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

Haemovigilance 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 reactions to blood and blood components is carried out by the National Blood Donor Vigilance Programme of India (NBDVP). The purpose of this program is to monitor the safety and efficacy of blood transfusions and to identify any adverse reactions that may occur. The program is regulated by the Ministry of Health and Family Welfare, Government of India, and is overseen by the National Institute of Biologicals (NIB). The program collects and analyzes data on all blood donations in the country, and the results are used to inform clinical practice and improve patient outcomes.
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.

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

| 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/iritation                                 |
|            | 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

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was 1,998,101, out of 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

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            |
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.

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.”

### 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

| 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    |

| 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

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

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