QUALITY CONTROL

THE ROLE OF SIX SIGMA IN A MODERN QUALITY MANAGEMENT STRATEGY

RANDOX

The Role of Six Sigma in a Modern Quality Management Strategy

Introduction

"To err is human…" - a phrase commonly used to attest to the inherent fallibility of humankind. People make mistakes, and often those mistakes have consequences; large and small.

The healthcare industry is no different. In their 1999 report, To Err is Human, Kohn and colleagues estimated that up to 98,000 deaths per year could be directly attributed to medical errors[1]. This fact, coupled with evidence that around 60-70% of all medical decisions are made based on laboratory results[2], shows that consistently accurate laboratory outputs are of paramount importance in reducing risk to patients.

The clinical laboratory plays a crucial role in patient care, and this role is increasingly being shown the recognition it deserves. Consequently, laboratories are becoming busier than ever before, and with increased workloads, it stands to reason that the rate of error will also increase. Coskun and colleagues maintain that this increased probability of error should be offset with new, innovative solutions aimed at decreasing the risk of error[3]. However, before we can develop strategies to reduce the risk of error, we must first understand the potential sources of error.

Sources of Error

When it comes to laboratory testing, errors are not restricted to the laboratory itself, as they can occur at nearly any stage. The 'total testing process' is a multistep clinical process which begins and ends with the needs of the patient[4]. It consists of 9 steps:

1. Test selection and submitting a laboratory test request
2. Sample collection (serum, plasma, urine, CSF, etc.)
3. Identification
4. Transport of the sample to the laboratory
5. Sample preparation
6. Sample analysis
7. Reporting test results
8. Interpretation of test results
9. Action

Each of these steps has the potential for error, and some steps are more prone to error than others due to increased human involvement[5]. These steps can be further broken down into 5 phases; Pre-Pre Analytical Phase (Step 1), Pre-Analytical Phase (Step 2-5), Analytical Phase (Step 6), Post-Analytical Phase (Step 7), Post-Post Analytical Phase (Step 8-9).

In order to properly quantify and account for potential error throughout the total testing process, it is essential for each laboratory to implement a Quality Management System (QMS). There are many different kinds of QMS, and one of the most popular QMS strategies in the 1990s was that of Total Quality Management (TQM). The generic TQM model was based around the Plan-Do-Check-Act strategy. First the lab must plan what strategy to implement, and then do it. The next step is to check the data obtained, then act upon the results.

One of the major developments in quality improvement was the implementation of Six Sigma methodologies. Six Sigma was developed by Motorola in the mid-1980s, and since its inception it has been incorporated into many different industries, and has recently risen to prominence in the healthcare sector due to its application in laboratory quality.

What is Six Sigma?

Six Sigma is a method of process improvement which focuses on minimizing variability in process outputs. Variation in a process leads to wasted time and resources in re-running tests and altering SOP's etc. Reducing variation will ultimately reduce costs, improve performance and increase profitability.

The Sigma model looks at the number of standard deviations (SD) or 'sigmas' that fit within the quality specifications of a process. In the laboratory, the quality specifications relate to the Total Allowable Error (TEa) for each test. The higher the number of standard deviations that fit between these limits, the higher the sigma score and the more robust the process or method is. As sources of error or variation are removed from a process, the SD becomes smaller and therefore the number of deviations that can fit between the allowable limits is greater; ultimately resulting in a higher sigma score.

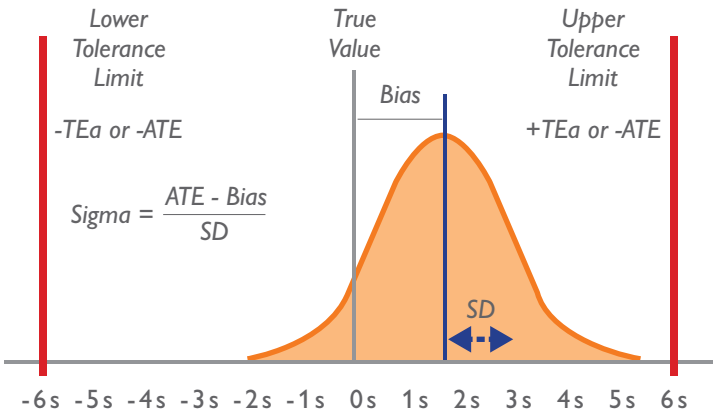

Figure 1. Predicting defects using imprecision (CV), inaccuracy (Bias) and total allowable error (TEa)

Six Sigma is a scale, and typically runs from zero to six, though process performance can exceed Six Sigma providing variability is sufficiently low enough as to decrease the defect rate[8]. In the clinical laboratory, a sigma score of three is considered the minimum acceptable performance, while a score of six is considered the gold-standard. A test which has achieved Six Sigma performance will experience approximately 3.4 errors (out of range QC results) per one million QC tests run – showing the accuracy and reliability of a Six Sigma standard test.

How is Sigma Calculated?

In the clinical laboratory, the most common method of calculating Sigma is by measuring variation[8]. The imprecision (CV) and inaccuracy (Bias) are routinely calculated for each test, and these metrics can be used in Sigma calculation, in conjunction with the Total Allowable Error (TEa). Westgard QC define the TEa as the name given to the limits for both the imprecision (random error) and inaccuracy (systematic error) that are tolerable in a single measurement or test result[10]. The TEa for each test can be found from numerous sources. CLIA, Rilibak and Biological Variation (Ricos Goals) provide TEa limits for each test, and are commonly used by labs worldwide. Sigma can then be calculated using the following equation:

Sigma = (TEa – %Bias) / %CV

Where:
TEa – Total Allowable Error
Bias – The deviation (%) between obtained mean and the reference value or peer group target
CV – Imprecision of the data (%)

Example

A lab is running Aldosterone and wants to evaluate whether it is performing close to Six Sigma. The lab checks the CLIA database, which shows that Aldosterone has a **TEa of 36.7%.** The lab then calculates the %Bias of their Aldosterone assay when compared to their peer group, and find that they are running with a **Bias of 5%**. The Aldosterone assay also has a **CV of 10%**. Using the above calculation, we can see that:

Sigma = (TEa – %Bias) / %CV
Sigma = (36.7% - 5%) / 10%
Sigma = 3.17

In this instance, the Aldosterone assay is running just above 3 Sigma, which is around the minimum acceptable performance. The lab will need to make efforts to decrease their %CV and %Bias to improve the overall Sigma Score for their Aldosterone assay.

What are the Benefits of Sigma?

There are many benefits to incorporating Sigma calculations in your QMS.

One of the main functions of Sigma is to give laboratories a quantitative indication of the approximate number of Defects Per Million Opportunities (DPMO). In a laboratory context, this would be the rate of failed QC results per million QC tests run.

As the Sigma Score for a test increases, the approximate number of failed QC results will decrease.

The below graph shows the probability test results will be within acceptable limits in relation to Sigma Score:

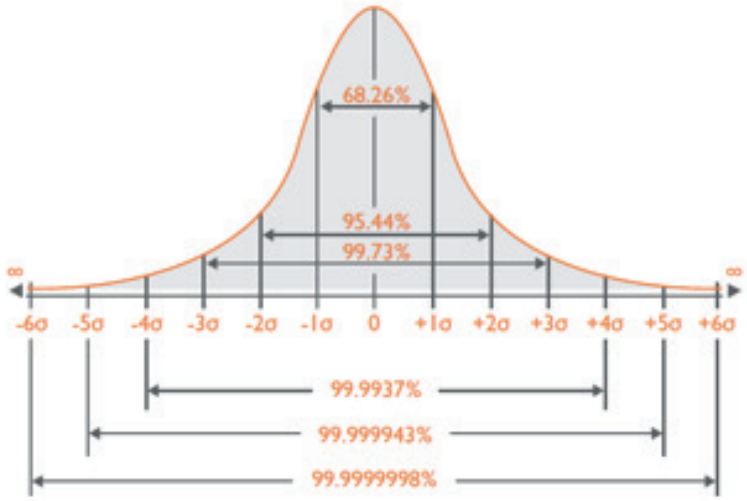

Figure 2. Graph showing percentage probability of achieving a result within acceptable limits

According to the above graph, a Six Sigma test will have only 0.2 defects per million opportunities (DPMO). However, it is widely accepted that over time, the Sigma Score of tests will gradually decrease or fluctuate due to inevitable variability. For this reason, many labs incorporate a 1.5 sigma shift into their Sigma calculations in order to account for any variability over time[11]. Table 1 shows the percentage accuracy and approximate number of failed tests per million QC runs. Once labs are able to quantify their approximate number of QC failures, they can identify any poor performing tests and take steps to improve their performance.

Sigma level (with a 1.5 sigma shift)	% Accuracy	Failed QC Results per million
1	30.9%	697,700
2	69.1%	308,700
3	93.72%	66,810
4	99.4%	6,210
5	99.98%	233
6	99.9997%	3.4

Six Sigma can be used to help answer one of the most commonly asked questions in laboratory quality control; **How often should I run QC?**

The Six Sigma model allows laboratories to evaluate the effectiveness of their current QC processes. Its most common use is to help implement a risk-based approach to QC, where an optimum QC frequency and multi-rule procedure can be based on the sigma score of the test in question. The performance of tests or methods with a high sigma score of six or more may be evaluated with one QC run (of each level) and a single 1:3s warning rule. On the other hand, tests or methods with a lower sigma score should be evaluated more frequently with multiple levels of QC and a multi-rule strategy designed to increase identification of errors and reduce false rejections.

The below table shows how multi-rules and QC frequency can be applied according to Sigma Metrics[9]:

Sigma Score	QC Frequency	Number of QC Samples	QC Rules
6 or more	Once per day	Each level of QC	1:3s
5	Once per day	Each level of QC	1:3s/2:2s/R4s
4	At least twice per day	Each level of QC	1:3s/2:2s/R4s/41s
< 4	At least four times per day	Each level of QC	1:3s/2:2s/R4s/41s/8x

The benefits of a more dynamic QC strategy include reduced cost and time implications in the long-run, as well as greater levels of error detection, thereby drastically reducing risk to the patient.

Conclusion

The laboratory is a rapidly-evolving and dynamic environment, and the old 'one size fits all' model of quality management is not sufficient to meet the time and cost-saving requirements of the modern lab. New, innovative solutions are needed, as well as a constantly vigilant approach to QMS optimization.

As discussed, sources of potential error permeate every facet of laboratory testing. Six Sigma and DMAIC are effective and proven ways of identifying goals, using metrics to establish current performance, critically evaluating all processes, identifying and implementing potential solutions, and evaluating results. The entire testing process can be quantified using these methodologies, and steps can be taken to implement continuous process improvement.

Every laboratory should be invested in the quality of their results. But to ensure the quality of our output, we must ensure the quality of our input.

Acusera 24•7

Compatible for use with the Acusera range of third party controls, the Acusera 24•7 software is designed to assist laboratories in the management of daily QC activities. With access to an impressive range of features, including the automatic calculation of Sigma Scores, the software provides the necessary tools to monitor and improve assay performance. Delivering unique access to peer group statistics updated instantly in real-time the software will significantly speed up the troubleshooting process in the event of a QC failure. This coupled with access to an impressive range of interactive charts and reports that make it easier to identify QC failures and emerging trends makes Acusera 24•7 the most comprehensive QC data management platform in the world. For more information visit **www.randoxqc.com.**

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