BY FORREST W. BREYFOGLE III

Monitor and Manage

Diabetes measurement tracking at the 30,000 foot level

IN THE QP article, "It's a Process: DMAIC Helps Manage Diabetes," John Jennings defined diabetes and the detrimental impact that this disease has on our population.[1] Jennings also described an experiment he conducted to evaluate the effectiveness of whether a medication change would improve his blood sugar levels (BLS).

I asked Jennings if I could analyze his diabetes measurements from a 30,000-foot-level metric perspective.[2] He agreed to this integrated enterprise excellence (IEE) measurement assessment and publishing the results of my findings from this analysis.

My previous 30,000-foot-level articles described issues and resolutions to special-cause signals that may not be valid when using traditional control charts. Also, these past articles covered issues with traditional process-capability index statements. The control charts described in these articles, with their process capability and report-out enhancement opportunities are:

- X-bar and R charts.[3]
- P-chart.[4]
- C-chart.[5]
- Non-normal data with negative values.[6]
- Process stability and capability reporting when there are no specifications.[7]

The creation of an IEE 30,000-foot-level report has two steps:[8]

1. Assess whether the process is stable.
2. If the process is stable, data from a recent region of stability is used to estimate and provide a prediction statement—that is, what can be expected in the future if nothing were to change.

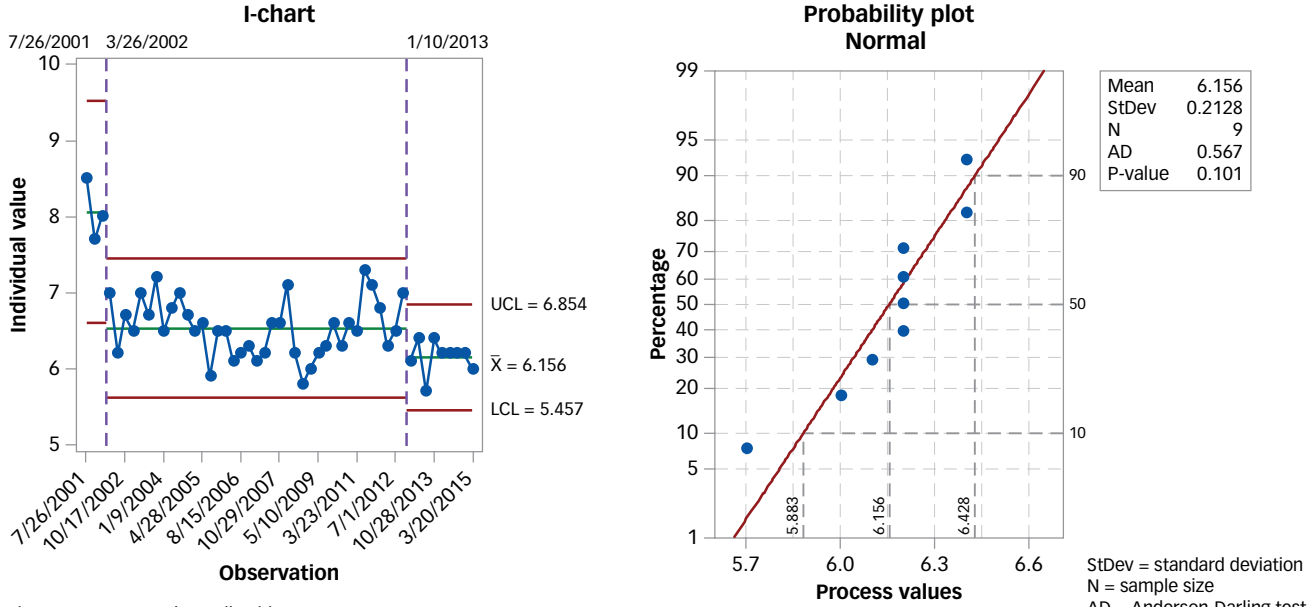
If a specification exists, report an estimated nonconformance rate. If not, report the estimated median and 80% frequency-of-occurrence range—that is, you expect about four out of five measurements to be within an 80% frequency-of-occurrence range.

An IEE 30,000-foot-level report-out provides an easy-to-understand prediction statement at the bottom of the charts.

Physician tests for diabetes

In addition to BLS tests that a diabetic can self-administer one or more times daily,

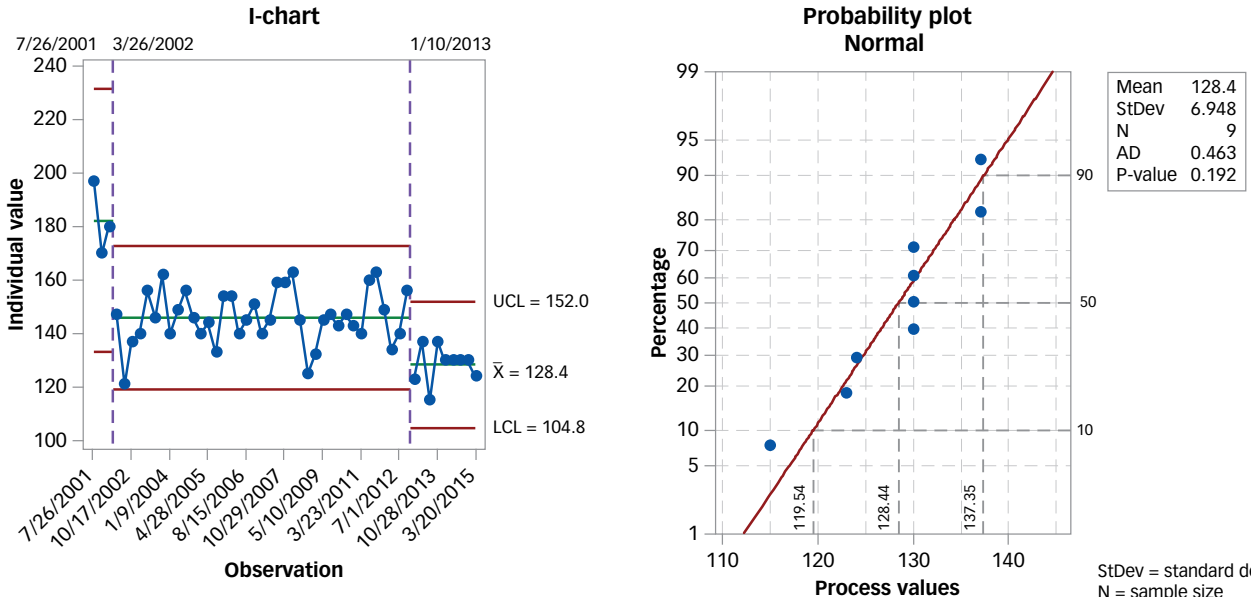
IEE scorecard for hemoglobin A1c / FIGURE 1



The current process is predictable.
The estimated median is 6.1555 with 80% of the events between 5.8828 and 6.4282.
IEE = integrated enterprise excellence

StDev = standard deviation
N = sample size
AD = Anderson-Darling test
LCL = lower control limit
UCL = upper control limit

IEE scorecard for blood sugar / FIGURE 2



The current process is predictable.
The estimated median is 128.44 with 80% of the events between 119.54 and 137.34.
IEE = integrated enterprise excellence

StDev = standard deviation
N = sample size
AD = Anderson-Darling test
LCL = lower control limit
UCL = upper control limit

there are physician-prescribed lab tests that occur less frequently. One such test is the hemoglobin A1C test, which reflects an average BSL for the past two to three months. An A1C level below 5.7 is considered normal. An A1C between 5.7 and 6.4 indicates prediabetes. Type two diabetes is diagnosed when the A1C is more than 6.5.

Blood sugar in the United States is normally measured in milligrams of glucose per deciliter of blood (mg/dl). After awakening, a fasting blood sugar for a person without diabetes should be under 100 mg/dl. Before a meal, normal sugar levels should be 70 to 99 mg/dl. Sugar levels two hours after meals should be less than 140 mg/dl. Whenever conducting a physician-prescribed fasting glucose (sugar) lab test, the patient should abstain from food or drink (except water) for eight to 10 hours before the blood draw.

Jennings' blood lab test results over the years are listed in Online Table 1, which can be found on this article's webpage at www.qualityprogress.com.

With IEE 30,000-foot-level reporting, the following steps are to be conducted for each of the above two data-set responses:

1. A stability assessment is made by plotting each value on an individual's chart—that is, there is no subgrouping of multiple-measured values for any time period. When a process change occurs, the individuals' chart is staged so that any apparent process shifts are separated and where the data from each stage determine the region's control-chart limits.
2. For this process, there are no specifications. Hence, for any recent region of individuals chart stability, a median and 80% frequency of occurrence is to be determined from a probability plot of the data from this stable process region.
3. The results of these analyses are to be documented at the bottom of the chart pair in a prediction-statement format.

Figures 1 and 2 show the two IEE 30,000-foot-level report-outs from this diabetes data set. These two charts indicate that the results from Jennings' diabetes lab tests improved from a process measurement point of view on March 26, 2002 and Jan. 10, 2013. The current level of measurement response is noted at the bottom of each chart.

For both measurements, you could expect a similar response if Jennings were to maintain a consistent process relative to controlling his diabetes through exercise, medication and the types of food that he eats (for example, concentrating on eating low-glycemic-level foods).

Daily tests for diabetics

For those controlling diabetes, a personal blood test is conducted once or more daily. Jennings provided data from his daily blood testing, which can be found in Online Table 2.

It is common knowledge that sugar levels depend on food intake throughout the day. Because Jennings administered four blood tests per day, you should incorporate a daily subgrouping of these four measurements when assessing process stability.

With IEE 30,000-foot-level charting, individuals' charts of daily mean and daily log standard deviation values are used when making a process stability assessment.[9] If the process is stable, all individual values from the recent region of stability are plotted in a probability plot.

This probability plot is used to provide an estimated process capability and prediction statement about individual measurements for not only the current conditions, but also future performance—that is, whether Jennings' process relative to diabetes control remains the same.

The BSL IEE 30,000-foot-level report-out from the diabetes data set, shown in Figure 3, indicates stability and provides a prediction statement at the bottom of the chart: The 80% frequency of occurrence estimates that four out of five individual readings will be between 92 and 168.

Analyzing daily diabetics data

If someone wants to improve a stable process' response, an analysis of data from a region of process stability can provide insight on what might be done differently to achieve an improved response. For this situation, you can gain insight to the variation in blood sugar throughout the day by examining the data graphically and statistically to assess differences in the measured response as a function of time of day.

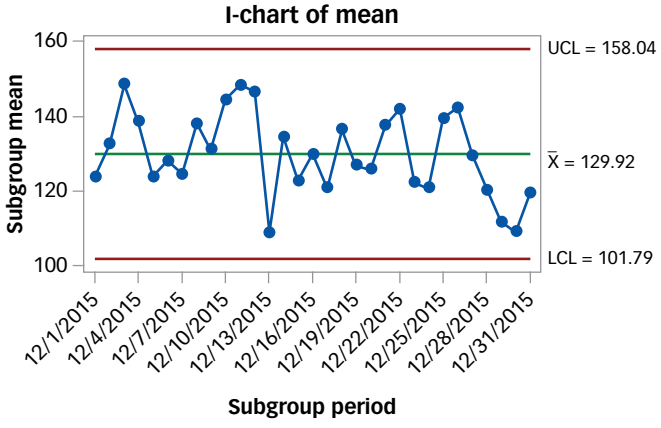
Because the process is stable for the entire timeframe that was examined, you can use all the data to create the dot plot and analysis of means statistical assessment, as shown in Figures 4 and 5.

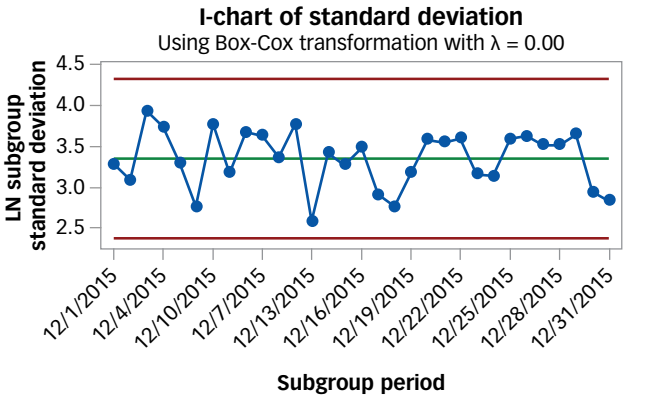
From these blood sugar plots, you can conclude:

- At bedtime, the mean blood sugar response is considered statistically significant different (higher) than an average blood sugar measurement throughout the day.
- In the evening, the mean blood sugar response is considered statistically significant different (lower) than the average blood sugar measurement throughout the day.

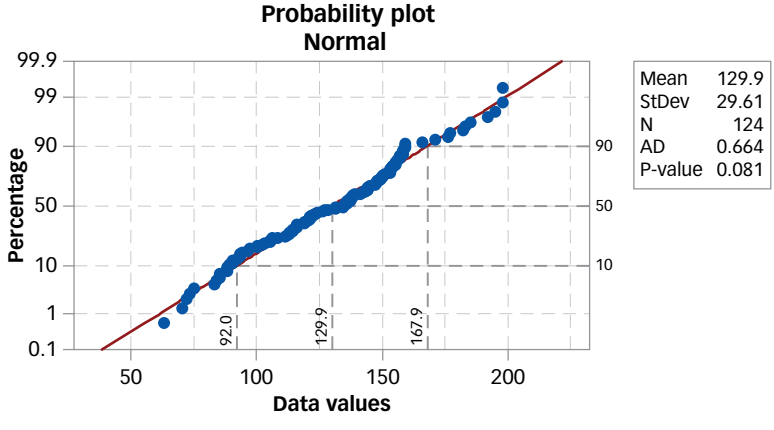
What you can infer from this time-of-day analyses is that even though Jennings is doing a good job managing his overall diabetes measurements, he could perhaps

IEE scorecard for daily blood sugar / FIGURE 3





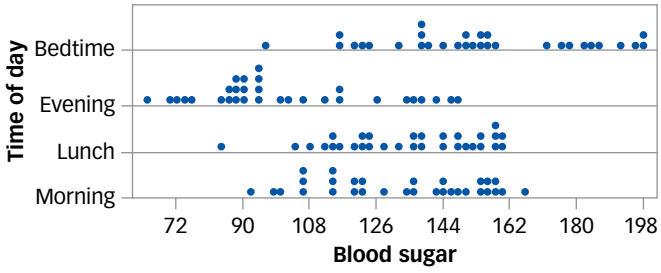
A natural log (LN) transform was applied to account for skewness of standard deviations.



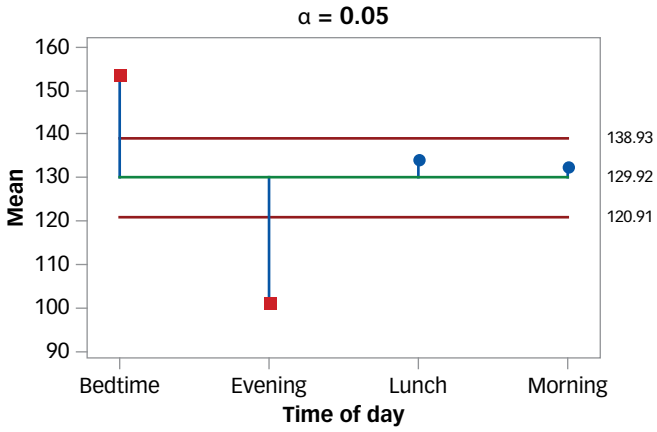
StDev = standard deviation
N = sample size
AD = Anderson-Darling test
LCL = lower control limit
UCL = upper control limit

The process is predictable.
The estimated median is 129.91 with 80% of the events between 91.967 and 167.87.

Dot plot of blood sugar / FIGURE 4



One-way normal ANOM for blood sugar / FIGURE 5



ANOM = analysis of means

do even better if his evening meals were smaller, eaten earlier in the day and foods he consumed had a lower glycemic index.

Performance metric reporting

What was just described was an approach for tracking diabetes data, but the techniques also can apply to organizational performance metric reporting. An IEE 30,000-foot-level charting perspective can provide an excellent mechanism for separating high-level, common cause variability from special cause conditions.

With this perspective, you can gain insight into whether a process needs improvement or whether a special event just occurred that needs individualized attention. In other words, IEE 30,000-foot-level reporting can help organizations get out of the firefighting mode where common cause variability is addressed as though it were special cause.

When applying these techniques in an organization, metrics can be linked through an IEE value chain to the processes that created them.[10] By implementing this method, data could be updated automatically. Because of this automation, reference can be made to updated information whenever making decisions.

There is also no reason to create special reports for various meeting and executive presentations because updated information would be available with a click of a mouse. With this form of report generation and reporting, there also would be transparency in reporting. This form of reporting can offer much risk-reduction value to organizations—for example, avoiding the risk in creating up-the-chain-of-command reports so a situation (such as frequency of safety incidents) is reported to make the situation appear better than what is actually occurring.[11] QP

CREATING IEE 30,000-FOOT-LEVEL CHARTS WITH SOFTWARE HELP

Microsoft Excel does not offer a probability plot function. Probability plot add-ins to Excel do not provide a good alternative for the creation of probability plots. Minitab also is not set up to create integrated enterprise excellence (IEE) 30,000-foot-level charts.

There is a free, easy-to-use Minitab add-in, however, that can be used to create these high-level charts for a variety of situations—for example, attribute data and lognormal data with negative values. For more information, visit http://tinyurl.com/30000-reporting.

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