USING STATISTICAL PROCESS CONTROL (SPC) TO MEASURE AND IMPROVE HEALTH CARE QUALITY

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ABSTRACT

The use of statistical process control (SPC) and TQM to improve health care processes is discussed and illustrated. Particular attention is given to the Deming quality philosophy, the role of SPC, practical applications, and common errors to avoid. Several recent studies illustrate these concepts, including clinical pathway variances, Cesarean section rates, lengths-of-stay, billing errors, and others.

INTRODUCTION

This paper provides a brief introduction to the use of quality management, control charts, and other statistical process control (SPC) methods to measure and improve health care process quality. This approach is based on the management philosophy of the late quality pioneer, Dr. W. E. Deming, and his contemporaries, who emphasized the need to develop an understanding of a system, statistically and otherwise, in order to improve quality and reduce costs.

Although many health organizations have adopted some form of continuous quality improvement (CQI), use of basic SPC has yet to become widespread. Many processes, in fact, are prime candidates for analysis via these graphical methods in order to help understand and improve delivery and clinical quality. The paper's overall objectives therefore are to:

- provide an overview of the role of SPC within a quality management philosophy,
- illustrate the use and interpretation of control charts via several examples,
- emphasize the associated cost savings, and
- provide references for further information.

Ultimately, readers are encouraged to consider possible applications within their own processes. The paper therefore concludes with some common errors to avoid and several references where readers can seek further information.

THE DEMING QUALITY PHILOSOPHY IN HEALTH CARE

The Deming Approach to Quality

Health care organizations aspiring to adopt quality management must recognize that the Deming approach is not simply an additional program that can be implemented in a short span of time. The Deming philosophy, in fact, requires a fundamentally different approach to viewing processes, as well as a dramatic shift in the primary roles and responsibilities of all layers of management, from the board of directors through line supervisors. While full discussion is not possible here, further information on Deming's approach to managing for quality can be found in several of the listed references [9, 15, 17].

This philosophy challenges traditional approaches to managing any organization, health care or otherwise, and impacts every aspect of the organization, including the use of data and, perhaps most importantly, management focus and responsibilities. These responsibilities and barriers to health care quality are summarized in Dr. Deming’s well-known "14 Management Points" and "7 Deadly Diseases" [9], which are equally applicable to health care, service, manufacturing, or any other type of process.

In studying this approach, a common theme emerges that management’s job is to study process performance and remove barriers which inhibit its im-

provement - rather than to evaluate, reward, and/or penalize individuals for system problems often beyond their control. Deming, in fact, was quite clear that a fundamental purpose of collecting and examining data is to understand and improve a process, and not for scrutinizing nor "grading" the performance and relative value of individuals, a historic management style which deters optimal process performance. As discussed below, this quality management viewpoint has significant implications for the collection and analysis of health care data.

**Role of SPC in Quality Management**

Within this quality management and improvement philosophy, all health care processes should be recognized as existing across time and producing data which exhibit various amounts of natural (i.e., consistent) and unnatural (i.e., inconsistent) variability. One ultimate objective of quality management, in fact, is to study, control, and reduce this variation - and to otherwise improve process performance - via various statistical quality control methods.

Specifically, the use of statistical thinking, quality control charts, and related methods are vital for developing an understanding of the present system, studying its behavior over time, and controlling and reducing process variation. The applicability and value of SPC in health care has been discussed by Benneyan [1-7], Laffel and Blumenthal [13], Finison et al [11], and others. Additionally, the Joint Commission (JCAHO) and other accrediting and regulatory bodies have begun to require health care providers to be engaged in CQI activities, including the use of analytical methods such as SPC.

**QUALITY CONTROL CHARTS**

**Key Concepts**

The natural variability of a process is the systemic ("common cause") variation inherent as a regular part of the process, such as time of day, patient-to-patient differences, and varying case mixes. A process which exhibits only natural variation is stable and predictable over time, is referred to as being in a state of statistical control, and can be improved only by significantly changing the process itself.

Conversely, occurrences of unnatural variability represent atypical deviations from the regular process and tend to be traceable to "special causes" for management intervention, such as changes in methods, skill degradation, equipment failure, or new staff. A process which exhibits unnatural variability is unpredictable, is referred to as being out of statistical control, and can be improved by identifying and removing special causes.

Note that without the aid of statistical methods it usually is difficult to determine - intuitively - which type of variation exists and, therefore, whether management intervention would be beneficial or harmful. Dr. Shewhart therefore developed control charts in the 1920's at Bell Laboratories in order to help differentiate between "common cause" natural process variation and "special cause" unnatural outcomes. Due to their value and ease of use, control charts have become one of the primary tools of modern quality improvement and SPC in many industries.

**Types of Control Charts**

Without getting into statistical specifics, several common types of control charts exist, each being appropriate for different types of processes and each constructed using different formulas [10,16]:

- either an np or p control chart should be used for discrete binomial data;
- either a c or u chart should be used for count data generated by Poisson distributions; and
- both an \( \bar{X} \) (pronounced "x-bar") and an \( S \) chart should be used, always together, for normally distributed continuous data.

One of the above usually will be reasonably appropriate for many health care processes, although several other types of data and charts also can be appropriate in other situations. For example, g and h control charts [5] should be used for count data which are geometrically distributed and are useful for monitoring low rates, such as the number of surgeries between infections or rare adverse events [1,3]. Several health care examples of each type of chart and additional guidance on selecting which chart to use in particular situations can be found in several of the references [1-7,11].

**Format and Interpretation**

Most simply, control charts are chronological displays of process data, such as the number or rate of Cesarean-section births per week, which are plotted and interpreted soon after they become available in
the manner shown in Figure 1. Three horizontal lines also are plotted, called the center line (CL), the upper control limit (UCL), and the lower control limit (LCL), which define the central tendency and range of natural variation, and are used to detect if the underlying process performance has changed.

Values outside the control limits indicate that non-systemic causes exist which should be investigated, identified, and removed in order to achieve a single consistent process. (Trends, cycles, and other types of non-random patterns which also indicate a lack of control are defined by various rules described elsewhere [3].) In the $p$ control chart in Figure 1, for example, the monthly rate of births via Cesarean-section varies randomly between the control limits and thus is fairly stable over time, with the exception of month 9 being above the upper control limit.

An attempt therefore should be made to identify and remove any process differences that caused month 9 to differ from the regular rate. As a technical aside, note that a non-constant number of total births per month causes the control limits to be uneven, which is perfectly acceptable. (Also, ideally more time periods of data should be available in order to confidently assess the statistical control of this process.)

**Cyclic Improvement Process of Using SPC**

After a removal of root causes or some other process change, the control limits should be recalculated and additional process data should be plotted and examined for statistical control. This iterative and ongoing process of investigating, identifying, testing, removing causes of unnatural and natural variation, and re-testing would continue in the cyclic manner suggested by Shewhart's Plan-Do-Check-Act (PDCA) improvement cycle shown in Figure 2.

Comprised of four interdependent and balanced activities (a plan stage, a do stage, a check stage, and an act stage), this iterative PDCA cycle indicates that the continual task of process improvement is never done, with past results driving future activities. The process of using control charts and the focus in various stages of the process improvement cycle are described further by Benneyan [1,3].

![Plan-Do-Check-Act (PDCA) Iterative Continuous Process Improvement Cycle](#)
SOME IMPORTANT IMPLICATIONS

Consistent Levels of Clinical Care: The use of SPC and the achievement of consistent processes is especially critical where a lack of standard processes can have serious health consequences. For example, Figure 3 indicates that adherence to a particular care protocol, or "clinical pathway", is inconsistent on a weekly basis. Variances from this protocol were beneath the lower control limit in week 6 and then above the upper control limit in weeks 7 and 9, with an increasing trend from weeks 11 through 23.

This lack of standardized clinical methods has serious implications on the quality and consistency of patient care. Under the philosophy of SPC, a first step in improving adherence to this clinical pathway is to bring the process into a state of statistical control so that a consistent process exists, with all patients receiving the same care in a standard manner.

Role of Management: Within a Deming-oriented approach, one primary responsibility of health care managers is to continually ensure process improvement and to remove barriers which prevent employees from improving the process and from doing their jobs better. An essential responsibility of top management, therefore, is to significantly refocus health care personnel, capital, and other resources in order to develop an understanding - physically, statistically, and otherwise - of the performance of critical processes. This is a different mindset than currently exists in many health care and other organizations.

Role of Measurement: The role of measurement also should change significantly, with data now being gathered much more frequently in order to develop fact-based information about process performance over time, rather than basing decisions on intuition or anecdote. These data then are evaluated via SPC, in the manner discussed above, in order to understand and improve process performance. Note that this collection and use of data is a fundamental change away from traditional purposes of reports, documentation, and evaluation of individuals.

Process Focus: As the above examples suggest, important distinctions exist between traditional QA and SPC/CQI methods. Most importantly, a TQM approach requires that the day-to-day operating philosophy throughout an organization radically change towards focusing on continuous improvement in process quality and service. For health care providers this means, among other things, transitioning from traditional quality assurance orientations largely focused on inspection, reporting, and regulatory adherence to quality improvement orientations focused more on process study, continual improvement, and designing and re-designing better systems.

Note also that a minimum of 25 to 35 subgroups of data are necessary in order to conclude that a process is in statistical control, a requirement which has radical implications on how data should be gathered and analyzed by quality organizations. Even using quarterly data, for example, it can take 6 to 9 years to determine if a critical process is in statistical control. Many current uses of data therefore are insufficient for the purpose of statistical quality control.
Aggregate Report Cards: Annual, semi-annual, and quarterly reporting of large amounts of aggregated outcome-oriented data - including current trends towards simplistic report cards, variance reports, and other metrics as attempts to measure quality - should be replaced with more frequent and smaller sub-groups of process-oriented data.

In fact, much of the data collected for various report cards should be plotted on control charts much more frequently and closer to the continuous manner in which they are produced, as discussed elsewhere [2]. A few recent successful examples include patient falls, prescription errors, admit rates, infection control, needle sticks, patient satisfaction, mammography and other laboratory screenings [1-3,7].

Performance to Standards: Similarly, performance to standards should be evaluated as a process via quality control charts. For example, Figure 4 examines the monthly fraction of psychiatric lengths-of-stay which met a standard of not exceeding 10 days. In this case, aside from a slight upward trend ($r = .58$, slope = .05 ± .03), this process appears to be in a state of statistical control. Also note that although adherence is a consistent state, the process only meets the standard about 45% of the time.

The process should be studied in order to identify and remove reasons for the gradual increase, after which, once in-control, its performance can be improved only by changing the fundamental process. That is, no cases within the limits should be considered as process exceptions. (Similarly only week 9 in the earlier maternity example should be considered as deviating from the normal delivery process.)

OTHER SPC TOPICS

Related CQI Tools

Control charts, of course, are only one of several tools associated with CQI, including process flow diagrams, Pareto charts, scatter plots, regression analysis, histograms, designed experiments, root cause analysis, error-proofing, work simplification, quality workgroups, and others. It is important to emphasize that any tool alone typically is not as effective as when used together with others, as appropriate.

As a recent example, many of these tools were used together to significantly improve an HMO enrollment and billing department. Due to a high rate of data entry errors, all work traditionally was 100% checked for keying errors, as shown in Figure 5, consuming time and money. By using quality management, the PDCA cycle, control charts, and several other SPC tools, accuracy was improved from approximately 8% errors to less than 0.5%. For example, Pareto and control charts helped identify and quantify causes of keying errors, and scatter plots and regression were used to investigate possible causes of these errors. Further details are described in a tutorial case study by Benneyan [4].
**The "Cost" of TQM and SPC?**

Although several individuals have suggested that greater attention to quality and additional quality control programs only will further increase health care costs, this view tends to reflect a traditional quality assurance approach to health care management, rather than a quality management orientation. For example, contrary to Deming's philosophy, Dr. Inhorn [12] recently stated:

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

This traditional pre-TQM viewpoint that higher quality can be achieved only via additional quality assurance programs also has been echoed by others within health care. For example, Mango [14] stated:

"In my opinion, there are no known quality control procedures that do not impact workload or costs."

While some so-called "quality management" efforts, as currently implemented, may have increased costs, this general reasoning is contrary to the quality philosophy advocated by Dr. Deming and his contemporaries, which holds that as process quality improves, costs decrease and satisfaction increases. Under this approach, unnecessary work is removed and hidden costs of rework, waste, and liability are reduced, often accounting for savings of 15% to 25% of total costs, contrary to the viewpoints expressed above.

Using TQM and various SPC tools to improve the above data entry process, for example, resulted in an annualized combined savings of approximately $120,000. Even before removing the end-of-the-line quality control inspection (which immediately saved almost $78,000 annually), the use of SPC and related tools resulted in approximately $42,000 savings per year, demonstrating that incremental continual improvement increased quality and reduced costs, as Dr. Deming theorized:

"Improve quality, you automatically improve productivity, you capture the market with lower price and better quality. You stay in business, and you provide jobs. So simple."

This success led to the identification of an estimated $600,000 annual possible savings simply by replicating the same methodology in various other departments, including medical records, internal audit, cash...

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**Inspection Analysis**

One of the fundamental tenets of quality management is to achieve such high quality processes that costly inspections such as the above are unnecessary. In fact, one of Deming's key concepts is to build quality into a process in the first place rather than to try to inspect it in after the fact:

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

While this quote represents an ideal objective, two very important practical questions are:

- When should one inspect or not inspect?
- At what point can one cease inspecting?

Fortunately, a simple method exists to help determine where it is and is not cost effective to inspect or audit a process in order to minimize total costs of poor quality (CPQ). In many cases, considerable savings are possible by changing from an inspection-oriented mentality to a quality control philosophy based on statistical process control. In the above data entry process, for example, significant improvements meant that the end-of-the-line inspection was no longer justified. Further information can be found in Papadakis [18], Deming [9], and Benneyan [4].
J. Benneyan: "Using SPC to Measure and Improve Healthcare"

handling, accounts receivable, and outside utilization authorization. Recent laboratory studies also have applied similar SPC and CPQ methods to Pap smear, mammography, HIV, and hepatitis screening accuracy [7,8]. The inspection analysis method also has been applied in service, finance, manufacturing, administration, and distribution functions of biomedical, automotive, plastic, machining, shipbuilding, and computer industries, to name just a few [4].

More Advanced Topics

In addition to those mentioned above, more advanced types of control charts exist which tend to detect small process shifts slightly quicker. Control charts also can be constructed for autocorrelated, multivariate, non-parametric, categorical, and other types of data. Related SQC methods include:

- determining the optimal subgroup size, frequency, and control limits,
- estimating the statistical performance capability of a process, and
- using experimental design to identify and reduce causes of variability.

Although not the focus of this paper, additional information on these topics can be found in some of the listed references [1,3,10,16].

CONCLUSION AND SOME CAUTIONS

Statistical quality management is an effective approach which should be used to help study and improve health care quality, be it for administrative, clinical, or laboratory processes. Equally important, these tools should be used correctly. Unfortunately, several misunderstandings and over-simplifications of quality and SPC seem endemic in health care, with the literature ranging in technical detail and accuracy. For example, improper use of quality methods has contributed to not detecting infection rate increases and to liability in laboratories and in the manufacture of hospital equipment and biomedical devices.

An impression of particular concern is that concepts of natural and unnatural variability are not as applicable in health care as elsewhere. Related misperceptions include “management by average”, reacting to natural variation, confusing SPC with software, and confusing quality with satisfaction. Common statistical errors include using incorrect control charts or insufficient data, misusing so-called “individuals” charts, and using “short-cut” formulas. Further discussion of errors to avoid and statistical quality control in health care can be found in several of the references [1-7] or by contacting the author.

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REFERENCES


**BIOGRAPHICAL SKETCH**

James C. Benneyan is a practitioner, educator, and consultant in quality engineering, both within and outside of health care. Previously the Senior Quality Engineer at Harvard Community Health Plan in Boston, Jim has successfully used SPC, quality engineering, and related methods in a wide variety of settings, including IBM, Digital Equipment Corporation, and numerous other health care, manufacturing, and service organizations.

An active member of ASQC, HIMSS, IIE, and SHS, he has published several articles in the Journal of Quality Technology, Quality Progress, health care and manufacturing journals, co-authored several chapters in various health care quality books, and currently is writing a textbook on successfully using statistical quality control in health care. Current interests include applications of SQC methods to infection control and clinical laboratories.