

COMPARATIVE ANALYSIS OF A BLOOD CENTRE'S PERFORMANCE INDICATORS - A THREE-YEAR RETROSPECTIVE STUDY AT A TERTIARY CARE HOSPITAL IN NAVI MUMBAI

Laboratory Medicine

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ABSTRACT

Background & Objectives: Blood is a valuable human drug and maintenance of quality standards is essential for safe transfusion. Quality or Performance Indicators, part of Quality Management Systems help in measurement of transfusion services' efficiency and this study was undertaken to analyse the quality indicators comprehensively to analyse the root causes of deviations and implement safer and better transfusion practices. **Methods:** This retrospective analytical study was conducted in the Blood Centre at a Tertiary Care Hospital in Navi Mumbai. The five mandatory Quality Indicators devised by NABH i.e. TTI Positivity %, Adverse Transfusion Reaction Rate, Wastage Rate, Turn Around Time & Component QC failure were monitored, analysed, and compared over a period of January 2022 to December 2024. Comprehensive Root Cause analysis of any deviations or trends was conducted. **Results:** The overall TTI positivity rate was found to be 0.81%. 0.24% of the issued components led to Adverse Transfusion Reactions in recipients. 5.74% of the components issued were discarded. Turnaround time for routine cases was 57.7 Mins, for emergency cases was 34.1 Mins and for life-saving cases, 12.1 Mins. The overall QC Failure Rate to 4.43%. Interpretation & **Conclusions:** Safe Transfusion Practice is a multidisciplinary responsibility. QMS & Performance monitoring help in ensuring safety and quality in blood transfusion services. Better transfusion practices can be accomplished by following regulations and protocols strictly as well as by increasing awareness of blood centre personnel, clinicians & public.

KEYWORDS

Blood Centre, Nabh, Performance Indicators, Quality Management Systems, Safe Transfusion Services

INTRODUCTION

Blood is a major, vital, and liquid component of the human body. It also is a revivifying drug and an altruistic form of therapy. However, it is an expensive & scant resource.¹ In the last 10-15 years, transfusion medicine has emerged as prominent segment of emergency medicine due to the rise in the need for safe blood supply.² The goal of Blood Transfusion Services (BTS) is to ensure that the quality standards mandated by the regulatory bodies are met, thereby aiming to provide optimal therapeutic benefit to the transfusion recipients. Safe blood transfusion comprises of a lucid principle - 'right blood, right patient, right time & right place'.^{1,3}

Blood Centres (formerly known as Blood Banks – Amendment made in Drugs and Cosmetics Rules 1945 on 11th March 2020 – G.S.R. 166(E) released by Ministry of Health & Family Welfare (MOHFW, term "Blood Bank" replaced by "Blood Centre")⁴ are licensed to collect, test, process, store and provide donated blood units and/or components for timely transfusion requirements and they function under the directives set by the Drugs Controller General of India (DCGI) i.e. the head of the Central Drugs Standard Control Organization (CDSCO), along with the State Blood Transfusion Council (SBTC), National Blood Transfusion Council (NBTC) and National AIDS Control Organization (NACO).^{5,6}

The National Accreditation Board of Hospitals & Healthcare Providers i.e. NABH is an external accreditation board that operates under the Quality Council of India (QCI).^{1,7} It has drafted standards in alignment with the Drugs and Cosmetics Act, 1945 for Blood Centres to follow. It has also devised the Key Performance Indicators (KPI) or Quality Indicators (QI), which are a part of Quality Management Systems i.e. QMS, for Blood Centres which facilitates timely evaluation and plays a pivotal role in Continuous Quality Improvement (CQI), right from the donor vein to the patient vein. This facilitates Root Cause Analysis (RCA) and helps in taking Corrective and Preventive Action (CAPA) whenever any deviations or non-conformities are noted.^{1,6,7,8}

The ten QIs or KPIs designed by the NABH are: TTI Positivity Rate (TTI) (%), Adverse Transfusion Reaction Rate (ATRR) (%), Wastage Rate (%), Turn Around Time (TAT) (Minutes or Mins), Component Quality Control (QC) Failure (%), Adverse Donor Reaction Rate %, Donor Deferral Rate %, % of components prepared, TTI outliers % & Delays in transfusion beyond 30 min after issue. Of these, the first five have been mandated for an accredited Blood Centre or an accredited hospital's Blood Centre to be monitored, audited and reported to NABH every six months.⁷

This study was undertaken to perform a total, thorough and comparative analysis of the Performance Indicators of three years (2022-2024) to observe the trends across different parameters. The primary goal of this study was to perform a Root Cause Analysis and identify the non-compliances, deficiencies, minimize over-consumption & wastage and ensure optimal utilization of blood components. Ultimately, the study aimed to enhance blood transfusion safety, quality & improve patient outcomes, and care.

MATERIALS AND METHODS

This 3-year retrospective analytical study was carried out in the Blood Centre of Department of Immunohematology & Blood Transfusion at a Tertiary Care Hospital in Navi Mumbai. The first 5 mandatory Quality Indicators prescribed by the NABH⁷ i.e. TTI%, ATRR%, Wastage %, TAT & Component QC Failure Rate were comprehensively analysed. The formulae⁷ for calculation of these indicators are mentioned in Table 1. All the records available at the Blood Centre from January 2022 to December 2024 related to these Performance Indicators were reviewed, and no data was excluded. Ethical clearance was obtained prior to the commencement of the study. Data compilation was done using Microsoft Excel Sheets and statistical methods were applied for analysis, wherever applicable.

Table 1: Formulae for calculation of Quality Indicators

INDICATOR	Formulae for Calculations ¹⁵
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TTI Positivity (%)	Combined TTI Cases (HIV + HBV + HCV + Syphilis + MP) x 100 / Total No. of Donors
ATTR (%)	No. of Adverse Transfusion Reactions x 100 / Total number of Blood & Component Issued
Wastage (%)	No. of Blood or Blood Components Discarded x 100 / Total number of Blood & Component Issued
TAT (Mins)	Sum of Time Taken/ Total number of Blood or Blood Components cross-matched or reserved (Time taken is calculated from the time the request/ sample is received in the blood centre till the blood is cross matched/ reserved and available for transfusion. MGM Blood centre has upper limits for routine and emergency issues as 75 Mins and 40 Mins respectively, along with an additional TAT for life-saving cross-matches to be 15 Mins.)
Component QC Failure Rate (%)	No. of Component QC failures x 100/ Total No. of Components Tested (QC = Quality Control)

RESULTS

In the three-year study period, a total of 15170 units were collected from majorly voluntary blood donors (14901, **98.22%**) and few replacement donors (269, **1.77%**) at blood donation drives or the Blood Centre. The donor whole blood units were separated by centrifugation into Packed Red Cells (PRC), Random Donor Platelets (RDP), Fresh Frozen Plasma (FFP) and Cryoprecipitate (Cryo). Whole Blood Units were not kept in the inventory and Single Donor Platelets (SDP) were not prepared during the study period. The total components prepared were 34881, of which 15035 (**43.10%**) were PRCs, 5049 (**14.47%**) were RDPs, 14264 (**40.89%**) were FFP and 533 (**1.52%**) were Cryo. Under collected (Small Volume) units were not utilized for patients and subjected to discard.

The donor blood units were subjected to Transfusion Transmitted Infection (TTI) screening of five infections – HIV I & II, Hepatitis B, Hepatitis C, Syphilis & Malaria as mandated by authorities. The overall TTI positivity rate was found to be **0.81%** (123 of 15170 units). After testing & labelling of components, they were taken into inventory to be issued in need. Out of the total components issued in the study period (29890), **0.24%** led to Adverse Transfusion Reactions in recipients. **5.74%** of the components issued were discarded. Turnaround time for routine cases was **57.7 Mins**, for emergency cases was **34.1 Mins** and for life-saving cases, **12.1 Mins**. PRCs, RDPs and FFP-Cryo showed **6.8%**, **0%** and **6.13%** QC failure rates respectively, totalling the overall QC Failure Rate to **4.43%**. A comparative analysis of the results of three years is shown in Table 2. The trends in TTI %, ATTR %, Wastage % and TAT (Mins) over three years have been graphically represented in Figures 1- 4 respectively.

Table 2: Results of Three-Year Quality Indicators 2022-2024

INDICATOR	Parameter	2022	2023	2024	Total	NABH Benchmark ^{1,5,6}
TTI Positivity (%)	Total Donors	4501	5100	5569	15170	< 4%
	Positive Units	43	39	41	123	
	%	0.95 %	0.6 %	0.73 %	0.81 %	
ATTR (%)	Total Issues	8705	10513	10672	29890	< 2%
	Transfusion Reactions	19	31	22	72	
	%	0.21 %	0.29 %	0.2 %	0.24%	
Wastage (%)	Total Issues	8705	10513	10672	29890	
	Discarded Units	811	454	453	1718	
	%	9.31 %	4.31 %	4.24 %	5.74 %	
TAT (Mins)	Routine	62.8 Mins	55.8 Mins	54.7 Mins	57.7 Mins	< 60 min
	Emergency	39.4 Mins	31.9 Mins	31.1 Mins	34.1 Mins	
	Life-saving	14.5 Mins	10.7 Mins	11.1 Mins	12.1 Mins	

Component QC Failure Rate (%)	Total Failures	2.32 % (4/172)	5.37 % (10/186)	5.33 % (11/206)	4.43 % (25/564)	< 25%
	PRC	5.5 % (3/54)	6.89 % (4/58)	7.81 % (5/64)	6.8 % (12/176)	
	RDP	0 % (0/54)	0 % (0/58)	0 % (0/58)	0 % (12/176)	
	FFP & Cryo	1.85% (1/64)	8.57% (6/70)	7.69% (6/78)	6.13 % (13/212)	

Figure 1: Transfusion Transmitted Infection (TTI) Positivity (%)

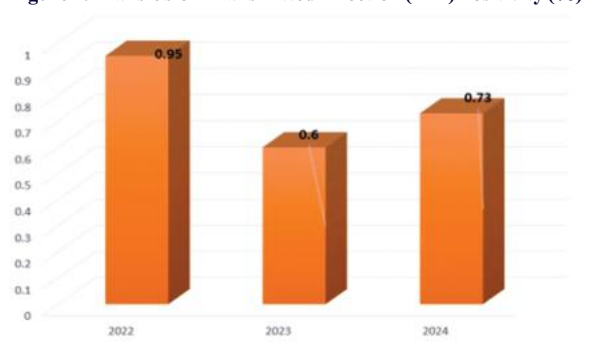


Figure 2: Adverse Transfusion Reaction Rate (ATTR) (%)

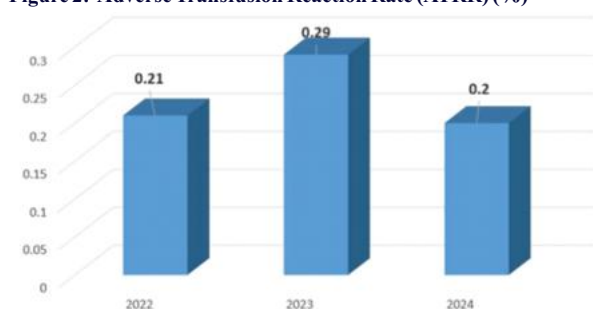


Figure 3: Wastage/Discard Rate (%)

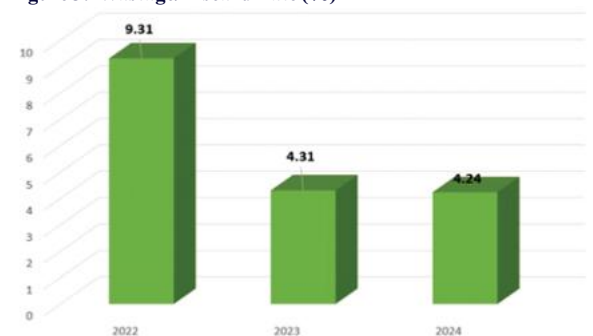


Figure 4: Turn Around Time (Minutes)



DISCUSSION

Blood is an irreplaceable, biological resource which comes solely from healthy, voluntary human donors. Blood Transfusion is a medical breakthrough with a lion's share in medical and surgical therapies. However, there is always a scarcity of blood units and hence, a need for judicious and optimal use of blood units. Blood Centre is a licensed

setup working under the directives of DCGI, CDSCO, SBTC, NBTC and NACO and is equipped to collect, lab-test, separate, screen, label and distribute blood units.⁵ It forms a requisite part of the Blood Transfusion Services (BTS) which contributes to superior healthcare in a hospital setting evinced by its Key Performance or Quality Indicators.¹⁰

AABB (American Association of Blood Banks, rebranded since 2021 as Association for the Advancements of Blood & Biotherapies)¹¹ defines Quality indicators as the specific performance measurements designed to monitor one or more processes during a defined time and are useful for evaluating service demands, adequacy of personnel inventory control, and process stability.^{8,12,13,14} Quality Indicators (QI) or Key Performance Indicators (KPI), part of the Quality Management Systems provide a pathway to achieve zero risk transfusion, help in maintaining Quality Control and practice Continuous Quality Improvement (CQI).⁸

NABH is an accreditation board that operates under the QCI which has drafted standards as well as QIs/KPIs in alignment with the Drugs and Cosmetics Act, 1945 for Blood Centres to follow. Blood Centres can seek NABH accreditation either by receiving a standalone accreditation or by being a part of a NABH accreditation hospital.¹⁷ Our hospital is NABH Accredited and the Blood Centre in under process of independent NABH accreditation.

Hospital Transfusion Committee (HTC) comprising of Hospital Director, Medical Superintendent, Blood Centre In-charge, heads of multidisciplinary medical and surgical departments, technical and nursing Supervisors meets as per the hospital policy to review the KPIs, conduct RCA, define or revise blood policies, share audit findings, incorporate national guidelines and reduce transfusion related wastage and/or incidents.⁵ Root-cause analysis (RCA) refers to a comprehensive, systematic analysis of a problem with the view to exacting the most fundamental reason (s) that have generated the problem.⁸ Corrective and Preventive Action (CAPA) is then taken wherever applicable.

In our study we noted that the overall TTI Positivity rate was 0.81%. There was a variable trend in the three years, and rates were within NABH Benchmarks^{14,9}. Similar results were noted as 1.87%, 0.93%, 1.82%, 1.1%, 1.54% and 1.6% in studies by Nikhil et. al.², Varshney et. al.¹⁰, Mukherjee et. al.¹⁵, Priya et. al.⁹, Rajkumar et. al.⁴, Bassi et. al.¹⁶. A slightly higher rate was observed as 3.39% in a study by Gnanaraj et. al.¹. Most common TTI was Hepatitis B, which is also observed in studies by Gnanaraj et. al.¹ & Varshney et. al.¹⁰ HIV, Hepatitis C and Syphilis was the most common Seroreactive infection screened in studies by Nikhil et. al.², Bassi et. al.¹⁶ and Rajkumar et. al.⁴ Strict adherence to screening protocols, having a dedicated counsellor, mobilization and recruitment of voluntary donors, conduction of donor awareness and motivation programme, deferral of risky population, strengthening pre-donation counselling, practicing voluntary over directed donation, implementation of newer testing modalities like Chemiluminescent Immunoassay (CLIA) and Nucleic Acid Testing to narrow window period and processing of sample in time can help in reducing TTI positivity rate even further as is also evidenced and suggested in other studies^{1,2,4,9-10,15-18}.

The ATRR % was found to be 0.24% overall, showed variable but borderline similar rates in all three years of the study & within NABH Benchmarks^{14,9}. These findings are concordant with studies by Gnanaraj et. al.¹, Nikhil et. al.², Varshney et. al.¹⁰, Mukherjee et. al.¹⁵, Priya et. al.⁹, Rajkumar et. al.⁴ and Bassi et. al.¹⁶ with findings as 0.12%, 0.18%, 0.16%, 0.30%, 0.3%, 0.37% and 0.35% respectively. The most common Adverse Transfusion Reaction was Febrile Non-haemolytic Transfusion Reaction (FNHTR), like studies by Gnanaraj et. al.¹, Priya et. al.⁹ and Bassi et. al.¹⁶ However, Allergic Reactions were most common in studies by Nikhil et. al.², Varshney et. al.¹⁰, Mukherjee et. al.¹⁵ & Rajkumar et. al.⁴ Usage of Leucoreduction filters has significantly reduced the number of FNHTRs, especially in Thalassemia afflicted patients. Our blood Centre participates in reporting of ATR to the Hemovigilance Programme of India (HVPI) which helps the authorities scrutinize the blood centre efficiency. Separation of Whole Blood into components & utilization of SDP over RDP minimizes the risk of adverse reactions & alloimmunization and hence, our Centre implemented the preparation of SDP to mitigate this risk. Clinician education as well as Blood Centre Personnel education plays a vital role in reducing the number of ATR, for which a

Continuing Medical Education (CME) event was also conducted to enlighten all stakeholders. Priya et. al.⁹ also suggests the avoidance of pre-medication and continuous education regarding reaction reporting can be initiated.

The overall wastage rate was noted to be 5.74% with a steady decline over three years. Similar discard rate (5.96%) was noted in the study by Gnanaraj et. al.¹. A considerably lower rate of 0.2% was noted in a study by Priya et. al.⁹, whereas a higher rate of 12.9% was noted in the study by Nikhil et. al.² Most discarded product were RDPs due to expiry primarily due to their short lifespan and demand-supply mismatch, a finding similar to studies by Varshney et. al.¹⁰ & Bassi et. al.¹⁶ PRCs and FFPs were most discarded due to TTI Positivity, followed by expiry and other reasons like leakage, under-collection, haemolysis, etc. Concordant results were also seen in studies by Nikhil et. al.² and Gupta et. al.¹⁷ Lack of awareness regarding transfusion guidelines is the primary cause of wastage. Over-ordering, liberal requests & not utilizing the units leads to wastage of precious blood units. For this purpose, a Knowledge, Attitude, Practices (KAP) study has been undertaken to understand the perspectives of clinicians regarding transfusion guidelines. First In First Out (FIFO) Policy, preparation of platelets based on demand, strict adherence to Maximum Surgical Blood Ordering Schedule (MSBOS) by surgeons should be followed to lessen wastage. Similar suggestions and practices have been documented in studies by Nikhil et. al.², Varshney et. al.¹⁰, Mukherjee et. al.¹⁵, Bassi et. al.¹⁶, Priya et. al.⁹ A study by Remakanth & Abhishek et. al.¹² suggests that the implementation of computer-based physician order entries can drastically aid in reducing discard rate. An audit of inventory is of utmost importance to maintain blood stock favourably. Our centre also practices the raising of an incident report in case of wastage if the thirty minute return policy is not adhered to. This helps the hospital's quality cell monitor any negligence and helps reduce wastage. Priya et. al.⁹ also recommends a similar strategy.

TAT for Routine and Emergency Transfusion was 57.7 Mins (within NABH Benchmarks^{14,9}) & 34.1 Mins respectively and both showed a steady downtrend over the three years. For Routine cases, our study had findings consistent with studies by Rajkumar et. al.⁴, (66.7 Mins) whereas studies by Nikhil et. al.², Varshney et. al.¹⁰ and Mukherjee et. al.¹⁵ showed markedly higher TAT of 140.99 Mins, 135.8 Mins and 141.38 Mins respectively. The TAT for Emergency cases was similar to studies by Nikhil et. al.², Varshney et. al.¹⁰, Mukherjee et. al.¹⁵ and Priya et. al.⁹, which had findings noted as 27.11 Mins, 29.87 Mins, 28.50 Mins and 30 Mins respectively. Documentation errors such as incomplete forms, multiple requests, wrong blood component request, etc. were eliminated at the grassroots level. Conducting only type and screen and providing blood units only after release requests (similar policy adopted by Priya et. al.⁹) notably shortened the TAT. Understaffed blood Centre is a major reason for TAT delays as is noted in studies by Nikhil et. al.² and Mukherjee et. al.¹⁵ However in our study, there was an addition of new Blood Centre technical and medical staff along with the application of newer technologies for lab work, and adequate monthly training of staff in the last two years. This fortified the transfusion services & streamlined the workflow thereby causing prompt and unhindered supply of blood units. An annual orientation programme and a monthly induction programme regarding transfusion protocols is also conducted to guide newly inducted residents and nurses respectively.

In the study duration, 4.43% was found to be the Component QC failure altogether. Individually all components, in all years showed QC failure rates within NABH threshold limits (<25%)^{14,9}. PRCs showed a QC failure rate of 6.8%, similar to a study by Priya et. al.⁹ (8%) and Varshney et. al.¹⁰ (10.67%). FFP-Cryo's QC failure rate overall was 6.13% concordant with studies by Varshney et. al.¹⁰ (8.63%), Bassi et. al.¹⁶ (8.2%), and Priya et. al.⁹ (6%). The most noteworthy finding in our study that the Platelets (RDP) showed no QC failure in all three years. All three components showed rates lower in comparison to the studies by Gnanaraj et. al.¹ (PRC – 23.33%, FFP – 41.11% and Platelets – 21.67%) and Rajkumar et. al.⁴ (PRC – 13.5%, FFP – 15.5% and Platelets – 22.4%). The main reason for QC failure was found to be lack of manpower during excessive workload, especially during camps could be attributed to the failed QC results. Other reasons like improper stripping of blood segments, delay in separation or testing or freezing of blood units, technical errors like not following Standard Operating Protocols (SOP) strictly, equipment related issues like failure, maintenance, calibration, if not resolved timely were also a cause of QC failure. These observations were also noted in studies by

Gnanaraj et.al.¹, Nikhil et. al.², Varshney et. al.¹⁰, Mukherjee et. al.¹⁵, Priya et. al.⁹ & Rajkumar et. al.⁴ Usage of Weighing scales instead of Blood Collection Monitors (BCM) was observed in Gupta et. al.¹⁷. However, our centre strictly adhered to using BCM for all donors. Regular training, interdepartmental activities, appropriate management of manpower, and strict adherence to SOPs are the keys to lowering QC failure.

CONCLUSION

Blood transfusion is a humane therapy and its safety & quality are a collective responsibility of healthcare providers. Monitoring of Quality Indicators is beneficial in devising newer strategies to optimize blood unit usage and taper wastage. Awareness and policies regarding transfusion should be thoroughly known to transfusion as well as clinical healthcare providers. Donor Motivation programme should be conducted frequently to help public voluntarily and benevolently donate blood for those in need. Constant edification of stakeholders is the focal element of ensuring safe transfusion services.

CONFLICT OF INTEREST: Nil

LIMITATIONS: Unicentric study and only first five mandated NABH Quality indicators have been studied.

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