

also excluded 49 WB collection events in which a citrate reaction was recorded because these records most likely represent miscoding or misclassification of complications after WB donation, as well as 43 PLT donations and 45 R2 donations recorded for 16-year-old donors. Donor age was not recorded for 94 WB and 2 PLT donations.

Complications experienced by donors before the donation process or unrelated to phlebotomy (e.g., injuries caused by other accidents at the site) or experienced by individuals who did not donate blood (e.g., canteen volunteers) were excluded from the analysis. The denominator for the number of donations of each procedure type was the number of satisfactory collections plus the number of incomplete ("quantity not sufficient") collections. Donor complication rates were calculated per 10,000 collections for minor and major complications and for cases receiving outside medical care for different donor age groups.

Statistical analysis

Complication rates for different procedure types and among different age groups were compared by calculating odds ratios (ORs) and 95 percent confidence intervals (CIs; InStat, GraphPad, Inc., San Diego, CA). Linear regression and analysis of variance for the correlation between the proportion of young donors and monthly complications rates was performed with computer software (SAS Version 9.1.3, SAS Institute, Inc., Cary, NC).

A multivariate logistic regression analysis was performed to identify demographic variables that were independently associated with complications after WB, R2, or PLT donations using software (SAS STAT, SAS Institute, Inc.). There was an inverse and nonlinear relationship between donor age and the rate of complications, and complications were disproportionately represented in donors under age 20 and fairly constant above age 20. Consequently, the multivariate analysis considered the donors in the age groups as 16-year-olds, 17-year-olds, young adults (18- and 19-year-olds), and adults in each subsequent decade (e.g., 20-29, 30-39, up to 80+). A "STEP-WISE" selection method was used to determine which effects entered the logistic regression model and also which effects remained in the model. A significance level of not greater than 0.05 was necessary for an effect to enter into the model and a significance level of not greater than 0.05 was necessary for an effect to remain in the model at any iteration step. The regression analyses for WB, PLT, and R2 procedures evaluated the independent variables (regional blood center, donor age, sex, donation status) and the dependent outcome (any complication). Outlier regions that performed fewer than 150 procedures in 2006 were not reported (three regions) in the R2 model. The ARC Institutional Review Board determined that the research was exempt under 45CFR46, 21CFR50.

RESULTS

Donations and donor complications at regional blood centers

In 2006, the donor hemovigilance program analyzed a total of 6,014,472 WB, 449,594 PLT, and 228,183 R2 collections, which were associated with 209,815, 25,966, and 12,282 adverse reactions (348.9, 577.5, and 538.3 per 10,000 donation), respectively. Minor symptomatic (presyncopal) reactions accounted for the majority of complications (258.3 per 10,000 collections) for WB, and small hematomas, for PLT and R2 donations (377.0 and 217.9 per 10,000 collections, respectively; Table 2). Excluding large hematomas, the overall rates of major complications were 7.4, 5.2, and 3.3 per 10,000 collections for WB, PLT, and R2 procedures, respectively (Table 2).

Regional and monthly variability in complications after WB donation

The complication rates observed for WB donation in the 36 regions demonstrated considerable regional and monthly variability; the systemwide mean was 348.9 ± 140.7 (range, 145.9-679.5) complications per 10,000 donations (Fig. 1). The overall WB complication rates in the 36 regions were normally distributed and 24 regions were within 1 standard deviation (SD) of the mean, and 34 regions were within 2 SDs of the mean (data not shown). For adverse reactions recorded by collection staff, mean monthly rates of reactions at the donation site varied over a wider range for the small- and medium-sized regions (approx. 57,000-207,000 WB collections per year) compared to the largest regions (with $>208,000$ WB collections per year).

Complication rates across the system demonstrated seasonal variation that was most pronounced for WB donation and strongly correlated with donor age. Specifically the rates of systemic (syncopal-type) complications (i.e., presyncope, LOC, injury, prolonged recovery) and the proportion of young donors (16-19 years old) for WB and R2 donations were higher in the spring and autumn compared to the winter and summer, whereas the rates of phlebotomy-related complications remained constant throughout the year (Fig. 2A). Systemic (syncopal-type) complications after WB donation correlated strongly with the proportion of donors less than 20 years old ($R^2 = 0.96$) and logistic regression demonstrated that the model explains a significant portion of the variation in the data ($F = 248.00$; $p < 0.0001$). Monthly variation was substantially less pronounced for systemic (syncopal-type) complications after automated collections (Fig. 2B) and did not correlate as strongly with the proportion of donors less than 20 years old as observed for WB ($R^2 = 0.58$; $p = 0.004$); no correlation was observed for PLT donations ($R^2 = 0.03$; $p = 0.58$).

TABLE 2. Rates of complications after WB and automated collections per 10,000 donations

Complications	WB (6,014,472)	Apheresis PLTs (449,594)	R2 (228,183)
Systemic (syncopal-type) complications			
Presyncopal (symptomatic, pre-faint)	258.3	61.3	195.2
Short LOC	7.9	2.1	6.5
Major			
Long LOC	1.8	0.5	0.9
Prolonged recovery	2.4	0.8	1.0
Injury	1.1	0.3	0.1
Systemic (other) complications			
Citrate			
Minor		121.4	112.8
Major		2.2	0.4
Allergic (minor, major)	0.1	0.4	0.2
Other (minor, major)	0.6	1.0	1.0
All systemic			
Rate	272.1	190.1	317.9
Number of events	163,663	8,546	7,255
OR* (95% CI)	1.00	0.69 (0.68-0.71)	1.17 (1.15-1.20)
Phlebotomy-related complications			
Small hematoma			
Major	74.5	377.0	217.9
Large hematoma			
Large hematoma	0.4	9.4	1.9
Suspected nerve irritation	0.7	0.8	0.1
Suspected arterial puncture	1.1	0.2	0.4
Phlebotomy-related			
Rate	76.7	387.5	220.3
Number of events	46,152	17,420	5,027
OR (95% CI)	1.00	5.21 (5.12-5.31)	2.91 (2.83-3.00)
All reactions			
Rate	348.9	577.5	538.3
Number of events	209,815	25,966	12,282
OR (95% CI)	1.00	1.70 (1.67-1.72)	1.57 (1.54-1.60)
Major reactions			
Rate†	7.4	5.2	3.3
Number of events	4,443	232	76
OR (95% CI)	1.00	0.70 (0.61-0.80)	0.45 (0.36-0.57)
Outside medical care			
Rate	3.2	2.9	2.9
Number of events	1,903	132	66
OR (95% CI)	1.00	0.93 (0.78-1.11)	0.91 (0.72-1.17)

* ORs shown for univariate analyses compared to the rate for WB collections.

† Excluding large hematoma; univariate comparison of donation types.

Allogeneic WB donation and complications

The most common complications associated with allogeneic WB collections were systemic (syncopal-type) reactions (272.1 per 10,000 donations), most of which were mild symptomatic (presyncopal, pre-faint) reactions that occurred at an overall rate of 258.3 per 10,000 donations (2.5%; Table 2). Of the major reaction categories, the most frequently reported was prolonged recovery (2.4 per 10,000 donations) or LOC for more than 1 minute (1.8 per 10,000 donations). The overall complication rate decreased with increasing donor age (Fig. 3) for both first-time and repeat donors (data not shown).

Young donors (<20 years old) accounted for 874,922 (14.5%) WB donations in 2006 and had a significantly higher reaction rate than older donors (Fig. 3). An analysis of complications in these young donors is presented elsewhere.¹⁰ Multivariate analysis confirmed that regional blood center, age, sex, and first-time donation

status are independent correlates for adverse events (Table 3). Donor age was the strongest independent predictor of complications; the effect of age effectively leveled off above age 40, although the differences between age groups was still significant. Other variables, including donor race, height, and weight, were not available on all donations for inclusion in this analysis. The overall complication rate was lower but the proportion of small hematomas was higher in the older age group (>60 years) compared to younger age groups (Fig. 3).

Overall, 1,903 WB donors had outside medical care documented after a complication, for a rate of 3.2 per 10,000 collections. Forty-six of these donors reported hospitalization after donation. The observed rate of reported outside medical care after WB donation was higher after first-time (5.7 per 10,000) compared to repeat (2.6 per 10,000) donations (OR, 2.2; 95% CI, 2.0-2.4). Major

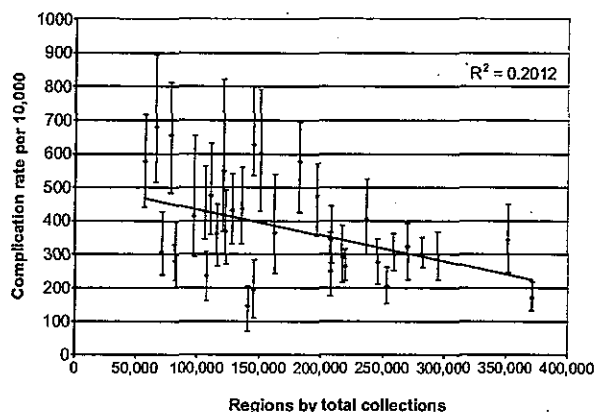


Fig. 1. Variability in rate of complications among ARC blood centers. The 36 regional blood centers are ordered by total collections in 2006 and plotted against their mean monthly overall complication rate per 10,000 collections. Bars show the maximum and minimum monthly complication rate for each center.

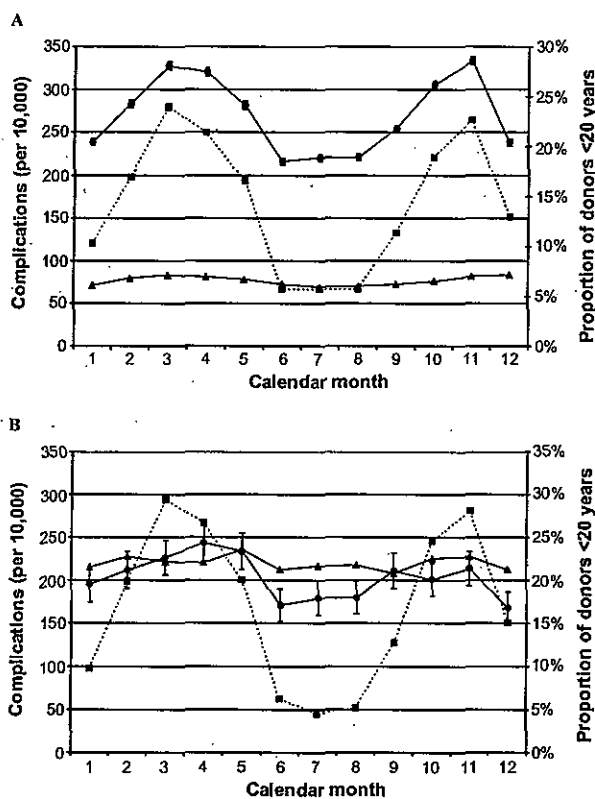


Fig. 2. Seasonal variability in donation-related complications correlates with the proportion of young donors. (A) WB; (B) R2. (●) Systemic (syncopal-type) complications; (▲) phlebotomy-related complications; (■, dotted line) proportion of donors less than 20 years old.

syncopal-type reactions (long LOC, LOC or presyncope with injury, prolonged recovery) accounted for approximately half (46%) of all reactions associated with outside medical care (Fig. 6A).

Automated collection procedures and donor complications

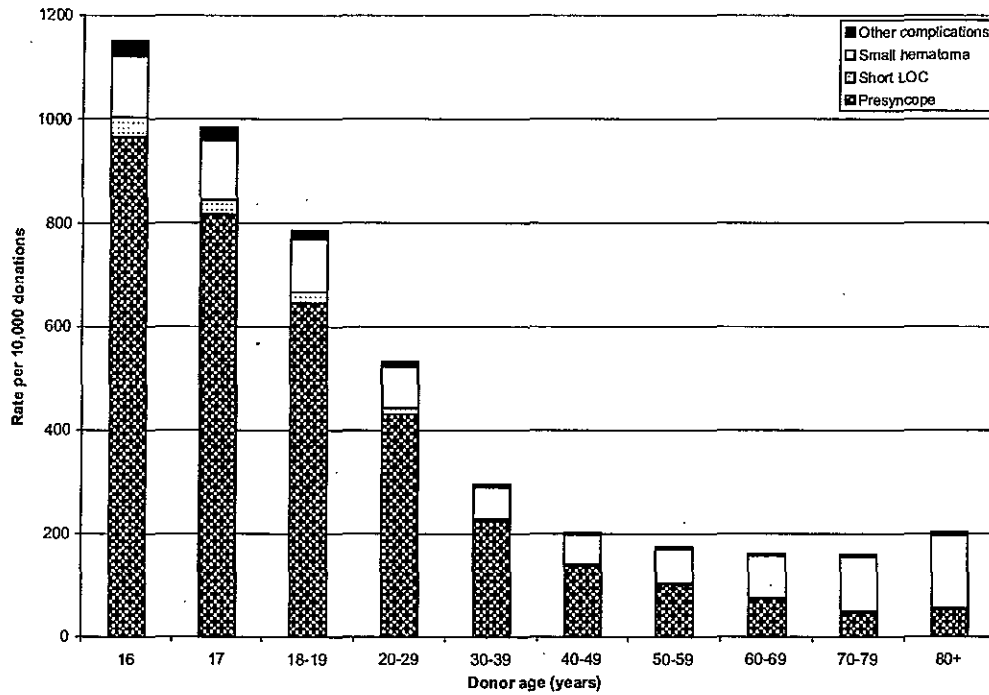
The most common complications associated with PLT and R2 donations were hematomas, followed by systemic citrate and syncopal-type reactions (Table 2). The rate of systemic reactions was lower for PLT donations (OR, 0.69; 95% CI, 0.68-0.71) and slightly but significantly higher for R2 donations (OR, 1.17; 95% CI, 1.15-1.20) compared to WB collections in a pairwise, univariate analysis (Table 2). The rate of major reactions, however, was significantly lower for both PLT (OR, 0.70; 95% CI, 0.61-0.80) and R2 (OR, 0.45; 95% CI, 0.36-0.57) collections. The rate of outside medical care was not significantly different for PLT and R2 (2.9 per 10,000) collections compared to WB (3.2 per 10,000) collections (Table 2).

As with WB donation, younger donors were more likely to experience complications after PLT (Fig. 4) and R2 (Fig. 5) collection, but the influence of age on the rate of donor complications was considerably less pronounced. Multivariate analysis confirmed that regional blood center, age, sex, and first-time donation status are independent correlates for adverse events (Table 3). Age was a strong independent predictor of complications, but there were no differences in complication rates in age groups above age 50 for R2 and above age 30 for PLT donation. Significant differences were observed among regional blood centers.

The observed rate of reported outside medical care was not different for WB (3.2 per 10,000) compared to automated procedures (2.9 per 10,000), but the composition of reaction types differed. Phlebotomy-related complications (large hematoma, possible nerve irritation) accounted for 39 percent of outside medical care reported after automated collections (Fig. 6B). Eight of these 198 donors reported hospitalization after donation.

DISCUSSION

A safe and adequate blood supply encompasses efforts to minimize the risk to the blood donor as well as the transfusion recipient. The present analysis represents the first report of the comprehensive ARC donor hemovigilance program. The data confirm the overall safety of blood donation and provide an estimate of risk currently associated with allogeneic WB and automated collection procedures. We have used the data internally for program and procedure development and have shared the data externally with various organizations to evaluate the impact of regulatory guidance and inform public policy. For



Donor age (years)	16	17	18-19	20-29	30-39	40-49	50-59	60-69	70-79	80+
Total donations	46,274	404,033	424,615	812,190	822,429	1,319,311	1,314,912	616,876	223,185	30,553

Fig. 3. Rates of donor complications associated with allogeneic WB donation. The overall rates are significantly ($p < 0.05$) different between each successive age group, except between the 60- to 69- and 70- to 79-year age groups.

example, the lower rates of serious reactions with automated PLT collections compared to WB collections served as the basis for a response to the FDA draft guidance on collection of PLTs by automated methods¹³ to demonstrate that additional requirements for medical supervision at the collection site were unwarranted and would unnecessarily restrict PLT collection and availability. These data support the conclusions reached by others that plateletpheresis is associated with the lowest rate of systemic reactions compared to other collection procedures.¹⁴

The AABB has proposed the establishment of a national biovigilance program that would include a donor adverse reaction component.¹² The national collection of donor complication data is currently constrained by the different definitions of reactions and data collection procedures in use by blood centers in the United States, which prevents direct comparisons between the complication rates reported by various blood collection agencies. We now demonstrate that even in a large multicenter system utilizing standardized protocols, considerable variability is apparent in reported reaction rates among different regional blood centers. Reaction rates are known to vary with donor age, gender, race, weight, and first-

time donation status.⁶⁻¹⁰ A major source of the variability we observed between regions relates to donor demographics, as evident by the strong correlation of higher reaction rates with the higher proportion of young donors in spring and fall compared to summer and winter. Nevertheless, we show that the blood region was also independently associated with complications separate from donor characteristics (age, donation status, and sex), suggesting that regional practices may affect the likelihood of reactions or the recognition and reporting of those reactions. Regional variability likely cannot be eliminated because of the inherent subjectivity in evaluating and recording donor complications. Any comparison of complication rates between different regional centers, for example, to evaluate staff performance or compare collection equipment, could be misleading. Despite the variability among regions, data from an individual region or a small subset of regions in a more controlled operational trial have proven useful to evaluate donor complications associated with implementation of new collection procedures or new equipment (data not shown). Further analysis of the regional variability may provide insight into practices consistently associated with lower complication rates.

TABLE 3. Multivariate logistic regression analysis of donor complications

Effect	WB		R2		Apheresis PLTs	
	Point estimate	95% Wald CI	Point estimate	95% Wald CI	Point estimate	95% Wald CI
Age (years)						
16	3.42	3.14-3.73	NA	NA	NA	NA
17	3.33	3.07-3.62	2.94	1.56-5.55	1.77	1.37-2.28
18-19	3.11	2.87-3.37	3.02	1.60-5.70	1.69	1.37-2.08
20-29	2.25	2.07-2.44	2.83	1.50-5.33	1.30	1.08-1.56
30-39	1.33	1.22-1.44	2.30	1.22-4.33	1.06	0.88-1.28*
40-49	0.95	0.88-1.03*	1.95	1.04-3.67	0.90	0.75-1.08*
50-59	0.84	0.78-0.92	1.84	0.98-3.46*	0.92	0.77-1.11*
60-69	0.80	0.73-0.87	1.81	0.96-3.41*	0.95	0.79-1.14*
70-79	0.80	0.73-0.87	1.69	0.89-3.23*	0.84	0.70-1.02*
80+	1.00 (referent)		1.00 (referent)		1.00 (referent)	
Sex						
Male	0.56	0.55-0.56	0.64	0.60-0.68	0.53	0.52-0.55
Female	1.00 (referent)		1.00 (referent)		1.00 (referent)	
Donation status						
First	2.00	1.98-2.02	1.33	1.25-1.40	2.04	1.83-2.28
Repeat	1.00 (referent)		1.00 (referent)		1.00 (referent)	
Region						
A	0.90	0.86-0.94	3.61	2.72-4.80	1.99	1.75-2.26
B	2.00	1.90-2.10	1.18	0.16-8.83*	2.25	1.94-2.62
C	0.90	0.86-0.95	0.88	0.65-1.19*	0.98	0.85-1.13*
D	1.11	1.06-1.16	1.90	1.42-2.55	1.52	1.34-1.72
E	0.82	0.78-0.86	1.15	0.86-1.54*	1.83	1.61-2.08
F	2.12	2.01-2.24	5.34	3.72-7.68	1.58	1.34-1.85
G	2.46	2.35-2.58	3.52	2.60-4.77	2.48	2.18-2.83
H	0.84	0.80-0.88	1.00	0.72-1.38*	1.54	1.35-1.76
I	0.54	0.51-0.57	0.89	0.66-1.19*	2.12	1.87-2.40
J	0.85	0.81-0.90	1.18	0.87-1.60*	2.72	2.34-3.15
K	1.96	1.87-2.06	1.56	1.16-2.09	2.54	2.20-2.92
L	1.25	1.19-1.31	1.68	1.25-2.26	3.15	2.77-3.58
M	1.10	1.05-1.16	1.15	0.82-1.63*	1.68	1.45-1.96
N	0.44	0.42-0.47	0.26	0.18-0.36	2.13	1.82-2.48
O	0.82	0.78-0.86	NA	NA	0.75	0.64-0.88
P	1.40	1.33-1.46	NA	NA	1.37	1.20-1.57
Q	0.59	0.56-0.62	0.44	0.32-0.60	1.35	1.17-1.55
R	1.20	1.14-1.26	2.80	2.04-3.83	2.47	2.14-2.84
S	0.79	0.74-0.84	0.46	0.29-0.72	0.09	0.04-0.20
T	0.93	0.89-0.98	2.76	2.07-3.69	0.64	0.54-0.77
U	1.39	1.32-1.46	1.70	1.25-2.32	0.13	0.10-0.19
V	0.94	0.89-1.00	0.74	0.52-1.04*	2.98	2.55-3.48
W	1.98	1.89-2.07	2.00	1.49-2.67	1.84	1.61-2.10
X	0.62	0.59-0.66	0.24	0.16-0.37	2.29	1.95-2.68
Y	2.39	2.27-2.52	4.13	3.07-5.54	2.22	1.91-2.56
Z	1.24	1.17-1.30	1.91	1.39-2.63	0.81	0.70-0.94
AA	1.36	1.29-1.43	1.39	1.03-1.87	2.22	1.93-2.55
BB	1.33	1.27-1.40	4.53	3.37-6.08	2.69	2.35-3.09
CC	1.10	1.04-1.17	0.83	0.57-1.19*	0.44	0.34-0.56
DD	1.64	1.56-1.71	1.77	1.32-2.39	2.06	1.79-2.38
EE	1.30	1.24-1.37	1.01	0.70-1.45*	1.01	0.86-1.19*
FF	1.05	0.99-1.12*	1.24	0.91-1.70*	0.03	0.01-0.07
GG	1.10	1.05-1.15	1.81	1.35-2.43	1.44	1.26-1.63
HH	2.15	2.04-2.26	NA	NA	1.07	0.86-1.35
II	0.69	0.65-0.73	0.42	0.28-0.65	0.55	0.46-0.65
JJ	1.00 (referent)		1.00 (referent)		1.00 (referent)	

* Not significant.

Our experience also delineates the limitations of a national hemovigilance program and identifies opportunities for future improvement that may be tracked by the program. The approach to classify the type of complication rather than to capture specific signs or symptoms simplifies data collection, but we recognize that our definitions of donor complications are not mutually exclusive;

for example, donors in the prolonged recovery category may also have had LOC as a feature of their reaction. This redundancy leads to having more than one code that can be used to describe a reaction; in addition, more than one type of reaction is possible. In both circumstances, staff is instructed to record the reaction based on the most severe symptoms. This subjectivity in evaluation and

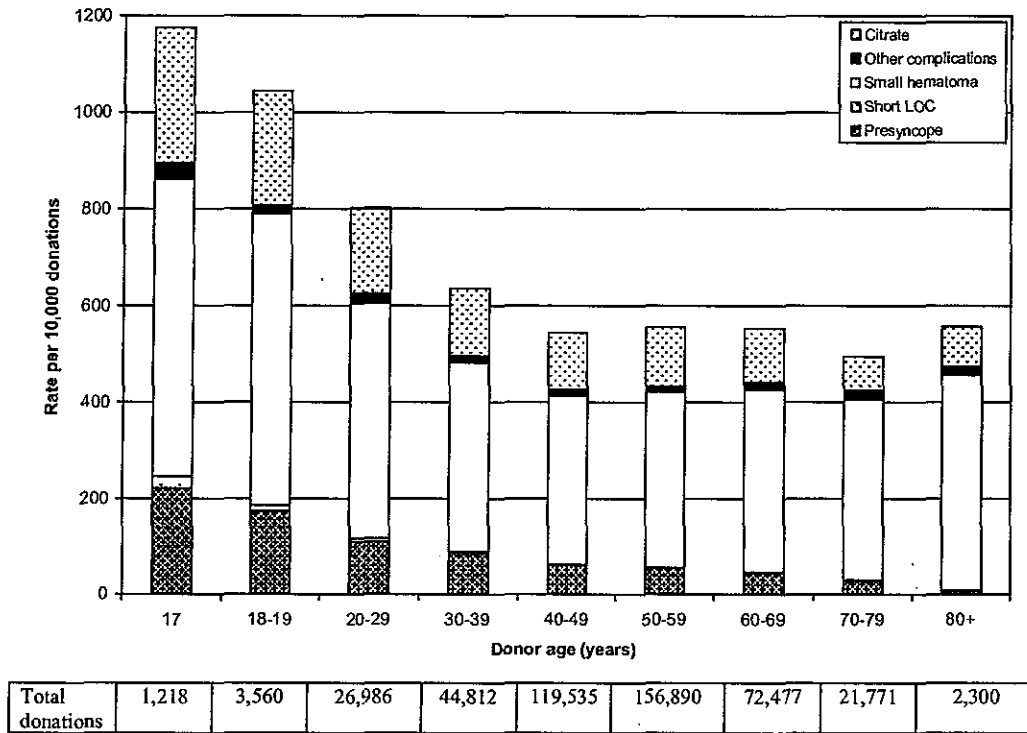


Fig. 4. Rates of donor complications associated with apheresis PLT donation. Differences in overall rates between successive age groups are different ($p < 0.05$) between 18- to 19-, 20- to 29-, and 30- to 39-year groups.

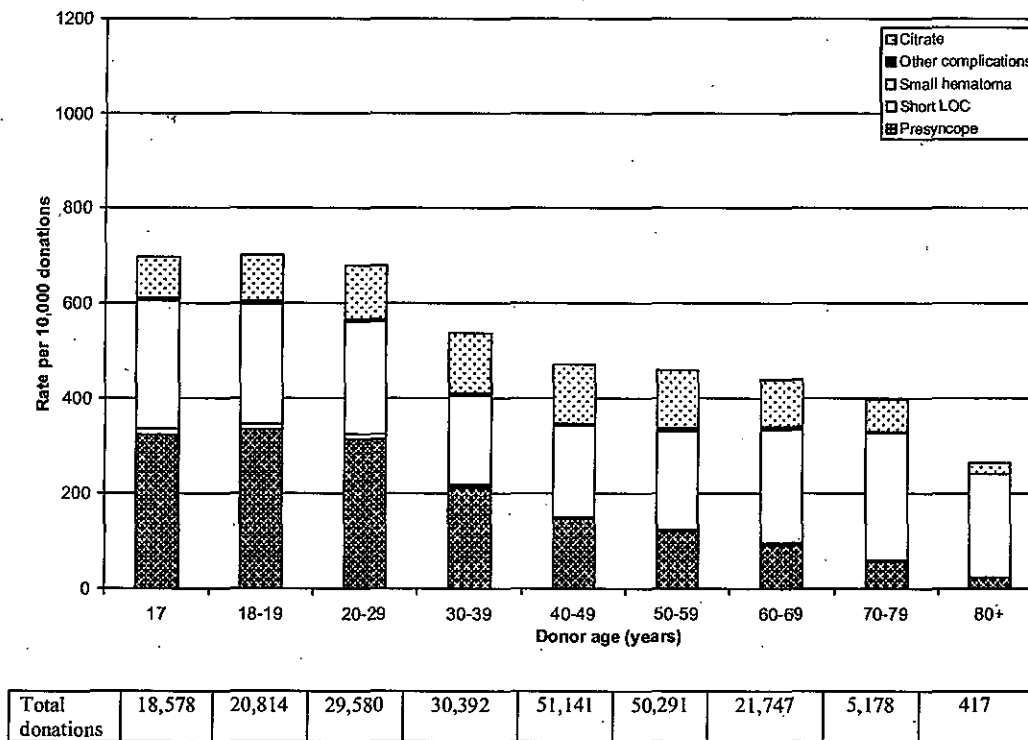


Fig. 5. Rates of donor complications associated with R2 donation. Differences between overall rates between successive age groups are significant between the 20- to 29- and 30- to 39-year groups only.

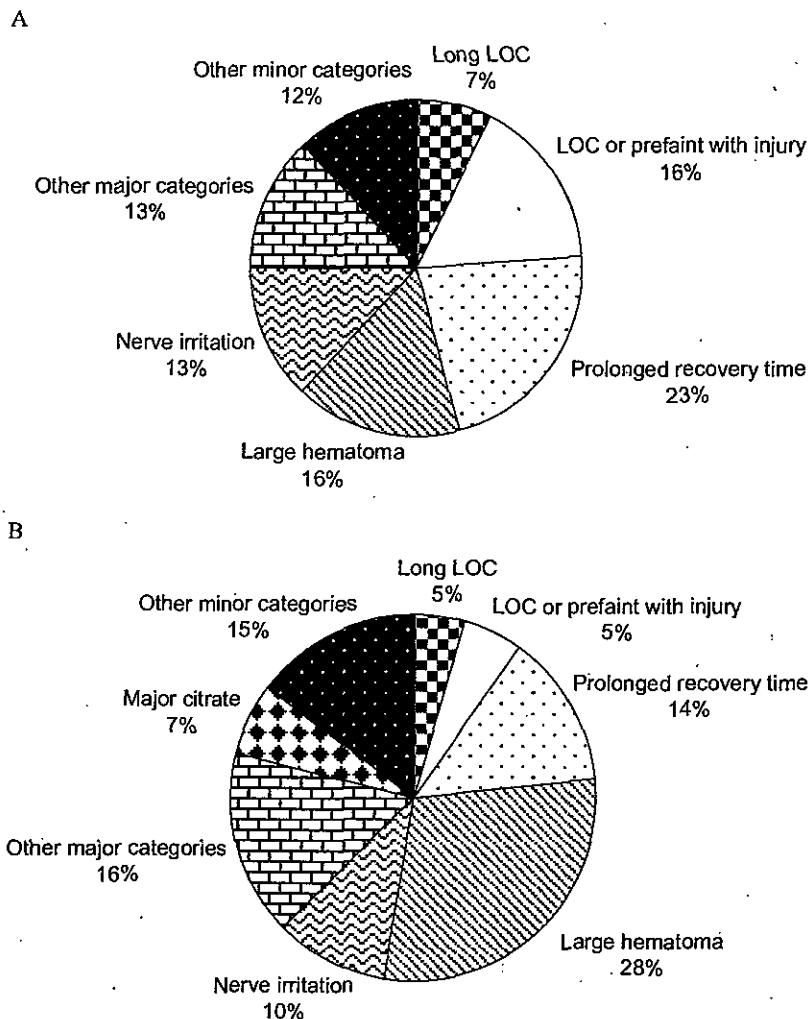


Fig. 6. Outside medical care reported after WB (A) and automated PLT and R2 collections (B). (A) WB (1,903 cases of outside medical care in 6,014,472 total WB collections; 3.2 per 10,000). (B) Automated (PLT, R2; 198 cases of outside medical care in 677,777 total automated collections; 2.9 per 10,000).

imprecision in coding undoubtedly contributes to regional reporting variability.

The utility of collecting systemwide data on hematomas and minor presyncopal reactions and the relevance of a distinction between short LOC and long LOC have been questioned. Hemovigilance efforts of a national system should be focused on moderate and severe reactions, which are more medically relevant than minor complications and require aggregation of data to evaluate trends and the effect of interventions on rare events. However, the common, minor reactions may provide important information if their rate serves as an indirect measure of the risk of more serious complications in individual blood centers. For example, an intervention that achieves even a small reduction in symptomatic (syncopal-type) reactions

may predict a comparable reduction in the infrequent, but more serious syncopal-type complications including LOC with injury. This assumption, while logical, has not yet been proven because a large data set is needed to evaluate the effect of any preventive measure on infrequent but medically more serious complications. Regardless, even the common, mild complications are unpleasant for the donor and reduce the likelihood of return donation thereby serving as a surrogate measure of the donation experience.¹⁵⁻¹⁷ Finally, we noted lower complication rates in young donors (<20 years) donating RBCs by apheresis compared to WB donations, providing a rationale for further study and for possibly expanding apheresis RBC donation programs in colleges and high schools.

Although blood collection establishments will likely not be able to eliminate all risk to healthy volunteer donors, they should continually foster a culture of safety and make a concerted effort to reduce the rate of donor complications, not only for the donors' health and well-being but also to enhance the likelihood of their future donation.¹⁷ The ARC hemovigilance program provides estimates of the current risks associated with WB and automated collection procedures and lays the foundation of our efforts to improve the donation experience. Establishment of a national donor hemovigilance system may afford an opportunity for systematic improvement in donor safety in every collection center. Our experience, however, cautions

against direct comparison of different blood centers in the absence of risk adjustment for donor demographics and consideration of differences in the identification, classification, and reporting of injuries.

REFERENCES

1. Popovsky MA, Whitaker B, Arnold NL. Severe outcomes of allogeneic and autologous blood donation: frequency and characterization. *Transfusion* 1995;35:734-7.
2. Kasprisin DO, Glynn SH, Taylor F, Miller KA. Moderate and severe reactions in blood donors. *Transfusion* 1992;32:23-6.
3. Ogata H, Iinuma N, Nagashima K, Akabane T. Vasovagal reactions in blood donors. *Transfusion* 1980;20:679-83.

4. Shehata N, Kusano R, Hannach B, Hume H. Reaction rates in allogeneic donors. *Transfus Med* 2004;14:327-33.
5. Poles FC, Boycott M. Syncope in blood donors. *Lancet* 1942;240:531-5.
6. Trouern-Trend JJ, Cable RG, Badon SJ, Newman BH, Popovsky MA. A case-controlled multicenter study of vasovagal reactions in blood donors: influence of sex, age, donation status, weight, blood pressure, and pulse. *Transfusion* 1999;39:316-20.
7. Tomasulo PA, Anderson AJ, Paluso MB, Gutschenritter MA, Aster RH. A study of criteria for blood donor deferral. *Transfusion* 1980;20:511-8.
8. Newman BH, Siegfried BA, Buchanan LA. Donor reactions among African-American and Caucasian first-time whole-blood donors. *Transfusion* 2005;45:1398-9.
9. Newman BH, Satz SL, Janowicz NM, Siegfried BA. Donor reactions in high-school donors: the effects of sex, weight, and collection volume. *Transfusion* 2006;46:284-8.
10. Eder AF, Hillyer CD, Dy BA, et al. Adverse reactions to allogeneic whole blood donation by 16- and 17-year-olds. *JAMA* 2008;299:2279-86.
11. Zou S, Musavi F, Notari EP, Fang CT. Changing age distribution of the blood donor population in the United States. *Transfusion* 2008;48:251-7.
12. AuBuchon JP, Whitaker BI. America finds hemovigilance! *Transfusion* 2007;47:1937-42.
13. Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods [monograph on the Internet]. Rockville (MD): U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration; 2007 Dec [cited 2008 May 24]. Available from: <http://www.fda.gov/cber/gdlns/plateletauto.pdf>
14. Wiltbank TB, Giordano GF. The safety profile of automated collections: an analysis of more than 1 million collections. *Transfusion* 2007;47:1002-5.
15. France CR, Rader A, Carlson B. Donors who react may not come back: analysis of repeat donation as a function of phlebotomist ratings of vasovagal reactions. *Transfus Apher Sci* 2005;33:99-106.
16. France CR, France JL, Roussos M, Ditto B. Mild reactions to blood donation predict a decreased likelihood of donor return. *Transfus Apher Sci* 2004;30:17-22.
17. Custer B, Chinn A, Hirschler NV, Busch MP, Murphy EL. The consequences of temporary deferral on future whole blood donation. *Transfusion* 2007;47:1514-23. ■



Advancing Transfusion and
Cellular Therapies Worldwide

ASSOCIATION BULLETIN #08-04

Date: August 28, 2008
To: AABB Members
From: J. Daniel Connor, MM, President
Karen Shoos Lipton, JD, Chief Executive Officer
Re: Strategies to Reduce Adverse Reactions and Injuries in Younger Donors

This Association Bulletin contains information for the membership on strategies that may mitigate the risk of injuries and adverse reactions in donors under 20 years of age. AABB is issuing this bulletin in anticipation of the renewal of high school and college blood drives. Blood collecting facilities may want to consider implementing some of these strategies in an effort to reduce the incidence of injuries and adverse reactions in this population of donors.

Association Bulletins, which are approved for distribution by the AABB Board of Directors, can include announcements of standards or requirements for accreditation, recommendations on emerging trends or best practices, and/or pertinent information. This bulletin does not contain specific recommendations, nor does it create a standard or accreditation requirement. It is based on reports from the AABB Younger Donors Adverse Reaction Working Group, which includes physicians, nurses, administrators, communications and legal experts, and representatives from AABB, America's Blood Centers, the American Red Cross, and Blood Centers of America. The working group reviewed and discussed available information and, on the basis of current practices, addressed three objectives: 1) reduce adverse reactions in young blood donors; 2) eliminate donor injuries related to adverse reactions; and 3) address donor education and consent issues related to young blood donors. The full texts of these reports, which are included as appendix 1 and appendix 2 to this bulletin, contain a number of strategies that may accomplish these objectives. Some of the suggested interventions are supported by studies and data, while others represent a common practice or, a practice that is expected, but not proven, to accomplish the stated objectives.

Background

Volunteer blood donations are the basis of the nation's blood supply. Donations are recruited from a healthy population that ranges in age from 16 (state law permitting) to 75 years or older. During the past several years, blood collection facilities have placed greater emphasis on donations from younger donors as donations from older donors are declining due to individual health issues and other eligibility barriers. Reports from blood collection facilities indicate that 10 to 20 percent of all whole blood collections in the

United States now come from blood donors who are less than 20 years old. In states where 16-year-olds are permitted to donate, the percentage of donations from this age group is even higher. The growth of this donation segment is related to the increase in blood drives at high schools. Blood donors of high school age generally embrace the opportunity to donate blood for a number of reasons, including their perception that donating is a "rite of passage," their attraction to the medical/technological aspects of blood donation, and the fact that they can often be excused from class. They are also ideal donors because they have lower deferral rates and, by experiencing donation early in life, they are more likely to continue donating in the future.

As data from young donors and high school drives accumulate, it has become clear that the rate of adverse reactions is more frequent in this group of donors – as much as five times the adult rate in some studies. Although serious syncopal reactions that can lead to donor injury are rare, they are proportionately elevated in this group. Moreover, age appears to be inversely related to the risk of suffering an adverse reaction. Several recent studies document this phenomenon as well as various strategies to reduce adverse reactions. These published results have drawn greater attention to this issue among blood collection facilities. Recognizing this new information and understanding the importance of assuring donors a safe and satisfying donation experience, blood collection facilities have joined forces to address safety for young blood donors.

Donor Adverse Reactions

The vast majority of blood donations are uncomplicated, with no side effects or discomfort. However, a small number of donors experience bruising and/or bleeding at the venipuncture site, mild nausea, or changes in consciousness, including dizziness, fainting, fainting or syncope leading to collapse or convulsions. The working group focused specifically on change of consciousness reactions, such as syncope, that can lead to donor injury if the donor falls. Several factors influence the risk of complications after blood donation: inherent donor characteristics and predisposition toward reactions, blood collection staff skill and experience, blood drive set-up and environmental site features, and donor education before and after donation.

The literature, published studies and blood collection facility experience document donor characteristics that correlate with higher syncopal complication rates after whole blood donation. These include young age, first-time donation status, low weight, low blood volume, female gender, and Caucasian ethnicity. Young age, total blood volume, and first-time donation status are known to be independent risk factors and leading determinants of syncopal reactions.

Given these predisposing factors, the working group reviewed many field practices and literature reports on measures to reduce reactions, including the following.

- **Predonation education.** Measures in this area greatly affect donor understanding of what to anticipate and how to deal with discomforts that might arise from donation. This area is addressed more specifically below under Donor Education.