Haemovigilance Programme of India (HvPI)

Summary of Transfusion Reactions Reported for Year 2018-2019 and key Recommendations for Blood Safety

NATIONAL INSTITUTE OF BIOLOGICALS
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Introduction

Haemovigilance Programme of India (HvPI) was launched on December 10, 2012 with the purpose to assure patient safety and promote public health through continuous monitoring of adverse reactions associated with blood/blood products transfusion to prevent their occurrence and recurrence.[1] The National Co-ordinating Centre for HvPI is a National Institute of Biologicals (NIB), NOIDA. Implementation and coordination of activities of HvPI is one of the mandates of NIB as per its bye-laws 3.4.1 as approved by the Governing Body of the Institute. The HvPI was started with the following key objectives: (i) monitor transfusion reactions, (ii) create awareness among health-care professionals, (iii) generate evidence-based recommendations, (iv) advise the Central Drugs Standard Control Organization for safety-related regulatory decisions, (v) communicate findings to all key stakeholders, and (vi) create national and international linkages.[1] A software – "Haemo-Vigil" was indigenously developed by HvPI division, NIB to collect and analyze the data related to hemovigilance all over the country.[3] This report consist of the data collected From 1st January, 2018 to 31st December, 2019. Hemovigilance data were collected through version 2.0 of the transfusion reaction reporting form (TRRF).

Enrollment and Participation of Centers

HvPI started with the enrollment of 90 blood centers in the year 2012. Following inception, the enrollment of new blood centers continued throughout each successive year and the total number of enrolled centers at the end of the years 2018 and 2019 was 800 and 959, respectively. Figure 1 shows year-wise enrollment of blood centers under HvPI with the highest number of enrollment in the year 2016. The participation of blood centers in HvPI is increasing continuously.

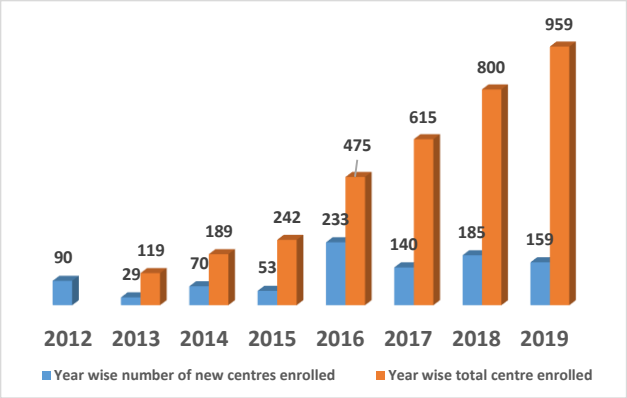


Figure: 1 Years wise total and new blood centres enrolled under HvPI

It was observed that only 366 blood centers out of 800 enrolled centers were active who submitted reports or nil report (also a type of reporting) in 2018 and 474 out of 959 enrolled centers were active who submitted reports or nil report (also a type of reporting) in 2019 [Figures 2]. There is a tremendous need to increase the awareness regarding the importance of reporting in hemovigilance as a step toward safe blood transfusion and patient safety.[4]

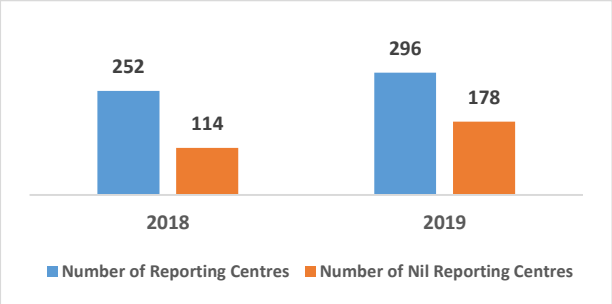
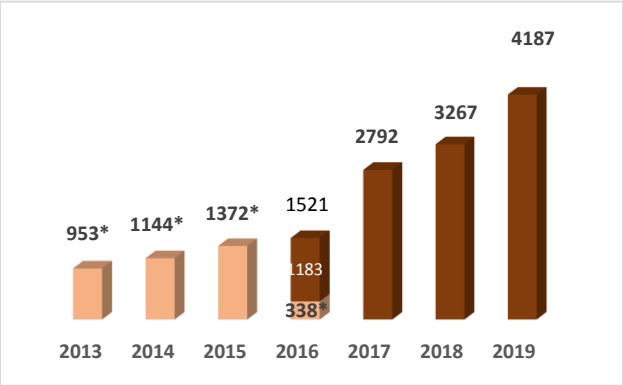


Figure: 2 Reporting centres

After the launch of the first version of reporting software "Haemo-Vigil" in January 2013 and a revised second version in 2016, the number of adverse blood transfusion reaction reports submitted to HvPI is a continuously increasing trend with the highest number of reports submitted to HvPI in 2019.[2] A total of 15236 adverse transfusion reaction reports have been reported to HvPI since inception till December, 2019. Year wise report submitted by the enrolled centres are depicted in Figure 3



*Reports submitted via TRRF version- 01

Figure: 3 Year wise reports submitted to HvPI

A tota1 of 8169 transfusion reactions were reported to Haemo-Vigil Software(s) during the year 2018 and 2019. In the year 2018, 3572 reactions were reported in 3213 patients while in the year 2019, 4597 reactions were reported in 4104 patients. Table:1 Further 852 patients experienced more than one transfusion reaction

One hundred thirty seven reports were excluded from the analysis, 54 reports from 2018 data, and 83 reports from 2019 data due to the following three main reasons after review:

(i) Incomplete information, (ii) not a transfusion reaction, and (iii) discrepancy in symptoms and investigations data. Hence, these reports did not meet the validation criteria. The transfusion reactions as reported through the TRRF version 2.0, from 1st January, 2018, to December 31, 2019 were analysed as per International Society of Blood Transfusion definitions of adverse transfusion reactions[4, 2] and compared with regard to the following parameters:

- Type of adverse transfusion reactions
- Age and gender of patients
- Frequency of blood transfusion
- Blood components implicated
- Outcome of adverse transfusion reactions
- Incidence rate of adverse transfusion reactions
- Implication rate of blood components
- Time gap of blood products from time of issue to time of transfusion

Table:1 Number of reports and reactions included in the analysis

Year	No. of Reports submitted via Haemo-Vigil Software	No. of Reports included in Analysis	No. of Reactions included in Analysis
2018	3267	3213	3572
2019	4187	4104	4597
Total	7454	7317	8169

Mortality/Death reports

Mortalities reported to Haemovigilance Programme of India. A total of 22 death cases has been reported to HvPI in both years 2018 & 2019 , with 12 cases reported in year 2018 & 10 cases reported in the year 2019.

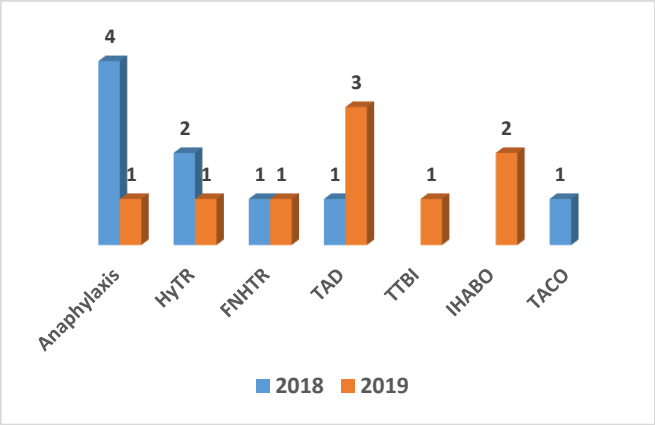


Figure: 4 Adverse reactions in mortality cases

HyTR= Hypotensive Transfusion Reaction; IHABO= Immunological Haemolysis due to ABO Incompatibility;

Year 2018

Mortality was reported in 12 patients in the year 2018. On reviewing the reports, no transfusion reaction was observed in one case, in one there was incomplete information and in another, there was no record of pre- and post-transfusion vitals. Thus, all 03 reports were excluded from the analysis. The underlying clinical condition of the patient contributed to mortality in all the cases. The transfusion reaction as a cause of death was excluded in 4 cases, unlikely in 1 case, possible in 3 cases, and probable in 1 case. The transfusion reactions that occurred in these patients were anaphylaxis, TACO, hypotensive transfusion reaction, FNHTR, and TAD.

Year 2019

Death was reported in 10 patients in the year 2019. One death report was excluded from the analysis as the record of the vitals of the patient was not available for analysis. The transfusion reactions that occurred in 9 patients were Immunological haemolysis due to ABO incompatibility, anaphylaxis, TTBI, hypotensive transfusion reaction, FNHTR, and TAD. The causal relationship of mortality with adverse transfusion reaction was definite in 2 patients who experienced Immunological haemolysis due to ABO incompatibility. In the remaining 7 cases, the adverse transfusion reaction as a cause of death was excluded in 3 cases, unlikely in 3 cases, and possible in 1 case.

Rates of Adverse Transfusion Reactions Reported to HvPI from year 2018 & 2019.

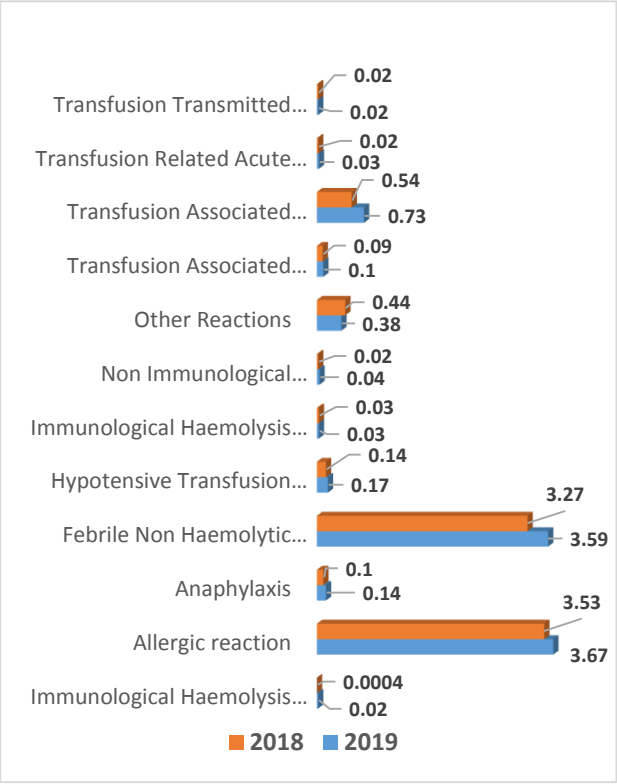


Figure 5: Incidence of adverse transfusion reaction per 10,000 blood components issued

The overall incidence of adverse reactions reported to HvPI from 1st January, 2018, to 31st December, 2019 was 8.6 per 10,000 of blood products transfused with a rate of 8.25 in 2018 and 8.94 in 2019. The incidence of various transfusion reactions per 10,000 blood products transfused is shown in Figure 5.

Age Group wise Distribution of Males and Females

Total number of males and females with age groups reported to HvPI in 2018-2019 shown in table 2.

Table 2: Male and female with age groups reported to HvPI

	Year 2018		Year 2019		
	Males	Females	Males	Females	Total
Pediatric (<=12Years)	143	89	205	134	571
Adolescent (12 to <=18)	88	87	105	80	360
Adult (>18)	1320	1486	1715	1865	6386
Total	**1551**	**1662**	**2025**	**2079**	**7317**

Implicated Blood Products

Almost all blood components were implicated in adverse transfusion reactions. However the most commonly implicated blood product in adverse transfusion reactions is packed red blood cells (PRBC) as shown in Figure: 6

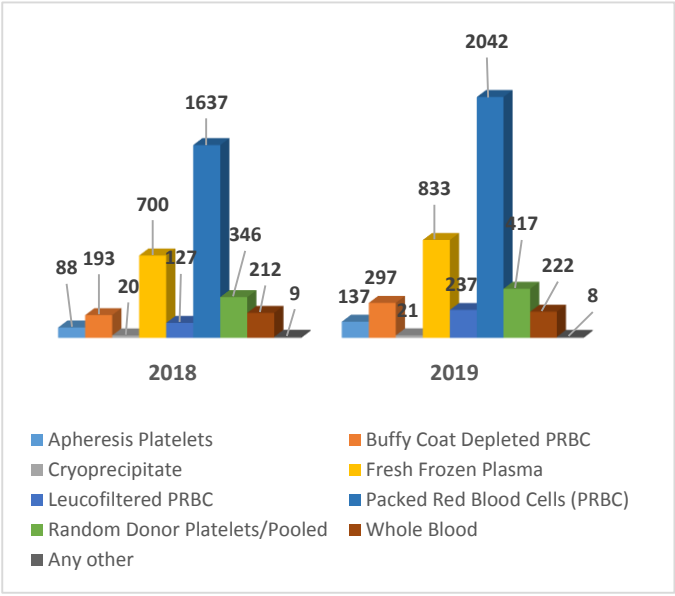


Figure 6: Details of blood components implicated in adverse transfusion reactions, In Any Other blood products included:- Saline washed packed red blood cells, Cryo Poor Plasma CPP, Granulocyte concentrate

Blood components issued by blood centres and their implication rate

Highest number of transfusion reactions were reported with apheresis platelets both in the year 2018 -2019. Implication rate was 1.48 and 1.67 per 1000 apheresis platelets issued for in

the year 2018 & 2019 respectively. This was followed by PRBCs where implication rate was 1.08 and 1.11 per 1000 PRBC issued for the year 2018 and 2019 respectively as represented in Table: 3

Table 3 Denominator data and rate of implication of blood components.

Blood Products	2018		2019	
	Blood Products issued	Rate of Blood Products Implicated in ATR	Blood Product Issued	Rate of Blood Products Implicated in ATR
Apheresis Platelets	59440	88 (1.48/1000)	82348	138 (1.67/1000)
Buffy Coat Depleted PRBC	228500	193 (0.85/1000)	324182	297 (0.92/1000)
Cryoprecipitate	82674	20 (0.24/1000)	107508	21 (0.2.0/1000)
Fresh Frozen Plasma	1132546	700 (0.62/1000)	1295599	833 (0.64/1000)
Leucofiltered PRBC	171827	127 (0.74/1000)	219307	237 (1.08/1000)
Packed Red Blood Cells (PRBC)	1510448	1637 (1.08/1000)	1835446	2042 (1.11/1000)
Random Donor Platelets/Pooled	751917	346 (0.46/1000)	912094	418 (0.46/1000)
Whole Blood	350334	212 (0.61/1000)	338311	222 (0.66/1000)
Any other	44051	9 (0.20/1000)	36409	4 (0.10/1000)
Saline Washed Red Cells	*	-	71	0
Total	**4331737**	**3332 (0.76/1000)**	**5151275**	**4214 (0.81/1000)**

Outcome of Adverse Transfusion Reactions reported to HvPI in year 2018 & 2019

Majority of the patients (97.85% and 98.49% in the year 2018 and 2019 respectively) recovered after experiencing adverse transfusion reaction. In the year 2018, recovery with sequelae was reported in 0.72% patients and in the year 2019 recovery with sequelae was reported in 0.95 % of the patients (Figure:7).

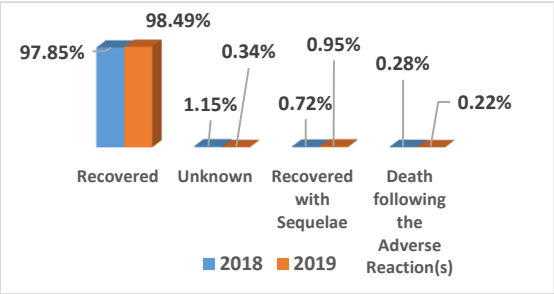


Figure: 7 Outcome of adverse transfusion reaction

Summary and Key Recommendations

- Almost all blood components were implicated in adverse transfusion reactions. However in total numbers the most commonly implicated blood product in adverse transfusion reactions is packed red blood cells (PRBC) as these were the most frequently transfused blood products.
- The overall incidence of adverse reactions reported in the year 2018 and 2019 was 8.25 and 8.94 per 10,000 blood components issued respectively.
- Highest number of transfusion reactions were reported with apheresis platelets both in the year 2018 -2019. Implication rate was 1.48 and 1.67 per 1000 apheresis platelets issued for in the year 2018 & 2019 respectively. This was followed by PRBCs where implication rate was 1.08 and 1.11 per 1000 PRBC issued for the year 2018 and 2019 respectively.
- Majority of the patients (97.76% and 98.47% in the year 2018 and 2019 respectively) recovered after experiencing adverse transfusion reaction. The majority of patients recovered within 6 hours.
    1. FNHTRs and allergic reactions remain the most frequently encountered acute adverse transfusion reactions.
    2. Amongst the haemolytic transfusion reactions the Non-immune and ABO mismatch were due to bedside errors. Staff training is essential for good bedside transfusion practices.
    3. Other allo-antibody identification technology needs to be improved.
    4. For TTBI blood culture results from blood bag sample has been documented and in some cases even patients post transfusion blood culture has shown microorganisms.
    5. TACO reactions constituted 1.03 % of total adverse transfusion reactions in year 2018 and 1.22 % of total reaction in year 2019.
    6. TRALI comprised of 0.28% of overall reactions in year 2018 and 0.39% overall reaction in year 2019.
    7. TAD comprised of 6.60% of overall reactions reported in year 2018 and

8.19% of overall reactions reported in year 2019.

8. Recognition of reactions with respiratory symptoms indicates that haemovigilance information is reaching clinical staff.

- There has been enrolment of new reporting centres in both 2018 and 2019, despite the programme being voluntary.
- A guidance document on good clinical transfusion practices has been brought out by HvPI and centres are being encouraged to use it for bedside staff training.

References

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Conflicts of interest

There are no conflicts of interest.

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