Section: Immunohematology and Blood Transfusion

Original Research Article

ANALYSIS OF ADVERSE DONOR REACTION IN WHOLE BLOOD DONORS AT A TERTIARY HEALTH CARE CENTRE OF ROHILKHAND REGION

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Received : 13/08/2024
Received in revised form : 06/10/2024
Accepted : 20/10/2024

Keywords:
Adverse Donor Reaction, Whole Blood Donors.

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DOI: 10.47009/jamp.2024.6.5.122

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2024; 6 (5); 646-651

Abstract

Background: The blood donation process is generally safe and straightforward, and most donors have positive experiences; however, even a very low rate of adverse reactions can have negative consequences, potentially reducing the likelihood of donors returning. Therefore, hemovigilance is essential for investigating patterns of adverse reactions and their contributing factors, playing a crucial role in ensuring the safety of blood donation and providing opportunities to implement appropriate risk mitigation strategies. This study aimed to observe the incidence and severity of adverse donor reactions (ADR) in whole blood donors and to evaluate the association and strength of the relationship between donor characteristics and the occurrence of ADR. **Materials and Methods:** This retrospective observational study was conducted in the Department of Immunohematology and Blood Transfusion, over a period of 2.5 years on 17,951 whole blood donors, from January 2021 to June 2023 at a tertiary care institute of North India. Incidence of ADR was observed with respect to donors' age, gender, weight, haemoglobin, donor category [Voluntary/Replacement/Family replacement], first time or repeat; and various grades of severity. Frequency distribution of ADR with respect to place and time of occurrence, pre-donation anxious/relaxed state, sleep adequacy status and history of previous reaction was also observed. Strength of association of adverse reactions with respect to donor characteristics was evaluated using Chi-square test and Odds ratio, wherever possible. Results were considered statistically significant at $p<0.05$ at 95 % confidence interval. **Result:** The overall ADR rate was 0.59% with severity grade of 1 in 93.58%. Vasovagal reaction was most common comprising 95.41%. ADR was 2.76, 2.23 and 2.20 odds higher in females than males (1.56% vs 0.57%), in <40 years than >40 years (0.64% vs 0.29%) and in first time donors than repeat donors (0.69% vs 0.31%), respectively. No statistically significant association was observed with donor weight, hemoglobin and donor category. Onset of ADR was mostly after donation in phlebotomy room. Most of the donors who experienced ADR were relaxed, had adequate sleep and meals pre-donation. **Conclusion:** Blood donation is a safe procedure; however, it is not completely without risks. Identifying the at-risk population and factors contributing to adverse reactions will enable health care facilities to implement mitigation strategies; thereby preventing their occurrence and facilitating donor retention.

INTRODUCTION

Whole blood donation is generally a safe procedure; however, it can be associated with the occurrence of unexpected, undesirable, and unintended events before, during, or after the donation process. These events are collectively referred to as Adverse Donor Reactions (ADR).[1]

Several types of donor reactions in varying grades of severity have been described. Adverse donor reactions are categorized as local or systemic. Local reactions, mainly due to venous access issues, include hematomas, pain, redness, swelling, or nerve trauma at the puncture site. These are usually minor and require no treatment. Systemic reactions, often vasovagal in nature, may result from pain, anxiety, or

seeing blood. If untreated, they can escalate to syncope, with possible convulsions. [1-3]

Various studies have reported incidence ranging from 0.59-33%. [4-7]

Even the mildest form of an Adverse Donor Reaction (ADR) can be significantly detrimental to a blood transfusion service. Such reactions may negatively influence donors' psychological attitudes toward blood donation, often resulting in reluctance or unwillingness to donate again in the future. This challenge becomes even more pronounced in communities with limited awareness about the importance of blood donation, where the task of encouraging donations is already difficult. Additionally, due to fragmented BTS and resource constraint's ability to conduct effective donor motivational campaigns is hindered. The combined impact of these factors can lead to poor donor retention rates and a decline in the number of donated blood units, which ultimately strains the blood supply and hampers the ability to meet patient needs.

Since different regions exhibit heterogeneity in donor demographics, environmental factors, personal eating and drinking habits, blood donation policies, and blood centre infrastructure, it is crucial for blood transfusion services to thoroughly investigate the incidence and contributing factors associated with Adverse Donor Reactions (ADRs) within their local donor populations.

This current retrospective study was undertaken to observe the incidence, severity grades and associated donor related factors contributing to it among the local donor population of voluntary and replacement blood donors of this particular geographic region of North India; and further, to explore the strength of association between various donor factors and occurrence of ADRs

A comprehensive data analysis of the ADRs and their contributing factors can facilitate blood centers to develop personalized strategies to mitigate the occurrence of ADRs, enhance donor care, and create a more positive donation experience. By ensuring rapid recognition and management of adverse events, blood collection services can improve donor safety, enhance the donation experience, and foster long-term donor loyalty, ultimately supporting the sustainability of the blood supply chain.

MATERIALS AND METHODS

This retrospective, cross-sectional observational study was conducted by the Department of Immunohematology and Blood Transfusion at a tertiary care medical institute in the Rohilkhand region. Blood donor screening and testing records from January 2021 to June 2023 were retrieved from the electronic database. A total of 17,951 blood donors, aged 18 to 65 years, were included based on eligibility and deferral criteria, in accordance with the guidelines of the Drugs and Cosmetics Act and Rules, under the Ministry of Health and Family Welfare, Government of India.[8]

Whole blood was collected according to departmental standard operating procedures after providing pre-donation information, counselling, and conducting a medical examination. Donors meeting the eligibility criteria proceeded with the donation, during which 350/450 mL of blood was drawn under aseptic conditions.

Adverse donor reactions were classified into local and systemic reactions, and further categorized according to the latest amended criteria by ISBT, HvPI (Hemovigilance guidance document).[9] The data on adverse donor reaction was extracted from the electronic database and was analyzed retrospectively.

Statistical analysis included descriptive statistics and evaluation of incidence rate of ADR with respect to various donor variables. The dichotomous variables were analyzed using chi-square-test, and odds ratio. the continuous variables like age, Hb, weight, mean blood pressure was also categorized to observe their association with adverse donor reaction, wherever possible. P-value <0.05 at 95%was considered statistically significant.

RESULTS

The present study is a hospital based retrospective observational study.

Donor adverse reactions were analyzed across 14 parameters, encompassing both dichotomous and continuous variables. The dichotomous variables included gender, donor type, donation type, location of ADR occurrence, pre-donation sleep status, history of previous reactions, and timing of the last meal. The continuous variables comprised age, hemoglobin level, reaction time, and the volume of blood collected.

Over the one-year study period, 17,951 individuals donated blood, including 17,437 males and 514 females. Adverse reactions were reported in 107 donors, accounting for 0.59% of the total.

[Table 1] illustrates the statistical analysis of ADR rates with respect to donor's gender, donor type (First time/repeat), donation category (Replacement/family replacement/voluntary).

Gender: The incidence of adverse reactions was 0.57% (n=99) in males and 1.56% (n=18) in females, indicating that females had a 2.77 times higher likelihood of experiencing adverse reactions. The association of gender as a risk factor for adverse reactions was statistically significant, with a p-value of 0.004 (chisquare= 8.2365).

Donor Type: Adverse donor reaction rate among first time and repeat donors was 0.68% (n=93) and 0.335 (n= 14). The difference in two groups was statically significant with a p-value 0.004 (chisquare2 =7.9552)with a 2.2 times higher likelihood of ADR in first time donors (OR= 2.2 vs 0.45)

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Donation category: The rate of adverse reactions was higher among voluntary donors (0.80%, 9/1,127) compared to replacement donors (0.58%). However, the association was not statistically significant, with a chi-square value of 0.361602 and a p-value of 0.8323. The odds ratio was 1.37 for voluntary donors and 0.73 for replacement donors.

[Table 2] illustrates the statistical analysis of ADR rate with respect to donor age, weight and pre-donation hemoglobin levels.

Age: The age distribution of blood donors, divided into two categories: 18–40 years and 41–65 years. The rate of adverse donor reactions (ADR) was notably higher in the younger group (0.64%, n = 100) compared to the older group (0.29%, n = 7). This difference was statistically significant, with a p-value of 0.03 (chi-square= 4.4605). The odds ratios for the age groups 18-40 years and 41-65 years were 2.24 and 0.45, respectively, indicating that donors aged 18-40 years were 2.24 times more likely to experience ADR than those aged 41-65 years.

Weight: ADR rates with respect to weight. No statistically significant association was observed between various weight categories and adverse donor reaction rates. P-value is 0.067508 and chisquare value is 7.142

Hemoglobin: Based on hemoglobin levels, a higher incidence of adverse reactions (0.61%, 72/11,869) was observed in donors with hemoglobin between 14.1 and 16 g/dL, compared to 0.58% (35/6,082) in those with hemoglobin between 12.5 and 14 g/dL. However, this difference was not statistically significant . The chisquare- and p value was 0.659 and 0.797447, respectively. The odds ratio was 0.95 for the 12.5–14 g/dL group and 1.05 for the 14.1–16 g/dL group.

As illustrated in Figure 1, the highest number of cases of adverse donor reactions occurred after donation (61.47%, n=67), followed by 22.94% (n=25) during donation, 6.42% (n=7) before donation, and 7.34% outside the donation process.

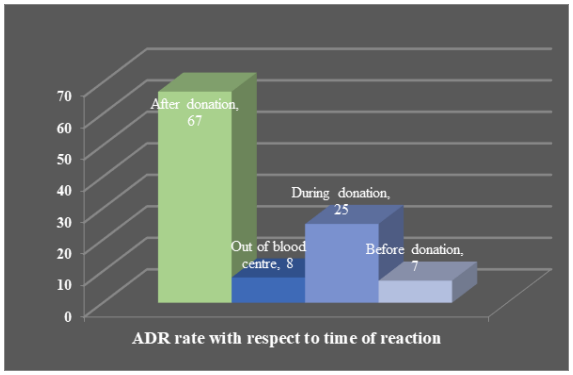

Figure 1: Distribution of ADRs with respect to time of reaction.

[Figure 2] illustrates the percentage distribution of ADRs with respect to history of previous donor reaction, pre-donation anxious/relaxes state and pre-donation sleep status

History of previous donor reaction: The higher ADR was observed among donors who had no prior donor reaction history 91.74%(n=100) and as compared to donors who had history of previous donor reaction, the reaction rate was 6.42%(n=7). [Figure 2a]

Pre-donation anxious or relaxed state: ADRs in relaxed state was 86.24%(n=94) followed by 11.93%(n-13) in anxious state. [Figure 2b]

Pre-donation sleep status: Adverse donor reaction comprised 84.40%(n=92) of the cases in donors who had adequate sleep as compared to those who had inadequate sleep(13.76%,n=15). [Figure 2c]

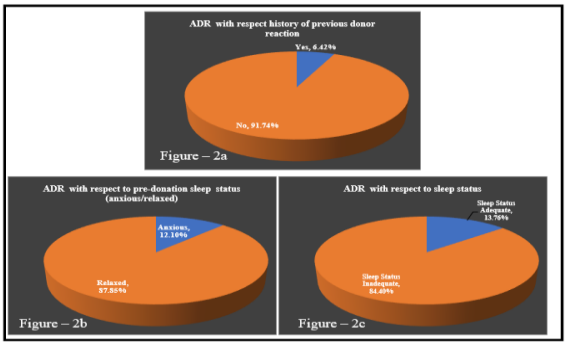

Figure 2: (a)ADR with respect history of previous donor reaction, (b) : ADR with respect to pre-donation sleep status(anxious/relaxed), (c): ADR with respect to sleep status

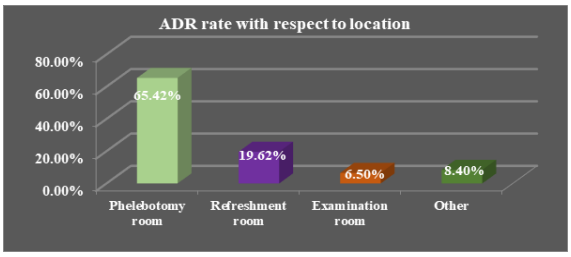

Figure 3: ADR with respect to location of the occurrence of reaction

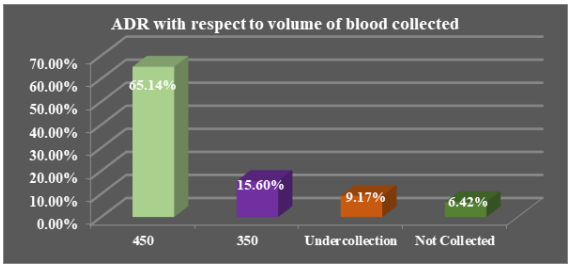

Figure 4: ADR with respect to volume of blood collected

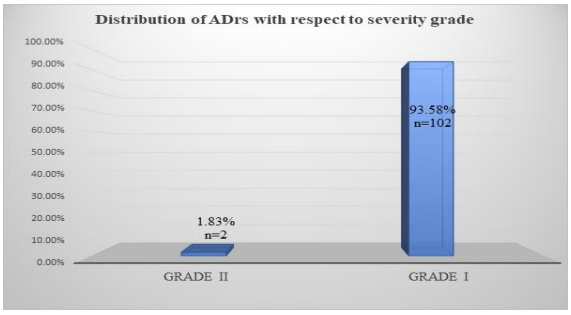

Figure 5: Severity grade of ADRs

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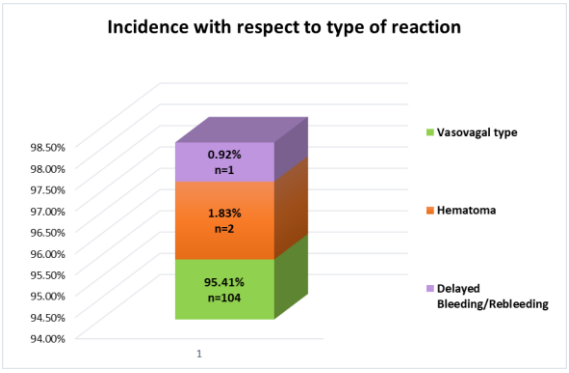
Adverse donor reactions were found to be maximum in phlebotomy room 65.42% (n=70) followed by refreshment room 19.62% (n=21) and examination room 6.50% (n=7). [Figure 3]

Adverse donor reactions were higher with 450 mL blood collections, accounting for 65.14% (n=71) of the cases, compared to 350 mL collections, which made up 15.60% (n=17) of the cases. [Figure 4]

Adverse donor reactions of severity grade I were more frequent than those of grade II, accounting for 93.58% (n=102) and 1.83% (n=2) of the cases, respectively, based on the severity grading system outlined in the HVPI guidance document.[Figure5]



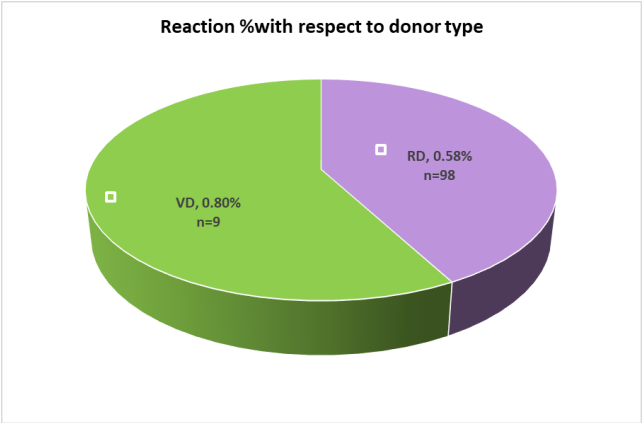


Figure 6: Incidence with respect to type of reactions.

Table 1: Statistical analysis of ADR rate with respect to donor gender, donor type and donation category.

S. N.	Parameter	Category	Total no of donors	No of reactions	Reaction%	Odd ratio	χ^2 Value	P value
1	Gender	Males	17437	99	0.57%	0.36	8.2365	0.004106
		Females	514	8	1.56%	2.77		
2	Donor type	First time	13494	93	0.68%	2.24	7.9552	0.004795
		Repeat	4457	14	0.33%	0.45		
3	Donation category	Voluntary	1127	9	0.80%	1.37	0.8323	0.361602
		Replacement	16824	28	0.58%	0.73		

Table 2: Statistical analysis ADR rate with respect to donor age, weight and pre-donation hemoglobin level.

S. N.	Parameter	Category	Total no of donors	No of reactions	Reaction%	Odd ratio	χ^2 value	P value
1	Age	18-40 yrs	15528	100	0.64%	2.24	4.4605	0.034688
		41-65 yrs	2423	7	0.29%	0.45		
2	Weight	45-65	8152	48	0.59%		7.142	0.067508
		66-85	8022	50	0.62%			
		85-106	1526	6	0.39%			
		>106	135	3	2.22%			
3	Hb	12.5-14	6082	35	0.58%	0.95%	0.8323	0.361602
		14.1-16	11869	72	0.61%	1.05%		

Table 3: Rate of adverse donor reactions in various studies.

S. N.	Year of publication:	ADR% (n=no of ADRs)
Pathak et al	2011	0.60%
Abhishek et al	2013	2.00%
Sadiya et al	2016	1.30%
Hamdan et al	2017	1.10%
Rubiya et al	2017	5.50%
Pawde et al	2018	0.30%
Sonam et al	2023	0.70%
Present study	2024	0.50%

DISCUSSION

Blood centres have a dual responsibility of providing safe and adequate supply of blood and its components to the patients and also to ensure the safety and well-being of donors.

Blood donors usually tolerate the donation very well, but occasionally adverse reactions of variable

ISSN (O): 2687-5365; ISSN (P): 2753-6556

severity may occur before, during or after the blood donation.

There is physiological element to most reaction so a friendly cheerful atmosphere can reduce donor anxiety and perhaps prevent any adverse reactions.[11] Appropriate categorization of adverse donor reaction is essential for effective donor management as well as haemo-vigilance reporting.[9]

The rate of adverse donor reaction in whole blood donors in the present study was 0.59%. This is in accordance with results of various studies, where rate of adverse reactions ranged from 0.3 to 5.5%. [Table 3]

Adverse events during donation of whole blood seems inevitable. The varying rate of ADR in various studies could be due to different criteria of reporting, donor population characteristics and sincerity in data collection. Under-reporting of adverse events might be the cause of these varying rate. Blood centres should be aware of the risk predictors highlighted in this, present study so that adverse events are anticipated prior donation and further interventional are taken to lower or eliminate the incidence of ADR's[3]

The rate of ADR observed in male donors was 0.57% (99/17,437) and 1.56% (8/514) in female donors. P-value<0.05; which shows ADR's have highly significant relationship with respect to gender. This is in accordance with the results of study conducted by Sonam Kumari et al,[12] and Rhyan et al,[13] where female donors reported higher frequency of reactions 2.8% and 8.5%respectively as compared to male donors (0.62%) and (5.3%) respectively.

Gender is associated with other difficulties in donating blood, like difficult veins in women and citing medical reasons as significant barriers. Women more than males also tend to mention the negative effects of blood donation on their emotional and physical well -being.[14,15]

We must draw attention to the potential barriers in our environment which might impede women from becoming a regular donor, in order to implement, measures to reduce or eliminate these obstacles.

Repeat blood donors had fewer ADR(0.31%) than first time blood donors (0.69%). The p value was<0.05%; which shows ADR have highly significant relationship with respect to first time donation. This is in accordance to study of Almurta et al,[16] in which first time donors have higher frequency of reaction (1.6%) than do repeat donors (0.6%) p value (<0.001) and in study by Rubiya Rhyan et al[13]in which also higher frequency of reaction was noted first time donors [8.7%] than repeat donors [2.8%] p value(<0.001).

In ADR being reported in first time donors, further investigations ought to be done and preventive strategies adopted to eliminate such unfortunate occurrences in the future to promote donor safety and satisfaction. As such donors eventually refrain from coming back in future. Known factors associated are needle phobia, anxiety in first time donors.[6]

Majority of the donors 86% were in the younger age group of 18-40 years followed by 13.49% donors in age group 41-65 years. Ryan et al,[8] 2017 in their study also observed higher frequency in younger age group,48% in age group (18-27 yrs) followed by 39.4% donors in age group (28-37 years) Almurtiri et al,[11] 2017 also observed higher frequency of donors in younger age group. 70.7% (<30 yrs) and 29.3% (>30 yrs) respectively.

In the present study the incidence of ADR was higher (0.64%) among donors in <40 yrs (0.64%) followed by 0.29% in age group >40 yrs. The association was found statistically significant (p<0.001) similar to study done by Almutiriet al,[11] where the incidence of ADR was higher among donors in <30 yrs 1.5%(p<=0.001).

A study from France postulated, that baro-receptors sensitivity is decreased in healthy young individuals,[12] In healthy young donors estimated blood volume is low; other factors such as fear also predisposes to adverse donor reactions. With increasing age, the body becomes haemodynamically stable. Also the young donors are more apprehensive to pain. Potential action must be undertaken to improve donor safety and make blood donation process a more pleasant experience.

Health historian interaction, push coping strategies for at risk donors [fear, low estimated blood volume], smaller collection volume, pre-loading 500 ml of H20 close to phlebotomy in young donors and must encourage prophylactic lower body muscle tension for young blood donors.[6]

In our study, significantly higher rate of adverse reactions (72/11,869) 0.61% and (35/6082) 0.58% were observed in donors with haemoglobin in the range (14.1-16 gm /dl) and 12.5-13.4 gm/dl, respectively. The finding was similar to study done by Almutiri et al [2017],[11] where ADR was significantly higher in donor with haemoglobin >15 gm/dl(1.3%) The frequency of adverse reaction to blood donation due to low haemoglobin appear conflicting. While some reports suggest predominance of reaction in low haemoglobin group while other were contradictory and concluded that reactions occurred more in higher haemoglobin group. Our findings are in agreement with latter reports. Contradictory to study done by Rhyan et al[2017],[8] adverse donor reaction was significantly higher in donor with haemoglobin (12.5-13.4gm/dl) as compared to donors with hb>14.5 (P-value<0.001).

In present study, the higher rate of adverse reaction 0.65% were observed in donors with weight in the range (91-130 kg) as compared to 0.59% in donors with weight in the range (45-90 kgs).

Contradictory to observations in present study done by Almutari et al,[16] where the incidence of adverse donor reaction where the incidence of adverse donor reactions was higher among donors weighing <75 kgs than donors' weight>75 kg (1.61%) (p<0.001).

An adverse event was frequently seen in donors who weighed less than 70 kgs, Donors who experienced

ISSN (O): 2687-5365; ISSN (P): 2753-6556

adverse reaction had a lower mean weight compared to donors without adverse events.[17]

Higher rate of adverse reactions was observed among voluntary donors (0.80%; n=9) compared to replacement donors (0.59%; n=70) and family donors (0.57%;n=28). The higher rate of ADR in voluntary donors is due to more number of females donors donating blood in voluntary blood donation camps.

The most common type of Adverse donor reaction was of vasovagal type (104) (95.41%,n=104) followed by hematoma (1.83%,n=2) and re bleeding (0.92% ,n=1) respectively. This is in accordance with the results of a study conducted by Pawed Yogesh et al,[18] where vasovagal reactions constituted 43.40% of all adverse donor reactions.

Local reactions are mainly caused by blood donation related neurological injuries which are commonly experienced by the donors after the donation in the form of hematomas/tingling, excessive or radiating pain, loss of arm/hand strength.[4]

In present study, higher rate of adverse reactions among donors were observed after donation (n=67), 61.47%and in phlebotomy room itself, (n=70); 64.22%.

In present study most of the ADR; belong to grade1 (93.5%,n=102) followed by grade 2 (1.83%,n=2) according to severity grading tool. No major reactions necessitating hospitalization or iv fluid administration were observed in the present study.

Other donor related factors such as pre donation sleep status and history of previous donor reaction were also evaluated for their frequency and percentage distribution.

CONCLUSION

In the present study the most common variables associated were young age, female donors and 1st time donation. While most donations were uneventful, even a minor complication reduces the likelihood of return donation. Blood centres have an obligation to constantly monitor risk of blood donation to make committed efforts to achieve the lowest possible rates of complications. Blood centres should be aware of the risk predictors highlighted in this study, so that adverse events are anticipated prior donation.

Vaso vagal reaction is a frequently encountered generalised donor adverse reaction. Mitigation strategies must be formulated and standardized for future prevention of ADRs in future and thereby encouraging repeat voluntary blood donations.

Pre-donation donation and post-donation counselling must be done for greater impact in reducing the incidence of ADR. Human errors can be mitigated by the use of technology such as barcoding, radio frequency identification.

. Virtually all dimensions of the blood donation experience have some impact on the risk of complications.

Thus, blood collection facilities should continue to monitor and report the effectiveness Continuous evaluation of the effectiveness of interventions for reduction of incidence of ADR and various management strategies of ADR's are essential aspects of donor haemo-vigilance, thereby improving donor safety.

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ISSN (O): 2687-5365; ISSN (P): 2753-6556