Statistics for Hospital Epidemiology

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Statistical Quality Control Methods in Infection Control and Hospital Epidemiology, Part I: Introduction and Basic Theory

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ABSTRACT

This article is the first in a two-part series discussing and illustrating the application of statistical process control (SPC) to processes often examined by hospital epidemiologists. The basic philosophical and theoretical foundations of statistical quality control and their relation to epidemiology are emphasized in order to expand mutual understanding and cross-fertilization between these two disciplines. Part I provides an overview of quality engineering and SPC, illustrates common types of control charts, and provides references for further information or statistical formulae. Part II discusses statistical properties of control charts, issues of chart design and optimal control limit widths, alternate possible SPC approaches to infection control, some common misunderstandings, and more advanced issues. The focus of both articles is mostly non-mathematical, emphasizing important concepts and practical examples rather than academic theory and exhaustive calculations (*Infect Control Hosp Epidemiol* 1998;19:194-214).

At its most basic level, statistical quality control is rooted in the graphical and statistical analysis of process data for the purposes of understanding, monitoring, and improving process performance—general objectives that in essence are quite similar to those of epidemiology. Particular advantages of quality control charts over other analysis methods are that they offer a simple graphical manner by which to display process behavior and outcomes, they examine these data chronologically as a time series, and, although based in valid statistical theory, they are easy to construct and use. Moreover, once constructed, even the more complex methods discussed in part II of this series[1] remain relatively easy to interpret.

Several previous articles that have appeared in this[2-5] and other journals[6-16] discuss healthcare applications of statistical quality control charts and other tools generally associated with statistical process control (SPC), total quality management (TQM), and continuous quality improvement (CQI). (Many of these applications are described further in the "Suggested References" section later in this article.) As one recent example, Sellick[2] and a subsequent letter by Lee[3] discussed the basic application of statistical control charts to such epidemiological concerns as surgical-site infections, bacteremia, *Clostridium difficile* toxin-positive stool assays, medical intensive-care–unit (ICU) nosocomial infections, and needlestick injuries. Additionally, several other authors[17-26] have discussed surveillance and related epidemiology topics that in essence are quite similar to the philosophy and methods of SPC.

For example, Birnbaum[18] recently stated that a "statistically valid, systems approach to surveillance analysis is the key to determining whether occurrence of unexpected events is generic . . . or an exception" and discussed some approaches—dependent upon whether the underlying rate is constant, very rare, and so on—for determining warning and threshold limits for sentinel events that would signal such exceptions. More recently, in a review of surveillance methods for detecting disease clusters, Jacquez et al[24] suggested examining the time between successive infectious diseases with respect to an appropriate null reference distribution (assumed by the above authors to be exponential) for non-random behavior. That is, a deviation from the theoretical exponential model—and in particular an excess of several consecutive short waiting times—would be a low-

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probability event *if* no clusters were occurring and infectious diseases were assumed to occur otherwise over time according to a Poisson process. Such deviant observations thus would be taken as signals of the presence of one or more infectious disease clusters.

As the above and other authors indicate, these concerns are quite similar to those in SPC and therefore also could be handled with "industrial" statistical quality control charts. The intent of the current series, therefore, is to relate the use of control charts to these general types of epidemiological issues and to expand on much of what has been written about SPC in the healthcare literature to date by clinicians, consultants, and other healthcare practitioners. It should be emphasized, however, that, much like epidemiology, statistical quality control is a broad field, and not all technical issues can possibly be covered in satisfactory depth here. The current series instead aims to provide a broad overview of subjects at the foundation of SPC, so that epidemiologists and other clinical researchers, based on their healthcare expertise, can consider if and how to best incorporate SPC into their other methodologies. Particular attention, for example, is given to providing a broader understanding of industrial and quality engineering, the general theoretical basis of SPC, various approaches to applying SPC to infection control data, and the role of control charts in establishing and improving consistent processes. For additional background information, Benneyan[6] recently provided a thorough general introduction to the use and interpretation of statistical process control charts in a wide variety of healthcare applications, and several references are provided here for readers wishing to pursue any of the discussed topics in greater depth.

A more general objective is to stimulate increased dialogue, collaboration, and cross-fertilization between industrial statisticians, quality engineers, epidemiologists, clinicians, and other healthcare practitioners. By developing a common understanding of each discipline, similarities between epidemiology and quality control, and their potential to complement each other, their various methods may be integrated better when and where they might be brought mutually to bear on important healthcare issues. Finally, this series hopes to clear up some confusion that appears to exist in many recent healthcare publications, seminars, and training materials, including the role(s) and use(s) of statistical control charts, selection of an appropriate control chart(s), underlying distributional assumptions, optimal control limit widths, various fundamental statistical and technical issues, and several other points of concern.

SOME BACKGROUND ON INDUSTRIAL ENGINEERING AND QUALITY ENGINEERING

Overview of Industrial Engineering

Due largely to its historic origins in the early part of this century, the fields of statistical process control and quality engineering typically are associated with industrial engineers and statisticians, often in, but certainly by no means limited to, manufacturing settings. Industrial engineering and the closely related field of operations research span many industries and utilize a host of methods, increasing their widespread general value but making explaining their specifics somewhat of a difficult task. Nonetheless, to establish some context for later discussion, the remainder of this section provides a basic overview of some typical skills and methods used by industrial engineers and common applications of these tools in health care, manufacturing, and other settings.

Most generally, industrial engineers and operations researchers can be described as being concerned with the scientific study, improvement, and optimization of processes and process outcomes of any type and in any industry. Clearly, this quite broad definition might describe many types of individuals in a variety of industries, perhaps including epidemiologists and health care. Of interest to the present article, TQM and SPC fit within the above definition and are an integral part of most industrial engineers' training. In addition to these areas, industrial engineers engage in several other activities that can range considerably from basic management support services through advanced mathematical and optimization techniques. For example, a "traditional" industrial engineer might use tools such as process flow analyses, time and motion studies, hypothesis tests, design of experiments, reliability methods, network theory, computer simulation, queueing analysis, Markov chain analysis, game theory, decision analysis, economic analysis, linear and nonlinear programming, mathematical modeling and optimization, and regression and other statistical analyses to study and improve issues related to inventory management, production scheduling, facility and location, scheduling, and capacity and throughput analysis.[27] Note that many of the same mathematical modeling and optimization methods also frequently are used in epidemiology, disease control, and public health research.[28-30]

Although the title of industrial engineering is an artifact of the field's origins, it is in many ways today an unfortunate and misleading label, perhaps implying a scope that primarily is limited to industrial or manufacturing concerns. An industrial engineer's multidisciplinary nature, in fact, increasingly finds such a person working in business, health care, finance, portfolio management, banks, fast-food restaurants, distribution, telecommunications, airline management, and various other service industries, to name but a few. This broad scope also is reflected by the variety of academic departments in which the above topics are taught, including management, industrial engineering, mathematics, statistics, computer science, economics, public policy, electrical engineering, and others.

To complicate matters further, within some of these specific industries, an industrial engineer or operations researcher might be known by some other label. For example, within the business community, these disciplines typically are referred to as *operations management* or *management science,* here focusing mostly on the application of scientific, quantitative, and optimization methods to such areas as employee and product scheduling, pricing and market strategies, service delays, process efficiencies,

demand forecasting, financial and investment planning, and basic statistical and exploratory data analysis. Although the more mathematical methods often are categorized as *operations research* or management science and the less theoretical methods as *industrial engineering* or operations management, distinctions between all of the above subspecialties can be quite gray.

Healthcare Applications

These same methods also have long been used in health care at operational, clinical, strategic, and public policy levels. For example, at least as early as 1916, Frank Gilberth suggested the use of process flow analysis and time and motion studies of hospital systems[31] to improve surgery outcomes and to reduce cycle times, delays, and wait times, with a steady growth in applications throughout the 8 decades since these origins. Over 50 years later, for example, during the period from 1967 to 1982, a team of industrial engineers, healthcare researchers, and others developed the now-familiar concept of diagnosis-related groups[32] to serve as a set of precise product or service-family definitions, much as those used in industry for more effective management, analysis, budgeting, and cost and quality control.[33] In many hospitals and health maintenance organizations (HMOs) today, individuals trained in industrial engineering skills generally exist within *systems engineering, management engineering, information systems,* or CQI or TQM departments. For the most part and with some exceptions, these functions tend mostly to be oriented more toward basic industrial engineering projects, rather than advanced mathematical optimization research. See Sahney,[34] Freis,[35] Flagle and Young,[36] and Smalley[37] for good overviews of the history of industrial engineering and operations research in health care.

Just a few typical examples[38,39] of the types of operational problems in which industrial engineers have been involved within health care include process flow analysis,[39] patient routing,[40,41] space planning,[42] information systems planning,[43] inventory control of hospital supplies,[44,45] time studies of patient or staff activities,[46,47] queueing analysis of appointment access and delays,[42,48] forecasting bed needs,[49] and computer simulation to optimize resources, staff, panel sizes, and so on.[41,42,48,50] Some examples of more operations research and mathematical-optimization–oriented problems in health care include resource scheduling,[51] patient admission scheduling,[52] nurse scheduling,[53,54] utilization and scheduling of operating rooms and recovery rooms,[50,55] facility design,[56] and bed capacity planning.[57] Examples of strategic, clinical, and public policy uses of operations research include Markovian analysis of patient care and recovery,[58-60] regional healthcare planning,[61-63] time and motion surgery standardization studies,[31,64-66] blood banking,[67-69] optimization of cancer screening programs,[70,71] optimal policies for when to accept a not perfectly compatible organ transplant,[72] optimal time between bladder cancer follow-ups,[73] and many others.

While perhaps not widespread, the use of industrial engineering or operations research in health care is common enough that several organizations and journals exist specifically for such applications and practitioners, including the healthcare divisions of the Institute for Operations Research and Management Science and of the Decision Sciences Institute, the Healthcare Information and Management Systems Society, and others. Additionally, the Institute of Industrial Engineers has a healthcare-specific organization called the Society of Health Systems, which publishes the *Journal of the Society of Health Systems.* Studies based more in mathematical optimization or operations research often appear in journals such as *Medical Decision Making, Health Services Research,* and others.

Quality Engineering, TQM, and SPC

Within the broad range of analysis and optimization methods discussed above, quality engineers and industrial statisticians focus on technical and implementation aspects of quality control, process improvement, variance reduction, and the like. The terms *statistical process control, statistical quality control,* and *quality engineering* typically are used somewhat interchangeably, broadly defined as the general use of probability theory and various graphical and statistical methods, including quality control charts and other tools, to study and improve processes, process quality, and thus process outcomes. Fundamental concepts within this quality-focused orientation is that almost all healthcare systems can be considered as processes, that all outcomes are the result of internal and external processes, and that these processes exist across time with inherent variability. That is, when viewed longitudinally (ie, over time), these processes exhibit various amounts of consistent and inconsistent temporal variability.

Objectives of quality management are to study, control, and reduce this variation and to improve process performance otherwise. The concepts and methods of SPC, more specifically, are based largely on the value of reducing variability and on achieving and maintaining consistent processes (ie, being in a stable state of statistical control), therefore playing an integral role within the process management philosophy advocated by the late quality pioneer Dr. W. Edwards Deming and his contemporaries. This approach emphasizes a continual focus on process and quality improvement via, among other things, the use of statistics and quality management in order to develop an understanding—physically, statistically, and otherwise—of the performance of critical processes. In some cases, this also may mean transitioning from a traditional quality-assurance orientation focused largely on inspection, reporting, and regulatory adherence to a quality-improvement orientation focused primarily on process study, continual improvement, and designing better systems. While full discussion is not possible here, additional information on Deming's approach to managing for quality in health care and other industries can be found in some of the listed references.[74-76]

It is important to emphasize that, beyond specific statistical and graphical methods, the use of SPC is part of this larger quality-management–philosophical approach to understanding, managing, and improving processes, and

that this approach is equally applicable to health care, service, manufacturing, or any other type of process. For example, in their well-known papers, Drs. Berwick[77] and Laffel and Blumenthal[22] suggested the potential value of several aspects of the Deming philosophy to viewing and improving healthcare processes. These include, among many other important topics, the application of industrial quality control methodologies and, most generally, a constant and almost obsessive focus on processes and on the study, control, and reduction of poor process performance.

As these physicians argue, these concepts and methods are as applicable to health care as they are to more traditional industries. In 1987, Dr. Deming wrote about the need to view health care as a collection of processes,[78] and the application of quality control charts to epidemiology and infection control had been suggested at least as early as 1984[17] and more recently[2,18,19,24] as previously noted. Moreover, various regulatory and accreditation bodies are expressing a growing interest in the concept of variation reduction and the use of control charts. For example, the Joint Commission on Accreditation of Health Care Organizations, the National Committee for Quality Assurance, and others require that hospitals and HMOs be engaged in CQI activities, including the application of statistical methods such as SPC to critical clinical and nonclinical processes. A paper[79] by several authors from the Centers for Disease Control recently stated that

> Many of the leading approaches to directing quality improvement in hospitals are based on the principles of W.E. Deming. These principles include the use of statistical measures designed to determine whether improvement in quality has been achieved. *These measures should include nosocomial infection rates.*

Finally, it is important to note that the field of quality engineering is considerably broader than simply using control charts to monitor and detect special events in an otherwise statistically consistent process (the "holding the gains" third phase of Juran's quality trilogy[80]). Some other key objectives of SPC, for example, include achieving a consistent process, identifying ways to improve this process, and, as the above quotation indicates, verifying these improvements are achieved. In addition to the use of statistical control charts in these activities (which will be discussed further in part II), SPC and quality engineering also involve traditional methods such as hypothesis tests, exploratory data analysis, histograms, scatterplots, correlation and regression analysis, analysis of variance (ANOVA), statistically designed experiments, computer simulation modeling, and others to develop a statistical understanding of a process. As discussed subsequently, many of these tools are either identical or quite similar to those used in health care by epidemiologists. While the present articles focus primarily on the use of statistical control charts in epidemiology, overviews of the general role of these other various quality engineering tools within health care are discussed further elsewhere.[81,82]

Just as in epidemiology, many quality engineers (the present author included) also engage in methods research, both of a general theoretical nature and situation-specific. For example, later discussion will suggest several to-date unanswered questions, some of potentially high interest to epidemiologists, for which further research is warranted. A few examples include the best approach to low-frequency data; the optimal control limit width in various healthcare scenarios; the impact on sensitivity and specificity of the "within-limit control rules" described in part II; the effect of using standard approaches when assumptions are not reasonably met; the effect of various proposed short-cuts and simplifications; possible ways to handle highly skewed data; SPC approaches to mixed or nonhomogenous populations; the effect on various types of control charts when the exact time of an infection is not known, and the best chart to use under such conditions; and when (and when not) to update the center line and control limits.

ROLE OF STATISTICAL CONTROL CHARTS

Basic Definitions and Meaning of a State of Statistical Control

As discussed above, all healthcare processes exhibit some amount of random variability. For example, although the rate of surgical-site infections may be somewhat consistent month to month, the exact number of infections is not expected to be identical every month but rather to vary a certain amount above and below its long-term average. Furthermore, all such process variability can be classified as either "natural" or "unnatural." The *natural variability* of a process is defined as the systemic variation inherent as a regular part of the process. Conversely, observations that 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 or environment fundamentally has changed and are considered to be occurrences of nonsystemic *unnatural variability.* The occurrence of these events is the result of one or more unique root causes that are not a part of the regular process, if it still was behaving in a random but consistent manner and thus exhibiting only natural variability.

The term *statistical control* most generally refers to the stability and predictability of a process over time. A process that is completely stable and predictable 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 changes from its regular performance, it will exhibit unnatural variability, and the process is referred to as being *out of statistical control.* It is important to note that either the existence or the lack of statistical control indicates what type of action is appropriate to improve the process. That is, a key concept within the philosophy of SPC is that unnatural process variation can be reduced or eliminated only by identifying and removing its nonsystemic causes from the regular process (or otherwise suppressing their effect). To improve a process that exhibits only natural variation, however, by definition it is necessary to change fundamentally the regular underlying "common-cause" process.

As a simple example, new staff who follow a different clinical procedure might be a source of atypical process performance. If a change (for better or worse) in the rate of surgical-site infections was identified and traced to such a cause, then processes and procedures might be standardized to eliminate this cause and to prevent its occurrence in the future (or to ensure its occurrence, if the assignable cause resulted in a process improvement—a lower infection rate, for example). If the same procedures always are followed by all staff, conversely, then—all else remaining unchanged—the monthly number of infections most likely will exhibit only natural variation, and it therefore will be necessary to study and change these standard procedures in order to reduce the infection rate. Of course, this is an oversimplified example to illustrate the above concepts. In many more realistic scenarios, without the use of statistical methods, it often is difficult to determine intuitively which type of variation (natural versus unnatural) is present and, therefore, which type of process intervention (ie, unique identification or systemwide experimentation) is in order. Furthermore, once an unnatural event has been detected, such as via control charts as discussed subsequently, more advanced epidemiological methods may be required in the search for its assignable cause(s).

Statistical Quality Control Charts

Quality control charts are graphical statistical tools specifically designed to help in the difficult task of distinguishing between process data that exhibit "common-cause" natural variation and those that exhibit "special-cause" unnatural variation, indicating the presence of one or more special assignable causes. The statistical control chart was developed at Bell Laboratories by Dr. Walter Shewhart in 1924 and has become one of the primary tools of modern quality improvement and SPC. While based in a bit more statistical theory than meets the eye, control charts also are intended to be relatively easy for nonstatisticians and practitioners to use and interpret. Although the basic format and interpretation of control charts are described in greater detail elsewhere,[2,6,11,83,84] a brief description follows.

A set of observations (called a *subgroup* in SPC terminology) periodically is sampled from the process, and some parameter or value of particular interest, such as the weekly number of patient falls, the weekly proportion of Cesarean-section births, or the monthly rate of a certain type of infection, is estimated from each such subgroup and plotted on an appropriate control chart, in the manner shown in later examples. The number of observations in each subgroup is called the *subgroup size* and usually denoted as n. Note that, in some cases, all data from each time period are included in the corresponding subgroups, and, in other cases, only a portion of these are sampled (basically for economic and logistic reasons, as discussed later in this series). When first constructing a control chart based on historical data, all past subgroup values are calculated and plotted at once, in their chronological order, whereas, when later monitoring a process in relatively real time, new subgroup values should be added onto an established chart as soon as possible after each becomes available.

Three horizontal lines also are plotted on the chart, referred to as the *center line* (CL), the *upper control limit* (UCL), and the *lower control limit* (LCL). The CL and control limits respectively help define the central tendency and amount of natural variability in the process (either historical or hypothesized) and thus are used to detect if the underlying process performance has changed statistically (ie, whether unnatural variation exists). The CL almost always is set equal to the arithmetic mean or expected value of the plotted statistic, so that approximately half of the process data will exist on each side. (The theoretic median alternatively might be used in cases of highly skewed data.[69,85]) The control limits then usually are set equal to the CL plus and minus three standard deviations of the plotted statistic (the issue of using some other number of standard deviations or probability-based limits will be discussed further in part II).

Control Chart Interpretation

By observing the behavior of an infection rate or other process over time with respect to a control chart, a determination can be made about the stability (the "state of statistical control") of that process. With process data collected and plotted frequently and close to the continuous manner in which they are produced, near-immediate action can be taken to initiate investigation and either to correct process deteriorations or to standardize improvements. Most generally, a process is considered (with high probability) to be in statistical control if all of the plotted subgroup values exhibit only expected random behavior over a sufficient span of time. The most familiar indication that a process is out of control is if values exist outside the control limits. Such outcomes exceed their specified probabilistic range and therefore are indications that nonsystemic (atypical) causes likely exist that should be investigated and, if possible, removed in order to achieve a single, stable, and predictable process.

There also should be no evidence of non-random variation between the limits, such as trends, cycles, shifts above or beneath the CL, and other forms of non-random or low-probability behavior. Several of these within-limit tests will be discussed further in part II of this series. Conversely, if no signals of special causes exist, then no outcomes should be considered as deviations from the regular process, regardless of any standards or thresholds imposed by management or some external body. Note that, although unequal subgroup sizes, such as a varying number of surgical procedures each week, result in varying control limits (see below), their interpretation basically is the same. Note also that a minimum of *at least* 25 subgroups of data are recommended in order to conclude that a process is in statistical control, a requirement that will be discussed further in part II.

Relation Between Quality Engineering and Hospital Epidemiology

As the previous discussions have suggested, many similarities exist between the general objectives and meth-

TABLE 1
RELATION BETWEEN STATISTICAL PROCESS CONTROL AND EPIDEMIOLOGY TERMINOLOGY AND CONCEPTS

Statistical Process Control	Epidemiology
Natural variation	Generic
Common-cause events	Endemic
State of statistical control	Constant infection rate
Unnatural variation	Nonendemic
Special-cause events	Adverse events
Out of statistical control	
Process monitoring	Infection surveillance
Increase in process rate	Epidemic
Out of control points	Sentinel events
Control limits	Threshold or action limits
Supplementary run rules	Disease trends or clusters
Confidence	Specificity
False alarm rate, type I error	Positive predictive value*
Power to detect process changes	Sensitivity
Type II error	Negative predictive value*
Reduction of both unnatural (uncommon) and natural (common) cause variation	Reduction of both epidemic and endemic events
Optimal economic design of control charts	Use of 3-sigma versus 2-sigma or other threshold limits
Reliability and queueing methods	Incidence, prevalence, duration analysis

* Not precisely identical concepts.

ods of industrial quality engineering and those of epidemiology. In fact, if the language and terminology were modified slightly in several articles authored by epidemiologists, many of their statements easily could read as if they were written about SPC by a quality engineer or industrial statistician. For example, Birnbaum[19] distinguished between generic process events "requiring systematic correction" and exceptions that represent "a new class of generic problems (*special cause events* in CQI jargon)." In a 1979 paper, McGuckin and Abrutyn[20] described a surveillance method quite similar to quality control charts for detecting potential epidemics and triggering investigative action.

Additionally, several other epidemiologists[2,17,19] have proposed monitoring infection rates over time in manners that are either identical or quite similar to SPC. Other authors[13,86] and a recent series of articles in *Quality Progress*[8,9] also discussed similarities and differences between epidemiology and statistical quality control methods, as well as some possible difficulties related to the application of basic control charts to infection control. Although a few authors[87] to some extent have suggested an "either/or" viewpoint, this perspective poses the danger of drawing attention away from the mutual objective of analyzing data created by a process over time in order to study and improve that process. It is encouraging that, despite some concerns about the use of control charts in epidemiology, most healthcare practitioners appear to view SPC as an additional set of tools for epidemiologists to use when and where appropriate, rather than as a different or competing field.

Table 1 summarizes several similarities between the concepts and terminology of epidemiology and statistical process control. For example, hospital epidemiology programs tend to be concerned with both epidemic (nonsystemic) and endemic (systemic) infections,[88] which in SPC terminology equate to unnatural (special-cause) and natural (common-cause) variability, respectively. While surveillance programs focus on the detection of sentinel and epidemic events (ie, monitoring for unnatural process variation), the often greater epidemiology concern of reducing endemic occurrences equates to the often greater quality-control concern of improving a process whose defect rate is in a state of statistical control but still is unacceptably high. Additionally, the quality-control activity of bringing a process into a state of statistical control (to be discussed further in part II) basically is the same as the infection control activity of removing preexisting chaos suggested in the recent letter by Lee.[3]

Based on these discussions and similarities, it seems clear that SPC can make several potential contributions to healthcare epidemiology. For example, after various epidemiology methods first discover the risk factors or predictors that are important to monitor and control, SPC charts can help monitor these factors. (Similar to epidemiology, a quality engineer also might use hypothesis tests, experimental design, ANOVA, regression, truth tables, time-series analysis, and exploratory data analysis for the investigative and identification purpose, although generally not getting into more advanced statistical methods that

epidemiologists or biostatisticians might use.) Once identified, other epidemiological or SPC methods also might be used to analyze these factors, develop a better understanding of their effect, reduce their influence on the clinical outcomes of concern, and so on.

Statistical process control also can complement epidemiology in the reverse order. That is, SPC charts can identify special-cause (atypical, nonendemic) events that then could be examined in greater detail via classic epidemiology, such as in order to identify explanatory factors or underlying root causes. As another example of this potential interaction, several epidemiologists[79] recently reported important distinctions in infection rates (such as for adult and pediatric ICUs, surgical patients, and high-risk nursing patients) and recommended that infection rates be based on the number or duration at-risk (such as the number of patient days, surgeries, and device-use days), rather than being based simply on the number of admissions or discharges. A later SPC paper[89] by a quality engineer discussed some approaches to applying SPC charts to any of these specific recommended calculation methods and (fairly) homogeneous patient categories.

In addition to control charts and the other tools mentioned previously, many quality engineers also work with stochastic processes and reliability methods that are quite similar to other epidemiology tools. For example, the equation discussed by Birnbaum[18] relating the prevalence of the total number of cases (P), the incidence of the number of new cases (I), and the mean duration of disease (D)

$$P=(I)(D)$$

is the same formula that industrial engineers refer to as Little's law[27,90] and use to investigate the average duration and average number of people or items in a particular state at any given time (typical uses are to study queueing, waiting, capacity, and throughput). Quality engineers also study system and product reliability with various survival analysis and special-purpose control charts based on the same cumulative infection incidence formulas used by epidemiologists.[8]

Finally, very similar to the analytic maps and location plots recently described by Jacquez et al[24] for cancer cases and bone-fracture incidences, industrial and quality engineers sometimes use defect location or concentration plots to analyze problems and inform process improvement.[83,91-93] Some representative examples of the range of applications include the location of scratches on refrigerators, the type and location of defects and contamination particles on printed circuit boards and semiconductor wafers, the location of automobile paint blemishes and manufacturing defects in engine blocks, and the location of bullet holes in military airplanes that returned from battle (in order to design more resistant aircraft). Examples of nonmanufacturing applications include concentration plots of the locations where postal mail is lost or misplaced, in order to improve mail delivery; traffic accidents, to reduce the number of fatalities; and automobile dents, so that an insurance company can influence driver education programs in order to reduce claims and premiums.[93]

It also is important to emphasize that control charts are by no means just a "manufacturing" tool but rather can be used to examine outcomes and other data produced by any process, be it manufacturing, healthcare, or otherwise. For example, it is noteworthy that Dr. Shewhart's classic 1939 text, *Statistical Method from the Viewpoint of Quality Control,*[94] was not written for a manufacturing audience (note Shewhart's industry-nonspecific title) but rather was developed from a series of lectures invited by the US Department of Agriculture, which wished to consider how these concepts and methods could be applied to agricultural research. In this text, Shewhart suggested that control charts were applicable to a wide range of scientific or statistical studies and that non-engineering "data are not to be regarded differently with respect to the assumption of statistical control" (p 65). Other early uses of control charts by Deming and Shewhart included their application to measurements of the velocity of light, census data, financial processes, and other nonmanufacturing concerns. Also see Latzko,[95,96] Rosander,[97] Deming,[98] Philpot,[99] Benneyan,[100] Bicking,[101] Mandel,[102] Selover,[103] Anderson and Diaz,[104] and Ramsey and Cantrell[105] for discussions of quality and control charts in the boardroom, service, administration, banking, accounting, finance, insurance, mail distribution, clerical work, government, transportation, freight administration, accounts receivable, retail trade, national census, criminology, and public utilities.

Finally, it is interesting that several metaphors often used when training SPC in other industries utilize medical concepts, such as monitoring a "patient" (eg, a manufacturing process) for early indications that its condition has deteriorated, so that an intervention could be taken before deteriorating further. Using such metaphors, factory workers and management often get beyond their resistance to the application of SPC in their workplace (where things surely must be different) and are shown that, just as taking a patient's vital signs at the end of every month might indicate only that the patient had died or survived, manufacturing should use real-time information to intervene when a change first occurs.

As another example of a "problem-diagnosis-prescription" type of metaphor, consider the language of Dr. Juran's[80] "Diagnostic Journey" of discovery, in which one seeks to understand the possible cause(s) of deterioration, and subsequent "Remedial Journey," in which process interventions are made to remedy this condition. Having established the above philosophical foundation, the following section briefly reviews the theoretical basis of standard types of control charts and illustrates possible epidemiology applications of each type.

COMMON PROBABILITY DISTRIBUTIONS AND CONTROL CHARTS

Control Chart Selection

Control charts are statistical tools and, as such, are based on probability theory. Several different types of con-

trol charts exist (customarily denoted by various letters such as *np, p, c, u,* $\bar{X}$, and *S),* each being appropriate in different situations. Because there appears to be some confusion regarding when each chart is appropriate and the charts' underlying assumptions, this section clarifies the relation between probability distributions and control charts. Several common types of process data and probability distributions exist, such as measured values, counts, fractions, and rates, and specific control charts have been developed for each of these situations. Just as there are different types of hypothesis tests for means, variances, proportions, and counts, each control chart is based mathematically on a particular underlying statistical distribution that is appropriate for its corresponding type of empirical process data.

The selection of an appropriate control chart for any given situation, therefore, is based directly on identifying which type of process data is being investigated. Although it is somewhat popular in introductory SPC articles to provide diagrams or tables to aid in control chart selection, most of these can be problematic and somewhat misleading. The most straightforward and accurate approach, instead, is to recognize what type of process data (eg, discrete or continuous) is being analyzed and to identify an appropriate probability distribution that reasonably describes these data. In many common applications, this is not nearly as difficult as it may seem, especially as just a few distributions and their corresponding control charts can be applicable to a wide range of situations. For example,

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

These three probability distributions—binomial, Poisson, and normal—will be familiar to many readers as being among the most common for many practical empirical situations, and the six charts listed above therefore are appropriate for most (but not all[69]) basic applications of SPC. For example, many types of continuous measurements can be expected to be distributed according to the well-known normal (Gaussian) bell-shaped distribution, and $\bar{X}$ and *S* charts would be applicable in such situations. Examples might include patient waits, procedure durations, the timing of preoperative antibiotics, other time intervals, various physical measurements, and other physiological variables.

Alternatively, many types of discrete counts are assumed to occur according to Poisson distributions, for which *c* and *u* control charts are appropriate, such as the number of patient falls per month, arrivals to an emergency room, maternity cases per week, and infectious diseases per time period. A second very common discrete distribution is the binomial, for which *np* and *p* control charts are appropriate. Binomial and Poisson distributions are discussed in greater detail subsequently in order to demonstrate the relation between probability distributions and control charts. As with any statistical methodology, there are exceptions for which some other, and perhaps more complex, distributional phenomenon is at play. In such situations, an alternate statistical approach should be taken to developing appropriate control charts based on some alternate probability model.

Bernoulli Trials and Binomial Distributions: np *and* p *Control Charts*

A basic building block of the binomial-based *np* and *p* control charts (and of many other parametric and nonparametric statistical methods) is a dichotomous event called a *Bernoulli trial,* which basically is any situation that results in one of two outcomes, each with some probability. Examples include a coin toss resulting in either a "head" or "tail," a birth being via either a vaginal or Cesarean delivery, a surgical site developing or not developing an infection, a discharged patient having had no or some variances from the appropriate clinical pathway, a maternity length of stay exceeding or not exceeding 48 hours, a particular procedure resulting in mortality or survival, and multiple diagnoses or repeated laboratory results agreeing or disagreeing with each other, to name just a few.

When more than one of the same type of Bernoulli trial are considered together (eg, several surgeries of a particular type performed in a given month), each presumably independent from the others and with the same (or reasonably the same) probability *p* of resulting in a particular outcome (eg, a surgical-site infection), the total number and the fraction of such outcomes from all these cases are binomial random variables. Note that many processes either are described directly by such independent and identically distributed (ie, "i.i.d.") Bernoulli trials and binomial distributions or can be framed to be viewed in such a manner. For example, in the above maternity example, although length of stay is a continuous variable, this duration also can be considered simply as exceeding or not exceeding a recommended 48 hours (although see later comment regarding reduction in statistical power). The *np* and *p* control charts (and any other statistical methods based on binomial distributions) therefore can be widely applicable in health care or any other environments interested in the total number or fraction of all (reasonably similar) cases that result in a particular outcome.

The distinction between these two control charts is that an *np* chart is used for the total number of a certain outcome per subgroup, whereas a *p* chart is used for the fraction (proportion) of cases per subgroup that result in this outcome. Other *np* and *p* chart examples might include the total number of catheters and other devices that result in associated infections, the fraction of complication-free coronary artery bypass graft surgeries, and the number or fraction of handlings of needles and other sharp objects that result in inadvertent sticks. (Of course, detailed data such as for the latter example may be less likely to be easily accessible; see later discussion about the use of Poisson-based *c* and *u* control charts in such cases). An implicit assumption in

any example is that each case has reasonably the same probability of the given outcome occurring (eg, reasonably the same infection rate). If this assumption is not thought to be met fairly well, then the data should be adjusted appropriately or stratified into more homogeneous subsets[79] and separate control charts applied to each of these.

Before proceeding, note that Bernoulli trials also can be combined in several other manners, resulting in other probability distributions, although the binomial distribution by far is the most common. For example, hypergeometric distributions result if sampling (without replacement) from a finite population, and any of several types of pooled or mixed binomial distributions result if considering nonhomogeneous events together for which the probability of a particular outcome is not reasonably the same.[69] A simpler example that will be discussed further in part II is the geometric probability distribution, which, like the binomial, assumes that such an outcome is equally probable case-to-case but now results from counting the number of cases (ie, Bernoulli trials) *between* particular outcomes (rather than the number of such outcomes *within* a given number of cases or trials). Note that any Bernoulli process that could be viewed via a binomial distribution also could be tabulated slightly differently in order to form a geometric distribution, such as now by counting the number of coin tosses between "heads," the number of surgeries between infections, the number of needle handlings between sticks, and, in nonparametric tests, the number of consecutive values *above* a median value. As will be shown in part II, this transformation may be advantageous in certain situations.

Example of Relation Between Probability Distributions and Control Charts

As an example of the relation between np and p charts and binomial distributions, Table 2 contains two hypothetical sets of monthly catheter-associated–infection data, each spanning 36 consecutive months. For simplicity of illustration, the first example assumes that a constant number of patient records, n=50, are sampled from all patients who received a urinary catheter at some point during each month and that these patients represent a fairly similar group with respect to their duration of catheterization, age, and other attributes (so that each had reasonably the same Bernoulli probability, p, of developing a catheter-associated urinary tract infection). Then, assuming these data came from a stable process, the theoretical probability of any particular number of catheter-associated infections, x, out of the total number of patients considered, n, can be obtained using the familiar binomial probability distribution function:

$$\text{Prob.}\{X = x\} = \frac{n!}{x!\,(n-x)!}\,p^x(1-p)^{n-x}$$

Figure 1 compares a relative frequency histogram of the example 1 data with this theoretical binomial distribution, with the parameter n=50 and the probability of infection p estimated from the historical data, via the method of maximum likelihood as shown in Table 2, as $\hat{p} \approx .084$. As can be seen by simple visual comparison, with the exception of the high number of infections during months 28 and 29, the empirical data appear to fit the theoretical binomial model fairly well. More rigorously, a chi-squared goodness-of-fit test (excluding months 28 and 29, as it will be shown later that something atypical likely occurred during these months), results in a significance P value of .73, indicating that the data statistically fit a binomial distribution very well (generally, we would reject the null hypothesis of a good fit if $P<.05$ or $P<.01$). While several other more sophisticated goodness-of-fit methods exist,[106] the histogram and chi-squared test suit the present purposes of demonstrating the usefulness of theoretical probability models, describing empirical process data, and graphically illustrating the high level of agreement between the two. (Note that some statisticians prefer more powerful distribution-checking methods, although these tend to be more complicated to use, less intuitive from a lay perspective, and beyond the scope of the current discussion.) Additionally, as more data (subgroups) become available, the binomial fit visually will improve even more (if the process is, and remains, in a state of statistical control).

Given that these data are binomial, they also can be examined via an np or p control chart for departures from this underlying probability distribution. The formulas and mechanics for constructing all common control charts tend to be fairly easy to use and are detailed in several quality control texts.[83,84,91,107] For the present example, the CL and k-sigma control limits for binomial-based np charts are calculated as follows:

$$\text{Center Line (CL)} = n \times p = np$$

$$\text{Upper Control Limit (UCL)} = np + k\sqrt{(n\,p\,(1-p)}$$

$$\text{Lower Control Limit (LCL)} = np - k\sqrt{(n\,p\,(1-p)}$$

with p often (but not always) estimated from the data as discussed above and shown in Table 1, k≈3 standard deviations typically (but not always) used in the control limits, and a LCL < 0 by convention set equal to 0. In this case, substituting $\hat{p}$ for p (note that some texts alternatively use the notation $\bar{p}$) yields:

$$\text{Center Line (CL)} = n \times \hat{p} = n\hat{p}$$
$$\approx 50 \times .084 \approx 4.22$$

$$\text{Upper Control Limit (UCL)} = n\hat{p} + k\sqrt{(n\,\hat{p}\,(1-\hat{p})}$$
$$\approx 4.22 + 3\sqrt{50\,(.084)\,.916)} \approx 10.084$$

$$\text{Lower Control Limit (LCL)} = n\hat{p} - k\sqrt{(n\,\hat{p}\,(1-\hat{p})}$$
$$\approx 4.22 - 5.884 \approx (-1.884) \rightarrow 0$$

The trial np control chart corresponding to example

TABLE 2
NUMBER OF CATHETER-ASSOCIATED URINARY TRACT INFECTIONS PER MONTH

	Example 1		Example 2	
Month No.	No. of Patients Sampled (Subgroup Size *n*)	Total No. That Resulted in Catheter-Associated Nosocomial Infections	Total No. Patients Who Received Catheters (Subgroup Size n_j)	Total No. That Resulted in Catheter-Associated Nosocomial Infections
1	50	8	213	15
2	50	4	212	12
3	50	5	182	15
4	50	3	286	21
5	50	3	248	23
6	50	1	228	19
7	50	6	258	15
8	50	4	340	13
9	50	5	68	9
10	50	5	201	12
11	50	2	290	20
12	50	3	229	19
13	50	6	271	22
14	50	1	226	13
15	50	2	213	17
16	50	6	268	19
17	50	2	311	25
18	50	8	251	29
19	50	5	211	20
20	50	4	290	31
21	50	0	232	28
22	50	2	273	30
23	50	7	246	26
24	50	2	321	39
25	50	1	167	9
26	50	5	190	7
27	50	0	255	11
28	50	11	302	16
29	50	12	268	4
30	50	3	369	14
31	50	4	240	13
32	50	6	267	18
33	50	3	246	11
34	50	7	255	21
35	50	4	199	18
36	50	2	362	25
Totals:	$36\times50=1,800$	152	8,986	659
Average number of catheter-associated infections per month:		$152/36\approx4.22$		$8,986/659\approx13.64$
Estimated per-patient probability of a catheter-associated infection ($\hat{p}$):		$152/(36\times50)\approx0.084$		$659/8,986\approx0.073$

1 (with k=3) for the total number of catheter-associated infections per month is shown in Figure 2. Alternatively, a p control chart could be constructed using the formulas shown below for the fraction of catheters that developed infections per month (this p chart would be identical in appearance and statistical properties to the above np chart, with the CL, control limits, plotted values, and vertical axis all reduced by a function of $\frac{1}{n}$).

Note that in Figure 2 the subgroup values corresponding to months 28 and 29 are outside the control limits and therefore should be considered as probable deviations from the norm, whereas all other months appear to be part of the same catheter-associated infection process. That is, with high probability, the observations from months 28 and 29 were not generated by the same underlying distribution as those from all other months examined. In practical terms, this means that these data probably were produced by something other than the standard and consistent process that existed during the rest of the examined time period, suggesting an epidemiological or other investigation may be appropriate to identify and remove, if possible, any causal factors. Under the philosophy of SPC, a first step in reducing the infection rate is to bring the process into a state of statistical control, so that it is operating with only natural variability (ie, no indications exist of a lack of statistical control) and thus can be studied more methodically as a definable system.

Relation of Control Charts to Hypothesis Tests, Goodness-of-Fit Tests, and Other Statistical Concepts

The previous example illustrates several similarities and differences between control charts and related statistical methods. For example, using $\bar{X}$ control charts is

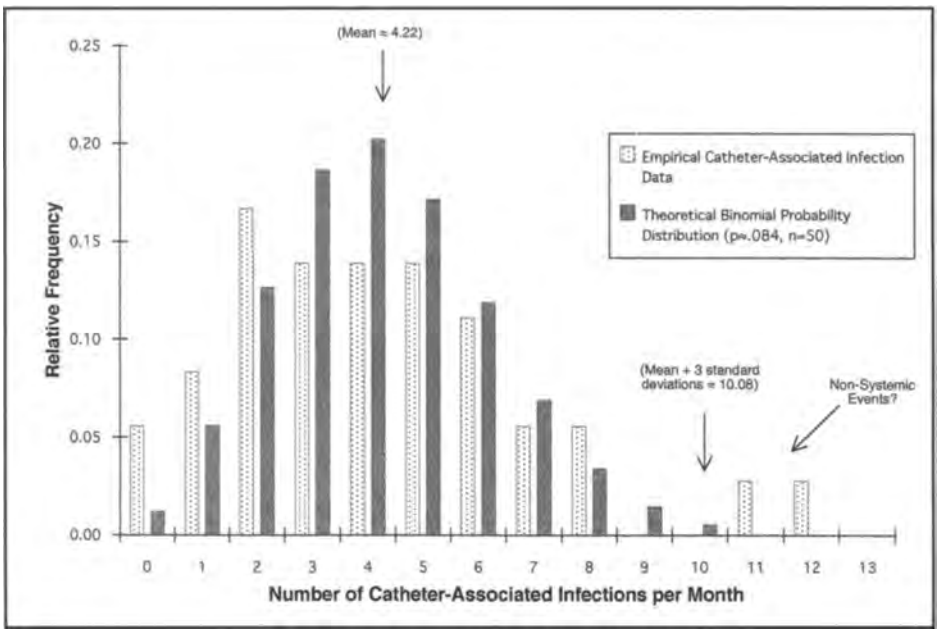

FIGURE 1. Relative frequency histogram of catheter-associated infections per month data from example 1 in Table 2 and comparison to theoretical binomial probability distribution.

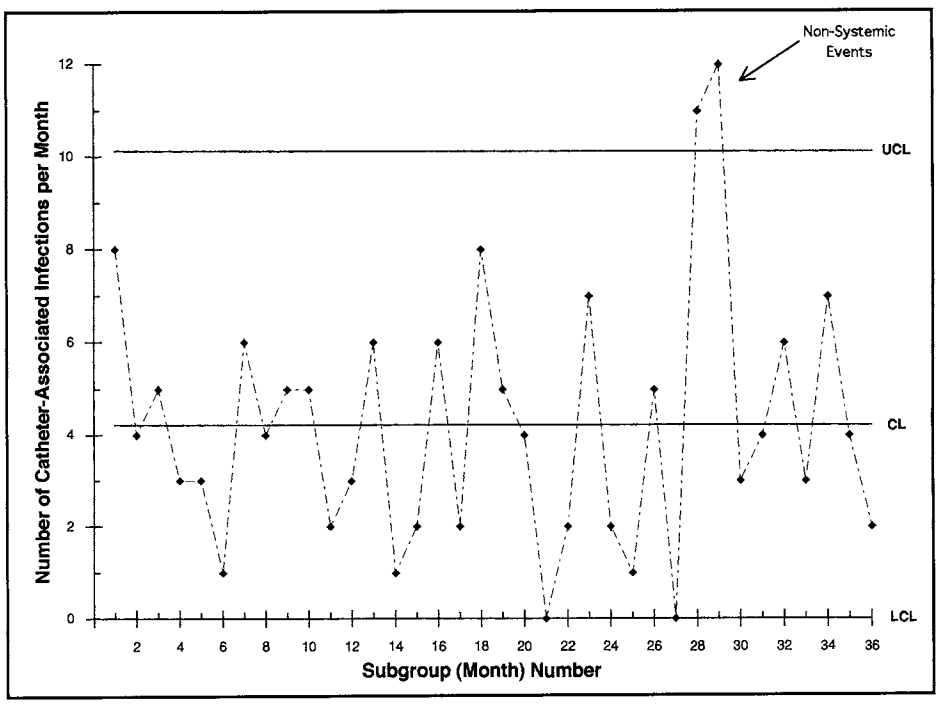

FIGURE 2. Trial *np* control chart of catheter-associated infections per month for example 1 in Table 2. Abbreviations: CL, center line; LCL, lower control limit; UCL, upper control limit.

directly analogous to using hypothesis tests or ANOVA to test whether all means likely came from the same distribution, but now also examining the time-order of the data in order to assess this equality and stability longitudinally. That is, many traditional tests do not consider data in their natural time order nor in small quantities, often aggregating data into a few larger time-independent quantities; this aggregation can pool natural and unnatural variation together, thereby losing some ability to detect process irregularities.[94] Although the example in the previous section was fairly simple, control charts also can identify trends and cycles in the time-ordered data, as discussed further in part II, that traditional tests might not detect. As a recent example,[85] an ANOVA (which ignores chronological order) resulted in a conclusion that no significant difference existed in cervical-smear data, whereas control chart within-limit tests revealed that a significant change had occurred over time. In this application, the use of SPC also helped to identify quickly when particular individuals were in need of retraining.

As the previous section suggests, control charts also are related to tests for distributional fit, here augmenting traditional (time-independent) tests with an examination of the goodness-of-fit *over time*. While histograms and classic

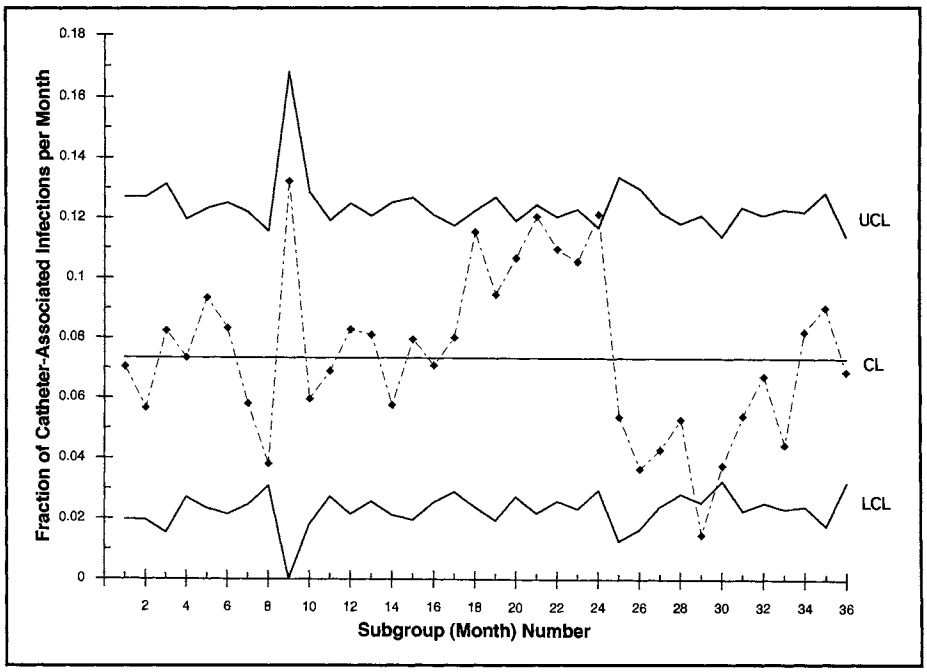

FIGURE 3. Trial *p* control chart of rate of catheter-associated infections per month for example 2 in Table 2, based on unequal subgroup sizes (unequal number of monthly catheterizations). Abbreviations: CL, center line; LCL, lower control limit; UCL, upper control limit.

goodness-of-fit analysis examine the distributional form, en masse, of all data aggregated together (thus ignoring their time order), a control chart essentially tests whether process data consistently occur individually across time according to the same particular distribution. (This concept is related very closely to Shewhart's objective to examine the stability of a distribution over time.) Again, while histograms and classic goodness-of-fit tests ignore trends, process shifts, cycles, and other non-random behavior within an unordered data set, control charts will flag these distributional departures. Conversely, if the process were more dramatically out of statistical control than in the previous section, histograms and goodness-of-fit tests would not produce such good results and even could (and in practice often do) suggest an incorrect process distribution. While this sometimes is a different way of thinking, the importance of using both goodness-of-fit tests and control charts to test the "dual hypothesis" of distributional form and process stability simultaneously has been discussed elsewhere.[69]

Additionally, while (most) control charts are based on the assumption that data come from a reasonably homogeneous group, in the reverse sense, they also test whether this assumption is reasonable. For example, much like a hypothesis test for equal proportions, a *p* or *np* control chart tests whether all data were generated from a binomial process with the same probability of resulting in a certain outcome. It also should be emphasized strongly that, while this is the most common use, it is *not* true that control charts can not nor should not be based on anything but historical process data (contrary to frequent statements). That is, although control charts usually are used to test whether a process is in a state of statistical control with respect to itself (and thus are developed based on its own data), they also can be developed based on some internal or external specified values, much like hypothesis tests can be used either to test whether all means are equal to each other or to test whether one or more means all equal a specified value (such as a clinically or epidemiologically relevant value). This use often is referred to as a *standards-given* control chart, in contrast to the more common *parameters-estimated* control chart. Possible and perfectly valid uses of standards-given control charts might (and arguably should) include testing whether a given institution is in a state of statistical control with respect to some national standard or with respect to the performance of another facility.[108,109]

Finally, much like the power and significance level of simple hypothesis tests, control charts occasionally will signal erroneously that a significantly atypical outcome occurred when in fact the process remained in a state of statistical control or, conversely, will fail to detect a true process change. The general topics of power (sensitivity) and confidence (specificity) will be taken up further in part II. Of course, all of the above discussion and analogies concerning *np*, *p*, and $\bar{X}$ charts apply to all other types of statistical control charts as well.

Handling Unequal Subgroup Sizes

Note that, in some cases, particularly when all subgroups are of equal size, the choice between whether to use an *np* or a *p* control chart (and likewise whether to use a *c* or *u* control chart) can be largely preferential (total vs fraction or rate), be based on established reporting conventions, and so on. Equal subgroup sizes occur when a specified constant number of cases are sampled from all cases in each time period (even if more data exist), such as due to the economics or work load of data collection and analysis. In many practical cases, however, the total number of cases per time period may vary from period to period, with unequal subgroup sizes being especially common when all historical data are readily available for analysis.

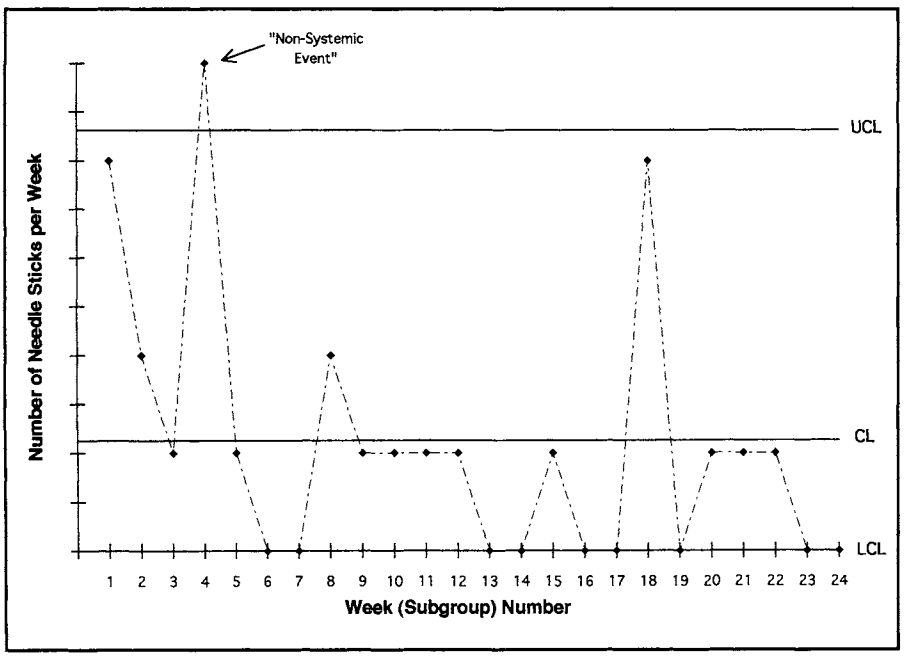

FIGURE 4. Trial c control chart of number of needlesticks per week.

Examples might include differing total numbers of patients receiving catheters or differing numbers of surgeries being performed each month. Contrary to some statements in the healthcare literature, unequal subgroups also are very common in industrial uses of SPC, such as when differing numbers of items are manufactured or differing volumes of paperwork are processed each month.

To illustrate, the second example in Table 2 contains a data set for all patients who received catheters in each month and the number of these catheterizations that resulted in infections. (If easily accessible, it generally is better to use all available data rather than to sample partially from these data to obtain a constant subgroup size.) In such situations, *p* (and *u*) control charts have the advantage over *np* (and *c*) charts of being adapted more easily to unequal samples, still directly based on exact probability theory (adapting standard $\bar{X}$ and *S* charts is a bit trickier, but possible nonetheless[110]). In the case of *p* charts, for example, the CL and *k*-sigma control limits now are calculated (for equal or unequal subgroups) as follows:

$$\text{Center Line (CL)} = \bar{p}$$
$$\text{Upper Control Limit (UCL)} = \bar{p} + k\sqrt{\bar{p}(1-\bar{p})/n_i}$$
$$\text{Lower Control Limit (LCL)} = \bar{p} - k\sqrt{\bar{p}(1-\bar{p})/n_i}$$

where the parameter $\bar{p}$ is estimated much as before as

$$\hat{\bar{p}} = \frac{\text{Total number of cases that yield the outcome}}{\text{Total number of cases examined in all subgroups}}$$

and n_i denotes the size of each subgroup *i*, where *i*=1, 2, ..., 25, ... (eg, month 1, month 2, etc). Using these formulas, the trial *p* control chart corresponding to the data in example 2 (with *k*=3) is shown in Figure 3.

Note that this *p* chart plots the *fraction* of patients with an infection, whereas the earlier *np* chart in Figure 2 plotted the *total* number of infected patients. The control limits vary because each subgroup now represents a different binomial distribution, each with the same parameter *p* (eg, the same per-catheterization probability of an infection) but a different parameter n_i (eg, a different denominator number of catheterizations per month). The sampling distributions corresponding to each subgroup *i* therefore have the same mean or expected value ($\bar{p}$) but different variances ($\bar{p}(1-\bar{p})/n_i$), and thus each subgroup is interpreted with respect to a constant CL but varying control limits. In Figure 3, note that the catheter-associated infection rate is out of control, with the fraction of infections in month 24 being above the upper control limit and that in month 29 being beneath the lower control limit.

This chart also illustrates the importance of adjusting control limits for materially different subgroup sizes. For example, if "average" straight control limits were used, then the subgroup values corresponding to months 9, 21, 24, and 29 might fall on the other side of the limits as they do here and thus lead one to an incorrect conclusion. (To help see this, visualize straight lines drawn horizontally through the middle of each control limit.) Finally, although any control chart with varying control limits can be made visually more appealing by using various transforms and other statistical methods[83,84,110] to produce straight limits, these tend to make the plotted value lose physical meaning. (Technically, none of these methods are necessary or add statistical value. Moreover, simply averaging the subgroup sizes introduces unknown approximations and, unless they vary only slightly, is not recommended in order to maintain statistical integrity—that is, roughly the desired sensitivity and specificity).

Poisson Distributions: c *and* u *Control Charts*

While much of the above discussion was motivated from the perspective of binomial distributions and *np* and *p*

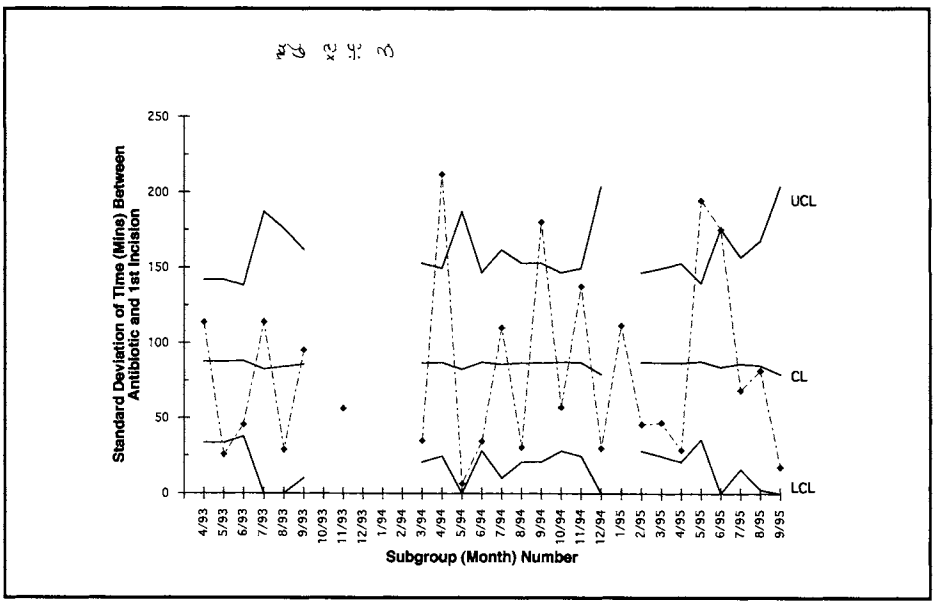

FIGURE 5a. Trial S control chart. Abbreviations: CL, center line; LCL, lower control limit; UCL, upper control limit.

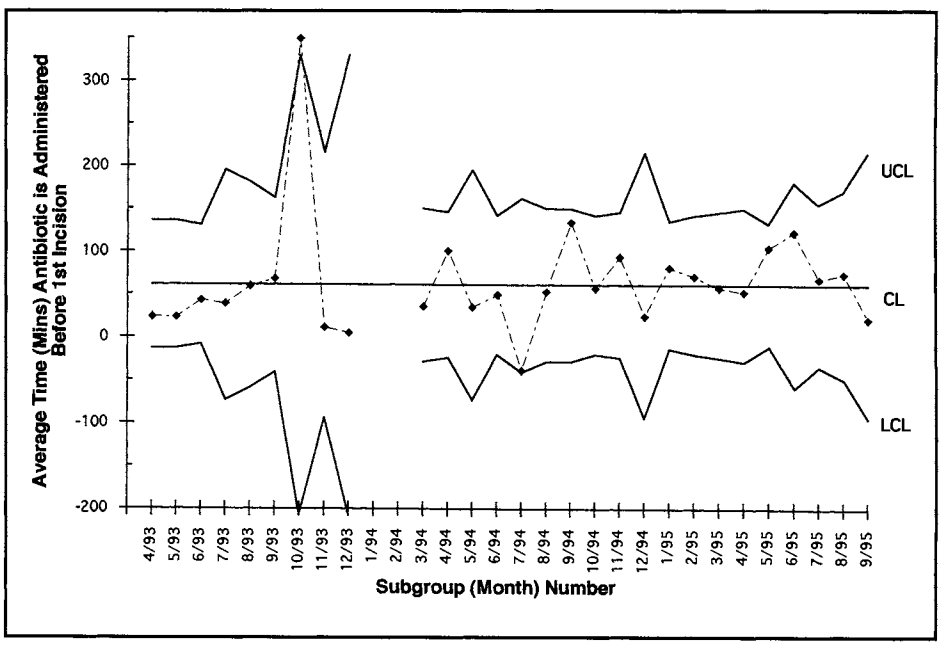

FIGURE 5b. Trial $\bar{X}$ control chart of the time (number of minutes) prophylactic antibiotic is administered before first surgical incision. Abbreviations: CL, center line; LCL, lower control limit; UCL, upper control limit.

control charts, the same basic concepts regarding chart selection, interpretation, and relation to other statistical methods apply to all other charts as well. For example, as one common alternative to the binomial, Poisson distributions generally (but not always) apply to the number of events that occur where an event is equally likely at any time or location, no clear Bernoulli trials exist, and no clear maximum exists. Poisson distributions also often provide good models for the number of events that occur—and especially the number of rare events that occur infrequently—in any given unit of time, space, volume, or other dimension. For example, in an earlier column on disease clustering methods, Jacquez et al[24] discussed infectious diseases in a given population as occurring according to a Poisson process.

In such cases, either a *c* or *u* control chart should be used to monitor the total number or the average number, respectively, of occurrences per subgroup or time period. Note that these two types of control charts are directly analogous to the *np* and *p* charts illustrated previously for the total number and fraction per subgroup, but now mathematically based on a Poisson distribution rather than a binomial distribution and thus calculated slightly differently.[83,84,91,107] Figure 4 illustrates a recent *c* control chart of the total number of needlesticks reported per week in a small 75-bed rural hospital, here assuming relatively constant opportunities for exposures week-to-week (eg, relatively constant census and amount of needle handlings). As can be seen, this chart suggests that something atypical occurred in week 4.

Contrary to some statements, it should be emphasized that *c* charts, like *np* charts, assume that the denominator population, even if unknown, must be of *identical* size for each subgroup (what statisticians often refer to as the equal "area of opportunity"). If the opportunity for sticks were thought to differ considerably each month, then, analogous to the previous use of *p* charts, a *u* chart should be used with the control limits properly adjusted (to reflect differing amounts of relative risk) by plotting the average number of sticks per some specified base amount of potential exposures, such as average sticks per 1,000 "units" of some type. (As the data and effort to adjust each month's figures exactly might be impractical, such as per every 1,000 handlings of needles or per 1,000 opportunities to transmit an infection, some more convenient representation of approximate relative risk typically might be used, such as the number of needles used or, more practically, patient days.) Another common application of a *u* chart might be for the monthly number of bloodstream infections per 1,000 patient days, where the total number of patient days (ie, the "area of opportunity") per month varies. Also see Sellick[2] for an example of a *u* control chart with varying control limits for the average number of medical ICU nosocomial infections per 1,000 ICU patient days each month.

Note that, while the Poisson and binomial are distinct distributions applicable in distinct situations, in some cases they can appear only subtly different. Determining which chart is appropriate can be dependent on specifically how data were collected, on what collection method is most feasible, or on what reporting method is preferable. In the earlier catheter scenario, for example, any given patient theoretically might develop more than one catheter-associated infection during the course of hospitalization. Although a binomial distribution would be appropriate for the number of like patients who develop one or more infections, a Poisson distribution would be more appropriate for the *total* number of such infections (including any multiple cases per same patients, assuming these occur at the same rate; see later section on "Other Probability Distributions and Control Charts").

Similarly, the number of like patients who fall (one or more times) is a binomial random variable, although these data are likely to be less accessible than simply the total number of falls (not tracked at the patient-specific level of detail and including any multiple falls per patient), which is a Poisson random variable (again assuming that subsequent falls occur at the same rate). In such cases, defining subgroups slightly differently as above and using a *c* or *u* chart can be more convenient and in some cases even preferred statistically. That is, "reducing" Poisson counts into binomial random variables of the "one-or-more" type indirectly ignores some of the process data, thereby sacrificing statistical power, although insignificantly so for low rates. (This reduction in power tends to be much larger when transforming continuous data into dichotomous events and then using *np* or *p* charts instead of $\bar{X}$ and *S* charts.) Additionally, patients with significantly different lengths of stay might be accommodated by tracking the number of falls per patient day, where a patient day here represents the equal "area of opportunity."

In other cases for which it is difficult to obtain the data detail necessary for *np* and *p* charts, a Poisson distribution sometimes can be used to approximate the underlying binomial very accurately. For example, in Figure 4, it would be infeasible to record every time a needle was handled by any personnel (which would more closely fit the binomial description), whereas one of the above surrogates for relative risk (eg, patient days, needles used) is collected more easily. In such situations, the Poisson-based *c* and *u* charts often can be used as good approximations to the binomial-based *np* and *p* charts, respectively. Mathematically, as the binomial subgroup size *n* converges to infinity, any binomial distribution converges to a Poisson distribution with rate parameter $\lambda \equiv np$. For practical purposes, this means that, for sufficiently small *p* and large *n*, such as often might be encountered with low infection rates, the difference will be negligible. (Although a few ballpark rules-of-thumb exist for when a binomial distribution might be reasonably approximated by a Poisson distribution, it always is better to use the correct chart if the necessary data are available rather than introduce possible error.)

As another example, Burnett and Chesher[4] recently described their application of CQI tools to laboratory needlesticks caused by arterial blood-gas syringes arriving with needles still attached, which is a binomial (and not Poisson) random variable. If the number of syringes sent to the laboratory is not reasonably constant each month, then a *p* chart with varying control limits would be most appropriate and exact. Alternatively, if the number of syringes per month is assumed to be fairly constant, then an *np* chart also could be used, which, given the above conditions, could be further approximated, as in the authors' example, with a *c* chart. (Again, if the denominator is likely to vary, a *u* chart could be used to approximate the *p* chart, adjusted as in Figure 3, in order to account for differing sampling variances, such as per 1,000 patient days.) As any approximation introduces error[69,85] and as the calculations are not much simpler, these approximations are recommended only in cases for which the subgroup denominators are not known precisely but either can be related closely to some other measure (such as patient days) or can be assumed to be relatively constant. When dealing with small subgroups and in other situations when these approximations are not appropriate, however, clearly distinguishing which distribution and chart is most appropriate remains an important endeavor.

Normal Distributions: $\bar{X}$ *and S Control Charts*

While the above discrete control charts are appropriate for many situations involving counted data, $\bar{X}$ and *S* charts[83,84,91,107] now should be used when dealing with continuous normally distributed data. However, unlike the cases for binomial and Poisson data, in which only one control chart is used, these charts now are used simultaneously as a pair. Somewhat analogous to hypothesis tests

for equal means and equal variances, an $\bar{X}$ chart monitors the process mean, and an S chart monitors the process standard deviation. These two charts are used together because either the process mean or standard deviation of a normal distribution can change while the other remains in control; thus, both charts must be in control for the overall process to be in a state of statistical control. (Technically, this is because the normal probability density function is completely specified by two parameters, μ and σ, and the arithmetic mean and the empirical standard deviation of data generated from a normal universe are independent random variables. As a statistical aside, and to address a point of confusion, it is important to comment that control charts do more than control *only* a process mean, variance, or rate, in fact controlling estimates of all parameters that define the entire shape of any given probability function and thus controlling all percentile points and all properties of that distribution completely. This reasoning also helps to explain why only one chart—and not one for the mean and one for the variance, for example—is used to control data generated by binomial or Poisson distributions, whose mathematical functions each contain only one parameter.)

A few healthcare examples of $\bar{X}$ and S charts described in other papers[6,11,12,111] include laboratory turnaround times, blood-sugar levels, laboratory supply costs, peak expiratory flow rates, blood pressures, heart rates, blood clotting times, and others. As a more recent example, the $\bar{X}$ and S control charts in Figure 5 examine the monthly average and standard deviation, respectively, of the elapsed times before incision of perioperative antibiotic administration in a midsize, public, urban hospital. Because it has been linked to postsurgical infections,[112-114] the timing of presurgery prophylactic antibiotics has been identified as an important key "upstream" surgical process measure to control.[7] As Figure 5 illustrates, however, this process is not in a state of statistical control (in fact, both the S and $\bar{X}$ charts are out of control). A negative time indicates that the antibiotic was given either during or after the surgery. No subgroup values exist for the months of January and February 1994 due to missing data.

Note that, while several authors place the $\bar{X}$ chart on top, the S chart typically should be examined first (the reasoning is analogous to first testing for homoscedasticity prior to conducting an ANOVA or other hypothesis test for equal means). That is, the process mean can not be determined to be in control unless the process standard deviation also is in control (conversely, however, the S chart does not necessarily have to be in control in order sometimes to be able to determine that an $\bar{X}$ chart is out of control). In the present example, the S chart indicates that the process standard deviation is not in a state of statistical control (the subgroup standard deviations corresponding to April 1994, September 1994, May 1995, and June 1995 are above the UCL, and that in May 1993 is below the LCL of the S chart). The excess of values above the UCL of the S chart causes the overall process standard deviation, if it were in control, to be overestimated (resulting in all control limits on both charts being too wide); nonetheless, note that the $\bar{X}$ chart still indicates that the process mean is not in control (with the average times in October 1993 being above the UCL and in July 1994 being below the LCL of the $\bar{X}$ chart). This lack of statistical control potentially is of clinical concern, as by definition no consistent preventive process exists patient-to-patient.

Of further practical interest, note that, even if these out-of-control conditions did not exist, the antibiotic currently is administered an average of 61.15 minutes before the first incision, which may or may not be acceptable, but the amount of variability is very large and probably of greater concern, with a standard deviation of 89.61 minutes. For example, based on normal probability, 99.73% of cases from an in-control process will receive an antibiotic anywhere within approximately 1 hour $\pm$4.5 hours before the surgery (assuming the process was brought into control; more probably will be outside this interval, given the process is out of control). Additionally, again assuming an in-control process with this mean and variance and using standard normal probability, the portion of surgery patients who receive antibiotic prophylaxis within a recommended window of 0 to 2 hours before the first incision[7,113,114] is less than 49.7%.

Again, while varying subgroup sizes result in nonconstant control limits (in most $\bar{X}$ and S cases it is easier to sample a constant number of patient records), alternatively, if the average subgroup size was used in the limit calculations as an approximation, then several points (eg, March 1993, May 1994, and September 1995 on the S chart and July 1994 on the $\bar{X}$ chart) would be on the opposite (that is, incorrect) side of the control limits. Finally, note that a normal distribution sometimes is used to approximate binomial and Poisson distributions that have large averages; while this simplifies probability calculations that otherwise involve the difficulty of computing large factorials, it is much less useful in setting k-sigma control limits (which are fairly easy to calculate exactly), can introduce some statistical problems, and thus is not recommended in most control chart situations. (Also note that S charts for subgroup standard deviations always technically are preferred for several statistical reasons over the alternate R charts for subgroup ranges.)

Other Probability Distributions and Control Charts

Although not the primary focus here, it is important to comment that, while binomial, Poisson, and normal probability distributions are perhaps the most common (and their corresponding control charts therefore are the most commonly used), they are by no means the only possibilities.[115] Process data periodically can occur according to several other types of continuous and discrete distributions, and to minimize the risk of using incorrect control charts in any given situation, one should confirm whether the general assumptions of a chart's underlying distribution are reasonably satisfied. If not, different control charts based on a more appropriate underlying statistical model should be constructed. Contrary to some statements, failure to identify an appropriate distribution and then to select

or design control charts based on this distribution can result in erroneous conclusions about the statistical control of a process, a situation that will be illustrated in part II and that has been illustrated elsewhere.[69,85,92]

While a complete review is beyond the present scope, further discussion and examples of several alternate possible distributions can be found in many good statistics publications.[115-119] As quick examples of alternate continuous distributions, waiting times and lengths of stay, when considered as continuous random variables, are unlikely to have normal distributions,[110] but rather are likely to be skewed positively (with a longer tail stretching to the right). In such cases, lognormal, gamma, exponential, Rayleigh, Weibull, or Gumbel distributions—to name a few—may be more appropriate, as they are commonly used to describe event durations and in other life analysis. Fortunately, from a practical standpoint, $\bar{X}$ and S charts can be moderately robust to slight departures from their underlying theoretical distributions, with only slight degradation in statistical power and confidence. If the departure is substantial (such as if very significant skewness is suggested by simple histograms or more advanced methods), however, their use can result in greater error. For example, surveillance of the time between disease detections has been discussed by Jacquez et al[24] as an exponential distribution (if no clustering occurs). Because exponential distributions are highly skewed, decaying left-to-right and not at all approximately normal, a special control chart based on this distribution should be used for examining this random variable, as will be illustrated in part II.

A discrete analog to this highly skewed and decaying shape is the geometric distribution, which can arise either as the number of discrete i.i.d. (ie, similar) Bernoulli trials between certain outcomes as described earlier (as opposed to the continuous exponential inter-occurrence length of time) or simply as a shape that occurs as a "state of nature." Because none of the standard control charts are even remotely appropriate for geometric data, different control charts, called g and h charts, have been developed for such situations.[120,121] Recent papers[69,85] illustrated several applications of g and h control charts to certain length-of-stay data and several other processes where geometric distributions were found to be appropriate. Infection control examples of geometric and exponential distributions, histograms of their "shapes," and uses of the corresponding alternate control charts will be illustrated in part II.

Among other discrete probability distributions that periodically arise[69,115] are negative binomial, Neyman, and various types of mixed, compound, and truncated distributions. As one example of truncated distributions, Newell[122] applied a certain type of right-truncated Poisson distribution to the number of occupied hospital beds, given that there is some maximum number available. Negative binomial distributions can arise either as the sum of independent and identically distributed geometric random variables, due to various types of mixtures of populations, or again simply as a state of nature. For example, when recorded as an integer number of days, length-of-stay data can be significantly non-Poisson and asymmetrical, often more closely following a negative binomial distribution.[110]

Negative binomial, Neyman, and related-count distributions also can be particularly appropriate in situations that exhibit a natural clustering or lack of independence between events, such as the geographic distribution of disease (for this reason these distributions tend to be used more in biological sciences than in manufacturing).[92,120] From a practical viewpoint, more importantly, because they are more flexible in shape than the Poisson (basically due to being 2-parameter rather than 1-parameter distributions), these can be useful alternate general-purpose count distributions in cases for which neither a Poisson nor a binomial distribution seems to fit reasonably (although their mathematics and parameter estimation are somewhat more involved). For example, negative binomial models can be fit to data with various amounts of positive skew (such as the discrete length-of-stay example), and Neyman and other compound distributions can be fit to naturally multimodal data.

As an example of these more complex distributions, the proportion of patient days spent in the ICU[2,12] typically is *not* a binomial random variable (even if stratified into homogeneous patient groups). The complexity of this random variable and the lack of a binomial, in particular, can be seen by recognizing that, whether any given patient day is spent in the ICU is dependent largely on where that patient spent the previous day (ie, in the ICU or not). The probability of an ICU day therefore is neither independent nor identically distributed for each patient day. (More precisely, this is a certain type of compound random variable[115,116,120] for which each patient first either does or does not end up in the ICU, with some probability, and then the number of days that each ICU patient spends in the unit is described by another distribution. As alternative motivations, a zero-inflated count distribution[69,115] also could be used to model the total number of days each patient spends in the ICU, and a Neyman, Thomas, Short, or some other compound or cluster distribution[92,115,116,120] could be used for the total number of ICU days summed across all patients.)

In either case and contrary to some advice, np and p control charts would be inappropriate for these random variables and could result in substantial error, and therefore a correct control chart or charts instead based on one of the above mentioned random variables should be used. Another common example of a similar type of compound random variable, where an occurrence of one event leads in some way to the possibility of one or more additional events, is the number of babies delivered per time period, where there are a random number of maternity cases in each period, each of which could result in one or more newborns. Similarly, if the risk of acquiring subsequent infections is significantly greater than that of acquiring one's first such infection,[123] then control charts based on alternate probability models for the number of infections per patient or the total number across all patients per time period should be developed. (In practice, however, using a Poisson distribution with the rate parameter estimated

from the empirical total number of infections or falls often still may be appropriate here for several statistical reasons.)

SUGGESTED REFERENCES

Good standard SPC texts used by quality engineers include those by Montgomery,[83] Duncan,[84] Banks,[107] and Grant and Leavenworth,[91] all of which are excellent technical sources for further details on statistical quality control methods, calculations, and underlying theory. While Duncan's book is somewhat of a comprehensive desk reference, readers might find the other three to be a bit more approachable but still to contain very thorough treatments of the fundamental and intermediate aspects of statistical quality control, well beyond those of several recent popular publications. (A slight drawback of the above books, from a practitioner's viewpoint, is that they tend to read like the textbooks they are. However, while a considerable number of more practitioner-focused books have appeared in the past several years, many of these tend to be less rigorous and exact, often losing important information in their efforts to oversimplify statistical methods.)

Within health care, Drs. Berwick[21] and Blumenthal[23] each followed up on their earlier papers[22,77] with general discussions of the utility of SPC to control healthcare process variation and to inform medical decision making. Both also suggested that statistical process control charts might be used to verify whether clinical interventions, in fact, resulted in an intended benefit or unintended consequence. Later papers by the present author and others provide more specific overviews and illustrate the use and interpretation of control charts in health care,[6,9,10,81,82,124,125] as well as some common pitfalls to avoid. Some empirical applications in these papers include patient falls, prescription errors, infection rates, needlesticks, cesarean-section births, clinical pathway variances, lengths of stay, admission rates, billing errors, HMO disenrollment, blood counts, emergency room arrivals, mortality, and others.

In more clinical applications, in 1990, Zimmerman et al[111] explored the utility of control charts to monitor the heart rate, systolic blood pressure, and diastolic blood pressure of surgery patients; Schnelle et al[14] illustrated the use of control charts for managing nursing home patients with urinary incontinence; and Liu et al[126] proposed a crude SPC type of graphical approach to evaluating carpal tunnel syndrome risk. Blumenthal, Laffel, and others[22,23,108,127] also suggested using control charts to examine mortality rates, and several other authors[11-16,128] have discussed healthcare applications of SPC, although some of these tend to range considerably in terms of technical accuracy and detail. The use of control charts in chemistry and clinical laboratories also was suggested at least as early as 1946 by Wernimont[129] and later by Levey and Jennings,[130] with some more recent applications[131-133] including radiology, mammography imaging, repeated chest radiographs, processing times for beta human-chorionic gonadotrophin laboratory tests, and the accuracy of Pap smear, human immunodeficiency virus assay, and hepatitis results.

The current trend in high-level aggregate metrics, "report cards," and "dashboard indicators" also has been discussed and criticized from a statistical quality-management perspective,[8,9,108,134] including the application of control charts to these process data. As part of an effort to manage costs, Ramsey and Cantrell[105] applied SPC to healthcare cost variances. Finally, as mentioned previously, several epidemiologists have discussed (and debated) the relation of control charts and other CQI and SPC tools to epidemiology[13,85,86] or illustrated specific uses.[2-5,7] For example, Intermountain Health Care reports using CQI techniques to reduce its postsurgical infection rate from 1.8% to 0.4%.[7] A recent slightly more technical paper[89] reviewed and examined alternative SPC approaches to low-frequency infection control and needlestick data (as discussed further in part II).

In terms of journals and organizations, the American Society for Quality (ASQ) is the primary interindustry US organization for quality practitioners, currently with approximately 140,000 members. While ASQ recently formed a healthcare division, it still is maturing. Several other more established healthcare-specific quality organizations exist, including the International Society for Quality in Health Care, the National Association for Healthcare Quality, the Institute for Healthcare Improvement, and others. The *Journal of Quality Technology* is one of the primary technical journals for statistical quality control and related research, with *Quality Engineering* being slightly more applications-oriented. *Technometrics* is published jointly by ASQ and the American Statistical Association and, along with the *Journal of the American Statistical Association,* tends to be the most mathematically advanced. *Quality Progress,* ASQ's monthly trade journal, has the highest circulation and tends to be the most readable by nontechnical practitioners, containing articles and case studies on a wide range of quality-management topics, often less quantitative than SPC (eg, quality planning, team building, benchmarking, customer satisfaction, cost of poor quality, basic data analysis, etc).

CONCLUSION OF PART I

Statistical process control and control charts provide another, and in many ways quite similar, effective statistical and graphical manner for viewing and analyzing processes and outcomes. The identification of what processes, variables, and outcomes (whether in-process or end-process) to study and monitor is another subject and one beyond the current intended scope. Once the appropriate process parameters or outcomes have been identified, through epidemiological or other methods, statistical control charts can be applied effectively to any of these. While the issue of process versus outcome measures has been discussed by others,[8,135] it should be emphasized that actual physical application of control charts is equally applicable to either manner of data.

In fact, some of the SPC emphasis on a "process orientation" as opposed to an "outcome orientation" is concerned with how any data, whether in-process or end-process, are considered—that is, frequently via control charts for the purpose of understanding, improving, and

controlling processes over time versus aggregated into large infrequent statistics for other purposes. (An example might be if total patient falls—regardless of whether this is considered an outcome or process measure—are reported on a semiannual basis in order to maintain accreditation or are monitored weekly in various departments via control charts for more real-time monitoring and improvement). Of course, as processes and causal factors become better understood, these also should be brought into statistical control and monitored, rather than only the end-process outcomes. The earlier application of $\bar{X}$ and S charts to prophylactic antibiotic timing is a good example of this type of "upstream" in-process quality control. If no factors are yet known to have a significant impact on a certain result, conversely, the utility of scrutiny of these outcomes for the purpose of passing performance judgment, rather than for process learning, is subject to considerable debate.

Part I has provided an overview of the theoretical foundation of control charts. Part II will expand on several related concepts, including the statistical properties of control charts (ie, sensitivity and specificity), some chart-design issues, and an alternate SPC approach to low-frequency data. The much-overlooked importance of bringing a process into a state of statistical control, the issue of using 3 or some other number of standard deviations in the control limits, and more advanced SPC concepts also will be discussed.

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Control of *Legionella pneumophila* in Hospital Hot-Water Supply

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Heat treatment and application of copper-silver ionization often are used for controlling *Legionella pneumophila* in high-volume hospital plumbing systems. However, the comparative efficacies of these measures in high-volume systems are unknown.

Investigators from Children's Hospital of Pittsburgh have reported on studies that show differences in efficacy. Thermal treatment of a hot-water circuit was accomplished by flushing hot water (>60°C) through distal fixtures for 10 minutes. Copper-silver ionization was conducted in three circuits by installing units into return lines immediately upstream from hot-water tanks. Recovery rates of *L pneumophila* were monitored by culturing swab samples from faucets. Concentrations of copper and silver in water samples were determined by atomic absorption spectrophotometry. Four heat-flush treatments failed to provide long-term control of *L pneumophila.* In contrast, ionization treatment reduced the rate of recovery of *L pneumophila* from 108 faucets from 72% to 2% within 1 month and maintained effective control for at least 22 months. Only three samples (1.9%) of hot water from faucets exceeded Environmental Protection Agency standards for silver, and none exceeded the standards for copper. Of 24 samples obtained from hot-water tanks, 42% and 50% exceeded the silver and copper standards, respectively.

The authors concluded that copper-silver ionization effectively controls *L pneumophila* in high-volume plumbing systems and is superior to thermal treatment. However, high concentrations of copper and silver can accumulate at the bottom of hot-water tanks.

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