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## 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

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## Controversies and Contradictions in Statistical Process Control

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Statistical process control (SPC) methods are widely used to monitor and improve manufacturing processes and service operations. Disputes over the theory and application of these methods are frequent and often very intense. Some of the controversies and issues discussed are the relationship between hypothesis testing and control charting, the role of theory and the modeling of control chart performance, the relative merits of competing methods, the relevance of research on SPC and even the relevance of SPC itself. One purpose of the paper is to offer a resolution of some of these disagreements in order to improve the communication between practitioners and researchers.

### Introduction

STATISTICAL methods play a vital role in the quality improvement process in manufacturing and service industries. As evidence of the interest in statistics among quality professionals, the membership of the Statistics Division of the American Society for Quality (ASQ) (11,000) is roughly 60% of that of the entire American Statistical Association (18,000).

As pointed out by Woodall and Montgomery (1999), there are a number of disputes in the area of statistical quality control (SQC). There are differences of opinion in all areas of statistical science, but disagreements tend to be more common and more intense in the quality area. This could be due in part to the diversity of those working in the quality field, including quality gurus and their followers, consultants, quality engineers, industrial engineers, professional practitioners, statisticians, managers, and others. Another contributing factor to disagreements is competition for the large investments companies make in quality improvement and quality certification programs.

Statistical process control (SPC), a sub-area of SQC, consists of methods for understanding, monitoring, and improving process performance over time. The purposes of this paper are to give an overview of some of the controversial issues in SPC, to outline some of the contradictory positions held by past and present leaders in this area, and, in some cases, to offer a middle ground for the resolution of conflicts. It is hoped that practitioners will better understand how SPC research can improve the use of methods in practice. Also, it is hoped that SPC researchers will better understand how their models fit into the context of an overall SPC strategy.

Some basic concepts of SPC are discussed in the next section. The debate over the relationship between hypothesis testing and control charting is reviewed in the third section. In the fourth section, the role of theory is covered and the usefulness of determining the statistical performance of control charts is supported. Various alternatives to Shewhart control charts are then discussed. The sixth section contains conflicting views on the role of SPC and research in SPC. Conclusions are given in the final section.

### Some Concepts of SPC

Understanding of the variation in values of a quality characteristic is of primary importance in

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