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

TITLE: Why Do We Need Quality Control?

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Slide 1:
Hello. My name is Lakshmi Kuchipudi. I am a senior scientist at Bio-Rad Laboratories. Our research group is dedicated in improving Laboratory Quality Control. We work with laboratories addressing issues specific to Quality Control Design. The "QC Design: Things You Need to Know" series is intended to educate the audience on statistical quality control design and testing. This is the first Pearl in this series and I will talk about the importance of statistical quality control, different types of failure modes in the patient testing process, and where statistical quality control testing applies. So, welcome to the "QC Design: Things You Need to Know" series.

Slide 2:
What is quality control design? In clinical diagnostics settings, we can define it as a 2-step process. The 1st step is identifying the quality required for each test offered, and the 2nd step is designing the statistical process controls needed to alert the user if the quality goal is not being met.

Slide 3:
Now our next question is: "Why do we need quality control?" This question comes up when laboratory expenses are being scrutinized. Aren't clinical diagnostic systems reliably engineered? It's the manufacturers' job to ensure the reliability of the diagnostic system. If so, why do we have to continually check the quality of clinical diagnostic processes? Because all clinical diagnostics processes will experience failure at some point. It is the laboratories' responsibility to ensure the reliability of patient results – even in the presence of equipment failure.

Slide 4
Failure modes can occur in any stage of the patient testing process. I have listed some examples of failure modes occurring during Pre-Analytical, Analytical, and Post-Analytical steps of the process. Most of the Pre-Analytical and Post-Analytical failure modes affect single patient results. Example: if a specimen is mislabeled and an incorrect test is ordered as a result of that, only that patient is affected.

There might be cases where more than one patient specimen are affected but is limited to just that group. For example: during transportation of patient specimens when it's a hot summer day and 100 degrees outside and the temperature in the vehicle wasn't well maintained. All the patient specimens in the vehicle are affected as a result but this failure mode is limited to just these patient specimens in the vehicle.

However, Analytical failure modes are the ones that span across multiple patient results. These are the failure modes that may persist until detected. E.g.: A calibration drift was undetected for a month; all the patient specimens tested during that period are affected.

I want to give you a more general example which my mentors gave me when I was learning this concept. It's the difference between one person falling off a cruise ship and an entire cruise ship sinking. There might be a few cases where a person falls off a cruise ship but when a cruise ship sinks, it's a major disaster affecting thousands of people. We don't want disasters. This is where statistical QC helps. Now, let's talk more about these analytical failure modes.

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Failure modes can be grouped into 2 categories. Full stop malfunctions or Silent malfunctions. Full stop malfunctions occur when the testing system does not work. These are easy to identify because the testing is stopped and no results are produced. However we are not so lucky with Silent malfunctions. These silent malfunctions lead to out-of-control conditions. The testing system continues to process specimens and produce results, but these results are not suitable for their intended purpose. These malfunctions/out-of-control conditions are hard to identify and are the target of quality control.

Slide 6:

The silent malfunctions can be grouped into intermittent or persistent out-of-control conditions. The Intermittent out-of-control conditions do not last long. They compromise the testing system for a short period of time and may only affect a single patient result. E.g. bubble in a reagent line. Intermittent out-of-control conditions are important and procedures such as delta checks or discordance checks as well as many built-in instrument checks are designed to try to detect these, but intermittent out-of-control conditions are not the focus of this series. Persistent out-of-control conditions persist until corrected. They affect multiple patient specimens. E.g. Calibration drifts. These persistent out-of-control conditions are usually the focus of statistical quality control.

Slide 7:

Now why do we care about these out-of-control conditions? Because we care about the quality of the patient result produced. The quality of a patient result depends on the difference between the correct concentration and the value reported by the laboratory. If this difference is greater than a specified allowable error limit, then we define the patient result as unreliable. I will discuss the concept of allowable total error in the second Pearl of this series. All patient results contain some measurement error. When the process is in-control, only a few results with measurement error are unreliable. When an out-of-control condition exists, additional error is added, so now a higher percentage of patient results are unreliable.

Slide 8:
Let us look at a sequence of events that could lead to patient harm. A failure mode occurs and leads to an out-of-control condition. If the out-of-control condition persists, it produces unreliable patient results. If the condition is still undetected when reporting patient results, the unreliable patient results go out the door. All these sequences above occur within the lab. Once the results are reported, the laboratory loses control over the unreliable patient results. Now what happens outside the laboratory? There's some chance that an incorrect action is taken as a result of the unreliable patient result. If an incorrect action is taken, it might lead to patient harm.

Slide 9:
So what can laboratories do? Laboratories have control of what happens within a lab. It's always better to prevent the failure modes but when prevention is not possible, we have to look at the cure. So, if an out-of-control condition exists, we want to detect the condition and take corrective measures so no unreliable patient results are reported. This is where the statistical QC comes into place.

Slide 10:
Our goal in the subsequent webinars is to learn to design statistical quality control to detect persistent out-of-control conditions that affect multiple patient results and reduce the number of unreliable patient results reported. Our main focus would be to minimize patient risk.

Slide 11 & 12:
References

Outro:
Thank you for joining me on this Pearl of Laboratory Medicine on "Why Do We Need Quality Control?" from the "QC Design: Things You Need to Know" series. I am Lakshmi Kuchipudi.