Evaluating Performance of Testing Laboratory using Six Sigma

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Abstract *— Ensuring quality of testing Laboratory services plays an important role in the field of health care. Acknowledging the revolution occurred by Six Sigma concept in corporate world, Health care sector can also be benefited by the application of the same. Six Sigma contributes a general procedure to explain the performance on sigma scale. Six Sigma is currently being deployed in several laboratories around the world. Despite this situation, few articles have been published in the peer-reviewed literature on this subject. The aim of this article is to evaluate performance of testing Laboratory using Six Sigma and to clarify the different aspects of Six Sigma and their potential applications in clinical laboratories, as well as to discuss Six Sigma strategy implementation in the laboratory field.*

Keywords *— Six sigma, Health care Services, Critical success factors, Performance measures, Clinical laboratories, DPMO, Institute of Medicine (IOM), Quality control, Sigma Metrics, Six Sigma*

I. INTRODUCTION

The concept of quality management in Testing Laboratory remains an evergreen discussion, As many decisions regarding Clinical sector, Engineering sector and Environment are to be taken using test results from Testing Laboratories. Testing Laboratory is classified into three categories namely, Clinical, Engineering and Environmental.

Considering Health care sector, Clinical Laboratories plays a vital role in decision making. A study by the Institute of Medicine reports annual preventable death of 44,000- 98,000 in USA alone (Coskun 2010).Among healthcare services, clinical laboratory services remain important as around 70% of the patient related decision are based on the clinical laboratory (Tamer Inal 2010).The total testing procedure is divided into preanalytical, analytical and postanalytical phase. Estimated error rate in the three phases are 30-75% for preanalytical, 4-30% for analytical, and 9-55% for postanalytical phase (Shah S 2014)Hence stringent quality control in testing laboratory will improve patient care.

Six Sigma methodology is a manufacturing strategy first pioneered by Motorola Company in 1980s, with the goal of decreasing the defect rates in production. It has improved the production efficiency of different industries. To achieve the similar high quality and near zero defect rates in healthcare system, six sigma metrics is being used in many clinical laboratories and diagnostic industry. The goal is to attain the highest possible sigma scale within the acceptable limits of total allowable error. This article reviews the basic principles of Six Sigma methodology & their practical utility in the Testing laboratory.

A. What is Six Sigma?

Six Sigma is a management policy that explores to improve the quality of process outputs by analysing and abolishing the source of defects (errors) and reducing variability in manufacturing and business practices. It is precise approach to cut down the existing errors or mistakes in terms of defects per million (DPM).

Six Sigma is a business management approach used to improve the quality and efficiency of operational processes. Six Sigma aims essentially to make operation more reliable and accurate through the utilization of statistical methods.

Six Sigma was initially developed by Bill Smith of Motorola in 1986 for eradicating defects in manufacturing. This defect is explained to be a process or product which fails to meet customers' requirements and expectations.

The term Six Sigma is defined as the near perfect defect rate of 3.4 defects per million opportunities. As a process improvement strategy, Six Sigma A variety of systematic methodologies for identifying, assessing and improving processes have been developed as part of the Six Sigma approach. The Six Sigma improvement model, *Define,Measure, Analyze, Improve, and Control*

(DMAIC) specifies the following sequence of steps for understanding and improving a process: 1) defining the project goals and customer (internal and external) requirements; 2) measuring the process to determine current performance; 3) analyzing and determining the root cause(s) of relevant defects; 4) improving the process by eliminating defect root causes, and 5) controlling future process performance.

In application to Laboratories, Six sigma provides the manner to make fewer mistakes in all processes (filling in an order form to the most complex analytical process and report delivery) by removing errors before they appear.

B. Six Sigma as a Metric (σ)

Six Sigma as a metric is defined as a statistical measure of capability of a process, it is a metric that expresses how well a process is performing. A higher sigma means higher performance.

A sigma metric is calculated by finding out number of defects produced per million opportunities. This can be converted to a sigma metric by comparing with normal Gaussian distribution. As per Gaussian distribution 0.682689 % of the distribution falls within one standard deviation, implying 0.317310 % of the data outside the one standard deviation range. Multiplying by 1,000,000(1million) gives a value of 317,310 defects per 1 million opportunities, which corresponds to tolerance limits of one standard deviation, or a 1 σ process.

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. Table I shows the chart having sigma metric and its corresponding DPM.

Table I. Sigma Value of Defects per Million Products or Tests

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

II. GROWING IMPORTANCE OF TESTING LABORATORIES

Testing Laboratories are employed by all types of businesses to contribute objective analytical data on the quality of a process or a product. Some association gets their product certification from testing labs, which can be critical marketing tool, while others examine the results of employee drug tests. Still additional companies uses testing laboratories for checking soil and water quality before making a major land or facility purchase. Testing laboratories are proving themselves helpful to business (industry sectors).

Over the last few decades the size and number of testing laboratories in many industrialized nations have increased significantly. According to researchers this rise in growth is just because of the rise in product testing. According to an executive of testing industry, the demand for testing and certification is increasing due to diversity in products, growth in consumer demand and the globalization of sourcing. With these product analysis factors, there are various key factors which are responsible for increased dependence on external testing labs.The increasing cost of product liability insurance has encouraged many companies to employ testing labs to settle-up unique or upgraded products prior to general launch. Small to mid-sized companies usually look forward to independent labs to handle their quality control department. For preserving proportionate facilities in-house, testing laboratories have considered this role with small companies. Finally for securing autonomous results in fields of quality control and failure analysis results many big companies are also trying their luck.

At last, it is important that testing laboratories focuses themselves only to a particular testing area. For instance, a company that administers analysis of employee drug tests will hardly propose services in the realm of environmental analysis; alike, a company that conducts tests on soil or water will not be of use to a small business owner who is seeking product quality testing services.

III. QUALITY PROBLEMS FACED BY TESTING LABORATORY

According to the report of the Institute of Medicine, each year in the USA, approximately 98,000 people die from medical errors Coskun (2010). Unfortunately, more people have died each year during mid-1990s from medical errors than from AIDS or breast cancer Tamer Inal (2010).Regardless of this position; we are not in a condition to say that enough concentration has been paid to the development of high standards in the sector of health care to efficiently prevent medical errors. In industry, Modern quality control has been applied effectively for preventing errors and producing high quality goods. Therefore, as a result of these continuous efforts rate of errors has stopped to a negligible level.

Unfortunately, this case is not same for medical services, because the defects and errors produced by components are in large number as compared to any industrial or business sectors.
In spite of these facts, the quality of medical services plays a vital role as compared to quality of other goods. Therefore, Professionals involved in healthcare sector must pay attention to quality than any other professionals involved in industry. Among healthcare services, clinical laboratories are particularly important because physicians make their decisions mostly in accordance with laboratory results Coskun (2010). In this situation, precise test results are mandatory for physicians and their patients. Before any other dimension of quality becomes necessary, testing laboratory should be able to produce precise results. From this point of view, the evaluation of laboratory performance is critical to maintaining accurate laboratory results Coskun (2010).

In clinical laboratories, the total testing processes is divided into three phases:

pre-analytical, analytical, and post-analytical phases. These phase are having some percentage of errors which is shown in Fig 1. However, the selection and interpretation of tests are also prone to errors and must be considered in the total testing process. 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. Clinical Laboratories plays a vital role in Healthcare sector. It is but obvious that Physicians are in need of precise test results to make their decision regarding effective treatment and diagnosis. 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 Tamer Inal (2010). 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 Ibrahim Unsal (2010). 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.

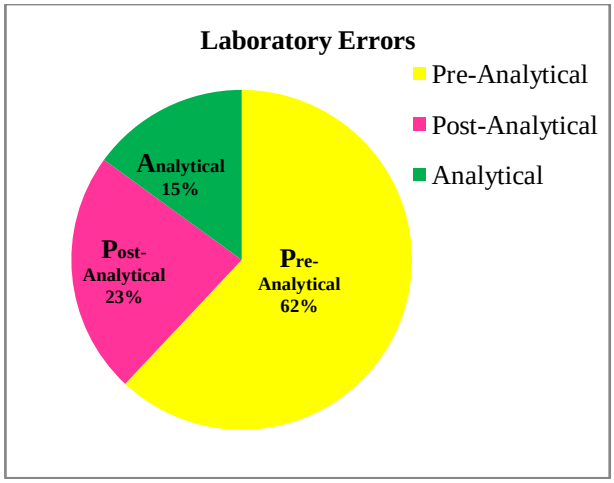

Fig. 1: Sources of Laboratory errors

IV. CLASSIFICATION OF LITERATURE ON CONTRIBUTION TO RESEARCH BY VARIOUS RESEARCHERS

The table II below gives the Researcher name, the year of research and contribution to research. The referred name on the left most column indicates the name by which the publication has been referred in the rest of the review paper. The Researchers have provided their contribution to their area of research; based on this contribution we will be validating our area of study i.e application of six sigma in testing laboratories.
As per Researcher E, Six sigma provides tools and principles, which can be applied to any process in order to measure error rates and defects; Researcher F depends on Quality Indicators which play an important role in comparing individual laboratory performance in order to improve quality in laboratory. At the end Researcher I conveys that quality control processes like Statistical process control and process capability analysis as a part of six sigma project can be applied effectively in healthcare service.
From table II it is observed that a countable research work has been done by various researchers in the field of application of six sigma in healthcare sector; It is seen that six sigma is contributing to laboratory by improving its quality.

TABLE 2. CLASSIFICATION OF LITERATURE ON CONTRIBUTION TO RESEARCH BY VARIOUS RESEARCHERS

Researcher Name	Year	Contribution to Research
A	2000	Quality system solutions for performance improvement may provide a systematic approach to improving laboratory performance.
B	2004	Six Sigma is far more than a quality metric; it is a strategy for decision-making, process improvement, and problem resolution.

C	2007	Lean with its 5S concepts (Sort, Simplify, Scrub, Standardize, Sustain) associated with Six Sigma provides a structured methodology to achieve a strategy that can reduce cycle times and process variations.
D	2009	Sigma Metric analysis provides not only an objective assessment of analytical methods and instrumentation, but it also provides the critical design information needed for operational implementation.
E	2010	Six Sigma provides principles and tools that can be applied to any process as a means to measure defects and/or error rates.
F	2010	Quality Indicators plays a vital role in the comparison of individual laboratory performance with the aim of improving laboratory quality.
G	2011	There is need for detailed evaluation and adoption of ameliorative measures in order to effectuate six sigma standards for all the analytical processes.
H	2014	Six sigma as a business strategy allows health care sector to deliver a truly high-class service to patients. The application of six sigma in health care industry will continue to grow
I	2014	Statistical process control and process capability analysis as a part of six sigma project can be applied effectively in healthcare service
J	2015	The application of Six Sigma DMAIC methodology reduces patient dissatisfaction regarding healthcare facility, service providers etc. along with optimization of healthcare cost.

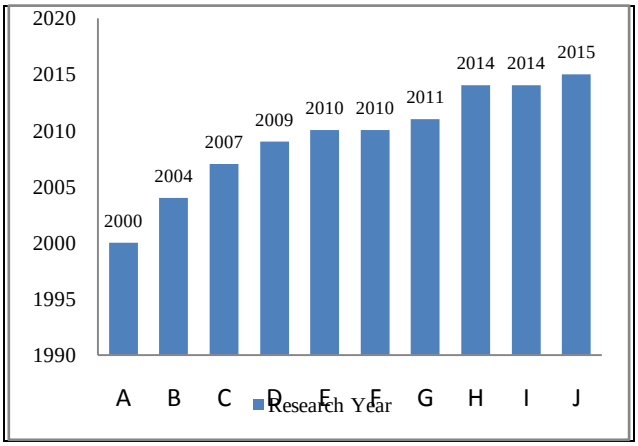

Fig. 2: Year wise classification of literature

Fig2 is a graph showing Researcher Vs Year of Research. In this, Research from year 2000 till year 2015 in the field of quality in testing laboratory is considered. From this graph it is observed that Research shows an increasing trend from 2000 till 2015. Also it shows a gap between year (2000 &2004), (2004& 2007), (2007&2009) and (2011&2014). Research work has taken its momentum from year 2010 and shows continuous trend of increase. As considerable research is being continuously propagated from last 15 years, Application of Six sigma in laboratory is catching its popularity as research topic in the recent trends.

V. PROBLEMS IN IMPLEMENTATION OF SIX SIGMA IN TESTING LABORATORIES

There are several challenges and obstacles under the surface of testing laboratory which are to be considered before application and deployment of six sigma strategies. Firstly the important challenge is the initial investment in Six Sigma belt program (training), secondly the difficulty or absence in obtaining baseline data on process performance. There will be considerable amount of data available in testing laboratories; the problem is that these data are not readily available for its analysis.

For testing laboratory, it is difficult or hard tries to identify samples and processes which can be converted or measured with respect to error or defects per million opportunities. Other challenges to six sigma deployment in health care industry are about the psychology of workforce and issues in organizational culture. End of the day, it is important to communicate recommendations using languages in terms of business rather than statistical.

Issues in strategy

Y.H. Kwak and F.T. Anbari, (2004) argued that six sigma has been the target of criticism and controversy in the quality community characterizing it as 'Total Quality Management on Steroid'. One of the main criticisms is that six sigma is nothing new and simply repackages traditional principles and techniques related to quality F.T. Anbari (2004).Management should understand that Six sigma is not an universal approach for each and every business issues, For long term adaptation and feasibility of six sigma method, organization need to consider and analyze its strength, weakness, application steps, concept, principles and tools.

Issues in organizational culture

Quality concepts need to be embedded into the process of designing rather than just monitoring the quality at the manufacturing level Y.H. Kwak, (2004).Change in Organizational Culture plays an important role with

regards to quality of planning. Success rate depends upon the complete and clear understanding of obstacles of six sigma projects. Senior management's strong commitment, leadership and support are essential factors in dealing with any cultural issues related to implementation of six sigma. Without fulfilling these factors, organization should not think for adopting six sigma.

Issues in training (Belt Program)

Training is an important part for favorable implementation of six sigma projects. This should start from top management and should be followed in entire organization. The content of belt program should reproduce the requirement and needs of the organization. It should be framed in a way to fulfill managerial and economic benefits. The curriculum of Training should reflect quantitative, qualitative measures and metrics, skills, leadership, and project management practices. For developing various belt level experts, formal training plays an important role. Participants should have knowledge regarding tools, techniques and latest trends of six sigma and communicate with actual data analysis.

VI. Proposed methodology for performance evaluation of Testing Laboratories

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. The second approach is useful especially for analytical phase. To calculate the sigma level of the process as described in equation (I) we have to measure and calculate some variables: bias (systematic errors), imprecision (CV, random errors) and total error allowable.

To apply Sigma Metrics for quality assessment of laboratory processes, there are two methodologies that are useful:

• For pre-analytic and post-analytic processes, count the number of defects in a group, calculate the defects per million (DPM), then utilize a standard table to convert DPM to the sigma value.

• For analytic processes whose performance characteristics are known, i.e., whose precision (s) and accuracy (bias) can be estimated directly from experimental data, define the "tolerance limit" in the form of an allowable total error, TEa, such as specified in the CLIA proficiency testing criteria for acceptable performance, and calculate the sigma from the following equation:

$$\text{Sigma} = (\text{TEa} - \text{bias})/s \quad \text{..... (I)}$$

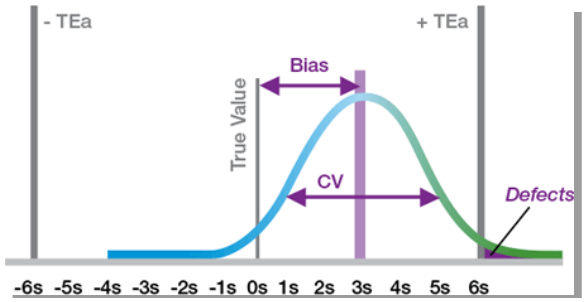

Fig 3. Visual representation of the Six Sigma metric. Results that fall outside TEa are considered defects.

After proposed methodology for performance evaluation, there is a need of model of Six Sigma approach to Testing Laboratory for performance evaluation. The following fig 3 shows the model for same, having some important steps for performance evaluation in testing laboratories.

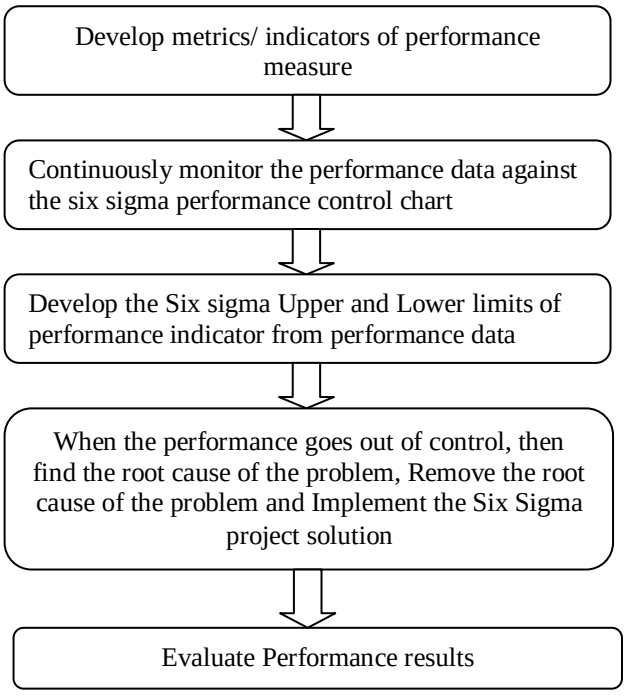

Fig 4. A model of Six Sigma approach to Testing Laboratory performance evaluation

VII. Use of Six Sigma metrices for Testing Laboratories

Six Sigma is a widely-accepted quality management system, perhaps best known outside of healthcare as the product of innovation at General Electric and Motorola. Six Sigma has been adopted by manufacturing and service industries, as well as healthcare institutions from hospitals to reference laboratories. Six Sigma is a metric that quantifies the performance of processes as a rate of Defects-Per-Million Opportunities, (DPM, or DPMO). Six Sigma programs also encompass robust techniques such as Define-Measure-Analyze- Improve-Control (DMAIC) and Root Cause analysis to find and eliminate defects and variation within a process. The goal of Six Sigma, in its simplest distillation, is to eliminate or reduce all variation in a process.

The Six Sigma scale typically runs from zero to six, but a process can actually exceed Six Sigma, if variability is sufficiently low as to decrease the defect rate. In industries outside of healthcare, 3 Sigma is considered the minimal acceptable performance for a process. When performance falls below 3 Sigma, the process is considered to be essentially unstable and unacceptable.

VIII. Performance Criteria for Testing Laboratories

Many Laboratorians today are in view that error are normal and can be accepted up to several percent, after converting this error into defects or number of affected patients per million creates another new perspective with regards to quality control. Due to this reason quality in Testing laboratories have become main area of concentration. Therefore, Evaluation of Testing Laboratory is mandatory in Health Sector. There are many performance criteria for testing Laboratories.

Proficiency Testing: In proficiency testing four results out of five must be within the performance specifications; this is a minimum requirement for acceptable proficiency testing under CLIA ’88. 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 Carl, (2004). The same report showed that PT performance in all other laboratories was 91% satisfactory, which is equivalent to 2.8 Sigma. Nevalainen et al., (2000) 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: Quality control is a statistical process to have a careful watch and to judge the analytical system.Its results are used to approve whether the system is working within the predefined conditions and to know whether the patients’ tests results are correct or not. There are basically two types of schemes – internal quality control (IQC) and external quality control (EQC). IQC ensures a continuous watch of the analytical system, so as to check whether the results are reliable enough to be released. Control charts like Levey Jennings chart and Westgard’s rules are applied on daily QC data. External quality control involves analysing and reporting of control samples supplied by an external agency, at a predefined time interval of a fortnight or a month. The external supplier of the QC sample studies the results of all the participating laboratories and then provides feedback to all Shah, (2014).The participating laboratories are divided in groups according to the analytical method and instruments used. This is followed by calculation of mean and standard deviation for a particular group and is referred to as consensus mean and standard deviation. Individual laboratory’s performance is judged by comparing the mean, standard deviation and CV (coefficient of variation) with consensus mean, standard deviation and CV.

Sigma Metrics: Performance of a testing laboratory is a measure of number of errors or defects per million products or tests. Sigma metrics are being accepted as a universal measure of quality, and we can measure the performance of testing processes and service provision using sigma metrics Coskun,(2007). 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 (Tamer, 2007). A simple technique that we can use in our laboratories is to translate the method validation results into sigma metrics Ibrahim, (2007). Performance is characterized on a sigma scale, just as evaluatingdefects 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:

$$\text{Sigma} = (\text{TEa} - \text{bias})/\text{CV}$$

where TEa 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 TEa of 10%, the sigma value will
be (10-2)/2 = 4.

Lean: Lean (also known as Lean Production, Lean Enterprise, and Lean Thinking) involves a set of principles, practices and methods for designing, improving and managing processes. The development of Lean is attributed to Taiichi Ohno's articulation of the Toyota Production System. Allard E (2009) aimed to improve efficiency by eliminating particular kinds of waste (called *muda*, in Japanese) which absorb time and resources but do not add value. Examples include mistakes which need rectification, unneeded process steps, movement of materials or people without a purpose, unnecessary waiting because upstream activity was not delivered on time, and the creation of goods or services that are not really needed by end users. Sharon A. (2009) A Lean process reflects the goal of continually reducing waste and improving work flow to efficiently produce a product or service that is perceived to be of high value to those who use it. Implementation of Lean involves systematic process assessment and analysis. The preliminary stages of Lean assessment include "value stream mapping" in which key people, resources, activities and information flows required to deliver a product or service are made explicit and depicted graphically. The value stream map is a key tool for identifying opportunities to reduce waste and more tightly integrate process steps, thus improving process efficiency.

CONCLUSION

This research demonstrates that many Laboratory staff report SS/LSS applications. The DMAIC method is widely used to implement SS. Although Six Sigma has been successfully applied to many high level manufacturing companies, its application in healthcare sector is still in its starting stage. Clinical laboratories associated with healthcare sectors are another area which could be benefitted from six sigma. In clinical Laboratory turnaround times can be lengthy and the workload could be infrequent rather than constant. Six Sigma can be used to help manage these issues by optimizing resources. Procedures related to Laboratories can also be inspected to assure unnecessary steps to be minimized while still obtaining the desired results.

Evaluation of Performance of Testing Laboratory can be successfully done by the mentioned techniques and Model. This can be achieved by the application of Six Sigma in Testing Laboratories. Another finding is about the difficulties faced in Six Sigma implementation by various laboratories, This involves initial investment in Six Sigma belt program (training), identification and conversion samples and processes with respect to defects per million opportunities, lack of human resources, lack of time, lack of leadership and internal resistance. There will be considerable amount of data available in testing laboratories; the problem is that these data are not readily available for its analysis.

Testing Laboratories are in the urge of different challenges: to increase their workload and efficiency at lower costs, that too maintaining quality standards and levels. "To reach quality level goals, many processes have been re-engineered using new technologies that are more automated and computerized for general chemistry, hematology and immunochemistry"; Jeremie M. Gras and Marianne Philippe (2007). Due to this atomization and computerization an increasing amount of results are being created automatically, while staffing strategies are getting lower in number. Considering all these changes tends to increase probability of producing false results. In relation to this, it is important to precisely develop QC rules in order to reduce errors (waste) in terms of time and money. To improve patient care, experienced and well-trained technologists should focus on less stable technologies.

As per Jeremie M. Gras (2007) "Lean and Six Sigma have proved very efficient in companies such as Motorola, Toyota and General Electric, and have grown exponentially in the healthcare field during the past 5 years". These approaches provide an effective framework for producing systematic innovation in healthcare.

"Lean with its 5S concepts (Sort, Simplify, Scrub, Standardize, Sustain) associated with Six Sigma provides a structured methodology to achieve a strategy that can reduce cycle times and process variations"; Jeremie M. Gras and Marianne Philippe (2007).

The first requirement is a project leader who is familiar with the Lean and Six Sigma concepts and who is accountable for obtaining improvement; the second is the involvement of laboratory staff in the project through communication, introduction of
core laboratory theories, and organized training sessions.

"In the next few years, it is very likely that several papers will report positive results generated by Six Sigma deployment and that application of Six Sigma breakthrough methodology in clinical laboratories will become a new reference in quality assurance"; Marianne Philippe (2007).

The internal Quality Improvement Team should concern with outside quality practitioner, who can train them in successful implementation, project management and optimum utilization of resources and tools. Successful implementation of six sigma produces beneficial outcomes in terms of cost-effectiveness, higher process quality and better operational efficiency.

Although, the research done in this field have not covered full aspects involved in this concept. Therefore, the gap of literature needs to be filled in a proper way to understand the full logical and practical aspects covered in the deployment of six sigma in laboratories.

Thus, Six Sigma approach to quality improvement can be successfully used in testing laboratory associated with

health care industry similar to the ways Six Sigma approach is being used successfully in manufacturing industries. Also Performance evaluation can be successfully achieved by the application of Six Sigma, and model mentioned in the paper.

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