illustration demonstrates the danger of tampering with a controlled process due to treating one data point incorrectly treated as a signal of a poor process. LWBS = left without being seen.**

---

**Table 1:** LWBS Dashboard Data

<table>
<thead>
<tr>
<th>Month</th>
<th>LWBS %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan</td>
<td>2.25</td>
</tr>
<tr>
<td>Feb</td>
<td>1.3</td>
</tr>
<tr>
<td>Mar</td>
<td>2.3</td>
</tr>
<tr>
<td>Apr</td>
<td>2.8</td>
</tr>
<tr>
<td>May</td>
<td>4.4</td>
</tr>
<tr>
<td>Jun</td>
<td>1.9</td>
</tr>
<tr>
<td>Jul</td>
<td>2.3</td>
</tr>
<tr>
<td>Aug</td>
<td>1.7</td>
</tr>
<tr>
<td>Sep</td>
<td>3.4</td>
</tr>
<tr>
<td>Oct</td>
<td>1.9</td>
</tr>
<tr>
<td>Nov</td>
<td>1.2</td>
</tr>
<tr>
<td>Dec</td>
<td>0.7</td>
</tr>
<tr>
<td>Jan</td>
<td>2.6</td>
</tr>
<tr>
<td>Feb</td>
<td>1.4</td>
</tr>
<tr>
<td>Mar</td>
<td>1.5</td>
</tr>
</tbody>
</table>

**Figure 9:** LWBS Control Chart

- **UCL** (Upper Control Limit): 4.94
- **CL** (Center Line): 2.25
- **LCL** (Lower Control Limit): -0.72

**Months:** Jan, Feb, Mar, Apr, May, Jun, Jul, Aug, Sep, Oct, Nov, Dec, Jan, Feb, Mar

---

L. Pimentel and F. Barrueto
work of Berwick in attributing quality problems to poor processes rather than underperforming workers (17,18). The most destructive response that managers can make in response to an underperforming process or a single data point within a controlled process is to blame an individual or cast aspersions on a group of workers as lazy or inefficient. Deming, the father of modern quality improvement, included “Drive out fear” among his famous 14 management points (19). SPC promotes healthy work dynamics by keeping the focus on processes for which managers and directors are responsible.

Health Care and Emergency Medicine Experience

SPC is gradually becoming incorporated into administrative health care research and quality improvement initiatives (20–28). Satisfaction with the methodology and the quality of statistical results has been very high. Shaha stated, “The capability of truly understanding processes and variation in a timely manner has resulted in the most dramatic, immediate, and ongoing improvements of any management technique applied at Intermountain Health Care” (29). Researchers have begun to use control charts for the statistical analysis of clinical studies, with intriguing results (30–34). Neuhauser et al. noted that “the protocol-driven, randomized trial research approach is a powerful tool for establishing efficacy but has limitations for evaluating and improving such complex processes as surgery, which are continually and purposefully changing over time” (35).

Emergency medicine has been slow to embrace statistical process control. The concept is not well known within the specialty in the United States, although the results of a few process improvement studies have been published (36–41). Advanced countries with nationalized health systems have more readily incorporated SPC into the improvement of ED processes (42–45).

CONCLUSION

SPC is uniquely suited to analyzing the complexity of the ED milieu. It preserves all of the information contained within the data and presents it in a rational context. Shewhart articulated the essence of process control in his first principle for understanding data: “No data have meaning apart from their context” (12). In a tutorial on SPC for health care organizations, Kaminsky et al. quoted statistician George Box: “Every job has a process in it and every process generates information that can be used to improve it” (46,47). Understanding variation is the essence of SPC and the key to analyzing and ultimately improving any process. The “noise” of common cause variation must be distinguished from the “signal” of special cause variation. The control chart elegantly provides the simplest analysis of the process, leading to the insight necessary to confidently guide improvement. SPC should be strongly considered by emergency physicians and leaders in their ongoing quest to provide quality emergency care.

Acknowledgment—The manuscript was copyedited by Linda J. Kesselring, MS, ELS, the technical editor/writer in the Department of Emergency Medicine at the University of Maryland School of Medicine.
REFERENCES

ARTICLE SUMMARY

1. Why is this topic important?
This topic is important because the management of emergency department (ED) operations is among the most important jobs of the ED medical directors and physician groups. Optimizing operational processes improves the quality of care, access to care, and patient satisfaction.

2. What does this review attempt to show?
This review attempts to demonstrate how and why the utilization of statistical process control (SPC) to analyze ED metrics provides invaluable information about the control, capability, and variation of an ED’s operational processes. This can be used to guide and analyze the impact of process change.

3. What are the key findings?
The key findings are that the statistical rigor of SPC is very well suited to the complexity of ED operations. The natural control limits calculated from one’s own key quality indicators provide a high degree of confidence when analyzing ED processes. This easily employed methodology should be considered for monitoring quality and process improvement initiatives.

4. How is patient care impacted?
Improving clinical operations in very practical ways impacts patient care. Diagnostic delays are minimized when metrics such as the door-to-physician time and percentage of patients leaving without treatment are consistently and meaningfully reduced. SPC guides ED leaders in the process of creating safer departments by maximizing efficiency.