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# Use Of Process Capability Indices In Evaluating A Clinical Laboratory Chain's Quality Control Procedures

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**Abstract:**

To determine how useful the process capability indices C p and C pk are for evaluating chain laboratory facilities' quality control procedures. Totalprotein, albumin, and urea showed trueness individual improvement, precision individual improvement, and precision common improvement, respectively, when the process capability indices at the Jinan KingMed Center were compared to the standard values. The results of the other assays remained stable. Process capability indices can help increase the accuracy and validity of laboratory tests and are helpful in assessingthe quality control protocols used in lab facilities.

**Keywords:** improvement, precision, process capability index, quality control, trueness, Clinical laboratory.

**Introduction:**

Two crucial procedures for quality management in laboratory medicine are external quality assessment (EQA) and internal quality control (IQC).

There are numerous tools available for internal quality control. For instance, bias and the coefficient of variation (CV) are used to assess the accuracy and veracity of assays, respectively. The analytical performance of a test is assessed using sigma metrics, such as (TEa-
|bias|)/CV. For instance, a sigma value >3 suggests that the testing procedure can satisfy clinical needs and can be controlled with a set ofstandard Westgard rules. However, the quality goal index (QGI), whichcan assist the laboratory in analyzing the reason for subpar performanceand suggesting corrective actions, must be computed when the Sigma value is ≤3 (Westgard , 2016) . In 1996, laboratory medicine was introduced to the process capability indices C p and C pk, which are employed in the manufacturing sector. Burnett et al. evaluated the usefulness of these indices in choosing suitable quality control rules. The number of products that can be produced within the allowedspecifications increases with higher values of the process capability indices ( Jones , 2017 ).

Thus, the process capability indices C p and Cpk were evaluated in this study for center, as well as for the quality control of a chain of clinical laboratories.

**Assay performance assist labs:**

Assay performance is typically assessed through IQC for precision and EQA or comparison of the IQC data for bias measurement. This procedure can assist labs in enhancing the detection system's performance.

Numerous instruments have been created to assess analyte performance, including QGI and the Sigma value. It is necessaryto calculate the quality goal index (QGI) when the Sigma value isless than 3. A QGI score of less than 0.8 denotes imprecision, a score of more than 1.2 denotes untruthfulness, and a scoreranging from 0.8 to 1.2 denotes both untruthfulness and imprecision (Shaikh , 2016).

**Sigma:**

Based on IQC data, the combined use of Sigma and QGI can pinpoint important areas for improvement (precision or trueness). However, using Sigma external comparison to further analyze the causes of imprecision or untruthfulness is not feasible due to the existence of two variables: bias and CV. Additional tools include SDI and CVI, which, based on IQC data, can pinpoint important areas for improvement (precision or trueness) as well as the reasons behind anomalies (Wang , 2019).

**However, the following drawbacks prevent its broader application:**

(1) There would be false positives or false negatives depending on the comparison group's size, the artificial division of "outliers" in statistics, and the quality requirements of the laboratories taking part in the study (Sayeed , 2019 ).

(2) Laboratory expenses are high, and the use of commercial software like Unity Real Time is necessary ( Yoon , 2018).
Not all tests can be covered only relevant to the use of particular quality control items.

(3) Only the QC products from the same manufacturer with the same batch number can be directly compared using parameters bias and CV for calculation; otherwise, the quality difference brought on by the QC material cannot be excluded, and the comparison has significant limitations ( Burnett , 1996).

**Difference between the process capability indices andSigma:**

One of the main distinctions between Sigma metrics andprocess capability indices is how bias is measured.

In practical application, systematic error is typically assessed using the following two methods: (1) computing the difference based on

the organizer's EQA results, and (2) computing the difference between the cumulative mean and the fixed mean ofIQCs. (Aslam , 2013 ).

**While it is possible to use the bias calculated for the EQA results, the following factors need to be taken into account:**

(1) Analyte levels in IQC samples are typically different from thosein EQA samples ( Wang , 2019).

(2) It's still unclear how the matrix effect affects IQC and EQA samples.

(3) The obtained bias value may not accurately reflect the true technical level of the laboratory due to variations in factors (such as reagent and analyzer) that are related to traceability between laboratories, which complicates the situation ( Chesher, 1997).

(4) The EQA's detection and evaluation cycle is quite lengthy.

**Recommendations:**

- IT is important to focus on accuracy and truthfulness, and increasingefforts should be made to enhance precision.
- stated that most facilities needed to improve their accuracy andtrueness, and that the hospital chain should prioritize improving accuracy above all else. The C p and C pk in other tests were stable,with the exception of these assays.
- In contrast to conventional approaches, the process capability indices C p and C pk offer various benefits for quality management in laboratory facilities. These indices, which provide a thorough analysisof both parameters gathered from chain laboratories, can assist laboratories in identifying problems with assays.

**Conclusion:**

The accuracy and validity of laboratory tests can be increased by using process capability indices to assess the quality control protocols used in lab facilities. Are you eager to investigate the reason when an unusual trend appears on the quality control chart? The core cause of the anomalies will remain unknown if we only rely on the laboratory Sigma analysis. The problem can be readily resolved with the introduction of newapplication indexes C p and C pk and comparative analysis between laboratories. We are able to identify the main areas that require improvement by comparing with the absolute standard. In the meanwhile, the interlaboratory comparison can assist us in identifying the underlying causes of anomalies (the unique factor of one laboratory or the commonfactor of most laboratories), as well as establish the necessity of improvement and the best course of action for it.

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