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National blood donor vigilance programme of India: Analysis of donor adverse reactions reported during initial 2 years of implementation (2016 and 2017)

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Abstract:

INTRODUCTION: The donor vigilance program is intended to collect and assess information on unexpected or undesirable effects or reactions resulting from blood donation. In this report, we discuss the analysis of the blood donor adverse reactions (DARs) reported in the National Blood Donor Vigilance Programme of India during the first 2 years of implementation.

MATERIALS AND METHODS: DAR reporting form prepared and approved by the National Executive Committee of the Haemovigilance Programme of India was used to capture the data by the blood centers and submitted to Donor-Vigil software prepared and hosted by the official website of the National Institute of Biologicals. Data reported for the years 2016 and 2017 were reviewed, analyzed, and validated by independent transfusion medicine experts.

RESULTS: During this period, a total of 19,98,101 donations denominator data were reported, in which 1,622,600 (80.9%) were valid. A total of 6091 DARs were reported, out of which 3980 (65.35%) were found valid. Only validated numerator and denominator data were included in the analysis. Generalized DARs were the most common type of DARs reported (83.7%), followed by "others" type (7.7%), localized (7.6%), allergic (0.4%), and complications related to apheresis (0.4%). The overall DAR rate was 2.45/1000 blood donations, which was higher in apheresis donations (3.07/1000) as compared to whole blood donations (2.39/1000). The DARs rates were higher in females (3.5/1000) compared to male donors (2.3/1000) and in the first time (2.5/1000) compared to repeat donors (2.15/1000).

CONCLUSION: In this report, we concluded that younger age, first time, and female donors are more prone to DARs as compared to older age, repeat, and male donors. During the analysis of the data, we found some limitations, which can be improved by upgrading the reporting form and conducting regular continuing medical education (CMEs) of participant blood centers.

Keywords:

Donor adverse reactions, National Blood Donor Vigilance Programme, recommendations

Introduction

Hemovigilance is a set of surveillance procedures covering the whole transfusion chain from the collection of

blood and its components to the follow-up of its recipients. The program is intended to collect and assess information on unexpected or undesirable effects resulting from therapeutic use of labile blood products and to prevent their occurrence and recurrence.^[1] In India, HvPI on adverse

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transfusion reactions was launched on December 10, 2012 and subsequently, the National Blood Donor Vigilance Programme (NBDVP) was launched on June 14, 2015.^[2,3]

Systematic monitoring of adverse reactions or incidents, during the first part of the transfusion chain, i.e., the process of blood collection is termed as donor haemovigilance. The aim of donor vigilance is to secure and improve the quality and safety of both the donor and the recipient. This report describes the analysis of donor adverse reactions (DARs) reported to the NBDVP during the first 2 years of its implementation (2016 and 2017).

Materials and Methods

Data on blood DAR, by both whole blood and apheresis procedure, were collected by Donor-Vigil software from January 2016 to December 2017. The data captured were only for allogeneic donations from reporting centers. Data collection parameters were collected into two parts, first, the numerator which are various parameters of DARs, while other one were denominators which included the total number of donations, male and female donors, first time and repeat donors, and type of blood bags used. DARs mainly included localized, generalized, and apheresis related adverse reactions [Table 1]. Definitions for DAR or complications and events with temporal association with blood donation were adopted from the Standard for Surveillance of Complications related to blood donation prepared by the International Society of Blood Transfusion in collaboration with the International Haemovigilance Network and American Association of Blood Banks (AABB) [Table 1].^[4,5]

The DAR reporting form was prepared and approved by the national executive committee of HvPI, while the Donor-Vigil software for reporting of the same was prepared by the hemovigilance team of the National Institute of Biologicals (NIB) and hosted on their website. After collecting the data of DARs of the years 2016 and 2017, it was analyzed and validated by independent transfusion medicine experts and the national executive committee of HvPI further approved it.

Validation of data consisted of independent validation of denominator and numerator data, followed by validation of individual DARs reports. All invalid data and any discrepancy between numerator and denominator were excluded from the analysis. Characterizations of generalized DARs were done based on association with loss of consciousness (LOC; less than or more than 60 s), injury, and location of the reaction. Severe generalized DARs or vasovagal reactions were defined when there was an associated LOC or an injury due to the reaction.

Table 1: Categorization and type of donor adverse reactions

Categories	Details of each categories
A	Local symptoms Blood outside vessel Hematoma (bruise) Arterial puncture Delayed (bleeding/rebleeding) Arm pain Nerve injury/irritation Other arm pain Localized infection/inflammation along the course of a vein Thrombophlebitis Cellulitis Other major blood vessel injury - serious conditions needing specialist medical diagnosis and attention DVT Arteriovenous fistula Compartmental syndrome Brachial artery pseudoaneurysm
B	Complications mainly with generalized symptoms: vasovagal reactions LOC <60 s LOC >60 s Without LOC With injury Without injury Within blood collection facility Outside blood collection facility
C	Complications related to apheresis Citrate reactions Hemolysis Air embolism Infiltration Infiltration of IV fluids
D	Allergic reactions Local allergic reactions Generalized allergic reactions (anaphylactic reactions)
E	Serious complications Acute cardiac symptoms MI Cardiac arrest TIA Cerebrovascular accident Death
F	Other reactions

LOC=Loss of consciousness, DVT=Deep venous thrombosis, MI=Myocardial infarction, TIA=Transient ischemic attack

All the data were analyzed in the "R" statistical package version 4.1.0 and Microsoft Excel 2016 software.

Results

The total numbers of centers which submitted reports for the years 2016 and 2017 were 162 and 218, respectively. During this period, the total number of donations reported

was 1,998,101, out which 1,964,523 were whole blood and 33,578 were apheresis donation [Table 2a]. On validation, 1,622,600 donations were included in the further analysis due to errors/disparity in specific dimension classes of denominator matrix, i.e., a total of 350 ml and 450 ml bags used did not match with total whole blood donations reported by the reporting centers. This error resulted in the invalidation of the complete denominator and numerator entries by the reporting center for that month. Based on these findings, data of 375,501 donations (18.79%) were found invalid and excluded from the analysis [Figure 1]. Finally, the total donation denominator used for analysis was 1,622,600 [Table 2b].

Out of 6091, 23% of reports (1407 reports) were not included for the validation process due to corresponding denominator data discrepancies [Figure 1]. Out of the remaining 4684 reports, 3980 were found valid for data analysis and were included in the study and reaction rate calculations. A total of 3902 donors experienced DARs in which 74 donors experienced more than one type of DARs [Table 3].

Demographic analysis of donors with donor adverse reactions

The mean age and weight of blood donors who experienced DARs were 28.26 ± 7.6 years and

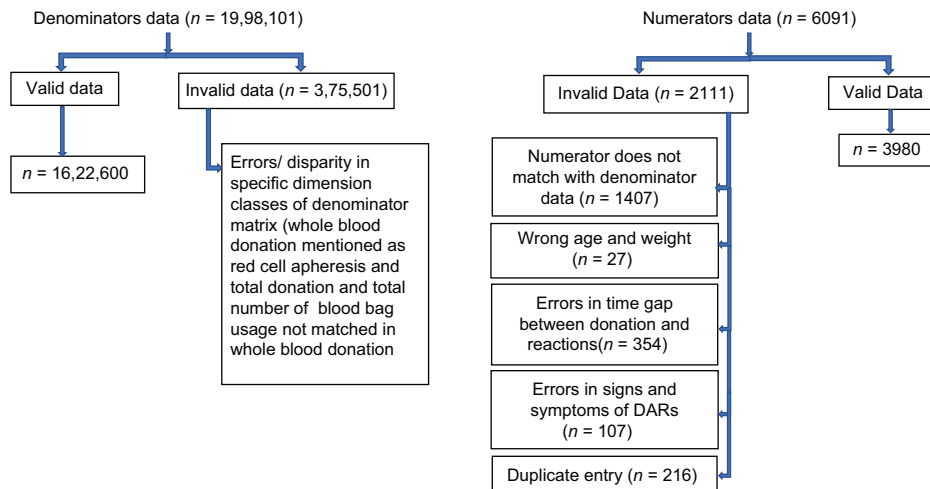


Figure 1: Data cleaning and validation

Table 2: Total denominator data submitted (a), and final data included for analysis after validation (b)

Parameter	2016, n (%)	2017, n (%)	Total
a: Total denominator data reported			
Whole blood donation	618,208 (31.4)	1,346,315 (68.6)	1,964,523
Apheresis donations	8335 (24.8)	25,243 (75.2)	33,578
Total donations	626,543 (31.3)	1,371,558 (68.7)	1,998,101
b: Total denominator data (after denominator data validation)			
Whole blood donation	465,202 (29.2)	1,130,689 (70.8)	1,595,891
Apheresis donations	6532 (24.4)	20,177 (75.6)	26,709
Total donations	471,734 (29.1)	1,150,866 (70.9)	1,622,600
Total male donors	445,724 (29.4)	1,071,495 (70.6)	1,517,219
Total female donors	26,010 (24.7)	79,371 (75.3)	105,381
Total first-time donors	271,817 (29.5)	651,002 (70.5)	922,819
Total repeat donors	199,917 (28.5)	499,864 (71.5)	699,781
Total 350 bags used	278,171 (28.5)	695,874 (71.5)	974,045
Total 450 bags used	187,031 (30)	434,815 (70)	621,846

Table 3: Number of donors reported with donor adverse reactions

Parameter	2016	2017	Total
Total donors who had single DAR	991	2837	3828
Total donors who had double DARs	9	61	70
Total donors who had triple DARs	0	4	4
Total donor who had DARs (numerator data; post validation)	1000 (1009 DARs)	2902 (2971 DARs)	3902 (3980 DARs)

DAR=Donor adverse reactions

68 ± 10.89 kg, respectively [Table 4]. These were predominantly male (90.3%), first time (61.3%) and whole blood (97.8%) donors [Figure 2]. Donors aged between 18 and 30 years and weight >55 kg contributed

to as high as 69% and 88.9% of all the reported DARs, respectively [Tables 5 and 6]. 2878 donors (73.8%) donated at the blood donation center and majority of data (98.6%) were collected within the blood center (on site).

Table 4: Demographic details of donors who experienced donor adverse reactions (n=3902) while donating whole blood and apheresis

Demography	Parameter	2016 (n=1000)	2017 (n=2902)	Total (n=3902), n (%)
Age (years)	Median	27	27	27
	Mean	28.3	28.2	28.26
	SD	±7.65	±7.65	±7.63
Gender	Male	915	2609	3524 (90.3)
	Female	85	293	378 (9.7)
Weight (kg)	Mean	67.5	68.4	68
	SD	10	10.91	10.69
Type of donation	Whole blood	983	2837	3820 (97.8)
	Apheresis	17	65	82 (2.2)
Type of donor	Voluntary	471	1506	1977 (50.6)
	Family	24	96	120 (3)
	Replacement	505	1300	1805 (46.2)
Donation status	First time	608	1784	2392 (61.3)
	Repeat	392	1118	1510 (38.6)
Data captured	Onsite	985	2866	3851 (98.6)
	Call back by center	2	8	10 (0.2)
	Call back by donor	13	28	41 (1.2)
Site of donation	Blood center	749	2129	2,878 (73.7)
	Camp	251	773	1024 (26.3)
Volume collected [#]	Incomplete donations*	52	223	275 (7.1)
	350 ml	313	970	1283 (33.5)
	450 ml	618	1644	2262 (59.2)
Outcome	Resolved	994	2865	3859 (98.8)
	Resolved on follow-up	6	25	31
	Unknown	0	12	12

[#]Total numbers of bags used are the total number of donors who experienced DARs while whole blood donations, *Total number of reports, which documented <350 ml of blood volume collected while whole blood donations (incomplete collections). DARs=Donor adverse reactions, SD=Standard deviation

Table 5: Demographic details of the donor who experienced donor adverse reactions (n=3902) based on the age of the donors

Age	Parameter	2016 (n=1000)	2017 (n=2902)	Total (n=3902)
18-30, years (n=2694; 69%)	Male	620	1807	2427
	Female	55	212	267
	First time	440	1321	1761
	Repeat	235	698	933
	Weight ≤ 55 kg	94	268	362
	Weight >55 kg	581	1751	2332
31-40, years (n=914; 23.4%)	Male	226	617	843
	Female	21	50	71
	First time	135	359	494
	Repeat	112	308	420
	Weight ≤ 55 kg	12	40	52
	Weight >55 kg	235	627	862
41-65, years (n=294; 7.5%)	Male	69	185	254
	Female	9	31	40
	First time	33	104	137
	Repeat	45	112	157
	Weight ≤ 55 kg	4	13	17
	Weight >55 kg	74	203	277

Table 6: Demographic details of the donor who experienced donor adverse reactions (n=3902) based on the weight of the donors

Weight range	Parameter	2016 (n=1000)	2017 (n=2902)	Total (n=3902)
Weight ≤55 kg (n=431)	Age 18-30 years	94	268	362
	Age 31-40 years	12	40	52
	Age 41-65 years	4	13	17
	Male	83	218	301
	Female	27	103	130
Weight >55 kg (n=3471)	Age 18-30 years	581	1751	2332
	Age 31-40 years	235	627	862
	Age 41-65 years	74	203	277
	Male	832	2391	3223
	Female	58	190	248

Distribution and categories of donor adverse reactions reported

Localized donor adverse reactions

There were 305 localized DARs, i.e., due to the process of phlebotomy, reported out of a total of 3980 DARs [Table 7]. Hematoma accounted for the maximum number (207 out of 305) of localized donor reaction, followed by delayed rebleeding. Other local complications included nerve injury, other painful arm, compartmental syndrome, and brachial artery pseudoaneurysms [Figure 3].

Generalized donor adverse reactions (vasovagal reactions)

Generalized DARs, such as vasovagal reaction, were the most common type of DARs reported (83.7%; 3328 out of 3980 reactions) [Figure 4]. 7.7% of DARs (309 out of 3980) were reported as “others,” which was the second highest number of total DARs reported followed by localized reactions.

Majority of vasovagal types of DARs were reported in younger 18–30 years age (69.7%) male donors (89.9%) with weight >55 kg (88.9%). The generalized DAR mainly occurred in the blood center (73.6%) and data captured onsite (99% times). These generalized systemic reactions (vasovagal) resulted in incomplete donations in 8.1% of donors (271 out of 3328 reactions). These generalized DARs resolved completely in 99.6%.

More information for vasovagal reactions (VVR) like the timing of LOC, details of injury, and details of the location of reaction were missing in 14.3%, 29.4%, and 31.6% reports, respectively. Out of 2852 reports with information on LOC, 1990 had no LOC, 779 had LOC for <60 s, while 83 had LOC for >60 s. Out of 2347 injury reports, 53 donors had sustained the injury after DARs, while 2294 had no injury [Table 8]. Twenty-three donors had both LOC and injury after blood donation. Considering both LOC and injury as an independent marker, 892 (26.8%) [(779 + 83 + 53) – 23] reports can be considered as severe type of VVR. Majority of VVR (91.9%) were reported within 30 min of donations, while 2.2% reported after 1 h of donation.

Table 7: Various categories of donor adverse reactions reported

Types	DAR								
	Total			Single DARs			Multiple DARs		
	2016	2017	Total	2016	2017	Total	2016	2017	Total
A	68	237	305	63	173	236	5	64	69
B	863	2465	3328	854	2433	3287	9	32	41
C	7	12	19	6	9	15	1	3	4
D	4	15	19	3	7	10	1	8	9
E	0	0	0	0	0	0	0	0	0
F	67	242	309	65	215	280	2	27	29
Total	1009	2971	3980	991	2837	3828	18	134	152

A = Localized DAR, B = Generalized DAR, C = Related to apheresis, D = Allergic Reactions, E = Serious complications, F = Others reactions, DAR = Donor adverse reactions

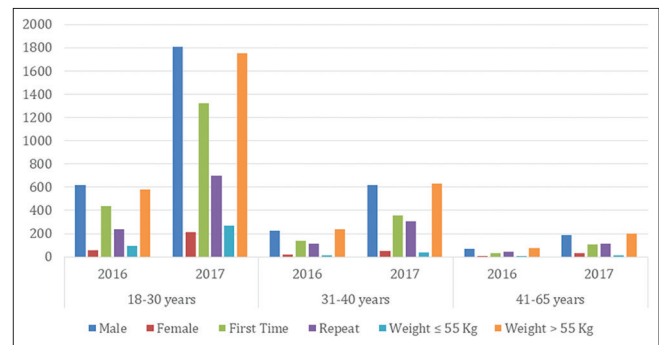


Figure 2: Demographic details of the donor who experienced donor adverse reactions (n = 3902) based on the age of the donors

Donor adverse reactions specific to apheresis donations (citrate effect)

Among 82 donors who experienced reactions during apheresis donation, only 19 (23.1%) experienced DARs due to citrate toxicity. All 19 donors were male, majorly younger age group, first-time donors, and with weight >55 kg [Table 7].

Allergic donor adverse reactions

A total of 19 out of 3980 DARs were reported due to allergic reactions. 12 out of 19 donors reported local allergies due to either phlebotomy

preparation solution or medicated bandage used to seal the phlebotomy area. Rest 7 reported generalized allergic reactions. However, none were serious DARs [Table 7].

Other donor adverse reactions

A total of 309 DARs (7.7%) were reported as “others” DARs. These were all nonspecific, which were not categorized in any of the above type of category due to inappropriate reporting. Table 9 describes the terms used by the reporting center to report the DARs under the “others” category and we tried to recharacterize them into DAR categories. Majority of the terms

entered under “others” indicated toward a generalized DAR. Since these were originally reported as “others,” hence these numbers were not considered for analysis under any specific type of DAR and considered only as “Others.”

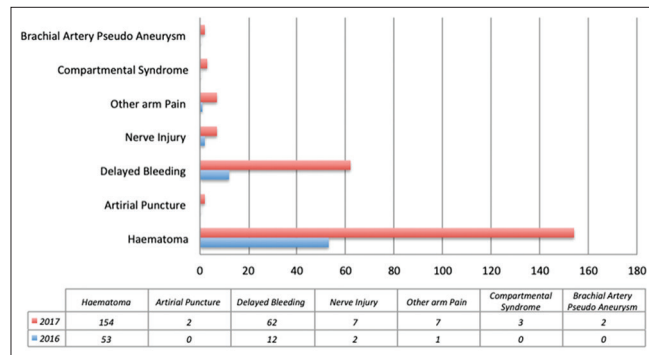


Figure 3: Distribution of localized donor adverse reaction reported

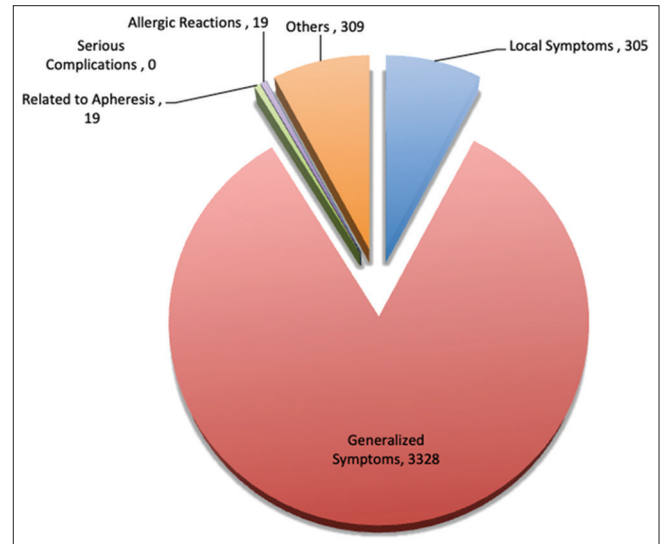


Figure 4: Distribution of all the total validated donor adverse reactions reports of 2016 and 2017 (n = 3980 [1009 + 2971])

Table 8: Characterization of generalized (vasovagal) donor adverse reactions (n=3328) while donating whole blood and apheresis

Characterization	Parameter	2016 (n=863)	2017 (n=2,465)	Total (n=3328), n (%)
LOC	No LOC	432	1558	1990 (59.7)
	<60 s	190	589	779 (23.4)
	>60 s	26	57	83 (2.4)
	Not reported	215	261	476 (14.3)
Injury	No injury	675	1619	2,294 (68.9)
	Injury	5	48	53 (1.5)
	Not reported	183	798	981 (29.4)
Location of reaction	Within blood center	663	1550	2213 (66.4)
	Outside blood center	13	50	63 (1.3)
	Not reported	187	865	1052 (31.6)

LOC=Loss of consciousness

Table 9: Characterization of donor adverse reactions (n=309) reported as “others”

Terms used to describe the reaction by the reporting center	Category they might belong to	2016 (n=67)	2017 (n=242)	Total (n=309)
Rebleeding/pain at phlebotomy site/delayed bleeding/pain in the arm/tingling in the distal arm and phlebotomy site	A: Local complications	1	6	7
Dizziness/anxiety/fainting/giddiness/“Gabhrana”/Mild VVR/Mod VVR/vitiligo/perspiration/sweating/uneasiness/weakness/“Chakkar”/cold skin/convulsions/discomfort/light headedness/low BP/abdominal pain/postural hypotension/tiredness	B: Generalized symptoms (suggestive mainly of vasovagal reactions)	64	232	296
Hyperventilation		1	1	2
Citrate reaction/shivering and feeling cold	C: Citrate effect during apheresis donations	1	1	2
Allergy to medicated adhesive tape	D: Allergic reactions	0	1	1
Shock	E: Other serious reactions	0	1	1

VVR=Vasovagal reactions, BP=Blood pressure

Multiple donor adverse reactions

Seventy-four donors (1.9% of total DARs) reported multiple (more than one type) DARs in which 70 had double, while 4 had triple DARs. Out of 74 multiple DAR, 8 occurred during apheresis donation and 66 during a whole blood donation. Out of total multiple DARs, 50 occurred within the blood center, while the rest 24 were seen at the campsite [Table 10].

Imputability

Maximum imputability reported for overall DARs was “definite” (39%; 1522 out of 3902), followed by “Probable” (37.9%; 1481 out of 3902) and “possible” (23%; 899 out of 3902). For generalized DARs reported, imputability was “probable” (39.9%; 1331 out of 3328), followed by “definite” (37.1%; 1237 out of 3328) and “possible” (22.8%; 760 out of 3328).

Donor adverse reactions rates

The overall total DAR rate was 2.45 for every 1000 blood donations, with the most common as generalized DARs (2.05/1000). The incidence of DARs was higher in apheresis donations (3.07 for every 1000 apheresis donations) as compared to whole blood donations (2.39 for every 1000 whole blood donations). The overall

DARs reported were higher in females (3.5 for every 1000 female donors) compared to male donors (2.3 for every 1000 male donors) and in the first time donor (2.5 for every 1000 first time donors) compared to repeat donors (2.15 for every 1000 repeat donors).

Discussion

The objectives of donor HvPI are to improve donor safety and satisfaction in order to improve donor retention, recruitment, and return. It can be achieved through monitoring and analyzing DARs, risk factor assessment, implement, and evaluate evidence-based preventive measures to reduce the frequency and severity of DARs.

In the present report, we analyzed DARs data for the first 2 years (2016 and 2017) of the implementation of the donor vigilance program in India. A total of 162 blood centers reported DARs in the “Donor-Vigil” software for the years 2016 and 218 blood centers for 2017. A total of 1998,101 blood donations were the denominator for the reporting period and 6091 DARs were reported. There were errors in data reported by many blood centers, hence data cleaning and validation were done. Only validated data of DAR were further analyzed for calculations and

Table 10: Details of multiple donor adverse reactions reported by reporting centers, (a) Double Donor Adverse Reactions and (b) Triple Donor Adverse Reactions

		Double donor adverse reactions		
Combination of double DAR		2016	2017	Total
A1: Hematoma	A1: Rebleeding	0	3	3
A1: Hematoma	A2: Nerve injury	0	1	1
A1: Hematoma	B: VVR	4	16	20
A1: Hematoma	A2: Other painful arm	0	2	2
A1: Hematoma	C: Citrate reaction	0	1	1
A1: Hematoma	F: Others	0	1	1
B: VVR	A1: Delayed/rebleeding	0	5	5
B: VVR	A1: Article puncture	0	1	1
B: VVR	A2: Other painful arm	0	1	1
B: VVR	A2: Nerve injury	1	1	2
B: VVR	C: Citrate reaction	1	2	3
B: VVR	D: Local allergy	1	2	3
B: VVR	F: Others	2	1	3
F: Others	A1: Delayed/rebleeding	0	16	16
F: Others	A2: Other painful arm	0	1	1
F: Others	A4: Major vessel injury*	0	2	2
F: Others	D: Local allergy	0	5	5
Total		9	61	70
(b) Triple donor adverse reactions				
Combination of triple DAR			n	
A1: Hematoma	B: VVR	A2: Pain full arm	1	
A1: Hematoma	B: VVR	D: Local Allergy	1	
A1: Hematoma	A2: Nerve injury	F: Other (weakness)	1	
A1: Delayed/rebleeding	B: VVR	A4: Major vessel injury**	1	

*Compartmental syndrome and brachial artery pseudoaneurysm, **Compartmental syndrome, VVR=Vasovagal reactions, DAR=Donor adverse reactions

interpretations [Figure 1]. Out of total reports, 18.7% of denominator data and 34.6% numerators were excluded from analysis due to inappropriate reporting. A similar finding of inappropriate data reporting (28.6%) was also observed in AABB Donor Haemovigilance Report 2012.^[6]

After validation and analysis, 1,622,600 blood donations (both whole blood and apheresis) were included into the final analysis, which was around 7.19% of the total annual donation for the year 2016–2017 (22.54 million) of India.^[7] Total donations mainly consisted of whole blood donations (98.3%), while only 1.7% were apheresis donations. Lesser number of apheresis donations take place in India due to lack of expertise and high cost of the procedure. On analysis, we found very small number of female donors reported during the assessment year [6.5%, Table 2]. In India, the prevalence of female donors is less due to the prevalence of low hemoglobin, low weight, and fear of needles. Majority of donations were from first-time donors (56.8%) as compared to repeat donors (43.1%) [Table 2].

In the present analysis, 0.24% DARs were reported out of 1,622,600 donations (2.45 per 1000 donation), while AABB reported 2.2% DARs in years 2012–2017 from 8,553,601 donations in the USA.^[8] In other countries like Japan, the overall DARs reported during 2016 were 0.835%.^[9] Serious hazards of transfusion in the United Kingdom reported a slight increase in DARs from 0.20 to 0.26 per 10,000 donations from 2015 to 2017.^[10] DARs incidence rate was almost similar like 308 and 309 per 10,000 donations in Australia and New Zealand, respectively, during the period of 2016–2017.^[11,12] To the best of our knowledge, till now, only a few developed countries published data about DARs under donor hemovigilance program none of the developing country published this kind of data. The frequency of DARs reported from previous studies in India ranges from 0.6% to 5.06% [Table 11].

Almost all parameters were similar in both years (2016 and 2017) except DARs in replacement donors were more in 2016 (50.5%) as compared to 2017 (44.7%). Majority of DARs were reported from a younger age group (69% from donors' age 18 to 30 years) as compared to donors of age more than 31 years [Table 5]. Due to lack of data on the age of donors (denominator data), it cannot be commented that whether the rate of DARs is more in the younger age group of donors. The first-time donation, anxiety, and fear to needle might be the reasons for higher proportion of DARs in the younger age group. Out of total donation for males and females, we found that younger age (18–30 years) female donors had more DARs (0.25%) as compared to younger age male donors (0.15%).

The DARs reported were more in voluntary donors (50.6%), followed by replacement (46.2%) and less in family donors (3%). We found a minor difference between the rate of DARs in the first time (0.25%) and repeat donors (0.21%). The overall DARs reported were high when donations were done in the blood center (73.7%) as compared to outdoors camps (26.3%). These unexpected results might be due to lesser number of blood donation camps, underreporting of DARs from camps, lesser follow-up, and more donor observation with greater postdonation resting time in blood centers as compared to camps.

Most of the DAR data were captured onsite of the blood donation (98.6%), while only in 1.2% and 0.2% cases either donor called back to blood center or blood center called back to donor for DAR inquiry. This reflects that more awareness is required in blood donors to report the delayed DARs as well as blood centers may follow-up with blood donors more actively for DAR inquiry.

Whole blood was collected more (61%) in 350 ml blood bags as compared to 450 ml (39%). DARs were observed more in donors who donated 450 ml of whole blood (59.2%;

Table 11: Comparison of donor adverse reactions of multiple studies published from India with the present analysis

Authors	Year of analysis	Place of study	Total donation	Donor adverse reactions#			Most common*
				Overall (%)	Male/female (%)	FT/RT (%)	
Pathak <i>et al.</i> ^[13]	2007-2009	Delhi	19,045	0.6 (113)	NR	NR	GR (78.7)
Kumari ^[14]	2007-2014	Patiala	27,664	0.7 (195)	0.61/2.8	1.2/0.3	GR (81)
Agnihotri <i>et al.</i> ^[15]	2002-2003	Chandigarh	37,896	2.5 (948)	2.3/4.8	NR	GR (63.5)
Biswas <i>et al.</i> ^[16]	2017-2018	Kolkata	11,371	5 (576)	4.25/10.2	9.9/1.3	GR (60.5)
Gupta <i>et al.</i> ^[17]	2008-2012	Mumbai	11,034	2.33 (258)	NR	NR	GR (72.8)
Dogra <i>et al.</i> ^[18]	2011-2012	Jammu	29,524	0.36 (108)	0.29/4.25	1/0.1	GR (53.7)
Agarwal <i>et al.</i> ^[19]	2011-2014	Karnataka	30,928	3.25 (995)	1.74/6.5	NR	GR (67.7)
Rai <i>et al.</i> ^[20]	2016-2017	Gwalior	38,797	1.6 (664)	1.59/2.4	1.8/0.99	GR (96)
Present analysis	2016-2017	Donor Hemovigilance Programme of India	1,622,600	0.24 (3980)	0.23/0.35	0.25/0.21	GR (83.7)

*Percentage of most common DAR out of overall DAR reported, #Percentage calculation based on the specific denominator. FT=First time donor, RT=Repeat donation, GR=Generalized reaction, DAR=Donor adverse reactions

3.6 per 1000 donors) as compared to 350 ml (33.5%; 1.3 per 1000 donors). Two-hundred and seventy-five of 3902 donors (7.1%) resulted in incomplete whole blood donation due to DAR, out of which 97% (267/275) were due to vasovagal reactions. Almost 99.7% DARs were resolved either at the donation site (98.8%) or on follow-up (0.79%), while there was no reporting by 0.3% of donors whether they recovered or not.

Out of the total validated DAR, 7.6% were localized in nature. Hematoma was the most common type (67.8%), which was found more in apheresis donors (0.08%) as compared to whole blood (0.01%). It was observed more at blood center (82.12%) as compared to outdoor camps (17.88%) with no difference in the first time and repeat blood donors. This again reflects marked underreporting from blood donation camps. Almost 92.3% of hematomas were recorded at the site of blood donation, while 7.7% recorded when the donor left from the donation site. Largely hematomas were immediate type and only a few happened later or there was underreporting of delayed hematoma. Around 24.26% of localized DARs were delayed/rebleeding from the donation site after 30 min of donation. It might be due to donor conditions like coagulation abnormality or due to phlebotomy veins not properly bandaged after donation.

In generalized DARs, it was found that the younger age group (18–30 years; 0.14%) and female donors (0.22%) had more VVR as compared to older age (>31 years; 0.05%) and male donors (0.19%). VVR were found more common in whole blood donors (0.2%) of as compared to apheresis (0.1%). Around 8% of the total VVR resulted in incomplete blood donation. Most of the VVRs were observed in blood centers (73.6%) and data also captured at donation sites (99%). It reflects that blood center staff was on more vigilance at blood centers as compared to blood donation camps. More than 99% VVR resolved at the donation site only, while 0.3% resolved on follow-up. Out of total generalized DARs, 26.8% were of severe nature, presenting either with LOC or injury or both.

Very few donors (0.4%) experienced a local allergic reaction, which may be due to hypersensitivity of the donor to any particular object or antigens. In blood donation, these might be due to allergy to disinfectant constituents of medicated bandage.^[21] Taking the allergic history of donors before blood donations can prevent this kind of reaction. None of the serious DARs or events like acute cardiac symptoms, myocardial infarction, cardiac arrest, transient ischemic attack, cerebrovascular accident, or death was reported.

Out of the total DAR reported, only 2.06% were observed during apheresis donation, and among these, 23.1%

were due to the citrate effect. Rest were either localized or generalized DARs similar to whole blood donations. The “Other reactions” category was the second largest number (7.7%) of DAR reported after generalized DAR. In this category blood centers mostly reported the symptoms that can be categorized under generalized DARs (96.44%), followed by localized DARs (2.26%), citrate reaction (0.64%), allergic reaction (0.32%), and other serious reaction (0.32%) [Table 9]. It reflects that in some cases, blood centers were unable to classify the DAR correctly in the given options. This scenario can be due to an untrained staff entering the data in the software without the appropriate supervision of a transfusion medicine physician from the blood center.

A total of 74 donors experienced multiple DARs, 70 double, and 4 triples. These multiple DARs often were the association of generalized and localized DARs. This finding may be because when a donor experiences a generalized DAR they tend to move their hand resulting in a localized injury/reaction also. Even major vessel injuries resulting in compartmental syndrome and brachial artery pseudoaneurysm were also reported as a part of multiple DARs [Table 10]. Although the number of multiple DARs reported is very less (1.9%), this highlights the importance of monitoring and carefully managing DARs to minimize the risk of injury.

In our analysis of validated DAR in 2016 and 2017, the overall rate of DARs was 2.45 every 1000 donations, which was higher in female donors (3.58 every 1000 donations) as compared to male (2.32 every 1000 donations); in first-time donors (2.59 every 1000 donations) as compared to repeat (2.15 every 1000 donations) and during an apheresis donation (3.07 every 1000 donations) as compared to during whole blood (2.39 every 1000 donations).

The reaction rates and incidence of DAR are markedly lower in our study when compared to previous studies from India [Table 11]. There may be many reasons for underreporting such as very few blood centers participated in the donor hemovigilance program, as well as some of the participating blood centers also inappropriately reported DAR. Another reason for lower incidence may be that this study is a retrospective analysis of DAR submitted to the national portal. This has been observed that a prospective analysis usually reports a high incidence of DAR when compared to retrospective one^[15,16,22] due to better data capturing on regular basis. Gaining the confidence of the blood centers to document as well as to report the DAR voluntarily to the national portal is another challenge. Based on our current data analysis and for improvement of data reporting, we recommended some actions, which can be adapted by blood centers, blood donor organizations, HvPI stakeholders, and national regulatory authorities [Table 12].

Table 12: Future recommendations based on current analysis of data

Objectives	Recommendations
To reduce the incidence of DARs	<ul style="list-style-type: none"> • Improve donor questionnaires and examination about history of medicated tape allergy and bleeding or coagulation disorder. • Use measure to reduce the young age first time blood donor anxiety. • Improve phlebotomy technique and training of phlebotomy staff • Improve post donation care and vigilance for at least upto 30 minutes from donation • Early identification and management of first reaction to prevent secondary reaction or injury
To improve reporting of DARs to the Donor Hemovigilance Programme	<p>Blood Centres/ Departments of Transfusion Medicine</p> <ul style="list-style-type: none"> • Increase participation of blood centres in National Haemovigilance Programme of India (HvPI). • Training staff about correct identification and reporting of DAR. • Motivate blood donors to report immediate and delayed DARs. • Follow up of donors to ensure his/her wellness. <p>Blood donor organizations: encourage the blood donors to report all immediate and delayed DAR's to blood centres.</p> <p>Regulatory authorities: Central Drug Standards Control Organization (CDSCO) can play an important role in ensuring that the blood centres document and report all DARs.</p> <p>Upgrading the reporting software: Following suggestions may be incorporated in the form for better reporting and Characterization of the adverse events</p> <ul style="list-style-type: none"> • Updates for denominator data: <ul style="list-style-type: none"> i Age and Weight distribution ii Site (Blood centre and camps) and Type (voluntary, replacement & family) of blood donation iii Peripheral blood stem cells, granulocyte, and Autologous donation • Updates for numerator data entry: <ul style="list-style-type: none"> i Customized options for selection for entry in the software ii Mandatory fields marking iii Drop down options iv Detail symptoms for generalized reactions <p>Expert committee of Donor-Vigilance Programme of India</p> <ul style="list-style-type: none"> • Organize regular continuous medical education (CME) programme to encourage participation. • Regular training of the reporting centre. • Dedicated training module for staff of blood centres

DARs=Donor adverse reactions, HvPI=Haemovigilance Programme of India, CDSCO=Central Drug Standards Control Organization, CME= continuing medical education

Conclusion

After the successful implementation of HvPI, the Donor Vigilance Program was established in 2016 with an aim to further enhance the donor safety aspect of haemovigilance. This report summarizes the DARs reported under this program in the initial years of 2016 and 2017. Participation of blood centers in both recipient and donor vigilance is a very positive step. In this report, we concluded that younger age, first time, and female donors are more prone to DARs and compared to older age, repeat, and male donors. During the analysis of the data, we found some limitations, which can be improved by upgrading the reporting form and conducting regular CMEs of participant blood centers. Stakeholders in regulatory authorities (CDSCO) and donor haemovigilance programs need to work together to increase the participation of blood centers and ensure completeness of data in this program for more evidence-based blood donation safety measures.

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Conflicts of interest

There are no conflicts of interest.

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