

APPLICATION OF SIX SIGMA DMAIC METHODOLOGY FOR REDUCING PRE-ANALYTICAL AND POST-ANALYTICAL ERRORS IN CLINICAL LABORATORY TESTING

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Abstract

Laboratory scientists are required to guarantee precision and accuracy in the results of diagnostic tests, as this directly impacts patient satisfaction. The Total Testing Process (TTP) of medical laboratories experiences errors that are broadly classified into three types. The errors studied in this paper are pre-analytical and post-analytical errors, and the DMAIC (Define, Measure, Analyse, Improve, and Control) methodology is applied to reduce these types of errors. Pre-analytical errors are those that happen before the testing of the sample. The majority of errors happen in this testing process. Before the introduction of the improvements, the average percentage of pre-analytical errors was recorded as 16.12%. The average percentage of post-analytical errors, which happen after the testing of the sample but before the results are delivered, was recorded as 1.01% before improvements. The results show that there are significant reductions in both stages of errors, i.e., the rate of pre-analytical errors was reduced to 5.38%, and the rate of post-analytical errors was reduced to 0.37%. The results prove that the DMAIC methodology can be applied to improve quality and reduce errors in medical laboratory testing

1. Introduction

Quality in clinical laboratory services is at the center of the health care delivery system, since accurate and timely laboratory results are essential for appropriate diagnosis, treatment, and ultimately the preservation of life. A quality system is defined as “that part of the management system that consists of organizational structure, policies, procedures, processes, and resources needed for effective quality management.” The principles of total quality management, which include appropriate policies, procedures, organizational structure, qualified personnel, appropriate equipment, and compliance with safety standards, have been widely applied in pathology laboratories worldwide [1].

Research focusing on quality improvement, productivity, and standardization in pathology laboratories has also been reported in the medical literature [2] [3]. These studies highlight the increasing global recognition of structured

quality management systems in laboratory medicine. However, in many developing countries, the implementation of quality systems in clinical laboratory services remains fragmented and unsystematic.

Medical laboratories produce essential information that enables evidence-based clinical decisions. Moreover, a substantial number of clinical decisions, including diagnoses and therapeutic decisions, rely on laboratory test results. Laboratory services, therefore, form an integral component of both inpatient and outpatient settings. Laboratory service directly affects various facets of patient care, such as the duration of stay in the hospital, safety of patients, effective use of resources, and satisfaction of patients. It is essential to ensure that the appropriate test is conducted on the appropriate patient at the appropriate time to avoid mistakes and maximize the value of complex healthcare systems.

The whole process of laboratory testing, including the request for the test and the reporting of the results, is called the Total Testing Process (TTP). The TTP has three principal steps: the pre-analytical step, the analytical step, and the post-analytical step. The pre-analytical step includes all the steps in the process before the sample reaches the laboratory. This step is the most prone to errors and

accounts for 40-68% of the total laboratory errors. The analytical step includes the actual testing and examination of the sample in the laboratory and accounts for 7-13% of the total laboratory errors. The post-analytical step includes the validation and reporting of the results to the clinician and accounts for 19-47% of the total laboratory errors.

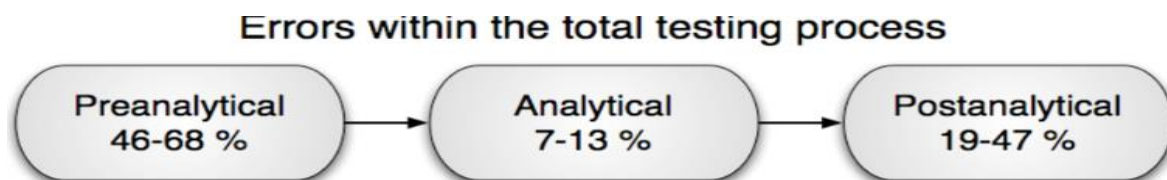


Figure 1 Errors in different phases of testing

Considering that laboratory diagnostics make a significant contribution to patient management and that errors occur in all phases of the Total Testing Process, it is imperative that quality management systems in clinical laboratories be strengthened. A systematic evaluation of quality practices in all phases of the Total Testing Process is essential for enhancing diagnostic accuracy, reducing preventable errors, and improving patient outcomes.

Six Sigma is widely used in industrial sciences as a statistical approach that combines management techniques for regulating process performance, enhancing quality, and reducing operational errors. Six Sigma was first developed by a Japanese company in the 1970s with the aim of reducing defect rates. However, it is now used as a quality management system that uses statistical analysis for quality management. The approach is based on six key elements that form the foundation of the Six Sigma approach. These elements include Define, Measure, Analyze, Improve, and Control (DMAIC), which form the foundation of the Six Sigma approach.

In the context of laboratory medicine, Six Sigma has been suggested to positively influence operational efficiency and laboratory safety [1] [4]. The application of Six Sigma in laboratory settings was first explored in pathology, where performance data from the Q-Probes Program developed by the College of American Pathologists have been extensively documented in the literature [5] [6] [7] [8].

Six Sigma functions as an error-detection and process-improvement strategy within the broader framework of total quality management. It aspires toward near-perfection, operationally defined as 3.4 defects per million opportunities, and serves both as a performance benchmark and as a statistical measure of process variation from optimal performance. In surgical pathology laboratories, the adoption of total quality management principles, including Six Sigma metrics, has increased significantly in recent years. Central to quality management in this domain is the systematic identification, analysis, and prevention of errors, ensuring enhanced diagnostic reliability and improved patient outcomes.

2. Literature Review:

For the first time the Total Testing Process (TTP) was defined by the Gambino in 1997. Who define the TTP in nine states that are as, ordering of test, collection of blood, samples transportation, identification of patient, separation of specimen, analysis of blood, correct reporting, evaluation of result and taking action [3]. Based on this idea Lundberg give explanation about these steps as the “mind to mind turnaround time”, and visualizing a comment loop that may be disturbed at any stage and resulting in an open loop [9]. Now a days this loop is generally referred to as the TTP, and it accommodate of all the stages between doctor referring the test and when the result is furnished to the medical doctor for

interpretation [10]. another research stated that the primary subject of any laboratory check is to discover the real value of analytical on the time of sampling, and that there as a supposition that the composition of the blood sample is not disturbed during the pre-analytical stage. This supposition has been truly examined in recent years [11].

The way to hit upon errors in laboratory test consequences that use patient fact as its personal manipulate has been advised at 1970's. So, by way of evaluating cumulative test outcome for patients and evaluation of repeat take a look at. He designated any errors into two capacity causes, noted as Group A - those mistake that happening outdoor the laboratory and Group B - those mistake that occurring inside the laboratory. After this the laboratory errors were classified into three categories that are as Pre-analytical errors [12], Analytical errors, and Post-analytical errors. These types of errors are recognized to be more accurate manner of identifying errors related with the TTP. The pre-analytical section is to be considered as anything that took place from the test request to the blood sample obtained in the laboratory for processing. The analytical stage is constrained to the processing of test take a look at in the laboratory while the post-analytical section is related with posting the result on the LIS, interpretation and comply with up of the check end result.

1.1. Pre-analytical errors

The errors that are involved in the pre-analytical phase of the total testing process are hemolysis, collected blood from the wrong patient, inappropriate container or product, insufficient blood collection, clotting of blood, contamination in container, use of tourniquet improperly, specimen labeled incorrectly, mislabeled specimen, specimen loss, tube damage, requisition form related errors [10].

1.2. Analytical errors

The errors that occurred in this phase of the laboratory testing process have been broadly classified by Wians 2009 as either they may be systematic (such as changes in the calibrations of the instrument) or they may be randomly occurred errors (i.e. errors does not depend on phlebotomist or technician). These errors

include machine or equipment malfunctioning, failure in procedures that are associated with the quality control, and mix up of specimens with in the machine during processing. Previously in the survey of Australia laboratories were found that in these laboratories analytical error average rates between 2% to 3%, when external quality end result was surveyed [13]

1.3. Post-analytical errors

These errors mainly include the verification of uncertain results to the patient, transcription errors due to incomplete information, wrong result interpretation, prolong turnaround times and failure to inform the clinician approximately important results [14]. It is also required that the clinician has the duty to follow up of the requested tests, to transmit these consequences to the patients in well time manner, and give result to correct patient [15]. One of the preceding researches located that as many as 37% of physicians surveyed had discovered an affected person whose previous important test results had not been followed up [16]. By more explanation the post-analytical errors recognized result review, to inform patients about their results, follow appropriate method, and enter the result carefully. It was found that the average rate of missed results to be 7.1% [17].

However, the average error rates varied at post analytical stage is from 0 to 26.2%. This shows that there are no standard procedures for informing patients of critical results. Failures to inform patients of their significant results is not only bounded to the clinicians or standard practice as showed by study performed in in the hospital setting [18], found that 0.9% of discharged patients had significant results that were not informed to the patients.

Several measurement and classification systems for errors are introduced in surgical pathology. A system that focuses on the clinical impact to the patient has been described by [19]. In this system, the errors were divided into two types: major and minor errors. Further, the major errors were divided into four types according to the extent of harm: no harm, near harm, harm, and unknown, respectively. Here, minimal harm is defined as the occurrence of unnecessary further non-invasive testing or the occurrence of a delay in diagnosis or therapy of less than 6

months. Further, the second type of error, mild harm, is defined as unnecessary invasive further testing, the occurrence of a delay in diagnosis or therapy of more than 6 months, or minor morbidity due to the aforementioned reason. The third type, moderate harm, is defined as the occurrence of moderate morbidity due to the aforementioned reason. Further, the fourth type, severe harm, is defined as the loss of life, limb, or body part, along with the occurrence of long-lasting morbidity of more than 6 months [20].

In our study, we aimed to examine pre and post analytical errors excluding analytical errors that had been encountered in a local clinical laboratory in Peshawar, to assess the effect of Six Sigma implementation in error reduction and process improvement.

3. Materials and Methods

The main OPD laboratory of a local hospital was used for data collection as it caters to large number of outdoor patients tests and also some indoor patients tests on daily basis.

The scope of the study was limited to the pre-analytical and post-analytical phases of the Total Testing Process (analytical phase was excluded). Pathology personnel (specimen registry personnel, laboratory technical personnel, or pathologist) determined the error, and recorded the characteristics of the error. The errors were then examined by the quality control supervisor and the causes were investigated. Six Sigma

principles were applied to the evaluation of problems.

In the defining phase, the causes and characteristics of problems and the damages they caused were investigated. The distribution of errors at pre-analytic and post-analytic phases was examined in the measuring phase. In the analysis phase, problem-solving activities were applied regarding the prevention of the occurrence of errors. Finally, the implementations for reducing all these errors were initiated in the improvement phase.

Regarding these errors, regular meetings were held with laboratory personnel and the quality supervisor for error analyses and personnel were given the opportunity to express their problems in these meetings with aim to resolve them and increase efficiency and decrease errors. Furthermore solutions offered by employees were prioritized for consideration and implementation.

In the below figure, it evaluates each step in the Total Testing Process involving. First a patient submits fees at receipt counter then take a work order at work order center. In work order the receipt form of the test are analyzed through bar code. Then patient move toward blood collection point. The blood sample transport to the main lab for further analysis. After centrifugation in main lab the analysis done through machining and the result should be interpret to the main report center.

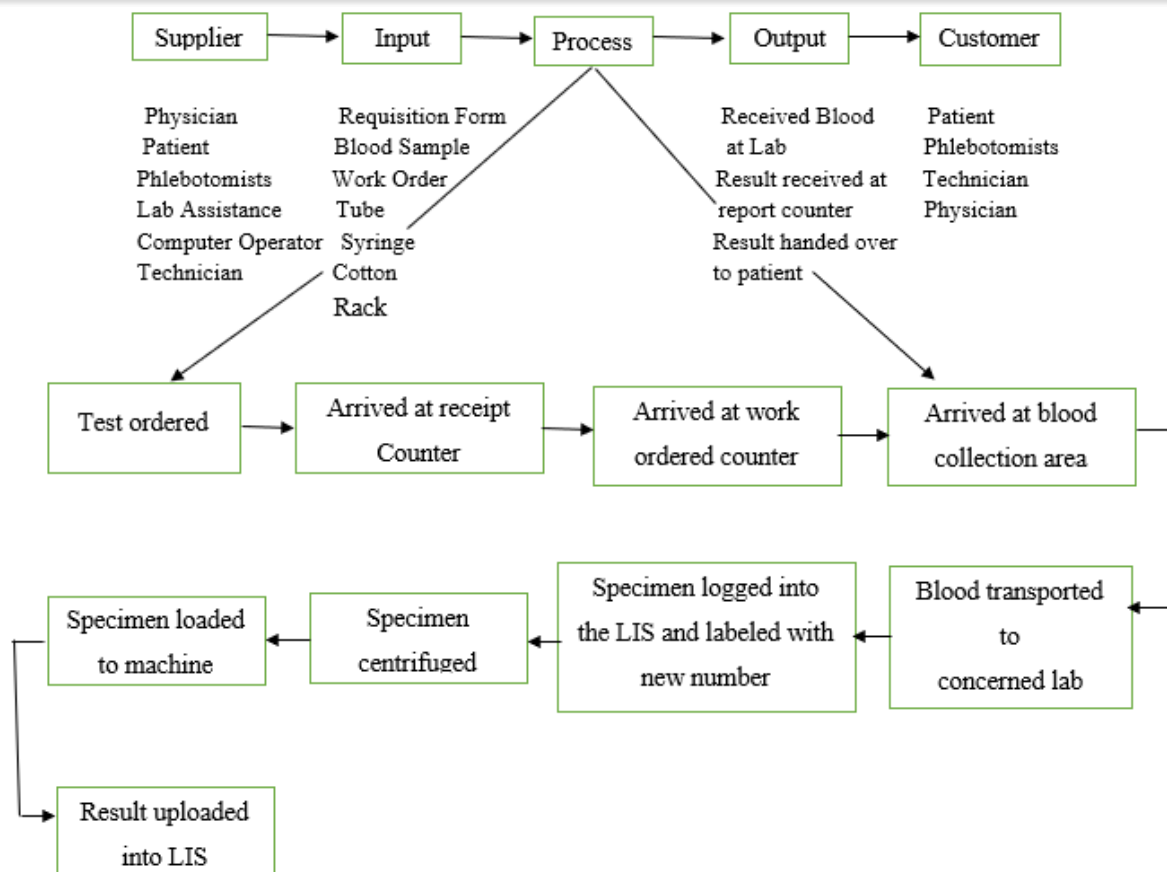


Figure 2 Lab testing process

4. Results

The pre-analytical errors are broadly fell into three classes, one related to specimen itself, related to collector, related to requisition form and interference by unconcerned personnel as shown in the below figure. Figure below presents the major errors identified in the pre-analytical phase of the Total Testing Process (TTP), categorized as specimen-related, collector-related, requisition form-related, and errors due to interference by unconcerned personnel. Specimen-related errors included mislabeling, insufficient volume, tube damage, hemolysis,

contamination, sample loss, transportation delays, and misdirection to incorrect laboratories. With regards to collector-related errors, these included misidentification of patients and containers, while requisition form-related errors included transcription errors and misprinted work orders. Other errors related to interference in the workflow included duplicate test entries, lost work orders, and mislabeling of samples. The results of the study emphasize the complexity of pre-analytical errors and the importance of quality control in improving the performance of the laboratory.

Table 1 Pre analytical errors

Specimens related	Collector related	Requisition form related	Interference by unconcerned personnel
Mislabeling of the specimen	Patient identification	Transcription errors	Double entry of the same test
Insufficient specimen	Wrong container selected	Misprint of the work order	Sample lost
Tube damage			Mislabeling
Sample lost			Tube damage

Delay in transportation to the concerned lab			Work order lost
Specimens transported to unconcerned lab			Hemolyzed samples
Hemolyzed sample			Insufficient sample
Double numbering of sample for centrifugation			Sample transported to unconcerned lab

Table 2 Data collected in Pre-analytical phases

Pre-analytical error	Pre-analytical errors recorded	Frequency (%)
Mislabeling	12	2%
Tube damage	9	1%
Patient identification	8	1%
Double entry of test	7	1%
Double numbering	17	2%
Sample lost	14	2%
Miss numbering	12	2%
Wrong container	17	2%
Insufficient sample	85	11%
Hemolyzed sample	96	12%
Waiting for inventory	21	3%
Transcription error	10	1%
Miss print of work order	8	1%
Delay in transportation to the concerned lab	95	12%
Transportation not to be concerned lab	78	10%
Interference by unconcerned personnel	289	37%
Total	778	

Table X illustrates the frequency and percentage distribution of pre-analytical errors identified during the study period, with a total of 778 recorded incidents. The most common error was that of interference by unconcerned personnel (37%), followed by hemolyzed samples (12%) and delays in the transportation of samples to the concerned laboratory (12%). The transportation of samples to the wrong laboratory was responsible for 10%, and insufficient samples was responsible for 11%. The common errors of waiting for the inventory (3%), sample mislabelling (2%), double

numbering (2%), sample loss (2%), miss numbering (2%), and selection of the wrong container (2%) were seen at moderate levels. The less common errors were damage to the tube (1%), patient identification error (1%), double entry of tests (1%), transcription error (1%), and misprinting of the work order (1%). This clearly indicates that procedural and workflow-related issues are the most important factors in the common preanalytical errors and that quality control and process improvement activities need to be strengthened.

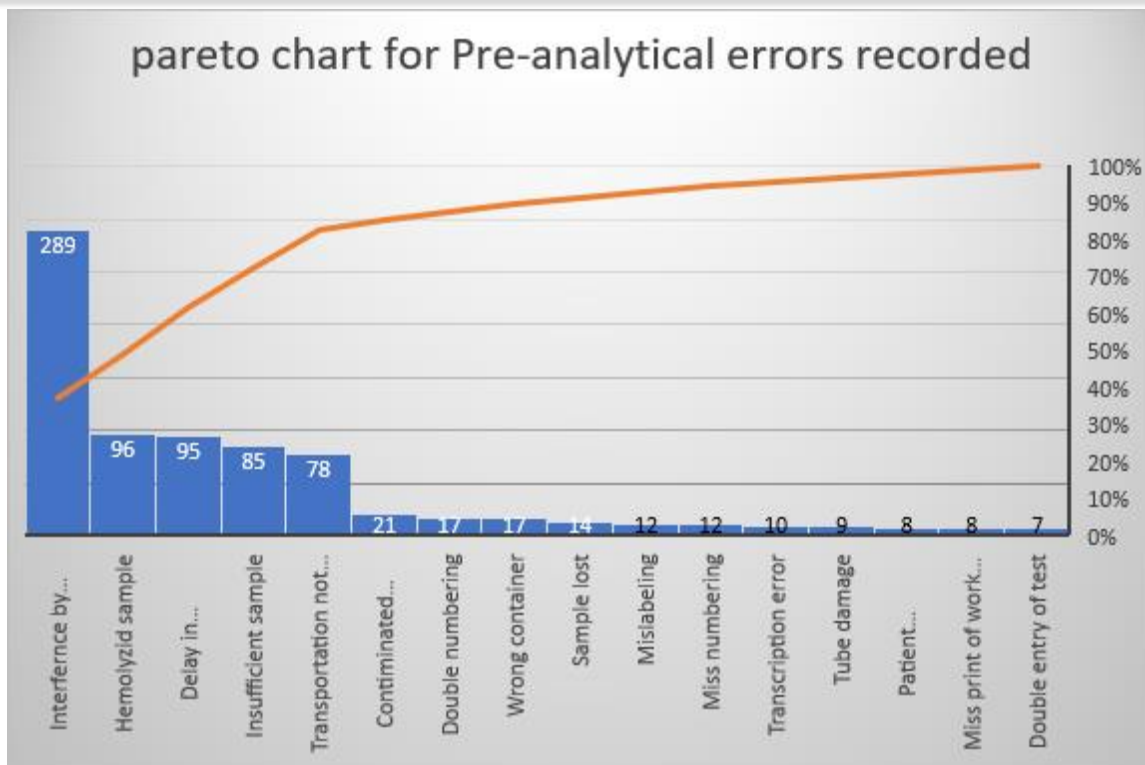


Figure 3 Pareto analysis for errors

The post-analytical phase includes the validation of the test result. Then the results are transmitted to the laboratory information system. Then it is transmitted to the clinicians

and the healthcare professionals. In this way, it can reach the clinical decision to manage the patients. The errors that occur in the post-analytical phase are as follows:

Table 3 Post analytical errors

Post-analytical errors	Post-analytical errors recorded	Frequency (%)
Verify wrong result	0	0%
Test result lost	3	6%
Report handed over to wrong patient	3	6%
More copy of same test is handover	2	4%
Prolonged TAT	41	84%
Total	49	

Table above indicates the distribution of post-analytical errors that were recorded during the study period. The total number of post-analytical errors was 49. The most common post-analytical error was prolonged TAT, which accounted for 84% of total post-analytical errors. This indicates that there is a significant problem in terms of delays in reporting test results. The second most common post-analytical error was test results

lost, which accounted for 6% of total post-analytical errors. The third most common post-analytical error was test reports given to wrong patients, which accounted for 6% of total post-analytical errors. The issuance of multiple copies of test reports for the same test accounted for 4% of total post-analytical errors. Verification of wrong test results was 0%.

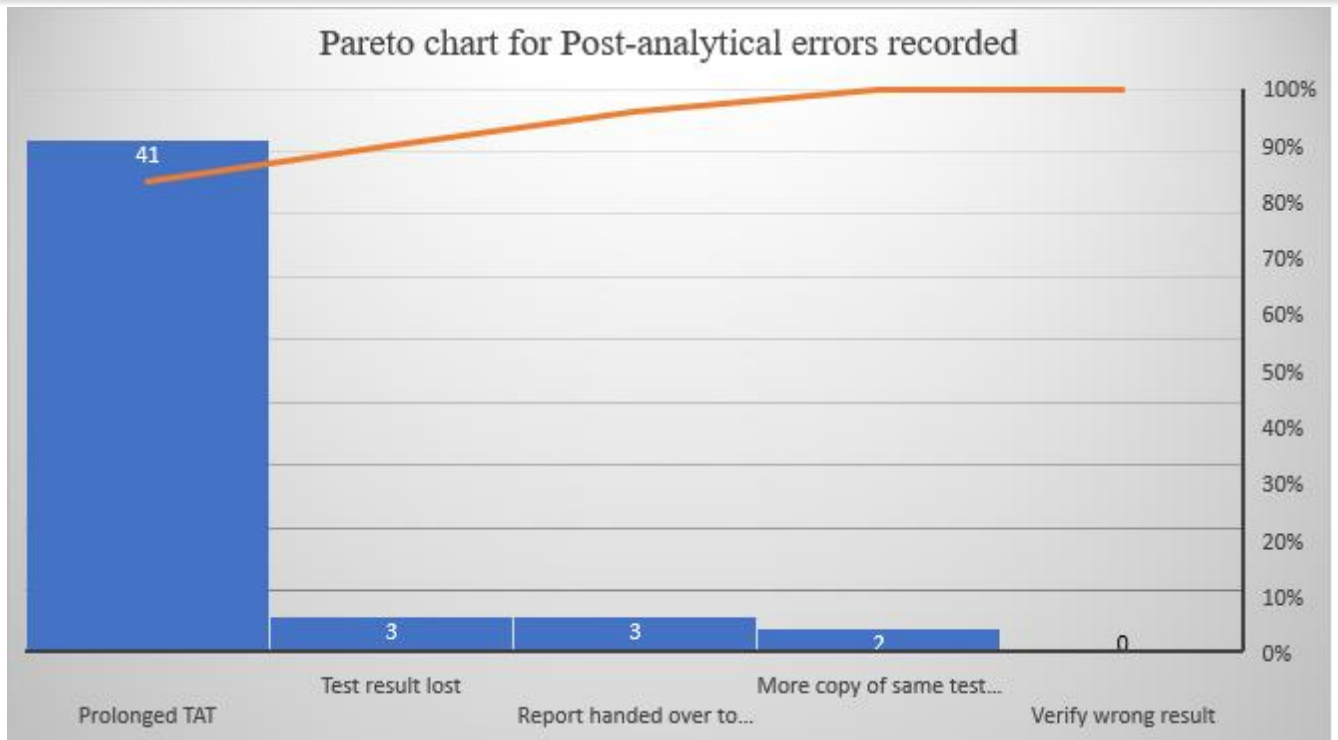


Figure 4 Pareto analysis for post analytical errors

The pre-analytical errors accounted for 94% of the 827 errors recorded in total while post-analytical errors amounted to 6% of the total.

Laboratory layout is as shown below in figure 5

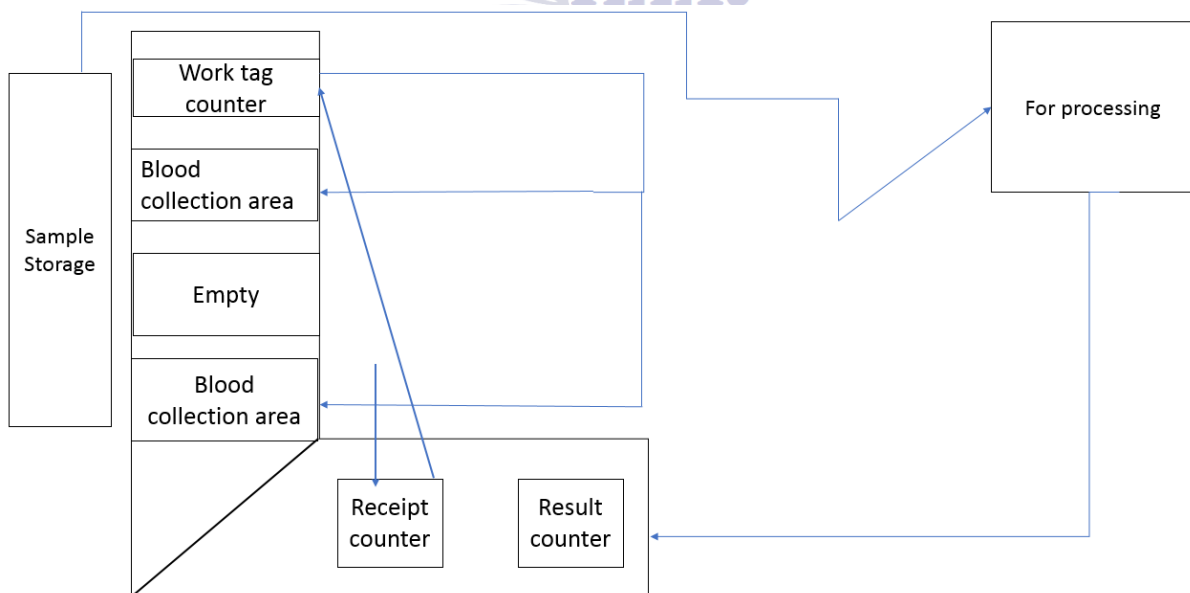


Figure 5 Laboratory layout before improvement

Now the process flow that is followed on this layout is as shown in the following figure 6.10. The Figure illustrates the workflow of the laboratory testing process from patient reception to report issuance, along with the average time

consumed at each service point and the number of workers allocated per counter. The process begins at the receipt counter (7.5 minutes; 2 workers), followed by the work tag counter (16 minutes; 1 worker) and the sample collection

area (16 minutes; 2 workers). After collection, samples proceed to storage and transportation (16.5 minutes; 1 worker), centrifugation (19 minutes; 1 worker), batching for machine processing (11 minutes; 1 worker), and laboratory processing (time not explicitly shown; 1 worker). Finally, reports are issued at the report counter (14.5 minutes; 1 worker). This figure shows that the total turnaround time for the entire process is 112.5 minutes, and the

total workforce required for the entire process is 10, distributed across different service points. The variations in time required for the entire process are also shown in the figure, where centrifugation, sample storage and transportation, and work tag/sample collection counters are significant contributors to the total time required for the entire process.

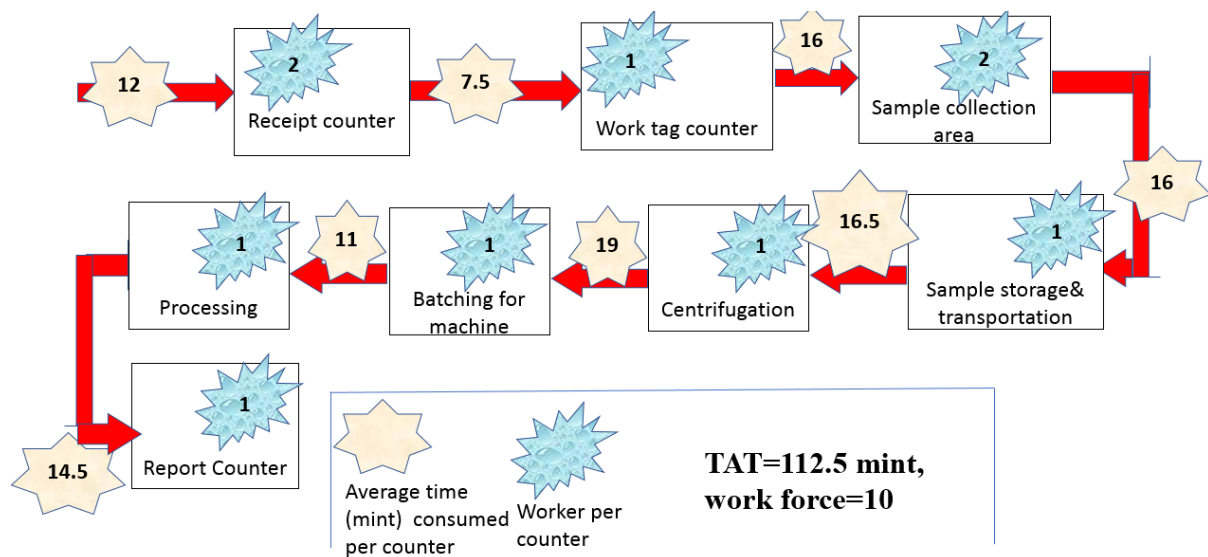


Figure 6 Process flow for Existing layout

As in this lay out, the project team member has provided one extra phlebotomist at the blood collection area, and in the same way, the team member has replaced the position of the blood collection counter with the work tag counter due

to which the most significant source of errors, i.e., interference by unconcerned personnel, is solved and TAT is minimized. The process flow for this improve layout is as follows figure 7

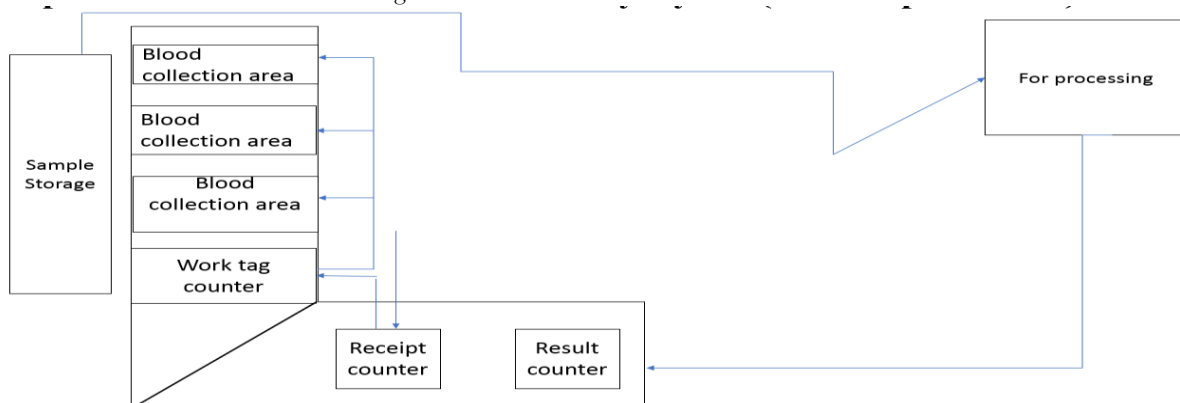


Figure 7 Laboratory Layout after improvement

The improved laboratory workflow is depicted in the figure below. From the improved workflow, there is a reduced TAT of 89.5 minutes with a workforce of 11. This is a reduced TAT by 23

minutes or 20% in comparison with the previous workflow where TAT was 112.5 minutes with a workforce of 10. There is also reduced time in key stages in the laboratory,

which include receipt counter, work tag counter, sample collection, centrifugation, sample storage, and transportation. The improvement is primarily attributed to process streamlining and the addition of one staff member in the sample

collection area, which helped reduce bottlenecks and enhance operational efficiency. Overall, the revised workflow demonstrates more effective resource allocation and improved laboratory performance.

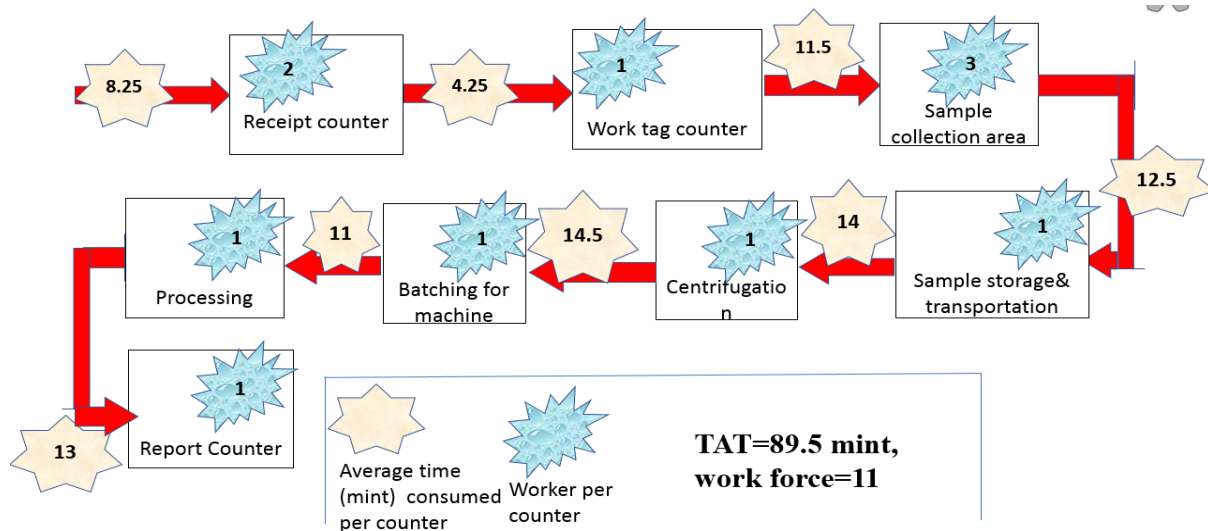


Figure 8 Process flow for improve layout

After improvement, to verify that process is controllable, pilot process control charts were drawn for errors rate in TTP before and after the

improvement, which is followed below in figure 9 and 10

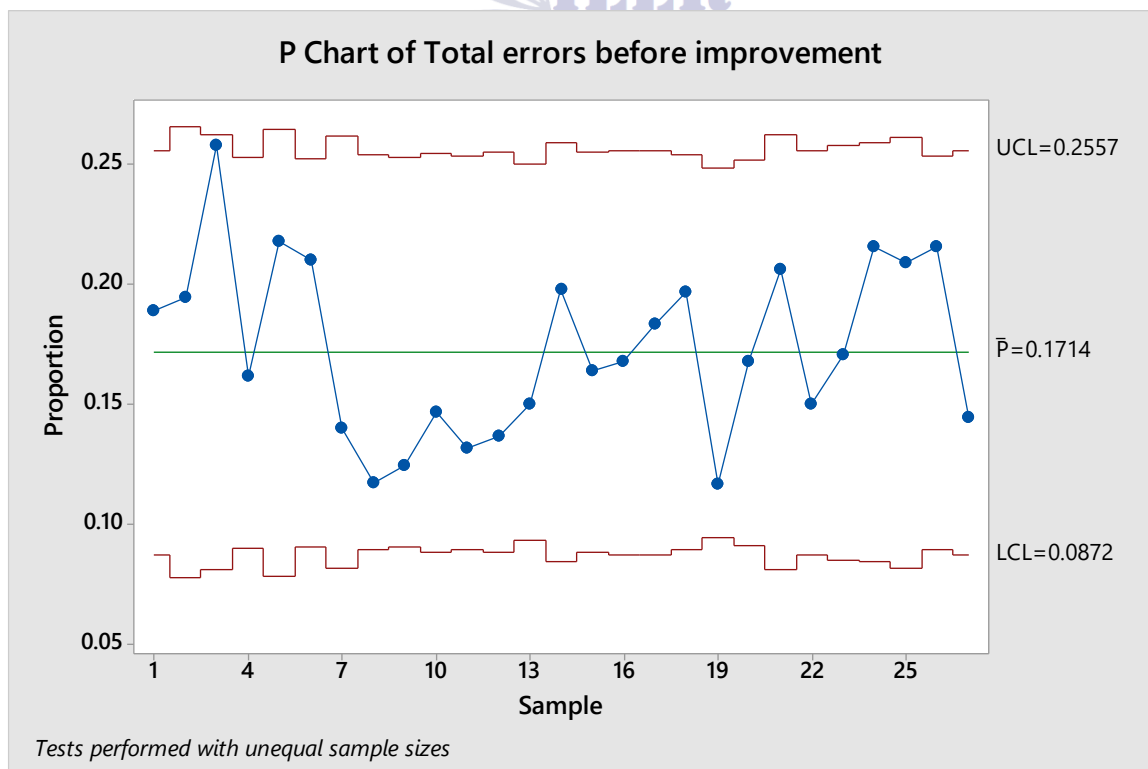


Figure 9 P chart of total error before improvement

P - bar control chart for total errors in TTP indicates that currently laboratory service

processes is in statistical control and the errors rate is reduced up to too much better level.

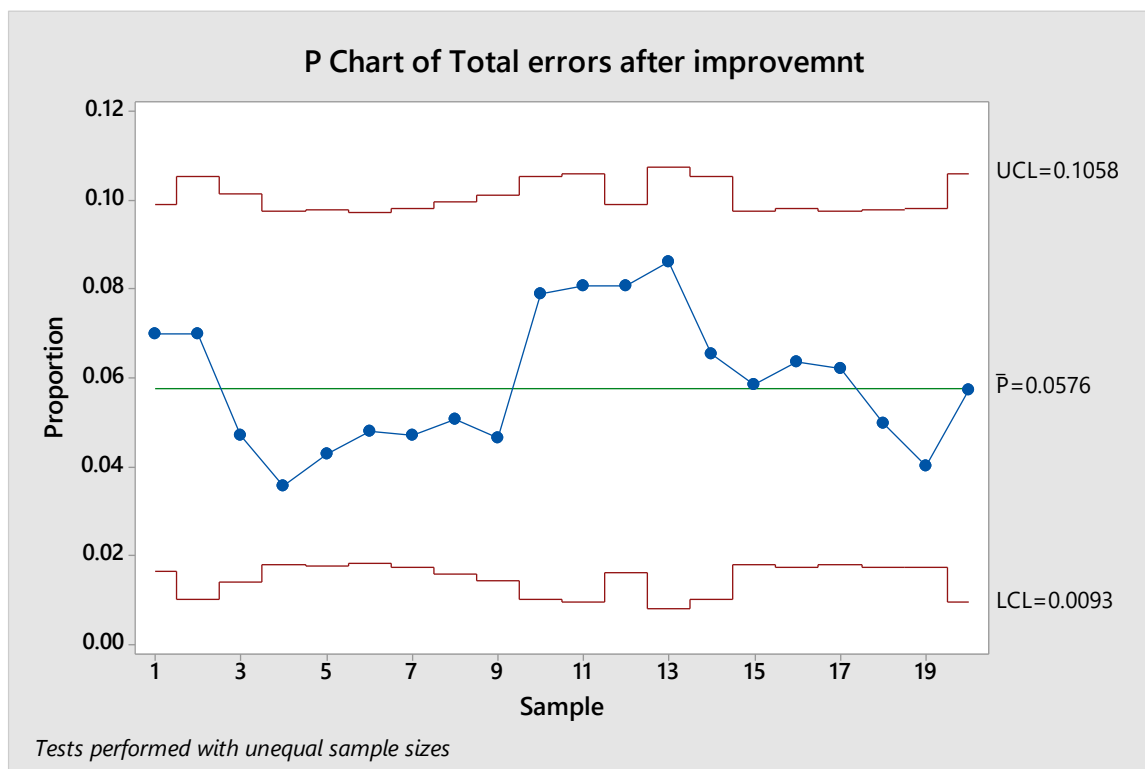


Figure 10 P chart of total error after improvement

The new average total yield is 99.73% as compared to 83.96 % before improvement. New process sigma value is 4.28, which is also higher

than early calculated process sigma value of 3.9. This shows that with the current improvements we have reduced to total errors rate in TTP.

Table 4 Comparison of process performance between before and after improvement

Before improvement process capability		After improvement process capability	
DPU	0.17323	DPU	0.057553
PPM	173229.99	PPM	57552.62
DPMO	8,249	DPMO	2740.601
Process Sigma	3.9	Process Sigma	4.28
Yield %	83.96	Yield %	99.73

5. Conclusion and Discussion

In this study, quality problems associated with the Total Testing Process (TTP) in a clinical lab were systematically investigated, with a particular focus on the pre-analytical and post-analytical phases, during which most diagnostic errors occur. To this end, a structured approach to problem solving, namely Six Sigma, following a DMAIC approach, was employed to detect, quantify, and solve errors. First, data collection was carried out through direct observation to determine error frequency and classify errors

under specimen, collector, requisition, and workflow error categories. Root cause analysis was then carried out using quality management tools to determine critical points such as errors caused by unconcerned staff and long turnaround time (TAT). On this basis, improvements were made, such as redesigning the lab, its workflow, and redistributing workforce, and finally, evaluation was carried out using statistical control tools and sigma values to assess the efficacy of improvements made.

Analysis of the Total Testing Process (TTP) showed that errors are mainly concentrated in the pre-analytical phase, constituting 94% of the total calculated errors, which were 827. On the other hand, post-analytical errors were found to constitute just 6%. The baseline error rates were also found to be 16.12% for pre-analytical and 1.01% for post-analytical. This again proves that the major causes of process variability are in the pre-analytical phase. Further analysis of the pre-analytical phase also showed that the most important factor is interference due to unconcerned personnel, constituting 37% of the total errors, followed by hemolyzed samples, transportation, and incorrect routing. This again proves that the major causes are process-driven and organizational rather than technical.

In the post-analytical phase, the main problem was related to turnaround time, and this problem contributed 84% to errors, while other problems, such as loss of reports and problems related to report delivery, were less important. This result clearly proves and demonstrates that problems related to sequencing, coordination, and report mechanisms play a critical role in service delivery, even if analytical accuracy is ensured. Therefore, improvement in process flow and communication channels has become critical in order to improve overall laboratory performance.

After applying DMAIC-based intervention, critical improvements were observed in terms of error minimization and process efficiency improvement. The overall error rate has been reduced from 30.62 to 15.45 errors/day, and this reduction is approximately 49.5% less than previous errors. Similarly, pre-analytical errors were reduced to 5.38%, and post-analytical errors were reduced to 0.37%. Furthermore, through process optimization, such as redesigning the layout and redistributing workforce, a reduction in turnaround time from 112.5 minutes to 89.5 minutes was also observed, and this improvement is approximately 20% less than previous time consumption. This result clearly proves and demonstrates that process re-engineering, such as minimizing workflow interference, has a critical and direct impact on error minimization and improvement in process efficiency.

In terms of process capability, the implementation of Six Sigma has resulted in improved performance, whereby the sigma level has improved from 3.9 to 4.28, and process yield has improved from 83.96% to 99.73%. The laboratory capacity has also improved from 42.67 to 59 tests per hour, implying a 38.27% improvement in terms of throughput. This, therefore, proves that quality improvement methodologies such as DMAIC are extremely effective, especially in healthcare organizations, especially in a resource-constrained environment. The study, therefore, proves that integrating process redesign with Six Sigma principles does not only improve productivity and reliability but also service quality in clinical laboratory systems.

6. Future Recommendation:

For future studies, it is recommended that the execution of Six Sigma practices be further extended through the inclusion of real-time digital monitoring technologies such as Laboratory Information Systems (LIS) to further reduce human errors. Moreover, the inclusion of statistical validation approaches would also enhance the reliability of the results. Training programs aimed at ensuring role clarity and standard operating approaches would also need to be institutionalized to ensure the sustainability of the results, while future studies may also include the analytical approach to ensure a comprehensive evaluation of the entire Total Testing Process.

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