JECT. 2004;36:224–230
The Journal of The American Society of Extra-Corporeal Technology

Guest Editorial

Understanding Variation in Cardiopulmonary Bypass: Statistical Process Control Theory

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Cardiopulmonary bypass (CPB) is a complex clinical process that takes place within an extremely complex care deliver system. During the past 50 years, many technical- and device-related improvements have been implemented. However, there remains enormous opportunity to improve. As has been shown in other industries, understanding variation is the key to improvement of any process, and Statistical Process Control Theory (SPCT) is a powerful method for studying variation. SPCT was first described and used by Walter Shewart in the 1930s to improve telephone component production at Bell Laboratories (1). Shewhart's hypothesis was that production quality improves when front-line workers are informed and empowered with information necessary for that improvement. He invented control charts as a method for transforming data concerning variation into understandable information. With the application of this theory in the form of control charts, Shewhart provided production workers with a deeper understanding of the variation in their production system.

Control charts distinguish random variation that exists in a system from variation that has a specific cause. Shewhart noted, "While every process displays variation, some processes display controlled variation whereas others display uncontrolled variation." He called the former "chance cause" and the latter "assignable cause," whereas today these types of variation are referred to as "common-cause" and "special-cause" variation, respectively. Common-cause variation requires no immediate action or intervention, whereas special-cause variation should be studied and perhaps acted upon. Acting on common-cause variation is wasted effort and, in many cases, may worsen circumstances because these actions often lead to making a process less stable than it was formerly. Shewhart referred to acting on common cause variation as "tampering" and considered it counterproductive (2). Stable processes are desirable because their outcome are likely predictable in their content and quality. Armed with this

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method of interpreting variation, we can direct our efforts toward addressing special cause and avoid wasting precious resources tampering with common-cause variation.

Only within the past 10 years has SPCT been applied to healthcare and, more specifically, cardiac surgery (2–7). SPCT has an important role in healthcare because it provides guidance concerning process stability and an appreciation of variation in outcomes and process measurement. It provides clinicians with a means for determining whether a process is stable. SPCT may alert clinicians to unexpected changes that occur, as well as assist in determining whether changes that we initiate actually lead to lasting improvement. This is demonstrated in the control charts in Figures 1–3 that follow. In Figures 1 and 2, use of an online monitor led to reduction in variation in arterial blood PCO_2. In Figure 3, use of smaller CPB circuits for smaller patients and use of an autologous priming technique resulted in a reduction in the proportion of patients with low HCT during CPB. Control charts in these examples clearly demonstrate the positive effect of the changes brought about through the use of SPCT principles.

There are a variety of control charts available to examine various types of data. The choice regarding which chart to use is determined in part by the type of data and research question under investigation. Table 1 lists examples of control chart types for respective data, and examples of questions that these charts may be used to address.

ANATOMY OF A CONTROL CHART

Control charts show time or sequential samples on the abscissa and the measurement of interest on the ordinate (Figure 1). A horizontal line is used to represent the central tendency, or mean. Horizontal lines also are plotted at 1, 2, and 3 sigma (standard deviations) from the mean value. The control limits are traditionally established at ±3 sigma. For data that are distributed normally, 99.7% of the observations should fall between the upper and lower control limits. Figure 4 lists the types of charts and respective formulas for calculating upper and lower control limits (reprinted with permission ELI Control Chart Reference Card [2002], Executive Learning Incorporated, Nashville, TN). The left side of the table shows the formulas for calculating central tendency, and upper and lower control limits. The constants listed on the lower left are used with X bar R charts. The X bar R charts address the question of variation between subgroups or clusters of sequential measurements. The constant adjusts for subgroup size. When a process is under better control, the control limits lines move closer together. When there is a change in variation, certain rules apply for determining whether this apparent variation is common or special cause. Seven of the most commonly used rules are described on the right side of Figure 4. For instance, the shift rule identifies special cause variation when a series of eight measurements are above or below the centerline. When one of these special cause rules (signals) is observed in a control chart we should focus our attention on what changed in our process that may have led to this variation.

Templates for control charts are available in Microsoft Excel format that facilitate their construction (several Website resources are listed in the appendix). These templates make it possible to move quickly from a series of data points to the formation of a chart. One need only understand which type of chart applies to the data. Excel

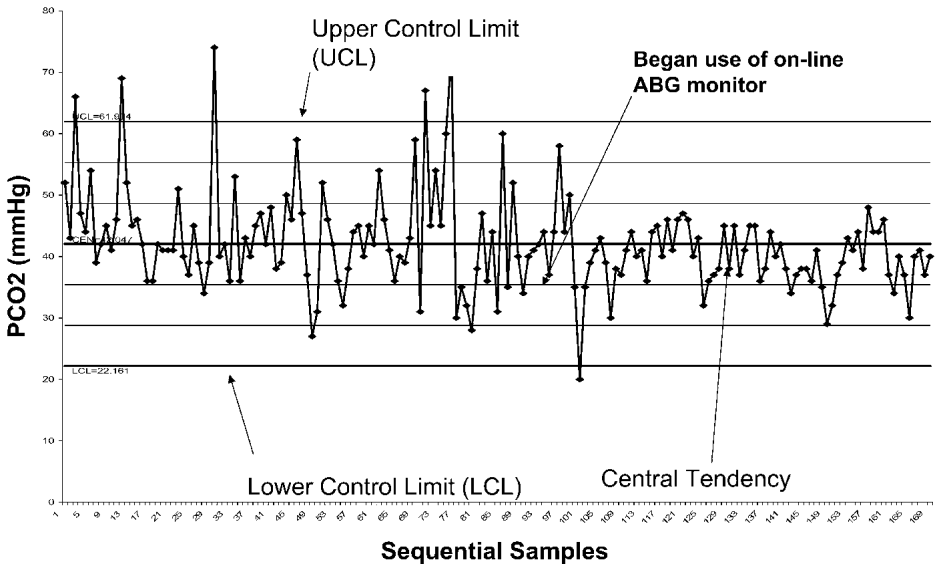

Figure 1. Arterial PCO_2 during CPB.

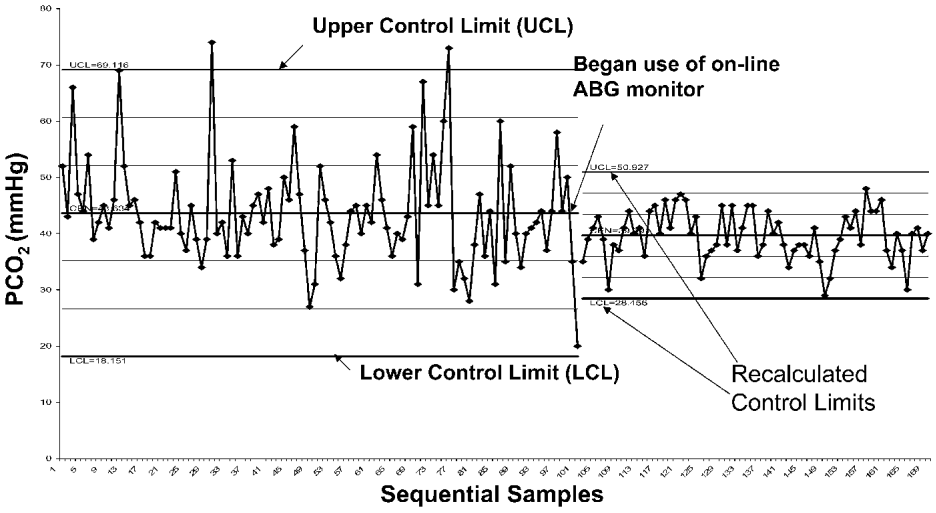

Figure 2. Arterial PCO_2 during CPB.

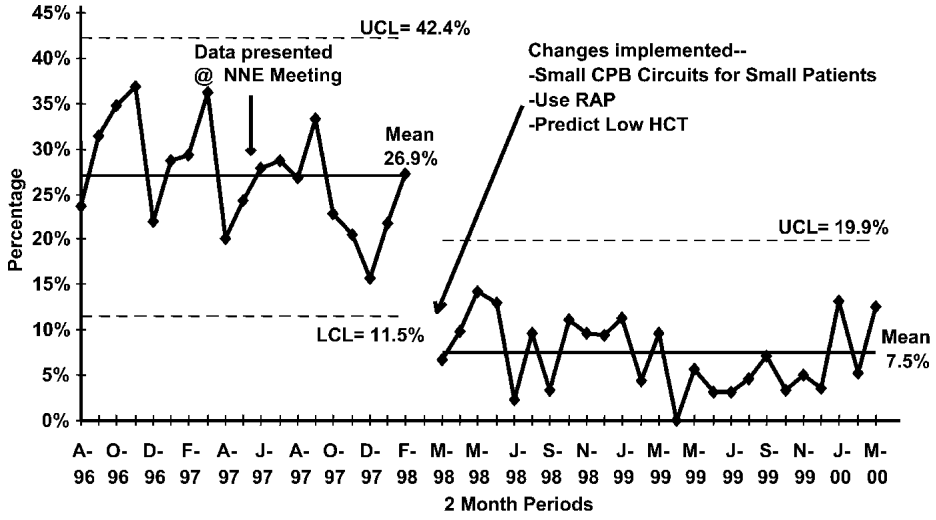

Figure 3. Percentage of patients with lowest HCT <21% on CPB.

based templates or companion programs such as SPC XL can be used to construct rapidly control charts from spreadsheets or data base program. Some of these tools are designed to highlight automatically areas of special cause variation displayed in the charts using colors or bold points. In Figure 5, there is special cause variation noted in bold where data is outside of the calculated control limits.

Data falling outside of the control limits suggest that a significant change in the process has occurred (special cause). Of note, two types of errors may be made in attempting to detect special cause variation: type I (inaccurately identifying special cause when special cause does not exist) and type II (concluding no special cause exists when special cause truly exists) (8). Shewhart believed that setting control limits at 3 sigma offered the best balance between committing a type I or type II error (1). Other special cause rules are shown in Figure 4. These rules provide guidance in discovering trends or runs, or patterns in measured values.

Example 1: Arterial Blood PCO_2 Measurements

Control charts may be used to address a number of questions related to CPB practice. Figure 1 is an example of an XmR or I-chart (or individual measurement chart) of consecutive arterial blood PCO_2 measurements during CPB procedures. The I-chart is selected for these data because we are examining a series of individual measurements. Each plotted value on the ordinate is a PCO_2 measurement. Consecutive samples of PCO_2 are numbered on the abscissa. The horizontal line in the center of the plot represents the central tendency (mean) of PCO_2. Values outside of the upper and lower control limits are considered special cause variation or variation in the process that is beyond the normal variation intrinsic in the system. Values outside of the 3-sigma control limit deserve study because this variation differs from the normal variation in the system and may be related to assignable causes. There is appreciable variation in the first 106 measurements. An online ABG monitor was in use during the subsequent 62

Table 1. Types of control charts.

Control Chart	Statistical Distribution	Example Variable	Question
XmR	Individual values	Number of procedures	Is there special cause variation in procedural volume?
X-bar and R	Gaussian/normal	Intubation time	Is the monthly mean intubation time for CABG patients stable? Have process changes increased or decreased our time?
X-bar and S	Gaussian/normal	LOS	Is LOS variable within (subgroups) and is it stable over time?
p-charts	Binomial	Mortality	Is this year's low mortality noise or is there some special cause for the decrease?
np-charts	Binomial	Number of orders with errors out of subgroups of 100 orders	Since we changed to the electronic order system, are the number errors in orders changing?
u-charts	Poisson rates	Patient falls (unequal opportunity)	Is our fall rate improving since we changed our process of patient surveillance?
c-charts	Poisson counts	Codes (virtually equal opportunity)	Are the number of codes stable each month?
g-charts	Geometric	Mediastinal infections	Is the incidence of this rare event on the rise?

CABG, coronary artery bypass grafting; LOS, length of stay.

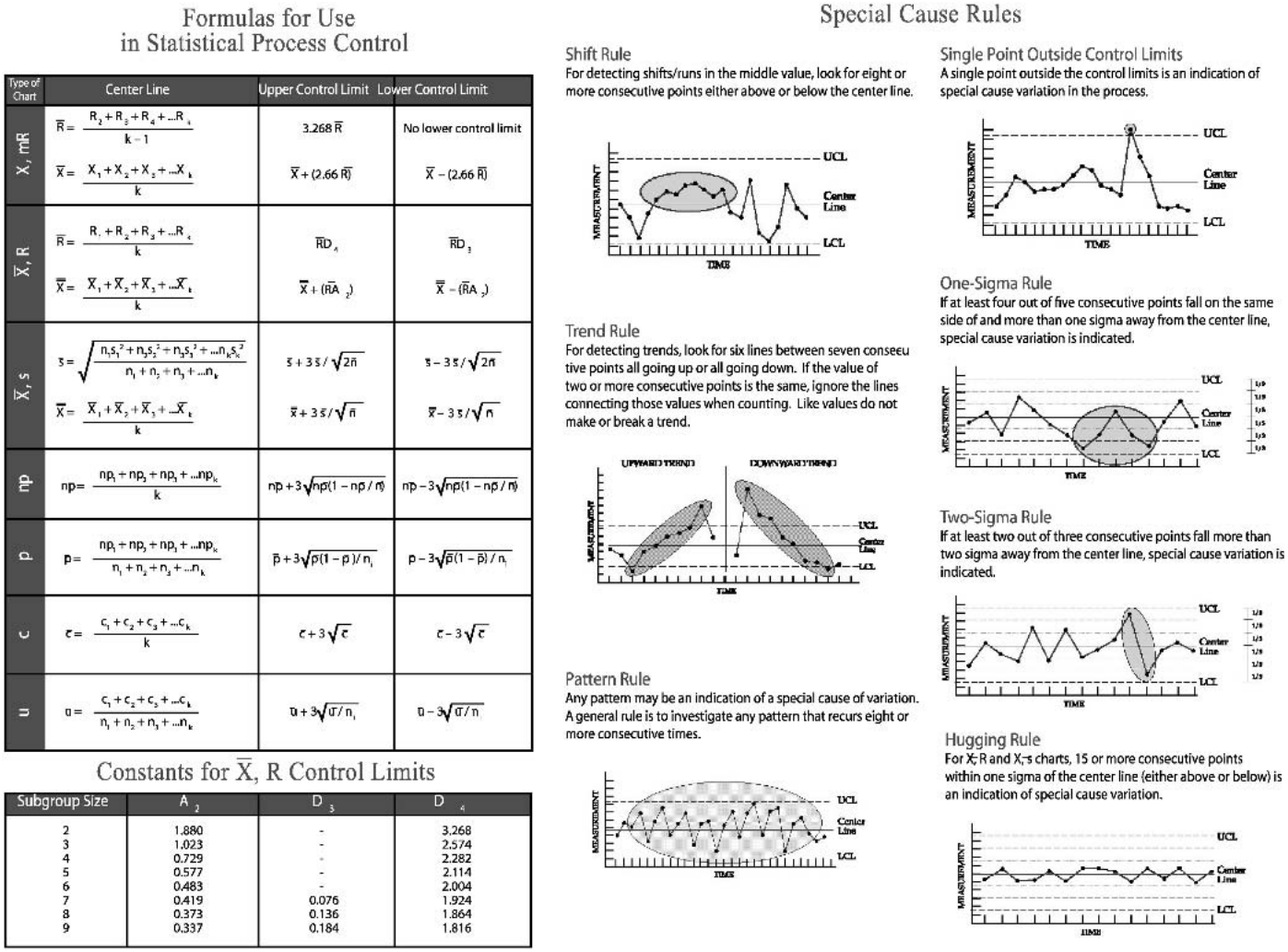

Figure 4. Formulas for use in statistical process control. Figure 4 was reprinted with permission from Executive Learning, Inc. (http://www.elinc.com).

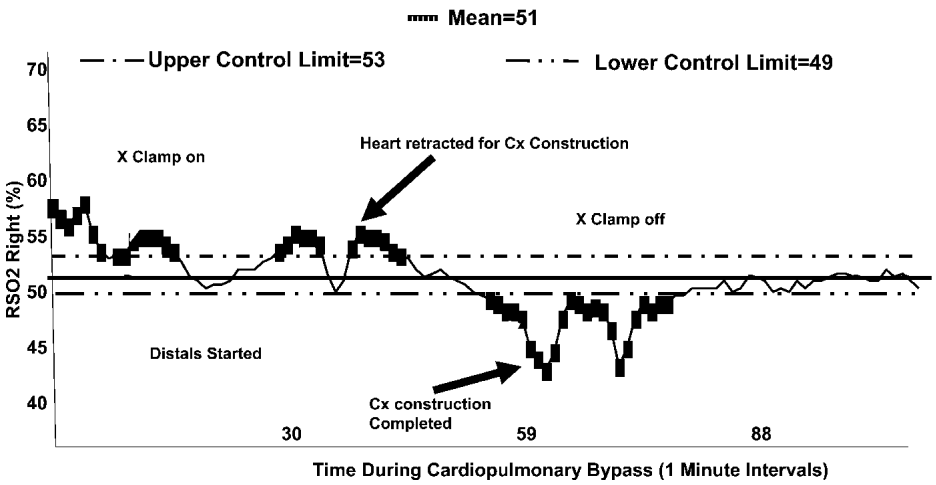

Figure 5. Regional oxyhemoglobin desaturation during CPB.

measurements. This chart demonstrates that the use of an online ABG monitor was associated with a reduction in the process' variation. Because the process is more in control after sample 106, the control limits may be appropriately recalculated beginning from sample 107 to sample 170. Figure 2 shows the I-chart with recalculated control limits (Note the changes in the upper and lower control limit). This is an example of how a control chart may be used to display how a process may become more stable (brought into better control) with the use of new technology, such as continuous online monitoring device.

Example 2: Low Hematocrit (HCT) and Mortality

Variations in proportions or rates may be displayed on control charts. In previous work, our regional consortium found an association between low HCT and mortality (8,9). Coronary artery bypass patients with a low HCT during CPB had a significantly higher use of intra aortic balloon pumps, higher incidence of prolonged use of inotropic support at 48 hours and higher in-hospital mortality rates. Figure 3 is an example of a "p chart" (proportion chart) that was constructed to determine the effectiveness of process improvements to reduce the incidence of a low HCT. The "p chart" is used for this data since we are examining changes in a measure of proportion (the percentage of patients with a HCT lower than 21%). Plotted on the abscissa is the proportion of patients with a HCT of less than 21% aggregated in 2-month intervals and on the ordinate the proportion of patients undergoing heart surgery with CPB that have at least one HCT during CPB that was less than 21%. During the 18 months from August 1996 to February 1998, we observed a stable process exhibiting only common cause variation. If the process does not change, we would expect in the future that the proportion of patients with HCT < 21% would be between 42.4% and 11.5%. In March 1998, three strategies to reduce the incidence of low HCT during CPB were adopted (use of a HCT prediction formula, use of small CPB circuits for small smaller patients, and the use of autologous priming techniques). Note the significant change in the proportion of patients with low HCT that occurred after the changes made to the system in March of 1998. After several months of stable measurement the control limits were reset. The change in the proportion of patients with a HCT of less than 21% is evident from the p-chart. The mean proportion of patients with low HCT changed from 26.9% to 7.5%. Control limits were recalculated after the process changes, and subsequently the proportion of patients with low HCT was reduced and consequently the process became more stable. The changes made in March of 1998 produced a desirable effect on low HCT. Our team continues to construct similar control chart to assess our system's performance as it relates to low HCT.

Example 3: Regional Cerebral Oxygen Saturation

Continuous monitoring of physiological parameters during surgery is used for instantaneous management of the patient, and in traditional practice is recorded at 5- to 10-minute intervals. With the availability of automated computerized data capturing systems it is now technologically possible to capture and record data during surgery with much greater frequency, precision, and accuracy. While the use of such a system provides a means for capturing data there remains a need for a method of transforming the data into information that may be of use to understand and improve the system.

Regional cerebral oxygen saturation (NIRS) is influenced by blood flow rate, arterial blood pressure, carbon dioxide level, hemoglobin level and saturation, and central venous pressure. There is some evidence that changes in NIRS may contribute to postoperative neurocognitive dysfunction or brain injury (10). NIRS is measured using near infrared spectroscopic sensors attached to the right and left frontal cerebral hemispheres, and is capable of determining the oxyhemoglobin saturation of tissues in that region. Previous studies have suggested that satura-

tion drops of 25% below baseline values, or an absolute value of less than 40%, may indicate cerebral hypoxia and/or organic brain injury (11). Interventions to improve NIRS may include some of the following: increase arterial blood PCO_2, increase perfusion flow rate, increase arterial blood pressure, or transfuse packed red blood cells.

Using a server based data acquisition system (i.e., The Stöckert Data Management System), we captured data every 20 seconds from the heart lung machine, including arterial blood pressure, CPB blood flow rate, venous blood saturation, central venous pressure, right and left NIRS (Somanetics, Troy, MI), and arterial blood gas. These recorded values were time synchronized with a video of the surgical procedure. XmR control charts were developed to track regional cerebral saturation, mean arterial pressure and central venous pressure during CPB (12,13).

Control charts were created using SPC XL (Sigmazone, Colorado Springs, CO) and Microsoft Excel (Microsoft Corporation, Redmond, WA). After the control charts were constructed, we noted intervals of special cause variation (below the lower control limit). We examined the other recorded parameters and case video for aspects of the process that may contribute to the variation in NIRS. The control charts were annotated with information gathered from reviewing the surgical case videos. The literature states that absolute values less than 40% may be indicative of significant cerebral desaturation. Although the specification limit was never reached in the chart in Figure 5, it is notable that there was variation in the NIRS measurement throughout the surgical procedure. When using the NIRS monitoring, the surgical team may respond to the variation in the cerebral saturation with use of the commonly described interventions noted above. In the patient displayed in Figure 5 the control chart allowed us to pinpoint episodes of special cause variation. The drop in saturation that began at 40 minutes and persisted until 62 minutes into the bypass run was related to positioning of the heart for construction of the circumflex distal anastamosis. With the use of control charts we have seen this pattern in a number of procedures and have shared this finding with the surgical team. The control chart provided a context for discussion regarding the effects of positioning the heart on cerebral venous drainage and NIRS values. Linking the continuous data via a control chart and accompanied with a video of the surgical procedure deepened our understanding of the effect of positioning the heart during the distal posterior anastomoses. The control chart assisted our team in becoming aware of the upstream process of care leading to this variation. We now look for this underlying cause of variation rather than immediately and randomly applying other described interventions. Moving forward this new awareness should result in less variation during CPB. We will know whether this hypothesis is true if in subsequent cases we observe less variation in NIRS values. The control chart used in this example is retrospective and it is not used to predict future values during the procedure. These charts provide a powerful iterative learning tool. The examination of these charts after the procedure provides a graphical analysis in the form of control charts to understand better physiologic variations in context of the underlying surgical process (Terumo Cardiovascular Inc., Tustin, CA lent us equipment for this work).

WHERE TO BEGIN

So how should one begin to use SPC to improve CPB at their center? Albert Einstein once said, "Theory precedes measurement" (3). We should begin with a research question. We should start with a critical question or hypothesis, for example: Have we improved our length of stay for elective cases? How will we know if our outcomes are better? Does a new intervention for atrial fibrillation result in a reduced rate of atrial fibrillation? Has the change in our method of myocardial protection had an effect on incidence of peri-operative myocardial infarction or in serum troponin leak? Has the change in anticoagulation management had an effect on the amount of mediastinal drainage?

Once the question has been formulated, we must then decide what measurement would be needed to answer our question. Nelson and colleagues recommend the following steps: (1) seeking usefulness in the measurement (it should be a measure that makes sense not a nonsense quotient); (2) using a balance set of process, outcome, and cost measurements; (3) keeping the measurement simple; (4) taking time to write out operational definitions for the variable; and (5) making a dummy display to evaluate variables that are under consideration before beginning (3). Nelson also stresses the concept of building data measurement into daily work. If we can make the measurement part of our routine daily practice, we are likely to be more persistent in complete and accurate collection. Mapping out the current process (the way we do the task) will help one decide where the opportunity for understanding and potential improvement resides in the system (14,15).

According to Wheeler we must align our efforts with a particular focus or a specific objective (15). Are our results improving? What areas of our process should we change? Was the recent change that we made effective? SPCT is an effective tool for addressing these questions. Shewhart would remind us that the real power in using the charts is realized when those closest to the process (anesthesiologists, surgeons, perfusionists, and nurses) study the charts and interact in a dialogue to unlock the desired information.

Managed care has caused medicine to become more

industrialized, increasing our focus on driving out unwanted variation and becoming more efficient. SPCT is an important tool born in modern industrial science but a great utility for revolutionizing the way we deliver healthcare. In our care to patients with heart disease, SPCT is a powerful tool, vital to our rigorous effort to improve the design and management of CPB. It has been said that there is only one way to really know if control charts will have value for your team—check it out (16).

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APPENDIX: RESOURCES—SUGGESTED REFERENCES AND SOFTWARE

Understanding Variation: The Key to Managing Chaos, 2nd Edition. 1999 by Donald J. Wheeler

Making Sense of Data by Donald Wheeler

Improving Healthcare with Control Charts: Basic and Advanced SPC Methods and Case Studies by Raymond G. Carey, Larry V. Stake

Software: SPC XL a program that runs as a companion to Microsoft excel. The companion program has a control chart tool that can build control charts from Microsoft.

Excel template spread sheets are available from:

http://www.sigmazone.com/

http://www.excel-spc-software.com/excel-spc-software.html

http://www.qualityamerica.com

http://www.isixsigma.com/st/control_charts/