ORIGINAL ARTICLE

Improving Transfusion Safety Through Enhanced Documentation: An Examination of Organizational Practices in a Tertiary Care Hospital Blood Bank in New Delhi

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ABSTRACT

Background: Safe blood transfusion depends not only on infrastructure and testing but also on meticulous documentation and effective haemovigilance. Incomplete records and under-reporting of adverse events compromise patient safety and limit system-level learning. **Aims & Objectives:** To evaluate organizational practices, documentation completeness, and predictors of transfusion safety, including adverse reaction reporting, in a tertiary care hospital blood bank in New Delhi. **Methodology:** A descriptive observational study was conducted from January to September 2021 at the Blood Bank of Safdarjung Hospital. Record reviews of 25,050 donations and 43,679 component issues were undertaken. Structured assessments of healthcare personnel and analysis of 31 transfusion reactions and 30 donor adverse events were performed. Chi-square tests and logistic regression identified factors associated with documentation completeness and reporting. **Results:** Documentation completeness was significantly higher among doctors than nurses and technicians (p=0.045). Technicians were less likely to complete records (AOR=0.42, p=0.030), whereas haemovigilance-trained staff were more likely to document accurately (AOR=3.20, p=0.005) and report reactions (AOR=2.70, p=0.030). Platelet transfusions showed higher adverse reaction rates (p=0.023). Patient satisfaction improved when risks were explained (p=0.017). **Conclusion:** Although infrastructure and internal documentation systems were robust, gaps in staff training, external haemovigilance reporting, and transport practices persist. Structured training, digital reporting integration, and strengthened protocol adherence are essential to enhance transfusion safety.

KEYWORDS

Blood transfusion safety; Documentation; Haemovigilance; Adverse reactions; Training; Tertiary care hospital

INTRODUCTION

Blood transfusion is a critical and life-saving intervention in modern healthcare; however, it carries inherent risks that require stringent monitoring and standardized documentation (1,2). Globally, errors in transfusion practice, particularly clerical mistakes and incomplete documentation, account for a substantial proportion of preventable adverse events (3,4). Accurate and comprehensive record-keeping serves as both a clinical safeguard and a medico-legal requirement, ensuring traceability, accountability, and timely detection of transfusion-related complications (5).

Regulatory authorities such as the Central Drugs Standard Control Organization (CDSCO) emphasize

strict adherence to documentation protocols in blood banks and transfusion services (6). In India, the Haemovigilance Programme of India (HvPI) was established to strengthen reporting and surveillance of transfusion-related adverse events (7,8). Despite this framework, under-reporting and inconsistent compliance remain significant concerns across healthcare settings (9,10). Incomplete transfusion records, including missing patient identifiers, timing details, and reaction documentation, can delay intervention and hinder root cause analysis (11). Furthermore, improper documentation during issue, return, and storage of blood units compromises traceability and cold chain integrity (12).

Aims & Objectives

•To assess the organizational practices of a tertiary care hospital blood bank.

•To evaluate the completeness of transfusion-related documentation.

•To identify gaps in adherence to haemovigilance protocols.

•To determine factors associated with documentation compliance and adverse event reporting.

MATERIAL & METHODS

Study Type and Study Design: This was a hospital-based descriptive, observational study conducted to evaluate organizational practices, documentation systems, and transfusion safety processes in a tertiary care blood bank.

Study Setting: The study was conducted at the Blood Bank of Safdarjung Hospital, New Delhi, a high-volume tertiary care center with a 24×7 functional blood bank processing more than 40,000 blood components annually.

Study Population: The study population included healthcare professionals involved in transfusion services (medical officers, residents, nurses, and laboratory technicians), documentation records related to blood donation and transfusion, and transfusion recipients, particularly those experiencing adverse events.

Study Duration: Data were collected over nine months, from January 2021 to September 2021.

Sample Size Calculation: All transfusion-related records and adverse event reports available during the study period were included. A total of 25,050 blood donations, 43,679 component issues, 31 transfusion reactions, and 30 donor adverse events were reviewed. Additionally, 50 healthcare personnel (20 nurses, 20 residents, 10 blood bank staff) and 31 transfusion recipients were assessed.

Inclusion Criteria

• All transfusion episodes documented during the study period.

• Healthcare workers directly involved in transfusion-related activities.

• Patients experiencing transfusion-related adverse events.

• Staff engaged in documentation and verification of blood units.

Exclusion Criteria

• Incomplete or irretrievable records.

• Staff unwilling to participate in interviews or feedback.

Strategy for Data Collection: Data were collected using structured checklists, record reviews, and interviews. Registers assessed included blood collection, issue logs, reaction forms, return logs, temperature monitoring charts, and SOP compliance records. Structured questionnaires evaluated staff knowledge and haemovigilance awareness. Feedback from transfusion recipients assessed risk communication and satisfaction.

Working Definitions: Documentation completeness: Accurate recording of patient identifiers, blood unit number, component type, date and time of issue, expiry, and reaction details where applicable. Adverse transfusion reaction: Any untoward event occurring during or after transfusion requiring clinical evaluation and documentation.

Haemovigilance training: Formal orientation or training received regarding HvPI protocols and adverse event reporting.

Ethical Issues and Informed Consent: Institutional ethical approval was obtained prior to study initiation. Confidentiality of patient and staff data was maintained. Written informed consent was obtained from healthcare personnel and transfusion recipients participating in interviews.

Data Analysis: Data were entered into Microsoft Excel (Version 16.93.1) and analyzed using IBM SPSS Statistics Version 29.0.2.0. Descriptive statistics were expressed as frequencies and percentages. Chi-square test assessed associations. Logistic regression analysis identified predictors of documentation completeness and adverse reaction reporting. A p-value <0.05 was considered statistically significant.

Flow Diagram

Total blood donations (Jan–Sept 2021): 25,050

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Total blood components issued: 43,679

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Donor adverse events reviewed: 30

Transfusion reactions reviewed: 31

↓

Healthcare personnel assessed: 50

Transfusion recipients interviewed: 31

↓

Data compilation and statistical analysis

RESULTS

The organizational layout of the blood bank included critical functional areas such as the donor counselling room, donor registration and examination room, blood collection room, refreshment cum recovery room, component preparation and quality control area, crossmatch and immunohematology laboratories, serology laboratory for testing transfusion transmitted infections, sterilization room, and records storage section. Table 1.

Table 1. Organizational Setup of the Blood Bank

Name of the Blood Bank:	**Blood Bank, Safdarjung Hospital**
Name of the Hospital / Institute:	Safdarjung Hospital, New Delhi
Average No. of Annual Blood Collection:	Approx. 45,000
Total No. of Donations During Study Period:	25,050
No. of Voluntary Donations:	10,916
No. of Replacement Donations:	14,134

The infrastructure of the blood bank was found to be hygienically maintained. The registration and examination rooms were separate and fully operational. Blood collection and donor rest areas were air-conditioned and adequately furnished. The serology and component preparation laboratories were well lit, with washable walls and floors. The sterilization area was functionally isolated, and the waiting area was clean and organized.

The blood bank operated 24×7 with robust staffing. The workforce comprised a Head of the Department (Pathology), one unit in-charge, four medical officers, 12 senior residents, 20 junior residents, postgraduate students on rotation, one counsellor, four registered nurses, seven nursing attendants, 14 technicians, one blood center technical supervisor, one apheresis nurse, and one upper division clerk, in addition to some contractual staff. Table 2.

Table 2. The manpower distribution of the Blood Bank

MANPOWER	
Staff	**Total no. of personnel**
Unit In-Charge	01
Medical Officers	04
Senior Residents	12
Junior Residents (Non-postgraduation)	20
Junior Residents (Pursuing Post Graduation, Pathology)	5
Counsellor / Medical Social Worker	01
Registered Nurse	04
Nursing attendants	07
Blood Centre Technical Supervisor	01
Blood Centre Technician	14
Apheresis Nurse / Technologist	01
Others (Upper Division Clerk)	01

A wide range of functions was carried out round-the-clock, including donor screening, blood donation, blood issue to wards and other hospitals, and apheresis procedures. Investigations conducted included ABO and Rh grouping, Coombs test, hemogram, hemoglobin estimation, and quality control of blood components. Mandatory TTI screening included testing for syphilis, malaria, HIV, HBsAg, and HCV. Processed components included packed cells, pediatric units, platelet-rich plasma, and fresh frozen plasma, with quality monitored via automated counters.

Donor selection followed standard criteria, with thorough history taking involving medical, surgical, immunization, transfusion, and lifestyle-related questions. Female donors were asked obstetric history. Physical examination included blood pressure, pulse, and hemoglobin assessment. Temperature was checked only when fever was suspected, and height was self-reported. Aseptic precautions during phlebotomy and vein-to-vein traceability were ensured. Labelling and blood bag expiry dates were properly recorded.

Blood was collected and stored at optimum temperature with continuous monitoring through temperature graphs and alarms. However, blood was transported manually without insulated carriers. Testing for TTIs was strictly adhered to, and reactive donors were notified and permanently deferred.

Equipment included calibrated blood bank refrigerators with alarms, weighing scales, autoclaves, incinerators, emergency power backup, and sufficient donor beds. Emergency drugs like adrenaline, noradrenaline, and IV fluids were readily available along with oxygen cylinders and sterile IV sets.

The documentation system was comprehensive. Registers were maintained for blood collection, processing, testing, crossmatching, and issue to patients. A master stock register was updated daily, and specific records were maintained for adverse reactions in both donors and recipients.

In transfusion-related procedures, documentation included patient identifiers, CR number, date/time

of issue, blood unit number, type of component, blood group, and expiry date. In case of adverse reactions, clinicians stopped transfusion, reassured the patient, administered antihistamines/steroids, filled out the transfusion reaction form, and returned the blood bag and post-transfusion sample to the blood bank. The blood bank verified details, checked for clerical errors and signs of hemolysis, and repeated grouping, Coombs, and compatibility tests.

Documentation completeness was significantly higher among doctors compared to nurses and technicians (p=0.045). Platelet transfusions were associated with a significantly higher rate of adverse reactions compared to RBCs and FFP (p=0.023). Patients who were informed about transfusion risks reported significantly greater satisfaction (p=0.017), while those who experienced an adverse reaction were significantly less satisfied (p=0.034). No significant difference was observed between ward and ICU transfusions. Table 3.

Table 3. Associations between Staff, Components, Patient Factors and Outcomes

Category	Variable / Component	Positive Outcome (%)	Negative Outcome (%)	Chi-square	p-value
Staff vs Documentation	Doctors (n=16)	87.5	12.5	6.21	0.045
	Nurses (n=20)	60.0	40.0	-	-
	Technicians (n=10)	50.0	50.0	-	-
	HvPI Training (Yes, n=15)	80.0	20.0	-	-
	HvPI Training (No, n=31)	45.2	54.8	-	-
	Experience <5 yrs (n=25)	64.0	36.0	-	-
	Experience ≥5 yrs (n=21)	71.4	28.6	-	-
Component Type vs Adverse Reactions	Packed RBC (n=50)	6.0	94.0	7.52	0.023
	Platelets (n=30)	20.0	80.0	-	-
	FFP (n=20)	10.0	90.0	-	-
Patient Information vs Satisfaction	Informed about risks (Yes, n=18)	88.9	11.1	8.13	0.017
	Informed about risks (No, n=13)	53.8	46.2	-	-
	Experienced reaction (Yes, n=8)	37.5	62.5	6.74	0.034
	Experienced reaction (No, n=23)	82.6	17.4	-	-
	Ward transfusion (n=20)	70.0	30.0	0.32	0.580
	ICU transfusion (n=11)	63.6	36.4	-	-

For documentation completeness, technicians were significantly less likely than doctors to complete records (AOR=0.42, 95% CI: 0.19-0.91, p=0.030). Staff who had received haemovigilance training were over three times more likely to document correctly (AOR=3.20, 95% CI: 1.40-7.10, p=0.005).

For adverse reaction reporting, training was a significant predictor, with trained staff more likely to report reactions (AOR=2.70, 95% CI: 1.12-6.51, p=0.030). Elective transfusions were also nearly twice as likely to be reported compared to emergency transfusions (AOR=1.95, 95% CI: 1.02-3.72, p=0.040). Table 4.

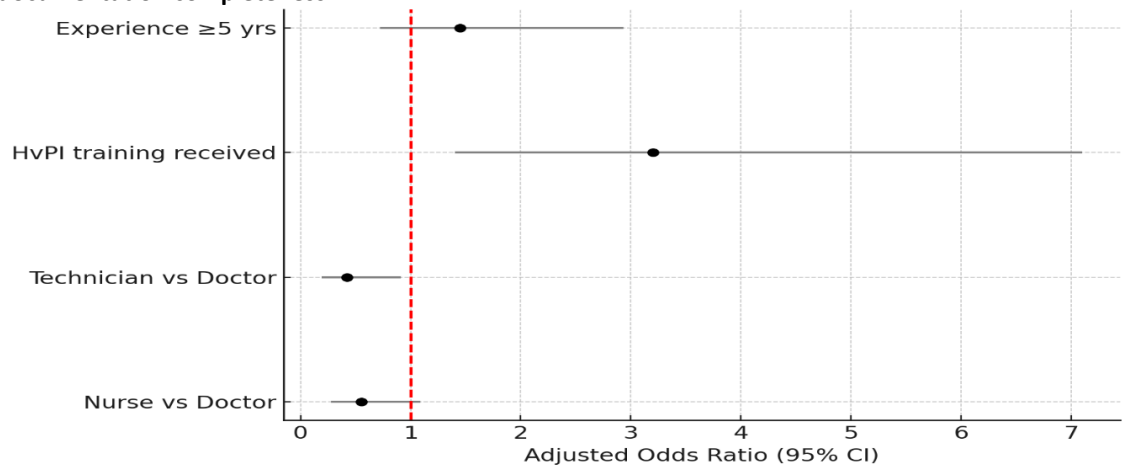
Table 4. Logistic Regression Analysis of Predictors of Documentation Completeness and Adverse Reaction Reporting

Predictor	Adjusted Odds Ratio (AOR)	95% CI	p-value
Documentation Completeness			
Nurse vs Doctor	0.55	0.28-1.09	0.080
Technician vs Doctor	0.42	0.19-0.91	0.030
Received HvPI training	3.20	1.40-7.10	0.005
Experience ≥5 yrs	1.45	0.72-2.93	0.290
Adverse Reaction Reporting			
Nurse vs Resident	0.61	0.30-1.24	0.170

Predictor	Adjusted Odds Ratio (AOR)	95% CI	p-value
Training received	2.70	1.12-6.51	0.030
Elective vs Emergency transfusion	1.95	1.02-3.72	0.040

Logistic regression showed that technicians were significantly less likely than doctors to complete documentation (AOR=0.42, 95% CI: 0.19-0.91, p=0.030). Staff who had received haemovigilance training were over three times more likely to document correctly (AOR=3.20, 95% CI: 1.40-7.10, p=0.005). Differences for nurses versus doctors (AOR=0.55, p=0.080) and staff with ≥5 years of experience (AOR=1.45, p=0.290) were not statistically significant. Fig. 1

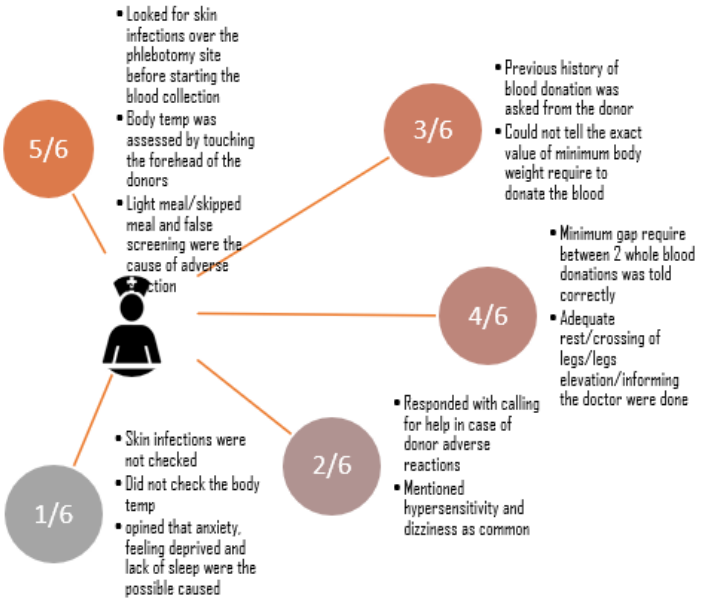
Fig. 1 Forest plot showing adjusted odds ratios with 95% confidence intervals for predictors of documentation completeness



Despite being enrolled in the Haemovigilance Programme of India (HvPI), regular adverse event reporting on the HvPI portal was not consistently performed. However, internal documentation of donor and recipient adverse reactions was well maintained.

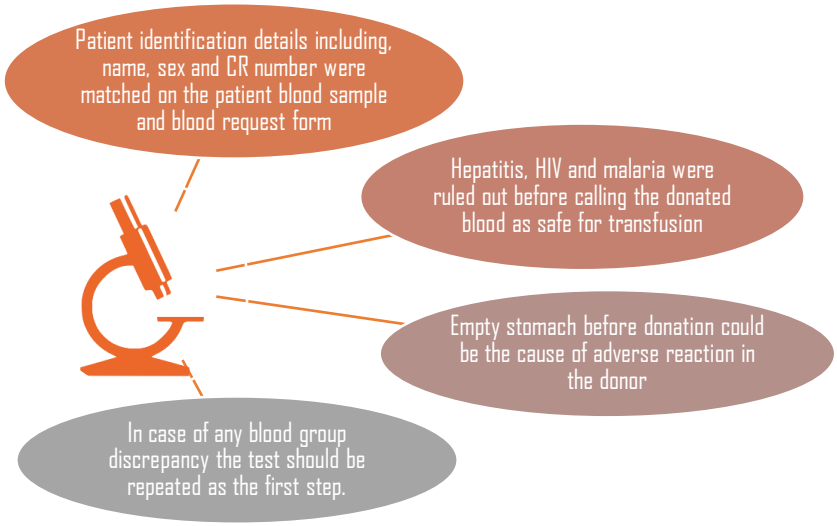
Six nursing personnel were assessed for procedural compliance. Most (83.33%) checked the phlebotomy site and meal intake but only half inquired about previous donations. All nurses asked about food intake, but only 50% knew the correct minimum body weight required for donation. Temperature was checked by hand, not with a thermometer. While most (66.66%) identified syncope and dizziness as warning signs, 83.33% believed adverse events were due to skipped meals or screening errors. Four nurses followed SOPs during reactions, while two only called for help. Fig. 2a.

Fig. 2a Assessment of Nursing Personnel in the Blood Bank



One laboratory technician participated in the study and confirmed that identity verification was done before testing. Testing for hepatitis, HIV, and malaria was routine. Donors without food intake were flagged as high-risk for reactions. In the event of a blood group discrepancy, tests were repeated as the first line of action. Fig. 2b.

Fig. 2b Assessment of Lab Technician in the Blood Bank (CR= Central Registration; HIV= Human Immunodeficiency Virus)



DISCUSSION

The study was conducted at Safdarjung Hospital in collaboration with the Blood Bank of the Safdarjung Hospital, New Delhi. The data was collected from January 2021 to September 2021. A total of 43,679 blood components were issued from Blood Bank and a total of 25,050 donors donated blood at Blood Bank during January 2021 to September 2021.

This study aimed to assess the organizational practices, documentation systems, and transfusion safety processes at a high-volume tertiary care blood bank in New Delhi. We observed that the blood bank had a well-defined infrastructure with designated areas for donor counselling, registration, examination, collection, and component preparation. This kind of structured physical setup aligns with best practices for safe transfusion environments as recommended in national guidelines (13).

The presence of comprehensive internal documentation systems, including registers for donor screening, blood issue, and adverse reaction reporting, indicates strong institutional adherence to transfusion protocols. However, our study also identified that despite being enrolled in the Haemovigilance Programme of India (HvPI), the facility was not regularly reporting adverse events on the HvPI portal. This finding echo earlier observations from government hospitals in India, where external reporting compliance remains a challenge despite robust internal documentation (14, 15).

Our results showed that the blood bank operated with adequate staffing, including medical officers, residents, nursing personnel, and technical staff. Similar workforce structures have been linked to better compliance with standard operating procedures (SOPs) and fewer documentation errors (16). However, the gap in continuous training and haemovigilance-specific education, especially for junior staff, poses a significant barrier to full program implementation (17).

Among nursing personnel, although awareness about general donor management and reaction signs was moderately good, critical gaps persisted. For instance, only 50% of the staff knew the exact minimum body weight criteria, and temperature checks were done by touch rather than using a thermometer. This inconsistent knowledge and informal practice have been reported in other studies from Indian blood banks, where lack of structured continuing education was a major concern (18).

The laboratory technician assessed in our study demonstrated good adherence to key protocols, including reconfirmation of patient identity and mandatory TTI testing. These steps are consistent with WHO and AABB-recommended practices for pre-transfusion safety (19).

Documentation during transfusion and in case of an adverse event was thorough. The protocol of stopping transfusion immediately, stabilizing the patient, filling out the reaction form, and sending the implicated blood unit back for investigation was followed. However, as found in similar studies, while in-house documentation was compliant, real-time external reporting remained irregular due to lack of training, time, or designated haemovigilance officers (20, 21).

Our study also revealed that blood units were transported to wards by hand without insulated carriers. This is a critical gap, as improper temperature maintenance during transport can compromise blood quality. Studies have recommended the use of thermally insulated containers to prevent the risk of hemolysis or contamination during delays in transfusion (22).

Internal audit practices such as storage temperature monitoring, expiry tracking, and maintenance of adverse reaction logs were being followed regularly, contributing positively to transfusion safety. Nonetheless, without integration of these findings into the national haemovigilance network, valuable data remains underutilized at the policy-making level (23).

Overall, our study highlights that while many foundational elements of haemovigilance including organizational structure, documentation protocols, and emergency preparedness were present and functioning, gaps in staff training, external reporting, and cold chain management still pose a risk to optimal transfusion safety.

CONCLUSION

This study underscores the pivotal role of accurate and standardized documentation in ensuring transfusion safety in tertiary care settings. Documentation completeness was significantly higher among doctors compared to nurses and technicians, and staff who had received haemovigilance training were over three times more likely to document correctly. Conversely, technicians were significantly less likely than doctors to complete records. Platelet transfusions were associated with a higher rate of adverse reactions than RBCs and FFP, and patients who were informed about transfusion risks reported significantly greater satisfaction, whereas those who experienced an adverse reaction were less satisfied. For adverse reaction reporting, both staff training and the context of transfusion emerged as key predictors, with trained staff and elective transfusions more likely to be reported. These findings highlight that while strong internal infrastructure and record-keeping exist, systemic gaps remain in staff training, external reporting, and adherence to protocols. Addressing these deficiencies through structured training, mandatory digital reporting, and improved interdepartmental coordination can strengthen both institutional safety practices and national haemovigilance outcomes.

RECOMMENDATION

At the National Level

- Strengthen the Haemovigilance Programme of India (HvPI) by enforcing mandatory reporting of transfusion-related adverse events from all licensed blood banks and linking compliance to licensure or accreditation renewals.
- Provide centralized online and offline training modules for all transfusion-related healthcare personnel, focusing on documentation standards and haemovigilance protocols.

At the State/Regional Level

- State health departments should regularly audit documentation quality and adverse event reporting from blood banks under their jurisdiction to ensure data consistency and compliance.
- Encourage inter-hospital collaboration to standardize SOPs and data-sharing frameworks, improving regional haemovigilance coordination.

At the Hospital Level

- Establish or revamp the Hospital Transfusion Committee (HTC) to routinely monitor, review, and act on transfusion documentation and adverse event trends.
- Mandate periodic training and orientation sessions for junior residents, nursing staff, and blood bank personnel focused on transfusion safety documentation and HvPI procedures.
- Introduce insulated and validated blood transport containers for ward-level transfusions to maintain cold chain integrity.

At the Blood Bank Level

- Integrate digital tools to improve real-time entry and traceability of all transfusion-related data, minimizing manual errors.
- Conduct internal audits of documentation registers at fixed intervals to identify gaps in traceability, consent, and adverse event reporting.
- Encourage post-donation feedback from donors and transfusion recipients to continuously monitor quality of care and documentation compliance.

LIMITATION OF THE STUDY

The study was conducted at a single tertiary care blood bank, which may limit the generalizability of

its findings to other hospitals or blood centers with different infrastructure, staffing patterns, or documentation systems. Additionally, the observational design limits causal inference, and reliance on recorded data may be subject to documentation bias. The assessment of healthcare personnel was based on a limited sample size, which may not fully represent all transfusion-related staff.

Relevance of the Study

This study provides a comprehensive evaluation of organizational practices, documentation completeness, and haemovigilance reporting within a high-volume tertiary care blood bank. It highlights the critical association between structured training and improved documentation and adverse event reporting. The findings underscore the gap between internal documentation practices and external haemovigilance reporting, offering practical insights for strengthening transfusion safety systems in similar tertiary care settings across India.

Authors Contribution

IK, MC formed the proposal of this study. IK and RK performed the statistical analysis. Data collection done by IK. IK, MC prepared the manuscript. All the authors reviewed and approved the final manuscript.

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Nil.

Conflict of Interest

The authors declare no conflict of interest.

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Declaration of Generative AI and AI Assisted Technologies in the Writing Process

During the preparation of this work, the authors used ChatGPT (OpenAI) for language refinement and structuring of the manuscript. After using this tool, the authors carefully reviewed, edited, and validated the content and take full responsibility for the accuracy and integrity of the publication.

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