

Six Sigma as a Quality Management Tool: Evaluation of Performance in Laboratory Medicine

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1. Introduction

In medical school, the first concept expressed to students is a Latin phrase, *primum non nocere*, meaning "first, do no harm." This phrase is well known among health workers and dates back to Hipocrates. However, in reality, the situation is slightly different. According to the report of the Institute of Medicine, each year in the USA, approximately 98,000 people die from medical errors (Kohn et al., 2000). Unfortunately, more people have died each year during mid-1990s from medical errors than from AIDS or breast cancer (Kohn et al., 2000). Despite this situation, we cannot say that adequate attention has been paid to the application of high standards in the healthcare sector to effectively prevent medical errors. Yet in industry, for more than a century, modern quality control has been applied to prevent errors and produce high quality goods. The result of these long-term efforts is that in many companies, the rate of errors approaches a negligible level. Regrettably, we cannot say the same thing for medical services, because the components that produce errors or defects in medical services are many more than those involved in any industrial or business sector. Despite these facts, it is clear that the quality of medical services is more important than the quality of most other goods. Consequently, healthcare professionals must pay more attention to quality than any industrial professionals do.

Among healthcare services, clinical laboratories are particularly important because physicians make their decisions mostly in accordance with laboratory results (Forsman, 1996). In this context, accurate test results are crucial for physicians and their patients. First, the laboratory must be able to produce an accurate test result before any other dimension of quality becomes important. From this point of view, the evaluation of laboratory performance is critical to maintaining accurate laboratory results (Coskun, 2007).

In clinical laboratories, we traditionally divide the total testing processes into three phases: pre-analytical, analytical, and post-analytical phases. However, the selection and interpretation of tests are also prone to errors and must be considered in the total testing process. For this reason, in laboratory medicine, we analyze the total testing process in five phases: pre-pre-analytical, pre-analytical, analytical, post-analytical, and post-post-analytical phases

(Goldschmidt, 2002). Errors that occur in each phase may affect patients negatively, and for a realistic approach, the total frequency of errors in all five phases must be calculated (Coskun, 2007). Except for the analytical phase, the quality of work in the other phases is not presently satisfactory (Coskun, 2007). In the past decade we have found that in clinical laboratories, the analytical errors made by instruments have been reduced to acceptable levels. The high quality of the analytical phase is a result of continuous efforts made by manufacturers because they must produce high-quality instruments to be competitive in the marketplace. As laboratory workers, we have to improve the quality of the other phases, especially the pre-analytical phase, to produce accurate test results for patients.

Mistakes are unfortunately a part of human nature; but fortunately, the ability to create solutions and find better alternatives is also a part of human nature. We can shift the balance toward solutions and better alternatives using modern quality-management tools such as Six Sigma.

Six Sigma methodology represents an evolution in quality assessment and management that has been implemented widely in business and industry since the mid-1980s (Westgard, 2006). Six Sigma methodology was developed by Motorola, Inc. to reduce the cost of products, eliminate defects, and decrease variability in processing. It consists of five steps: define, measure, analyze, improve, and control (DMAIC) (Westgard, 2006a; Westgard, 2006b; Brussee, 2004). These steps are universal and could be applied to all sectors of industry, business, and healthcare. The sigma value indicates how often errors are likely to occur; the higher the sigma value, the less likely it is that the laboratory reports defects or false test results. The best or "world class" processes for industry or business have a six-sigma level, which means that in such a process, fewer than 3.4 defects (or errors) occur per million products (Westgard, 2006a; Westgard, 2006b; Brussee, 2004). However, in the healthcare sector, the six-sigma level may not be adequate for many situations. For example, in blood banking or other critical medical services, an error may cause fatal or irreversible results. Thus, in medical services, the six-sigma level should not be accepted as the ultimate goal. We have to decrease the number of defects by as much as possible, and indeed, the sigma level should be higher than six. Our slogan should be 'zero defects.'



Fig. 1. Six Sigma may not be adequate for quality in healthcare sector

To calculate the sigma level of a laboratory, we have to determine the errors or defects and measure the performance of the unit or process in which we are interested. If you do not measure, you do not know, and if you do not know, you cannot manage. So Six Sigma shows us how to measure and, consequently, how to manage the laboratory.

In this chapter we will examine the Six Sigma methodology and its application to healthcare services, particularly laboratory medicine. We will also evaluate laboratory performance using sigma metrics.

2. Clinical Laboratories in the Healthcare Sector

One of the most important units of the healthcare sector, particularly in hospitals, is undoubtedly clinical laboratories. Obviously, without accurate test results, physicians cannot make diagnoses or provide effective treatment. This is true even for experienced physicians. Currently, clinical laboratories affect 60~70% of all critical decisions, such as the admission, discharge, and drug therapy of patients (Forsman, 1996). Based on our experience, we believe that this rate is even higher. Despite these vital functions, in the healthcare sector, laboratory costs are a very low proportion (5~10%) of the total cost of patient care (Forsman, 1996).

To be effective, clinical laboratories must be organized and accredited. Accreditation by independent non-profit organizations is indispensable for modern clinical laboratories. Accredited laboratories usually perform more than 500 different tests, and as many as 1500 tests may be performed in well-organized central laboratories. This means that the laboratory produces 1500 different products. This is very high in comparison with any industrial sector. Furthermore, the accuracy of each test (product) is vital because it is directly related to patient health. To obtain accurate test results, clinical laboratories are organized according to sub-disciplines such as clinical biochemistry, clinical microbiology, hematology, anatomical pathology, and genetics. Each sub-discipline may be organized further into sub-sub-disciplines. For example, clinical microbiology is further divided into immunology, virology, bacteriology, parasitology, and mycology. The organization scheme may differ from country to country and even from laboratory to laboratory. All these sub-disciplines increase the diagnostic power of laboratories, which are crucial for hospitals.

Despite the vital functions of clinical laboratories, healthcare managers have not paid adequate attention to them. In addition, healthcare administrators frequently manipulate laboratories. These interventions decrease the diagnostic and competitive power of laboratories relative to other medical services.

3. Total Testing Process

Total testing process is a multistep process that begins and ends with the needs of the patient (Barr, 1994). The number of steps may vary according to test types and laboratory organisation. We can describe nine activity steps in laboratory medicine:

1. Test selection and ordering a laboratory test request
2. Collecting the sample (seum, plasma, urine and so on)
3. Identification
4. Transport the sample to laboratory
5. Preparation of the sample
6. Analysis
7. Reporting test results
8. Interpretation of test results
9. Action

Historically in clinical laboratories, the total testing process was assumed to consist of only three phases:

1. Pre-analytical phase (step 2-5),
 2. Analytical phase (step 6), and
 3. Post-analytical phase (step 7).
- Further, the pre-analytical phase contain two sub-phases:
- a. Outside the laboratory (step 2-4) and
 - b. Within the laboratory (step 5).

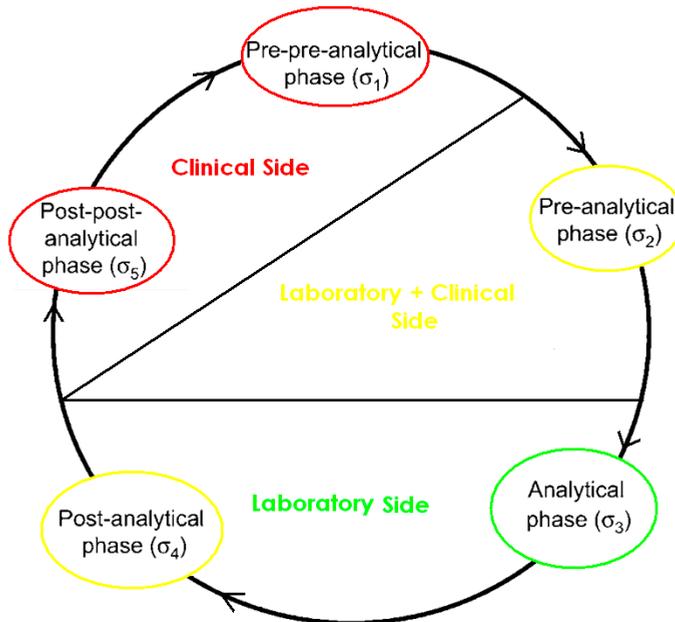


Fig. 2. Total testing process in modern clinical laboratories.

Currently this classical approach is not adequate for clinical laboratories. The total testing process begins when the patient is examined by a physician, and it ends when the patient leaves the hospital (Goldschmidt, 2002). To cover all steps in this cycle, currently we examined the total testing process in five phases. In addition to classical pre-analytical, analytical and post-analytical phases, pre-pre-analytical (step 1) and post-post-analytical phases (step 8 and 9) are also indispensable part of the total testing process. In the pre-pre-analytical phase, the physician decides which test(s) should be requested for the patient, and in the post-post-analytical phase, the physician interprets the test results. In daily practice items such as 'Pre-pre-' and 'post-post-' seem to be more abstract for many laboratory workers. Instead of these items we thought that the re-named of phases of total testing process which is listed below (Table 1) will be more useful. To evaluate laboratory performance, we must add the errors made in all phases of the total testing process.

Current names	Recommended names
Pre-pre-analytical phase	Clinical pre-analytical phase
Pre-analytical phase	Laboratory pre-analytical phase
Analytical phase	Analytical phase
Post-analytical phase	Laboratory post-analytical phase
Post-post-analytical phase	Clinical post-analytical phase

Table 1. Phases of total testin process. The names that we recommend is more meaningful and is not abstract

4. Errors in Laboratory Medicine

The report *To Err is Human: Building a Safer Health System* by Kohn *et al.* was a milestone in the history of quality and safety in the healthcare sector. The report stated, "Each year, more than 1 million preventable injuries and 44,000–98,000 preventable deaths occur in the United States alone" (Kohn, 2000). This report shocked many healthcare managers and officials, as they had not considered this reality. Furthermore, this report has broken the silence that has surrounded and masked medical errors. Since 1999, reducing medical errors and improving patient safety have become an international concern. The World Health Organization (WHO) has launched the World Alliance for Patient Safety (www.who.int/patientsafety) in response to increasing public and officials' awareness of this issue worldwide. In the United States, approximately 2 trillion dollars are spent on medical care each year, and the health standards are higher than in many other countries. Therefore, we postulate that preventable injury and death rates due to medical errors in many countries are higher than those in the United States.

To make a comparison, in 1999 (the year when the report was published), nobody died due to errors in the aviation sector in the United States. For healthcare managers, 1999 was a time when they had to accept reality. One of the main differences between the healthcare and aviation sectors is the application of quality assessment. Unfortunately, healthcare managers do not pay as much attention to quality assessment as do aviation managers. In the aviation sector, an error that has accident potential may mean the end of a company. The same is not true for a hospital. In addition, if a pilot makes a mistake that causes the plane to crash, he or she dies along with the passengers, but a doctor does not die when he or she kills a patient because of a mistake. To decrease medical errors to acceptable levels, physicians and other healthcare staff must periodically be strictly audited, both professionally and legally.

The reactions and approach of people to hospitals and aviation companies are quite different. The approach of people to hospitals is more psychological than logical. Community reactions to deaths in hospital and to deaths in accidents are not the same. The first may be accepted as an ordinary event, whereas this is not the case for an accident. Despite these realities, we cannot claim that adequate attention has been paid to quality in the healthcare sector. For example, Six Sigma quality management has been applied to almost all major industrial organizations since the mid-1980s. Unfortunately, as far as we know, no international hospital has applied Six Sigma quality management. This is partly due to the different types of work, services, and products produced in hospitals versus companies. However, despite all these differences, Six Sigma quality management can be

easily applied to any hospital because Six Sigma quality management has no restrictions or limits that are not suitable for hospitals or any healthcare organization (Westgard, 2006a; Nevalainen, 2000). Six Sigma quality management is universal and can be applied to all sectors easily.

How much are clinical laboratories responsible for medical errors? Unfortunately we have limited data about medical errors originating from clinical laboratories (Bonini, 2002; Plebani, 1997). General practitioners from Canada, Australia, England, The Netherlands, New Zealand, and the United States reported medical errors in primary care in 2005. For all medical errors, the percentage of errors originating from the laboratory and diagnostic imaging were 17% in Canada and 16% in the other reporting countries. For 16 of the reported errors (3.7%), patients had to be hospitalized, and in five cases (1.2%), the patients died (Rosser, 2005). This result shows that erroneous laboratory results are not innocent and can lead to the death of patients. Therefore, we have to examine the nature and causes of laboratory errors in detail and find realistic solutions.

We can classify errors as errors of commission and of omission (Bonini, 2002; Plebani, 2007; Senders, 1994). Today, many scientists focus on errors of commission, such as wrong test results and delayed reporting of results. Many physicians and laboratory managers believe that all errors are errors of commission. However, the reality is quite different. Errors of omission are the dark side of known errors, and we have to include this category of errors in the overall error concept. Sometimes errors of omission may be more serious and cause patient death. For example, if a physician cannot make a diagnosis and discharges a patient with cancer, diabetes, or a serious infectious disease such as hepatitis C virus (HCV) or human immunodeficiency virus (HIV) because of inadequate test requests, he/she commits a serious error, and the result may be catastrophic for the patient. Consequently, we cannot neglect errors of omission. Unfortunately, this is not easy because, due to their nature, errors of omission are hidden, and it is quite difficult to quantify them.

In contrast to errors of omission, errors of commission can be measured. But with errors of commission, we have a limited ability to measure all components of the errors because these errors are not homogenous, and we have no method for measuring the errors exactly in the pre- and post-analytical phases. It is clear that "if you cannot measure you do not know, and if you do not know you cannot manage." This side of errors in laboratory medicine is also a weakness in contemporary quality assessment.

Only when we can measure the errors of commission and of omission in clinical laboratories exactly and take prevention actions will it be possible for hospitals to compete with the aviation sector.

5. Quality Control in Laboratory Medicine

Quality-control principles that are currently being applied in laboratory medicine originated in industry, and the philosophy behind them is also industry based (Westgard, 2006a; Westgard, 2006b; Westgard, 1991). These principles were developed with regard to industrial, rather than medical, requirements. Consequently, the goals and problem-solving methods are not appropriate to the healthcare sector. Despite this, the application of quality assessment in laboratory medicine has dramatically increased the reliability of test results and the diagnostic power of clinical laboratories.

Within the five phases of the total testing process, quality-control rules, especially statistical ones, are applied properly only in the analytical phase, especially because it is much easier to apply statistical quality principles to machines and data than to people. No written quality principles have been issued by the IFCC or any other international laboratory organization for the pre-analytical or post-analytical phases. In these two phases, personal or organizational experience is more commonly a guide than are written principles. For the pre-pre-analytical and post-post-analytical phases, no quality rules are imposed to prevent errors. In fact, in these phases, we do not even *know* the error rates in detail. However, according to a limited number of studies, the error rates in these two phases are much higher than those in other phases of the total testing process (Goldschmidt, 2002).

Quality management means more than statistical procedures; it involves philosophy, principles, approaches, methodology, techniques, tools, and metrics (Westgard, 2006b). Without the physician's contribution, it is impossible to solve all the problems originating from laboratories (Coskun, 2007). In fact, laboratory scientists can solve only problems of the analytical and, to a degree, the pre-analytical and post-analytical phases. The pre-analytical and post-analytical phases are the gray side, and the pre-pre- and post-post-analytical phases are the dark side of clinical laboratories.

It is easier to apply quality principles to clinical laboratories than to other clinical services, such as surgery and obstetrics and gynecology, because laboratory scientists use technology more intensively than do other medical services. However, even within clinical laboratories, we cannot apply quality principles to all sub-disciplines equally. For example, we can apply quality principles to clinical biochemistry or hematology quite readily, but the same thing cannot be done for anatomical pathology. Consequently, the error rate in anatomical pathology is higher than that in clinical biochemistry.

Errors in analytical phases have two main components: random and systematic errors. Using these two components, we can calculate the total error of a test as

$$TE = \text{Bias} + 1.65CV \quad (I)$$

where TE is total error, bias and CV (coefficient of variation) are the indicator of systematic and random errors respectively (Westgard, 2006b, Fraser, 2001).

For the pre- and post-analytical phases, we can prepare written guidelines and apply these principles to clinical laboratories. Then, we can count the number of errors within a given period or number of tests. For the pre-pre- and post-post-analytical phases, we do not have the experience to prepare guidelines or written principles. However, this does not mean that we can do nothing for these two phases. Laboratory consultation may be the right solution (Coskun, 2007).

6. Six Sigma in Laboratory Medicine

The sources of medical errors are different from those of industrial errors. To overcome the serious errors originating in clinical laboratories, a new perspective and approach seem to be essential. All laboratory procedures are prone to errors because in many tests, the rate of human intervention is higher than expected. It appears that the best solution for analyzing problems in clinical laboratories is the application of Six Sigma methodology.

In the mid-1980s, Motorola, Inc. developed a new quality methodology called "Six Sigma." This methodology was a new version of total quality management (TQM) (Deming, 1982), and its origins can be traced back to the 1920s. At that time, Walter Shewhart showed that a three-sigma deviation from the mean could be accepted without the need to take preventive action (Shewhart, 1931). For technology in the 1920s, a three-sigma deviation may have been appropriate, but by the 1980s, it was inadequate. Bill Smith, the father of Six Sigma, decided to measure defects per *million* opportunities rather than per *thousand*. Motorola developed new standards and created the methodology and necessary cultural change for Six Sigma (Westgard, 2006a; Harry, 2000). Due to its flexible nature, since the mid-1980s, the Six Sigma concept has evolved rapidly over time. It has become a way of doing business, rather than a simple quality system. Six Sigma is a philosophy, a vision, a methodology, a metric, and a goal, and it is based on both reality and productivity.

Regrettably, we cannot say that Six Sigma methodology is being applied to the healthcare sector as widely as it is to business and industry more generally. However, we do not suggest that this is due to shortcomings in Six Sigma methodology. Based on our experience, we suggest that it is due to the approaches of healthcare officials. Within medical disciplines, *laboratory* medicine is the optimal field for the deployment of Six Sigma methodology.

Total quality management was popular by the 1990s, and its application in clinical laboratories is well documented (Westgard, 2006a; Westgard, 1991; Berwick, 1990). The generic TQM model is called "PDCA": plan, do, check, and act. First, one must *plan* what to do, and then *do* it. The next step is to *check* the data, and in the last step, *act* on the results. If this does not achieve a satisfactory result, one must *plan* again and follow the remaining steps. This procedure continues until the desired result is obtained.

The Six Sigma model is similar to TQM. The basic scientific model is "DMAIC": define, measure, analyze, improve, and control. In comparison with TQM's PDCA, we can say that define corresponds to the *plan* step, measure to the *do* step, analyze to the *check* step, and *improve* to the *act* step. The Six Sigma model has an extra step, *control*, which is important in modern quality management. With this step, we intend to prevent defects from returning to the process. That is, if we detect an error, we have to solve it and prevent it from affecting the process again. With this step, we continue to decrease the errors effectively until we obtain a desirable degree of quality (Westgard, 2006a; Gras, 2007).

Six Sigma provides principles and tools that can be applied to any process as a means to measure defects and/or error rates. That is, we can measure the quality of our process or of a laboratory. This is a powerful tool because we can plan more effectively, based on real data, and manage sources realistically.

Sigma Metrics

The number of errors or defects per million products or tests is a measure of the performance of a laboratory. Sigma metrics are being adopted as a universal measure of quality, and we can measure the performance of testing processes and service provision using sigma metrics (Westgard, 2006a).

Usually, manufacturers or suppliers claim that their methods have excellent quality. They praise their instruments and methods, but the criteria for this judgment frequently remain vague. Furthermore, in the laboratory, method validation studies are often hard to interpret. Many data are generated that can be used; many statistics and graphs are produced. Nevertheless, after all this laborious work, no definitive answer about the performance of

the method is available. Although many things remain to be improved, statistical quality control procedures have significantly enhanced analytical performances since they were first introduced in clinical laboratories in the late 1950s. Method validation studies and application of quality control samples have considerably reduced the error rates of the analytical phase (Levey, 1950; Henry RJ, 1952). A simple technique that we can use in our laboratories is to translate the method validation results into sigma metrics (Westgard, 2006a; Westgard, 2006b). Performance is characterized on a sigma scale, just as evaluating defects per million; values range from 2 to 6, where "state of the art" quality is 6 or more. In terms of Six Sigma performance, if a method has a value less than three, that method is considered to be unreliable and should not be used for routine test purposes. A method with low sigma levels would likely cost a laboratory a lot of time, effort, and money to maintain the quality of test results. Sigma metrics involve simple and minimal calculations. All that is necessary is to decide the quality goals and calculate the method's imprecision (CV, coefficient of variation) and bias levels as one would ordinarily do in method validation studies. Then, using the formula below, the sigma level of the method in question can readily be calculated:

$$\text{Sigma} = (\text{TE}_a - \text{bias})/\text{CV} \quad (\text{II})$$

where TE_a is total error allowable (quality goal), bias and CV (coefficient of variation) are the indicator of systematic and random errors respectively.

For example, if a method has a bias of 2%, a CV of 2%, and TE_a of 10%, the sigma value will be $(10-2)/2 = 4$. This calculation needs to be done for each analyte at least two different concentrations.

Evaluation of Laboratory Performance Using Sigma Metrics

Although the activities in laboratory medicine are precisely defined and therefore are more controllable than many other medical processes, the exact magnitude of the error rate in laboratory medicine has been difficult to estimate. The main reason for this is the lack of a definite and universally accepted definition of error. Additionally, the bad habits of underreporting errors and insufficient error-detection contribute to the uncertainty in error rates. The direct correlation between the number of defects and the level of patient safety is well known. However, number of defects alone means little. It is important to classify the defects first, and then to count the number of defects and evaluate them in terms of Six Sigma.

There are two methodologies and both are quite useful in clinical laboratories to measure the quality on the sigma-scale (Westgard, 2006a). The first one involves the inspecting the outcome and counting the errors or defects. This methodology is useful in evaluation of all errors in total testing process, except analytical phase. In this method, you monitor the output of each phase, count the errors or defects and calculate the errors or defect per million and then convert the data obtained to sigma metric using a standard Six Sigma benchmarking chart (Table 2). The second approach is useful especially for analytical phase. To calculate the sigma level of the process as described in equation (II) we have to measure and calculate some variables: bias (systematic errors), imprecision (CV, random errors) and total error allowable.

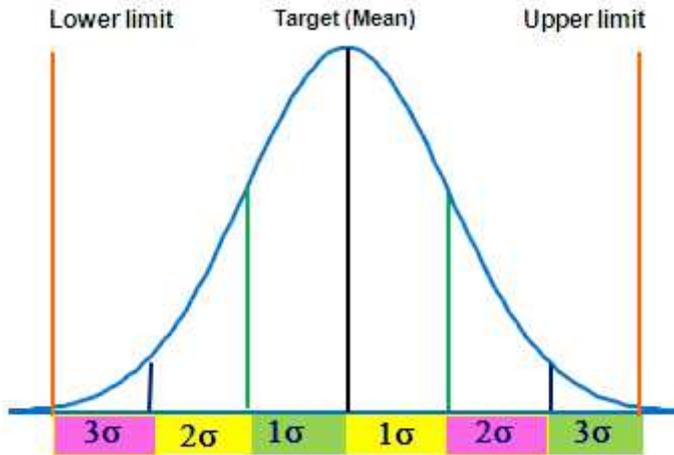


Fig. 3. A 3 sigma process.

The laboratory is responsible for the whole cycle of the testing process, starting from the physician's ordering a laboratory investigation to the use of the test results on behalf of the patient. To find realistic and patient based solution, total testing process, mentioned above, are examined in five main steps: pre-pre-analytical-, pre-analytical-, analytical, post-analytical and post-post-analytical phases (Figure 1). We can also analyze each step in detail. For example pre-analytical processes to be monitored include patient preparation, specimen collection, labeling, storage, transportation, rejection, and completeness of requisitions. The errors in each step can be monitored and consequently the performance of the step can be calculated.

The error rate in each step is quite different. For example the average error rates for the preanalytical, analytical, and post-analytical phases were reported by Stroobants and Goldschmidt as 2.0% (Stroobants, 2003), 0.2% (Stroobants, 2003), and 3.2% (Goldschmidt, 2002) respectively. However the average error rates in pre-pre- and post-post-analytical phases are very high (Bonini, 2002; Stroobants, 2003; Dighe, 2007). Stroobants and co-workers reported that, in the pre-pre- and post-post-analytical phases the average error rate are approximately 12% and 5% respectively (Stroobants, 2003). Among all the phases of a testing process, the analytical phase presents the lowest number of possible errors. Now if we calculate sigma level for only analytical phase we'll obtain 4.4 sigma for a 0.2% error rate which initially appear to be adequate. However this value does not reflect the reality and even mask it. Because analytical phase is not represent the total testing process and it is only a part of total testing process. However in many clinical laboratories, only analytical errors are taken into account and the laboratory performance are calculated usually based on only error rates in analytical phase. Consequently sigma is calculated for the analytical phase of a testing process. In this situation the laboratory manager may assume that the performance of laboratory is acceptable and he/she may not take any preventive actions but the reality is quite different.

The total error frequency of each phase must be calculated separately, and then expressed as error per million (epm) (Coskun, 2007). It should be noted that the characteristics of errors in all phases of total testing process are not homogenous. For example errors in the analytical

phase show a normal distribution, whereas errors in other phases are binomially distributed. For this reason, errors in each phase of the total testing process should be treated as binomially distributed and summed. Then the total errors calculated for the total testing process can be converted to sigma levels using the standard Six Sigma benchmarking chart (Table 2) (Coskun, 2007).

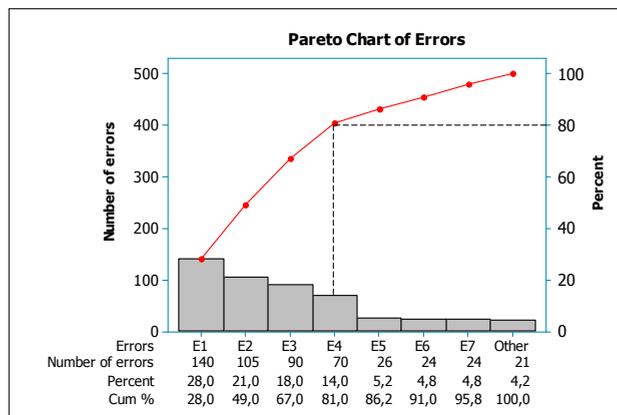


Fig. 4. Pareto chart. The chart was prepared for the source of 10 different errors. In the figure 80% of problems stem from only 4 sources.

The errors in clinical laboratories may originate from several sources. In this situation it is not cost effective and logical to deal with all error sources. Because, there may be numerous trivial sources of errors. Instead, we should deal with the sources which cause more errors. For this purpose we should use Pareto Chart to decide the most significant causes of errors (Nancy, 2004). According to Pareto principle 80% of problems usually stem from 20% of the causes and this principle is also known as 80/20 rule. Thus if we take preventive action for 20% major sources of errors then 80% of errors will be eliminated (Figure 4).

Sigma Metric	Defects per million
1.0	698,000
2.0	308,000
2.5	159,000
3.0	66,800
3.5	22,750
4.0	6,210
4.5	1,350
5.0	233
5.5	32
6.5	3.4

Table 2. Sigma value of defects per million products or tests

To estimate the sigma level of errors, a trustworthy (reliable) technique to collect data is needed. Feedback from persons involved in any part of this cycle is crucial. The main point in collecting data is to encourage staff to acknowledge and record their mistakes. Then, we

can count the mistakes; turn them into sigma values by calculating defects per million, and start to take preventive actions to prevent the same mistakes being repeated.

7. Lean Concept

In recent years, special emphasis has been placed on enhancing patient safety in the healthcare system. Clinical laboratories must play their role by identifying and eliminating all preventable adverse events due to laboratory errors to offer better and safer laboratory services. All ISO standards and Six Sigma improvements are aimed at achieving the ultimate goal of zero errors. The main idea is to maximize "patient value" while reducing costs and minimizing waste. The "lean concept" means creating greater value for customers (i.e., patients, in the case of laboratories) with fewer resources. A lean organization focuses on creating processes that need less space, less capital, less time, and less human effort by reducing and eliminating waste. By "waste," we mean anything that adds no value to the process. Re-done tasks, transportation of samples, inventory, waiting, and underused knowledge are examples of waste. One of the slogans of the lean concept is that one must "do it right the *first* time." Lean consultants start by observing how things work currently, and they then think about how things can work faster. They inspect the entire process from start to finish and plan where improvements are needed and what innovations can be made in the future. Finally, they subject this to a second analysis to find ways to improve the process. Lean projects can generate dramatic reductions in turnaround times as well as savings in staffing and costs. It is said that 'Time is money.' However, in laboratory medicine, time is not only money. Apart from *correct* test results, nothing in the laboratory is more valuable than rapid test results. The turnaround time of the tests is crucial to decision making, diagnoses, and the earlier discharge of patients. Although Six Sigma, and the lean concept look somewhat different, each approach offers different advantages, and they do complement each other. The combination of Lean with Six Sigma is critical to assure the desirable quality in laboratory medicine for patients benefit and safety.

Taken together, Lean Six Sigma combines the two most important improvement trends in quality science: making work better (using Six Sigma principles) and making work faster (using Lean Principles) (George, 2004).

8. Laboratory Consultation

The structure of laboratory errors is multi-dimensional. As mentioned previously, the total testing process has five phases, and errors in each phase contribute to errors in test results. Laboratory scientists predominantly focus on the analytical phases. Similarly, physicians focus on pre-pre-analytical and post-post-analytical phases. Errors of omission primarily occur in the pre-pre-analytical phase. A large proportion of errors of commission also occur in the pre-pre- and post-post-analytical phases. To decrease laboratory errors efficiently, consultation and appropriate communication are crucial (Coskun, 2007; Witte, 1997; Jenny, 2000).

Physicians, laboratory scientists or managers alone cannot overcome all laboratory errors. Errors outside laboratories which are the biggest part of total errors result from a lack of interdepartmental cooperation and organizational problems. As mentioned above the highest error rates in total testing process occur in pre-pre- and post-post-analytical phases.

If we improve the communication between the laboratory and clinicians we may solve laboratory errors efficiently and consequently increase the performance of the laboratory. We should identify key measures to monitor clinical structures, processes, and outcomes. In addition to clinicians, laboratory scientists need help of technicians for laboratory information system and other technical subjects. The error rates in the post-analytical phase have also been significantly improved by the widespread use of laboratory information systems and computers with intelligent software.

9. Conclusions

To solve analytical or managerial problems in laboratory medicine and to decrease errors to a negligible level, Six Sigma methodology is the right choice. Some may find this assertion too optimistic. They claim that Six Sigma methodology is suitable for industry, but not for medical purposes. Unfortunately, such claims typically come from people who never practiced Six Sigma methodology in the healthcare sector. As mentioned previously, if we do not measure, we do not know, and if we do not know, we cannot manage. The quality of many commercial products and services is very high because it is quite easy to apply quality principles in the industrial sector. Regrettably, currently, the same is not true in medicine. Unfortunately, people make more errors than machines do, and consequently, if human intervention in a process is high, the number of errors would also be expected to be high. To decrease the error rate, we should decrease human intervention by using high-quality technology whenever possible. However, it may not currently be possible to apply sophisticated technology to all medical disciplines equally; however, for laboratory medicine, we certainly have the opportunity to apply technology. If we continue to apply technology to all branches of medicine, we may ultimately decrease the error rate to a negligible level.

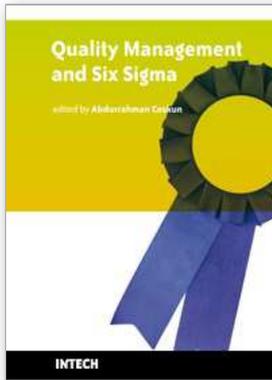
Six Sigma is the microscope of quality scientists. It shows the reality and does not mask problems. The errors that we are interested in are primarily analytical errors, which represent only the tip of the iceberg. However, the reality is quite different. When we see the whole iceberg and control it all, then it will be possible to reach Six Sigma level and even higher quality in clinical laboratories.

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If you do not measure, you do not know, and if you do not know, you cannot manage. Modern Quality Management and Six Sigma shows us how to measure and, consequently, how to manage the companies in business and industries. Six Sigma provides principles and tools that can be applied to any process as a means used to measure defects and/or error rates. In the new millennium thousands of people work in various companies that use Modern Quality Management and Six Sigma to reduce the cost of products and eliminate the defects. This book provides the necessary guidance for selecting, performing and evaluating various procedures of Quality Management and particularly Six Sigma. In the book you will see how to use data, i.e. plot, interpret and validate it for Six Sigma projects in business, industry and even in medical laboratories.

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