# **Original Article**

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# Reporting adverse transfusion reactions: A retrospective study from tertiary care hospital from New Delhi, India

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# Abstract:

**CONTEXT:** Blood transfusion services have achieved newer heights in the last decade, with developments in cellular techniques, component separation, and integration of molecular methods. However, the system of recording and reporting of the adverse events related to blood transfusion is developing countries like India is grossly inadequate and voluntary in nature.

AIMS: This study was undertaken to analyze the retrospective data on adverse events related to blood transfusions in our hospital.

**SUBJECTS AND METHODS:** This retrospective study was done to examine all the transfusion related adverse events reported in a Regional Blood Bank Transfusion Centre of North India over a period of 9 years. Adverse transfusion events related to whole blood, red cell concentrates (RCCs), and all other components were analyzed and classified on the basis of their clinical features and laboratory tests. Average rate of transfusion reactions with the components was also assessed.

**STATISTICAL ANALYSIS USED:** Categorical variables were analyzed using the Chi-square test. P < 0.05 was taken to indicate a significant difference.

**RESULTS:** During this period, a total of 1,60,973 blood/blood component units were issued by our blood bank to various departments of the hospital and 314 immediate transfusion events were reported. The rate of immediate transfusion reactions during the study was 0.19%. Average transfusion reaction rate with RCC was 0.25% with febrile nonhemolytic reactions being the most common type of adverse event (37.2%).

**CONCLUSIONS:** Awareness should be increased among clinicians to correctly prevent, identify, and report transfusion-related adverse events. These measures should be implemented to increase blood transfusion quality and safety.

#### Key words:

Adverse reactions, blood transfusion, leukodepletion

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Submission: 16-05-2016 Accepted: 05-10-2016 Blood transfusion services have undergone major advancements in the last decade. With the opening of new vistas of component separation, apheresis technology and integration of molecular methods, the transfusion services are achieving newer heights. However, the system of recording and reporting of the adverse events related to blood transfusion is lagging. The concept of hemovigilance was introduced in 1990's in France.<sup>[1]</sup> Hemovigilance is defined as a set of surveillance procedures covering whole transfusion chain from the collection of blood and its components to the follow-up of its recipients; intended to collect and access information on unexpected or undesirable effects

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resulting from the therapeutic use of labile blood products, and to prevent their occurrence and recurrence.<sup>[2]</sup> A complete analysis of adverse events is the most important objective of a hemovigilance system.

In the developing countries like ours (India), blood transfusion services are fragmented, nonuniform, with different levels of care depending on the institution. National AIDS Control Organisation (NACO) lays down the policies for blood banks and transfusion services, and regulatory body is the Drug Controller, India.<sup>[3]</sup> Adverse event reporting in India is voluntary in nature. Although NACO

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has introduced the concept of hemovigilance in National Blood Policy, it was practically nonexistent, however recently Centralized Haemovigilance Programme, has been launched on December 10, 2012, with National Institute of Biologicals (NIB) as National Coordinating Centre.<sup>[4]</sup>

Since adverse event identification, recording, and reporting are grossly inadequate; this study was undertaken to analyze the retrospective data on adverse events related to hemovigilance in our country.

# **Subjects and Methods**

The study was conducted in Regional Blood Transfusion Centre (RBTC) of Lady Hardinge Medical College and associated SSKH and KSCH Hospitals. Together these have combined the capacity of 1227 beds. Retrospective data were retrieved from archives of RBTC from January 2005 to June 2013. Records of all the events related to adverse events were tabulated and analyzed.

# Protocol followed before issue of bag

As per the standard operating procedures (SOP's) of the blood bank, the blood sample (for blood group/indirect antiglobulin test and cross-match) along with transfusion requisition form is sent for any requirements of blood components.

- The hospital central registration number (CR no.) is unique for the patient, irrespective of name/age/sex. The CR no. should be tallied on blood sample and transfusion requisition form. The form is to be completely filled and signed by the doctor on duty
- The details on the blood sample and the form are checked by the technician at the receiving counter
- At the time of issue of any blood component, recheck of the details on the blood bag, cross-match label, and blood transfusion requisition form is done, correlated, and signed by the technician. Issue number, time of issue along with all the others details are documented in blood bank records
- The necessary instructions regarding transfusion are printed on the blood transfusion issue forms and also on the blood bag labels
- The resident doctor is required to check all the necessary details on the form, blood bag, and the issue label before the start of the transfusion.

#### Protocol followed following adverse event

All the adverse events are reported on the pro forma as per the SOPs of our blood bank [Figure 1]. This includes patient and component details, time of start of the blood transfusion, amount of blood volume transfused and time when the transfusion was stopped due to an adverse event. Details of clinical signs and symptoms (i.e., fever, chills, hypotension, rigors, cola-colored urine, rashes, respiratory discomfort, and any other untoward events developed during transfusion or the following transfusion) are thoroughly recorded. Classification of the transfusion reaction, whether immediate or delayed in onset and with or without any evidence of hemolysis is done after correlating the sign and symptoms of the patient. Any transfusion-related adverse events occurring within 24 h are considered as acute transfusion reaction (ATR). Type of reaction is documented after correlating the sign and symptoms of the patient. The clinician in charge signs the pro forma.

#### Analysis of acute transfusion reaction

Analysis of ATR includes collaborative effort of both transfusion specialist and clinician. Residual blood bag along with BT set and patients posttransfusion blood sample (clotted and ethylenediaminetetraacetic acid) along with the duly filled up pro forma is sent to the blood bank for the complete work up. After checking for the clerical errors, blood bag along with its tubing and patient's posttransfusion sample is observed for hemolysis. Repeat blood group of the blood bag, patient's pre- and post-transfusion sample and Coombs cross-match is done. Direct Coombs test of patient's posttransfusion sample is done. Antibody screening of pretransfusion sample is done. Color of the urine is noted. If red in color, then it is centrifuged to distinguish between hematuria and hemoglobinuria. Blood sample from the residual blood bag is sent for sterility testing to the microbiology laboratory. Investigations for renal function tests, liver function tests, and complete blood count are sent to the respective laboratory by the clinician in charge.

#### Criteria for classifying acute transfusion reaction

The criteria for febrile nonhemolytic reactions (FNHTRs) was strictly followed as a rise in temperature of  $\geq$ 1°C above 37°C, associated with transfusion, for which no other cause is identifiable. Such reactions are usually accompanied by chills and rigors. Chills and rigors in absence of fever are also included in FNHTR because of presumed common mechanism.<sup>[5]</sup>

Serious hazards of transfusion (SHOT) guidelines define transfusion-related acute lung injury (TRALI) as acute dyspnea with hypoxia, and bilateral pulmonary infiltrates during or within 6 h of transfusion, not due to circulatory overload or other likely cause.<sup>[6]</sup> However, in India, due to lack of awareness among the clinicians and financial constraints among the patients, complete investigations are not done in all patients with dyspnea, thereby missing a substantial number of TRALI patients.

# Results

Until 2005, all the units issued were whole blood (WB). Component processing was started in the year 2006 and has increased substantially to 85%–90% in the year 2012 and 2013 with a consequent decrease in the utilization of WB. Between January 2005 and June 2013; 160,973 blood/component units were issued by our blood bank to various departments of the hospital. The number of different blood products transfused is given in Table 1. Total number of transfusion reactions reported to our blood bank during the study was 314, of which 170 (54%) were males and 144 (46%) were seen in females. Mean age was 22.5 years (range: 1 month to 82 years).

Mean volume of blood unit transfused, when the reactions were noted was 75 ml (range: 10–250 ml). All the reactions in this study were immediate transfusion reactions. None of the delayed transfusion reactions were reported to our blood bank during the study. The mean time at which reactions was noted was 15 min (range: 5–250 min).

The frequency of transfusion reaction was found to be 0.19% (314 out of 160,973). Average transfusion reaction rate with red cell concentrate (RCC) was 0.250%. This was reduced

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H_	Restlessness					Chest X					_			Hemolysis due to inappropriate warming of PRBC Units						
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Figure 1: Transfusion reaction reporting form in India

# Table 1: Details of blood products transfused during study

Year	WB	RCC	Buffy coat depleted RBC	Leukodepleted RBC	PC/PRP	FFP	Total
2005	7569	0	0	0	0	0	7569
2006	7489	947	0	0	0	0	8436
2007	2776	4855	1056	0	0	0	8687
2008	2863	6210	2462	0	0	0	11,535
2009	2822	7102	2588	0	5853	3824	22,189
2010	1595	7898	2696	0	6756	5085	24,030
2011	1356	7679	3530	1845	7240	10,623	32,273
2012	1220	7511	3645	2105	14,152	6522	35,155
2013	408	2564	1862	2545	2454	1266	11,099
Total	28,098	44766	17,839	6495	36,455	27,320	160,973
Percentage of total	17	28	11	4	23	17	100

WB = Whole blood, RCC = Red cell concentrates, FFP = Fresh frozen plasma, PC/PRP = Platelet concentrate/platelet rich plasma

to 0.084% by buffy coat depleted RCC and was further reduced to 0.030% with use of leukodepleted RCC. In contrast, use of WB cells had a high reaction rate of 0.587% [Table 2].

# **Categorization of transfusion-related adverse reactions** *Febrile nonhemolytic transfusion reaction*

Platelet concentrate and platelet-rich plasma had reaction rate of 0.033%. In contrast, average reaction rate with fresh frozen plasma (FFP) was 0.029% [Table 2].

FNHTR was most commonly encountered adverse reaction in this study comprising 54.7% (172/314) of all the reactions [Figure 2]. Clinical signs and symptoms observed in decreasing order of frequency were chills and rigors in 86 patients, fever in 79, and myalgia in 26 patients. Mean

Table 2: Transfusi	Table 2: Transfusion-related adverse donor reactions due to blood products	nor reactions due to	o blood products				
Year	WB	RCC	Buffy coat depleted RBC	Leukodepleted RBC	PC/PRP	d H H	Total
2005	54	0	0	0	0	0	54
2006	56	5	0	0	0	0	61
2007	22	9	2	0	0	0	30
2008	6	S	2	0	0	0	14
2009	5	14	c	0	2	-	25
2010	11	27	-	0	-	-	41
2011	9	21	5	-	7	0	40
2012	2	31	2	-	0	5	41
2013	0	5	0	0	2	-	8
Total	165	112	15	2	12	8	314
Percentage of total reactions due to components	0.587 (165/28,098)	0.25 (112/44,766)	0.084 (15/17,839)	0.03 (2/6495)	0.033 (12/36,455)	0.029 (8/27,320)	0.19 (314/160,973)
WB = Whole blood, RCC =	WB = Whole blood, RCC = Red cell concentrate, FFP = Fresh frozen plasma, PC/PRP = Platelet concentrate/platelet rich plasma	Fresh frozen plasma, PC/PR	3P = Platelet concentrate/pla	atelet rich plasma			

rise of body temperature observed in 79 patients were 1.86°C ± 1.05°C (range:  $0.5^{\circ}$ C–2.5°C). FNHTR was seen in 97 (58.4%) after WB, 64 (57.1%) after RCCs, 6 (54.5%) after platelets, and 2 (25%) after FFP [Table 3]. The FNHTR was reduced to 20% (3/15) of all reactions with the use of Buffy coat depleted RCC. None of the patients had FNHTR when they were issued leukodepleted RCC. This drastic reduction of FNHTR was statistically significant (P < 0.05) [Figure 3]. Buffy coat depleted red cells, by themselves, led to significant reduction in the incidence of FNHTRs [Figure 3].

# Allergic reactions

Allergic reactions were the second most common type of transfusion reaction found in 41.4% (130/314) of all reactions [Figure 2]. Clinical signs and symptoms in decreasing order of frequency were rash in 88 patients, pruritus in 26, and urticaria in 16 patients. WB was implicated in 59 (45%) allergic reactions, RCCs in 46 (35%), platelets in 5 (4%) and FFP in 6 (5%) reactions. There was statistically significant reduction in the incidence of allergic reactions with use of buffy coat depleted RCC with saline, adenine, glucose and mannitol and leukodepleted RCC suspended in additive solutions (P < 0.05) [Figure 3].

# Anaphylactic/anaphylactoid reactions

Anaphylactic/anaphylactoid reactions were seen in 4/314 (1.27%) [Figure 2]. Three out of four patients were females. Both were from obstetrics and gynecology department. Two patients had a history of intrauterine death with severe anemia. One patient had postpartum hemorrhage and was in shock. One patient was male who had a history of multiple transfusions due to cirrhosis liver. Clinical signs and symptoms in these patients were hypotension (2), rash (1), and respiratory distress (1). All these reactions were implicated to WB [Table 3].

#### Transfusion-related acute lung injury

A single case was reported from Medicine Department. A 43-year-old female patient developed severe sudden dyspnea and cyanosis after she was transfused with single unit of WB. Her posttransfusion X-ray showed bilateral pulmonary edema without cardiomegaly. As all the investigations required to meet the criteria of TRALI could not be done, it was a possible case of TRALI.

# Transfusion-associated circulatory overload

Transfusion-associated circulatory overload (TACO) contributed to 0.955% (3/314) of transfusion reactions [Figure 2]. All three of them received WB transfusion and presented with dyspnea, cyanosis, jugular venous distension, pedal edema and increased blood pressure with wide pulse pressure. Two of these three cases were children diagnosed with aplastic anemia who had already received multiple transfusions earlier in other hospitals before being referred to KSCH. One of them was an adult female suffering from severe postpartum hemorrhage who was given multiple WB transfusions. These cases were immediately resuscitated by providing supplementary oxygen and reducing intravascular volume with diuretics.

# Acute hemolytic transfusion reaction

Acute hemolytic transfusion reaction was seen in 1.27% (4/314) of overall reactions [Figure 2]. Three out of four were due to

Type of adverse reaction	WB (166)	RCC (112)	Buffy coat depleted RBC (15)	Leukodepleted RBC (2)	PC/PRP (11)	FFP (8)	Total (314)
Acute hemolytic transfusion reaction	2 (1.2)*	2 (1.7)	0	0	0	0	4
Acute nonhemolytic transfusion reaction	า						
Immune							
FNHTR	97 (58.4)	64 (57.1)	3 (20)	0	6 (54.5)	2 (25)	172
Allergic reaction	59 (35.5)	46 (41)	12 (80)	2 (100)	5 (45.5)	6 (75)	130
Anaphylactic	4 (2.4)	0	0	0	0	0	4
TRALI	1 (0.6)	0	0	0	0	0	1
Nonimmune		0	0	0	0	0	
TACO	3 (1.8)	0	0	0	0	0	3

\*Brackets represent the percentage of type of adverse reactions. TACO = Transfusion-associated circulatory overload, TRALI = Transfusion-related acute lung injury, FNHTR = Febrile nonhemolytic reactions, WB = Whole blood, RBC = Red blood cell, FFP = Fresh frozen plasma, PC/PRP = Platelet concentrate/platelet rich plasma

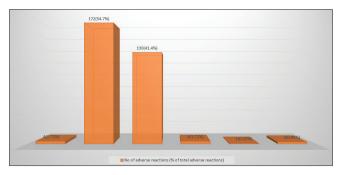


Figure 2: Number of different type of adverse transfusion reactions

major ABO-mismatched blood transfusion event and were due to clerical/transcriptional error. One occurred in a 23-year-old female suffering from cold agglutinin disease, in whom urgent lifesaving blood transfusion was required. Both of these were immediately identified, and immediate rectifications were done.

# Discussion

Adverse event reporting requires the collaboration between blood bank and the clinicians. It depends chiefly on the knowledge of transfusion procedures, hazards of the use of blood, timely identification of an event related to blood transfusion with its clinical management and further investigations at the blood bank. There are several reports on adverse events including transfusion-associated deaths, but the relative risk, based on the number of actual cases divided by the number of blood product units is relatively low.[7]

The approach to hemovigilance is different between countries. The French and British systems illustrate this diversity. In France, the hemovigilance system is nationwide, with a legal obligation to notify, in written form, every untoward effect in relation to blood transfusion.[8] In the UK, only serious adverse reactions are reported, on a voluntary basis, SHOT.<sup>[9]</sup> In India, hemovigilance program was launched on December 10, 2012, with NIB as national coordinating center.<sup>[4]</sup> We have adopted the transfusion reporting format of India however online reporting has not been started yet [Figure 1].

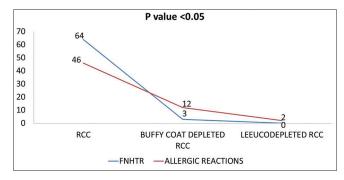


Figure 3: Number of transfusion reactions due to components

The frequency of transfusion events in our study was 0.19% (314 out of 160973). This rate is similar to other published results, varying from 0.22% to 0.42% transfusion events.[10-12] This rate was very similar to another Indian study by Bhattacharya et al. where the incidence of adverse transfusion reaction was 0.18% (105 reactions out of 56,503 units of blood and blood component transfused).[3]

FNHTR is the most common adverse effect of blood transfusion. Rate of FNHTR by red cells in most studies ranged from 0.5% to 1%.<sup>[13]</sup> In this study, the frequency of FNHTR with use of WB is 0.34% (97/28098), packed red blood cell (PRBC) is 0.14% (64/44766), platelets is 0.016% (6/36455), FFP is 0.007% (2/27320) [Table 4]. Lower rates in our study probably attributed to use of quadruple bags with internal filter and RBC filters. These rates are in concordance with study of Kumar et al.[14] The cause of FNHTR is usually immune-mediated, because of the reaction of white cell antibodies in the recipient's plasma with the leukocytes in the transfused component.

As shown by Ibojie et al., in RBC transfusions the rate of FNHTRs was about 0.4% before leukodepletion and diminished to 0.2% after the introduction of leukodepletion.<sup>[15]</sup> Similar results were shown by Michlig et al.<sup>[10]</sup> Similarly, in our study, the FNHTR rate markedly decreased from 0.14% to 0.00% with the use of leukodepleted RCC [Figure 3]. Even buffy coat depletion of packed RCC showed marked decrease in FNHTRs with the incidence of 0.017% [Figure 3]. We, therefore, feel that in resource-limited settings, where universal leukodelpetion is not economically feasible, buffy coat depleted red cells can be a viable alternative.

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Type of adverse reaction	WB (%)	RCC (%)	Buffy coat depleted RCC (%)	Leukodepleted RCC (%)	PC/PRP (%)	FFP (%)
Acute hemolytic transfusion reaction	2 (0.007)	2 (0.004)	0	0	0	0
Acute nonhemolytic transfusion reaction						
Immune						
FNHTR	97 (0.345)	64 (0.143)	3 (0.017)	0	6 (0.016)	2 (0.007)
Allergic reaction	59 (0.21)	46 (0.103)	12 (0.067)	2 (0.031)	5 (0.014)	6 (0.022)
Anaphylactic	4 (0.014)	0	0	0	0	0
TRALI	1 (0.004)	0	0	0	0	0
Nonimmune		0	0	0	0	0
TACO	3 (0.011)	0	0	0	0	0

Brackets represent the percentage of reactions from total units of the component issued. TACO = Transfusion-associated circulatory overload.

TRALI = Transfusion-related acute lung injury, FNHTR = Febrile nonhemolytic reactions, WB = Whole blood, RBC = Red blood cell, FFP = Fresh frozen plasma, PC/PRP = Platelet concentrate/platelet rich plasma

The overall incidence of allergic reactions in studies vary from 0.2% to 3%.<sup>[16]</sup> In the present study, it was 0.21% with WB, 0.102% with red cells, 0.013% with platelets, and 0.021% with FFP. Tanz et al. in their study on leukodepleted component found the rate to be as low as 0.06%.<sup>[17]</sup> High rate of allergic reactions was seen in FFP and platelet transfusions. Geiger and Howard in their study reported rise of allergic reactions between 0.09% and 21% in patients who received platelet transfusions.<sup>[18]</sup> Higher rate of allergic reactions by FFP could probably be explained by reaction to plasma proteins like IgA and haptoglobin.<sup>[19]</sup>

Anaphylactic reactions were seen in 0.014% with WB and none with red cells, platelets or FFP. However, further differentiation of anaphylactic reactions and anaphylactoid reactions could not be done as IgE estimation was not done in our hospital.

A single case of TRALI in a female patient was reported in our study, giving an incidence of 0.003% (1/28098). TRALI reported in various studies in western literature ranged from 0.001% to 0.008%.<sup>[20]</sup> TRALI is often underdiagnosed due to it being a great mimicker of other clinical conditions which cause acute lung injury and also due to lack of investigations to meet criteria of TRALI in resource-limited set ups.

TACO was seen in three cases in our study giving an incidence of 0.01% (3/28098). In a study by Popovsky incidence of TACO was estimated to be 0.03% (1/3168) in patients transfused by PRBC.<sup>[21]</sup> All our cases were of severe anemia and probable explanation in them was due to hyperkinetic circulation and severe anemia, even slightest increase of blood volume was not tolerated by heart. Therefore, it is necessary to follow AABB recommendations of infusing RBC at rate of 2-4 ml/min in these cases.

Acute hemolytic transfusion was seen in 4/314(1.27%) patients. 3/4 were due to major ABO-mismatched blood transfusion event and were due to clerical/transcriptional error. Erroneous transfusion of ABO-incompatible blood is the most common transfusion error and almost always reflects a preventable breakdown in transfusion protocol and SOP. These errors can have disastrous outcomes, accounting for significant iatrogenic morbidity and mortality. Vigilance on the part of blood bank staff can help minimize the risk and occurrence of transfusion errors.

Transfusion errors generally remain under-reported, primarily, due to lack of awareness, and also due to the inadequate feedback system. Developing institutional guidelines and having an appropriate adverse event reporting format is crucial. It is important to ensure appropriate use of blood components. Hospital blood transfusion committee has an important role to play.

# Conclusion

The frequency of transfusion reactions in our patients was 0.19% (314/160973). Majority of reactions were FNHTR (54.7% [172/314]) closely followed by allergic reactions (41.4% [130/314]).

Developing institutional guidelines, HBTC meetings and adequate, complete hemovigilance reporting should be emphasized. Education of the staff and awareness regarding reporting of adverse events is the key step in improve the safety of blood transfusions.

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#### **Conflicts of interest**

There are no conflicts of interest.

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Table 4: Frequency of transfusion	events (type	of reactions	/compone
Type of adverse reaction	WB (%)	RCC (%)	Buffy coa

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