AABB Donor Hemovigilance Report

2012-2014

Advancing Transfusion and Cellular Therapies Worldwide

The 2012-2014 AABB Donor Hemovigilance Report

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1. Introduction

The goal of Donor Hemovigilance (DHV) is to continuously improve donor safety and satisfaction through monitoring, analyzing, and researching adverse events associated with blood donation prior to, during, and after the donation event. Donor Hemovigilance Analysis & Reporting Tool (DonorHART™), a DHV software developed by Knowledge Based Systems Inc. with initial funding from the US Department of Health and Human Services, using specifications provided by the AABB Donor Hemovigilance Working Group, allows blood collectors to report donor adverse reactions using a centralized platform, benchmark against other blood collectors, and perform univariate, bivariate and multivariate analyses.

This report provides a comparative analysis of the 2014 data reported to DonorHART™ by blood collectors with previous years. Updated analyses for the five US blood centers reported in year 2012 using the revised donor adverse events definitions (introduced by the Working Group on Donor Vigilance of the International Society of Blood Transfusion (ISBT), Working Party on Haemovigilance in collaboration with the International Haemovigilance Network (IHN), and the AABB Donor Hemovigilance Working Group in December 2014)[1] are provided here. Donor safety— not the characteristics (safety, potency, efficacy, etc.) of the blood component produced — is the focus of this report.

2. Methods:

Participation:

Both US and non-US blood centers (BC) and hospital blood banks (HBB), are eligible to participate in the AABB Donor Hemovigilance Program. In 2014, 9 blood centers and 3 hospital blood banks from the United States enrolled in the Donor Hemovigilance program with 8 BC and 2 HBB actively contributing data. Participation in Donor Hemovigilance includes use of the Donor Hemovigilance Analysis & Reporting Tool (DonorHART™). Data from non-US blood collectors participating in the AABB Donor Hemovigilance Program have not been included in the scope of this report due to differences in reporting thresholds making comparisons inappropriate.

Definitions:

Consensus-based, standardized vocabularies are the backbone of any data reporting and analysis effort. The relationship of the definitions within the vocabulary (i.e. the ontology) is also critical. Only through the consistent use of standardized definitions can events be identified, reported, and analyzed for benchmarking (both within a system and across organizations). Revised definitions were introduced by the Working Group on Donor Vigilance of the International Society of Blood Transfusion (ISBT), Working Party on Haemovigilance in collaboration with the International Haemovigilance Network (IHN), and the AABB Donor Hemovigilance Working Group in December 2014. AABB adopted the revised definitions and these were harmonized within DonorHART™. Examples of the definitions are provided in **Table 1**. A complete list of definitions and the workings of the database can be found in the Donor Hemovigilance System Definitions, a resource on the AABB Donor Hemovigilance website.[1]

Table 1: Donor Reactions		
Reaction Type	**Reaction Category 2012**	**Reaction Category 2014**
Vasovagal	Prefaint, no Loss of Consciousness (LOC), (uncomplicated or minor)	Prefaint, no Loss of Consciousness (LOC), (uncomplicated or minor)
	LOC, any duration, uncomplicated	LOC
	LOC, any duration, complicated	
	Injury	
Local Injury Related to Needle	Nerve Irritation	Nerve Irritation
	Hematoma / Bruise	Hematoma / Bruise
	Arterial Puncture	Arterial Puncture
		Painful Arm
		Delayed bleeding
		Infection
		Major Blood Vessel Injury
Apheresis Related	Citrate	Citrate
	Hemolysis	Hemolysis
	Air Embolus	Air Embolus
		Infiltration
Allergic	Local	Local
	Systemic	Systemic
	Anaphylaxis	Anaphylaxis
Injury		Major Injury
		Minor Injury
Major Cardiovascular Event		Angina pectoris within 24 hours
		Cardiac arrest
		Cerebrovascular accident
		Myocardial infarction within 24 hours
		Transient Ischemic Attack within 24 hours (TIA)
Other	Other	Other

Database:

DonorHART™ captures and analyzes donor reaction information from blood collection organizations. The DonorHART™ program is a web-based application that allows users, through an internet browser, to report, view, and analyze data related to donors' adverse reactions in their organization or organizations. In addition to recording and viewing data on donor reactions, users can capture denominator data for donors, perform targeted analyses of reaction data and compare their data with the group in the system.

The database was developed by Knowledge Based Systems, Inc. (KBSI, College Station, TX) with subject-matter expertise provided by the AABB US DHV Working Group. A more complete description of the tool along with its ability to verify and validate the data is available in the DonorHART™ User Manual on the AABB Donor Hemovigilance website.[2] In this report, the five US-blood centers that reported data in 2012, 2013 and 2014 have been defined as core organizations.

2012 Database:

Following the release of the 2012 AABB Donor Hemovigilance report, definitions for complications related to blood donation in the DonorHART™ database were harmonized with the revised ISBT/IHN/AABB definitions. In addition, one of the participant blood centers updated its data for the year 2012 after the release of the report. In this report, we include the updated database for the five blood centers that reported in 2012. As a result, some changes in the results of the 2012 AABB Donor Hemovigilance report were observed.

2014 Database:

Twelve blood collection organizations (including three hospitals) reported some 2014 donor hemovigilance data in the AABB US DHV program using DonorHART™. In this report we include results from only eight blood centers and 2 hospital blood banks that reported denominator data which were sufficiently complete to calculate reaction rates.

Data Cleaning and Imputation:

We examined the missing data and internal inconsistencies in the data by organization, for all months in the 2012 and 2014 databases. Edit and imputation rules were applied to key variables in the denominator database including age, collection site, donation history, donation type, gender, procedure type, and total donations. Data were imputed on nine responding organizations for a total of 20 data items. The main objective of data manipulation was to maintain internal consistencies of key variables with the total donations for each organization. The total donation variable was edited through arithmetic operations (addition or subtraction) to maintain consistencies. For other variables, imputation was based on the average distribution and proportional adjustment.

Reaction Rate:

Reaction rates were calculated as reactions per 1,000 donation procedures. For the calculation of reaction rates, reactions reported without corresponding reports of monthly denominators were excluded. For the calculation of overall reaction rate, therapeutic donations were also excluded. However, for the calculation of individual reaction rates, the number of therapeutic donations by age, gender, donation history, procedure type, collection site, and location, could not be identified in the denominator data and were not excluded. The reaction rates were compared using simple 2-sample tests assuming equal variances.

3. Results

Reporting Centers:

In 2012, five organizations reported denominator data that were sufficiently complete for rates to be calculated. In 2014, ten organizations reported sufficient denominator data to be included. Additional organizations have begun providing data into the training environment and others are known to have begun adoption of the common definitions. The majority of blood centers and hospitals reporting to DonorHART™ are small to medium sized blood collectors.

Data Elements:

The AABB US DHV Program has, through DonorHART™, the ability to collect many data elements about the donor, the donation, and the adverse reaction. Entry of all attributes for every donor and donor reaction, however, is not required. Blood collection organizations are encouraged to report as many attributes as are readily available in order to maximize the utility of reporting. In **Table 2**, reported attributes are listed by the percentage reported by the reporting organizations for years 2012 and 2014. The percentage reported was calculated as months with available data for a given variable over months with total data, for each organization. Denominator data elements were more completely reported in 2012 compared to 2014. This change coincides with the date of use of the DonorHART™ Lite application, which permits collection of a limited dataset. Age, donation history (first-time/repeat donor), donation type (autologous, allogeneic, etc.), gender, and procedure type (manual whole blood collection, apheresis, etc.) were the most often reported variables in both years. Some attributes of the donor or the collection procedure were reported by fewer organizations, while other attributes, such as device software, were poorly reported by all reporting organizations.

Table 2: Denominator Data Elements Reported

Variable	2012 (n=5)	2014 (n=10)
Age	100%	79%
Diastolic Pressure	40%	21%
Collection Site	83%	98%
Donation History	100%	89%
Donation Type	100%	100%
Ethnicity	80%	49%
Gender	100%	79%
Height	27%	32%
Procedure Type	100%	99%
Pulse	60%	40%
Race	100%	56%
Sponsor Group Type	60%	40%
Weight	67%	50%
Device Manufacturer	20%	12%
Device Model	20%	14%
Device Software	0%	4%
Container Manufacturer	0%	5%

Donor Information:

A total of 1,175,262 donations in 2012; and 1,312,130 donations in 2014 were reported to the Donor Hemovigilance program through DonorHART™. There were more donations from male donors (52.1% in 2012, and 52.7% in 2014) compared to female donors (47.9% in 2012, and 47.2% in 2014). Most donations were from donors who had donated previously, (repeat donors: 85.4% in 2012, and 84.3% in 2014), relative to first time donors (14.6% in 2012, and 15.7% in 2014). Nearly 98% of donations were allogeneic donations (98.5% in 2012 and 98.3% in 2014). The remaining donation types reported included autologous, directed, and therapeutic (data not shown).

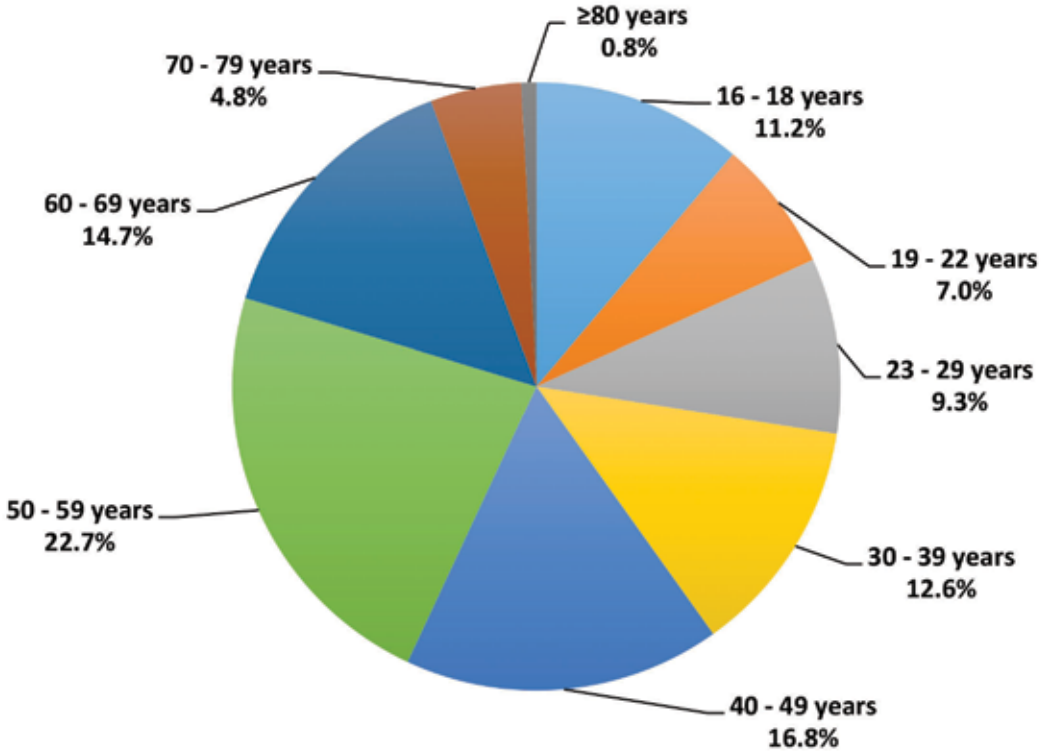
Donations were predominantly whole blood donations (75.5% in 2012 and 78.3% in 2014). In 2012, there were 14.1% double red cell apheresis, 5.4% platelet pheresis, 1.6% platelet and plasma pheresis combined, and 1.2% platelet and red cell

pheresis combined collections. All other automated combinations made up the remaining 1.8% collections reported. In 2014, apheresis procedures included double red cell apheresis (10.8% of total collections), platelet pheresis (5.6% of total collections), platelet and plasma pheresis combined (2.2% of total collections), and platelet and red cell pheresis combined (1.0% of total collections). All other automated combinations made up the remaining 2.0% collections reported.

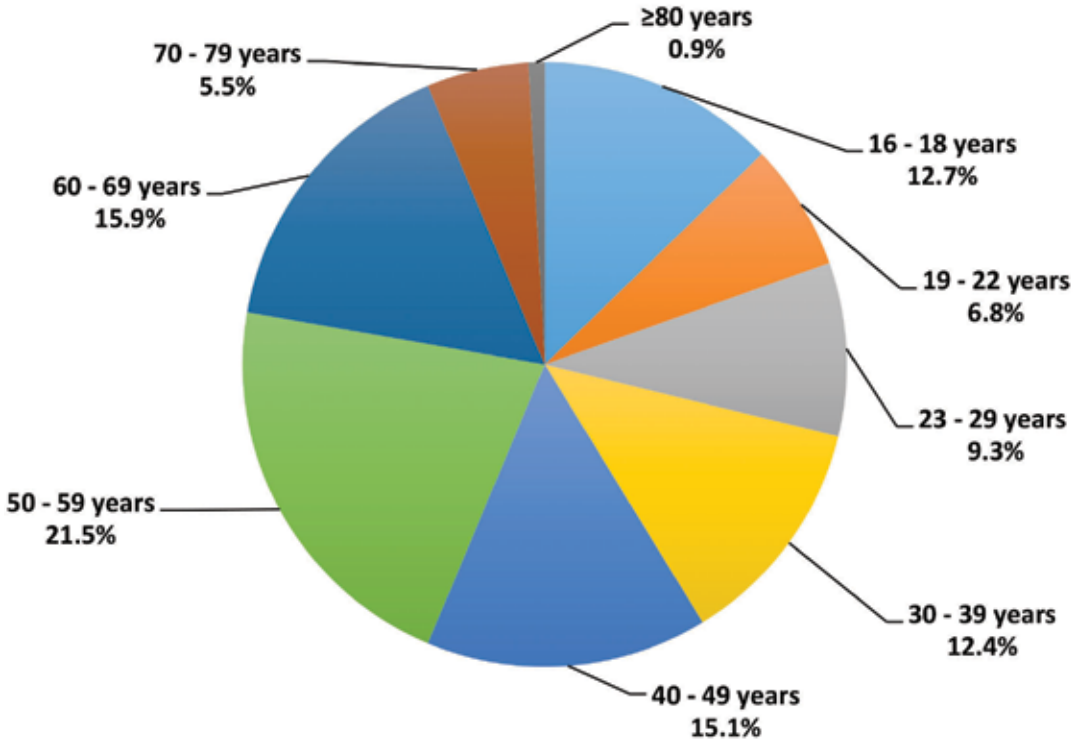
Donor Demographics:

Overall, nearly 60% (59.9% in 2012 and 58.7% in 2014) of donations were made by donors over the age of 40 years old **(Figure 1)**. More donations came from donors who were between the ages of 50 and 59 (22.7% in 2012 and 21.5% in 2014) at the time of donation than from any other single age cohort. In 2014, there was a slight increase in donations from donors between the ages of 16 and 18 (12.7% versus 11.2%), 60 and 69 years (15.9% versus 14.7%), and 70 and 79 years (5.5% versus 4.8%).

Figure 1: Donor Age 2012 (n=1,175,262 donations)



Donor Age 2014 (n=1,312,130 donations)



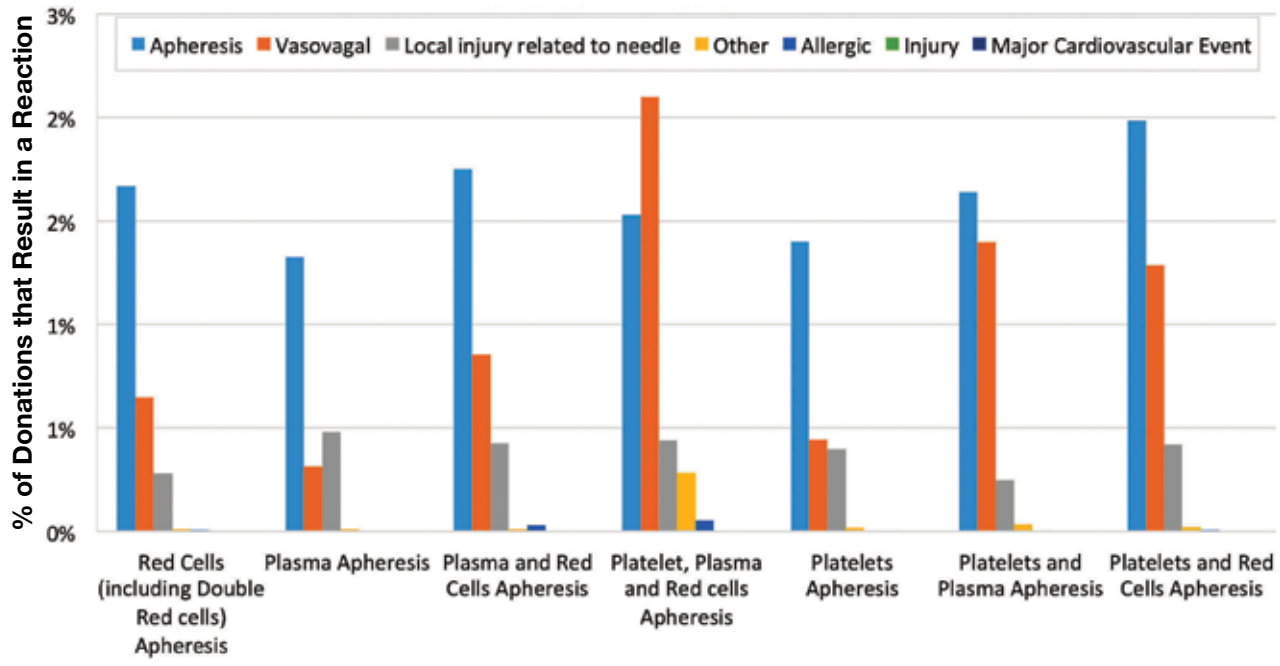
Basic Reaction Rates:

Basic reaction rates are listed in **Table 3**. The overall donor adverse reaction rate in 2014 was 22.8 per 1,000 donation procedures, comparable to the overall reaction rate in 2012 (22.2 per 1,000 donation procedures). The most common reaction type, vasovagal reactions, increased slightly in 2014 to a rate of 16.3 per 1,000 donations compared to 15.9 per 1,000 donations in 2012. Most of these reactions (84.8%) were categorized as "Prefaint" with no actual loss of consciousness (LOC). Local injury related to needle was the second most common type of reaction (3 per 1,000 donations), with hematoma or bruise being the most common occurrence from this reaction category. The rate of apheresis-related reactions calculated over apheresis donations (excluding whole-blood, sample and other donation types) was 25.9 per 1,000 donations in 2014, slightly higher than 22.0 per 1,000 donations in 2012. Most of the apheresis–related reaction were categorized as "Infiltration." **Figure 2** shows the proportion of all reaction types that occurred from apheresis donations in 2014. With the exception of the platelet, plasma and red cells apheresis procedure, which had vasovagal as the most common reaction type, apheresis reaction was the most common reaction type among all other apheresis donations.

Table 3: Reaction Rates	Reaction Rate/1,000	
Reaction Type	**2012 (n=5)**	**2014 (n=10)**
Overall Reactions	22.2	22.8
Vasovagal	15.9	16.3
Prefaint, no LOC (uncomplicated or minor)	13.6	14.0
LOC	2.3	2.3
Local Injury Related to needle	3.0	3.1
Nerve Irritation	0.2	0.2
Hematoma / Bruise	2.7	2.8
Arterial Puncture	0.0	0.0
Painful Arm	0.1	0.1
Delayed bleeding	0.0	0.0
Infection	0.0	0.0
Major Blood Vessel Injury	0.0	0.0
Injury	0.1	0.1
Major Injury	0.0	0.0
Minor Injury	0.1	0.1
Apheresis-related*	2.8	2.9
Citrate	0.2	0.2
Hemolysis	0.0	0.0
Air Embolus	0.0	0.0
Infiltration	2.6	2.7
Allergic	0.2	0.2
Local	0.2	0.2
Systemic	0.0	0.0
Anaphylaxis	0.0	0.0
Major Cardiovascular Event	0.0	0.0
Angina pectoris within 24 hours	0.0	0.0
Cardiac arrest	0.0	0.0
Cerebrovascular accident	0.0	0.0
Myocardial infarction within 24 hours	0.0	0.0
Transient Ischemic Attack within 24 hours (TIA)	0.0	0.0
Other	0.2	0.2

*Apheresis-related reaction rate as it relates only to apheresis-related donations (excludes whole-blood, sample, and other donations) is: 22.0 per 1,000 donations in 2012 and 25.9 per 1,000 donations in 2014. The apheresis-only rates include therapeutic donations, as the number of donations that are both apheresis-related and therapeutic could not be distinguished.

Figure 2: Types of Donor Adverse Events among Apheresis Donations, 2014



The blood donor adverse reaction rate was lower during the summer months in both 2012 and 2014 **(Figure 3)**. The higher reaction rate during the first half of the year 2014 compared to 2012 was associated with the higher reaction rate from female donors **(Figure 6)** and influx of data from 3 new centers reporting to DonorHART™. The lower rate of adverse reaction rate during the summer months may be attributed to the fact that fewer donations were contributed by young donors during these months **(Figure 4)** and that younger donors are more likely to experience an adverse reaction from blood donation.[3-4] The reduced number of donations from younger donors during the summer months from blood collection drives at high schools and colleges were compensated with increased donations from adult donors (23-69 years) in 2012 as well as 2014 **(Table 4)**.

Figure 3: Aggregate Reaction Rate by Month 2012-2014

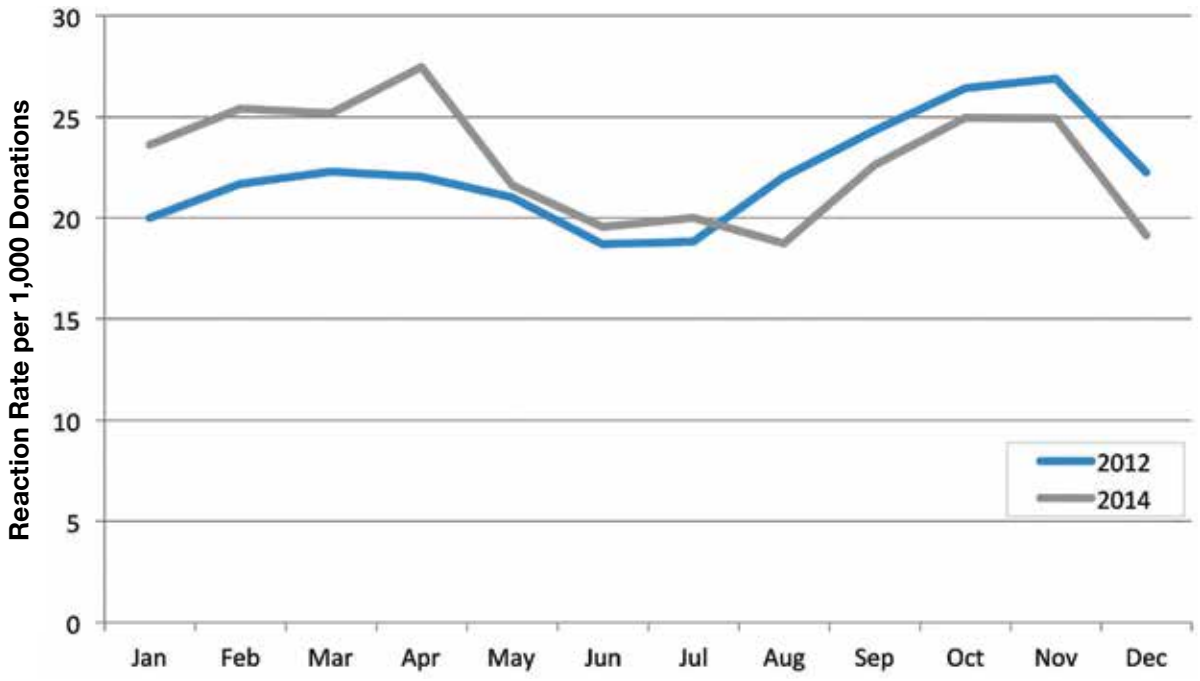


Figure 4: Seasonal Donation Patterns among Donors by Age, 2012-2014

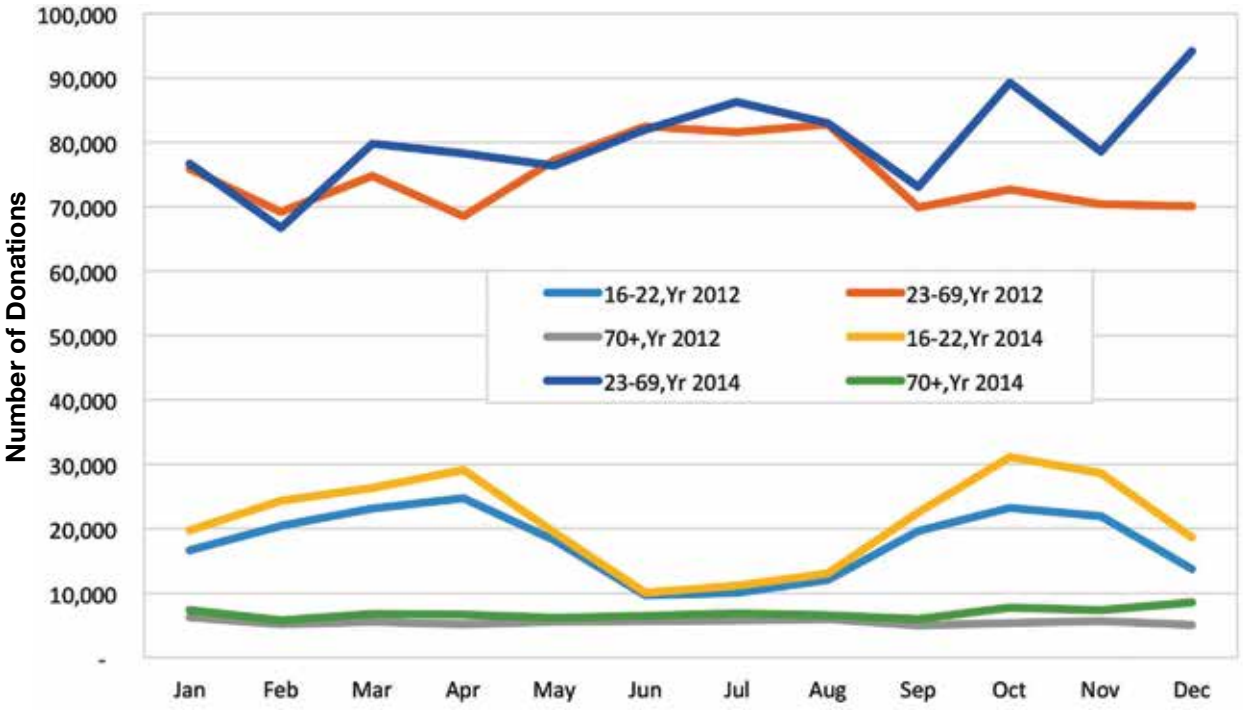
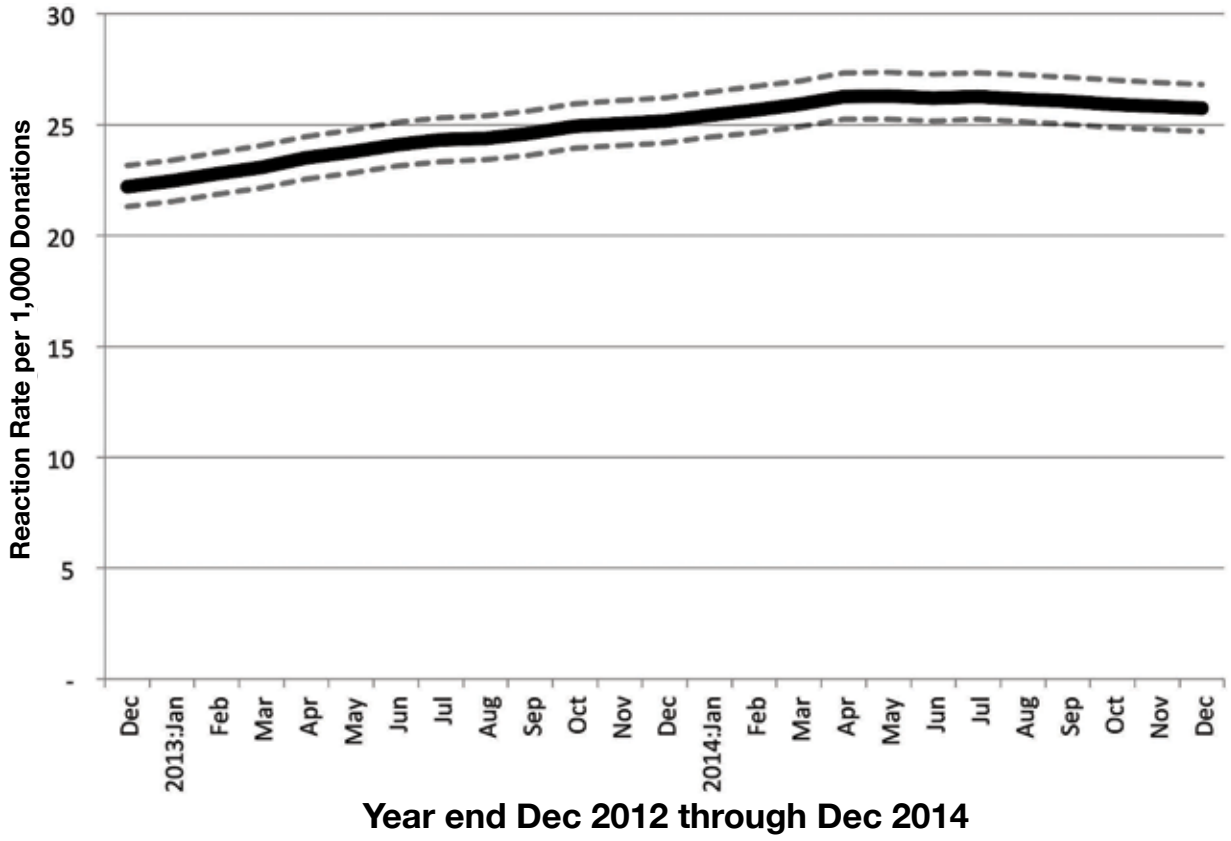


Table 4: Donation by Age Groups and month*						
	Age Groups					
	2012			2014		
Month	16-22 years	23-69 years	>70 years	16-22 years	23-69 years	>70 years
January	16,651 (16.9%)	75,871 (76.8%)	6,262 (6.3%)	19,732 (19.0%)	76,679 (73.9%)	7,339 (7.1%)
February	20,462 (21.6%)	69,216 (73.0%)	5,157 (5.4%)	24,382 (25.2%)	66,716 (68.9%)	5,767 (6.0%)
March	23,158 (22.4%)	74,805 (72.2%)	5,603 (5.4%)	26,378 (23.4%)	79,834 (70.7%)	6,729 (6.0 %)
April	24,696 (25.1%)	68,527 (69.7%)	5,121 (5.2%)	29,179 (25.6%)	78,245 (68.6%)	6,628 (5.8%)
May	18,297 (18.1%)	77,205 (76.4%)	5,523 (5.5%)	19,469 (19.1%)	76,394 (74.8%)	6,203 (6.1%)
June	9,624 (9.8%)	82,517 (84.4%)	5,669 (5.8%)	10,031 (10.2%)	82,033 (83.3%)	6,444 (6.5%)
July	10,049 (10.3%)	81,617 (83.8%)	5,776 (5.9%)	11,163 (10.7%)	86,256 (82.7%)	6,840 (6.6%)
August	12,079 (12.0%)	82,791 (82.1%)	5,930 (5.9%)	13,041 (12.7%)	83,023 (80.9%)	6,597 (6.4%)
September	19,622 (20.8%)	69,848 (73.9%)	4,997 (5.3%)	22,498 (22.1%)	73,073 (71.9%)	6,011 (5.9%)
October	23,243 (22.9%)	72,685 (71.8%)	5,364 (5.3%)	31,143 (24.3%)	89,249 (69.6%)	7,755 (6.1%)
November	21,939 (22.4%)	70,408 (71.8%)	5,669 (5.8%)	28,650 (25.0%)	78,596 (68.6%)	7,369 (6.4%)
December	13723 (15.4%)	70,120 (78.9%)	5,037 (5.7%)	18,599 (15.3%)	94,220 (77.6%)	8,537 (7.0%)

*Donations with complete donor age and month of donation information.

Figure 5 shows the 12 month moving average overall reaction rate over the time (to remove seasonality) with 95% confidence interval for five core organizations, which reported data from 2012 to 2014. There was an uptrend in the overall reaction rate from 2012 to 2014. The upward trend was driven by a large blood center that had an increase in reaction rate (from 18.3 per 1,000 donations in 2012 to 24.7 per 1,000 donations in 2014). Of the five core organizations, three organizations showed drop in the reaction rates from 2012 to 2014. Reaction rates ranged from 7.0 to 8.2 per 1,000 donations in an organization with the lowest reaction rates and from 33.5 to 37.3 per 1,000 donations in an organization with the highest reaction rates.

Figure 5: 12 month Moving Average Overall Reaction Rate Over Time for Five Core Organizations, with 95% Confidence Interval



Reactions by Gender:

While 52.7% of collections were from male donors, only 40.4% of reactions occurred in males in 2014. This is comparable to 2012, where 52.1% of collections were from male donors, and only 38.2% of reactions occurred in males. As in 2012, female donors were almost twice as likely to experience an adverse reaction when donating blood compared to males (28.7 versus 17.5 per 1,000 donations).

The aggregate blood donor adverse reaction rate was lower during the summer months for both males and females **(Figure 6)**. The seasonal effect was larger in donations from female donors. After the month of July, the reaction rate was lower for both males and females in 2014 compared to 2012. Similar to 2012, female donors were 2.2 times more likely to experience vasovagal reactions (22.5 versus 10.1 per 1,000 donations females to males) and 1.4 times more likely than were male donors to have local injury related to needle (3.7 versus 2.6 per 1,000 donations) **(Figure 7)**. Interestingly, males were twice as likely to experience apheresis reactions in 2012 and 2014 (2.2 versus 4.6 per 1,000 donations in 2014) when compared to females. However, further analysis based on gender and donation procedure type could not be conducted due to the univariate reporting by most participants in the denominator database.

Figure 6: Reaction Rate by Gender by Month

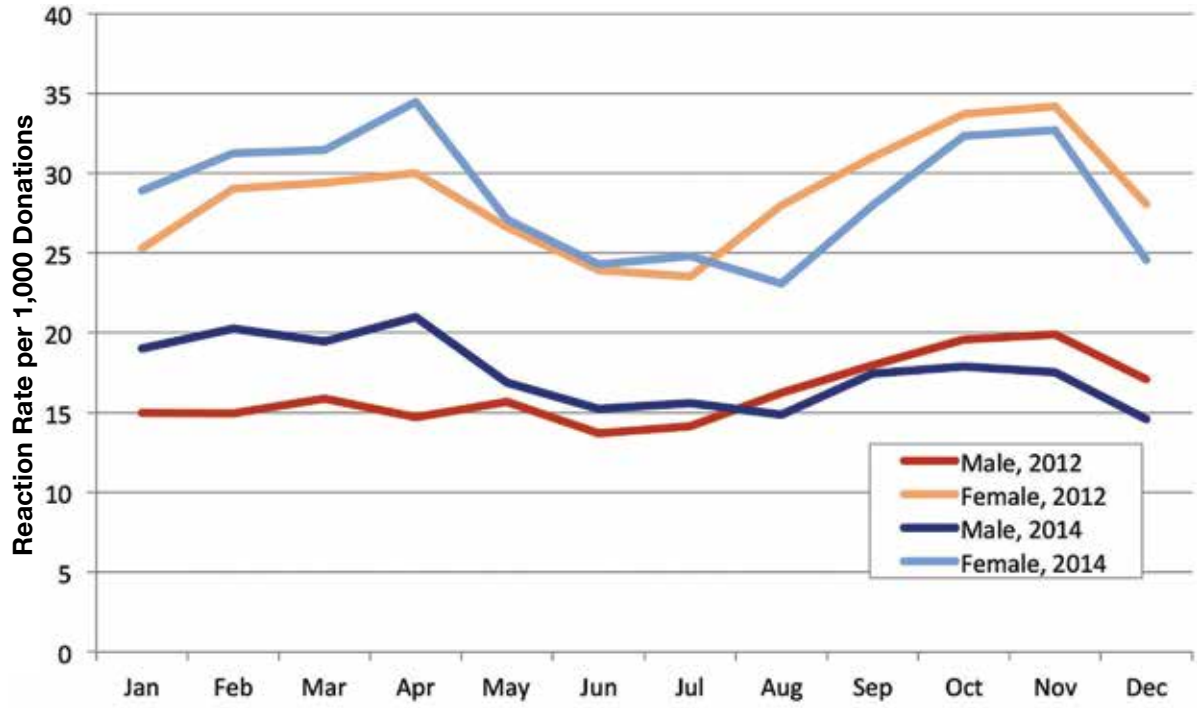
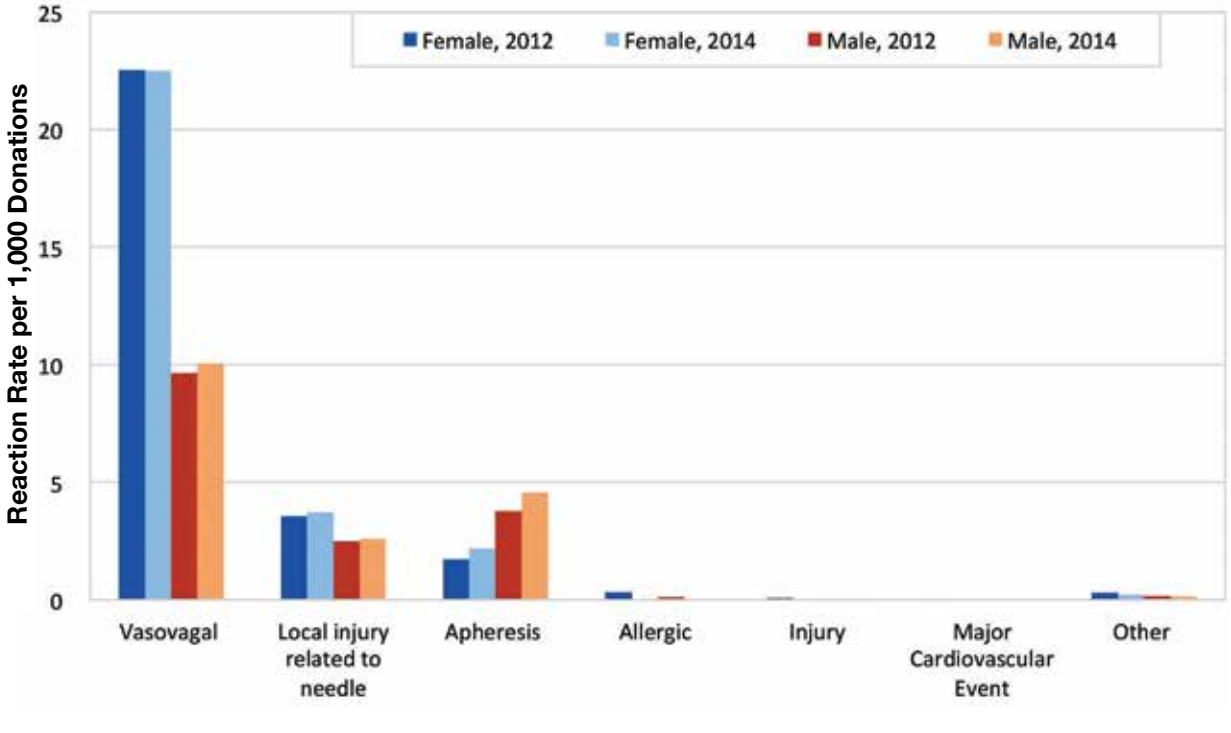


Figure 7: Reaction Rate by Donor Gender



Reactions by Age:

Overall, younger donors were more likely to experience an adverse reaction to blood donation **(Table 5)**. In 2014, donors aged 16-22 years contributed 19.5% of the donations reported, but accounted for 40.3% of adverse reactions and had a reaction rate of 47.0 per 1,000 donations ($p<0.001$ as compared to donor aged 23 and older). The younger donor effect was most evident in donors aged 16-18 years (29.0% of adverse reactions, 51.9 per 1,000 donations). In 2012, the 16-22 year old donor group contributed 18.2% of the donations, accounted for 38.2% of adverse reactions, and had a reaction rate of 46.5 per 1,000 donations ($p<0.001$ as compared to donor aged 23 and older).

In 2014, donors aged 23-69 years contributed 74.1% of the donations, but accounted for 56.1% of the adverse reactions and had a reaction rate of 17.3 per 1,000 donations ($p<0.001$ as compared to donor aged 70 and older). Among the donors aged 23-69 years, the donor group aged 23-29 years had the highest reaction rate (12.1% of adverse reactions; 29.8 per 1,000 donations). The reaction rate in the donor age group 23-69 years was comparable to 17.0 per 1,000 donations in 2012.

Table 5: Reaction Rate by age

Donor Age	Reaction Rate/1,000 Donations (Relative Risk Ratio*)	
	2012	2014
16-22	46.5 (2.1)	47.0 (2.1)
16 - 18	51.0 (2.3)	51.9 (2.3)
19 - 22	39.4 (1.8)	38.0 (1.7)
23-69	17.0 (0.8)	17.3 (0.8)
23 - 29	29.0 (1.3)	29.8 (1.3)
30 - 39	20.1 (0.9)	20.9 (0.9)
40 - 49	15.1 (0.7)	16.0 (0.7)
50 - 59	13.6 (0.6)	13.3 (0.6)
60 - 69	14.0 (0.6)	13.5 (0.6)
70+	13.4 (0.6)	12.8 (0.6)
70 - 79	13.2 (0.6)	12.8 (0.6)
>= 80	14.8 (0.7)	12.6 (0.6)

*Reaction rate compared to mean rate for overall population (22.2 per 1,000 in 2012 and 22.8 per 1,000 in 2014)

Figure 8 compares the reaction rate among the donors aged 16-22 year old with donors aged 23 and older for the five core organizations. The young donor effect persisted from 2012 to 2014.

The reaction rates for the older age group was comparatively stable over the period of observation, while the rate for the youngest donors (16-22 years) varied widely.

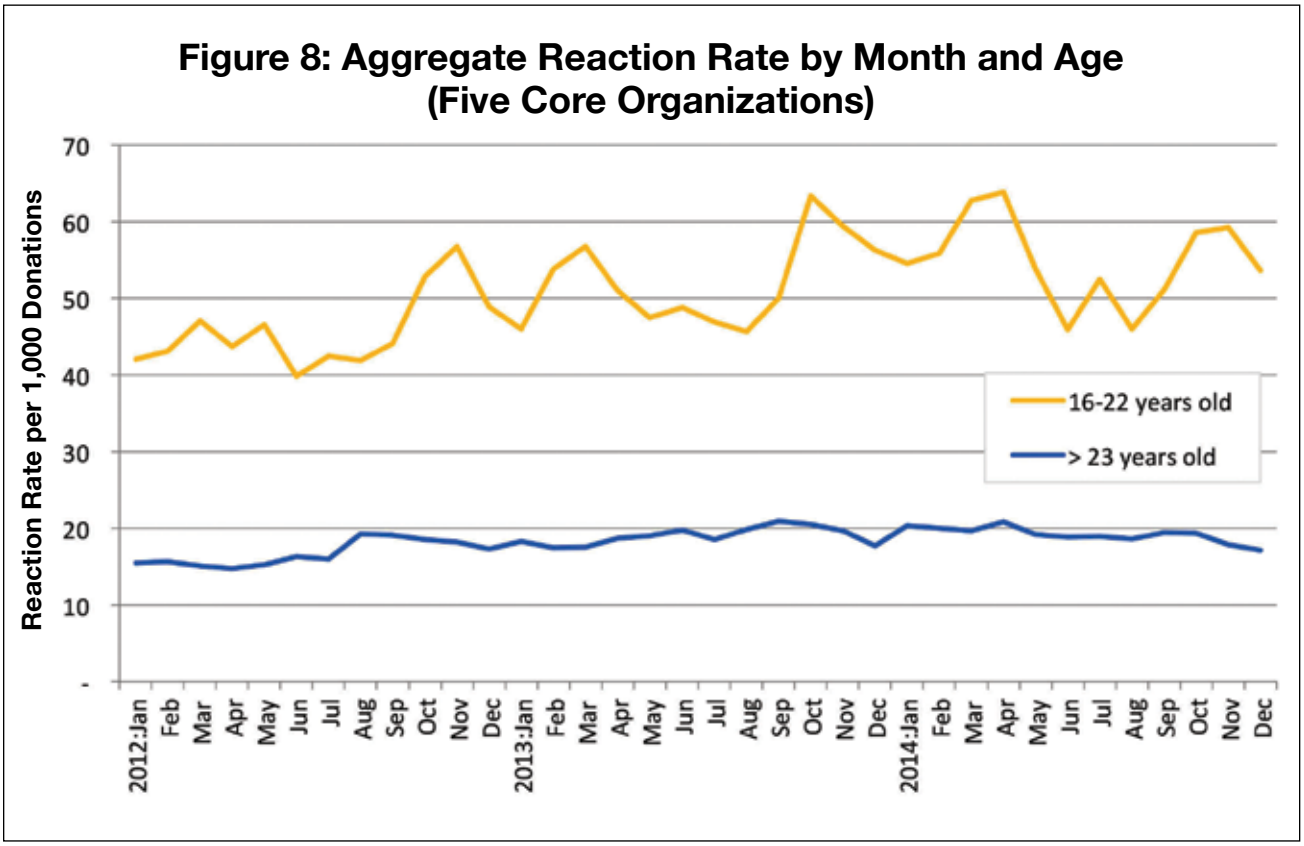
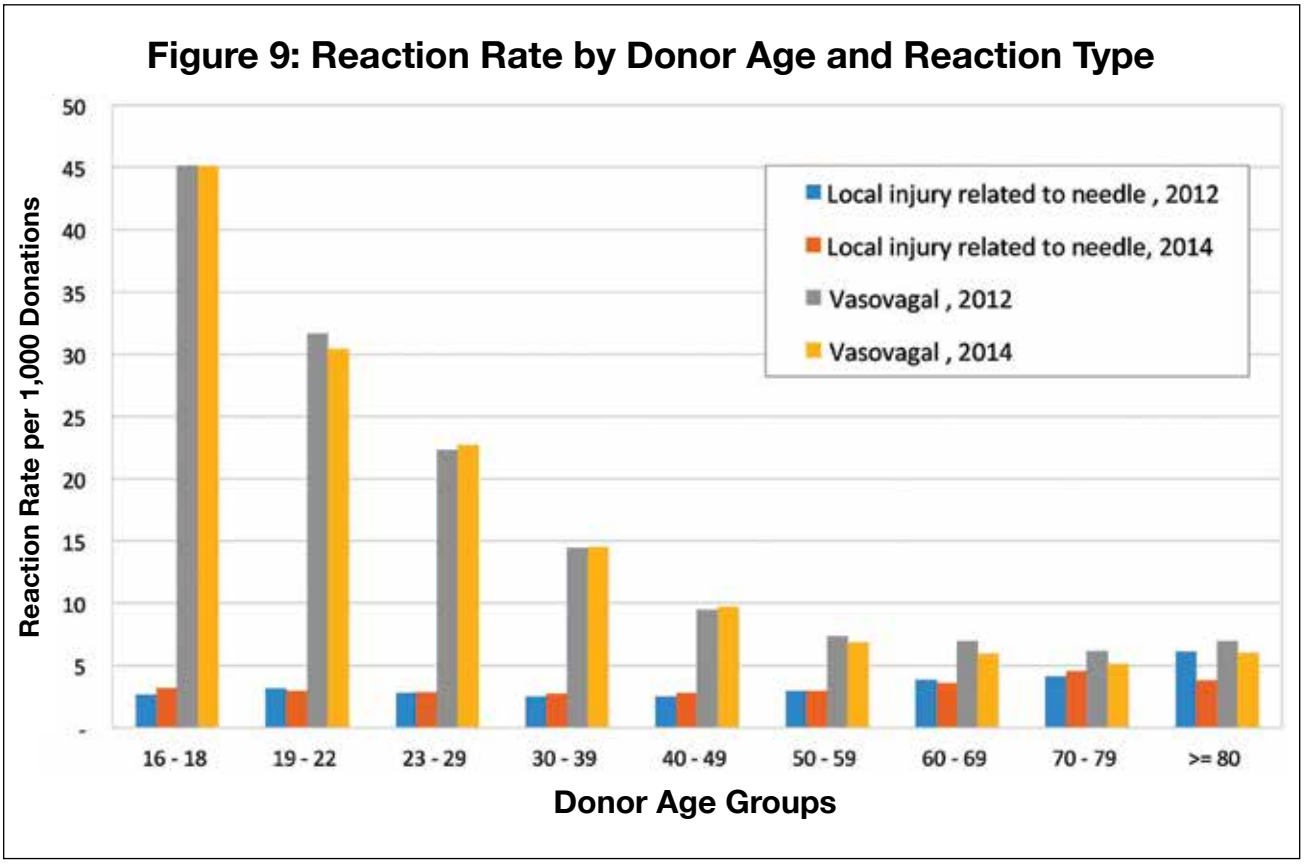


Figure 9 compares the rate of vasovagal reactions and local injuries related to needle by donor age groups. The downtrend of vasovagal reaction rates with donor age was apparent in both 2012 and 2014. Vasovagal reaction rates were consistently lower than 10 per 1,000 donations in donors aged 40 and older. Local injuries related to the needle were lowest among donors aged 16 to 59, lower than 3.0 per 1,000 donations, compared to the oldest donors (> 60 years). A similar trend was observed in 2012.

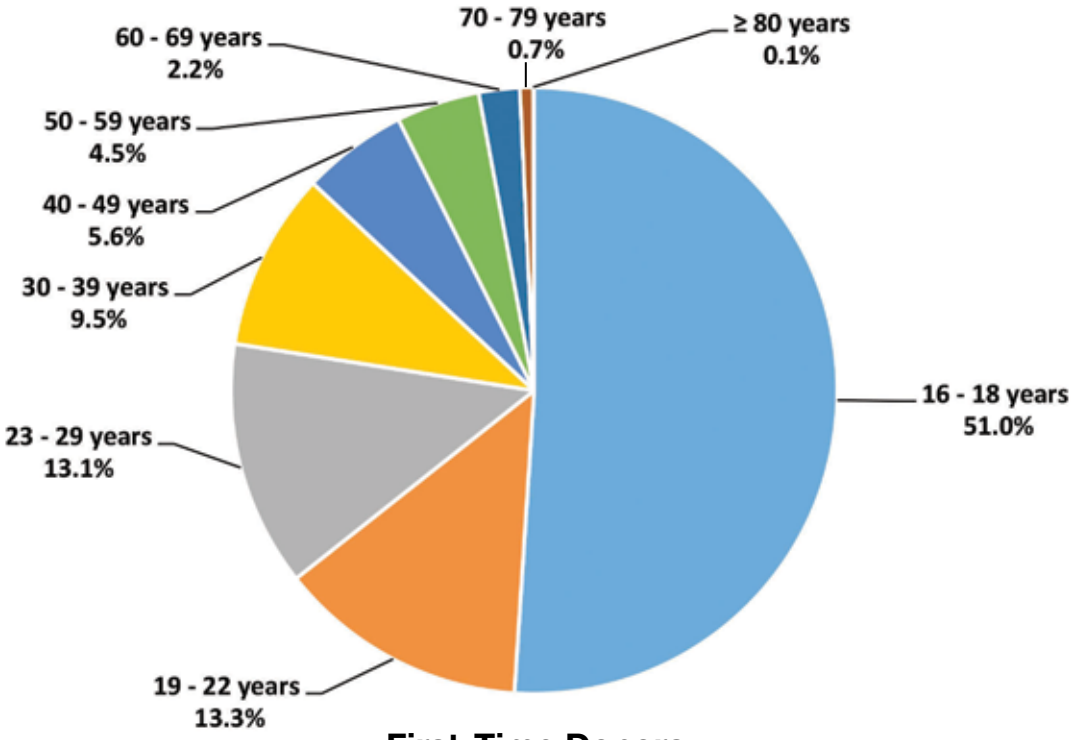


Reaction Rates by Donation History and Procedure Type:

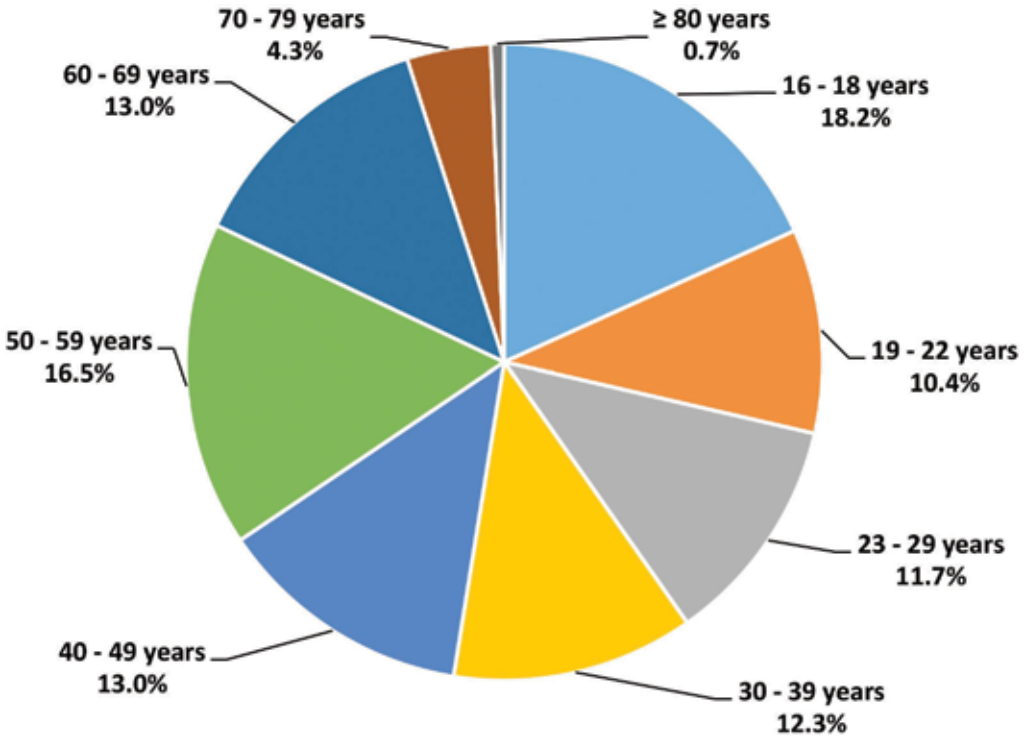
Overall, young first-time donors were more likely to experience an adverse reaction **(Figure 10)**. In 2014, donations from first-time donors represented only 15.7% of the donations, but made up 32.8% of adverse reactions for a reaction rate of 47.9 reactions per 1,000 donations. This was similar to 2012 where first-time donations accounted for 14.6% of the donations and 31.1% of adverse reactions, with a rate of 47.2 reactions per 1,000 donations.

In 2014, vasovagal reactions among first-time donors occurred at a rate of 41.9 reactions per 1,000 donations, comparable to 2012 (41.1 reactions per 1,000 donations in 2012) **(Figure 11)**. There was a slight increase in the apheresis reaction rate among repeat donors in 2014 (3.7 reactions per 1,000 donations in 2014 versus 2.9 reactions per 1,000 donations in 2012).

Figure 10: Reactions by Donation History and Donor Age

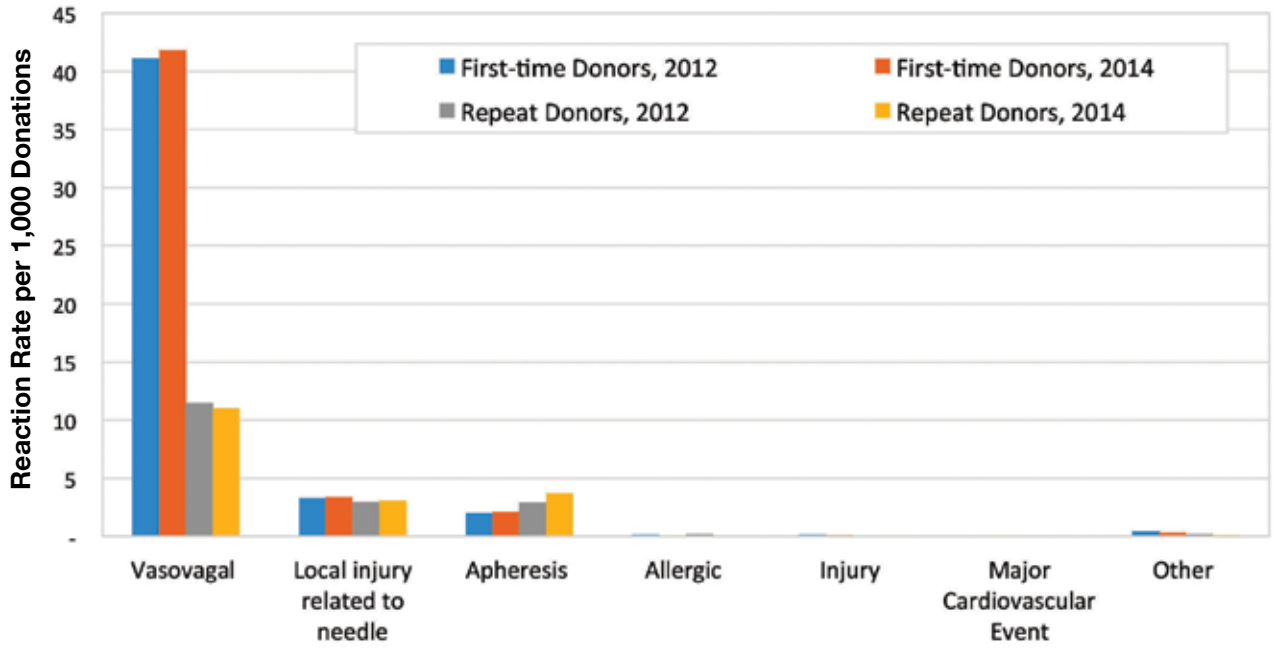


First-Time Donors



Repeat Donors

Figure 11: Reaction Rate by Donation History and Reaction Type



While 21.4% percent of donations were from automated procedures, 24.9% of all types of reactions were reported from these procedures. In 2012, automated collection procedures represented 24.1% of total collections with 24.2% total reactions reported.

Reaction Rates by Collection Site and Location:

Reaction rates by the type of collection site are reported in **Figure 12**. Similar to 2012, organizations reported the lowest reactions rates in mobile collection sites that used donor coaches, but the highest reaction rates at inside mobile collection sites (those requiring setups inside another facility: 27.1 versus 12.5 per 1,000 donations). Of the 37.6% of overall reactions in 2014 that had information on the location where the reactions began, 77.6% of reactions began on the donor bed, 12.9% of reactions began at the canteen, and 5.6% of reactions began off site **(Table 6)**. A smaller number of reactions also occurred at other on-site locations such as the rest-room (1.7%), in transit to the canteen (1.3%), in donor screening (0.8%) and donor registration (0.1%). In 2012, there were fewer reactions that occurred in bed (54.7%) and more reactions that occurred at canteen (23.9%), off site (13.1%), other on site location (4.0 %), screening (1.7%) and transit to canteen (2.4%).

Figure 12: Reaction Rate by Collection Site, 2012 - 2014

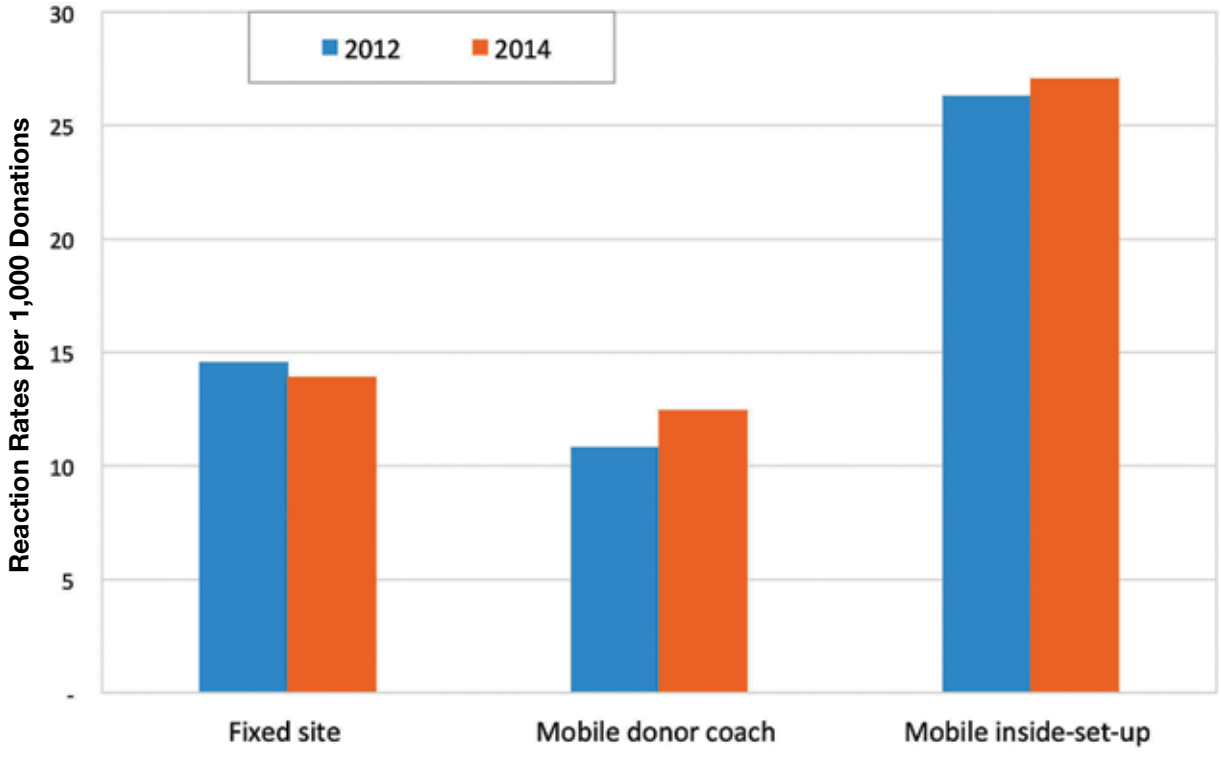


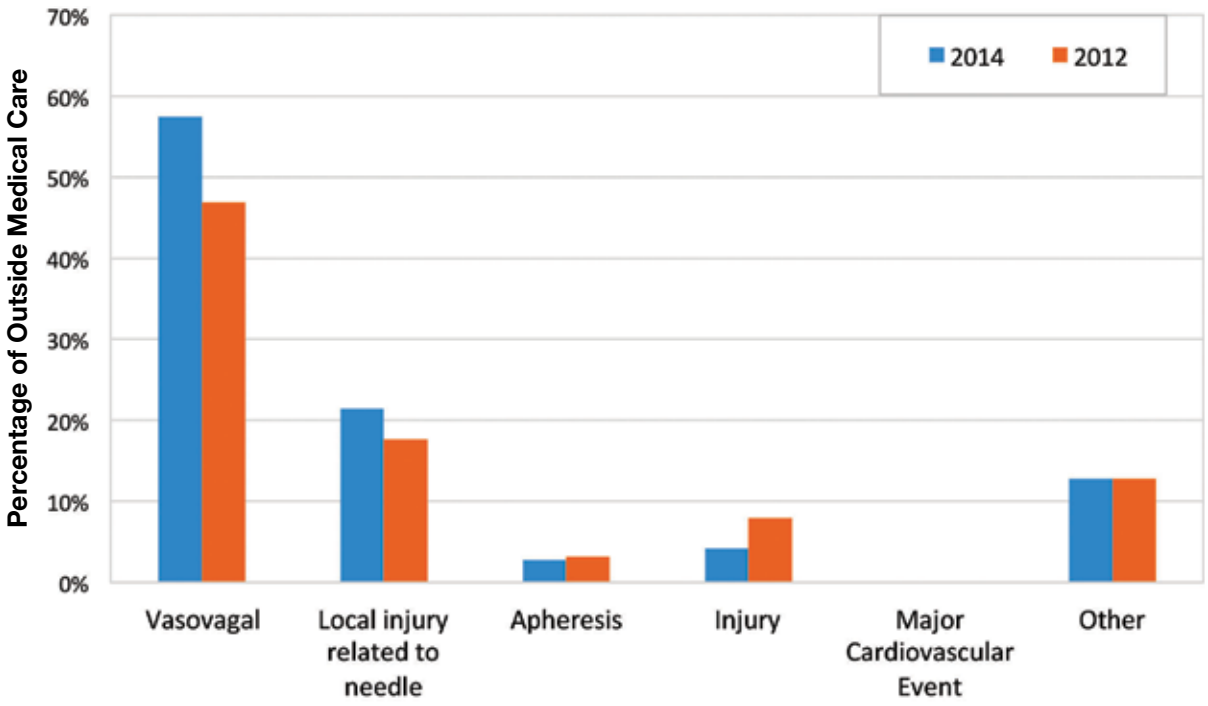
Table 6: Reported Reaction Location		
	Number of reactions (% among reactions with location)	
Location	2012 (n=4,538)	2014 (n=11,346)
Bed	2,484 (54.7%)	8,804 (77.6%)
Canteen	1,084 (23.9%)	1,468 (12.9%)
Off site	596 (13.1%)	635 (5.6%)
Other location on site	181 (4.0%)	190 (1.7%)
Registration	6 (0.1%)	9 (0.1%)
Screening	77 (1.7%)	91 (0.8%)
Transit to canteen	110 (2.4%)	149 (1.3%)

Outside Medical Care:

Of the 30,207 donor reactions reported in 2014, 289 were reported as requiring additional outside of blood center medical care (1.0 % of reactions). Of the 26,020 donor reactions reported in 2012, 352 (1.4% of reactions) were reported as requiring additional outside medical care. Among the cases requiring outside medical care, vasovagal reactions were the most common reaction type (57.4% and 46.9% of those reactions referred to outside care in 2014 and 2012 respectively; **Figure 13**). Local injury related to the needle represented the second most common type of reaction to require additional medical attention (21.5% in 2014 and 17.6% in 2012 of all reactions referred for additional care).

Of the reaction types in 2014, 25.5% (12/47) of all injuries (not needle related), 7.0 % (4/57) of allergic reactions, 1.5% (62/4,157) of local needle-related injuries, 0.8% (166/21,196) of vasovagal and 0.2% (8/4,517) of apheresis reactions required some outside medical care. Of the reaction types in 2012, 40.0% (28/70) of all injuries (not needle related), 15.5% (41/264) of allergic reactions, 1.8% (62/3,530) of local needle-related injuries, 0.9% (165/18,586) of vasovagal and 0.3 % (11/3,293)of apheresis reactions required some outside medical care.

Figure 13: Types of Donor Adverse Events among Cases requiring Outside Medical Care



4. Discussion

The need for a safe blood donation experience is paramount for donor recruitment and retention.[5-6] Active participation in national and international Donor Hemovigilance (DHV) program continues to be a simple, effective and direct way for blood centers to monitor performance and demonstrate a commitment to continuous improvement in donor outcomes to stakeholders including donors, patients, transfusion medicine colleagues, and the community.[7] Participation in DHV implies an effort to improve the donor care and safety infrastructure and a desire for national and international comparisons to determine best practices.

Data Elements:

US blood collection organizations collect data from donors and donation procedures. Most US blood collection organizations have data from four categories: donor, donation, reaction, and denominator. DonorHART™ allows data collection as well as analysis for some basic statistics and benchmarking with other blood centers.

Certain data elements are consistently reported to DonorHART™, including donor age, donation history, donation type, donor gender, procedure type and collection site. Other data elements including ethnicity, race, pulse and weight have not been uniformly reported. The decrease in the proportion of data elements reported in 2014 corresponds to the introduction of the DonorHART™ Lite tool, a version of DonorHART™ where only a critical, core subset of data is requested from the users. Blood collection organizations may not be able to report all data elements because of lack of electronic recording (manual nature of specific data elements), or lack of recording, in any form, of such data elements. In 2014, we observed some data reporting related to device manufacturer device model, device software and container manufacturer.

Denominator Data and Donor Demographics:

The 2014 AABB DHV database represents approximately 9% of the US donations.[8] Most organizations contributing data to DonorHART™ report denominator data categorically. Comparable to 2012, donors in 2014 were slightly more likely to be male (52.7%) compared to female (47.2%), and were repeat donors (84.3%) compared to first time donors (15.7%). Nearly 98% of donations were allogeneic donations and the remaining donation types reported included autologous, directed, and therapeutic. Donations were predominantly whole blood donations (78.3%), a slight increase compared to 2012 (75.5%). As in 2012, in 2014 younger donors donated less frequently during the summer months.

Reaction Rates:

The overall donor adverse reaction rate in 2014 was 22.8 per 1,000 donation procedures, comparable to 2012 (22.2 per 1,000 donation procedures). Vasovagal reactions remained the most common reaction type in 2014. 84.8% of these reactions were categorized into “Prefaint” with no actual loss of consciousness (uncomplicated or minor). In 2014, all complicated vasovagal reactions were categorized as vasovagal reactions with loss of consciousness. Local injury related to needle was the second most common type of reaction in 2014 as well as 2012 (3 per 1,000 donations), with hematoma or bruise being the most common of this reaction category.

Reaction rates and the reporting protocols vary among blood collection organizations, even collection sites within the same organization. The reaction rates reported by the blood centers cannot readily be compared to each other since reporting thresholds and procedures are specific to each organization. However, changes within an organization or at a collection center are more meaningful and may reflect changes in practices, policies, or procedures. DonorHART™ allows blood centers to review and monitor performance over time and compare different collection sites within an organization. Monitoring internal variation within an organization is the most valuable contribution of DonorHART™ at this time. Future studies and more information from

collection centers may identify why rates vary so much.

Younger donors were more likely to have an adverse event from blood donations compared to older donors, an observation similar to 2012. Donors aged 16-22 years contributed 19.5% of the donations reported, but accounted for 40.3% of adverse reactions and had a reaction rate of 47.0 per 1,000 donations, significantly higher compared to donors aged 23 and older ($p<0.001$). The younger donor effect was more evident in donors aged 16-18 years (29.0% of adverse reactions, 51.9 per 1,000 donations). This younger donor effect is also consistent with results from previous studies.[3-4]

Female donors were almost twice as likely to experience an adverse reaction to donating blood compared to males (28.7 versus 17.5 per 1,000 donations). While 52.7% of collections were from male donors, only 40.4% of reactions occurred in males. These results are consistent with the AABB Donor Hemovigilance Report 2012 and supports results from other published studies.[4,9]

In 2014, donations from first-time donors represented only 15.7% of the donations, but made up 32.8% of adverse reactions for a reaction rate of 47.9 reactions per 1,000 donations. There was a slight increase in the apheresis reaction rate among repeat donors (3.7 reactions per 1,000 donations in 2014 versus 2.9 reactions per 1,000 donations in 2012). Future prospective studies may help us understand adverse outcomes of repeat blood donations.

As reported in 2012, reaction rates appeared to vary based on the collection site. Lowest overall reactions rates were reported in mobile collection sites that used donor coaches, but the highest reaction rates were reported at mobile collection sites requiring setups inside the building of the mobile location (27.1 versus 12.5 per 1,000 donations). Compared to 2012, there was reduction in reported adverse events that began off site (5.6% in 2014 compared to 13.1% in 2012). Factors like donation environment, trained staff, bed arrangements and lighting could impact outcomes of blood donation at different collection sites. Reporting and coordination of reports back to the collection center is critical to understanding what happens to donors after they leave the collection site. Participation in a Donor Hemovigilance (DHV) program can help blood centers monitor their own performance and evaluate important factors to reduce donor adverse reactions and to establish best practices.

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