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Donor reactions in high-school donors: the effects of sex, weight, and collection volume

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BACKGROUND: The high incidence of donor reactions in first-time, 17-year-old Caucasian whole-blood donors makes this group ideal for the study of donor reactions.
STUDY DESIGN AND METHODS: Donor reaction rates were retrospectively evaluated in 7274 first-time, 17-year-old Caucasian whole-blood donors based on observations recorded at the collection sites. The effect of sex and weight on donor reactions was determined. In addition, a model was developed to estimate how different blood collection volumes would affect donor reaction rates.
RESULTS: The donor reaction rate was 12.0 percent (870/7274). Female donors overall had a higher donor reaction rate than male donors (16.7% vs. 7.3%) and also had a higher donor reaction rate than male donors at each 20-lb weight interval in the range from 110 to 189 lb. A model suggested that a change in the blood-unit volume from 450 to 500 mL would increase donor reaction rates by 18 percent in either female or male donors, whereas a reduction in the blood-unit volume from 500 to 400 mL would decrease donor reaction rates by 29 and 27 percent in female and male donors, respectively.
CONCLUSION: First-time, 17-year-old Caucasian female donors had a higher donor reaction rate than male donors overall and at equivalent donor weights. In the range of present US blood-unit volumes, a change in collection of as little as 50 mL could have a significant impact on blood donor reaction rates in high-school students.

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Clinical studies have evaluated the incidence of blood donor reactions[1] and have studied the correlation of donor characteristics such as weight,[2-6] age,[3-6] first-time or repeat donor status,[3-6] race,[6-8] and sex[3,4,6] to donor reaction rates. This study evaluated first-time, 17-year-old, Caucasian high-school students because these donors have a very high donor reaction rate of approximately 9 to 11 percent,[6,9] which is seven to nine times higher than the donor reaction rate in an experienced, general donor population.[2] We evaluated two nonfixed variables (sex, weight), but three variables (donor status, age, race) were fixed. We also developed a model for donor reaction rates as a function of sex and the ratio of whole-blood collection volume per donor weight, which allowed us to estimate the effects of various whole-blood collection volumes.

MATERIALS AND METHODS

Blood donor suitability and phlebotomy

High-school blood donors met acceptability criteria before being subjected to phlebotomy. The donors then lay in a supine position, and a 525-mL phlebotomy was performed in the antecubital fossa of the arm with a 16-gauge needle. The blood collection volume included 481 mL in a whole-blood unit, 33 mL in tubes for post-donation tests, and 11 mL trapped in the plastic tubing. Blood donor reactions observed at the collection site were recorded. A "donor reaction" was defined as the presence of any of the following symptoms or signs during or shortly after whole-blood donation: dizziness, diaphoresis (sweating), sudden weakness, hypotension, bradycardia, and syncope (faint). Approximately 97 percent of the reactions were nonsyncopal reactions.

Blood donor selection and data analysis

All high-school blood drive donor history records from 77 blood drives between October 1, 2003, and March 23, 2004, were reviewed. Donor selection was limited to 17-year-old, first-time, Caucasian donors who successfully donated a whole-blood unit. Studies have shown that African-American donors have a considerably lower donor rate than Caucasian donors, so African-American donors were excluded from the study.[6,7] The decision to use successful donations and exclude unsuccessful donations was an arbitrary one. A total of 7274 donor history records were deemed suitable for evaluation.

Statistical analysis

Confidence intervals (CIs) for reaction rates were calculated as minimum-length intervals by integration of the Bayesian posterior with diffuse priors[10] with the assistance of computer software (the Solver tool in Microsoft Excel 2002, Microsoft Corp., Redmond, WA). Logistic regression was performed with Epi Info.[11] Proportion comparisons were done with the Fisher Exact test.

RESULTS

Donor weight distribution

Figure 1 shows a bell-shaped curve for male donors, with some skewing toward higher weights. In contrast, the curve for female donors appears truncated, suggesting that many Caucasian high-school female donors weighed less than 110 lb and could not donate blood.

Donor reaction rates in 17-year-old, first-time Caucasian blood donors

Table 1 shows the donor reaction rate for the total population and for each sex in 20-lb incremental weight groups. The donor reaction rate for the total population was 12.0 percent. Female donors had a 2.3-fold higher donor reaction rate than male donors, 16.7 percent versus 7.3 percent, and female donors had higher donor reaction rates within equivalent weight groups. Female donor reaction rates were 61 to 149 percent greater than male donor reaction rates, depending on the weight group. Figure 2 shows the donor reaction rates versus weight for female and male donors. Donor reaction rates appeared to decrease asymptotically as donor weights increased. Thus, logistic regression of reaction rate against a linear function of coded sex, reciprocal weight, and the product of coded sex and reciprocal weight—representing an interaction between sex and weight—was performed. The model was

$$\ln\left(\frac{r}{1-r}\right)=a+bs+\frac{c}{w}+\frac{ds}{w}, \quad (1)$$

where r is proportion of donors of coded sex s and weight w having a reaction; s = 0 if donor is male or 1 if donor is female; w is donor weight (lb); and a, b, c, and d are constants.

The coefficient d of the term representing sex-weight interaction was not significantly different from zero ($p = 0.09$ by a two-tailed test), so this term was omitted from the model. The remaining constants were found to have the following values: $a = -4.2941$, $b = 0.6120$, and $c = 284.1776$. All were significantly different from zero ($p < 0.0001$ by a two-tailed test). These constants yield the following formulas, which are plotted in Fig. 2.

$$\ln\left(\frac{r}{1-r}\right)=-4.2941+\frac{284.1776}{w} \text{ for male donors} \quad (2)$$

$$\ln\left(\frac{r}{1-r}\right)=-3.6821+\frac{284.1776}{w} \text{ for female donors.} \quad (3)$$

These formulas were used to give estimates of donor reaction rates at infinite weight, which were 2.5 percent for female donors and 1.3 percent for male donors. In a more practical context, the estimated donor reaction rates at 300 lb were 6.1 percent for female donors and 3.4 percent for male donors.

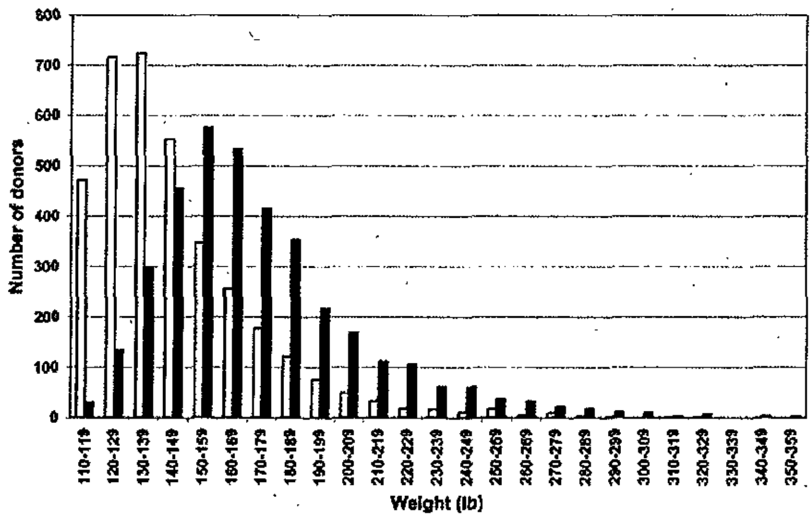

Fig. 1. Weights of first-time Caucasian high-school donors. (□) Female donors; (■) male donors.

Model for the effect of different blood-unit volumes on blood donor reaction rates

There is evidence that lower blood collection volumes are associated with lower reaction rates (see Discussion). We propose a unifying hypothesis that, for 17-year-old, first-time Caucasian donors, the donor reaction rate is a function of sex and the ratio of whole-blood collection volume to donor weight. Using the fact that Equations 2 and 3 were based on data obtained using a collection volume of 525 mL,

TABLE 1. Donor reaction rates in first-time, Caucasian high-school students

	Weight (lb)						
Donor sex	110-129	130-149	150-169	170-189	190-209	210+	Total
Female							
Number of reactions/number of donations	248/1187	206/1278	90/602	36/298	12/124	10/116	602/3605
Percent reactions	20.9	16.1	15.0	12.1	9.7	8.6	16.7
Male							
Number of reactions/number of donations	19/164	73/754	103/1108	39/768	15/386	19/489	268/3669
Percent reactions	11.6	9.7	9.3	5.1	3.9	3.9	7.3
Total							
Number of reactions/number of donations	267/1351	279/2032	193/1710	75/1066	27/510	29/605	870/7274
Percent reactions	19.8	13.7	11.3	7.0	5.3	4.8	12.0

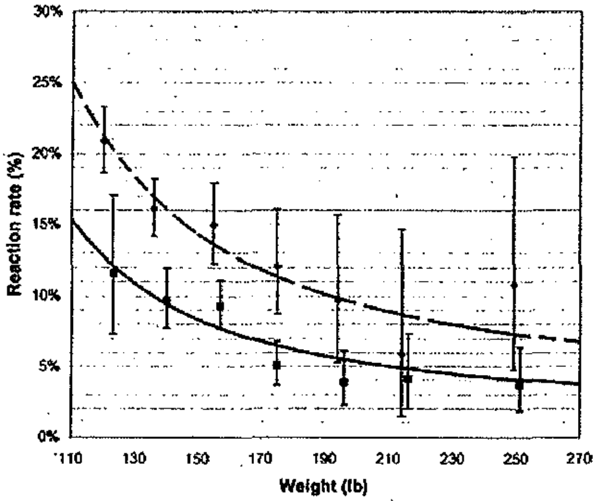

Fig. 2. Donor reaction rates in first-time Caucasian high-school students. Collections for each sex were grouped into 20-lb weight intervals for donor weights from 110 through 229 lb and a single interval for weights of 230 lb or more. The x coordinate of each group is the median weight, and the y coordinate is the reaction rate and its 95 percent CI. Curves were derived by logistic regression, as described under Materials and Methods. (◆) 95 percent CI, female donors; (■) 95 percent, male donors; (--) model, female donors; (—) model, male donors.

these equations were generalized to be consistent with the hypothesis

$$\ln\left(\frac{r}{1-r}\right)=-4.2941+0.5412907\frac{v}{w}\text{ for male donors} \quad (4)$$

$$\ln\left(\frac{r}{1-r}\right)=-3.6821+0.5412907\frac{v}{w}\text{ for female donors,} \quad (5)$$

where v is the blood collection volume in mL. When v = 525, Equations 4 and 5 are simplified to Equations 2 and 3, respectively.

The collection volume is the blood-unit volume plus the volume of blood in collection-set tubing and samples for testing. As previously stated, the latter is estimated to be 44 mL. Table 2 uses this estimate, the above model, and this study's donor weight distribution to give expected donor reaction rates at various blood-unit volumes. Table 3 compares the expected rates at different blood-unit volumes. The model suggests that an increase in the whole-blood unit volume from 450 to 500 mL would cause a 1.2-2.7 percent absolute increase in the donor reaction rate and a 17.9 to 18.2 percent relative increase in the donor reaction rate in first-time, Caucasian, high-school donors. Female donors had a greater absolute increase in the donor reaction rate (2.7 reactions per 100 collections vs. 1.2), but both sexes had similar relative increases of approximately 18 percent. A decrease in the whole-blood collection volume from 500 to 400 mL would decrease the donor reaction rate by 27 to 29 percent. Female donors would have a greater absolute decrease in the donor reaction rate (5.1% vs. 2.1%), but female and male donors would have a similar relative decrease (29% vs. 27%).

TABLE 2. Expected donor reaction rates at other collection volumes (reactions per 100 collections)

	Blood-unit volume (mL)						
Sex	500	481	450	400	350	300	250
Female	17.8	16.7	15.1	12.7	10.7	8.9	7.4
Male	7.8	7.3	6.6	5.7	4.8	4.1	3.5

TABLE 3. Expected effects of blood-unit volume changes on donor reaction rates*

	Blood-unit volume change (mL)		
Sex	450 to 500	500 to 400	500 to 250
Female	+2.7 (+17.9%)	−5.1 (−28.7%)	−10.4 (−58.4%)
Male	+1.2 (+18.2%)	−2.1 (−26.9%)	−4.3 (−55.1%)

* Absolute change in reactions per 100 collections (relative change).

DISCUSSION

Donor reactions are common. In a recent study, 7.0 percent of 1000 randomly selected interviewed whole-blood donors had a donor reaction.[2] The rate was 2.5 percent based on observation at the collection site, but an additional 4.5 percent were found after a donor interview 3 weeks later. Approximately 97 percent of the donors had mild reactions, meaning that the donors had symptoms and signs such as dizziness, diaphoresis, pallor, and sudden weakness but did not faint. A 1-year follow-up showed that donors who had a reaction were 34 percent less likely than asymptomatic donors to return and donate again within a 1-year period.[12] Studies show that the blood donation return rates are even lower when donors had syncope.[13-15] Therefore, it is clear that a nonsyncopal donor reaction decreases a donor's return rate, and syncope further decreases the return rate. Donor reactions are also a donor safety issue. One study showed a 14 percent injury rate in donors who progressed to syncope.[16] These injuries were often to the head and were generally minor, but lacerations and fractures occasionally occur. Serious injuries such as a closed-head injury are very rare but possible.

Three key factors associated with the probability of a donor reaction are weight,[2-6] age,[3-6] and first-time or repeat donor status.[3-6] Weight and age are the most important factors, and first-time or repeat donor status has marginal importance.[17] High weight, high age, and repeat status all protect donors against donor reactions. Caucasian donors have more risk for a donor reaction than African-American donors have.[6-8] Several studies have shown that female donors have more donor reactions than male donors,[3,4,6] but this was thought to be due to the female donor's smaller size because when female and male high-school donors over 149 lb were compared, the donor reaction rates were the same.[6] In addition, in 850 first-time, Caucasian donors from the same study, there were no differences in donor reaction rates when female and male donors in equivalent 20-lb weight groups were compared.[6] This study evaluated 8.6-fold more donors (7274 vs. 850) and detected large differences between reaction rates of female and male first-time Caucasian donors of similar weight.

Based on safety data for a 500 mL collection volume from a large blood center[18] and from the American Red Cross, most blood centers increased their whole-blood unit volume from 450 mL to a higher value. The American Red Cross collects 481 mL in each unit but 525 mL in total volume. This volume can be collected in any donor—even a donor with the lowest allowable weight, 110 lb (50 kg)—because it meets the AABB standard for a maximum whole-blood collection volume of 10.5 mL per kg of body weight.[19] Other blood centers collect two different whole-blood units—a 450-mL unit for low-weight donors and a 500-mL unit for donors weighing over approximately 120 lb.

A large blood center compared donor reaction rates in 282,000 donors who donated 450-mL whole-blood units and 547,000 donors who donated 500-mL whole-blood units.[18] The center did not detect a difference in donor reaction rates, which were 1.36 and 1.28 percent, respectively. But the subjects were from the general donor population, approximately 80 percent of whom were repeat donors and were much older and heavier than high-school students. A more sensitive study would have compared equivalent groups of very-high-risk donors such as the lower-weight female donors in this study, but this would have required entry of donor weight into the blood center's database, which is often not done.

In the donors studied here, the effect of two variables, sex and weight, on the reaction risk were determined. Three other variables, age, race, and first-time donor status, were fixed. It is probable but unproven that the bulk of the reactions in this group were caused by these five risk factors. Future studies could measure other factors that are thought to be associated with reactions such as a history of a donor reaction or being in the environment of a "group reaction." One could determine if there was an independent contribution from each variable by use of a logistics regression analysis, and such analysis could also quantify the contribution.

The model in this study, which relates the donor reaction rate in first-time, Caucasian high-school students to sex and the ratio of blood collection volume to donor weight, suggests that a 50-mL increase in whole-blood collection volume increased donor reaction rates by 18 percent. The model also suggests that a decrease in the blood-unit volume from 500 to 400 mL would decrease donor reaction rates by 29 percent in female donors and 27 percent in male donors, which is a very significant improvement. These lower rates are supported by Japanese data. The Japanese collect 400-mL (70% of collections) and 200-mL (30% of collections) units. They report a donor reaction rate of 0.6 to 0.7 percent based on 3.3 million whole-blood donations (H. Ikeda, Japanese Red Cross Society Central Blood Center, Japan; and M. Satake, Tokyo Red Cross Blood Center, Japan; written communications, 2003). Our data and model indicate that collecting 400-mL whole-blood units might be particularly effective in reducing donor reaction rates in young, low-weight, and first-time donors.

One limitation in this study was the lack of high-weight female donors. This made it difficult to show sex-related differences at high weights. A second limitation was that the data were based solely on observation of donors. In another study, a postdonation interview increased the number of reactions detected in a general donor population 2.3-fold, from 2.5 to 7.0 percent.[2] We do not believe that limiting the study to successful donations had an effect. The rate of unsuccessful donations in 4340 high-school students in the fall and winter of 2004 in our center was 5.0 percent (219/4340). It was 4.0 percent (21/525) in donors with a reaction and 5.2 percent (198/3815) in donors with no reaction ($p = 0.21$). These data also challenge the perception that donor reactions are associated with more unsuccessful donations.

In conclusion, first-time, female Caucasian high-school students have a much higher donor reaction rate than male donors of equivalent weight. A model suggested that a change in the blood-unit volume from 450 to 500 mL would increase the donor reaction rate in this group by approximately 18 percent, and a decrease in the blood-unit volume from 500 to 400 mL would decrease the donor reaction rate by 27 to 29 percent. This kind of decrease in donor reaction rates would have a significant positive impact on safety and blood donor retention rates—particularly in first-time, lower-weight, high-school donors and other donors at high risk.

REFERENCES

1. Newman BH. Donor reactions and injuries from whole-blood donation. Transfus Med Rev 1997;11:64-75.
2. Newman BH, Pichette S, Pichette D, Dzaka E. Adverse effects in blood donors after whole-blood donation: a study of 1,000 blood donors interviewed 3 weeks after whole-blood donation. Transfusion 2003;43:598-603.
3. Trouern Trend JJ, Cable RG, Badon SJ, et al. A case-controlled study of donor reactions in blood donors: influence of sex, age, donation status, weight, blood pressure, and pulse. A case-controlled multicenter study. Transfusion 1999;39:316-20.
4. Tomasulo P, Anderson AJ, Paluso MB, et al. A study of criteria for blood donor deferral. Transfusion 1980;20:511-8.
5. Kasprisin DO, Glynn SH, Taylor Miller KA. Moderate and severe reactions in blood donors. Transfusion 1992;32:23-6.
6. Newman BH. Donor reactions in high school students: findings relative to race, risk factor synergism, female sex, and non-high school participants. Transfusion 2002;42: 1557-60.
7. Newman B, Siegfried B, Buchanan L. The effect of ethnicity on the incidence of donor reactions in first-time whole-blood donors [letter]. Transfusion 2005;45:1398-9.
8. Graham DT. Prediction of fainting in blood donors. Circulation 1961;23:901-6.
9. Khan W, Newman B. Comparison of donor reaction rates in high school, college, and general blood drives [abstract]. Transfusion 1999;39(Suppl):31S.
10. Ross TD. Accurate confidence intervals for binomial proportion and Poisson rate estimation. Comput Biol Med 2003;33:509-31.
11. Dean AG, Arner TG, Sunki GG, et al. Epi Info, a database and statistics program for public health professionals. Atlanta (GA): Center for Disease Control and Prevention; 2002.
12. Newman B, Newman D. The effect of the blood donor's physical experience on blood donor return rates. Transfusion 2003;43(Suppl):140A.
13. Cable R, Trouern-Trend JJ, Badon SJ. The effect of blood donor syncopal reactions on subsequent blood donation [abstract]. Transfusion 1999;39(Suppl):114.
14. Gorlin JB, Petersen J. Reactions in first-time high school blood donors. Transfusion 2004;44:463.
15. Siegfried B, Newman B. Effect of reaction in allogeneic whole-blood donors on intervals from donation to next presentation [abstract]. Transfusion 2004;44(Suppl):78A.
16. Newman BH, Graves S. A study of 178 consecutive vasovagal syncopal reactions from the perspective of safety. Transfusion 2001;41:1475-9.
17. Newman BH, Roth AJ. Estimating the probability of a blood donation adverse event based on 1000 interviewed whole-blood donors. Transfusion 2005;45:1715-21.
18. Bianco C, Robins JL. Whole blood collection volumes and donor safety: equivalence between 450 mL and 500 mL collections [abstract]. Transfusion 1994;34(Suppl):15S.
19. Fridey JL, editor. Standards for blood banks and transfusion services. 22nd ed., Reference Standard 5.4.1A. Bethesda: American Association of Blood Banks; 2003. p. 69-73.

5

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.[1-5] 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	Brief description: 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