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Study of Application Suitability of Six Sigma in a Testing Laboratory

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Abstract— *Six Sigma is a universal management approach implemented to companies like Motorola and General Electric. Acknowledging grand success in terms of global profitability and customer satisfaction in corporate world, Health care sector can also be benefited by the application of the same to achieve similar benefits in healthcare sector; Six Sigma is currently being spread in several laboratories around the world. Acknowledging this situation, few articles have been published in the peer-reviewed literature on this subject. The aim of this article is to clearly focus on different features of Six Sigma and its successful applications in testing laboratories, as well as to systematically review articles and books discussing Six Sigma strategy implementation in the laboratory field.*
Keywords: *Quality control; Sigma Metrics; Six Sigma; DPMO; Institute of Medicine (IOM)*
Index Terms—*Component, formatting, style, styling, insert. (key words)*

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 post analytical 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 analyzing 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 Figure 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 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.

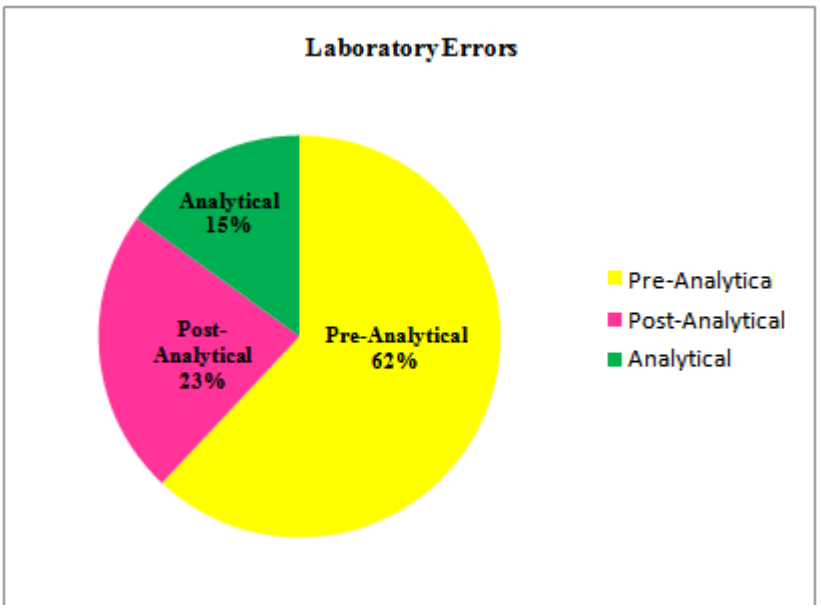

Fig. 1: Sources of Laboratory errors

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.

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.

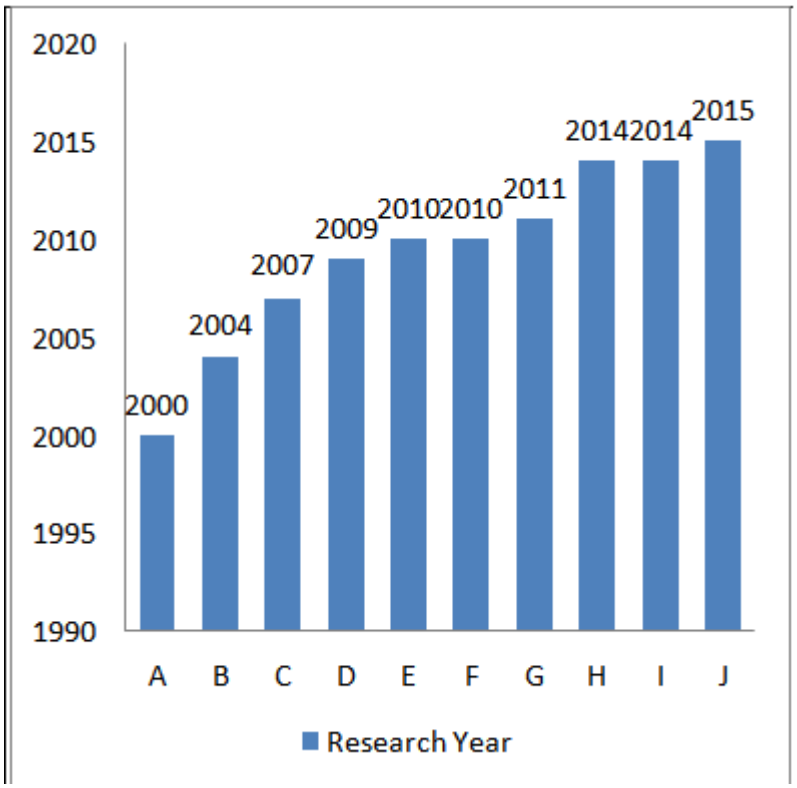

Fig. 2: Yearwise classification of literature

Figure2 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. Conclusion And Discussion

This research demonstrates that many Laboratory staff report SS 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. 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.

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.

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.

References

[1]. Abdurrahman Coskun, Tamer Inal, Ibrahim Unsal and Mustafa Serteser (2010)"Six Sigma as a Quality Management Tool: Evaluation of Performance in Laboratory Medicine"Quality Management and Six Sigma; August; 248-261.
[2]. Bhawna S, Binita G,Vinod KG, Ranjna C,Venkatesan M. (2011) "Application of Sigma Metrics for the Assessment of Quality Assurance in Clinical Biochemistry Laboratory in India: A Pilot Study".Ind J Clin Biochem 26(2):131–135.
[3]. Carl Garber, (2004). "Six Sigma Its Role in the Clinical Laboratory". Clin Lab News. April; 10-14.
[4]. Deachen Angmo and Suman kant; (2015); "Six Sigma Implementation in Healthcare Industry: Past, Present and Future"; International Journal of Engineering Research & Technology (IJERT) Vol. 4 Issue 06.
[5]. Jeremie M. Gras and Marianne Philippe (2007); "Application of the Six Sigma concept in clinical laboratories:a review"; Clin Chem Lab Med;45(6):789–796.
[6]. Mehmet Tolga Taner Bülent Sezen Jiju Antony, (2007),"An overview of six sigma applications in healthcare industry", International Journal of Health