

Enhancing Laboratory Efficiency: The Role of Lean Six Sigma in Improving Quality Metrics in a Clinical Biochemistry Setting.

Lean Six Sigma in Clinical Biochemistry.

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Abstract

This study aimed to assess the impact of Lean Six Sigma (LSS) methodologies on key quality indicators in a NABL-accredited clinical biochemistry laboratory, including Turnaround Time (TAT), redos, errors, and sample rejections. Conducted at the Clinical Biochemistry Laboratory, this study measured baseline metrics from April to July 2021. Workflow improvements were then implemented, including upgrading the immunoassay analyzer and refining testing processes. Post-intervention metrics were collected in June 2022 for comparison. Baseline data revealed substantial variability in TAT and elevated redo rates due to errors, primarily in the analytical phase. Immunoassays posed a bottleneck, prompting an upgrade from Roche Cobas e602 to e801 and the allocation of HbA1c testing to the Bio Rad D100. These interventions improved TAT efficiency by 15% and increased sigma values across test categories. Refining redo criteria reduced unnecessary retests by 20%. Additionally, addressing pre-analytical issues, including sample mislabeling and inadequate volumes, reduced sample rejection rates by 25%. Implementing LSS methodologies led to significant improvements in laboratory quality metrics, reducing errors and optimizing workflow efficiency in this high-volume setting. This study offers a scalable model for quality improvement in clinical laboratories, supporting broader adoption of LSS in healthcare quality management.

Keywords: lean six sigma, quality indicators, turnaround time, workflow efficiency, process improvement, laboratory errors

Introduction

Clinical biochemistry laboratories are central to patient care in healthcare facilities, providing timely and accurate laboratory results critical for diagnosis and treatment decisions. Quality indicators, which measure various facets of laboratory performance, are essential for monitoring and enhancing laboratory service quality [1,2]. Among these, turnaround time (TAT), error rates, non-conformances (NCs), and sample rejection rates are particularly important as they directly influence diagnostic efficiency and accuracy. Turnaround time, especially, serves as a benchmark for laboratory performance, capturing the speed and reliability of the testing process, which ultimately affects patient outcomes and satisfaction[3].

Non-conformances, defined as deviations from expected actions or processes, represent a core quality metric. These NCs, encompassing errors in pre-analytical, analytical, and post-analytical stages, can disrupt workflow and negatively impact diagnostic accuracy. Reducing NCs and minimizing errors across the testing process is thus essential to maintaining high standards in laboratory quality and service[4].

Lean Six Sigma (LSS) methodology combines Lean principles, which focus on waste reduction, with Six Sigma's defect minimization approach. Developed in manufacturing but increasingly applied in healthcare, Lean Six Sigma systematically identifies and eliminates inefficiencies, thereby optimizing workflows and improving outcomes. Lean methods aim to streamline operations by removing unnecessary steps, while Six Sigma's

statistical approach seeks to measure and reduce variation, quantifying quality in terms of "sigma levels" where a higher sigma reflects fewer defects [5-7]. The combination of these methodologies enables a laboratory to tackle multiple sources of inefficiency and error concurrently, thereby driving continuous improvement. Together, these methodologies address two critical questions: "How can we improve this process?" and "Is each step necessary?"

The application of LSS in clinical biochemistry laboratories allows these facilities to proactively address inefficiencies and manage quality risks. By implementing this framework, laboratories can systematically improve key performance indicators, such as TAT, by identifying bottlenecks and addressing root causes of delays and defects. Lean Six Sigma employs various tools, such as Pareto charts to highlight the most frequent defects, and value stream mapping to identify non-value-adding activities. In particular, the DMAIC (Define, Measure, Analyze, Improve, Control) approach within Six Sigma provides a structured, iterative process for continual enhancement of laboratory processes. This methodology has been shown to improve lab performance metrics and is now recommended as a best practice in high-stakes environments such as clinical laboratories[6-9].

This study investigates the impact of Lean Six Sigma methodologies on quality indicators within a NABL-accredited clinical biochemistry laboratory, with an emphasis on reducing TAT, errors, and sample rejections, and improving sigma metrics. By establishing a baseline for these quality indicators and applying targeted LSS

interventions, this research seeks to quantify improvements in laboratory performance and identify factors that are most influential in achieving enhanced outcomes. This exploration contributes to the growing body of evidence supporting the efficacy of Lean Six Sigma in healthcare, illustrating how systematic quality management can lead to sustainable improvements in laboratory accuracy, efficiency, and service quality.

Methods

This observational study was conducted in the Clinical Biochemistry Laboratory at the Department of Biochemistry, from April 2021 to October 2022. Data collection began in April 2021 and concluded by October 2022. To evaluate turnaround time (TAT), data from April 2021 to July 2021 and June 2022 were analyzed, while data on redoes, errors, and sample rejections were collected from January 2021 to August 2021 and January 2022 to August 2022.

The study examined data on all redoes, errors, and sample rejections. For TAT analysis, only tests performed on automated analyzers were included, as these tests capture data continuously in the laboratory information system, allowing verification 24x7. Manual tests and tests from the STAT, IEM, and Toxicology labs were excluded.

Ethical clearance was obtained from the Institutional Ethics Committee on 16-04-2021 (IEC: 121/2021), with the study being exempt from registration in the Clinical Trials

Registry of India (CTRI). As this was a retrospective data analysis of quality indicators, no consent or participant information sheets were required.

Quality indicators analyzed included TAT, redoes, errors, and sample rejections.

Baseline TAT data, encompassing timestamps from registration to verification, were collected over a four-month period, with TAT calculated from receiving to verification time for each analyte processed on an automated analyzer. Analytes were grouped based on measurement principles and analytical time, with sigma values calculated to evaluate quality. After laboratory workflow changes, TAT data were collected again for one month to recalculate sigma values for each group and compare them with baseline values.

Data on redoes, errors, and sample rejections were retrieved from the Medblaze software for initial baseline calculations. Following analysis, the laboratory identified problem areas and updated the criteria for redoes. These updates were communicated to the relevant hospital wards, and data on redoes, errors, and sample rejections were subsequently re-collected from the software and analyzed. Both baseline and post-intervention datasets were compared to assess improvement.

Microsoft Excel in Office 365 was used to compile and analyze the data. Pareto charts were utilized to identify areas causing the most defects, while bar and pie charts represented the data visually. Fishbone diagrams facilitated brainstorming of root causes for defects. Sigma values were calculated using the iSixSigma calculator and Microsoft

Excel. Statistical analysis focused on comparing baseline and post-intervention sigma values to evaluate the effectiveness of workflow changes.

Results

This study evaluated the impact of Lean Six Sigma methodologies on four key quality indicators in a NABL-accredited clinical biochemistry laboratory: Turnaround Time (TAT), redoes, errors, and sample rejections. Data was redoes collected in two phases, with baseline values established from April to July 2021 and subsequent values obtained in June 2022 following workflow improvements.

Turnaround Time (TAT):

A total of 676,388 tests were performed between April and July 2021. The average TAT per analyte varied, with most analytes meeting the targeted TAT of <120 minutes (Table 1). In June 2022, the number of tests performed was 271,977, and TAT metrics indicated increased efficiency, with reduced bottlenecks in immunoassay tests (Table 2).

Following workflow enhancements, including the upgrading of the Roche Cobas e602 immunoassay instrument to e801 and a shift of HbA1c testing to the Bio Rad D100, the sigma values showed improvement (Table 3).

Table 1: Average laboratory turnaround time (TAT) for test groups from April to July 2021

Table 1: Average Lab TAT per Group (April 2021 – July 2021)	
Group	Average Laboratory TAT (mins)
Chemistry	69
HbA1c	49
Immunoassay	94
ISE	62
Combined	70

Table 2: Average laboratory turnaround time (TAT) for different test groups in June 2022 after Lean Six Sigma interventions

Table 2: Average Lab TAT per Group (June 2022)	
Group	Average Laboratory TAT (mins)
Chemistry	72
HbA1c	44
Immunoassay	93
ISE	67
Combined	72

Table 3: Comparison of process sigma values before and after workflow changes in the laboratory.

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Group	2021	2022
Chemistry	2.84	3
HbA1c	1.63	3.19
Immunoassay	2.65	2.68
ISE	2.7	3.07

Redo Tests:

Initial data analysis from January to August 2021 indicated frequent redos due to pre-analytical and analytical errors. Common causes included sample quality issues and critical values needing confirmation (Table 4). Post-intervention criteria updates reduced redo rates significantly, resulting in better resource utilization and faster reporting times (Table 5).

Table 4: Redo count and percentage of various reasons for redos in the laboratory from January to August 2021.

Table 4: Redo count and Redo percentage of reasons for redos (January 2021 – August 2021)		
Reasons for redos	Redo count	Redo%
MORE THAN AMR	426	68.60%
CRITICAL VALUE REPEAT	156	25.12%
LESS THAN AMR	25	4.03%
REPORT WITH FLAG	8	1.29%
CLINICALLY NOT CORRELATING	3	0.48%
SAMPLE/BAR-CODE EXCHANGE	2	0.32%

Table 5: Redo count and percentage of various reasons for redos in the laboratory from January to August 2022 after intervention.

Table 5: Redo count and Redo percentage of reasons for redos (January 2022 – August 2022)		
Reasons for redos	Redo count	Redo%
MORE THAN AMR	146	58.63%
QC/ CALIBRATION ERROR	44	17.67%
CRITICAL VALUE REPEAT	43	17.27%
INSTRUMENT ERROR	8	3.21%
SAMPLE CLOT	3	1.20%
REPORT WITH FLAG	2	0.80%
CLINICALLY NOT CORRELATING	2	0.80%
LESS THAN AMR	1	0.40%
Grand Total	249	100.00%
SAMPLE CLOT	1	0.16%
Grand Total	621	100.00%

Errors and Non-Conformances:

Baseline error rates showed that most errors were related to the analytical phase, particularly transcription and process errors (**Table 6**) (**Figure 1-4**). After the Lean Six Sigma interventions, error rates decreased, notably in transcription-related issues. The fishbone analysis identified root causes, guiding corrective actions that minimized error recurrence.

Figure 1: Chart showing percentage of error types.

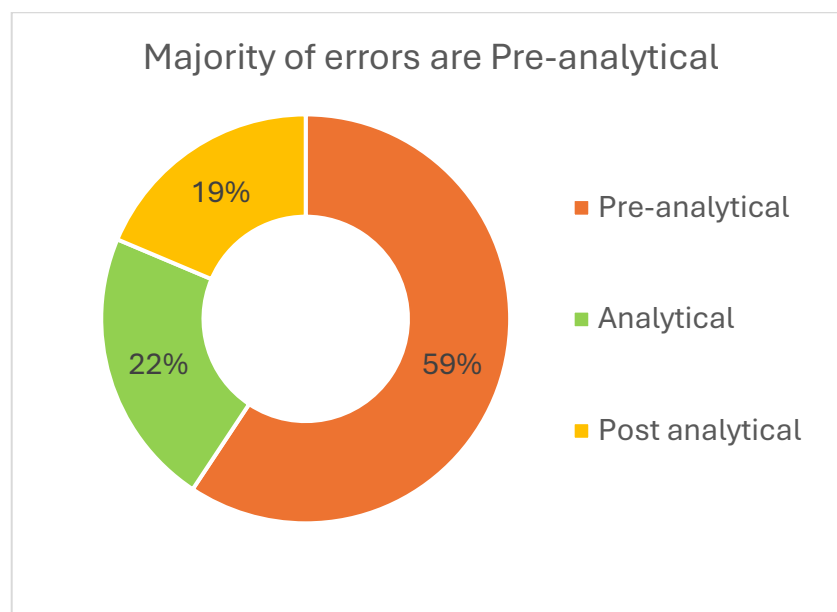


Table 6: Common root causes with corrective actions performed by laboratory

Root causes	Corrective actions
Ward staff/phlebotomist forgot to send test requisition slip/sample	Use of electronic test request forms
Ward staff /phlebotomist sent wrong sample to lab	Re-training and assessment of competency
Sample collection was done in wrong blood collection tube	
Billing technician overlooked a few tests while billing	Electronic test request forms with linking to billing software
Alarm given by machine was ignored	Block report release by machine when an alarm is raised by machine
QC rule violation was ignored	Re-training and assessment of competency
Flag was not entered during verification of reports	Automated flagging of sample status in reports
Failure to multiply dilution factor	Make provision in informatics systems to calculate results without human intervention

Figure 2: Chart showing causes of pre-analytical errors.

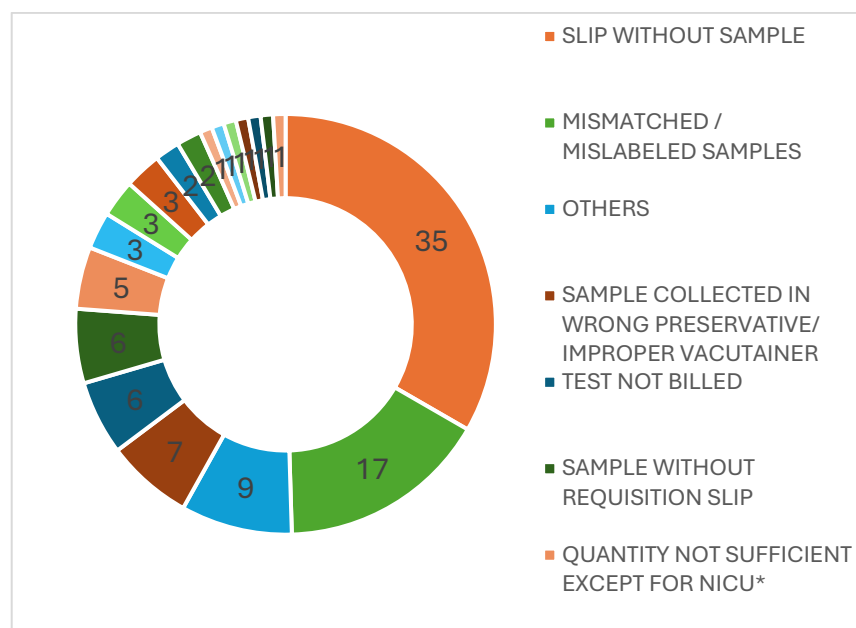


Figure 3: Chart showing causes of analytical errors

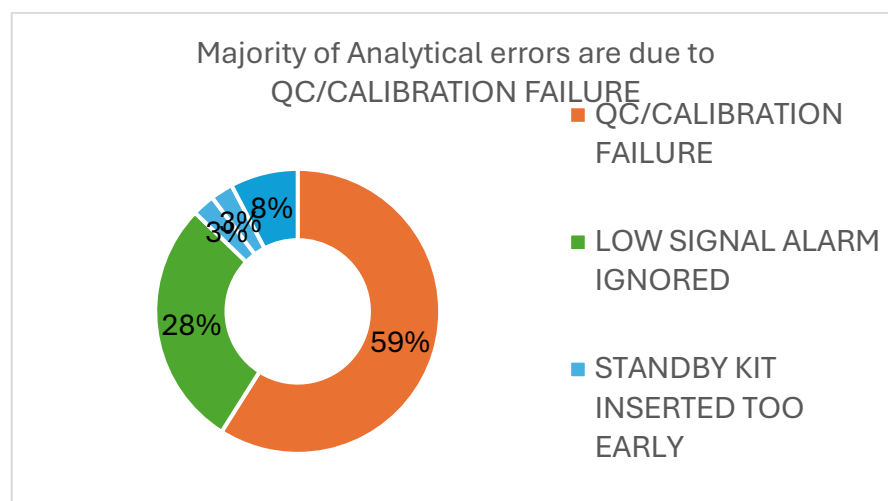
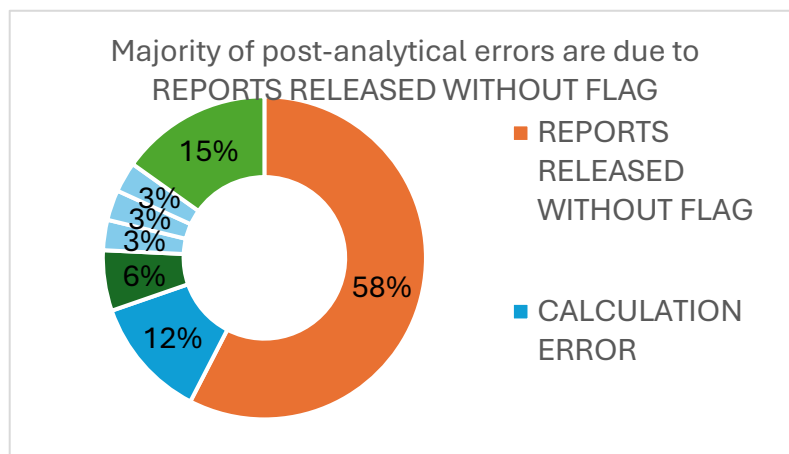


Figure 4: Chart showing causes of post-analytical errors.



Sample Rejections:

Initial sample rejection data (January–August 2021) showed high rejection rates due to mislabeling and insufficient sample volumes. By addressing identified root causes and enhancing pre-analytical processes, sample rejection rates improved, with a noted decrease in rejection rates from January to August 2022 (Figure 5,6).

Figure 5: Chart showing causes for sample rejections with counts.

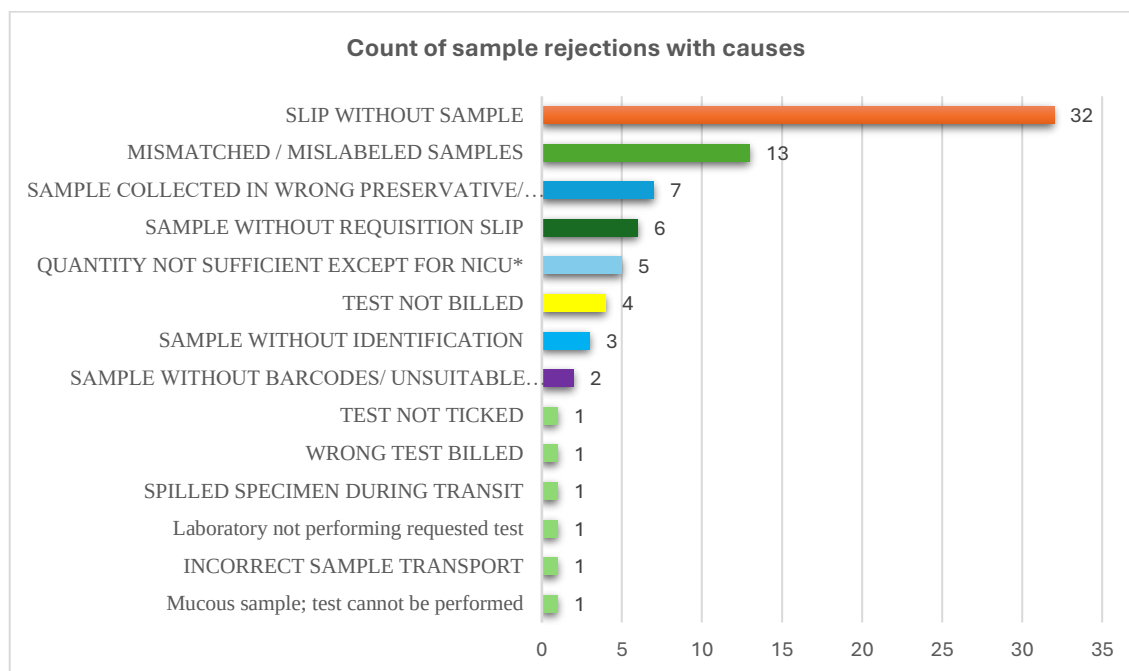
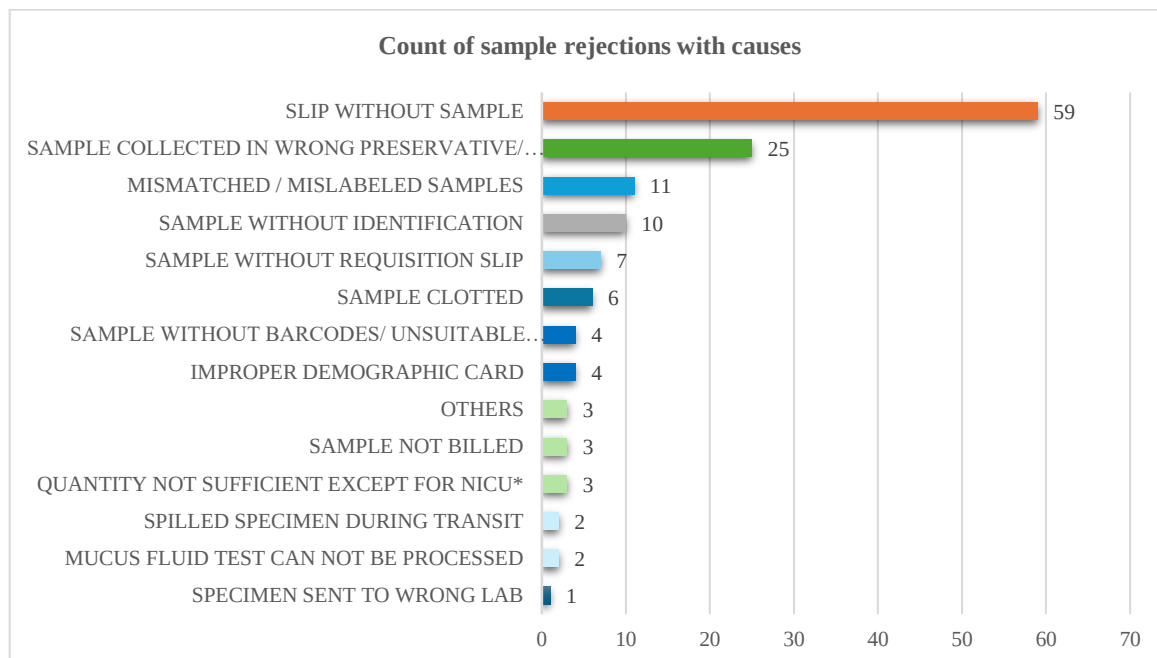


Figure 6: Chart showing causes for sample rejections with counts.



DISCUSSION

Quality indicators are essential tools for measuring the performance of laboratory processes. Each laboratory must define these indicators as per the guidelines set by regulatory bodies and evaluate them periodically to monitor performance. These indicators provide a measurable framework to assess the impact of workflow changes on laboratory efficiency. Among these, sigma metrics serve as a comprehensive tool to quantify improvements in quality indicators.

In this study, four quality indicators—turnaround time (TAT), redos, errors, and sample rejections—were analyzed to assess laboratory performance before and after implementing Lean Six Sigma methodologies. The results underline the effectiveness of these interventions in streamlining laboratory operations.

Laboratory TAT was analyzed using timestamps recorded in the Laboratory Information System (LIS), with unalterable timestamps for receiving and verifying results being used for accuracy. The baseline data from 2021 revealed an average TAT of 69 minutes for the chemistry group of tests, 49 minutes for HbA1c, 94 minutes for immunoassays, and 62 minutes for ISE tests, resulting in an overall average of 70 minutes (Table 1).

Post-intervention data from 2022 showed marginal changes, with an average TAT of 72 minutes for the chemistry group, 44 minutes for HbA1c, 93 minutes for immunoassays, and 67 minutes for ISE tests, culminating in an overall average of 72 minutes (Table 2).

A Study done by Lokesh et al, showed average TAT for tests to be 69 minutes with major causes for higher TAT identified to be delay in report verification and delay in

sample transport from collection site. They suggested improvement strategies like a popup alert to the doctor when the results are ready for verification, keeping separate bins for samples based on levels of priority and reducing bin size to increase frequency of sample transport to the lab [3,4]

A marginal decrease in average lab TAT of HbA1c tests and Immunoassay tests was observed and can be attributed to the change in testing instrument to a higher and faster throughput system. Despite only a marginal change in average Lab TAT the process sigma values showed drastic improvement as depicted in Table 3 with sigma values crossing 3 in 2022. Breyfogle, in his book states that an increase in sigma value from 2.5 to 3 indicates a reduction of 91848 defects per million opportunities/tests done[10,11]

The Pareto charts in Figure 1 and Figure 9 show that the defects in HbA1c, chemistry and ISE groups have drastically reduced but the immunoassay tests still showed higher number of defects. This may be attributed to the fact that immunoassay tests take longer to perform, and most tests are not available in both testing systems which requires transfer of sample from one analyser to another to perform the test. This delay causes a delay in verification of results since the LIS is programmed to verify results only after completion of all requested tests.

In 2021, 621 redos were recorded, predominantly due to results exceeding the analytical measuring range (AMR) of the analyzer (Table 4). These redos primarily involved diluting samples to obtain precise values, even without clinician requests. Post-

implementation in 2022, criteria for redos were refined, limiting repeat tests to clinician requests for critical values or precise measurements. This adjustment reduced the total number of redos to 249, although results exceeding AMR remained the leading cause (Table 5). The overall reduction in redos across all criteria reflects the efficacy of the revised protocol. Previous studies corroborate this finding. Motie et al. reported that 96% of repeat test results for critical values were within acceptable limits, emphasizing that repeat testing often fails to enhance result accuracy. Similarly, Niu et al. demonstrated that most repeat test results align with initial findings, suggesting the redundancy of unrequested retests [12,13].

Total number of errors documented from January 2021 to August 2021 are 177 with majority of them because of pre-analytical causes (Figure 1). Slip without sample and mismatched/ mislabelled samples accounted for most of the pre-analytical errors as shown in Figure 2. Majority of analytical errors were due to QC/Calibration failure (Figure 3) and post-analytical errors were due to Reports released without flag (Figure 4).

Root causes for the common errors were identified and corrective actions were proposed (Table 6). Usage of electronic test request forms integrated with the billing software and LIS can reduce majority of pre-analytical errors that can be attributed to human error. Retraining and reassessment of competency of ward staff and collection centre staff can reduce other human errors. A study done by Bhatt et al, in the clinical laboratory of the Kathmandu University Hospital, Nepal, showed that delay in TAT was

mainly due to the laboratory trying to fix the problems created by other departments like billing errors, hemolysed samples, mislabelled samples, missing samples, clotted samples and breakdown of informatics software [14,15]

Total number of errors documented from January 2022 to August 2022 are 221 with majority being pre-analytical. A study done by Shaherawala et al, showed that most 75% errors in a laboratory were due to pre and post analytical causes like lack of workforce, lack of identification of emergency samples and lack of informatics systems access in hospital wards [16,17]. Slip without sample still accounted for majority of pre-analytical errors but a reduction in number of mismatched/mislabelled samples is seen, which may be attributed to retraining of ward staff and collection centre staff. A drop in the number of post analytical errors was seen. Mrazek et al, state that most errors are in the pre-analytical phase like ordering the wrong tests, mislabelling the samples/request forms, insufficient volume of samples, collecting samples in wrong container, clotting of samples and inappropriate transport of samples to laboratory [18,19]

Total number of sample rejections documented from January 2021 to August 2021 are 78 with majority being due to slip without sample and mismatched/mislabelled samples (Figure 22) from MM8, MM2, MM6, MM and WH1 inpatient wards (Figure 5). Total number of sample rejections documented from January 2022 to August 2022 are 140 with majority being due to slip without sample but rejections due to mismatched/mislabelled samples was reduced. Rejections from inpatient wards which initially showed higher numbers had reduced (Figure 6). The increase in total number of

rejections being documented can be attributed to increased compliance of laboratory personnel to manually document the sample rejections. A study by Zemlin et al, states that extra analytical errors are a major problem for the laboratory and can be fixed by increasing automation in areas which have repetitive tasks[20-22].

Conclusion

This study systematically evaluated the impact of Lean Six Sigma (LSS) methodologies on key laboratory quality indicators, including turnaround time (TAT), redos, errors, and sample rejections, in a NABL-accredited clinical biochemistry laboratory. Pre-analytical errors, particularly missing test request forms and mismatched sample labels, emerged as major contributors to sample rejections. Targeted corrective actions, such as personnel retraining and improved workflow protocols, significantly reduced these errors, reinforcing the importance of continuous quality improvement initiatives.

By leveraging automated timestamps in the laboratory information system (LIS), the study established acceptable turnaround times for different test categories and identified key process inefficiencies. Addressing root causes, such as instrument bottlenecks, and upgrading to higher-throughput analyzers led to measurable process enhancements. A notable improvement in sigma metrics was observed, with values rising from approximately 2 to above 3 across multiple test groups, demonstrating substantial reductions in process defects and overall improvement in laboratory efficiency.

These findings align with previous studies that have shown Lean Six Sigma to be a highly effective methodology for optimizing laboratory workflows, minimizing errors, and improving process reliability. The integration of LSS principles, particularly the Define-Measure-Analyze-Improve-Control (DMAIC) framework, provided a structured approach to continuous quality improvement. Given the observed improvements, this study supports the broader adoption of LSS in clinical laboratory settings as a scalable model for sustainable quality enhancement.

Future research should focus on evaluating the long-term sustainability of these improvements, the integration of automation in error reduction, and the applicability of Lean Six Sigma in different laboratory environments. Expanding the scope of LSS interventions to include additional quality indicators, such as cost-effectiveness and staff efficiency, could further validate its role as a best practice for laboratory quality management.

Limitations

This study did not account for instrument breakdowns or laboratory personnel availability, and analytical indicators like CV and Bias were excluded. Quality indicators were documented across multiple software and physical records, complicating periodic analysis. A unified platform to consolidate these indicators would enable easier tracking and continuous improvement using Lean Six Sigma. Lean Six Sigma requires consistent data capture for meaningful analysis. Manual documentation

may lack uniformity, so automated data capture is recommended where feasible to improve data reliability and compliance.

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Data availability: The data generated during the research and analysis are not available publicly but are available from the corresponding author on a reasonable request.

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