DESIGN AND USE OF $g$-TYPE CONTROL CHARTS FOR INDUSTRY AND HEALTHCARE: SPC Charts for Hospital Infections and Adverse Events

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INTRODUCTION

This article examines approaches to the design and application of statistical control charts to low defect processes such as high yield manufacturing systems and various adverse healthcare events (hospital infections, contaminated needle sticks, heart surgery complications), with particular emphasis on the development of events-between $g$ and $h$ control charts, design issues, and their statistical operating characteristics. Due to ease of use, low infection or defect rates, and the immediate availability of each observation, a measure of particular interest is the number of events between occurrences, such as between infections, adverse events, or defects. Appropriate control charts for such scenarios, especially useful when the occurrence rate is low, were developed in 1989 by the author [6], investigated, and partially disseminated via several unpublished reports and conference papers [3-5] in circulation.

A primary purpose of this article is to summarize the use of this type of control chart and illustrate their application to healthcare and other concerns. These new charts, called $g$ and $h$ charts, are based on inverse sampling from underlying geometric and negative binomial distributions and are particularly useful in certain cases over conventional charts in terms of significantly improved detection performance. Several interesting properties and design issues of these new charts also are illustrated that can significantly improve the power to detect important process changes over conventional approaches, including use of supplementary rules, redefined Bernoulli trials, probability-based limits, and a new supplementary rule.

Hospital epidemiology is concerned with adverse events, surveillance, and the study of epidemic and endemic infections, which in SPC terminology equate to unnatural and natural variability, respectively. Nosocomial infections basically are any infections acquired or spread as a result of a patient being hospitalized, rather than being present at an admitting condition at the time of hospitalization. Some examples include surgical wound infections, pneumonia, bacteremia, urinary tract infections, cutaneous wound infections, bloodstream infections, catheter infections, and gastrointestinal infections. National costs of nosocomial infections have been estimated at approximately 8.7 million additional hospital days and 20 thousand deaths per year, and hospital accrediting bodies therefore are urging quality improvement methodology be applied to this process defect. For example, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), among others, requires hospitals be engaged in continuous quality improvement (CQI) activities, including the application of statistical methods such as statistical process control (SPC) to infection control.

STATISTICAL $g$ AND $h$ CONTROL CHARTS FOR THE NUMBER OF EVENTS, PROCEDURES, OR DAYS BETWEEN INFECTIONS

Several approaches to applying SPC to nosocomial infections are possible, dependent on the situation and ranging in complexity and data required. For example, two standard approaches are to use $u$ or $p$ Shewhart control charts, such as for the number of patient falls or the fraction of infected catheters per time period, respectively. As an alternate measure, the number of procedures, events, or days between infections has been proposed due to the low rate of infection, the near immediate availability of each individual observation, and the simplicity of use with which non-technical personnel can implement this measure. Being easy to calculate, a chart can be updated immediately, in real-time, on the hospital floor. In order to plot these type of data on control charts, however, note that none of the standard charts are appropriate. For example, standard $c$, $u$, $np$, and $p$ discrete control charts are based on Poisson and binomial distributions, whereas $\bar{X}$ and $S$ charts are based on continuous Gaussian distributions.
By description, conversely, the number of events between infections most closely fits the definition of a geometric random variable, as illustrated by the histogram in Figure 1. More appropriate control charts in such cases therefore are $g$ or $h$ charts, based on underlying geometric distributions, for the total and average number of days between infections, respectively. Use of inappropriate discrete distributions and control charts can lead to erroneous conclusions about the variability and state of statistical control of the infection rate, a situation which has been described by several authors [5,9,10]. The technical details of $g$ and $h$ charts were developed in a article in the *Journal of Quality Technology* [6,10], and later papers [4,5] illustrated several healthcare, manufacturing, distribution, administration, and finance examples of three general cases in which they may be applicable: (1) if dealing with scenarios described by the classic description of a geometric random variable; (2) if a geometrically decaying shape simply appears naturally; and (3) for more desirable or powerful control of low frequency data than by $p$ and $np$ charts.

![Comparison of Empirical Data with Geometric Distribution](image)

**Figure 1**

In cases with low defect or infection rates and with immediate availability of each observation, considering Bernoulli processes with respect to geometric rather than traditional binomial probability distributions can produce more plotted subgroup data and greater power to more quickly detect process changes. Given a subgroup size of the number-between $n = 1$ occurrences, the calculations for constructing nosocomial infection control $g$ charts conveniently simplify to those shown in Table 1, where:

- $\bar{x}$ = the average number of days between infections,
- $p$ = the rate of infection (if known), and
- $k$ = the number of standard deviations used in the control limits (with typically $k = 3$).

<table>
<thead>
<tr>
<th>Infection Rate Known</th>
<th>Infection Rate Estimated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Center Line (CL)</td>
<td>$\frac{1-p}{p}$</td>
</tr>
<tr>
<td>Upper &amp; Lower Control Limits</td>
<td>$\frac{1-p}{1} \pm k\sqrt{\frac{1-p}{p^2}}$</td>
</tr>
</tbody>
</table>

Table 1: Calculations for Infection Control $g$ Charts (with $n = 1$)
Note that a negative LCL customarily is rounded up to zero, as plotting points beneath this is not possible. Also note that several alternate approaches to constructing these charts exist, given the skewness of geometric data, including using probability-based limits and setting the center line to the median rather than the traditional arithmetic mean. Figure 2 illustrates an example of the corresponding g chart for the empirical data shown in Figure 1. Note that an increase in the number of days between infections corresponds to a reduction in the nosocomial rate. In this particular example, although all points are contained within the control limits, several within-limit signals of a rate increase exist between observations 34 to 55. Under the philosophy of statistical process control, a first step in reducing the nosocomial rate is to bring the process into a state of statistical control so that it is operating with only natural variability. See Duncan [8] and Benneyan [1,2] for additional information about statistical process control and its application to healthcare, respectively. Several other examples of the application of this type of control chart to industrial and healthcare concerns can be found in some of the cited references [4,5,10].

CHART PERFORMANCE AND SOME SIMPLE DESIGN OPTIONS

Two important properties of any control chart are the probabilities of detecting true changes in the nosocomial rate and of incorrectly indicating changes when, in fact, none have occurred. For example, Figure 3 illustrates these operating characteristics for the g chart shown in Figure 2, where the in-control daily probability of an infection is \( p' = 0.35 \). Note that an ideal curve would rise steeply to a probability of almost 1.0 and then descend steeply, corresponding to high power and a low false alarm rate. Of particular concern in Figure 3, conversely, is the lack of any power to detect increases in the infection rate, due to the lower control limit of zero. In such cases, two simple options are to use the standard rules mentioned above for detecting unnatural variability within the limits or to use the following new simple rule for detecting rate increases:

\[
\text{Number Consecutive Points on LCL} = \text{Number Infections on Same Day} \geq \frac{\ln(\alpha_{LCL})}{\ln p},
\]

where \( \alpha_{LCL} \) is the desired false alarm probability for erroneous signals of increases. A third simple option is to conceptually reverse the Bernoulli trials so as now instead to count the number of consecutive cases (or days) with infections between days without infections. As Figures 4 through 6 illustrate, all three approaches can increase a g chart's power to detect rate increases, although care should be taken not to also overly increase false alarms. Various combinations of these approaches also might be investigated to
achieve a chart with the most desirable properties. Also note while in general taking larger subgroups will result in higher power to detect smaller shifts, in the simplest case the number of days until the next infection constrains the subgroup size to \( n = 1 \).

![Graph](image)

**Power of \( g \) Chart Control Limits to Detect Changes in Infection Rates**

Figure 3

![Graph](image)

**Added Power of "Supplementary Rules" to Detect Changes in Infection Rates**

Figure 4

**DISCUSSION**

Statistical process control, applied correctly, is an effective technique that should be used to complement traditional hospital epidemiology methods. As the costs of nosocomial infection are high, rapid detection of an increase (i.e., unnatural variation) in a clinical unit is of obvious interest, as well as detection of (endemic) periods where the infection rate is statistically reduced, so that root causes of reductions can be investigated and standardized. A recent more extensive series of articles [2] also elaborates on and compares various alternate approaches in greater detail. Because significant differences can exist between service-specific infection rates, such as for adult and pediatric intensive care units, surgical patients, and high-risk nursery patients, separate control charts might be applied to each of these categories. Additionally, infection rates generally are more representative if based on the number and/or duration at-risk, such
as the number of patient days, surgeries, and devise-use/devise-days, rather than simply on number of admissions, discharges, etc. [13]. Of course, to study each category separately and adjusted in an appropriate manner requires more detailed data availability and additional calculations. For whatever denominator method, stratification, or at-risk adjustment used, some of the general approaches to SPC discussed in this article can be applicable.

![Graph of Probability of Point Not Indicating A Rate Change vs. Daily Probability of Infection (p'=35)](image1)

**Added Power of "Consecutive Points on Lower Control Limit" Rule**

**Figure 5**

![Graph of Probability of Point Not Indicating A Rate Change vs. Daily Probability of Infection (p'=35)](image2)

**Comparison of "Days Between Infections" versus "Days Between No Infections"**

**Figure 6**

More sophisticated charts also can be applied to the number of days between infections, such as geometrically weighted moving average (GWMA) and cumulative sum (Cusum) control charts [6,7], now based mathematically on geometric and negative binomial distributions. Although more complicated to construct and interpret, these charts tend to detect smaller process shifts more quickly, while still maintaining low false alarm rates. Additionally, like the g chart, these charts also can take immediate advantage of each observed infection, rather than waiting until the end of a specified time period. An alternate lay-approach suggested to applying SPC to the number of days between infections has been to search for a transformation that makes empirical data appear reasonably symmetric. Although situations exist where normalizing and other transformations can be advocated, in general blind transformation without statisti-
Statistical \( g \) Control Charts

cal basis and knowledge of underlying process stability can reduce the ability to identify existent unnatu-
ral variability (especially if the underlying distribution is known), a fundamental purpose of SPC. As an
example, an inappropriate transformation approach recently resulted in falsely reporting process stability
when the nosocomial infection rate had in fact significantly increased [5].

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