Number-Between $g$-Type Statistical Quality Control Charts for Monitoring Adverse Events

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Abstract. Alternate Shewhart-type statistical control charts, called "$g$" and "$h$" charts, are developed and evaluated for monitoring the number of cases between hospital-acquired infections and other adverse events, such as heart surgery complications, catheter-related infections, surgical site infections, contaminated needle sticks, and other iatrogenically induced outcomes. These new charts, based on inverse sampling from geometric and negative binomial distributions, are simple to use and can exhibit significantly greater detection power over conventional binomial-based approaches, particularly for infrequent events and low "defect" rates. A companion article illustrates several interesting properties of these charts and design modifications that significantly can improve their statistical properties, operating characteristics, and sensitivity.

Keywords: SPC, control charts, healthcare, adverse events, geometric distribution, $g$ charts

1. Introduction

1.1. Overview of article

This article illustrates a new type of statistical process control (SPC) chart for monitoring the number of cases between hospital-acquired infections or other healthcare adverse events, such as heart surgery complications, catheter-related infections, contaminated needle sticks, medication errors, and other iatrogenic events. These new charts, called "$g$" and "$h$" control charts, are based on inverse sampling from underlying geometric and negative binomial distributions and can exhibit improved shift-detection sensitivity over conventional approaches, particularly when dealing with infrequent events or low "defect" rates. The application and interpretation of these charts for detecting rate changes are illustrated by several examples involving cardiac bypass surgical-site infections, Clostridium difficile infections, needle stick exposures, and related concerns.

In a companion paper [5], the specificity and sensitivity of these new charts are investigated and contrasted with more conventional methods, with several simple design considerations – including standard within-limit rules, redefined Bernoulli trials, a new in-control rule, and probability-based control limits – shown to significantly improve the chart’s power to detect true process changes. These charts also are shown in some cases to exhibit better statistical operating characteristics over traditional binomial-based np and p control charts, especially when the rate of occurrence (i.e., the Bernoulli parameter $p$) is sufficiently low. In summary, these charts are found to be relatively simple to use and interpret, to exhibit comparable or superior performance to more traditional or more complicated methods, and to be a useful complement to conventional hospital epidemiology and infection control methods.

1.2. Hospital epidemiology and infection control

Epidemiology in the broadest context is concerned with the study, identification, and prevention of adverse healthcare events, disease transmission, and contagious outbreaks, with particular focus within hospitals on nosocomial infections and infection control. Nosocomial infections essentially are any infections that are acquired or spread as a direct result of a patient’s hospital stay (rather than being pre-existent as an admitting condition), with a few examples including surgical site infections, catheter infections, pneumonia, bacteremia, urinary tract infections, cutaneous wound infections, bloodstream infections, gastrointestinal infections, and others.

With estimates of the national costs of nosocomial infections ranging from approximately 8.7 million additional hospital days and 20,000 deaths per year [21] to 2 million infections and 80,000 deaths per year [30], it is clear that these problems represent quite considerable health and cost concerns. Additionally, the number of U.S. hospital patients injured due to medical errors and adverse events has been estimated between 770,000 and 2 million per year, with the national cost of adverse drug events estimated at $4.2 billion annually and an estimated 180,000 deaths caused partly by iatrogenic injury nationwide per year [2,4,13,15,18,31]. The costs of a single nosocomial infection or adverse event have been estimated both to average between $2,000 and $3,000 per episode. The National Academy of Sciences’ Institute of Medicine recently estimated that more Americans die each year from medical mistakes than from traffic
accidents, breast cancer, or AIDS, with $8.8 billion spent annually as a result of medical mistakes [24].

Given the above figures, it is not surprising that many federal, regulatory, and healthcare accrediting bodies — such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the National Committee for Quality Assurance (NCQA), the U.S. Center for Disease Control (CDC), the Health Care Financing Administration (HCFA), and others — either require or strongly encourage hospitals and HMO’s to apply both classical epidemiology and more modern continuous quality improvement (CQI) methodologies to these significant process concerns, including the use of statistical methods such as statistical process control (SPC). For example, the Joint Commission on Accreditation of Healthcare Organizations recently stated their position on the use of SPC as follows [27]:

"An understanding of statistical quality control, including SPC, and variation is essential for an effective assessment process... Statistical tools such as run charts, control charts, and histograms are especially helpful in comparing performance with historical patterns and assessing variation and stability."

Similarly, a recent position paper by several epidemiologists from the U.S. Center for Disease Control [33] 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 use of statistical measures designed to determine whether improvement in quality has been achieved. These measures should include nosocomial infection rates."

Conventional epidemiology methods, in fact, include both various statistical and graphical tools for retrospective analysis, such as described by Mausner and Kramer [34] and Gordis [22], and several more surveillance-oriented methods, such as reviewed by Larson [29] (also see Becker [3]). It is worth noting that collectively these methods tend to be concerned with both epidemic (i.e., outbreaks) and endemic (i.e., systemic) events, which in SPC terminology equate to unnatural and natural variability, respectively, and therefore are candidates for effective study via control charts. Several epidemiologists (for example, see Birnbaum [12], Mylotte [35], Burnett and Chesher [16], Childress and Childress [17], and Mylotte et al. [36]) have proposed monitoring certain infection and adverse event rates more dynamically over time, rather than "time-statically", in manners that are quite similar in nature and philosophy to SPC. It also is interesting that as early as 1942, Dr. Deming advocated the important potential of SPC in disease surveillance and to rare events [19].

1.3. Use of statistical process control (SPC)

The application of standard SPC methods to healthcare processes, infection control, and hospital epidemiology has been discussed by several authors, including a comprehensive review in a recent series in Infection Control and Hospital Epidemiology [6]. Example applications include medication errors, patient falls and slips, central line infections, surgical complications, and other adverse events. In some cases, however, none of the most common types of control charts will be appropriate, for example due to the manner in which data are collected, pre-established measuring and reporting metrics, or low occurrence rates and infrequent data. One example of particular note is the use of events between, number-between, days-between, or time-between type of data that occasionally are used by convention in some healthcare and other settings. Several important clinical applications of such measures are described below, and this article therefore derives and illustrates appropriate control charts for these cases, such as for the number of procedures, opportunities, or days between infrequent adverse events. (Note that these same methods, of course, are equally applicable for monitoring other types of low defect processes, such as in manufacturing and service settings.)

As a general background, statistical process control charts are chronological displays of process data used to help statistically understand, control, and improve a system, here an infection control or adverse event process. The general format of a Shewhart-type control chart is shown in figure 1. Observed process data, such as the monthly rate of infection or the number of procedures between infections, are plotted on the chart and interpreted, ideally, soon after they become available. Three horizontal lines also are plotted, called the center line (CL), the upper control limit (UCL), and the lower control limit (LCL), which are calculated statistically and help define the central tendency and the range of natural variation of the plotted values, assuming that the rate of occurrence does not change. By observing and interpreting the behavior of these process data, plotted over time on an appropriate control chart, a determination can be made about the stability (i.e., the "state of statistical control") of the process according to the following criteria.

Values that fall outside the control limits exceed their probabilistic range and therefore are strong indications that non-systemic causes almost certainly exist that should be identified and removed in order to achieve a single, stable, and predictable process. There also should be no evidence of non-random behavior between the limits, such as trends, cycles, and shifts above or beneath the center line. To aid in the objective interpretation of such data patterns, various "within-limit" rules have been defined, described in greater detail elsewhere. See Duncan [20] and Grant and Leavenworth [23] for further information about statistical process control in general and Benneyan [6-8] for discussion and application of SPC to healthcare processes.

1.4. Limitations of standard types of control charts

Several approaches to applying SPC to hospital infections or other adverse events 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 or the fraction of patients, respectively, per time period who acquire a particular type of infection. As an example, figure 2 illustrates a recent $u$ chart for the quarterly number of infections per 100 patient days, although it should be noted that this example ideally should contain many more subgroups (time periods) of data. In terms of proper control chart selection, note that each type of chart is based on a particular underlying probability model and is appropriate in different types of settings. In this particular example, a Poisson-based $u$ chart would be appropriate if each patient day is considered as an "area of opportunity" in which one or more infections theoretically could occur. Alternatively, a binomial-based $p$ chart would be more appropriate if the data were recorded as the number of patient days with one or more infections (i.e., Bernoulli trials). Further information on different types of control charts and scenarios in which each is appropriate can be found in the above references [6,20,23].

In either of the above cases, note that some knowledge of the denominator is required to construct the corresponding chart, such as the number of patient days, discharges,
or surgeries per time period. A more troubling problem is that use of these charts in some cases can result in an inadequate number of points to plot or in data becoming available too infrequently to be able to make rational decisions in a timely manner (especially, ironically, for better processes with lower infection rates). For example, recall that a minimum of at least 25–35 subgroups are recommended to confidently determine whether a process is in statistical control and that, in the case of $p$ and $np$ charts, a conventional rule-of-thumb for forming binomial subgroups is to pick a subgroup size, $n$, at least large enough so that $np \geq 5$.

For processes with low infection rates, say $p < 0.01$, the consequence of the above comments can be a significant increase in total sample size across all subgroups and in the average run length until a process change is detected. For example, even for $p = 0.01$, this translates to 500 data per subgroup $\times$ 25 subgroups $= 12,500$ total data. Additionally, this can necessitate waiting until the end of longer time periods (e.g., week, month, or perhaps quarter) to calculate, plot, and interpret each subgroup value, perhaps being too late to react to important changes in a critical process and no longer in best alignment with the philosophy of process monitoring in as real-time as possible. Note that similar subgroup size rules-of-thumb exist for $c$ and $u$ charts and lead to the same general dilemma as for $np$ and $p$ charts, in part because all conventional control charts consider the number of infections or adverse events either at the end of some time period or after some pre-determined number of cases.

### 1.5. The number of procedures, events, or days between infections

As an alternate measure, the number of procedures, events, or days between infections has been proposed due to ease of use, more timely feedback, near immediate availability of each individual observation, low infection rates, and the simplicity with which non-technical personnel can implement such measures. Being easy to calculate, a control chart can be updated immediately in real-time, on the hospital floor, without knowing the census or other base denominator (although assumed for now to be reasonably constant). In some settings, additionally, “number-between” or “time-between” types of process measures simply may be preferred as a standard or traditional manner in which to report outcomes.

As a few recent examples of the traditional use of such measures, Nelson et al. [37] examined the number of open heart surgeries between post-operative sternal wound infections, Plourde et al. [40] analyzed the number of infection-free coronary artery bypass graft (CABG) procedures between adverse events, Finison et al. [21] considered the number of days between *Clostridium difficile* colitis positive stool assays, Jacquez et al. [26] analyzed the number of time intervals between occurrences of infectious diseases, Nugent et al. [38] described the use of time between adverse events as a key hospital-wide metric, Fohlen [40] monitored the time between insulin reactions, and Benneyan [6] discussed the number of cases between needle sticks.

In order to plot any of these types of data on control charts, however, note that none of the standard charts are appropriate. For example, standard $c$ and $u$ control charts are based on discrete Poisson distributions, $np$ and $p$ charts are based on discrete binomial distributions, and $X$ and $S$ charts are based on continuous Gaussian distributions. By description, conversely, the number of cases between infections most closely fits the classic definition of a geometric random variable, as discussed below and illustrated by the histogram in figure 3 of surgeries-between-infections empirical data. Note that if the infection rate is unchanged (i.e., in statistical control), then the probability, $p$, of an infection occurring will be reasonably constant for each case (with patients stratified into reasonably homogenous groups if necessary), and this scenario therefore satisfies the definition of a geometric random variable.

As can be seen by comparison with the corresponding geometric distribution (with the infection probability $p$ estimated via the method of maximum likelihood), these data exhibit a geometrically decaying shape that is very close to the theoretic model. (More rigorously, a chi-square goodness-of-fit test indicates close statistical agreement, with an effective significance value of 0.693.) Appropriate control charts for these data therefore should be based on underlying geometric distributions, as developed and illustrated below, rather than using any of the above traditional charts. Use of inappropriate discrete distributions and control charts, in fact, can lead to erroneous conclusions about the variability and state of statistical control of the infection rate, a situation which has been described previously [9,25,28] and is shown in some of the examples below.

### 2. Events-between $g$ and $h$ control charts

#### 2.1. Three general application scenarios

Alternate control charts for such situations, called $g$ and $h$ charts, were developed and investigated by Benneyan [11] and Kaminsky et al. [28] based on underlying geometric and negative binomial distributions. With respect to the above motivation, these new charts were developed specifically to be appropriate for the following three general scenarios:

1. for situations dealing with classic geometric random variables, as discussed in greater detail below, such as for the various “number-between” types of applications described above;
2. for more powerful control (i.e., greater sensitivity) of low frequency process data than if using traditional $np$ and $p$ charts; and
3. for cases in which a geometrically decaying shape simply appears naturally, such as periodically observed in histograms of empirical data, even though the existence of a classic geometric scenario may not be apparent.
The first two scenarios are of particular interest in this article given the above discussion, with a few examples of the third type of application briefly also illustrated. As shown below, in cases with low 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 ability to more quickly detect process changes.

2.2. Theoretic motivation

To provide a context for comments to follow, and because some healthcare practitioners and other readers might not be familiar with the underlying mathematical development, a brief motivation of these charts is given here; further detail can be found in the cited references [10,11,28]. Recall that if each case (e.g., procedure, catheter, day, etc.) is considered as an independent Bernoulli trial with reasonably the same probability of resulting in a “failure” (e.g., an infection or other adverse event), then the number of Bernoulli trials until the first failure and the number of Bernoulli trials before the first failure are random variables with type I and type II geometric distributions, respectively. For example, the probabilities of the next infection occurring on the xth case or immediately after the xth case are well-known to be

\[ P(X = x) = p(1 - p)^{x-a} \quad \text{for } x = a, a+1, a+2, \]

where the minimum possible value \( a = 1 \) for type I (number-until) and \( a = 0 \) for type II (number-before) geometric data, with the sum of \( n \) independent geometric random variables,

\[ T = X_1 + X_2 + \ldots + X_n \]

being negative binomial with probability function

\[ P(T = t) = \binom{n(1-a) + t - 1}{n-1} p^n (1-p)^{t-na} \quad \text{for } t = na, na+1, na+2, \]

It follows that the expected values, variances, and standard deviations of the total number of cases, \( T \), and the average number of cases, \( \bar{X} \), before \( a = 0 \) or until \( a = 1 \) the next \( n \) infections or adverse events occur then are

\[ E(T) = n \left( \frac{1-p}{p} + a \right), \quad \text{Var}(T) = \frac{n(1-p)}{p^2} \]

\[ \sigma_T = \sqrt{\frac{n(1-p)}{p^2}} \]
Table 1
Parameters-known and parameters-estimated g and h control chart calculations.

<table>
<thead>
<tr>
<th>Rate known</th>
<th>Rate estimated</th>
<th>MVUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper control limit (UCL)</td>
<td>( n \left( \frac{1 - p}{p} + a \right) + k \sqrt{\frac{n(1 - p)}{p^2}} ) ( \bar{x} + k \sqrt{n(\bar{x} - a)(\bar{x} - a + 1)} )</td>
<td>( \frac{N}{N - 1} \left( \bar{x} - a + \frac{1}{N} \right) \left( \bar{x} - a + 1 \right) )</td>
</tr>
<tr>
<td>Center line (CL)</td>
<td>( n \left( \frac{1 - p}{p} + a \right) )</td>
<td>( \bar{x} )</td>
</tr>
<tr>
<td>Lower control limit (LCL)</td>
<td>( n \left( \frac{1 - p}{p} + a \right) - k \sqrt{\frac{n(1 - p)}{p^2}} ) ( \bar{x} - k \sqrt{n(\bar{x} - a)(\bar{x} - a + 1)} )</td>
<td>( \frac{N}{N - 1} \left( \bar{x} - a + \frac{1}{N} \right) \left( \bar{x} - a + 1 \right) )</td>
</tr>
</tbody>
</table>

chart: Average number events per subgroup

<table>
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</tr>
</thead>
<tbody>
<tr>
<td>Upper control limit (UCL)</td>
<td>( \left( \frac{1 - p}{p} + a \right) + k \sqrt{\frac{1 - p}{np^2}} ) ( \bar{x} + k \left( \bar{x} - a + 1 \right) n )</td>
<td>( \frac{N}{N - 1} \left( \bar{x} - a + \frac{1}{N} \right) \left( \bar{x} - a + 1 \right) )</td>
</tr>
<tr>
<td>Center line (CL)</td>
<td>( \left( \frac{1 - p}{p} + a \right) ) ( \bar{x} )</td>
<td>( \frac{N}{N - 1} \left( \bar{x} + \frac{1}{N} \right) )</td>
</tr>
<tr>
<td>Lower control limit (LCL)</td>
<td>( \left( \frac{1 - p}{p} + a \right) - k \sqrt{\frac{1 - p}{np^2}} ) ( \bar{x} - k \left( \bar{x} - a + 1 \right) n )</td>
<td>( \frac{N}{N - 1} \left( \bar{x} - a + \frac{1}{N} \right) \left( \bar{x} - a + 1 \right) )</td>
</tr>
</tbody>
</table>

and

\[
E(\bar{X}) = \frac{1 - p}{p} + a, \quad V(\bar{X}) = \frac{1 - p}{np^2},
\]

\[
\sigma_{\bar{X}} = \frac{1 - p}{np^2},
\]

where \( n = 1 \) and \( n \geq 1 \) for the geometric and negative binomial cases, respectively. In cases where the Bernoulli parameter \( p \) is not known, it can be estimated in several manners, with the conventional method of maximum likelihood and method of moment estimators both producing

\[
\hat{p} = \frac{1}{\bar{X} - a + 1}
\]

where \( \bar{X} \) is the average of all the individual data in all subgroups or samples. (Note that a few alternate approaches to the "parameters-unknown" or "parameters-estimated" case are possible, as mentioned briefly later in this paper.)

Also note that in the number-until and number-before Bernoulli cases, the uniform minimum variance unbiased estimator (MVUE) is recommended, especially when dealing with very few data, because the above tends to slightly overestimate \( p \). Although not the focus here and slightly more work for practitioners, using the above notation this can be shown to be

\[
\hat{p} = \frac{N - 1}{t - 1} = \frac{1}{\bar{X} - a + 1} \frac{N - 1}{N}
\]

where \( t \) is the sum of all the individual data adjusted for the shift parameter \( a \) to equate to the type I case,

\[
t = (x_{1,1} + \cdots + x_{1,n_1} - (a - 1)n_1) + (x_{2,1} + \cdots + x_{2,n_2} - (a - 1)n_2) + \cdots + (x_{m,1} + \cdots + x_{n,n_m} - (a - 1)n_m)
\]

\[
= \sum_{j=1}^{m} \sum_{i=1}^{n_j} x_{j,i} - (a - 1)N,
\]

and \( N \) is the total number of trials in all subgroups such that \( N = \sum_{j=1}^{m} n_j \) in general or \( N = nm \) if all subgroups are of the same size \( n \).

The above results can be used to develop appropriate k-sigma or probability-based control charts for the cases where the parameter \( p \) is known and the (more common) case where this probability must be estimated from historical data [11]. These calculations, for conventional k-sigma type \( g \) and \( h \) charts, are summarized in table 1. In the simplest and most likely case where the subgroup size \( n = 1 \), such as here for the number-between individual occurrences, note that these calculations conveniently simplify for the practitioner to those summarized in table 2, where:

- \( \bar{x} \) – the average number of procedures, events, or days between infections;
- \( n \) – the subgroup size (if other than 1);
- \( m \) – the number of subgroups used to calculate the center line and control limits;
- \( N \) – the total number of data used to calculate the center line and control limits;
- \( p \) – the infection or adverse event rate (if known); and

and
Table 2

<table>
<thead>
<tr>
<th>Rate known</th>
<th>Rate estimated</th>
<th>MVUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper control limit (UCL) ( \frac{1 - p}{p} + k \sqrt{\frac{1 - p}{p^2}} \left( \bar{x} + k \sqrt{\bar{x}(\bar{x} + 1)} \right) )</td>
<td>( \frac{m - 1}{m} \left( \frac{\bar{x} + 1}{m} \right) + k \left( \frac{\bar{x} + 1}{m} \right) (\bar{x} + 1) )</td>
<td>( \frac{m - 1}{m} \left( \frac{\bar{x} + 1}{m} \right) \left( \bar{x} + 1 \right) )</td>
</tr>
<tr>
<td>Center line (CL) ( \frac{1 - p}{p} )</td>
<td>( \frac{m - 1}{m} \left( \frac{\bar{x} + 1}{m} \right) )</td>
<td></td>
</tr>
<tr>
<td>Lower control limit (LCL) ( \frac{1 - p}{p} - k \sqrt{\frac{1 - p}{p^2}} \left( \bar{x} - k \sqrt{\bar{x}(\bar{x} + 1)} \right) )</td>
<td>( \frac{m - 1}{m} \left( \frac{\bar{x} + 1}{m} \right) - k \left( \frac{\bar{x} + 1}{m} \right) (\bar{x} + 1) )</td>
<td></td>
</tr>
</tbody>
</table>

Table 3

<table>
<thead>
<tr>
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</tr>
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<tbody>
<tr>
<td>Upper control limit (UCL) ( \frac{1}{p} + k \sqrt{\frac{1 - p}{p^2}} \left( \bar{x} + k \sqrt{\bar{x}(\bar{x} + 1)} \right) )</td>
<td>( \frac{m - 1}{m} \left( \frac{\bar{x} + 1}{m} \right) + k \left( \frac{\bar{x} + 1}{m} \right) (\bar{x} + 1) )</td>
<td>( \frac{m - 1}{m} \left( \frac{\bar{x} + 1}{m} \right) \left( \bar{x} + 1 \right) )</td>
</tr>
<tr>
<td>Center line (CL) ( \frac{1}{p} )</td>
<td>( \frac{m - 1}{m} \left( \frac{\bar{x} + 1}{m} \right) )</td>
<td></td>
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<td>Lower control limit (LCL) ( \frac{1}{p} - k \sqrt{\frac{1 - p}{p^2}} \left( \bar{x} - k \sqrt{\bar{x}(\bar{x} + 1)} \right) )</td>
<td>( \frac{m - 1}{m} \left( \frac{\bar{x} + 1}{m} \right) - k \left( \frac{\bar{x} + 1}{m} \right) (\bar{x} + 1) )</td>
<td></td>
</tr>
</tbody>
</table>

\( k = \) the number of standard deviations in control limits

(usually typically \( k = 3 \)).

Note that a negative lower control limit by convention usually is rounded up to \( a = 0 \), as plotting observed values beneath this is not possible given the non-negative nature of “number-between” data. As a slight variation, if the number-until the next occurrence are plotted, such as for the number of catheters until the next infection (i.e., up to and including the first infected catheter), then the alternate calculations shown in table 3 should be used, with the minimum possible value for the LCL now being \( a = 1 \) (i.e., on the first Bernoulli trial). Note that both approaches always will yield precisely identical results and statistical properties (e.g., the geometric type I event of exactly \( X \) cases until the next infection is identical to the geometric type II event of exactly \( X - 1 \) cases before the next infection), and thus the choice is strictly a matter of user preference or reporting conventions.

Also note that an alternate approach to constructing these charts, especially given the skewness of geometric data, could be to use probability-based limits and a center line equal to the median rather than the traditional arithmetic mean. Additionally, although traditional 3-sigma control limits almost always should be used, the \( k \)-sigma notation is meant to recognize that in some special cases \( k \) can be set to different values (hopefully only when based on sound analysis) in order to achieve the most preferable tradeoff between the false alarm rate, power to detect an infection rate change, and all associated costs and consequences. These concepts and probability-based control limits are explored in greater detail in a companion article [5].

3. Some examples

3.1. Example 1

To illustrate the construction and interpretation of \( g \)-type control charts, note that the average of the 75 number-between-infections heart surgery data shown previously in figure 3 (out of a total of 3,090 cases) is

\[
\bar{x} = \frac{3090}{75} = 41.2,
\]

resulting in an infection rate estimate of

\[
\hat{p} = \frac{1}{41.2 - 0 + 1} \approx 0.0237
\]

and a center line, upper control limit, and lower control limit of

\[
\text{CL} = 41.2, \\
\text{UCL} = 41.2 + 3\sqrt{41.2(41.2 + 1)} \approx 41.2 + 125.09 \approx 166.29,
\]

and

\[
\text{LCL} = \max\{a, 41.2 - 125.09\} = \max\{0, -83.89\} = 0.
\]

The MVUE results in this case are very similar, with

\[
\hat{p} = \frac{1}{41.2 - 0 + 1} \cdot \frac{75 - 1}{75} \approx 0.0234,
\]

\[
\text{CL} = \frac{75}{75 - 1} \left( 41.2 + \frac{1}{75} \right) \approx 41.7703.
\]
The corresponding infection control $g$ chart for these data is shown in figure 4, with the control limits for a conventional $c$ chart also added for comparison. In terms of visual interpretation of this type of chart, note that a decrease in the number of cases between infections corresponds to an increase in the infection rate and, unlike the case for more familiar types of charts, to values closer to, rather than further from, the horizontal $x$-axis. In this particular example, the process appears to exhibit a state of statistical control throughout the entire time period examined (in contrast with previous suggestions that an infection rate increase was followed by a subsequent reduction due to procedural interventions [37]). As an aside, note that if a traditional $c$ chart had been incorrectly used for these “count” data, an entirely different and erroneous conclusion would have been drawn about the consistency of this process, due to a grossly inflated false alarm $\alpha$ probability, with approximately 72% of the in-control values incorrectly being interpreted as out-of-control.

3.2. Example 2

As a second example for which $g$ charts are applicable, figure 5 compares a histogram of the number of days between positive Clostridium difficile infections with assays with the appropriate theoretic geometric probability distribution. Treating the number of days as discrete data, by definition a geometric distribution and $g$ control chart are appropriate for these data, as this histogram illustrates visually (assuming for now a reasonably constant infection probability from day-to-day; see section 4). Note that while ideally in such situations it would be preferable to know the exact number of cases, rather than the number of days, between positive specimens in order to have a more precise infection rate measure, in many cases such detailed data may not be available easily. Related examples for which the true underlying sample size typically may not be easy to obtain include the number of catheters used between catheter-associated infections, the number of needle handleouts between accidental sticks, the number of medications administered between adverse drug events (ADE’s), and so on.

In such cases, the number of days or other time periods often can serve as a reasonable surrogate, especially given the important considerations of feasibility of use and implementation by practitioners. For example, the corresponding $g$ control chart of days-between-infections for the above Clostridium difficile data is shown in figure 6. Note that although all points are contained within the control limits and
the rate of infection by this criterion thus appears to be in a state of statistical control (i.e., unchanged), several within-limit signals indicate a rate increase between observations 34 and 55. Under the philosophy of statistical process control, therefore, a first step in reducing the infection rate would be to bring this process into a state of statistical control so that it is operating with only natural variability. An epidemiologic investigation thus might be conducted in an attempt to determine and remove the cause(s) of this increase. (As previously, again note the significant error in the UCL if a c control chart incorrectly had been used based on the reasoning that these are integer count data, which is not appropriate as by definition this process is not Poisson also see figures 8 and 12.)

Note that if days-between and other time-between measures were recorded as continuous data then a slight variation of the g chart, now based on a negative exponential distribution, would be used. (The formulae for the "rate estimated" case will be almost identical, simply omitting the a, na, and ±1 terms under the square root in the control limits.) For practical purposes, however, this alternative would only be appropriate if the specific time of day were recorded, whereas otherwise a g chart should be used to produce a more accurate approximation. In many cases with reasonably low infection rates, moreover, the difference is negligible, as the geometric distribution can be shown to essentially become continuous as p approaches zero and to converge to its continuous exponential analogue.
3.3. Other healthcare applications

In addition to the above examples, similar g charts also may be applicable to other types of adverse healthcare events and medical concerns, especially in cases for which occurrence rates are low, data are scarce or infrequent, and immediate interpretation of each data value is of interest, such as for needle stick staff exposures, medication errors, and other types of patient complications. As three examples, figures 7–9 illustrate g charts for the number of procedures between surgical site infections, the number of time intervals between infectious diseases [26], and the number of days between needle sticks [6], respectively. Again, in the last two cases note that ideally a better basis for comparison might be the number of “potential sticks” (procedures, injections, et cetera) between actual sticks and the number of patients between diagnoses (especially if the assumptions of a relatively constant probability day-to-day or patient-to-patient are not reasonable), although these data are extremely un-

![Image](https://example.com/image1)

Figure 7. g control chart of number of procedures between surgical site infections.

![Image](https://example.com/image2)

Figure 8. Time between infections diseases g control chart.
likely to be available easily. Thus in such cases the number of days or time periods again may suffice as a very reasonable surrogate.

Note that while the needle stick rate shown in figure 9 exhibits a state of statistical control (with a slight improving trend), figures 7 and 8 conversely exhibit several signals that these processes are not stable over time. For example, figure 7 indicates that the surgical site infection rate has increased, with the 8th plotted point being above the upper control limit and an evident downward trend in the data thereafter. Figure 8, conversely, exhibits several instances of unnatural variability in the form of rate decreases that represent important opportunities for improvement. (Namely, statistically longer sojourns are evident between occurrences 5 and 6, between occurrences 15 and 16, and between occurrences 20 and 21 than the higher disease rate associated with the remainder of this period.)

Other recent “number-between” and “time-between” applications in which $g$ control charts have been useful include:

- the number of days between gram stain errors;
- the number of patients between catheter-associated infections;

Figure 9. $g$ control chart of number of days between needle sticks.

Figure 10. Histogram of seniorcare lengths-of-stay (LOS), in days.
the number of blood cultures taken from patients with pyrexia between blood stream infections (BSI);

- the number of days between preventable adverse drug events; and

- the number of medical intensive care unit patients colonized with *Staphylococcus aureus* between methicillin-resistant (MRSA) cases.

Additionally, health care and other situations for which geometric distributions and $g$ charts have been found to be appropriate simply as a "state of nature", although sometimes counter-intuitive, have included certain patient length of stay (LOS) data, recidivism (number of revisits per patient), the number of re-worked welds per manufactured item, the number of detected software bugs, the number of items on delivery trucks, and the number of invoices received per day [9,10]. It is important to note that these applications will not always be appropriate and, just as in the case for other control charts, $g$ charts should not be blindly applied without investigating and verifying the underlying statistical distribution.

As one example of such an arisal, the histogram shown in figure 10 of patient lengths-of-stay in a particular seniorcare facility exhibits a geometric shape, with the corresponding $g$ control chart of individual LOS's shown in figure 11. Alternatively, figure 12 illustrates the use of an $h$ control chart for the average lengths-of-stay per week, subgrouped by admit date, of all patients admitted in each week. As is evident in these two control charts, early efforts to standardize procedures and reduce LOS's have been effective. As previously,
figure 12 also illustrates the significant possible consequence of an incorrect \( u \) chart leading to erroneous and potentially costly conclusions. In the bloodstream infection application mentioned above, for example, reacting to perceived (but in fact non-existent) increases in hospital-wide BSI's (i.e., "false alarms") can be expensive and potentially dangerous to patients, frequently resulting in the medical staff changing all intravenous lines or in inappropriate blanket administration of prophylaxis antibiotics.

4. Discussion

This article developed and illustrated the use geometric-based Shewhart-type SPC charts to help study and control adverse events as processes over time. Several empirical examples demonstrated that statistical process control, applied correctly, is an effective technique that can complement traditional hospital epidemiology methods. Because the costs of nosocomial infection and other adverse events can be quite high, rapid detection of an increase in a clinical unit is of obvious interest (as well as detection of rate decreases so that root causes can be investigated and standardized).

An appealing surveillance feature of these new charts is that they can take immediate advantage of each observed adverse event, rather than waiting until the end of a pre-specified time period, increasing the likelihood of identifying root causes soon after detecting rate changes. The ability of these charts to detect rate changes of different magnitudes and several variations are explored extensively in a companion article [5], including comparison to conventional \( np \) charts and several simple ways to improve performance.

In addition to the Shewhart-type charts discussed in this article, more sophisticated types of \( g \) charts also can be applied to number-between type data, such as exponentially weighted moving average (EWMA) and cumulative sum (CUSUM) \( g \) control charts [10,14,32], here based on geometric and negative binomial distributions. Although slightly 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 Shewhart-type \( g \) chart, these charts also can take immediate advantage of each observed adverse event, rather than waiting until the end of a specified time period. CUSUM charts also tend to be particularly effective with samples of size \( n = 1 \), as often will be the case in these applications.

In terms of chart administration, note that because significant differences typically 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 or duration at-risk when these are known, such as the number of patient days, surgeries, and device-use/device-days, rather than simply on the number of admissions, discharges, etc. [33]. Of course, to study each category separately and adjusted in an appropriate manner requires more detailed data availability and additional calculations. Conversely, note that when combining process data with significantly unequal rates—such as various types of infections or adverse events for different departments or nonhomogeneous patients—for an overall rate, standard charts will be incorrect and an alternative should be used [9]. Also see Alemi et al. [1].

Another important assumption in many applications, of course, is that the probability of an infection or other adverse event remains fairly constant for each time period or device used, such as due to a fairly constant census or duration in use. (This assumption also is inherent in most transformation approaches, so the applicability and performance of \( g \) charts are no worse in this respect.) In the use of other types of charts (such as for \( p, u, \) and \( \bar{X} \) charts), however, the impact of a small amount of variation in the denominator usually is considered negligible and, therefore, frequent advice is that it is fairly safe to ignore if it does not vary from its average by more than around 10%.

In other cases, although beyond the present scope, number-between approaches also could be developed for situations in which the probability is not constant from case-to-case. Additionally, if the census varies quite considerably, approaches to the number of events between occurrences might be developed by adjusting on the area of opportunity in some manner analogous to \( u \) and \( p \) charts or by using a prior distribution on the infection rate, although these concepts are not yet well-developed. Although beyond the present scope here, bootstrap, non-parametric, or robust approaches also might be explored if exact results prove mathematically intractable or if distributional assumptions are not reasonably satisfied; see [6] for further discussion.

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References


