# A Retrospective Evaluation of Quality Indicators in a Tertiary Care Blood Centre: A Quality Management Perspective

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## ABSTRACT

### Background

Ensuring the safety, efficiency, and traceability of blood transfusion services requires a robust quality management system. Quality indicators serve as critical tools to monitor, evaluate, and improve performance across the transfusion chain. It can further enhance operational efficiency by eliminating waste and reducing process variation.

### Objectives

To retrospectively evaluate the performance of selected quality indicators in a tertiary care blood centre and to identify priority causes of sample rejection using Pareto analysis.

### Methods

A retrospective observational analysis was conducted using quality indicator data collected from June 2025 to May 2026. Indicators included donor deferral rate, adverse donor reaction rate, TTI reactive rate, adverse transfusion reaction rate, component quality-control failure rates, percentage of components issued, and sample rejection rate. Descriptive statistics and month-wise trend analysis were performed. Pareto analysis was used to identify the principal causes of sample rejection. No intervention, control group, pre-intervention comparator, or inferential statistical testing was available; therefore, causal effects of the quality management system were not estimated.

### Results

Across the 12-month study period, the donor deferral rate was 6.97%, adverse donor reaction rate 0.16%, TTI reactive rate 0.53%, adverse transfusion reaction rate 0.06%, PRBC QC failure rate 2.56%, platelet QC failure rate 8.54%, component issue rate 98.95%, and sample rejection rate 0.45%. The four leading causes of sample rejection—wrong IP number, wrong blood in tube, missing IP number, and insufficient sample—accounted for 81.65% of documented defects. These findings describe service performance and identify priority areas for quality improvement; they do not demonstrate that QMS interventions caused the observed performance.

### Conclusion

Quality indicators can provide a practical framework for monitoring blood-centre performance and prioritising corrective action. In this retrospective study, the June 2025–May 2026 data showed generally favourable descriptive performance for several indicators, while platelet QC failures and pre-analytical identification errors require focused improvement. Because the study did not include a pre-intervention comparison, control group,

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measured intervention exposure, or inferential analysis, the findings should not be interpreted as evidence that the quality management system, training, counselling, supervision, audits, or committee activities caused the observed outcomes. Future prospective quality-improvement cycles should document baseline performance, specific interventions, implementation dates, process-compliance measures, corrective actions, and post-intervention outcomes so that changes over time can be evaluated.

**Keywords:** Blood Centre,Continuous Improvement, Retrospective Study, Quality Management, Quality Indicators.

# INTRODUCTION

Patient safety, as one of the healthcare priorities, is defined as “reducing the risk of healthcare-related harm to minimum” [1, 2]. The medical diagnosis laboratory is one of the most important departments in every hospital, as more than 70% of crucial medical diagnosis decisions rely on the outcomes of laboratory tests. Errors in department’s work processes can result in the wrong or delayed treatment, which consequently endanger patient safety [3]. This is while most errors are preventable [4].

Many processes are performed in medical diagnosis laboratories, including hemovigilance process [5]. The term hemovigilance is a combination of the Greek word “hema=blood” and Latin word “vigilance=alertness”. Hemovigilance is a collection of monitoring methods that covers the blood transfusion chain “(from blood or blood product collection to monitoring the recipient or vein to vein)” for the purpose of data collection and evaluation [6]. Blood transfusion is a complex process consisting of several sub-processes [7]. It involves various individuals, including physicians, nurses, blood bank personnel, hospital porters, hospital drivers, and personnel of blood transfusion centre [8]. Also, any error in each of the blood transfusion sub-processes can have severe and irreparable consequences for patients [9].

The Serious Hazards of Transfusion (SHOT) report in 2018 showed that 84% of error reports were related to human errors, and only 10% were unavoidable [4]. Errors can occur at any stage of blood transfusion process, including improper collection and labeling of blood samples, improper transportation of blood and blood products from the mother blood centre to the storage blood centre or sending them to departments for transfusion, improper identification of blood group and crossmatching, and failure to check the patient’s information before transfusing the blood. These errors occur as a result of not following the hemovigilance procedure’s guidelines and standards [6, 7].

Unfortunately, despite the importance of patient safety in the hemovigilance process in hospitals, over the past few years, errors and challenges in this process have resulted in unwanted and undesirable patient complications [12,13]. This study is one of the few studies conducted in our tertiary care centre (Model Blood Centre) to examine the quality of hemovigilance process [14]. Considering the importance of hemovigilance process in patient safety, this study was conducted to investigate the quality of hemovigilance process at tertiary care Hospital

# MATERIALS AND METHODS

A retrospective observational analysis was conducted using quality indicator data collected over a 12-month period. The study evaluated donor deferral, adverse donor reaction, TTI reactive rate, adverse transfusion reaction, component QC failure, percentage of components issued, and sample rejection rate. Pareto analysis was used to identify the major documented causes of sample rejection. Because the dataset did not contain a defined pre-intervention period, control group, intervention exposure measure, or inferential comparison, the study was designed and interpreted as a quality-indicator evaluation rather than an impact assessment.

**Study Design**

- A Retrospective observational study

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**Study Duration**

- Data reviewed from: June 2025 to May 2026 (12 months).

**Data Source**

- Internal quality management records, monthly quality indicator logs, and non-conformance reports.

**Variables Studied**

- Total collections
- Total deferrals
- Samples Rejection rate (%) (crossmatching)
- Quality indicators:
  - Donor deferral rate (%)
  - Donor Adverse Reaction rate (%)
  - TTI discard rate (%)
  - IQC failure rate of PRBC and Platelets (%)

**Table 1: Parameters used in analysis (Quality indicators) formula [15]**

| Sr. No. | Quality Indicator | Formula |
|---|---|---|
| 1 | Donor Deferral Rate (%) | ((No. of donor deferrals) ÷ (Total donations + Total deferrals))× 100 |
| 2 | Adverse Donor Reaction Rate (%) | (No. of donors with adverse reactions ÷ Total number of donors) × 100 |
| 3 | TTI Reactive Rate (%) | (Combined TTI reactive cases: HIV + HBV + HCV + Syphilis + Malaria) ÷ Total number of donors × 100 |
| 4 | Adverse Transfusion Reaction Rate (%) | (No. of adverse transfusion reactions ÷ Total blood/components issued) × 100 |
| 5 | Component QC Failures (%) | (No. of component QC failures ÷ Total no. of components tested)× 100 |
| | - PRBC QC Failure Rate (%) | Same formula applied to PRBC |
| | - Platelet QC Failure Rate (%) | Same formula applied to Platelets |
| 6 | % Of Components Issued | (Total components issued ÷ (Total whole blood + components issued)) × 100 |
| 7 | Sample rejection rate % | No. of rejected samples ÷ total samples received/crossmatch requests × 100; denominator should be verified against the centre's source register. |

**Data Analysis**

- Descriptive statistics (percentages and cumulative frequencies)
- Month-wise trend analysis using line/bar charts; no inferential hypothesis testing was performed.
- Root Cause Analysis (RCA) and Pareto analysis of documented sample-rejection causes.

Benchmark assessment: NABH quality-indicator guidance was used to define the indicators and calculation methods. Where NABH does not prescribe a universal numerical threshold, the result was classified as 'benchmark not numerically specified' rather than assigning an unsupported target.

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# RESULTS

Table 2: Analysis of quality indicators

| Month | Total Collections | Total donors counselled | Total deferral | Donor deferral rate (%) | Adverse donor reaction rate (%) | Total TTI reactive rate (%) | Adverse Transfusion Reaction rate (%) | IQC failure rate (%) | | % Of components issued | Sample rejection rate (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | PRBC | PC | | |
| **Jun-25** | 2349 | 2501 | 152 | 6.1 | 0.26 | 0.34 | 0.04 | 0 | 9.1 | 98.2 | 0.52 |
| **Jul-25** | 2611 | 2879 | 268 | 9.3 | 0.04 | 0.46 | 0.08 | 0 | 12.5 | 98.9 | 0.74 |
| **Aug-25** | 2698 | 2900 | 202 | 7.0 | 0.15 | 0.52 | 0.10 | 0 | 5 | 99.4 | 0.47 |
| **Sep-25** | 2988 | 3131 | 143 | 4.6 | 0.13 | 0.54 | 0.04 | 0 | 25 | 99.7 | 0.32 |
| **Oct-25** | 2989 | 3133 | 144 | 4.6 | 0.03 | 0.20 | 0.05 | 0 | 5 | 99.4 | 0.33 |
| **Nov-25** | 1853 | 2022 | 169 | 8.4 | 0.16 | 0.38 | 0.02 | 4.2 | 20 | 98.5 | 0.38 |
| **Dec-25** | 2192 | 2337 | 145 | 6.2 | 0.05 | 0.36 | 0.08 | 5 | 8.3 | 97.3 | 0.38 |
| **Jan-26** | 2517 | 2676 | 159 | 5.9 | 0.16 | 0.75 | 0.02 | 0 | 0 | 99.0 | 0.37 |
| **Feb-26** | 2177 | 2351 | 174 | 7.4 | 0.23 | 0.92 | 0.02 | 15 | 0 | 99.7 | 0.59 |
| **Mar-26** | 2815 | 3041 | 226 | 7.4 | 0.21 | 0.67 | 0.06 | 5 | 10 | 99.4 | 0.37 |
| **Apr-26** | 2763 | 3022 | 259 | 8.6 | 0.22 | 0.51 | 0.12 | 0 | 6.25 | 98.5 | 0.45 |
| **May-26** | 2167 | 2383 | 216 | 9.1 | 0.37 | 0.78 | 0.07 | 0 | 0 | 99.1 | 0.53 |
| **Total** | **30119** | **32376** | **2257** | **6.97** | **0.16** | **0.53** | **0.06** | **2.56** | **8.54** | **98.95** | **0.45** |

**Figure 1: Month wise distribution of Total WB collection**

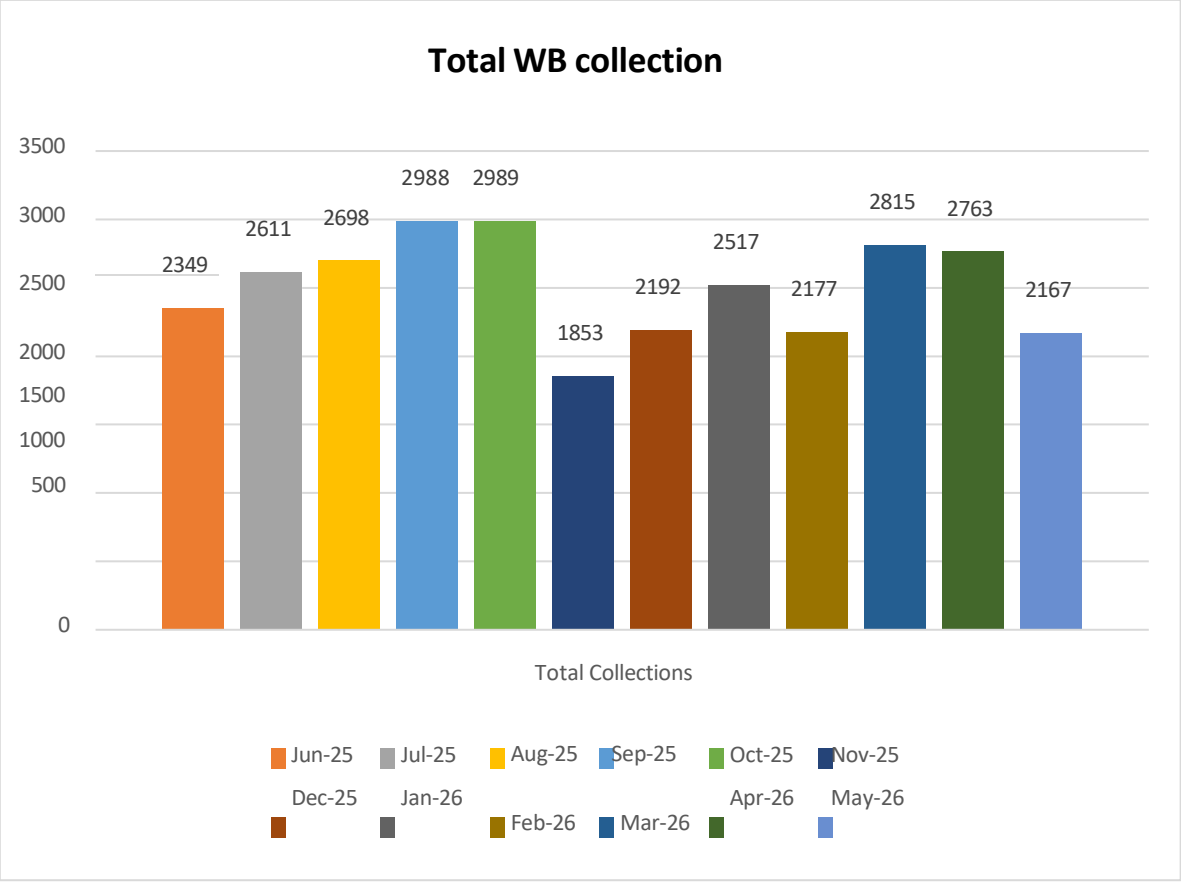


**Figure 2: Month wise distribution of Total donors counseled vs Total collections vs Total deferral**

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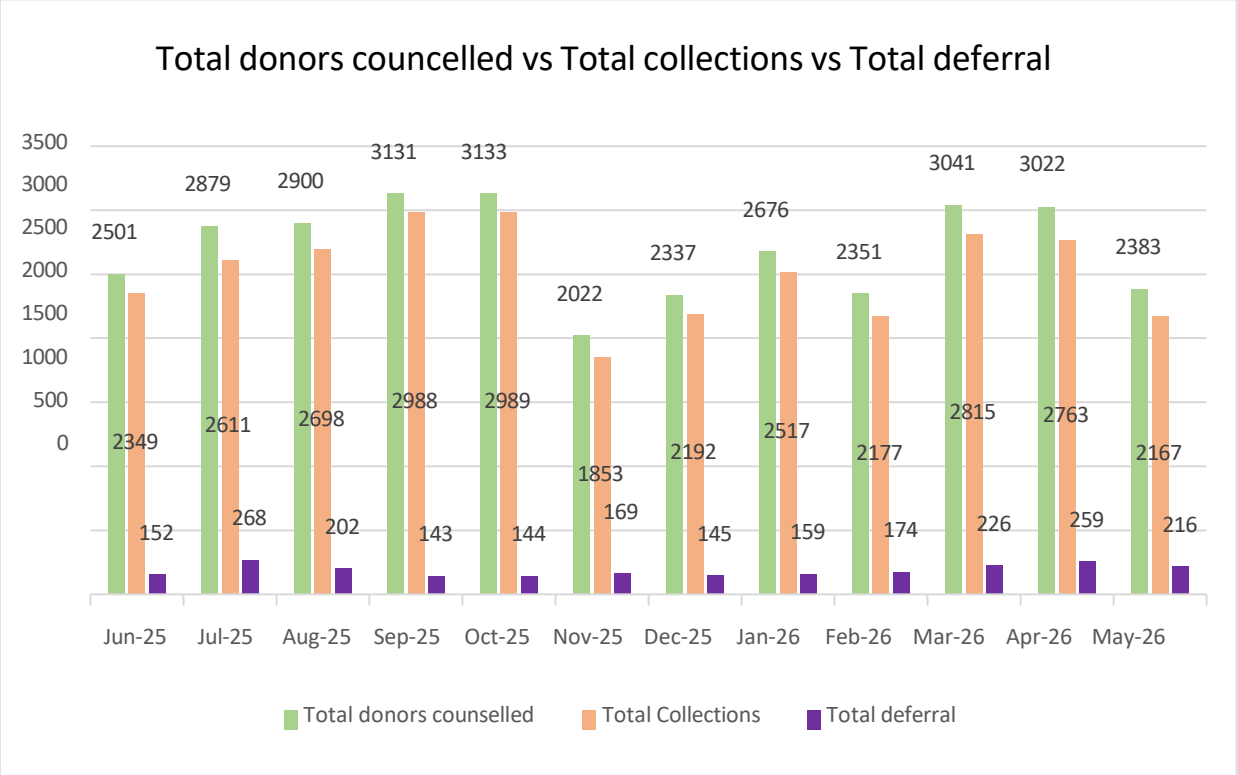


**Figure 3: Month wise distribution Total TTI reactive rate**

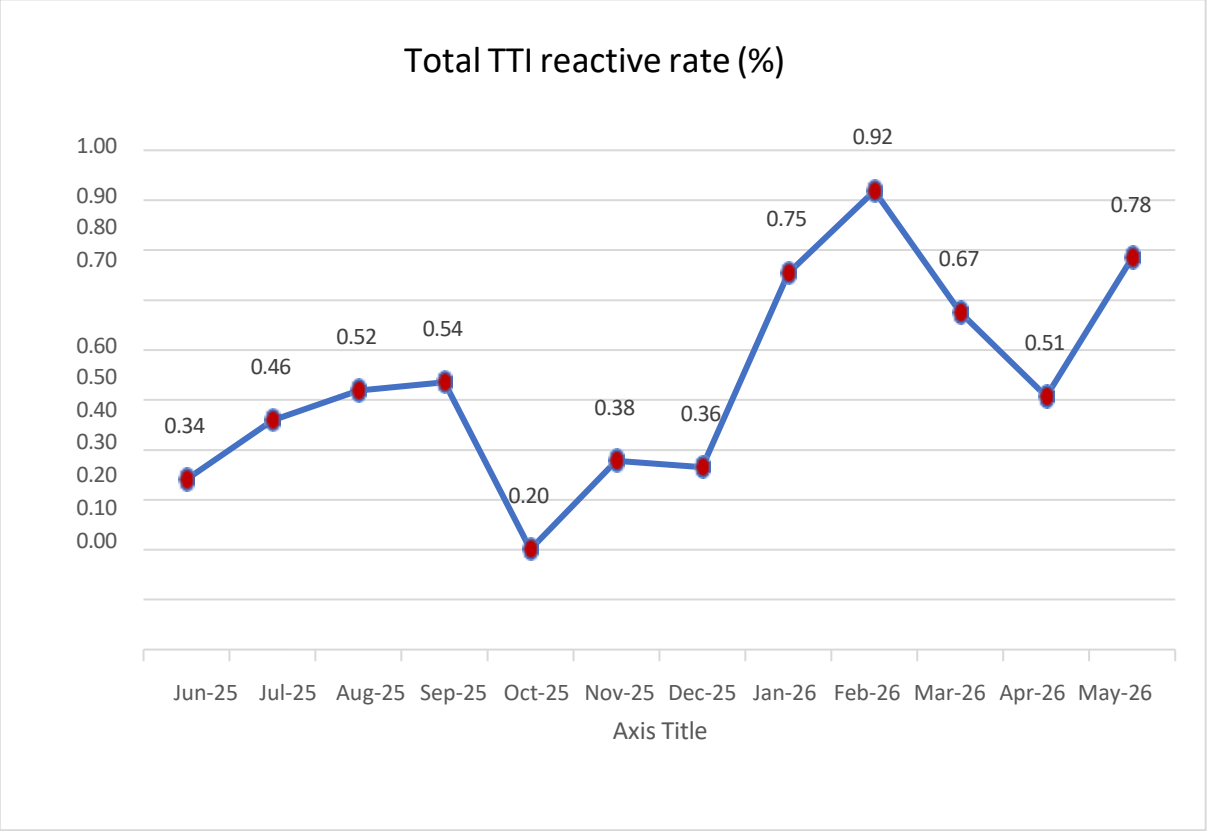


**Figure 4: Month wise distribution IQC failure rate of PRBC and PC**

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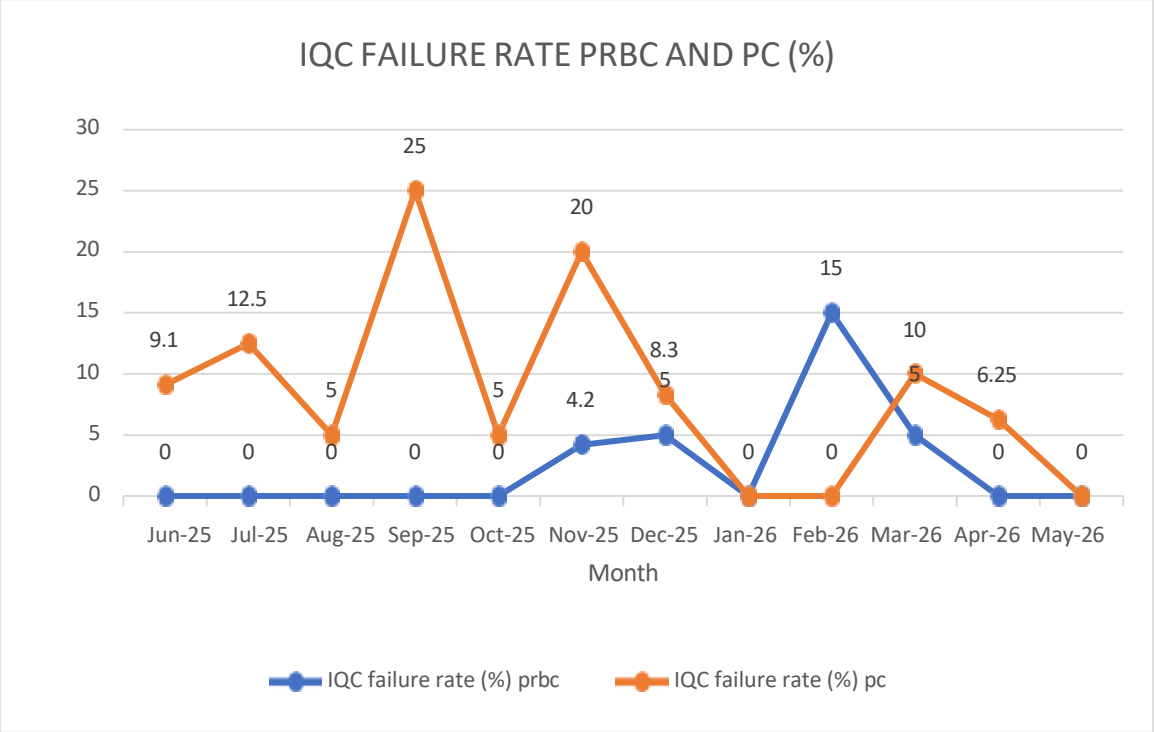


**Figure 5: Month wise distribution % of components issues**

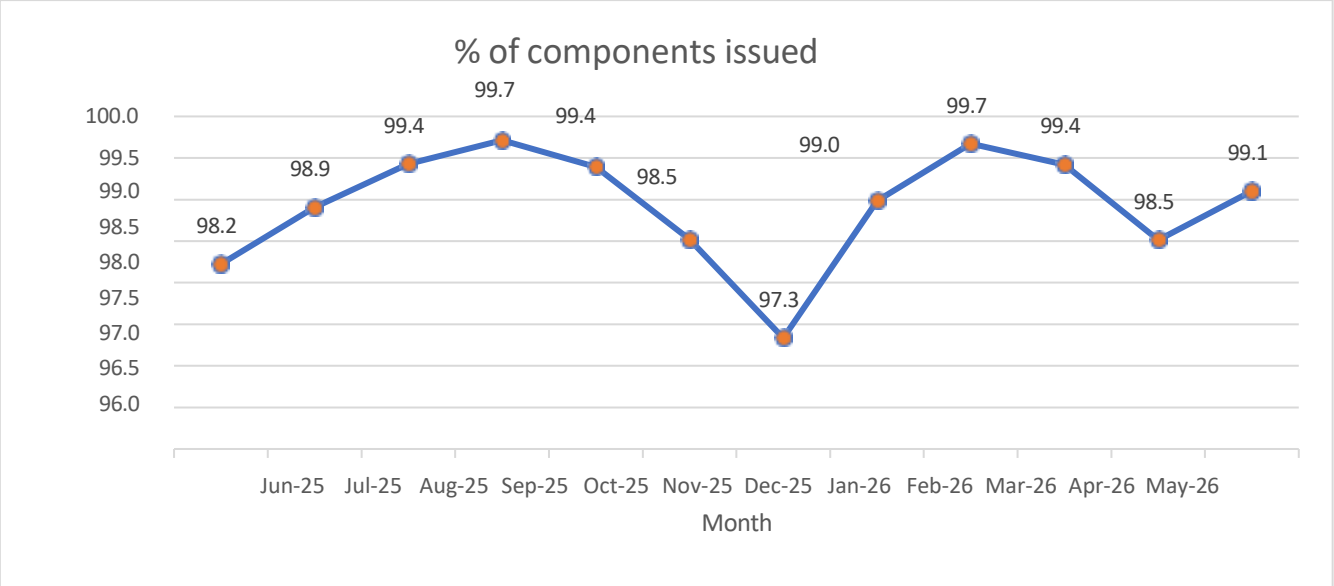


**Table 3: Cumulative causes for sample rejection**

| S.No | Causes | Defects | Cumulative% |
|---|---|---|---|
| 1 | Wrong IP number | 87 | 31.3% |
| 2 | WBIT* | 65 | 54.7% |
| 3 | No IP number written | 52 | 73.4% |
| 4 | Insufficient sample | 23 | 81.7% |
| 5 | Lysed sample | 21 | 89.2% |
| 6 | No label in sample | 15 | 94.6% |
| 7 | Wrong label in sample | 15 | 100.0% |

*Wrong blood in tube

The first four causes accounted for 81.65% of the documented sample-rejection defects and were therefore

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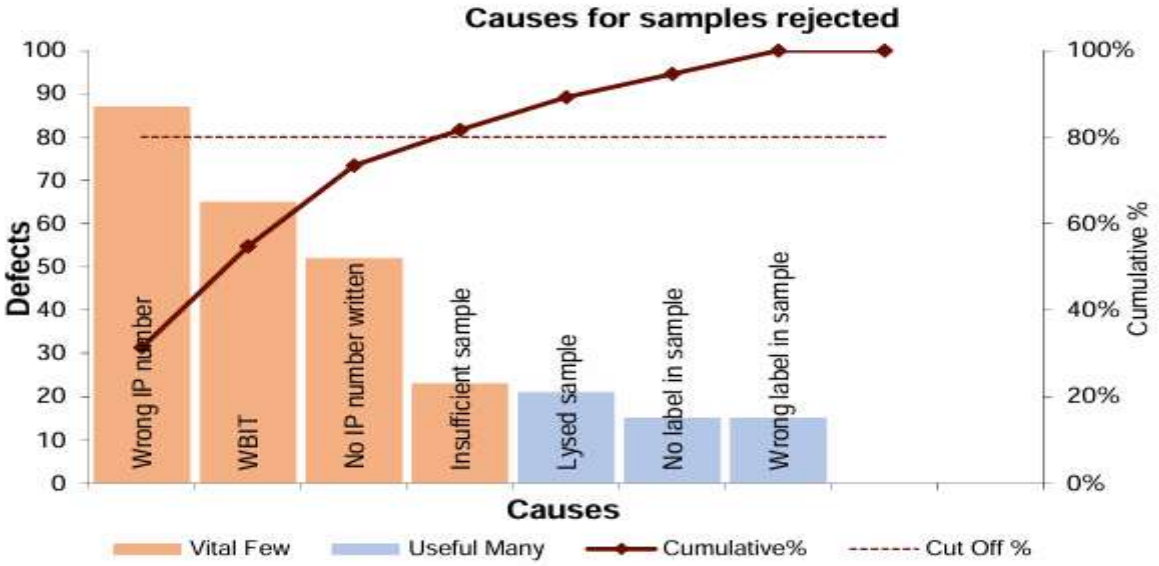
selected as priority areas for corrective action.

**Figure 6: Pareto chart for causes of sample rejections**




## DISCUSSION

**Table 4: Comparision of our study with different studies**

| Sr. No | Quality Indicators | Varshney et al [16] (2017) | Hariharan A et al.,[17] (2019) | Gananraj J et al.,[18] (2022) | Bassi et al.,[19] 2024 | Present Study |
|---|---|---|---|---|---|---|
| 1 | Donor Deferral Rate (%) | 8.23 | 8.99 | 15.19 | 14 | 6.97 |
| 2 | Adverse Donor Reaction Rate (%) | 1.15 | 0.58 | 1.71 | 0.78 | 0.16 |
| 3 | TTI Rate (%) | 0.93 | 0.60 | 3.39 | 1.6 | 0.53 |
| 4 | Adverse Transfusion Reaction Rate (%) | 0.16 | 0.14 | 0.11 | 0.35 | 0.06 |
| 5 | Component QC Failures (%) | | | | | |
| | - PRBC | 10.67 | 1.9 | 23.33 | 2.025 | 2.56 |
| | - Platelet | 8.22 | 10.2 | 21.67 | 5.375 | 8.54 |
| | - FFP | 8.63 | 3.3 | 41.11 | 8.2 | Not Available |
| 6 | % of Components Issued | 98.18 | 95.6 | - | 99.8 | 98.95 |

**Donor deferral rate**:

The observed rate was 6.97%. This is below the 10–12% range used as a benchmark in a published evaluation

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of NABH blood-centre KPIs, but donor deferral rate is influenced by donor population and screening practices; consequently, the lower value should not be interpreted as evidence of superior QMS performance without assessment of the reasons for deferral and possible missed deferrals.

**Adverse donor reaction rate**

The observed rate was 0.16%, which is below the <2% benchmark reported in the published NABH-KPI evaluation. This supports a favourable descriptive performance for this indicator, but does not establish that counselling, hydration advice, supervision, or staff training caused the observed rate because these exposures were not measured in the present study.

**TTI reactive rate**

The observed rate was 0.53%. NABH defines TTI rate as a quality indicator but the cited NABH indicator document does not prescribe a universal numerical cut-off. The present value should therefore be interpreted descriptively and reviewed against the centre's historical trend, donor-risk profile, and applicable national surveillance requirements.

**Adverse transfusion reaction rate**

The observed rate was 0.06%. The published NABH-KPI evaluation used <2% as its benchmark; the present value is below that benchmark. However, reporting completeness and case ascertainment must be considered before concluding that transfusion safety practices were responsible for the observed rate.

**Component QC failure**

PRBC QC failure was 2.56% and platelet QC failure was 8.54%. NABH identifies component QC failure as a core quality indicator, but the official indicator document does not provide a single universal failure-rate cut-off. Accordingly, the present study should avoid describing either QC failure rate as 'significantly better' or 'acceptable' unless the centre's component-specific specifications and statistical analysis are explicitly provided.

Percentage of components issued: The observed value was 98.95%. NABH defines this as a quality indicator, but the cited NABH quality-indicator document does not establish a universal 100% target.

**Sample rejection and Pareto findings:**

The sample rejection rate was 0.45%. The Pareto analysis showed that wrong IP number, wrong blood in tube, missing IP number, and insufficient sample accounted for 81.65% of documented defects. These findings provide a clear basis for corrective and preventive action. However, the retrospective dataset does not document the implementation date, compliance, or post-intervention performance of corrective actions; therefore, no reduction attributable to QMS activities can be claimed.

Comparison with previously published studies is retained only as contextual benchmarking. Differences between institutions may reflect donor demographics, case mix, component production practices, indicator definitions, reporting systems, and local policies. These comparisons were not subjected to inferential testing and should not be described as statistically significant.

The main limitation is the absence of a before-and-after design, control group, measured intervention exposure, and inferential statistical analysis. In addition, activities such as training, counselling, supervision, audits, and Hospital

**Table 5: Comparision of Quality indicators with NABH Benchmark basis**

| Quality indicator | Present study | NABH/NACO benchmark or standard basis |
|---|---|---|
| Donor deferral rate | 6.97% | 10–12% benchmark reported in published NABH-KPI evaluation; NABH defines the indicator |

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| | | |
|---|---|---|
| Adverse donor reaction rate | 0.16% | <2% benchmark reported in published NABH-KPI evaluation; NABH defines the indicator |
| TTI reactive rate | 0.53% | NABH defines the indicator; no universal numeric cut-off in the cited NABH QI document |
| Adverse transfusion reaction rate | 0.06% | <2% benchmark reported in published NABH-KPI evaluation; NABH defines the indicator |
| PRBC QC failure | 2.56% | NABH requires component-specific QC failure monitoring; no universal failure-rate cut-off in cited QI document |
| Platelet QC failure | 8.54% | NABH requires component-specific QC failure monitoring; no universal failure-rate cut-off in cited QI document |
| % components issued | 98.95% | NABH defines the indicator; no universal 100% target in cited QI document |
| Sample rejection rate | 0.45% | Quality-management framework supports monitoring and corrective action; no blood-centre-specific universal numerical cut-off identified in cited NABH QI document |

**Table 6: Pareto analysis based corrective action taken and follow up**

| Priority cause | Defects | Corrective action | Follow-up performance measure | Review frequency |
|---|---|---|---|---|
| Wrong IP number | 87 | Two-identifier verification at collection; mandatory IP-number check before sample acceptance; targeted staff re-orientation. | Wrong-IP-number defects per 1,000 samples; identification-check compliance. | Monthly for 3 months after implementation |
| Wrong blood in tube (WBIT) | 65 | Incident reporting and RCA for each WBIT; reinforce bedside patient identification and sample-labeling procedure; re-collection policy. | WBIT events per 1,000 samples; bedside identification audit compliance. | Monthly |
| No IP number written | 52 | Make IP number a mandatory field on request/sample label; incomplete requests handled according to SOP; audit compliance. | Missing-IP-number defects per 1,000 samples; percentage of forms with complete identifiers. | Monthly |
| Insufficient sample | 23 | Define minimum sample volume in SOP; phlebotomy refresher training; monitor repeat collection requests. | Insufficient-sample defects per 1,000 samples; repeat-collection rate. | Monthly |

## Summary

In summary, this comparative analysis demonstrates that our transfusion service performs strongly in critical indicators such as TTI detection, adverse donor and transfusion reaction rates, and component issuance efficiency. However, the elevated IQC failure rate in platelet concentrates suggests an area requiring immediate attention and corrective action. Comparing such indicators across institutions remains essential for benchmarking and continuous quality improvement in transfusion medicine.

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## CONCLUSION

Quality improvement enables an organization to attain higher level of performance by creating better standards and removing deficiencies in product, processes or services. To enhance the quality of blood transfusion services and prevent the occurrence of errors, it is imperative to employ a variety of quality management strategies and techniques that facilitate error prediction and the implementation of necessary safety measures. Continuous quality improvement measures such as Lean Six Sigma methodologies, regular staff training, internal audits, and Root Cause Analyses (RCA) after non-conformities will help sustain and improve our performance in transfusion service delivery.

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