RESEARCH PAPER

Pattern and Reporting Rate of Adverse Transfusion Reactions in a North Indian Tertiary Care Hospital: A Three-Year Retrospective Haemovigilance Study

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ABSTRACT
Hemovigilance data are useful only when reaction reports are interpreted against the number of components actually transfused. We reviewed all recipient transfusion reaction reporting forms submitted to the Department of Immunohematology and Blood Transfusion from 1 January 2023 through 31 December 2025. Reactions were classified using Hemovigilance Programme of India terminology, and reporting rates were calculated per 1,000 in-hospital component transfusions with exact Poisson 95% confidence intervals. Forty-four reaction episodes were documented in 43 recipients during 12,190 transfusions, for an overall reporting rate of 3.61 per 1,000 (95% CI 2.62-4.85). Annual rates were 3.44, 4.19 and 3.19 per 1,000 in 2023, 2024 and 2025, respectively, with no significant year-to-year difference ($p = 0.718$). Febrile non-haemolytic transfusion reactions accounted for 30 episodes (68.2%) and allergic reactions for 14 (31.8%). Packed red blood cells were implicated in 34 episodes (77.3%) and had the highest component-specific reporting rate (4.74 per 1,000). Thirty-seven episodes (84.1%) were judged definite or probable in imputability. All recipients recovered and no transfusion-related death was recorded. The findings support continued bedside reporting, stronger electronic documentation and prospective assessment of leucocyte-reduction strategies.

Keywords: adverse transfusion reaction; allergic reaction; febrile non-haemolytic transfusion reaction; hemovigilance; transfusion safety

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INTRODUCTION

Blood transfusion remains essential across medical, surgical and emergency care, but preventable and non-preventable adverse events can occur at any point in the transfusion chain. Haemovigilance provides a structured way to detect, investigate and learn from these events, linking bedside observation with transfusion-service review and corrective action.[1]

India established the Haemovigilance Programme of India (HvPI) to standardise reporting of donor and recipient adverse events. National guidance defines reaction categories, clinical information, outcomes and imputability, allowing institutional data to contribute to broader surveillance.[2,3] Indian hospital series have consistently shown febrile non-haemolytic transfusion reactions (FNHTRs) and allergic reactions among the most frequently reported recipient events.[2,4,5]

Reported reaction rates are not directly comparable across centres. Patient mix and component exposure matter, but so do component processing and the method used to identify reactions. Passive systems depend on recognition and submission of a report by the clinical team; active surveillance generally identifies additional events that routine reporting misses.[6,7] For a passive system, the term reporting rate is therefore more appropriate than true incidence.

Three-year institutional data from western Uttar Pradesh that use components actually transfused as the denominator are limited. This study was undertaken to quantify the overall and annual reporting rates at our centre and to describe the reaction spectrum, implicated components, recipient characteristics, timing, laboratory work-up, imputability and outcomes.

MATERIALS AND METHODS

Study design and setting

This single-centre retrospective observational study was conducted in the Department of Immunohematology and Blood Transfusion, Santosh Medical College and Hospital,

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Ghaziabad, Uttar Pradesh, India. The study period covered three complete calendar years, from 1 January 2023 to 31 December 2025.

Case identification and classification

All recipient transfusion reaction reporting forms (TRRFs) submitted to the blood centre during the study period were reviewed. A separately reported suspected reaction was counted as one episode; one recipient with two distinct reports therefore contributed two episodes. Donor reactions and reports related to components supplied to outside hospitals were excluded. Surveillance was passive and depended on recognition and TRRF submission by the treating team. Reaction category and imputability were retained as recorded using HvPI terminology and national guidance.[3] The analysable reaction categories were FNHTR and allergic reaction. Severity was not assigned retrospectively because a reproducible dedicated severity field was absent from the source database.

Data collection and reaction work-up

Extracted variables included age, sex, ABO/RhD group, diagnosis where recorded, transfusion indication, previous transfusion history, implicated component, reaction category, symptoms, timing, recovery, outcome and imputability. Laboratory fields included pre- and post-transfusion ABO/RhD grouping, compatibility testing, antibody screening, direct antiglobulin testing (DAT) and bag culture when performed. Direct identifiers were excluded from analysis.

PRBC units transfused during the study period were neither leucoreduced nor buffy-coat depleted. In 2023, transfusion indication and reaction symptoms were documented for all 11 completed reactions, although the primary-diagnosis field was blank. Indications were anaemia in 10 episodes and coagulopathy in one. Time to reaction was calculated from the documented transfusion start and reaction-onset date and time. Timing entries that appeared inconsistent after spreadsheet extraction were rechecked against the source TRRF records, including 24-hour clock and midnight-crossing entries. After source verification, onset times were usable for all 44 reactions. Missing values were not imputed.

Transfusion denominators and outcomes

Annual denominators were taken from transfusion records and included only components actually transfused within the hospital. Returned or cancelled units and components supplied to outside hospitals were not counted. Denominators were stratified as packed red blood cells (PRBC), fresh frozen plasma (FFP), random donor platelet concentrate (RDPC) and single donor platelet concentrate (SDPC). The primary outcome was the number of reported reactions per 1,000 component transfusions. Secondary outcomes included reaction type, implicated component, clinical presentation, timing, laboratory findings, imputability and recovery.

Statistical analysis

Categorical data are presented as counts and percentages. Age is summarised by mean with standard deviation (SD) and median with interquartile range (IQR). Onset and recovery times are reported as medians, IQRs and ranges. Overall, annual and component-specific reporting rates were calculated per 1,000 transfusions; exact two-sided 95% confidence intervals were derived from the Poisson distribution. Annual rates were compared with a chi-square test under the null hypothesis of a constant rate across the three years. A two-sided p value <0.05 was considered statistically significant. Data were entered, tabulated and analysed in Microsoft Excel (Microsoft Corporation, Redmond, WA, USA).

Ethical considerations

This retrospective study used de-identified information generated during routine haemovigilance. Formal Institutional Ethics Committee approval or waiver was not obtained for this retrospective record review. No direct patient identifiers were included in the analytical dataset or manuscript. The manuscript was prepared with reference to the STROBE recommendations for observational studies.[8]

RESULTS

Transfusion activity and reporting rate

A total of 12,190 components were transfused during the three-year period: 3,198 in 2023, 4,291 in 2024 and 4,701 in 2025. Transfusion activity increased by 47.0% from 2023 to 2025. Forty-four adverse reaction episodes were reported in 43 recipients. The overall reporting rate was 3.61 per 1,000 transfusions (95% CI 2.62-4.85). Annual rates did not differ significantly (chi-square = 0.664, df = 2, p = 0.718) (Table 1).

Table 1. Annual transfusion activity and adverse transfusion reaction reporting rates

Year	PRBC	FFP	RDPC	SDPC	Total transfused	Reported reactions	Rate per 1,000 (95% CI)
2023	1,941	730	496	31	3,198	11	3.44 (1.72-6.15)
2024	2,428	1,095	750	18	4,291	18	4.19 (2.49-6.63)
2025	2,800	995	885	21	4,701	15	3.19 (1.79-5.26)

Year	PRBC	FFP	RDPC	SDPC	Total transfused	Reported reactions	Rate per 1,000 (95% CI)
Total	7,169	2,820	2,131	70	12,190	44	3.61 (2.62-4.85)

CI, confidence interval; FFP, fresh frozen plasma; PRBC, packed red blood cells; RDPC, random donor platelet concentrate; SDPC, single donor platelet concentrate. Denominators represent components actually transfused within the hospital.

Reaction type and implicated components

FNHTR was the most frequent category, representing 30 of 44 episodes (68.2%); the other 14 episodes (31.8%) were allergic reactions. PRBCs were implicated in 34 episodes (77.3%), FFP in eight (18.2%) and RDPC in two (4.5%). No reaction was reported after an SDPC transfusion. Component-specific reporting rates were 4.74 per 1,000 for PRBC, 2.84 for FFP and 0.94 for RDPC (Table 2).

Table 2. Component-specific reporting rates and reaction types

Component	Transfused	All reactions	Rate per 1,000 (95% CI)	FNHTR	Allergic
PRBC	7,169	34	4.74 (3.28-6.63)	24	10
FFP	2,820	8	2.84 (1.22-5.59)	5	3
RDPC	2,131	2	0.94 (0.11-3.39)	1	1
SDPC	70	0	0.00 (0.00-52.70)	0	0
Total	12,190	44	3.61 (2.62-4.85)	30	14

Exact Poisson 95% confidence intervals are shown. The absence of an SDPC-associated report should not be interpreted as absence of risk because only 70 SDPC transfusions were included.

Recipient characteristics

Recipients ranged in age from 2 days to 73 years. Mean age was 42.98 years (SD 16.18), and median age was 45 years (IQR 27.75-56). Twenty-three episodes (52.3%) occurred in female recipients. A history of one to ten previous transfusions was recorded for 27 episodes (61.4%) (Table 3).

Table 3. Characteristics of adverse transfusion reaction episodes (n = 44)

Characteristic	Value
Recipients / reaction episodes	43 / 44
Age, mean ± SD (years)	42.98 ± 16.18
Age, median (IQR), range	45 years (27.75-56); 2 days-73 years
Age <18 years	1 (2.3%)
Age 18-40 years	17 (38.6%)
Age 41-60 years	22 (50.0%)
Age >60 years	4 (9.1%)
Female	23 (52.3%)
Male	21 (47.7%)
First transfusion	17 (38.6%)
Previous 1-10 transfusions	27 (61.4%)
ABO/RhD: A+ / B+ / O+ / AB+	10 / 14 / 11 / 6
ABO/RhD: B- / O-	1 / 2

The youngest recipient was 2 days old (0.005 years). Percentages use reaction episodes as the denominator. IQR, interquartile range; SD, standard deviation.

Clinical presentation and timing

Signs and symptoms were documented for all 44 reactions. Fever was most frequent (27/44, 61.4%), followed by pruritus (11/44, 25.0%), chills or rigors (10/44, 22.7%), tachycardia (9/44, 20.5%) and dyspnoea (5/44, 11.4%). More than one symptom could be recorded. Across all 44 episodes, median onset was 47.5 minutes (IQR 9.0-107.5; range 0-240). Median recovery time was 50 minutes (IQR 35-70; range 20-174) (Table 4).

Table 4. Clinical presentation and timing of reported reactions

Variable	n/N	% or summary
Fever	27/44	61.4%
Pruritus	11/44	25.0%
Chills or rigors	10/44	22.7%
Tachycardia	9/44	20.5%
Dyspnoea	5/44	11.4%
Hypoxaemia	3/44	6.8%
Infusion-site pain	3/44	6.8%
Anxiety or restlessness	2/44	4.5%
Urticaria	1/44	2.3%
Hypotension	1/44	2.3%
Wheeze	1/44	2.3%
Cough	1/44	2.3%
Hypertension	1/44	2.3%
Nausea or vomiting	1/44	2.3%
Onset after start of transfusion	44	Median 47.5 min (IQR 9.0-107.5); range 0-240
Recovery after reaction	44	Median 50 min (IQR 35-70); range 20-174

Symptom percentages use all 44 reactions and may total more than 100% because multiple symptoms could be recorded. All 44 onset-time records were included after source-level verification of the recorded date and 24-hour time fields.

Laboratory investigation, imputability and outcome

Pre- and post-transfusion ABO/RhD groups were concordant, compatibility testing remained compatible, and antibody screens and DAT results were negative in all 44 episodes. Bag culture showed no growth in all 33 reactions cultured during 2024-2025 and was recorded as not done for all 11 reactions from 2023. Imputability was definite in 18 episodes (40.9%), probable in 19 (43.2%), possible in six (13.6%) and unlikely in one (2.3%). All recipients recovered; no sequela or death was recorded (Table 5).

Table 5. Investigation, imputability and outcome of reported reactions (n = 44)

Variable	n	%
Pre-/post-transfusion ABO/RhD concordant	44	100.0
Pre-/post-transfusion crossmatch compatible	44	100.0
Pre-/post-transfusion antibody screen negative	44	100.0
Pre-/post-transfusion DAT negative	44	100.0
Bag culture: no growth / not done	33 / 11	75.0 / 25.0
Imputability: definite (certain)	18	40.9
Imputability: probable (likely)	19	43.2
Imputability: possible	6	13.6
Imputability: unlikely (doubtful)	1	2.3
Recovered without recorded sequelae	44	100.0
Death	0	0.0

DAT, direct antiglobulin test. Bag culture was not done for the 11 reactions from 2023; all 33 cultures performed in 2024-2025 showed no growth. A separate severity grade was unavailable.

DISCUSSION

Across 12,190 transfusions, 44 reaction episodes were reported, corresponding to 3.61 reports per 1,000 transfusions. FNHTR represented just over two-thirds of the events and PRBCs were implicated in more than three-quarters. Most episodes (84.1%) were assigned definite or probable imputability. Although transfusion activity rose substantially over the study period, the annual reporting rate did not change significantly. All recipients recovered and no transfusion-related death was recorded.

The overall reporting rate exceeded figures reported by several Indian studies, including the nine-year New Delhi series (approximately 1.95 per 1,000), a recent prospective North Indian study (1.84 per 1,000), and Saha et al. (1.4 per 1,000).[5,9,10] Other Indian institutional reviews also show considerable variation.[11] These differences should not be read as simple differences in biological risk. Surveillance design, denominator construction, case definitions, clinical services and local reporting culture all influence the number of events that reach the transfusion service. Active surveillance, in particular, detects reactions that passive systems miss.[6,7]

FNHTR was the dominant reaction in our series. This pattern is consistent with several Indian reports: FNHTR comprised 54.7% of reactions in the New Delhi study, 73% in another North Indian tertiary-care centre and 51.4% in a Bangalore haemovigilance initiative.[5,12,13] National HvPI analyses have also identified febrile reactions as a major reported category.[2] By contrast, Rajwal et al. found allergic reactions more frequently than FNHTR.[9] Such variation is expected when component use, processing methods and recognition of mild symptoms differ between centres.

PRBCs represented 58.8% of all components transfused but 77.3% of reported reactions; 24 of the 34 PRBC-associated episodes were FNHTRs. The red-cell units used at our centre were not leucoreduced or buffy-coat depleted. This observation does not establish causation, but it identifies a practical area for quality improvement. Universal prestorage leucoreduction has been associated with fewer FNHTRs, and Indian data suggest that buffy-coat reduction can lessen the burden of febrile reactions with red-cell components.[14,15] A prospective local evaluation of leucocyte-reduction strategies, with cost and component availability considered alongside reaction reporting, would be more informative than adopting a policy on the basis of retrospective data alone.

FFP accounted for eight reports (2.84 per 1,000) and RDPC for two (0.94 per 1,000). No event was reported after 70 SDPC transfusions, but the wide 95% confidence interval shows that the denominator was too small to support a safety comparison. International surveillance studies likewise show that the distribution of reaction types varies by component, with allergic events commonly associated with plasma-containing products and platelets.[16,17]

Serological work-up showed no ABO/RhD discrepancy, incompatible crossmatch, positive antibody screen or positive DAT. All 33 bag cultures performed in 2024-2025 were negative; culture was not done for the 11 reactions from 2023. Thirty-seven of 44 episodes had definite or probable imputability, and median recovery was 50 minutes. The absence of severe outcomes should still be interpreted in the context of passive case ascertainment.

Remaining gaps included a blank primary-diagnosis field in 2023, no bag culture for those 11 reactions and absence of a dedicated severity field. Transfusion indication and reaction symptoms were available for all 2023 episodes. Several timing entries required source-level verification because spreadsheet extraction could misinterpret 24-hour and midnight-crossing date-time entries; after verification, all 44 onset intervals were usable. Structured electronic diagnosis, timing and severity fields with chronology checks would improve data quality.

Strengths and limitations

Strengths of this study include coverage of three complete calendar years, use of components actually transfused rather than units merely issued, exclusion of outside-hospital supplies, episode-level review and component-specific denominators with exact confidence intervals. Reaction episodes were also distinguished from individual recipients, and missing data were reported with the relevant denominator.

The principal limitation is passive bedside reporting, which can miss mild, delayed and cardiopulmonary reactions.6,7 With only 44 episodes, estimates for uncommon components were imprecise. Recipient-level denominators for age, sex, previous transfusion and diagnosis were unavailable, so these variables cannot be treated as risk factors. Absence of reported delayed haemolysis, TACO or TRALI may reflect case ascertainment rather than true absence.

CONCLUSION

Adverse transfusion reactions were reported at a rate of 3.61 per 1,000 transfusions, with no significant change across the three study years despite increasing transfusion activity. FNHTR was the predominant reaction and conventional non-leucoreduced PRBCs accounted for most reports. All recipients recovered and no death was recorded. Regular bedside refresher training, structured electronic reaction reporting, periodic feedback to clinical departments and prospective evaluation of leucocyte-reduction strategies are practical next steps for strengthening local haemovigilance.

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DECLARATIONS

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data may be available subject to institutional and ethics requirements. Author contributions: AC: Conceptualization, methodology, investigation, data curation, formal analysis, and writing-original draft. MST: Conceptualization, methodology, supervision, validation, and writing-review and editing. AK: Methodology, validation, clinical interpretation, and writing-review and editing. All authors reviewed and approved the final manuscript. AI-assisted editing: ChatGPT assisted language editing and organisation; the authors verified the final manuscript and remain responsible for its content.

REFERENCES

1. World Health Organization. A guide to establishing a national haemovigilance system. Geneva: World Health Organization; 2016.
2. Bisht A, Marwaha N, Kaur R, Gupta D, Chhabra R. Haemovigilance Programme of India: comparative analysis of transfusion reactions reported over a 5-year period through two reporting formats and key recommendations for blood safety. Asian J Transfus Sci. 2020;14(2):103-116. doi:10.4103/ajts.ajts_192_20.
3. National Institute of Biologicals. Guidance document for reporting adverse reactions in blood transfusion. Version 3. Noida: Haemovigilance Programme of India, National Institute of Biologicals; 2019.
4. Bhattacharya P, Marwaha N, Dhawan HK, Roy P, Sharma RR. Transfusion-related adverse events at the tertiary care center in North India: an institutional hemovigilance effort. Asian J Transfus Sci. 2011;5(2):164-170. doi:10.4103/0973-6247.83245.
5. Pahuja S, Puri V, Mahajan G, Gupta P, Jain M. Reporting adverse transfusion reactions: a retrospective study from tertiary care hospital from New Delhi, India. Asian J Transfus Sci. 2017;11(1):6-12. doi:10.4103/0973-6247.200779.
6. Agnihotri N, Agnihotri A. Active hemovigilance significantly improves reporting of acute non-infectious adverse reactions to blood transfusion. Indian J Hematol Blood Transfus. 2016;32(3):335-342. doi:10.1007/s12288-015-0568-4.
7. Hendrickson JE, Roubinian NH, Chowdhury D, Brambilla D, Murphy EL, Wu Y, et al. Incidence of transfusion reactions: a multicenter study utilizing systematic active surveillance and expert adjudication. Transfusion. 2016;56(10):2587-2596. doi:10.1111/trf.13730.
8. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. PLoS Med. 2007;4(10):e296. doi:10.1371/journal.pmed.0040296.
9. Rajwal AR, Nijhawan VS, Kaushal ML. Incidence and risk factors of adverse transfusion reactions in a tertiary care hospital: a prospective study. Int J Med Pharm Res. 2025;6(6):1166-1173.
10. Saha S, Krishna D, Prasath R, Sachan D. Incidence and analysis of 7 years adverse transfusion reaction: a retrospective analysis. Indian J Hematol Blood Transfus. 2020;36(1):149-155. doi:10.1007/s12288-019-01174-x.
11. Kumar P, Thapliyal R, Coshic P, Chatterjee K. Retrospective evaluation of adverse transfusion reactions following blood product transfusion from a tertiary care hospital: a preliminary step towards hemovigilance. Asian J Transfus Sci. 2013;7(2):109-115. doi:10.4103/0973-6247.115564.
12. Bassi R, Aggarwal S, Bhardwaj K, Thakur KK. Patterns of adverse transfusion reactions in a tertiary care centre of North India: a step towards hemovigilance. Indian J Hematol Blood Transfus. 2017;33(2):248-253. doi:10.1007/s12288-016-0684-9.
13. Pai S. Surveillance of transfusion related adverse reactions in a tertiary care centre in Bangalore: a 4-year hemovigilance initiative. Indian J Hematol Blood Transfus. 2020;36(4):733-739. doi:10.1007/s12288-020-01312-w.
14. King KE, Shirey RS, Thoman SK, Bensen-Kennedy D, Tanz WS, Ness PM. Universal leukoreduction decreases the incidence of febrile nonhemolytic transfusion reactions to RBCs. Transfusion. 2004;44(1):25-29. doi:10.1046/j.0041-1132.2004.00609.x.
15. Singh L, Prinja N, Jain A, Sharma RR, Marwaha N. Impact of buffy coat reduction on the severity of febrile nonhemolytic transfusion reactions with red cell components. Asian J Transfus Sci. 2023;17(1):69-73. doi:10.4103/ajts.ajts_90_22.
16. Cho J, Choi SJ, Kim S, Alghamdi E, Kim HO. Frequency and pattern of noninfectious adverse transfusion reactions at a tertiary care hospital in Korea. Ann Lab Med. 2016;36(1):36-41. doi:10.3343/alm.2016.36.1.36.
17. Kracalik I, Mowla S, Basavaraju SV, Sapiano MRP. Transfusion-related adverse reactions: data from the National Healthcare Safety Network Hemovigilance Module-United States, 2013-2018. Transfusion. 2021;61(5):1424-1434. doi:10.1111/trf.16362.