Using Statistical Process Control to Drive Improvement in Neonatal Care

A Practical Introduction to Control Charts

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KEYWORDS

- Control chart • Statistical process control • Quality improvement
- Special cause variation • Common cause variation

KEY POINTS

- Quality improvement requires the analysis of data measured over time and the ability to understand variation in that data in order to evaluate processes and guide change.
- Common cause variation is natural variation inherent to any process; special cause variation is unnatural variation owing to external factors.
- Control charts are tools within statistical process control (SPC) that provide a robust method for understanding data over time and identifying common and special cause variation.
- Health care providers engaging in quality improvement should use SPC methods and control charts to help guide their efforts.

INTRODUCTION

Data measurement is critical for quality improvement (QI). Although health care practices are often designed or changed based on the knowledge and expertise of the clinical care team, only by measuring processes or outcomes can practices truly be assessed and evaluated.

Data for QI, however, differ fundamentally from data measured for other purposes in health care. Typically, health care outcomes are measured statically, meaning that any given outcome is measured for a specific population over a fixed period of time.

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Examples include population-level public health measures (ie, rates of preterm birth for a state for a particular period), metrics reported to regulatory agencies by hospitals (ie, central line infection rates for an intensive care unit for a particular year), and outcomes measured by research trials (ie, the rate of chronic lung disease in preterm infants who received a medication as compared with the rate in preterm infants who did not). These types of static measures can be analyzed using traditional statistics familiar to most in health care, including descriptive statistics such as mean values and standard deviations, and comparative statistics such as χ^2 tests, *t* tests, analyses of variance, and regression models.

Conversely, QI requires that data be measured dynamically over time, to allow for the ability to evaluate the reliability of current processes and to measure adequately the impact of changes in practice on desired outcomes. Over the past several decades, the quality and safety movement in health care has made clear the need to be able to understand dynamic rather than static data.[1,2] Analyzing data over time to understand and address the performance of the underlying system or process requires a different set of tools than traditional statistics, and statistical process control (SPC) methods are the most commonly used tools for this type of analysis.

In this review, we provide a practical overview of SPC and its most powerful tool, the Shewhart control chart, with an emphasis on the use of these methods in neonatology. Of note, the focus of this article is the analysis of data over time; we do not address other essential aspects of QI, including defining the improvement goal, setting specific aims, choosing and defining appropriate measures, understanding processes and current states, developing a theory of change, and using structured plan–do–study–act cycles to test and then implement changes. Also, this article is not meant to be a complete guide to the use of SPC. This review focuses on control charts, and does not address other important SPC tools such as run charts. In addition, although the intent of this review is to encourage clinicians to adopt control charts in their QI efforts, more comprehensive resources and textbooks should be consulted to understand important considerations of control chart use that are beyond the scope of this article.[3–6]

THE IMPORTANCE OF DATA OVER TIME

There is a natural tendency for those engaged in QI in health care to use more familiar traditional statistics. This practice often translates into the use of comparative tests to compare outcomes before and after an intervention, with the *P* value determining the impact of that intervention. Before–after comparisons do not adequately describe trends and patterns that may be essential to understanding the impact of changes in QI. A hypothetical example is provided in **Figs. 1** and **2**. In **Fig. 1**, a certain outcome is measured before and after an intervention, with the average score in each group shown. This before–after comparison suggests the intervention reduced the average score from 8 to 3, and if the improvement goal was to lower this measure, the obvious conclusion would be that the intervention was successful. **Fig. 2** shows 3 potential patterns of the same measure plotted over time. In each, the average score of the points before and after the intervention are 8 and 3, respectively, and would produce identical before–after bar graphs. However, the 3 patterns lead to very different conclusions regarding the impact of the intervention. In **Fig. 2**A, the pattern suggests the intervention did have a meaningful impact, with the score consistently higher before the intervention and then consistently lower after. In **Fig. 2**B, the pattern suggests the intervention had no impact at all, with the measure naturally declining over time. In **Fig. 2**C, the pattern suggests