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Data Analysis of Recipient Haemovigilance in SMS Jaipur: A Retrospective Study of Transfusion Reactions in Recipients (January-March 2026)

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Abstract: ***Background: Haemovigilance is a systematic surveillance process designed to detect, report, and analyse adverse events associated with the transfusion of blood and blood products, with the goal of improving transfusion safety. Aim: To conduct a retrospective analysis of adverse transfusion reactions among recipients at SMS Jaipur over a three-month period (January to March 2026). Methods: Data on blood units issued and transfusion reactions reported were retrospectively reviewed. Descriptive statistics were used to calculate the proportion of reactions, and a 95% confidence interval was estimated using the standard error of a binomial proportion. Results: Of 17,890 blood units transfused, 17 transfusion reactions were recorded, giving a reaction proportion of 0.095% (p = 0.000950; SD = 0.000230). The 95% confidence interval for the true reaction rate was 0.0499%–0.1402%. Conclusion: The observed transfusion reaction rate at this centre was low and consistent with rates reported by other haemovigilance programmes in India, supporting the effectiveness of current transfusion safety protocols while underscoring the continued need for vigilant reporting.***

Keywords: Haemovigilance; Transfusion reaction; Blood safety; PvPI; HvPI; Confidence interval

1. Introduction

Blood transfusion is a life-saving intervention, but it is not without risk. Adverse transfusion reactions ranging from mild febrile or allergic responses to rare but serious events such as haemolytic reactions, transfusion-related acute lung injury (TRALI), and transfusion-associated circulatory overload (TACO) can compromise patient safety if not systematically monitored and addressed.

In India, a structured mechanism for monitoring these events was established through the Haemovigilance Programme of India (HvPI), instituted under the umbrella of the Pharmacovigilance Programme of India (PvPI). The PvPI itself was constituted under the aegis of the Indian Pharmacopoeia Commission (IPC) and the Central Drugs Standard Control Organization (CDSCO) in July 2010. [1]

The HvPI was formally launched on 10 December 2012 by the National Institute of Biologicals (NIB) under the Ministry of Health and Family Welfare (MoHFW), Government of India, with the NIB serving as the National Coordinating Centre (NCC) for the programme. [2] The recipient-side component of haemovigilance reporting of adverse transfusion reactions in patients began with this 2012 launch, while a complementary donor-side vigilance mechanism was introduced in 2016 to capture adverse events occurring during blood donation. [3]

Reporting centres generate transfusion reaction reports, perform imputability assessment, and submit these reports through the Haemo-Vigil software to the NCC, which reviews the completeness and quality of the data before collating it for national-level analysis. [4] The CDSCO–Drugs Controller General of India (DCGI) uses this collated evidence to formulate safety-related regulatory decisions and to communicate transfusion-safety guidance to stakeholders, while also monitoring compliance across reporting units.

The present retrospective study was undertaken at SMS Medical College, Jaipur, to analyse recipient transfusion reactions reported over a three-month period and to statistically characterise the observed reaction rate.

2. Objectives

The broader objectives of institutional haemovigilance activity, in line with the national programme, are to:

- Monitor transfusion reactions among recipients.
- Create awareness among healthcare professionals regarding transfusion safety.
- Generate evidence-based recommendations for clinical practice.
- Advise the CDSCO on safety-related regulatory decisions.
- Communicate findings to all key stakeholders.
- Establish national and international linkages for shared learning.

The specific objective of this study was to retrospectively quantify the proportion of transfusion reactions among recipients at SMS Jaipur between January and March 2026, and to estimate the precision of this proportion using a 95% confidence interval.

3. Materials and Methods

Study Design and Setting

This was a retrospective, descriptive study conducted in the Department of Immunohematology and Transfusion Medicine, SMS Medical College, Jaipur, covering all blood units issued and transfusion reactions reported between January 2026 and March 2026.

Data Source

Data on the total number of blood units supplied and the number of reported transfusion reactions were retrieved from institutional transfusion and haemovigilance records maintained in accordance with the HvPI reporting framework (Transfusion Reaction Reporting Form).

Statistical Analysis

Descriptive statistics were used to summarise the data. The proportion of transfusion reactions was calculated as p = x / n, where x is the number of reactions observed and n is the total number of blood units transfused. The standard deviation (SD) of this proportion was estimated using the standard error formula for a binomial proportion:

$$SD = \sqrt{[p(1 - p) / n]}$$

A 95% confidence interval (CI) for the true population reaction rate was then computed using the normal approximation:

$$CI = p \pm Z \times SD, \text{ where } Z = 1.96 \text{ for a 95\% confidence level.}$$

4. Results

Over the three-month study period, a total of 17,890 blood units were transfused, during which 17 transfusion reactions were reported.

Proportion of Reactions

The proportion of reactions was calculated as:

$$p = 17 / 17{,}890 = 0.000950, \text{ or } 0.095\%.$$

Standard Deviation

The standard deviation of the observed proportion was:

$$SD = \sqrt{[0.000950 \times (1 - 0.000950) / 17{,}890]} \approx 0.000230.$$

95% Confidence Interval

Applying the normal approximation, the 95% confidence interval was:

$$CI = 0.000950 \pm (1.96 \times 0.000230) = (0.000499, 0.001402), \text{ i.e. } (0.0499\%, 0.1402\%).$$

Summary Table

Table 1: Summary of transfusion reaction data and statistical estimates, SMS Jaipur, January–March 2026.

Parameter	Value
Total blood units transfused	17,890
Number of transfusion reactions observed	17
Proportion of reactions (p)	0.000950 (0.095%)
Standard deviation (SD)	0.00023
95% Confidence interval	0.0499% – 0.1402%

Overall, the standard deviation of 0.000230 indicates minimal variability in the proportion of reactions across the total units transfused, and the narrow 95% confidence interval (0.0499%–0.1402%) suggests that the true underlying reaction rate in the source population is likely to fall within this range with 95% confidence.

Demographic and Sample Characteristics of Transfusion Reactions

The distribution of the 17 observed transfusion reactions by blood group, Rh status, gender, and blood component transfused is summarised in Table 2.

Table 2: Demographic and sample characteristics of the 17 observed transfusion reactions, SMS Jaipur, January–March 2026 (n = 17 for each category)

Category	Subgroup	n	%
Blood group	O	6	35.30%
	A	2	11.80%
	B	2	11.80%
	AB	7	41.20%
Rh status	Rh positive	14	82.40%
	Rh negative	3	17.60%
Gender	Male	12	70.60%
	Female	5	29.40%
Blood component	PRBC	12	70.60%
	FFP	5	29.40%

AB blood group and Rh-positive recipients accounted for the largest proportions of reported reactions, and PRBC transfusions were associated with more than two-thirds of reactions, broadly reflecting the relative frequency with which each component is transfused at this centre.

Distribution of Transfusion Reactions by Type

The clinical type of each of the 17 transfusion reactions is summarised in Table 3.

Table 3: Distribution of the 17 observed transfusion reactions by clinical reaction type, SMS Jaipur, January–March 2026

Reaction type	n	%
Febrile non-haemolytic transfusion reaction (FNHTR)	6	35.30%
Anxiety reaction	4	23.50%
Allergic reaction	3	17.60%
Transfusion-associated dyspnoea	2	11.80%
Non-immune haemolytic transfusion reaction	1	5.90%
Transfusion-associated hypotension	1	5.90%
Total	17	100.00%

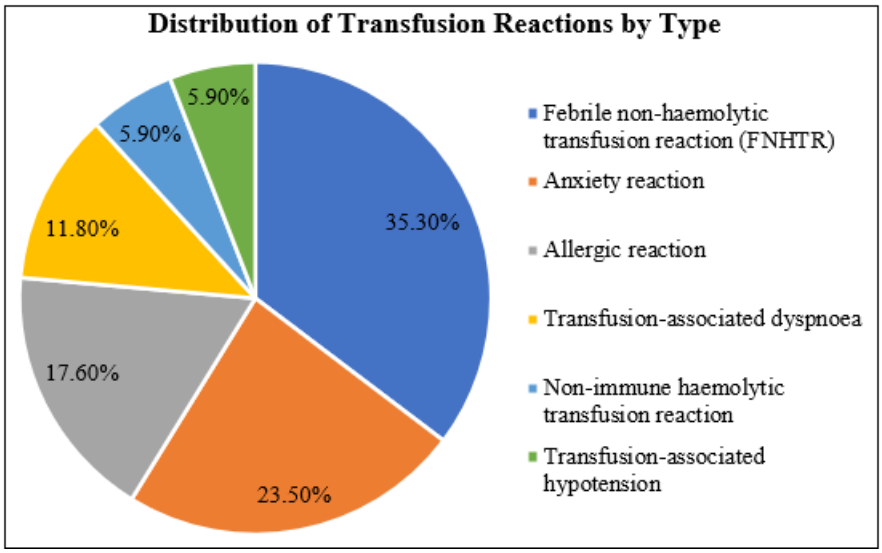

Figure 1: Distribution of Transfusion Reactions by Type

FNHTR was the single most frequent reaction type, followed by anxiety-related and allergic reactions; transfusion-associated dyspnoea, non-immune haemolytic reactions, and transfusion-associated hypotension were each infrequent. No cases of TRALI, TACO, or immune-mediated haemolytic transfusion reaction were recorded during the study period.

5. Discussion

The observed transfusion reaction rate of 0.095% at SMS Jaipur during this three-month period is low and falls within the range of rates reported by other haemovigilance studies from Indian tertiary care centres, most of which report reaction rates below 1% of total units transfused [5], [6]. Nationally, HvPI data have shown a progressive rise in the absolute number of reported reactions since the introduction of the Haemo-Vigil reporting software in January 2013, a trend attributed at least in part to improved awareness and reporting compliance rather than to a true increase in adverse event incidence [7], [8].

Febrile non-haemolytic transfusion reactions (FNHTR) and mild allergic reactions have consistently been reported as the most common categories of transfusion reaction nationally, together accounting for the large majority of reported events, while more serious reactions such as TRALI, TACO, and haemolytic transfusion reactions are comparatively rare [9]. As shown in Table 3, FNHTR was indeed the most frequently observed reaction type in the present series, followed by anxiety-related and allergic reactions, while transfusion-associated dyspnoea, non-immune haemolytic reactions, and transfusion-associated hypotension were infrequent and no TRALI, TACO, or immune-mediated haemolytic reactions were recorded. This pattern is consistent with a transfusion service in which serious reactions are infrequent and predominantly mild reactions predominate.

The narrow confidence interval obtained here (0.0499%–0.1402%) reflects the large sample size (17,890 units), which allows for a relatively precise estimate of the reaction rate despite the small absolute number of events. This illustrates a broader principle in haemovigilance statistics: with rare events, large denominators are required to generate stable and clinically meaningful rate estimates, which is part of the rationale for pooling data at state and national levels through coordinating centres such as the NIB.

A low but non-zero reaction rate should not be interpreted as an indication to relax vigilance. Under-reporting is a recognised limitation of voluntary haemovigilance systems worldwide, and the true incidence of transfusion reactions may be higher than that captured through routine reporting channels [10], [4]. Strengthening clinician awareness, simplifying the reporting workflow, and regular feedback to reporting units, as envisaged under the HvPI framework, remain important strategies to improve the sensitivity of detection.

6. Limitations

This study is limited by its short observation period of three months, its single-centre design, and its modest number of reported events. The retrospective nature of data collection also carries the inherent risk of under-ascertainment common to all passive surveillance systems. Future studies incorporating longer follow-up and multi-centre data would provide a more comprehensive picture of transfusion safety at this institution.

7. Conclusion

This retrospective analysis of recipient haemovigilance data at SMS Jaipur found a low overall transfusion reaction rate of 0.095% (95% CI: 0.0499%–0.1402%) over a three-month period, consistent with rates reported elsewhere in India. These findings support the continued effectiveness of existing transfusion protocols at this centre while reinforcing the importance of sustained reporting, clinician training, and adherence to the national haemovigilance framework to further improve transfusion safety for both donors and recipients.

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