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# TURNAROUND TIME OPTIMIZATION IN HEMATOLOGY LABORATORIES: EVALUATING THE IMPACT OF ERROR-FREE TESTING INTERVENTIONS THROUGH SIX SIGMA METHODOLOGY

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## ABSTRACT

**Introduction:** Laboratory Turnaround Time (TAT) serves as a critical performance indicator in clinical laboratories and varies depending on the nature of the test (stat versus routine), analyte type, and institutional protocols. TAT is broadly defined as the duration from the initiation of a laboratory test order to the final reporting of results. The comprehensive TAT encompasses the entire "brain-to-brain" cycle starting from the clinician's test request to the interpretation and application of the result in patient management. Six Sigma focuses on quantifying process defects as Defects Per Million Opportunities (DPMO), with an aspirational target of 3.4 defects per million, signifying near-zero error.

**Materials and Methods:** This analytical study was conducted at the hematology departments of multiple tertiary care hospitals in Lahore, Pakistan. Complete blood count (CBC) samples were collected systematically over a one-month period. All samples were analyzed using a fully automated five-part differential hematological analyzer (Sysmex XN-9000) ensuring standardized processing and reporting protocols. The routine TAT for CBC in these laboratories was set at 4 hours. The Sigma metric for CBC parameters was calculated using the formula: Sigma (σ) = [TEa - bias)/CV]. Where $TE_a$ represents Total Allowable Error, Bias is the systematic deviation from the true value, and CV denotes the Coefficient of Variation.

**Findings:** Defects were identified based on delayed reporting exceeding the standard TAT, and Six Sigma values were derived by calculating the DPMO. An initial assessment of TAT and Sigma metrics was performed before any intervention. Subsequently, laboratory personnel underwent targeted training focused on optimizing analytical processes, emphasizing sample handling, analyzer operation, and result validation. After the one-month intervention period, the TAT and Sigma metrics were reassessed to evaluate the impact of training on process efficiency and error reduction.

**Conclusion:** This study provides an evidence-based framework for applying Six Sigma methodology to optimize laboratory TAT in tertiary care settings. By identifying key process inefficiencies and implementing targeted corrective actions, significant improvements in TAT and analytical quality can be achieved, ultimately enhancing patient care delivery.

**Keywords:** Turnaround Time (TAT), Six Sigma, Hematology, Quality Improvement, Laboratory Efficiency, Error Reduction

## INTRODUCTION

Clinical diagnostic laboratories constitute an indispensable component of modern healthcare systems, underpinning the diagnosis, monitoring, and management of a vast spectrum of human diseases [1]. Laboratory testing is widely recognized as a cornerstone of medical decision-making, contributing to an estimated 60–70% of clinical judgments globally. In the evolving landscape of healthcare delivery marked by escalating demands for efficiency, precision, and cost-effectiveness diagnostic laboratories have transcended their traditional operational roles, necessitating close collaboration with clinicians, administrators, and allied healthcare personnel to optimize patient outcomes [2]. The significance of laboratory professionals, or laboratorians, has been reinforced by their integral role in ensuring the accuracy, reproducibility, and clinical relevance of diagnostic outputs [3]. As healthcare systems globally embrace value-based care paradigms, laboratories must demonstrate consistent contributions to patient safety, clinical efficiency, and service excellence.

The formalization of quality assurance practices in diagnostic laboratories traces back to the seminal introduction of statistical quality control (SQC) by Levey and Jennings in 1950 [4]. Their pioneering work laid the foundation for embedding quality metrics into laboratory operations, eventually evolving into a globally accepted standard by the 1960s [2,5]. Since then, quality improvement initiatives in laboratory medicine have progressively matured, incorporating advanced analytical methodologies, data-driven strategies, and structured quality frameworks designed to systematically identify root causes of deficiencies and implement corrective measures. Contemporary laboratory management mandates the continuous integration of statistical process control, evidence-based guidelines, and standardized operating procedures, particularly in high-stakes diagnostic domains [6].

Among various operational metrics, Turnaround Time (TAT) has emerged as a critical indicator of laboratory efficiency, directly influencing the perceived and actual quality of diagnostic services. Although TAT definitions vary by institutional protocol and analyte complexity, it is broadly conceptualized as the interval extending from the initiation of a diagnostic request by a clinician to the final communication of verified results to the treating team. The total TAT, encompassing the comprehensive "brain-to-brain" cycle, includes multiple process stages: test ordering, specimen collection, transportation to the laboratory, sample accessioning, pre-analytical preparation (centrifugation, aliquoting, etc.), analytical measurement, result verification, and final report dissemination. Each component of this chain represents a potential source of delay or error, underscoring the need for meticulous process optimization. In critical care environments such as emergency departments and surgical theaters, timely diagnostic reporting is often directly correlated with reduced patient morbidity and mortality, reinforcing TAT as a pivotal quality indicator in clinical diagnostics [7].

Despite considerable advancements in laboratory automation and digitization, a significant proportion of laboratory-associated errors continue to originate from the pre-analytical and post-analytical phases. Numerous studies have consistently demonstrated that while analytical processes are subject to rigorous control mechanisms, errors upstream and downstream of the measurement phase remain comparatively prevalent [8]. Factors such as improper specimen handling, delayed sample transport, clerical errors in test requisitioning, and inefficient result communication protocols substantially contribute to extended TATs and compromise clinical efficiency [5,6,9]. Consequently, modern quality management strategies must adopt a process-wide approach, recognizing that analytical precision alone is insufficient to guarantee overall diagnostic excellence. Among various quality

improvement methodologies, Six Sigma has gained prominence as a statistically robust, data-driven framework designed to minimize process variability and systematically eliminate defects. Initially conceptualized by Motorola in the 1980s, Six Sigma employs a structured Define, Measure, Analyze, Improve, and Control (DMAIC) framework to achieve near-perfection in operational processes. Within the context of Six Sigma, a defect represents any deviation from defined quality standards or client expectations. Performance is quantitatively expressed in terms of Defects Per Million Opportunities (DPMO), with a Six Sigma level denoting an exceptionally low error rate of 3.4 defects per million operations [10]. By applying Six Sigma methodologies to laboratory medicine, diagnostic services can not only reduce internal process variability but also enhance the consistency and reliability of patient outcomes. The approach further facilitates data-centric decision-making, leveraging real-time quality monitoring through internal quality control (IQC) systems and external quality assessment (EQA) programs to continuously benchmark laboratory performance. Although Six Sigma principles have long been entrenched in industrial engineering and manufacturing, their formal integration into clinical laboratory workflows remains relatively nascent in several regions, particularly in resource-constrained healthcare settings [11]. Nonetheless, empirical evidence demonstrates that Six Sigma applications in diagnostic laboratories especially in hematology, pathology, and clinical chemistry can significantly improve laboratory performance indicators such as TAT, defect rates, and resource utilization. Furthermore, the incorporation of Six Sigma methodologies into total quality management (TQM) paradigms aligns with internationally recognized quality frameworks such as ISO 9001 and ISO 15189, further reinforcing their relevance to clinical laboratories striving for accreditation and international benchmarking [12].

In laboratory operational frameworks, the diagnostic process is classically delineated into three sequential phases: the pre-analytical phase, encompassing all procedures from test ordering to sample preparation for analysis; the analytical phase, representing the actual measurement of the analyte; and the post-analytical phase, involving result verification, reporting, and clinical integration. Delays or process inefficiencies at any stage can critically impair overall TAT, adversely affecting both clinical decision-making and patient satisfaction. Therefore, systematic process optimization, guided by validated quality models such as Six Sigma, remains essential for ensuring comprehensive diagnostic excellence. The terminology of “quality systems” in laboratory medicine is deeply rooted in the principles of ISO 9000 series standards, originally conceptualized for industrial and business applications but subsequently adapted for healthcare settings. These quality systems encompass structured organizational hierarchies, defined responsibilities, documented procedures, continuous personnel training, equipment calibration, reagent standardization, and robust documentation trails [13]. Collectively, they constitute the backbone of total quality management (TQM), facilitating sustainable quality improvements in diagnostic laboratories worldwide. The integration of Six Sigma within these frameworks enhances precision, reduces variability, and contributes to higher diagnostic confidence for clinicians and patients alike. Given the critical importance of diagnostic timeliness in patient care, particularly in hematological testing where rapid results can influence urgent clinical decisions, continuous quality improvement remains imperative [14]. This study was therefore undertaken to evaluate the impact of targeted interventions on key laboratory quality indicators specifically Turnaround Time (TAT) and Six Sigma metrics within the hematology department of a tertiary care hospital in Lahore, Pakistan. Utilizing state-of-the-art hematology analyzers and adhering to established internal quality control protocols, this research aims to provide empirical insights into the application of Six Sigma methodologies in optimizing hematology laboratory performance in resource-limited healthcare settings.

## METHODOLOGY

This prospective descriptive study was systematically conducted to evaluate the analytical efficiency and operational performance of hematology laboratories within four tertiary care hospitals in Lahore, Pakistan. The study spanned a period of two consecutive months, from 1st January 2025 to 28th February 2025, encompassing a comprehensive assessment of routine hematological parameters.

These laboratories were selected based on their high diagnostic workload, technical capacity, and representation of diverse healthcare settings, ensuring robustness in the study's generalizability and translational applicability. A prospective, descriptive, interventional study design was adopted to assess the diagnostic accuracy and process capability of automated hematological testing. Emphasis was placed on evaluating Turnaround Time (TAT) and Six Sigma performance metrics to quantify laboratory efficiency both before and after targeted procedural interventions.

During the study period, 1,654 venous blood samples were consecutively included using a non-probability, purposive sampling technique. These samples were submitted for routine Complete Blood Count (CBC) analyses across all four participating institutions. The sample size was considered adequate to achieve meaningful statistical power in evaluating variations in TAT and Sigma performance, thereby enabling pre- and post-intervention comparisons. All blood samples received for routine CBC investigations, including red blood cell (RBC) count, hemoglobin (Hb), hematocrit (HCT), white blood cell (WBC) count, and platelet count, were eligible for inclusion. Only samples accompanied by complete clinical and demographic documentation and meeting institutional sample quality standards were processed. Samples that exhibited clot formation, which could compromise analytical integrity, were excluded. Additionally, samples submitted solely for peripheral blood smear examination without concurrent CBC requisition were omitted from the study cohort.

The study was conducted in two sequential phases:

**Phase I (Pre-Intervention/Baseline Assessment – January 2025):** During the initial phase, standard laboratory operating procedures (SOPs) were followed without additional intervention. TAT was meticulously recorded for each hematological parameter from the point of sample receipt to the final validation and reporting of results. Simultaneously, Sigma metrics were computed utilizing error rates derived from internal quality control (IQC) data in conjunction with established analytical performance standards.

**Phase II (Post-Intervention Assessment – February 2025):** Following baseline assessment, a structured and focused capacity-building intervention was implemented. Laboratory technologists, phlebotomists, and analytical personnel underwent targeted training workshops emphasizing critical aspects of pre-analytical and analytical workflows. The training modules were designed in accordance with international best practices, particularly focusing on sample handling protocols, prevention of pre-analytical errors, instrument calibration procedures, reagent stability management, and error-proof result authorization. The aim was to systematically mitigate sources of variability and error across all procedural steps of hematological testing. Upon completion of the training intervention, TATs were reassessed using identical data collection methodologies, and comparative analysis of Sigma performance was conducted to evaluate the tangible impact of the educational and operational interventions on laboratory efficiency.

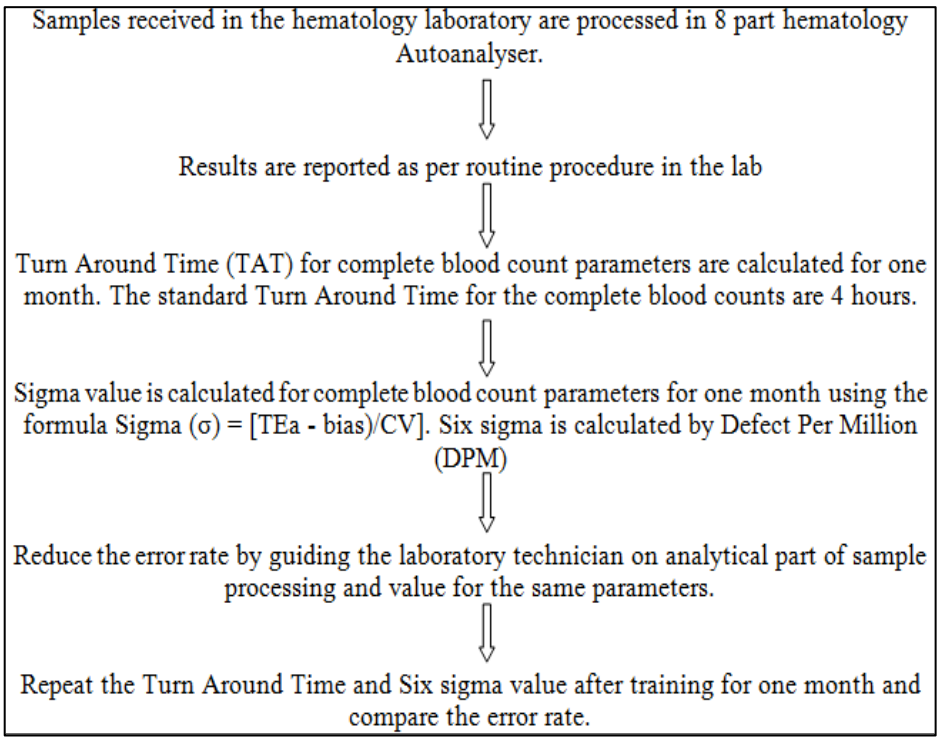
Analytical performance was quantitatively assessed using the Six Sigma methodology. Sigma levels were calculated based on the following formula:

Sigma ($\sigma$) = [TEa - bias)/CV].

Where:

TEa = Total Allowable Error (as per CLIA or locally established standards), Bias = Systematic deviation from the true value (measured via proficiency testing or external quality assessment data), CV = Coefficient of Variation, representing intra-assay imprecision.

Defects per Million Opportunities (DPMO) were computed, and corresponding Sigma levels were interpreted according to conventional Six Sigma classification standards, where higher Sigma levels correspond to superior process performance and minimal defect rates. All collected data were subjected to descriptive and inferential statistical analyses. Continuous variables such as TAT were presented as means ± standard deviation (SD), while Sigma levels were expressed in absolute values for inter-phase comparison. Statistical significance was established at $p < 0.05$.




## RESULTS & FINDINGS

The present study was conducted over a two-month duration, from 1st January 2025 to 28th February 2025, across four tertiary care hospitals in Lahore, Pakistan. A total of 1,654 blood samples submitted to hematology laboratories for complete blood count (CBC) analysis were included in this evaluation. Key hematological parameters analyzed in this study comprised red blood cell (RBC) count, hemoglobin (Hb), hematocrit (HCT), white blood cell (WBC) count, and platelet count. The laboratory information management system (LIMS) was utilized to record the test completion times, allowing for the precise assessment of Turnaround Time (TAT) for each analyte.

**Pre-Intervention Analysis (Phase I):** During the pre-intervention phase (January 2025), a total of 827 samples were processed under routine laboratory operational protocols. Of these, 85.3% (705/827) of RBC count, hemoglobin, and hematocrit results were reported within the prescribed TAT. Similarly, 86.5% (716/827) of WBC counts and 81.9% (677/827) of platelet counts were delivered within the established time benchmarks.

**Post-Intervention Analysis (Phase II):** Following targeted training interventions and the implementation of enhanced operational practices during Phase II (February 2025), a marked improvement in laboratory performance was observed. Out of 827 post-training samples, 91.1% (753/827) of RBC count, hemoglobin, and hematocrit results met the prescribed TAT, while 89.3% (739/827) of WBC counts and 87.8% (726/827) of platelet counts were completed within the specified turnaround period.

The percentage improvements in TAT compliance between pre- and post-intervention periods were as follows:

***Table 1: percentage improvements in TAT pre & post intervention months***

| *Parameter* | **Pre-Intervention (n=827)** | **Post-Intervention (n=827)** | **Percentage Improvement** |
|---|---|---|---|
| *RBC, Hb, HCT* | 705 (85.3%) | 753 (91.1%) | +5.8% |
| *WBC* | 716 (86.5%) | 739 (89.3%) | +2.8% |
| *Platelet Count* | 677 (81.9%) | 726 (87.8%) | +5.9% |

Further performance evaluation was conducted using Six Sigma metrics, which provided quantifiable insights into process efficiency in terms of Defects Per Million Opportunities (DPMO) and Sigma levels.

***Table 2: Defects Per Million Opportunities (DPMO) and Sigma Values Before and After Intervention***

| *Parameter* | **DPMO (Pre-Intervention)** | **Sigma (Pre-Intervention)** | **DPMO (Post-Intervention)** | **Sigma (Post-Intervention)** |
|---|---|---|---|---|
| *RBC Count* | 4,695 | 4.1 | 3,078 | 4.3 |
| *Hemoglobin* | 8,201 | 3.9 | 5,335 | 4.1 |
| *Hematocrit* | 4,695 | 4.1 | 3,644 | 4.3 |
| *WBC Count* | 6,013 | 4.0 | 3,078 | 4.3 |
| *Platelet Count* | 11,603 | 3.7 | 7,317 | 3.9 |

The pre-intervention phase demonstrated moderate Sigma levels, ranging from 3.7 to 4.1, with relatively higher defect rates, particularly for platelet counts. Following the structured capacity-building interventions implemented in Phase II, there was a consistent reduction in DPMO across all hematological parameters evaluated. The most significant improvements were observed for platelet count (from 11,603 to 7,317 DPMO), reflecting better handling of pre-analytical variables such as anticoagulant mixing and prompt sample processing. Correspondingly, the Sigma metrics improved, with RBC count, hematocrit, and WBC count achieving a Sigma level of 4.3, indicative of robust process capability. The progressive enhancement in Sigma performance reflects the tangible impact of targeted interventions focusing on pre-analytical accuracy, analytical precision, and staff competency reinforcement. These findings substantiate that strategic training and workflow optimization in hematology laboratories can lead to statistically and operationally significant improvements in diagnostic efficiency. The reduction in TAT variability and defect rates emphasizes the necessity of continuous quality management interventions, specifically in resource-intensive laboratory settings.

## DISCUSSION

The foundation of any robust laboratory quality management system lies in the establishment of quantifiable and measurable quality objectives. In clinical diagnostics, the implementation of measurable quality indicators (QIs) is paramount, as these provide objective metrics for assessing the effectiveness of laboratory operations and ensuring continuous performance enhancement. By definition, quality indicators must be measurable, analyzable, and actionable, enabling laboratories to systematically evaluate operational outcomes, identify deviations from predefined standards, and instigate corrective actions as necessary. As stipulated in ISO 15189:2012 (Clause 4.12.4), accredited laboratories are required to implement comprehensive quality indicator programs that facilitate systematic monitoring of the laboratory's contribution to patient care. Critically, when deviations or opportunities for improvement are identified through this framework, laboratory management is mandated to initiate interventions regardless of the operational phase or origin of the deficiency [14]. Clause 3.19 of the same standard defines Quality Indicators (QIs) as essential tools for evaluating how effectively an organization fulfills user requirements and maintains the integrity of all processes across the pre-analytical, analytical, and post-analytical phases. Complementing this, Clause 4.14.7 explicitly emphasizes that laboratories must establish, monitor, and evaluate quality indicators across all critical processes to ensure sustained compliance with diagnostic quality standards [15].

In the current study, adherence to these international standards was operationalized through the measurement of Turnaround Time (TAT) as a primary quality indicator, with detailed statistical analysis applied to CBC samples received from Inpatient Departments (IPDs), Outpatient Departments (OPDs), and Intensive Care Units (ICUs). The baseline average TAT for hematological

investigations across all departments was determined to be 4 hours, prior to the initiation of quality improvement interventions. Comparable studies corroborate these findings. For instance, Hallam CR et al. demonstrated a progressive reduction in TAT non-conformance, reporting a decrease from 6.4% in 2011 to 4.6% by 2023 [16]. Although slightly higher prolonged TATs were observed in our study initially, these delays were primarily attributable to pre-analytical bottlenecks, including registration delays, billing discrepancies, analyzer calibration issues, reagent shortages, and extended consultation periods. Subsequent stratified analysis in the present investigation revealed that approximately 75% of the delays were attributable to pre-analytical factors, while 24% were linked to analytical issues. This finding aligns closely with data from Hanna MG et al., who reported that 74.2% of TAT delays stemmed from pre-analytical shortcomings [17]. Recognizing these contributory factors, targeted training interventions focusing on pre-analytical process optimization were implemented. The training emphasized correct sample handling, prioritization of stat investigations, verification of electronic order entries, and mitigation of documentation errors. This focused approach resulted in a notable post-intervention improvement in TAT compliance, achieving a post-training adherence of 91.1%, in concordance with findings by Graban M et al [18]. A significant adjunct to the TAT analysis in this study was the application of Six Sigma metrics, providing a granular assessment of process efficiency. Post-intervention Sigma metrics ranged between 4.1 and 4.3, demonstrating tangible improvement when compared to the pre-training range of 3.9 to 4.2. These observations are consistent with findings by Halwachs-Baumann et al., underscoring the efficacy of structured competency enhancement programs in elevating diagnostic process quality [19]. In parallel, the study demonstrated a substantial decline in Defects Per Million Opportunities (DPMO) and overall error rates, further affirming the positive impact of continuous professional development (CPD) on laboratory quality assurance. The yield percentages for the evaluated hematological parameters ranged from 99.5% to 99.8%, a finding that aligns closely with prior work by Schroeder RG et al., who similarly demonstrated high process yields as a proxy indicator of minimal analytical error rates in clinical laboratory settings [20].

The evidence generated from this study reinforces the strategic necessity of continuous quality improvement (CQI) initiatives in diagnostic laboratories. Beyond structured in-house training, participation in external conferences, symposia, and continuing medical education (CME) programs was encouraged to enhance both theoretical knowledge and technical expertise among laboratory personnel. These multifaceted educational strategies fostered greater engagement, technical competence, and overall motivation, contributing to sustainable process improvement.

## CONCLUSION

The findings of this study decisively highlight that the implementation of measurable quality indicators, particularly Turnaround Time (TAT) and Six Sigma metrics, serve as critical instruments for optimizing laboratory performance. These metrics facilitate precise monitoring, enable the early detection of process inefficiencies, and support timely corrective actions. Furthermore, their integration into the quality management framework enhances diagnostic efficiency, minimizes analytical errors, and significantly contributes to patient-centered laboratory services. Sustained improvements in laboratory performance were observed through structured, periodic, and targeted training programs, emphasizing that quality management in healthcare laboratories is an ongoing, dynamic process. The integration of periodically reviewed quality indicators within the operational matrix of the laboratory is therefore essential for ensuring process sustainability, regulatory compliance, and continuous advancement in healthcare delivery outcomes.

### Conflict of Interest

The authors declare no conflict of interest related to this study

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