

Six Sigma

Its Role in the Clinical Laboratory

BY CARL GARBER, PHD, FACB

Six Sigma has received much attention in the clinical laboratory community over the past several years, primarily as a quality metric (1,2). From its name, most laboratorians assume—rightly so—that Six Sigma has something to do with six standard deviations. But Six Sigma is far more than a quality metric; it is a strategy for decision-making, process improvement, and problem resolution. Perhaps Six Sigma is best-described as a process for problem elimination.

Why Six Sigma?

With 44,000 to 98,000 unnecessary deaths projected per year in the U.S. as the result of improper health care services, the message from the 1999 Institute of Medicine (IOM) report "To Err is Human" (3) is clear: health care service providers need to make some major improvements in the quality of services. While many of the causes of untimely death and adverse effects are related to administration of medications and therapeutic drugs, as laboratorians, we cannot overlook the role that the clinical laboratory has in overall outcomes. In fact, by some estimates, 70% of all information used for patient care

example, in the airline industry, 99.9% error-free performance would result in two unsafe landings per day at the largest airport in the U.S., and in the U.S. banking industry, 22,000 checks would be deducted from the wrong accounts every hour. Assuming that labs consider plus or minus three standard deviations (SD) as a criterion for acceptable performance, by comparison, the airline and banking industries are functioning at much lower defect rates. Clearly, what might be considered acceptable, error-free work in some instances is not acceptable in other instances. In order to provide a safer health care environment, it is imperative that U.S.

laboratory, and then we need to examine those processes that will facilitate closing the gap.

Six Sigma is unique in its rigorous approach to outlining the details that are necessary to achieve significant improvement in process quality and efficiency. The process begins with developing a clear understanding of required performance. It then applies a variety of statistical tools to analyze process measures, which facilitates proving the root cause(s) for problem(s). The task then becomes revising the process in order to eliminate the causative factor(s).

Overall, the Six Sigma process offers a new approach to thinking about performance in terms of numbers of defects, rather than percentage rates of acceptable performance. What's more, it provides focus on the individual patient rather than the overall population.

What is Six Sigma?

First developed by the Motorola Company in the early 1980s, the Six Sigma process revolutionized the way the company managed its business from the design, to the manufacturing, to the sale of its electronic systems. After four years of applying the Six Sigma strategy, Motorola realized a savings of \$2.2 billion through improved quality and elimination of waste and reruns.

Figure 1 presents a graphic overview of the Six Sigma process, commonly called the DMAI²C Process. This pictorial may give the impression that Six Sigma is like many other continuous improvement processes, such as the classical PDCA cycle (Plan, Do, Check, Act) proposed by W.E. Deming (4) or the Juran Trilogy (Quality Planning, Quality Control, Quality Improvement) proposed by Juran (5). However, there are some key elements contained within Six Sigma that make it truly unique. These are defined by five distinct phases, which are presented below.

Define Phase. There are basically four things that need to be defined when initiating a Six Sigma investigation or project:

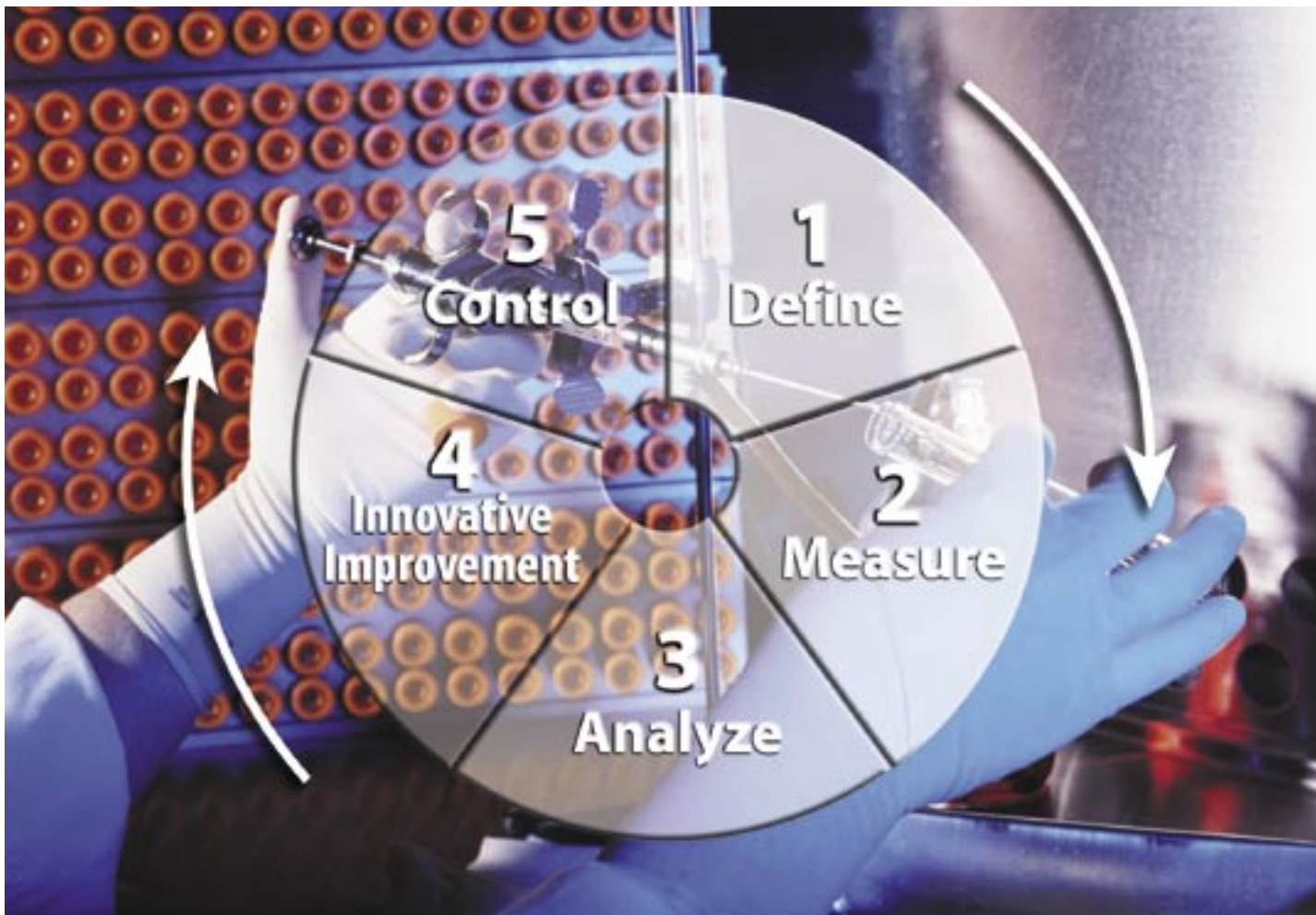
1. The process of interest that needs to be improved, including a clear definition of the beginning and the end;
2. The definition of a defect or failure in the eyes of the customer;
3. The scope of the problem today, in terms of number of failures or defects, and asso-

is provided by the clinical laboratory. The challenge before us is to ensure "error-free" processes along the entire way, from the pre-analytical, to the analytical, to the post-analytical functions of laboratory services.

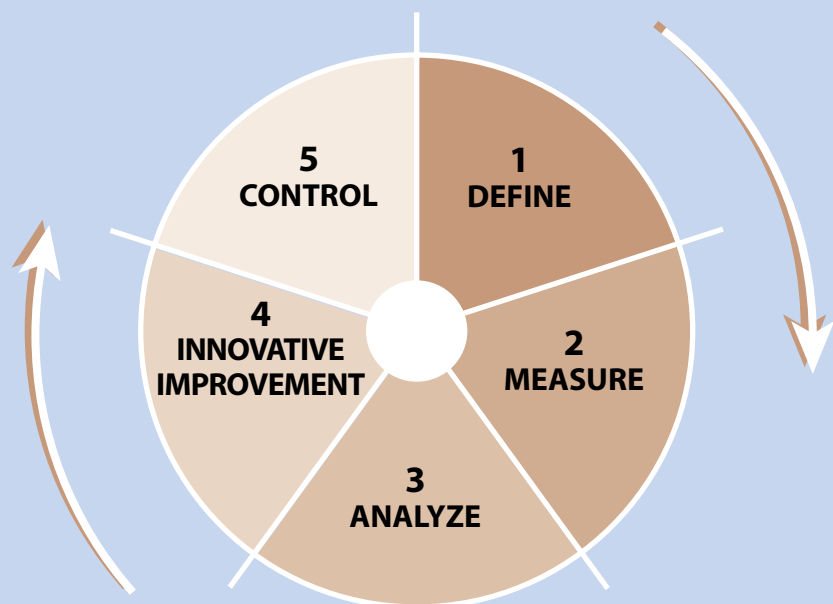
What does "error-free" mean? It is interesting to look at examples of common expectations in some other industries and compare these "what-if" situations to the tolerance for error in clinical labs. For

health care service providers demand even higher, safer levels of performance than those that are in place today.

To achieve significant change and improvement, laboratorians need to start with specific measures about the current status of performance in clinical laboratories, such as those reported by Nevalainen et al. (1). We must also be very clear about standards of performance required for the clinical labo-



Overview of the DMAI²C Method



ciated costs, including unnecessary follow up services; and

4. The desired process performance after applying Six Sigma, including the expected improvements in customer satisfaction, process efficiencies, and cost savings.

Measure Phase. Once a process to be investigated is defined, it is necessary to take some time to collect data regarding various process inputs. One needs to make sure the measures reflect routine operation and that staff do not change the process just because there is some “project” going on. As one gains more knowledge of a process, it may

ship between a process input element and process failure, the Design of Experiments approach is applied. As with FMEA, this is a well-known approach in industry that is used to co-optimize test system conditions for optimum performance.

Innovative Improvement Phase. After the cause of a problem has been identified and proven, the challenge is to redefine the process to remove the cause. This may require some brainstorming and in particular, discussion with individuals who are not experts in the process. Often, fresh ideas will stimulate creativity and innovation.

Common Tolerance Limits in the Clinical Laboratory for “Acceptable Performance”

If Target +/- 2 SD is OK	4.56 % out of limits (defects)	95.4% error free
If Target +/- 3 SD is OK	0.3 % out of limits (defects)	99.7% error free

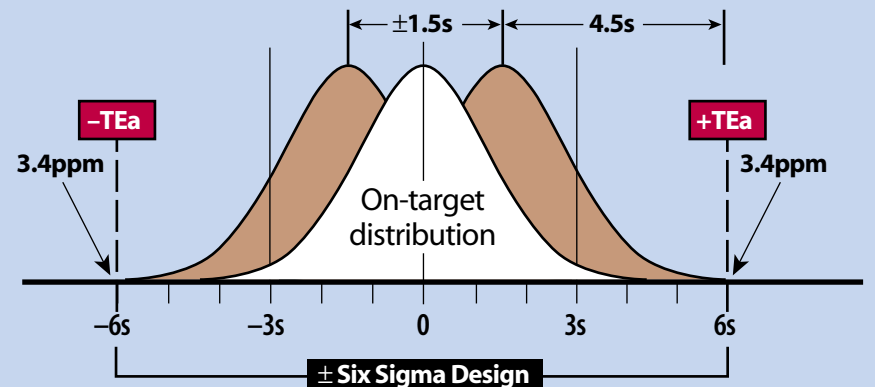
be necessary to collect different data or more data, so there may be some interplay between this and the next phase.

Analysis Phase. Many tools are invoked from flow charts, fishbone charts, graphical techniques, hypothesis testing, and various regression analyses to identify not only those process attributes (inputs) that may have the greatest relation to process problems (defects) but more importantly those that have a causative relation. One output of this phase is to be able to describe a process as a mathematical function of the input variables, from which one can identify those elements that uniquely affect the outcome and the potential for interactive effects among several inputs. Another technique that is commonly employed in manufacturing, Failure Modes Effects and Analysis (FMEA), can also be used in this phase to sort out key relationships. FMEA helps rank overall risk among a number of potential causes for which corrective/preventive actions are defined. Finally, to prove the causative relation-

The new process is then defined with new flow charts, new written procedures, and training to be tested in a pilot study. Process measures are taken of the pilot process to demonstrate the elimination of defects or errors. Of particular interest will be the new process measures and a comparison of these to the “old process.”

Control Phase. In the last step in the DMAI²C process, full documentation of

A View of Six Sigma Performance



If the process is so precise that the SD is less than one sixth of the Quality Goal, then even if the assay shifts off target by 1.5 SD, there will be only 3.4 errors per million (3.4 ppm).

the new process and training must be completed. Most importantly, a process control scheme is established to obtain key process measures and to track them for each time the process is performed. In the laboratory, this is akin to quality control processes. Outside the clinical laboratory, there are very few process measures and even fewer occasions of control procedures; however, this phase offers a completely new element to process management outside the laboratory.

In the first pass review of a process, it is often difficult to achieve the ultimate in Six Sigma performance, 3.4 defective parts per million (PPM) or fewer. Often times, in the overall investigation of the problem, several potential causes may have been identified, but only one cause is eliminated during the first pass of the Six Sigma cycle. In addition, new information about other problems may have been uncovered that were outside the scope of the initial project. Consequently, it may be necessary to cycle through the Six Sigma process several times to address other problem causes of the same process or even different aspects of the process being investigated.

A Six Sigma-Capable Process And the Six Sigma Metric

One simple way to think about Six Sigma is that it is about reducing variation. This can be illustrated by examining a process that is said to be “Six Sigma Capable” (Figure 2). Every process has two components of variation; *random variation*, referred to as ‘common cause’ by statisticians in the Six Sigma literature, and *offset or bias*, referred to as ‘special cause.’ A Six Sigma-capable process has so little random variation that the stan-

dard deviation, when multiplied by six, gives a quantity that meets the customer requirement for that process. In other words, 6 SD is less than or equal to process specification.

Depending on the process, process specifications might specify the maximum waiting time in an outpatient clinic, the requirements for turn-around time for STAT testing, or specifications for analytical performance, such as allowable total error (TEa) as illustrated in the figure.

Figure 2 also shows that if the assay shifted off-target by 1.5 SD, this would leave 4.5 SD for random variation within the bounds set by the customer specification. This is the basis for the Six Sigma model. Statistics tables of the normal distribution show that the residual in the tail beyond 4.5 SD is 3.4 PPM. In summary, the Six Sigma model requires 6 SD less than the customer specification, or TEa for analytical performance and bias ≤ 1.5 SD or \leq TEa/4.

Admittedly, many processes are not Six Sigma capable. Table 2 (page 14) compares the process Sigma metric to accuracy rates and error rates in terms of defective PPM or defects per million opportunities (DMPO).

Current Process Measures Compared to Six Sigma

How do some common laboratory performance measures compare to the process Sigma levels in Table 2? Some examples have been published (6), some of the findings in the IOM report to measures in other industries in the context of the Six Sigma model.

While laboratorians today think that error rates of several percent are normal and

See **Six Sigma**, continued on page 14

Six Sigma Evaluation of Typical Monthly Interlab QC Data

Test	Units	Lab Mean	Lab SD	Lab CV%	Peer Mean	TEa	Bias / TEa	Sigma Level
BUN	mg/dL	16.0	0.7	4.4	16.2	2 or 9%	0.1	2.5
Creatinine	mg/dL	0.86	0.05	5.8	0.83	0.3 or 15%	0.1	6.0
Phosphorus	mg/dL	2.36	.06	2.54	2.50	0.3 or 11%	0.47	2.67

Comparing Six Sigma to Current Measures

Six Sigma, from page 11

acceptable, looking at how this translates into defects or numbers of affected patients per million creates a whole new perspective on quality control. It is enlightening to look at other laboratory examples to gain a clearer understanding of how the Six Sigma process can be applied to the lab.

Proficiency Testing. Under CLIA '88, four results out of five must be within the performance specifications in order to meet the minimum requirements for acceptable proficiency testing (PT). This is an 80% accuracy rate or a 20% defect rate, which is equivalent to 200,000 defects per million challenges or 2.4 Sigma. The proficiency testing error rate reported for the first year after CLIA '88 took effect in 1994 showed that satisfactory rates in hospital and independent laboratories was 97%, or a defect rate equivalent to 3.4 Sigma (7). The same report showed that PT performance in all other laboratories was 91% satisfactory, which is equivalent to 2.8 Sigma. Nevalainen et al. (1) reported an "average" PT performance of 9,000 defective PPM, or about 3.9 Sigma. While both are well above the minimum acceptable passing rates established by CLIA '88, all indicators show a significant opportunity for improvement.

Quality Control Measures. Monthly QC summaries offer insight into the process capability of an assay, based on total imprecision and bias from the "peer group" mean value. Consider, for example, a summary of typical monthly interlab QC data (Table 3, page 11). Of these three selected cases, the BUN performance shows good accuracy within the Sigma model, where the bias is only 10% of TEa. However, the overall Sigma level is only 2.5, reflecting relatively large imprecision. The review of this assay should focus on identifying and eliminating the cause(s) for imprecision.

While the bias from the peer mean for the phosphorus assay is only 0.14 mg/dL, it constitutes 47% of the allowable total error for this test at this concentration. Because the bias is so large, the remaining error that can be allocated to imprecision is 0.16 mg/dL, which when divided by the SD gives a Sigma level of 2.67. If bias were $< TEa/4$, the Sigma level would approach 5. Consequently, the response to this situation should focus on identifying cause(s) for inaccuracy by working through the Six Sigma process.

On the other hand, the creatinine assay shows it meets the criteria for Six Sigma capability, and no further action is required.

Overall Process Performance. Of course, test result variability is a function of more

The Six Sigma Performance Scale

Process Sigma	% Accuracy	PPM or DPMO
6	99.9997%	3.4
5	99.98%	233
4	99.4%	6210
3.5	97.7%	22,700
3	93.3%	66,807
2	69.1%	308,537

PPM = parts per million
DPMO = defects per million opportunities

than just the analytical process. The overall process Sigma reflects the total defects from beginning to end, and therefore, it can only be as good as the chain's weakest link or the worst Sigma Level of any sub-process. Boone (8) reported that 46% of all sources of laboratory errors result from pre-analytical sources, while 7% of lab errors come from analytical causes, and 47% are from post-analytical factors. There are many pre-analytical processes that need to be monitored and tracked to ensure that the right test is ordered, that the right specimen is collected from the patient at the right time, and that specimen integrity is maintained. Post-analytical processes may need greater clarification to prevent reporting and interpretation errors.

The Six Sigma Focus

Overall, the Six Sigma approach creates a focus on ensuring that specifications for performance of any process or sub-process are determined based on "customer requirements." It also provides a detailed process to achieve these requirements to a high degree of reliability. For the clinical laboratory, Six Sigma provides an opportunity to communicate measures of performance quality in a common or normalized format that is easily understood by people outside the laboratory.

In many industries today, Six Sigma has become the currency of quality and excellence around the world. What an opportunity we, as clinical laboratory professionals, are missing by not communicating excellence in laboratory testing in these terms to our customers, physicians, and patients. Clearly, one of the keys in using Six Sigma to improve quality is to first know what the customer requirements are. Without a clear definition of these, the traditional way that labs assess quality by method evaluation studies is nothing more than data collection.

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