A Study of the Six Sigma Concept's Use in Clinical Labs

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ABSTRACT: ***Six Sigma is a worldwide management approach that first appeared in the 1980s in the industrial world. This approach has been extensively used by businesses like as Motorola, GE, Allied Signal, and others, with great success in terms of customer satisfaction and worldwide profitability. Six Sigma is now being used in many labs across the globe to obtain comparable results in the healthcare sector. Despite this, just a few papers on the topic have been published in peer-reviewed journals. The purpose of this article is to explain the many elements of Six Sigma and their possible applications in clinical labs, as well as to conduct a systematic evaluation of papers and books on Six Sigma strategy implementation in the laboratory sector.***

KEYWORDS: *Clinical Laboratories, Processes, Quality Control, Quality Check, Six Sigma.*

INTRODUCTION

Six Sigma is a management concept that was originally presented by Motorola in 1979, shortly after engineers found that better quality in industrial processes resulted in reduced production costs. In terms of production, the fundamental idea of Six Sigma is to develop goods that are so excellent that they produce almost no defects. Motorola employees were certain that minimizing process variances would result in fewer failures [1]. Under the early 1980s, a process was deemed in control if the variation, represented as standard deviation (s), was less than 1/3 of the difference between the control limits and the process mean, according to conventional statistical quality control (QC). If the variance between the process mean and the control limits was kept at 1/6 of the difference between the process mean and the control limits, Motorola workers believed defect frequency could be reduced by 1000-fold. A process that achieves Six Sigma performance is one in which the process variance is less than 6sigma and falls within the process or product quality tolerance limits. There will be relatively few flaws in such a process: 3.4 flaws per million possibilities (DPMO). The term "world class" refers to a process that operates at a Six Sigma level and produces 3.4 DPMO [2]. This decade's most popular term is "digital transformation." New technology and tools are assisting businesses large and small in their transformation journeys as they fight for a larger share of the market in a fast-paced competitive climate. Is it, however, sufficient to ease a company's transformational process? Is it possible to solve a production bottleneck or diagnose a service design fault with a stand-alone technological implementation? Although digital transformation accelerates a company's development, it must be accompanied with quality control and business transformation management techniques [3].

In 1986, Motorola, an American corporation, created a new idea of quality management process in response to expanding markets and procedures. Six Sigma is a collection of management tools and procedures intended to enhance company by decreasing the probability of mistake. It has been developed and polished over the years into a solid theory of principles and practices, aiming at business transformation via a clearly defined process[4]. It is a data-driven approach to defect elimination that employs a statistical technique. The Greek sign "sigma" or "," a statistical word for quantifying process variation from the process mean or goal, is used in the etymology. The term "Six Sigma" originates from the statistical bell curve, where one Sigma represents a single standard deviation from the mean. The fault rate is defined as "very low" if the process has six Sigma, three above and three below the mean [5].

The normal distribution graph below highlights the Six Sigma model's statistical assumptions. The wider the range of values encountered, the greater the standard deviation. The idea of Six Sigma has a simple objective – providing near-perfect products and services for company transformation for optimum customer satisfaction. This is founded on the common notion that the "customer is king," and the main goal is to provide maximum value to the client. To do so, a company must first understand its consumers, their requirements, and what motivates them to buy or stay loyal. This necessitates setting a quality standard based on what the client or market wants. Map the stages in a particular process to identify waste areas [6]. Gather information to identify the particular issue that needs to be addressed or changed. Establish specific data collecting objectives, such as identifying the data to be gathered, the purpose for the data collection, the anticipated insights, assuring measurement accuracy, and creating a consistent data collection methodology. Determine if the data is assisting in the achievement of the objectives, and whether the data needs to be improved or more information gathered. Determine the issue. Ask inquiries to identify the source of the issue [7]. Once the problem has been identified, make modifications to the process to reduce variance and therefore faults. Remove any steps in the process that do not provide value to the consumer. If the value stream fails to disclose the source of the issue, techniques are employed to find outliers and trouble regions.

To achieve quality control and efficiency, streamline operations. Bottlenecks in the process are eliminated in the end by removing the above-mentioned junk. Involve all stakeholders. Adopt a systematic method for problem-solving in which your team participates and collaborates on their various areas of expertise. Because Six Sigma procedures may have a significant effect on a company, the team must be well-versed in the concepts and methods used. To minimize the risk of project or re-design failures and guarantee that the process works effectively, specific training and expertise are needed. The core of Six Sigma is business transformation and change [8]. When a defective or inefficient process is eliminated, it necessitates a shift in work practices and employee attitudes. A strong culture of flexibility and openness to changes in processes may help guarantee that projects are completed quickly and efficiently. People and departments involved should be able to adapt to change quickly and seamlessly, therefore procedures should be structured to support this. Finally, a competitive advantage may be gained by a business that keeps an eye on the data, analyzes the bottom line on a regular basis, and changes its procedures as needed [9]. The Six Sigma breakthrough technique, as further explained in this article, is a problem-solving strategy aimed at improving processes in order to achieve Six Sigma strategy performance. As a result, Six Sigma is a metric that differentiates world-class performance. The Sigma scale, which is a universal method to describe how well a process works relative to its criteria, may be used to any process, from industrial production to aviation security to laboratory testing. The number of defects and the value of the s level have a negative exponential relationship, which means that each time a s value is achieved in a process, many chances to produce faults are removed. DPMO and s values, as well as the associated numbers of faults given as a percentage [10].

DISCUSSION ON UTILIZATION OF SIX SIGMA IN CLINICAL OPERATION

Quantification of laboratory test performance is one of the most extensively researched implementations of the Six Sigma idea in clinical labs, and it is the topic of one of his books and many articles accessible on his website. This study delves into this particular use of Six Sigma and the effect of performance measurement on QC rule selection. Six Sigma is more than just a technique for calculating quality on a scale. It's also a technique that may be applied to almost any human endeavor. The Six Sigma breakthrough approach is a concept that is used to enhance quality, eliminate defects, save costs, and meet customer expectations. The ultimate objective is to establish Six Sigma-compliant procedures. Application of this approach by industrial giants like Motorola and General Electric has resulted in billions of dollars in cost savings in terms of reduced product failures and rework. The abbreviation DMAIC, which stands for Define, Measure, Analyze, Improve, and Control, is frequently used to describe the Six Sigma breakthrough approach. In reality, the technique includes height

stages, thus this acronym is inadequate. Six Sigma, in a nutshell, is the most recent form of comprehensive quality management. The Six Sigma breakthrough technique is a problem-solving approach that has shown to be very effective in increasing organizational performance. It is used to achieve Six Sigma performance, which is the highest level of performance.

During the 1990s, a growing number of businesses adopted Six Sigma, which is today a widely accepted concept in the marketplace and an integral component of the quality culture of major multinational corporations. Six Sigma has been a topic of interest for clinical laboratory managers since the laboratory community must continue to meet doctors' requirements under growing budgetary constraints. Despite the obvious potential effect of Six Sigma applications in clinical labs, there are few peer-reviewed papers in this area addressing the implementation of Six Sigma breakthrough technique. The purpose of this study is to conduct a literature review on Six Sigma's applicability in laboratory management. Six Sigma applications in clinical labs may be split into two categories: 1) use of the Six Sigma breakthrough approach to solve issues, decrease defects, and better delight customers; and 2) sigma-scale measurement of laboratory test performance. Boone stated in a classic paper that 93 percent of clinical laboratory mistakes are related to the pre- or post-analytical phases of the procedure. A recent review paper that pre-analytical variables account for the majority of mistakes (46 percent –68.2 percent of overall errors), whereas post-analytical errors account for 18.5 percent –47 percent of total errors. Another study found that most laboratory mistakes occur during the pre- and post-analytical stages. As a result, it's no surprise that the initial implementations of Six Sigma breakthrough technique in clinical labs focused mostly on these stages. The authors examined quality indicator data from three labs reported as variance (a typical way to publish this kind of data) and parts per million (ppm, or DPMO, an industrial measuring technique). Quality metrics for the pre-analytical (number of sample label mistakes, number of requests with missing data), analytical (number of laboratory examination errors), and post-analytical phases were compared (laboratory reporting errors). Finally, they compared the three labs' quality indicators to data from the CAP Q-Probes program. There were two main results that were highlighted: In many instances, the variance expression of quality indicators looked acceptable, but the same findings stated in ppm performed differently when compared to other, non-laboratory sectors; 2) previous quality assurance systems did not seem to improve quality throughout the whole testing process.

At the North Shore-Long Island Jewish (LIJ) Health System laboratory, a Six Sigma effort is underway to decrease access mistakes. The central hub of this network of labs is a consolidated core laboratory that is strategically situated and processes more than 3.5 million exams per year using total laboratory automation (TLA). Access mistakes arise while inputting patient information, ordering tests, and labeling samples. These mistakes were a long-standing issue at North Shore Laboratory that no outside experts could fix. As a result, this was an excellent chance to put the Six Sigma breakthrough approach to the test. This Six Sigma project was conducted by a multidisciplinary team with the goal of reducing access faults by 50% and increasing employee productivity. They discovered that 5% of laboratory testing requests were incorrect or incomplete during the Define phase of the project, and this was classified as a fault. The DPMO as a consequence was 7210, or 3.9 sigma. They found that 50 percent of the mistakes were due to incorrect input of the patient's social security number during the Analyze phase. The project's Improve phase included replacing addressographs (which were often misread) with barcoded labels that would be attached to laboratory requests, as well as developing a new training program for accessions. The admittance staff's involvement ensured that employees were committed to the Six Sigma initiative and enabled them to offer creative suggestions for reorganizing the admission department. DPMO frequencies were regularly checked during the Control phase. The accession department's performance improved from 3.9 to 4.2 sigma at the conclusion of the project, saving $339,000 per year in costs and increasing benefit.

In 2004, performance improved even further, reaching 4.5 sigma, which equates to a DMPO of 1387. At Fretter Memorial Lutheran Hospital in Milwaukee, WI, the Six Sigma breakthrough approach was also used to address issues with the pneumatic tube transport system. The adoption of a pneumatic system as the laboratory's general transportation method resulted in a lengthy turnaround time (TAT) and specimen loss in this instance, and was a significant cause of dissatisfaction for laboratory clients. Staff at Fretter were able to decrease travel time by 20% using the Six Sigma approach and working closely with the pneumatic tube system vendor, while the Six Sigma laboratory project improved the mean TAT by 7.5 minutes and reduced mistakes by 35%. The success of a Six Sigma project at the North Shore LIJ core laboratory concerns the post-analytical phase of laboratory testing. A fault was defined in this project as the requirement to change a laboratory test result after the verification procedure had been completed by a laboratory technician for any reason. They defined the DPMO as 355, which corresponds to a high performance level of 4.8 sigma, during the Measure stage. Post-analytical mistakes were divided into six categories by the researchers: procedural, auto-verification error, sample, clerical, mechanical, and error of unknown origin. The project's goal was to decrease post-analytical mistakes by 35% and achieve a 5 sigma performance level. Statistical research showed that just two kinds of inaccuracies were responsible for 86 percent of errors: 52 percent were attributable to procedural errors made by workers when evaluating findings, and 34 percent were due to auto-verification faults in the Laboratory Information System (LIS).

The Six Sigma team created a streamlined result-review guideline tool in the Improve phase to reduce laboratory technician mistakes. IT department employees developed new software that enabled for real-time monitoring of analyzer findings, as well as audible alerts whenever a possible issue arose. They checked DPMO for rectified findings on a regular basis throughout the Control phase. Finally, when the Six Sigma breakthrough approach was used in the post-analytical phase, the number of corrected results dropped substantially, and the performance level achieved the 5.0 sigma target. Some writers think that laboratory staff should focus on minimizing analytical mistakes rather than worrying about the pre- and post-analytical stages. However, bringing Six Sigma breakthrough methodology to the analytical phase has sparked only a small amount of interest. Improving laboratory technique performance in a mostly automated clinical chemistry system, according to Westgard's book, is primarily dependent on cooperation with the manufacturer. The significance of Six Sigma in the development of new in vitro diagnostic tools. Since only 7% of laboratory errors occur during the analytical phase, we believe it is also the duty of laboratory management and workers to concentrate on minimizing flaws, which account for over 90% of laboratory errors. In a recent paper, many possible disadvantages of the Six Sigma approach were discussed. According to the author, the Six Sigma idea should be seen as a basic tool for improving clinical laboratory management rather than a revolutionary approach that can address every issue.

Six Sigma is an expensive process to adopt, according to him, and clinical labs and hospitals in general may not be able to spend as much money as multinational companies like Motorola and others. As a result, they cannot anticipate the same rate of return on their investment (ROI). Another problem with Six Sigma is that it necessitates the full-time involvement of the finest technicians in Six Sigma initiatives. Finally, the author claims that achieving a 3.4 DPMO level in clinical labs is unrealistic. These articles show the heated discussion over Six Sigma adoption in clinical labs. The most challenging aspect of Six Sigma implementation is persuading laboratory senior leadership to believe in the Six Sigma breakthrough technique enough to spend the required resources in training people and launching the first projects. We think that the initial Six Sigma initiatives should concentrate on areas where chronic issues occur and flaws cause the most mistakes and take the longest time to resolve. It should be simpler to demonstrate the efficacy of Six Sigma methodology in clinical labs once the first good quantifiable outcomes are achieved, and additional Six Sigma projects will likely follow at a faster pace.

In the clinical laboratory, appropriate metrics may be readily established by selecting TAT or mistakes in the pre- or post-analytical phase represented in DPMO, as demonstrated in the publications listed above. These indicators offer a strong foundation for evaluating performance and recording laboratory improvements. While resistance to culture change may be a barrier to Six Sigma implementation in the laboratory, it has been shown that by engaging employees in a Six Sigma project, people commitment to the project can be gained, leading to creative ideas and more Six Sigma implementation. Finally, since laboratory automation is becoming more prevalent in the generation of laboratory findings, a laboratory is distinct from global healthcare operations. The financial effect of implementing Six Sigma in a clinical laboratory. Staff at DSI Laboratories used the concepts of Lean and Six Sigma to remove waste and decrease variation in laboratory operations after establishing a Lean and Six Sigma team. Waste was defined as production components that did not contribute value to the product or service being produced. In the first year of implementing Lean and Six Sigma, this resulted in a net savings of $400,000.

Overtime costs were reduced by 60%, resulting in cost savings. Data on sigma-scale quantification of clinical laboratory performance has mostly focused on the analytical phase and primarily involves test performance quantification rather than the application of the Six Sigma breakthrough methodology to the whole laboratory process. There are two reasons for this: first, because the main business of a clinical laboratory is to produce accurate results, it made sense to start with the analytical process; second, because improving analytical methods necessitates close collaboration with manufacturers (which can be difficult to establish), it's worth improving quality control procedures for more efficient detection of true positives. In practice, using the sigma scale to determine test performance may aid in determining which QC standards to apply. Several software applications that enable sigma values to be calculated for a variety of clinical laboratory tests. The sigma values are typically computed at the same levels as the controls. Westgard suggests calculating the sigma level using CV and bias seen at clinically relevant decision-making points since various CVs occur at different levels of analyte concentrations. For example, given the CVs and bias found at 3 and 5.5 mol/L, two sigma values for potassium may be computed. One benefit of Six Sigma adoption in clinical labs, according to Westgard, is that it allows for a much more quantitative assessment of laboratory quality (3). Quantification of laboratory test performance on the s scale is helpful not only for establishing QC guidelines, but also for daily quality monitoring: if a test's s level suddenly decreases, this may suggest an underlying analytical issue. Furthermore, quantifying laboratory test performance allows the laboratory management to compare test results from different manufacturers.

CONCLUSION AND IMPLICATION

Clinical labs are now confronted with a number of difficulties, including increasing workload and efficiency while reducing costs while preserving quality. Many procedures in general chemistry, hematology, and immunochemistry have been re-engineered to achieve these objectives, utilizing new technologies that are more automated and computerized. Automatically produced outcomes are becoming more common, and staffing strategies are increasingly focused on reducing and cross-training employees. All of these factors, when combined, enhance the chance of obtaining erroneous findings. In this environment, it's critical to systematically optimize QC standards in order to minimize time and money waste, concentrate experienced and well-trained technicians on less reliable technologies, and enhance patient care. As this study has shown, Six Sigma is not only a technique for quantifying analytical performance, but also a management approach for improving an organization in a systematic manner, with the goal of achieving optimum quality at a level of 3.4 DPMO. Several publications are expected to reveal good outcomes produced by Six Sigma deployment in the next years, and the use of Six Sigma breakthrough technique in clinical labs will become a new standard in quality assurance. Healthcare, as an industry, has to adopt a new style of thinking to enhance efficiency and effectiveness due to increasing costs, staff shortages, downward pressure on reimbursement, and quality standards. Lean and Six Sigma have shown to be very effective at businesses like Motorola, Toyota, and General Electric, and have

exploded in popularity in the healthcare sector over the last five years. These methods offer a useful foundation for generating systematic healthcare innovation.

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