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Statistical Process Control Charts

To the Editor:

Statistical process control (SPC) is possibly the most enticing gadget in the industrial quality control toolbox. It promises much. While reading John Sellick's article,' an old aphorism came to mind: "There is no such thing as a free lunch."

The potentials of SPC are dual: A) that control charting of clinical variables will reveal "opportunities for improvement" by directing scrutiny to events that involve special causes of variation; and B) that a clinical process, once tuned to eliminate special cause variation, is as well-suited as it can be for alterations aimed at reducing common cause variation or producing more desirable mean values of a process variable. The *A-B* sequence is crucial to quality improvement (CQI). *A* feeds to CQI signals sorted from noise. *B* seems a safe approach to the hornet's nest inherent in improving clinical care because it limits opportunities for drawing erroneous cause-effect inferences after details of care are altered to improve outcome.

Shewhart[2] derived SPC from theoretical considerations that involve normal (ie, Gaussian) distributions, but it is a common misconception that SPC is hampered for processes whose inherent variation is other than normal. "Being in control" is not tantamount to "being in a normal (or Poisson or binomial) distribution" and vice versa. Dr. Sellick's discourse on SPC's origin hints that he may think otherwise. Wheeler and Chambers" have compared charting of normally distributed data and data from a variety of non-normal distributions (Burr, chi-square with two degrees of freedom, right triangle, uniform, and exponential) for hypothetical in-control processes. Shewhart 3-sigma charts give false alarms for a meager 1% to 2% of process data in this test. In these instances, SPC would have correctly advised managers with 98% to 99% accuracy to leave in-control processes unchanged.

I am confused by the statement that "the number of sigma that defines the control limits will determine the number of times that an out-of-control signal will be erroneous." This is nonsensical and should have been nailed by reviewers. What is meant by the word *erroneous?* A few pages later, the statement is made that "these charts should not be used for very infrequent events or small denominator samples." Is Sellick arguing that more data be gathered if infrequent defects are pursued? In what sense is "events" used here? Are "events" the denominator or the phenomena counted in numerators? The penalty of using small data sets in SPC is that genuine special variation may "hide" within putative common variation. However, this flaw cannot trigger ill-crafted CQI sorties. It is confusing to suggest that small data set control charts are "less accurate." They are just less useful, a different criticism.

SPC may hide useful CQI information. A case in point has emerged from our wound infection surveillance program." Using 1992 wound infection data in SPC (p-chart, 3-sigma limits), 86% of the complications appear as outcomes within common cause variation limits. SPC would suggest that the other 14% of flawed cases be searched for special causes of variation. Total case review in our system consistently reveals that about half of wound infections are associated with an identifiable departure from excellent practice. SPC would have led us to overlook a huge majority of cases, half of which on average contain valuable grist for the mill in feedback to surgical teams. This anecdote shows the conflicted linkage between putative variation causes and statistically defined special variation on a control chart. I think the conflict will haunt SPC applications to other prob lems in clinical care monitoring.

Many surgical outcome flaws lie in or below the same frequency range as wound infection and share its features of multifactorial etiology and few fully determinant preventative maneuvers. These thiigs make me worry that uncritical SPC use will hinder process improvement in my specialty (using Donabedian's definitions of "process" to denote technical aspects of care). Healthcare quality managers may shoot themselves in the foot by relying on SPC as a source for CQI projects, unwittingly confirming another old aphorism, "Out of sight, out of mind."

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The author replies.

Dr. Lee has reaffirmed the utility and potential shortcomings of statistical process control (SPC) charts. The risk of overreliance and overinterpretation were discussed in the "Caveats" section of the paper. Specific points raised by Dr. Lee bear comment:

1) Clearly, my intent in discussing attributes of SPC charts was to show that SPC theory can be used in the evaluation of nonparametric variables. However, the mechanics of generating the charts is based on normal approximations. Being "in (statistical) control" is defined by the fall of points within the control limits, which are based on the statistical distribution of data.'