Clinical Chemistry Trainee Council
Pearls of Laboratory Medicine
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"QC Design: Things You Need to Know" Series

TITLE: Sigma Metric

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Slide 1:
Welcome to "QC Design: Things You Need to Know" series. This is Lakshmi Kuchipudi. I am a senior scientist in Quality Systems Division at Bio-Rad Laboratories. This is the 4th Pearl of Laboratory Medicine in the series. In this Pearl, I will discuss Sigma Metric.

Slide 2:
Sigma metric is a measure of in-control capability of the process.

Slide 3:
The sigma metric is defined as your allowable total error specification for an analyte…

Slide 4:
…minus any inherent analytical bias in your test method…

Slide 5:
… divided by the stable analytical imprecision of your test method.

Slide 6:
The sigma metric is a measure of your process capability relative to your quality requirement – it is effectively the number of analytical standard deviations of your test method that fit within your allowable total error specification.

There's some buzz about Six Sigma in quality control. Let's discuss why a Six Sigma process is good.

Slide 7:
A Six Sigma process reflects a measurement procedure where 6 standard deviations (or 6 “Sigmas”) of measurement error fit within the allowable total error specification.

Slide 8:
When the process is in control, the measurement error distribution easily fits well within the TE_a limits. There is only a miniscule portion of distribution outside the TE_a limits.

Slide 9:
When the process is out of control, you can see the Six Sigma process accommodates the shift well and most of the distribution is within the TE_a limits. There’s a portion of the distribution in the right tail which is outside the TE_a limit but it’s very small.

Slide 10:
Let’s look at a Three Sigma process.

Slide 11:
When the process is in control, most of the distribution is within the TE_a limits.

Slide 12:
There is some small portion of the distribution in the tails outside the TE_a limits. With a Three sigma process when the process is in control, there is about 0. 3% chance that measurement error in patient results will fail to meet the TE_a limits.

Slide 13:
When the process shifts...

Slide 14:
...you can see a large portion of the distribution in the right tail is outside the TE_a limits.

Slide 15:
Finally, let’s look at a Two Sigma process.

Slide 16:
Even when the process is in control, you can see there is about a 5% chance that measurement error in patient results will fail to meet the TE_a limits. A Two Sigma process has a high in-control unreliability rate.

Slide 17:
When the process shifts, you can see a large portion of the measurement error distribution is outside the TE_a limits. A low sigma process has less tolerance to accommodate error.

Slide 18: Summarizing the in-control unreliability rate.
A Six Sigma process has a very low in-control unreliability rate. When the process is in-control, there is approximately 1 in 2 billion chance that measurement error in patient results will fail to meet the TE_a limits, which is negligible.

A Three Sigma process has 0.3% unreliability. When the process is in-control, there is approximately 3 in 1000 chance that measurement error in patient results will fail to meet the TE_a limits.

A Two Sigma process has a high in-control %unreliability which is approximately 5%. When the process is in-control, there is approximately 5 in 100 chance that measurement error in patient results will fail to meet the TE_a limits.

Slide 19:
It's always beneficial to know your sigma, because knowledge of your measurement procedures process capability can assist you in designing your quality control. High sigma metric processes require a relatively large out-of-control error condition to produce unacceptable patient results and are therefore, easy to QC. For low sigma metric processes, even relatively small out-of-control error conditions can produce high numbers of unacceptable patient results and are therefore, difficult to QC. So know your sigma.

Slide 20:
A low sigma process has a high in-control unreliability rate and an even higher out-of-control unreliability rate. As a result, even small out-of-control conditions can produce a large number of unacceptable patient results that might lead to patient harm.

Slide 21:
Our goal is to have a sigma metric value of greater than 3.5.

Slide 22:
Different analytes will have different sigma metric values based on the allowable total error for the given analyte, and the instruments bias and imprecision characteristics for the given analyte. Sigma metric may also vary by analyte concentration since instruments bias and imprecision characteristics may differ based on the concentration.

Slide 23:
Let's look at a couple of hypothetical examples. This example compares 2 different instruments in 2 different labs both testing Glucose. Both labs use an allowable total error of 10%, both labs have instrument bias of 1%. Lab A has higher instrument imprecision of 4% compared to Lab B which is 2%. Which lab in this case has better process capability?

Lab B, of course, since its sigma metric value is 4.5. Lab A has a sigma metric value of 2.3 and as a result, has a high in-control and out-of-control unreliability rate. As a result, Lab A produces large number of unacceptable patient results compared to Lab B.

Slide 24:
This hypothetical example compares 2 different instruments in 2 different labs both testing Albumin. Both labs use an allowable total error of 10%, both labs have instrument imprecision of 2%. Lab A has higher instrument bias of 4% compared to Lab B which is 1%. Now, which lab has better process capability?

Again, it's Lab B since its sigma metric value is 4.75. Lab A has a sigma metric value of 3 and as a result may produce large number of unacceptable patient results compared to Lab B.

Slide 25:
How to improve a low sigma metric value? Seek ways to reduce your test methods bias and imprecision. You may also need to reconsider whether your quality specification is realistic.

Slide 26:
In conclusion, sigma metric is useful for comparing the process capability of various measurement procedures. Sigma metric identifies problem analytes and guides quality control for each analyte.

Slide 27: References

Slide 28: References

Slide 29: Disclosures

Slide 30: Thank You from www.TraineeCouncil.org
Thank you for joining me on this Pearl of Laboratory Medicine on "Sigma Metric" from the "QC Design: Things You Need to Know" series. I am Lakshmi Kuchipudi. These presentations are being created for the Pearls of Laboratory Medicine as a part of the *Clinical Chemistry* Trainee Council.