Applications of Statistical Process Control (SPC) To Improve Health Care

Several examples illustrate the process of using SPC to analyze, improve, and monitor health care, including nosocomial infections, pap smear accuracy, laboratory TAT, falls, misprescriptions, LOS, utilization, patient satisfaction, and disenrollment.
INTRODUCTION

All health care systems are candidates for improvement using statistical process control (SPC). This paper illustrates the process of using control charts to analyze, improve, and monitor a variety of clinical, operational, and administrative processes.

The primary objectives of this paper are to encourage thought and inquiry by readers as to potential SPC applications and to provide an overview of the:

- Value of statistical process control;
- Key concepts of natural variability and SPC;
- General process of using control charts; and
- Possible applications to health care processes.

Certain aspects of SPC, however, remain beyond the scope of any introductory paper. Practitioners seeking to regularly apply SPC are strongly encouraged to develop a more in-depth comprehension, and additional information for this purpose can be found in several of the listed references [1, 2, 4, 13, 14].

Additionally, although not the primary focus of this paper, quality management is a powerful process improvement philosophy. Unfamiliar readers are urged to seek introductory materials on principles of quality management in general and the philosophies of Dr. W. E. Deming [2,11] in particular. Understanding these concepts is absolutely essential.

VALUE OF USING SPC IN HEALTH CARE

The concepts, philosophies, and techniques of statistical process control offer a powerful approach to understanding, managing, and improving health care. Proper use of methods and concepts of variability and SPC can help management accurately understand the performance and capability of a process, as well any effect of management action on improving or harming that process. SPC and related methods also are helpful for identifying and verifying ways to improve the delivery and clinical quality of health care.

Traditional hospital epidemiology methods also can be greatly enhanced through appropriate application of control charts and related techniques. Quality engineering methods can provide critical process information helping to reduce costs and avoid liabilities which traditional methods might fail to detect.

Therefore, apart from the standard benefits of using SPC, failing not only to use SPC, but to use it correctly, can directly result in liability and negligence, particularly in clinical and laboratory processes [4].

Most health care organizations have adopted some form of quality management. Moreover, many organizations have achieved considerable success with several aspects of "QM", most notably those related to teamwork, facilitation, training, human resources and development, customer and process focus, and various process improvement tools and methods. However, the use of basic statistical process control unfortunately has yet to become widespread within health care, with the philosophies and techniques of variability and SPC having received only moderate attention and understanding.

KEY CONCEPTS OF NATURAL VARIABILITY AND STATISTICAL PROCESS CONTROL

Natural Variability and Statistical Control

All health care processes exhibit some amount of variability, and all variability can be classified as either "natural" or "unnatural". The natural variability of a process is defined as the variation inherent as a regular part of the process. The causes of this type of variability generally are complex and can not be traced and assigned to obvious single root causes, and thus usually are less easily removed or controlled by management.

Examples of common causes of natural variability in clinical processes might include weight and physical condition of patients, respiratory rate, time of day, strength of phlebotomist, patient-to-patient differences, and varying patient lifestyles, behaviors, and demographics. Because they are caused by regular sources, data exhibiting natural variation tend to occur in predictable and relatively common frequencies.

Conversely, observations which have very small probabilities of occurrence based on the regular process usually are presumed to represent special events and deviations from the regular process. Such events suggest that the process fundamentally has changed and are considered to be occurrences of unnatural variability, and thus tend to be traceable to root assignable causes for management action. Examples of special causes of unnatural variability in clinical processes might include changes in clinical procedures, skill degradation, and equipment failure, new
staff, physical change in a given patient’s bodily processes, change in patient population demographics, or increased rate of disease.

Note that often it is difficult to determine intuitively which of these two types of variation most likely contributed to recently observed process performance and therefore whether management intervention would be beneficial or harmful. Figure 1 illustrates the distinction between the two types of variability (natural versus unnatural) and the difficulty interpreting which type a process is exhibiting.

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State of Statistical Control: The process operates with only natural variability.

Two Types of Process Variability

Figure 1

The term statistical control most generally refers to the stability and predictability of a process over time. A process which is completely stable over time exhibits only natural variability, as the regular behavior of the underlying process remains unchanged. Such a process is referred to as being in a state of statistical control. Conversely, if the process behavior or variation changes from its regular performance, it will exhibit unnatural variability, and the process is referred to as being out of statistical control.

Purpose and Value of Statistical Control Charts

Statistical control charts are chronological displays of process data used to help understand, control, and reduce process variability. Control charts help to distinguish between the two types of variability (natural versus unnatural), differentiating between process data which exhibit “common cause” natural variation from those which exhibit unnatural variation, indicating presence of a special assignable cause.

The statistical control chart was first developed at Bell Laboratories by Dr. Walter Shewhart in 1924 and has become one of the primary tools of modern quality improvement and statistical process control (SPC). Shewhart [16] proposed that control charts could be used for three valuable, mostly sequential, purposes—namely to:

1. Understand the present process performance and variation;
2. Confirm when statistical control or a desired quality level has been reached; and
3. Detect special causes and process changes.

General Format of Statistical Control Charts

Figure 2 shows the general form of a control chart. Sufficiently many process data must be collected over an adequate span of time and evaluated in chronological sequence relative to the process variance over time. A specified number of observations (called a subgroup) periodically are sampled from the process, and some statistic of particular interest, such as the number of patient falls each week, is estimated from the subgroup and plotted on the chart.
Anatomy of a Control Chart

What does a statistical control chart look like?

Along with these subgroups, three horizontal lines also are plotted on the chart. These lines are referred to as the centerline (CL), the upper control limit (UCL), and the lower control limit (LCL) and assist in defining the natural operation of the process.

The centerline and control limits respectively define the central tendency and the natural variability of the process data. The centerline almost always is set equal to the arithmetic mean or expected value of the plotted statistic, so that approximately half of the data exist on each side. The control limits then usually are set equal to the value of the centerline plus and minus three standard deviations of the plotted statistic (3-sigma limits especially should almost always be used by lay-practitioners).

**SUPPLEMENTARY RULES FOR STATISTICAL CONTROL**

1. Eight consecutive subgroups on one particular side of the centerline (CL);
2. Twelve of fourteen consecutive subgroups on one particular side of the centerline;
3. Three consecutive subgroups beyond 2 standard deviations on a particular side of the CL;
4. Five consecutive subgroups beyond 1 standard deviation on a particular side of the CL;
5. Thirteen consecutive subgroups within ± 1 standard deviation (on both sides) of the CL;
6. Six consecutive subgroups with either an increasing or decreasing trend; and
7. Cyclic or periodic behavior.

(\* Note: Several slight variations of supplementary rules exist)

It is also frequently observed that some charts are more suited to one type of control chart. For example, mean and range charts are used for variables data; mean and standard deviation charts are used for variables data; and cumulative distribution functions (CDF) charts are used for categorical data.
Interpretation of Control Charts

A chart is in statistical control if all of the plotted subgroup values are between the control limits, over a sufficient span of time. There also should be no evidence of non-random variation between the limits, such as trends, cycles, visibly evident shifts above or below the centerline, and other forms of non-random behavior such as those listed in Table 1.

APPLICATIONS OF CONTROL CHARTS

The Process of Using Control Charts

Selecting, constructing, and using control charts unfortunately are very misunderstood subjects. The use of control charts is comprised of three distinct phases, each with a slightly different focus and value to improving process quality. Each phase spans a considerable length of time, with the typical total process of control charting a process minimally spanning several years or continuing indefinitely. These three phases are illustrated in Figure 3 and described in greater detail in Benneyan and Kaminsky [2], Montgomery [14], and Gitlow et al [13].

Three Phases of Control Charting

Trial Control Charting
- Bring process into statistical control
- Remove sources of unnatural variability
- Determine natural variability

Monitoring a Stable Process
- Maintain a state of statistical control
- Identify & remove sources of unnatural variability

Improving a Process
- Remove sources of natural variability
- Position the centerline
- Tighten the control limits - reduce variability

Three Phase Process of Control Charting

Figure 3

Billing Input Error Rate

Unfortunately, the use and value of control charts often are associated only with the later and more "passive" monitoring activity of detecting if a stable process shifts out of statistical control due to "special cause" events. In fact, control charts should be exploited much earlier and throughout the entire quality improvement process, to improve the process by stabilizing and reducing its variation.

For example, Figure 4 illustrates the use of control charts to determine whether a billing process initially is in a state of statistical control, for improving the process performance, and then for detecting when the process becomes out of statistical control.

Figure 4
Examples of Common Types of Control Charts

Three common types of control charts exist, with each being appropriate for one of three different types of continuous and discrete process data. Dependent upon which specific type of control chart is used, the exact method varies for calculating the process average and variance. Each type of control chart, therefore, should be constructed using slightly different formulas, which can be found in just about any good quality control book [1, 2, 13, 14]. While numerous other types of data and control charts are possible, one of these three types of data usually will be reasonably appropriate for describing many health care processes.

Continuous Data: For continuous data which are normally distributed, both the $\bar{X}$ and $S$ control charts should be used, always together. Examples of this type of data might include patient weights, lung capacity, blood counts, patient intake and output, dosage amounts, recovery durations, and times to complete various activities. For example, Figure 5 illustrates $\bar{X}$ and $S$ control charts of the laboratory time to complete Beta-sub pregnancy tests. Similarly, Figure 6 shows $\bar{X}$ and $S$ charts for the turn-around-times in the billing process mentioned earlier.

Control Chart of Stat Beta-Sub Pregnancy Test T-A-T (Total X-Bar Control Chart)

Enrollment / Billing Turn-Around-Time

$X$-Bar Control Chart

Beta-Sub Lab Turn-Around Time

Figure 5

New Enrollment Processing Turn-Around-Time

$S$ Control Chart

Figure 6
Discrete Data: The two most common pairs of discrete control charts are called np and p charts (for binomial distributions) and c and u charts (for Poisson distributions). Given a certain number ("n") of random observations, np and p charts are used for monitoring the number (or fraction) of these which have a particular characteristic of interest (e.g., a billing error, a late arrival, or a Cesarean section birth), where the probability of this occurrence of interest is the same for each observation.

For example, Figure 7 shows a p chart of the fraction of members who voluntarily disenroll from a health plan each month, a surrogate for dissatisfaction. Other examples of p charts include those for the billing data errors shown earlier in Figure 4 and for patient falls and medication prescription errors shown respectively in Figures 8 and 9.
Conversely, $c$ and $u$ charts are used if no theoretical maximum exists, such as the number of occurrences of a particular outcome of interest per examined area, volume, or time period. Examples frequently (but not always [5]) include the number of arrivals to an emergency room per shift, phone calls per hour, heart fibrillations recorded per observation period, leukocytes per CBC, or skin melanomas per patient.

For example, the $u$ control chart in Figure 10 monitors the number of admits per month. Similarly, the $c$ chart in Figure 11 describes the utilization of a particular piece of equipment in terms of the number of times it is used per month.
Additional discrete charts that recently have grown in popularity, such as for low rates, are the g and h control charts, the mechanics of which can be found in Berneyan and Kaminsky [5]. These charts, based on geometric distributions, monitor the number of observations between situations of interest, such as the number of days between infections or the number of operations between mortalities.

For example, Figure 12 illustrates a g chart of the number of days between occurrences of nosocomial infections, a metric which has been proposed as easy for non-technical staff to implement and preferable due to low infection rates and the critical need for timely analysis of data [5, 12]. As can be seen via supplementary rules, an increase in the infection rate appears to have occurred in the vicinity of subgroup 14.

The control charts described above are the most commonly used and are based on certain assumptions which generally but by no means always hold true. Selection and design of an appropriate chart is dependent upon many factors, such as the underlying distribution, desired statistical properties, and process particulars. If in doubt as to whether assumptions and desired properties are reasonably satisfied, a qualified quality engineer should be consulted.
COMMON PITFALLS TO AVOID

Several misperceptions about SPC seem endemic within health care. Although exceptions certainly exist, working and interacting with numerous practitioners, managers, clinical personnel, and consultants has reinforced the concern that unfortunately SPC often is misunderstood, underused, and misused.

Additionally, an alarming number of publications, consulting, and seminar materials reveal a lack of thorough comprehension of the purpose, methods, and theory of SPC. Consequently, many statistical and philosophical errors are propagating through the health care quality profession [4, 6]. Two examples of particular concern are the impressions that:

1. Clinical processes can not be interpreted via concepts of natural vs. unnatural variability; and
2. Quality assurance should become more outcome-focused, rather than process-focused.

Over-Simplification and Other Statistical Errors

The intention of several authors presumably is to simplify SPC as much as possible for non-technical practitioners. Although ease of use certainly is valuable to quality improvement methods, the effects of statistical errors and over-simplifications can be quite significant. Common statistical errors include:

- Basing control limits on the overall standard deviation of the data instead of standard deviation formulas (e.g., $\pm A_2\bar{S}$ and $\pm 3\sqrt{\hat{p}(1-\hat{p})n}$);
- Using anything but $\pm 3\sigma$ control limits unless otherwise determined via economic design methods ($22\sigma$ limits are disturbingly frequent incorrect advice);
- Not using at least 25 to 35 subgroups;
- Using random sampling instead of rational subgroups;
- Not accounting for autocorrelation (e.g., systolic blood pressure or patient weights) or multivariate processes (e.g., patient condition), thereby raising false alarm rates;
- Not taking sufficiently large subgroups (e.g., of size twelve or more) if process data are not reasonably symmetric and bell-shaped;
- Failing to consider statistical properties and construct OC curves, sometimes resulting in no power to detect shifts of consequence; and
- Failing to understand assumptions and limitations of standard charts and to seek expertise otherwise.

Control Chart Selection Errors

Common errors in control chart selection include:

- Failure to construct histograms and identify correct control chart;
- Using an $\bar{X}$ chart alone without a $S$ or $S^2$ chart;
- Using an $\bar{X}$ chart with an inferior $R$ chart, especially for skewed distributions;
- Overuse and misuse of the approximate so-called "individuals" chart, especially for anything but individual (not monthly averages) normally distributed data; and
- Using standard control charts when combining data from different processes (these often are incorrect for the aggregate metric, if not adjusted appropriately).

Philosophical and Conceptual Errors

Frequent philosophical pitfalls to avoid include:

- Management by average, failing to understand concept of variability in people, parts, and processes, and to manage accordingly;
- Tampering and reacting to natural variability;
- Thinking it is not necessary to understand variability to use control charts;
- Believing that control charts are used primarily to "hold the gains";
- Believing that "SPC is not applicable to health care" (still all too common!);
- Confusing SPC with software and with plotting points;
- Dangerous sole reliance on outcome metrics, "Report Cards", and aggregate "Dashboard Indicators" (inadequate information to improve and remain competitive);
- Invalid use and interpretation of standards and metrics;
- Obsession with massive annual customer surveys, instead of much smaller and more frequent sampling.
• Confusing quality and improvement with related, but different, subjects of satisfaction, benchmarking, and measurement; and
• Confusing epidemiology, biostatistics, and traditional hospital quality assurance programs with quality engineering.

MORE ADVANCED CONCEPTS

Two important statistical properties of any control chart are (1) the probability of incorrectly indicating that a process has changed when it has not (often called the "false alarm" rate) and (2) the probabilities of detecting true changes of various magnitudes in the process (often called the "power" of a chart). A desirable and well-designed control chart has a low false alarm rate and strong power to detect important process shifts, all at the lowest possible cost.

These three control chart properties - false alarm rate, power to detect process shifts, and total cost - are affected in part by the following three important decisions made by the practitioner:

1. The size of the subgroups (n);
2. How frequently to sample a subgroup from the process; and sometimes
3. The number of standard deviations to use in each control limit (if other than 3).

Methods exist to optimize control chart design with respect to these decisions based on the costs of sampling process data, of searching for assignable causes, and of not detecting true process changes.

In addition to the simple control charts illustrated in this paper, more advanced types of charts exist. These include moving average (MA), geometrically weighted moving average (GWMA) (also sometimes referred to as exponentially weighted moving average or EWMA), and cumulative sum (CuSum) control charts. Although more complicated to construct and use, a particular advantage of GWMA and CuSum charts over traditional Shewhart charts is their ability to more quickly detect smaller process shifts while maintaining low false alarm rates.

Finally, additional SPC methods related to the use of statistical control charts include:

• Inspection planning to economically determine when and when not to inspect processes;
• Quantifying and estimating the performance capability of a process; and
• Using experimental design to identify and reduce common causes of natural variability.

Although not the subject of this paper, additional information on these topics can be found in some of the listed references [1, 2, 4, 5, 12, 13] or from the author at: 114 Marston Hall, Industrial Engineering / Operations Research, University of Massachusetts, Amherst, MA 01003, (617/522-0616), or by Internet email at BENNEY@ECS.UMASS.EDU.

REFERENCES AND SUGGESTED BIBLIOGRAPHY


This paper is based on excerpts from an introductory book on successfully applying SPC in health care, Using Basic Statistics and Quality Control to Improve Health Care [1].