

Haemovigilance of Blood Donation and Transfusion-Related Adverse Events At A Tertiary Care Centre in North-East India: A Retrospective Observational Study

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Abstract

Background: Haemovigilance enables systematic surveillance of adverse events associated with blood donation and transfusion. Institution-specific data are important for identifying local patterns and improving transfusion safety.

Methods: A retrospective observational study was conducted at a tertiary-care blood centre in North-East India. Donor and recipient haemovigilance records from January to December 2025 were analysed. Donor and recipient adverse-event frequencies, clinical characteristics, implicated blood components and outcomes were assessed.

Results: Among 51,258 blood donations, 41 donor adverse reactions were reported, corresponding to 80.0 reactions per 100,000 donations. Generalized reactions predominated, with dizziness being the most frequent manifestation (68.3%). Among recipients, 33 transfusion reactions were documented. Febrile non-haemolytic transfusion reactions (FNHTR) constituted 84.8% of reactions, while allergic reactions accounted for 15.2%. Packed red blood cells were implicated in 93.9% of recipient reactions. All documented donor and recipient reactions had favourable outcomes, with no deaths or permanent sequelae reported.

Conclusion: The haemovigilance profile was predominantly characterized by mild generalized donor reactions and FNHTR among recipients. Continued systematic surveillance, accurate denominator collection and timely reporting are essential for identifying preventable adverse events and improving transfusion safety.

Keywords: Haemovigilance; blood transfusion; donor reactions; transfusion reactions; FNHTR; North-East India.

Introduction

Blood transfusion is an essential component of modern healthcare and remains a life-saving intervention in a wide range of clinical settings, including severe anaemia, major haemorrhage, obstetric emergencies, surgery, haematological disorders and critical illness. Despite substantial advances in donor selection, infectious-disease screening, blood component preparation, compatibility testing and transfusion practices, transfusion is not entirely free of risk. Adverse events may occur at different stages of the transfusion chain and range from mild, self-limiting reactions to potentially severe and life-threatening complications. Consequently, systematic surveillance of both blood donors and transfusion recipients has become an integral component of modern transfusion safety systems.^{1,2}

Haemovigilance encompasses a set of surveillance procedures covering the transfusion chain from blood donation and component collection through processing, storage, distribution and transfusion, including subsequent follow-up of recipients. Its purpose is to systematically detect, document, investigate, classify and analyse unexpected or undesirable events associated with blood donation and transfusion, with the ultimate objective of preventing their occurrence or recurrence and improving the safety and quality of transfusion practice.³ Donor haemovigilance is an important component of this process, as adverse events associated with blood donation may affect donor safety, donor satisfaction and willingness to donate again, and consequently have implications for the sustainability of the blood supply.^{4,5}

The implementation of haemovigilance systems varies considerably across countries and healthcare settings. The World Health Organization (WHO) recommends haemovigilance as an important component of comprehensive blood safety systems. According to the WHO Global Status Report on Blood Safety and Availability 2025, systems for reporting adverse transfusion events were present in 68% of hospitals performing transfusions globally, while 88 of 168 responding countries reported having a national haemovigilance system.⁶ These differences reflect variation in transfusion infrastructure, reporting mechanisms, clinical awareness, regulatory systems and availability of resources. The establishment and strengthening of haemovigilance systems are therefore particularly important in low- and middle-income countries, where systematic reporting may remain incomplete.⁶

India established the Haemovigilance Programme of India (HvPI) in December 2012 as a national initiative for systematic monitoring of adverse reactions associated with blood and blood-component transfusion.⁷ Donor haemovigilance was subsequently incorporated through the National Blood Donor Vigilance Programme (NBDVP), launched in 2015, thereby extending surveillance to the donor component of the transfusion chain.⁴ Analysis of the first two years of the NBDVP, covering 2016 and 2017, demonstrated the feasibility of systematic donor surveillance at the national level. Among 1,622,600 validated donations, the overall donor adverse reaction rate was 2.45 per 1000 donations, with generalized reactions constituting the largest category. Donor adverse reaction rates were higher among female and first-time donors

than among male and repeat donors.⁵

Indian institutional studies have demonstrated considerable variation in the frequency and spectrum of adverse transfusion reactions. At the All India Institute of Medical Sciences, New Delhi, a retrospective analysis of 380,658 blood and blood components identified 196 reported adverse transfusion reactions, giving an overall reaction rate of 0.05%. Allergic reactions and febrile non-haemolytic transfusion reactions (FNHTR) constituted the majority of reported events.⁸ Similarly, an institutional haemovigilance study from a tertiary-care centre in India reported 105 adverse reactions among 56,503 blood and blood components issued, with FNHTR and allergic reactions being the predominant categories.⁹ Such variation between institutions may reflect differences in patient populations, blood components used, transfusion practices, leukoreduction policies, reporting systems and clinical recognition of adverse events, highlighting the importance of institution-specific haemovigilance data.

Evidence from North-East India is comparatively limited but provides important regional context. A prospective haemovigilance study conducted at the State-of-the-Art Model Blood Bank, Gauhati Medical College and Hospital, Guwahati, during September 2013 to May 2014 documented 106 adverse events among approximately 51,000 transfused blood components, corresponding to a reported rate of 0.208%. FNHTR was the most frequent reaction, followed by pruritus and rigors/chills, and all reported events were classified as non-severe.¹⁰ A study from a teaching hospital in Sikkim reported 32 acute transfusion reactions among 3455 transfusions over a 20-month period, giving a reaction rate of 0.92%; allergic reactions and febrile reactions constituted the majority of reported events.¹¹ More recently, a study from Assam Medical College and Hospital, Dibrugarh, reported 41 adverse transfusion reactions among 38,165 blood products issued during 2022–2023, corresponding to a reaction rate of 0.11%. FNHTR was the most frequently reported reaction, followed by allergic reactions, with packed red blood cells being the most commonly implicated component.¹²

These regional studies demonstrate the usefulness of haemovigilance surveillance in identifying the local pattern of transfusion-related adverse events. However, published studies from the region have predominantly focused on recipient transfusion reactions. Comparatively fewer studies have presented donor adverse reactions and recipient transfusion reactions together with their corresponding denominator data from the same blood centre. Furthermore, haemovigilance patterns may change over time with alterations in component preparation, transfusion practices, clinical awareness, reporting systems and blood-centre procedures. Contemporary institution-specific data are therefore important for evaluating current transfusion safety and for identifying potentially preventable adverse events.

Against this background, the present study was undertaken at a tertiary-care blood centre in North-East India to evaluate adverse events associated with both blood donation and blood-component transfusion during 2025. The study, titled “Haemovigilance of Blood Donation and Transfusion-Related Adverse Events at a Tertiary Care Centre in North-East India: A Retrospective Observational Study,” assesses the frequency, clinical pattern, demographic characteristics, implicated blood components, timing, severity, imputability and outcomes of reported donor and recipient adverse events. By analysing donor and recipient haemovigilance data together, the study aims to provide contemporary institution-specific evidence that may contribute to strengthening transfusion safety practices in the region.

Materials and Methods

Study design and setting

This retrospective observational study was conducted at a tertiary-care blood centre in Guwahati, Assam, North-East India. The study included all documented adverse events associated with blood donation and blood-component transfusion during the period 1 January to 31 December 2025.

Data collection

Data were obtained from routinely maintained haemovigilance records of the blood centre, including the Adverse Blood Donor Reaction Reporting Form (ABDRRF) and Transfusion Reaction Reporting Form (TRRF) of the Haemovigilance Programme of India (HvPI). Corresponding donor and recipient denominator data were obtained from the blood-centre records.

For donor reactions, demographic characteristics, donor status, clinical manifestations, timing of reaction, type of reaction, completion of donation and outcome were recorded. For recipient reactions, age, sex, blood group, indication for transfusion, transfused blood component, type of reaction, severity, imputability and outcome were analysed.

Definitions and outcome measures

Donor adverse reactions were classified according to the HvPI reporting system. Recipient reactions were classified based on the diagnosis documented in the transfusion-reaction records, with febrile non-haemolytic transfusion reaction (FNHTR) and allergic reactions being the principal categories identified in the study.

Donor reaction rates were calculated using the total number of adverse reactions as the numerator and total donations as the denominator and expressed per 100,000 donations. Recipient reaction rates were similarly calculated per 100,000 blood components, where corresponding denominator data were available.

The recipient denominator records for January–June 2025 were unavailable; therefore, recipient reaction rates were calculated only for the period July–December 2025, for which denominator data were available.

Statistical analysis

Categorical variables were expressed as frequencies and percentages, while continuous variables were summarized as mean $\pm$ standard deviation or median with interquartile range, as appropriate. Reaction rates were expressed per 100,000 donations or blood components. Where appropriate, 95% confidence intervals were calculated using the exact Poisson method. Categorical variables were compared using the chi-square or Fisher's exact test. A *P* value <0.05 was considered statistically significant.

Ethical considerations

The study involved retrospective analysis of routinely collected, de-identified haemovigilance data.

Results

During 2025, a total of 51,258 whole-blood donations were recorded at the study centre. Forty-one donor adverse reactions were documented, giving an overall donor reaction rate of 80.0 per 100,000 donations (95% CI: 57.4–108.5). During the same period, 33 recipient transfusion reactions were reported.

Donor adverse reactions

The mean age of donors experiencing adverse reactions was 27.1 ± 7.0 years, with a mean body weight of 67.5 ± 10.9 kg. Most affected donors were male (90.2%), first-time donors (70.7%) and replacement donors (90.2%). All reactions occurred following whole-blood donation at the blood centre and were classified as generalized reactions.

Dizziness was the predominant clinical manifestation, reported in 28 (68.3%) reactions, followed by generalized weakness (12.2%), sweating (9.8%), vomiting (7.3%) and convulsions (2.4%). Forty reactions (97.6%) occurred after donation, while one occurred during donation. Donation was completed in 38 (92.7%) cases. All donors recovered, with 40 reactions resolving at the donation site and one resolving on follow-up.

Recipient transfusion reactions

Thirty-three recipient transfusion reactions were documented during the study period. The mean age of affected recipients was 39.8 ± 17.8 years (range, 11–72 years), and 23 (69.7%) were female. The majority of reactions involved PRBCs (31; 93.9%), while two (6.1%) involved FFP.

FNHTR was the predominant transfusion reaction, accounting for 28 (84.8%) cases, while 5 (15.2%) were allergic reactions. Among the FNHTR cases, 14 had a documented 1°C rise in temperature, 10 had a 2°C rise and 4 presented with chills or rigors without the specified temperature-rise category.

Fever was the most frequently documented clinical manifestation (21; 63.6%), followed by chills (5; 15.2%), pruritus (4; 12.1%), rigors (2; 6.1%) and urticaria (1; 3.0%). Two recipients developed dyspnoea and one had infusion-site pain.

Anaemia or severe anaemia was the indication for transfusion in the majority of reaction cases. All 33 reactions were classified as probable/likely imputability, and all affected recipients recovered. No deaths or permanent sequelae were documented among the reported reactions.

The principal characteristics of donor and recipient adverse events are summarized in Tables 1 and 2.

Table 1. Donor adverse reactions during 2025 (n = 41)

Characteristic	n (%)
Sex	
Male	37 (90.2)
Female	4 (9.8)
Donor status	
First-time	29 (70.7)
Repeat	12 (29.3)
Donor type	
Replacement	37 (90.2)
Family donor	4 (9.8)
Reaction type	
Generalized	41 (100)
Timing	
After donation	40 (97.6)
During donation	1 (2.4)
Clinical manifestations*	

Characteristic	n (%)
Dizziness	28 (68.3)
Generalized weakness	5 (12.2)
Sweating	4 (9.8)
Vomiting	3 (7.3)
Convulsions	1 (2.4)
Donation completed	
Yes	38 (92.7)
No	3 (7.3)
Outcome	
Recovered at donation site	40 (97.6)
Recovered on follow-up	1 (2.4)

Table 2. Recipient transfusion reactions during 2025 (n = 33)

Characteristic	n (%)
Sex	
Female	23 (69.7)
Male	10 (30.3)
Blood component	
PRBC	31 (93.9)
FFP	2 (6.1)
Reaction type	
FNHTR	28 (84.8)
Allergic reaction	5 (15.2)
FNHTR pattern (n=28)	
1°C temperature rise	14 (50.0)
2°C temperature rise	10 (35.7)
Chills/rigors only	4 (14.3)
Outcome	
Recovered	33 (100)
Imputability	
Probable/likely	33 (100)

Discussion

The present study provides a combined assessment of donor and recipient adverse events recorded over one year at a tertiary-care blood centre in North-East India. Among 51,258 whole-blood donations, 41 donor adverse reactions were documented, corresponding to a rate of 80.0 per 100,000 donations. Among recipients, 33 transfusion reactions were reported, of which FNHTR constituted the predominant category. The findings demonstrate that the adverse events captured by the centre's haemovigilance system were predominantly mild reactions with favourable outcomes, although the absence of a complete recipient denominator limits estimation of the overall recipient reaction rate.

Donor adverse reactions

The donor adverse-reaction rate in the present study was relatively low at 80.0 per 100,000 donations. The majority of reactions were generalized reactions, with dizziness being the predominant manifestation. This pattern is consistent with the recognized predominance of vasovagal-type reactions among blood donors.

The National Blood Donor Vigilance Programme of India reported a substantially higher overall donor adverse-reaction rate of approximately 2.45 per 1000 donations during its initial two years of implementation. Generalized reactions constituted the predominant category, with higher rates observed among female and first-time donors.⁵ The lower rate observed in our centre may reflect differences in donor population, reporting practices, definition and classification of adverse events, and

the fact that our dataset represents reactions documented through routine haemovigilance reporting rather than actively solicited donor symptoms.

A recent prospective study from South India by Patel et al. further emphasizes the variability in reported donor adverse-event rates. Among 7188 eligible donors, 288 adverse events were documented, giving an incidence of approximately **4.0%**. Generalized vasovagal reactions were the most common, and 79.2% of events occurred after donation. Female, first-time and apheresis donors had higher rates of adverse events.¹³ The predominance of post-donation reactions in that study is consistent with our observation that 97.6% of donor reactions occurred after donation, although the overall event rate in our study was considerably lower.

In the present study, first-time donors accounted for 70.7% of donor reactions. However, because the total number of first-time and repeat donors was available, the reaction rates were relatively similar between these groups. This suggests that the predominance of first-time donors among reaction cases may partly reflect their larger representation among the overall donor population rather than necessarily indicating a markedly increased risk. The relatively small number of female reactions also limits interpretation of sex-specific differences.

The clinical profile of the reactions was reassuring. Dizziness accounted for more than two-thirds of reported reactions, while generalized weakness, sweating and vomiting were less frequent. Only one donor experienced convulsions, and no serious or persistent adverse outcome was recorded. These findings support the predominantly mild nature of donor reactions observed in the present study.

Recipient transfusion reactions

Among the 33 recipient transfusion reactions documented during 2025, FNHTR accounted for 84.8%, while allergic reactions accounted for 15.2%. This predominance of FNHTR is consistent with several Indian institutional haemovigilance studies.

Kumar et al., in a retrospective study from the All India Institute of Medical Sciences, reported 196 adverse transfusion reactions among 380,658 blood components, with allergic reactions and FNHTR constituting the majority of events.⁸ Bhattacharya et al. similarly reported FNHTR as the most frequent reaction (41%), followed by allergic reactions (34%), in their institutional haemovigilance study from North India.⁹ The predominance of FNHTR in these studies is broadly comparable with our findings, although the relative proportion of FNHTR in our study was higher.

The North-East Indian literature also demonstrates a predominance of relatively mild non-haemolytic reactions. Somagari et al., in a haemovigilance study from Gauhati Medical College and Hospital, reported 106 reactions among approximately 51,000 transfusions, with FNHTR accounting for 50% of reported reactions.¹⁰ This earlier study from Guwahati is particularly relevant because it provides a geographical and institutional context for comparison with the present study. The predominance of FNHTR has persisted in the region, although the proportion observed in our study was considerably higher. Similarly, Sharma et al. from Sikkim reported 32 acute transfusion reactions among 3455 transfusions, with allergic reactions predominating, followed by febrile reactions.¹¹ The difference from our findings illustrates the variation in transfusion-reaction patterns between individual centres despite their geographical proximity.

The study from Assam Medical College and Hospital, Dibrugarh, published in 2024, provides a particularly relevant contemporary comparison. Choudhury et al. reported 41 reactions among 38,165 blood products issued, corresponding to a reaction rate of 0.11%; FNHTR constituted 51.2% of reactions and allergic reactions 39%. PRBCs were the most frequently implicated component.¹² Our study shows a similar predominance of FNHTR and PRBC-associated reactions, although the relative proportion of FNHTR was higher in our cohort and the total number of documented reactions was smaller.

A recent retrospective audit from a tertiary-care hospital in South India by Priya et al. reported 105 transfusion reactions among 23,028 transfused units over approximately four years, corresponding to 0.5%. FNHTR accounted for 59% of reactions and allergic reactions for 31%.¹⁴ Thus, despite differences in study design and reporting rates, the pattern observed in the present study is consistent with the broader Indian literature, in which FNHTR and allergic reactions constitute the majority of reported transfusion reactions.

Blood components and clinical manifestations

PRBCs were implicated in 31 of 33 recipient reactions (93.9%) in the present study. This finding is comparable with the observations of Choudhury et al. from Assam and other Indian studies in which PRBCs constituted the predominant implicated component.^{12,14} The predominance of PRBC-associated reactions may partly reflect the high clinical utilization of red-cell components in tertiary-care hospitals, particularly for patients with anaemia and other conditions requiring red-cell transfusion. Therefore, the high proportion of reactions associated with PRBCs should not be interpreted as evidence that PRBCs intrinsically carry a higher risk without considering their overall utilization denominator.

Fever was the most frequently documented clinical manifestation among recipients, followed by chills and other febrile symptoms. The clinical predominance of fever and chills is compatible with the high proportion of FNHTR in the present series. The absence of documented acute haemolytic reactions, TRALI or fatal reactions is reassuring; however, these complications are uncommon, and a one-year single-centre dataset cannot establish their absence from the wider transfusion population.

Reporting and haemovigilance

An important consideration in interpreting the present findings is the possibility of under-reporting. Haemovigilance systems depend on recognition of a reaction by clinical personnel, appropriate documentation and transmission of the information to the blood centre. Bhat et al., in a multicentre pilot study involving blood banks enrolled under the HvPI, demonstrated substantial gaps between blood products issued and completed transfusion-reaction reporting forms. Only eight reactions were reported among more than 5000 transfusions observed during the study period, and the authors identified non-return of reporting forms and communication gaps as important barriers to effective surveillance.

This is relevant to the interpretation of our relatively low number of reported recipient reactions. The data should therefore be regarded as describing reported haemovigilance events, rather than necessarily representing the true biological incidence of all transfusion-associated symptoms. The finding also reinforces the importance of continued education of clinical staff, standardized reaction recognition and complete return of transfusion-reaction forms.

Overall interpretation

Taken together, the findings indicate that the haemovigilance profile of this tertiary-care centre during 2025 was dominated by mild generalized donor reactions and non-haemolytic recipient reactions, particularly FNHTR. The pattern is broadly consistent with previous studies from Guwahati, other centres in North-East India and tertiary-care institutions elsewhere in India.^{8-12, 14}

Summary

This retrospective observational study evaluated donor and recipient adverse events reported through the haemovigilance system of a tertiary-care blood centre in North-East India during 2025. Among 51,258 blood donations, 41 donor adverse reactions were documented, corresponding to a rate of 80.0 per 100,000 donations. Donor reactions were predominantly generalized and mild, with dizziness being the most frequent manifestation. Among recipients, 33 transfusion reactions were reported, of which FNHTR accounted for 84.8% and allergic reactions for 15.2%. PRBCs were the most frequently implicated component. All documented donor and recipient reactions had favourable outcomes, with no deaths or permanent sequelae recorded.

Conclusion

The present study demonstrates that the haemovigilance profile of the centre was predominantly characterized by mild generalized donor reactions and FNHTR among transfusion recipients. The findings are broadly consistent with previously reported Indian and North-East Indian haemovigilance studies. Continued systematic haemovigilance, accurate denominator collection, timely reporting and regular review of adverse events are essential to identify potentially preventable reactions and further improve the safety of blood donation and transfusion practices.

References

1. World Health Organization. Blood safety and availability [Internet]. Geneva: World Health Organization; 2026 [cited 2026 Oct 1]. Available from: <https://www.who.int/news-room/fact-sheets/detail/blood-safety-and-availability>
2. de Vries RR, Faber JC, Strengers PFW; Board of the International Haemovigilance Network. Haemovigilance: an effective tool for improving transfusion practice. *Vox Sang.* 2011;100(1):60-67. doi:10.1111/j.1423-0410.2010.01442.x.
3. Bisht A, Singh S, Marwaha N. National blood donor vigilance programme: India. *Asian J Transfus Sci.* 2016;10(1):1-2. doi:10.4103/0973-6247.175384.
4. Goldman M, Land K, Robillard P, Wiersum-Osselton J. Development of standard definitions for surveillance of complications related to blood donation. *Vox Sang.* 2016;110(2):185-188. doi:10.1111/vox.12323.
5. Bisht A, Marwaha N, Arora S, Patidar GK, Chhabra R. National blood donor vigilance programme of India: analysis of donor adverse reactions reported during initial 2 years of implementation (2016 and 2017). *Asian J Transfus Sci.* 2021;15(1):1-11. doi:10.4103/ajts.ajts_195_20.
6. World Health Organization. Global status report on blood safety and availability 2025 [Internet]. Geneva: World Health Organization; 2026 [cited 2026 Oct 1]. Available from: WHO Global status report on blood safety and availability 2025
7. Bisht A, Marwaha N, Kaur R, Gupta D, Singh S. Haemovigilance Programme of India: analysis of transfusion reactions reported from January 2013 to April 2016 and key recommendations for blood safety. *Asian J Transfus Sci.* 2018;12(1):1-7. doi:10.4103/ajts.AJTS_5_18.
8. 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.
9. 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.
10. Somagari DR, Sriram CS, Rachamalla CKV, Bezbaruah B, Dutta U, Chaliha T, et al. Haemovigilance study at a tertiary care hospital in the north-east of India. *ISBT Sci Ser.* 2015;10(2):61-64. doi:10.1111/vox.12182.

11. Sharma DK, Datta S, Gupta A. Study of acute transfusion reactions in a teaching hospital of Sikkim: a hemovigilance initiative. *Indian J Pharmacol.* 2015;47(4):370-374. doi:10.4103/0253-7613.161257.
12. Choudhury M, Ahmed Z, Dutta A, Sharma A. Adverse transfusion reactions following transfusion of blood and blood products in a tertiary care hospital: a step toward hemovigilance. *Asian J Med Sci.* 2024;15(3):196-200. doi:10.3126/ajms.v15i3.60578.
13. Patel P, Rajendran V, Nair AR, Gupta D. A study to assess and grade the donor adverse events using the severity grading tool of hemovigilance program of India. *Asian J Transfus Sci.* 2026;20(1):50-57. doi:10.4103/ajts.ajts_154_24.
14. Priya S, Karthikeyan V, Srinivasan S. Retrospective audit of transfusion reactions in a tertiary-care hospital in South India. *Cureus.* 2024;16(12):e74930. doi:10.7759/cureus.74930.