Discussion

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I WOULD LIKE to congratulate Prof. Woodall for another good overview paper on a large and important area. The use of control charts and other quality and productivity improvement methods developed in industrial contexts, such as six sigma, are finding increased application in medicine.

I have divided my comments into two general categories.

Control Charts for Process Improvement?

In an industrial context, a control chart usually has one of three goals:

1. Reduce variation, i.e., process improvement
2. Signal the need for a process adjustment
3. Demonstrate stability

In the current paper, Prof. Woodall states "control charts are often recommended for use in the monitoring and *improvement* of hospital performance" (italics added). I have argued in the past in a more general context (see discussion of Woodall (2000)) that control charts are reasonable tools for goals 2 and 3, but are not usually very effective for the first goal. At best, a control chart allows identification and elimination of special causes of variation. In many applications, however, I believe the goal is to reduce common-cause variation.

This issue is complicated by the fact that the definitions of common and special causes are tied to the process view, i.e., the sampling (subgrouping) scheme. For the purposes of this discussion, I assume the process view has been chosen in an appropriate manner.

There are some medical examples where the goal of a control chart is to detect and react to special causes of variation. Here, a control chart can be a reasonable tool. For instance, control charts have been proposed to monitor surgical performance. In this context, the goal of the chart is to signal the need for a review of surgical procedures if the chart suggests performance is substantially lower than expected. For example, a surgeon's skills may deteriorate with age. Control charts are also well suited for many applications in public-health monitoring. For example, we may monitor the sales of some specific over-the-counter medication. Spikes in sales may suggest localized disease outbreaks, such as *E. coli* contamination. Here, we do not attempt to change the process of people buying over-the-counter medication; instead, we hope to react quickly to the presence of a special cause.

In other proposed medical applications for control charts, such as, for example, monitoring hospital infection rates or patient falls, I do not believe a control chart would be an effective method. In this sort of application, the goal is to improve the process, i.e., reduce the infection rate or number of patient falls per week. In other words, the goal is to reduce the common-cause variation. For this goal, rather than use a control chart, a better approach would be to look for the large causes of variation in a more proactive manner. For example (as suggested by Shannon (2005)), to reduce peripherally inserted central catheter (PICC) line infections, we could examine each case of an infection in detail, looking for causes and commonalities.

In general, medical practitioners who are considering the use of a control chart should think carefully about the purpose of the chart and what they propose to do when the chart signals. They should think about this before implementing a control chart. With a goal of process improvement in mind, we are often more interested in addressing common causes of variation than special causes. A control chart is too passive a method for variation reduction. I believe it is important not to oversell the use of control charts, especially when other tools and methods are better suited.

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Implementation Challenges

Control charts are arguably not as easy to use effectively as it first appears. Producing the graphic with appropriate limits is not hard, but there are challenges in matching the chart to the goal (see previous section), choosing the sampling protocol, estimating the in-control process performance, and reacting to signals.

Choosing an appropriate sampling protocol (i.e., rational subgrouping), or what I like to call a process view, is difficult. This choice is critical, as it directly impacts which causes are classified as common and which are special. Causes that are common in one view can be special in another view. An appropriate choice depends on the nature of the process changes we want the chart to detect. However, as Professor Woodall points out, the problem of choosing rational subgroups is moot in some medical applications because 100% inspection is used either because the number of units processed each time period is small or because each process output is very important (e.g., surgical outcomes).

In my experience, there is usually a lack of appreciation in medicine for the distinction between Phase I and II in the application of control charts. In the literature, most applications present a retrospective use of the control chart, where the control limits are derived from the presented data. This corresponds to a Phase I application of a control chart. Usually it is mentioned that the main proposed application of the chart is to use it prospectively to quickly detect future performance problems (i.e., Phase II). In this light, there are a number of issues of concern. First, in Phase II, it is assumed the process performance in Phase I represents the process's in-control performance. The effect of estimation error in the use of control charts in Phase II can be substantial—see, for example, Jones et al. (2001). Second, in some applications in medicine, such as monitoring surgical performance, it is tempting to set the control limits based on established standards (from the literature) rather than from estimates of past in-control performance of the process. This makes the control chart setup easier because it eliminates the need for Phase I. However, using standards changes the purpose of the control chart. Now, rather than looking for changes in performance (special causes), we try to see if the process performance matches the standard. This difference has a big impact on interpretation of signals from the chart. With control limits estimated from past performance, a signal suggests a special cause has acted. With this time clue, we hope to be able to find the special cause and eliminate it. With signals from a chart based on standards, on the other hand, the process may be operating normally, but simply have a different failure rate than the standard. In this case, the chart tells us we have enough evidence to conclude the process performance does not match the standard, but gives us no information about how to improve the process.

To be effective at finding and eliminating special causes, signals from a control chart must be responded to in a timely manner. The signal suggests a special cause has acted, but the only clue provided regarding the identity of the cause is the time of the signal. This presents process owners with a logistics problem. They want someone to immediately follow up any signal, but they cannot schedule the work because they do not know when the chart will signal.

We also need to be careful about the proliferation of control charts. For instance, when monitoring surgical performance, it is tempting to stratify by surgeon, team, location, etc. With the simultaneous use of many control charts, multiple testing becomes an issue and the average run length to a false alarm (for the combined charts) can be quite small. Without additional external information, it is not possible to tell if a signal is a false alarm or not. The only logical conclusion is to respond to each signal in the same way. With many signals that don't lead to any special cause being identified, the charts will soon be ignored.

Additional References

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