The American Red Cross donor hemovigilance program: complications of blood donation reported in 2006

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BACKGROUND: The American Red Cross (ARC) initiated a comprehensive donor hemovigilance program in 2003. We provide an overview of reported complications after whole blood (WB), apheresis platelet (PLT), or automated red cell (R2) donation and analyze factors contributing to the variability in reported complication rates in our national program.

STUDY DESIGN AND METHODS: Complications recorded at the collection site or reported after allogeneic WB, apheresis PLT, and R2 donation procedures in 36 regional blood centers in 2006 were analyzed by univariate and multivariate logistic regression.

RESULTS: Complications after 6,014,472 WB, 449,594 PLT, and 228,183 R2 procedures totaled 209,815, 25,966, and 12,282 (348.9, 577.5, and 538.3 per 10,000 donations), respectively, the vast majority of which were minor presyncopal reactions and small hematomas. Regional center, donor age, sex, and donation status were independently associated with complication rates after WB, PLT, and R2 donation. Seasonal variability in complications rates after WB and R2 donation correlated with the proportion of donors under 20 years old. Excluding large hematomas, the overall rate of major complications was 7.4, 5.2, and 3.3 per 10,000 collections for WB, PLT, and R2 procedures, respectively. Outside medical care was recorded at similar rates for both WB and automated collections (3.2 vs. 2.9 per 10,000 donations, respectively).

CONCLUSION: The ARC data describe the current risks of blood donation in a model multicenter hemovigilance system using standardized definitions and reporting protocols. Reported reaction rates varied by regional center independently of donor demographics, limiting direct comparison of different regional blood centers.

Blood donation by healthy volunteers assures the availability of blood components for transfusion, which is a central tenet of modern health care. Accrediting and regulatory agencies (e.g., Joint Commission on Accreditation of Healthcare Organizations, Food and Drug Administration [FDA]) identify blood transfusion as a core function essential to quality medical care and promulgate specific requirements for appropriate use of blood components. Scientific efforts to improve blood safety have duly focused on the patient-recipient of blood transfusion and have substantially reduced the risk of infectious disease transmission. Similar scrutiny has not been applied to reducing the risk of blood donation, even though the infrequent occurrence of serious injury after blood donation may arguably now rival the residual risk of transfusion-transmitted infection.

ABBREVIATIONS: ARC = American Red Cross; LOC = loss of consciousness; R2 = automated red cell (donation).

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The blood supply depends entirely on the daily commitment of altruistic volunteers, who ostensibly gain little personal benefit from blood donation but are exposed to potential risk of discomfort, complications, and in rare cases, injury resulting from the collection procedure. Approximately 2 to 6 percent of all presenting donors experience a complication, most of which previously have been classified as light, mild, or minor reactions that resolve promptly but are still unpleasant for the donor.[1-9] Serious injury occurs infrequently, but typically results from a loss of consciousness (LOC), either at the donation site or after leaving the premises. Donor characteristics that correlate with higher syncopal complication rates after whole blood (WB) donation include young age, first-time donation status, low weight or total blood volume, female sex, and Caucasian race, although these may not all be independent predictors of reactions.[6-10] Changing population and donor demographics during the period 1996 through 2005 revealed that blood collection from young donors, aged 16 to 19 years, was increasing whereas blood donation rates by older individuals was declining.[11]

In light of these demographic trends, blood centers should continuously strive to improve the donation experience for all donors and should have an effective and comprehensive program to monitor donor complications as the keystone of a donor safety program. The importance of donor adverse reactions has been highlighted in the recent efforts by the AABB to initiate a US biovigilance program.[12] Our experience now provides a model system to assess the advantages and limitations of a national donor hemovigilance program.

Each year, the American Red Cross (ARC) has nearly 7 million encounters with individuals who present to donate WB or apheresis components to provide more than 40 percent of the US blood supply. The ARC established a national hemovigilance program to systematically analyze donor complications at its 36 blood regions. We describe annual hemovigilance data from 2006 and analyze factors contributing to variability in reported overall reaction rates in our system, which may serve as a basis for further improvements in hemovigilance efforts to protect healthy, volunteer blood donors.

MATERIALS AND METHODS

In 2003, ARC initiated a comprehensive hemovigilance program that prospectively collects data on events that occur at the time of donation, or that are reported later, including reports of donors receiving outside medical care. In mid-2005, the event definitions (Table 1) were modified to include citrate reactions for automated collections and the national reporting system was updated and fully implemented. This report describes data gathered in the first full calendar year of the modified program.

Collection site procedures

The 36 regional blood regions follow standard procedures for WB and automated collections from volunteer, allogeneic donors. WB is collected into 500-mL collection sets (Fenwal, Inc., Round Lake, IL; Pall Medical, Inc., East Hills, NY). The mean volume of collection is 517 ± 10 mL with trip scales and 524 ± 10 mL with electronic scales. Apheresis platelets (PLTs) are collected with one of three apheresis devices: Amicus (Baxter Healthcare, Round Lake, IL), Spectra (Gambro BCT, Lakewood, CO), or Trima (Gambro BCT). Automated red cell (R2) procedures for 2-unit red cell (RBC) collections are performed with Alyx (Fenwal, Inc.), Trima (Gambro BCT), or Haemonetics MCS+ 8150 (Haemonetics, Braintree, MA) systems. PLT procedures included plateletpheresis and plateletpheresis with infrequent plasma collection. PLT/plasma/RBC collections, plasma/RBC collections, and automated plasma and plasma/RBC collections were excluded from the analysis.

All adverse reactions occurring at the collection site are managed by collection staff, documented on the blood donation record according to the classification scheme (Table 1), and captured in a central electronic database. All donors are also instructed to contact the regional blood center if they experience problems or have concerns about their health after donation. Donor reactions or injuries reported by the donor or third parties after the donation event are managed by standard procedures, reviewed by a facility physician, and reported to the national hemovigilance program.

Classification scheme for donor complications

The standardized classification system for donor complications defines 15 reaction categories (Table 1). The scheme incorporates a severity rating (minor, major) for reaction types in most categories, and every category is further divided into whether or not the donor received outside medical care. Minor complications typically resolve within a short period of time (e.g., 30 min), and the donor recovers completely at the donation site and/or is managed solely by giving the donor instructions for care after an injury (e.g., hematoma) occurs. Major reactions typically require follow-up with the donor and review by ARC staff, either because they may be medically more serious or they may be more of a concern to donors (e.g., loss of bowel or bladder control during a short LOC), even if the reaction is not more medically significant than a minor complication. Presyncope defines a variety of symptoms (e.g., pallor, lightheadedness, dizziness, nausea) that may be related to vasovagal reactions, hypovolemia, or anxiety but do not progress to LOC. The small and large hematomas include true hematomas (e.g., a palpable mass), bruises, and infiltration at the venipuncture site. Reactions classified as "other" comprise a variety of

TABLE 1. Definitions of donor complications*

Complication	Brief description	
	Minor category	Major category
Systemic (syncopal-type):		
Symptomatic (presyncopal, prefaint)	Pallor, weakness, light-headedness, dizziness, diaphoresis, nausea/vomiting, no LOC.	
LOC	Short LOC: lasting less than 1 min.	Long LOC: lasting 1 min or more or complicated by seizures or convulsions or loss of bladder or bowel control.
Presyncopal or LOC with injury		Injury (e.g., head injury, fractures, abrasions, lacerations) associated with symptoms of prefaint or LOC.
Prolonged recovery		Symptoms of prefaint or LOC or other reaction that do not resolve within approx. 30 min.
Phlebotomy-related		
Hematoma	Small: involved area measures 2×2 in. or less.	Large: involved area measures more than 2×2 in.
Nerve irritation		Suggested by pain, tingling, numbness, or sharp shooting pains after phlebotomy.
Suspected arterial puncture		Suggested by rapid (<3 min) bleed time, pulsatile flow, and/or bright red blood.
Systemic (other)		
Citrate (automated procedures only)	Citrate reactions that persist despite intervention or are accompanied by additional symptoms such as nausea, muscle tightness, or cramping. Citrate reactions that involve perioral or peripheral tingling or numbness that resolves with reduced flow rate or calcium are not captured.	Symptoms of minor citrate plus prolonged or exaggerated muscle spasm (tetany), vomiting, chest tightness.
Allergic	Hives, itching, rash, or redness of skin.	Symptoms of minor allergic reactions, plus swelling of the face, neck, or throat; wheezing; or respiratory difficulty.
Other reaction	Symptom profile different from established categories (e.g., anxiousness, hyperventilation, headache).	Symptom profile different from established categories (e.g., chest pain, thrombophlebitis).

* Donor complications are classified according to type and severity (minor, major); cases in each minor and major complication category are further subclassified with respect to the need for outside medical care.

reactions or symptoms that do not otherwise fit into the established categories, including suspected thrombophlebitis and chest pain as major, other reactions. For every complication category, outside medical care is defined as medical advice or treatment provided by someone other than ARC staff (e.g., emergency medical services, a primary health care physician or specialist, or any health care professional), whether sought independently by the donor or at the advice of ARC staff. Donors may seek outside medical care for reactions that are common and self-limiting (e.g., large hematomas), as well as those that are medically more relevant to their well-being (e.g., syncope-related injuries).

National hemovigilance program

Every month, the hemovigilance program at the ARC National Headquarters Medical Office compiles and analyzes data on donor complications following WB and automated procedures that are either documented by collections staff at the time of donation or reported by the donor or a third party after the donation event, including cases that receive outside medical care. All major reactions (Table 1) that occur at the donation site and all reactions that are reported to the blood center after the donor leaves the site are captured on a standard case report form, investigated, and reviewed by the blood center physician and reported in a tally on a monthly basis to the National Medical Office. If a donor is referred for outside medical care by staff or later reports that he or she sought or received care from any outside health care provider, the complete blood donation record is reviewed by the National Medical Office and is maintained in a separate database. In this report, the actual medical care provided is not further differentiated and varies considerably from simple reassurance or advice to apply warm packs for the resolution of hematoma to administration of intravenous fluids and hospitalization.

Complications associated with allogeneic WB, apheresis PLT, and R2 procedures in 36 regions from January 1, 2006, to December 31, 2006, were analyzed; autologous and therapeutic collections were excluded. The analysis

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 "STEPWISE" 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, prefaint)	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	74.5	377.0	217.9
Major			
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, prefaint) 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

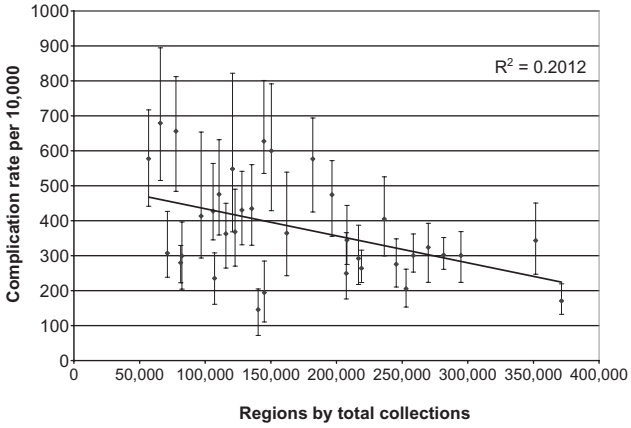


Fig. 1. Variability in rate of complications among ARC blood centers. The 36 regional blood centers are ordered by total collections in 2006 and plotted against their mean monthly overall complication rate per 10,000 collections. Bars show the maximum and minimum monthly complication rate for each center.

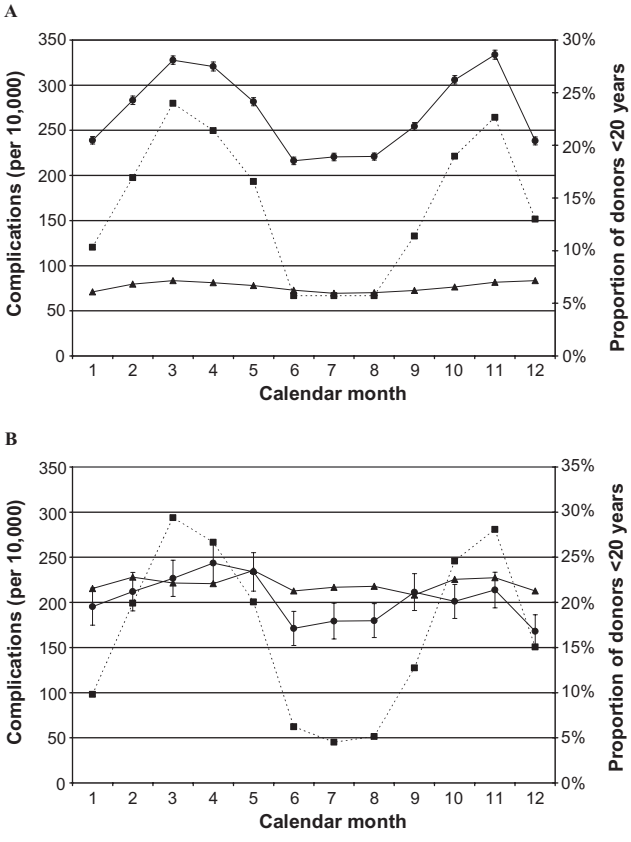


Fig. 2. Seasonal variability in donation-related complications correlates with the proportion of young donors. (A) WB; (B) R2. (●) Systemic (syncopal-type) complications; (▲) phlebotomy-related complications; (■, dotted line) proportion of donors less than 20 years old.

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

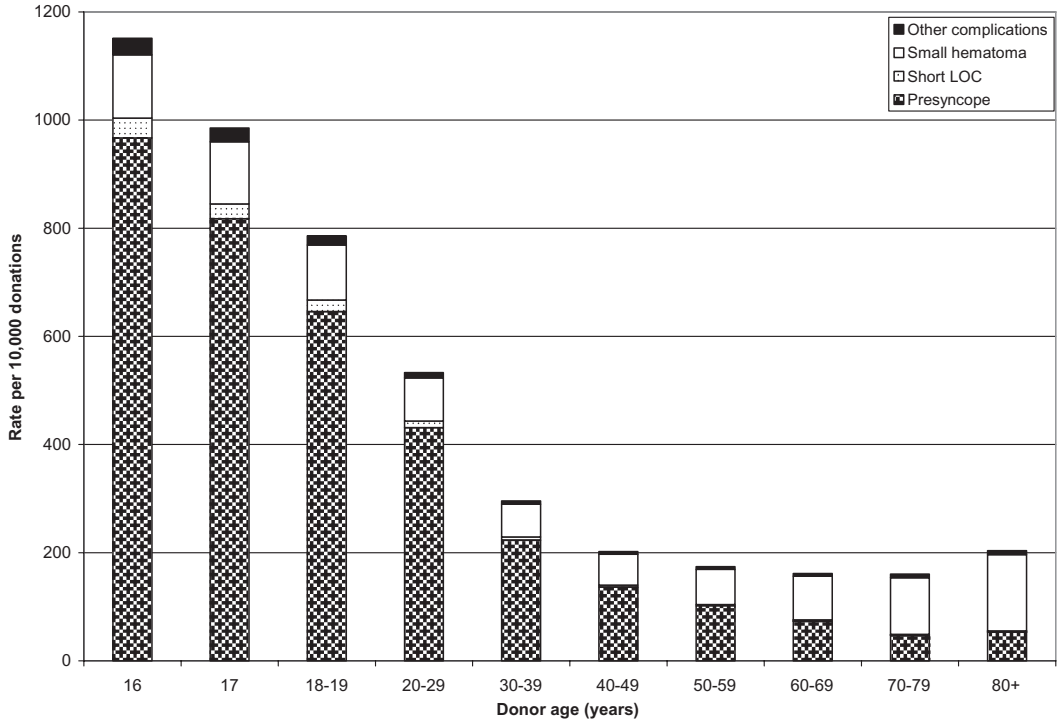
The most common complications associated with PLT and R2 donations were hematomas, followed by systemic citrate and syncopal-type reactions (Table 2). The rate of systemic reactions was lower for PLT donations (OR, 0.69; 95% CI, 0.68-0.71) and slightly but significantly higher for R2 donations (OR, 1.17; 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 methods[13] 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]

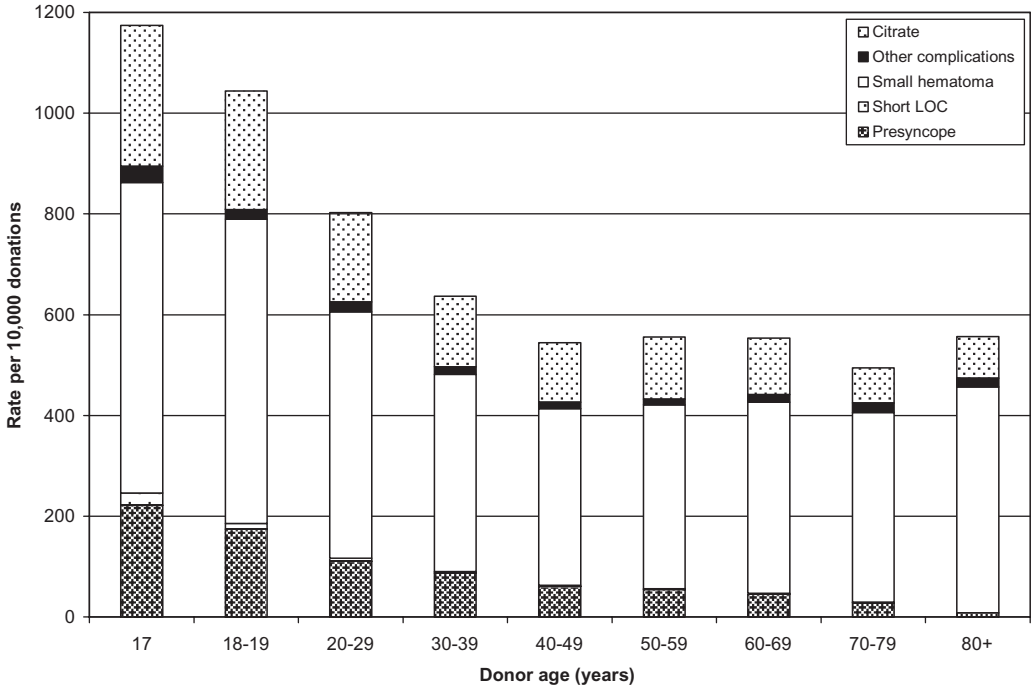
The AABB has proposed the establishment of a national biovigilance program that would include a donor adverse reaction component.[12] The national collection of donor complication data is currently constrained by the different definitions of reactions and data collection procedures in use by blood centers 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

	WB		R2		Apheresis PLTs	
Effect	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)	

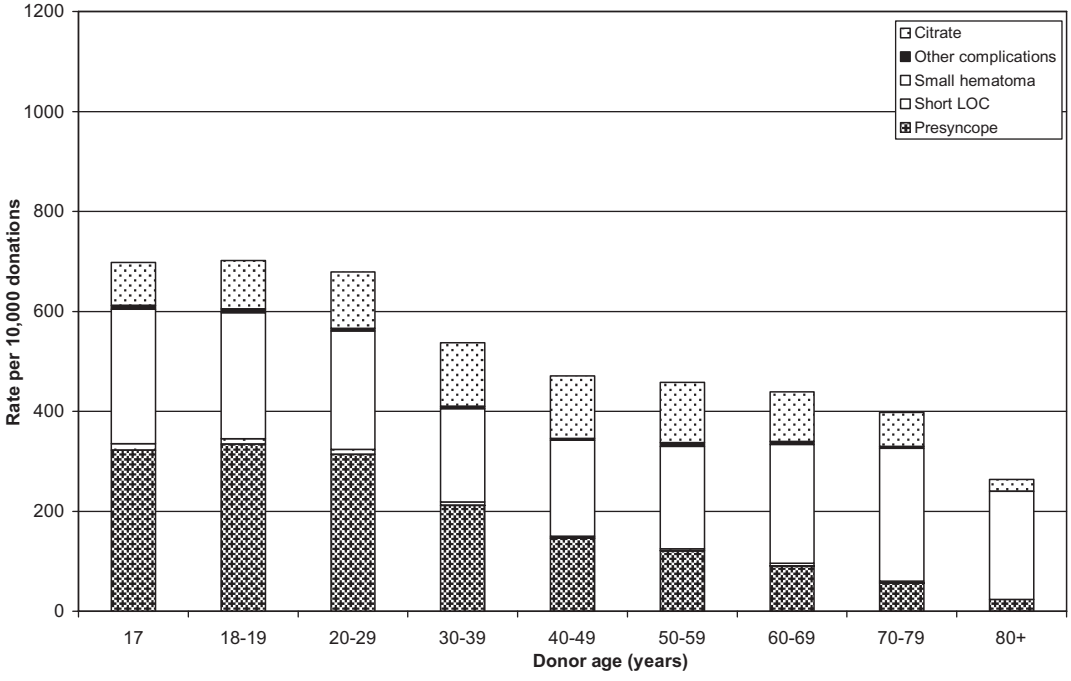
* Not significant.

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



Total donations	1,218	3,560	26,986	44,812	119,535	156,890	72,477	21,771	2,300

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.



Total donations	18,578	20,814	29,580	30,392	51,141	50,291	21,747	5,178	417

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.

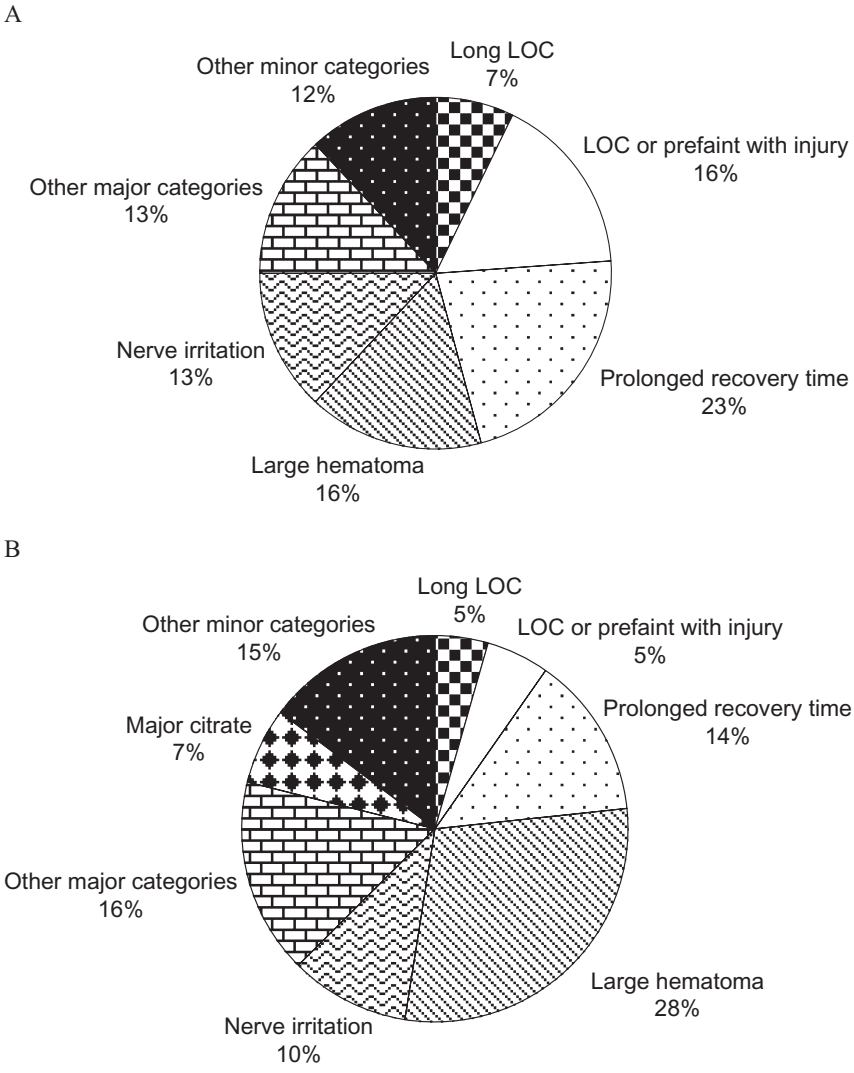


Fig. 6. Outside medical care reported after WB (A) and automated PLT and R2 collections (B). (A) WB (1,903 cases of outside medical care in 6,014,472 total WB collections; 3.2 per 10,000). (B) Automated (PLT, R2; 198 cases of outside medical care in 677,777 total automated collections; 2.9 per 10,000).

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.

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