

AABB Donor Hemovigilance Report

2012



Advancing Transfusion and
Cellular Therapies Worldwide

2012 AABB United States Donor Hemovigilance Report



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*Kevin Land, MD and Barbee I. Whitaker, PhD for the AABB US Donor Hemovigilance Working Group**

***AABB US Donor Hemovigilance Working Group:**

Anne Eder, MD, PhD, American Red Cross National Headquarters

Madhav Erraguntla, PhD, KBSI

Mindy Goldman, MD, Canadian Blood Services

Michelle Greenland, LifeShare Community Blood Services

Linda Gruber, BloodCenter of Wisconsin

Mary Gustafson, Plasma Protein Therapeutics Association

Barbara Hallenburg, LifeShare Community Blood Services

Hany Kamel, MD, Blood Systems, Inc.

Kevin Land, MD, Blood Systems, Inc.

Bruce Newman, MD, American Red Cross Blood Services

Kadi Schroeder, RN, Bonfils Blood Center

James Stubbs, MD, Mayo Clinic

Peter Tomasulo, MD, Blood Systems, Inc.

Mary Townsend, MD, Blood Systems, Inc.

Barbee Whitaker, PhD, AABB

Johanna Wiersum-Osselton, PhD, TRIP, The Netherlands

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D. Michael Strong, PhD, University of Washington School of Medicine

Alan Williams, PhD, US Food and Drug Administration

†Deceased November 18, 2012

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1. Abstract

Recognizing the importance of donor health, the absence of a national surveillance system, and separate formal surveillance systems in many United States (US) blood collection facilities, the AABB Inter-organizational Task Force on Biovigilance in 2007 established a Donor Hemovigilance (DHV) Working Group consisting of representatives from America's Blood Centers (ABC), the American Red Cross (ARC), Blood Systems, Inc., the US Department of Defense, the Plasma Protein Therapeutics Association, the Mayo Clinic, and Canadian Blood Services (CBS). The goal of the Working Group was to develop a DHV surveillance system that would be available to all US blood collection facilities as an easy to use, electronic, voluntary, confidential, and nonpunitive reporting service focused on improving donor safety. The Working Group provided the necessary subject matter expertise for the Donor Hemovigilance Analysis & Reporting Tool (Donor HART™) software developed by Knowledge Based Systems Incorporated (KBSI, College Station, TX) with funding from the US Department of Health and Human Services. Through this collaboration the AABB US DHV Working Group first established standard defini-

tions for adverse reactions after blood donation, taking into consideration then-current International Society of Blood Transfusion (ISBT), ABC, and ARC definitions, and defined the objective data elements surrounding the donor, donation, and reaction.¹⁻⁴ To ensure that all interested blood collection facilities could participate at some level, the vast majority of data elements were made optional. Facilities were asked, though, to report as much as they reasonably could. Finally, aggregate denominator data elements were developed in the system, which allowed for univariate, bivariate, and, ultimately, multivariate analysis, depending on which type of denominator data facilities were willing or able to provide. This first annual report describes the use and capabilities of the system for the initial five blood center participants and system-level analyses of the 12 months of aggregated data covering the 2012 calendar year. The value of the Donor HART™ system and the AABB US DHV Program to individual blood collecting facilities, current applications for evaluating donor safety interventions within a center, as well as the potential for further development are detailed in this report.

2. Introduction

It is the goal of donor hemovigilance (DHV) to continuously improve donor safety and satisfaction through monitoring, analyzing, and researching adverse events associated with blood donation just prior to, during, and after the donation event. The activities of prospective and continuous surveillance of donation-related complications are largely voluntary in the United States (US) but are mandated in the European Union (EU) in the EU Blood Directive, which requires “a set of organized surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients of blood components, and the epidemiological follow-up of donors.”⁵ While US federal regulations require blood collection facilities to conduct a thorough investigation of adverse reactions and to report suspected donation-related fatalities (21 CFR 606.170⁶), a more structured, prospective surveillance system to capture

and analyze the complications associated with blood donation is essential to a systematic approach to improvement of donor care. Several US blood centers have established systems by which to accomplish this goal and have demonstrated the effectiveness of those systems in reducing rates of reaction in blood donation among susceptible groups.^{3,4,7,8}

There are many manufacturing steps in the blood donation process, and all are subject to variations, which can sometimes lead to issues associated with product efficacy, potency, or safety. The entire manufacturing process must be monitored to ensure that it is under control, however, this monitoring goes beyond the scope of DHV systems. Donor safety and satisfaction — not the characteristics (safety, potency, efficacy, etc.) of the blood component produced — are the focus of this report.

3. Methods

Membership:

The AABB US DHV Working Group is comprised of representatives from large and small blood centers, hospital blood collectors, large blood systems, the Department of Defense, plasma collection organizations, and blood transfusion and collection organizations (AABB and America's Blood Centers (ABC)) as well as from international blood organizations (Canadian Blood Services (CBS) and International Society for Blood Transfusion (ISBT)). Several members had already implemented DHV (or vigilance) systems prior to the creation of the Working Group and its charges.

Database:

The focus of the Donor Hemovigilance Analysis & Reporting Tool (Donor HART™) is to capture and analyze donor reaction information from blood collection facilities. The Donor HART™ software program is a web-based application that allows users, through an internet browser, to report, view, and analyze data related to donors' adverse reactions in their facility or facilities. In addition to recording and viewing data on donor reactions, users can capture denominator data for donors and perform targeted analyses of reaction data.

The database was developed by Knowledge Based Systems, Inc. (KBSI, College

Station, TX) with subject-matter expertise provided by the AABB US DHV Working Group. A more complete description of the tool has been provided elsewhere and is available in the Donor HART™ User Manual on the AABB Donor Hemovigilance website.^{9,10}

Definitions:

Consensus-based, standardized vocabularies are the backbone of any data reporting and analysis effort. The relationship of the definitions within the vocabulary (i.e. the ontology) is also critical. Only through the consistent use of standardized definitions can events be identified, reported, and analyzed for benchmarking (both within a system and across facilities). This consistency is needed whether or not the data are to be used for general surveillance or for more detailed analysis in order to identify risk factors impacting reaction rates or for assessing the impact of a given intervention. The establishment of a DHV Common Definitions Set (CDS) has been and still is an iterative process (like all initiatives with a process for continuous improvement), starting with a comparison of the definitions previously adopted by ARC, ABC, and ISBT and then agreeing on draft definitions before sending them out for further input from the Working Group, followed by continued refinement until a final CDS is achieved.¹⁻⁴ A decision was made early on to focus on

capturing objective and specific information (e.g., vasovagal reactions (VVRs) with or without loss of consciousness), rather than to use subjective and variably interpreted criteria (mild, moderate, severe, etc.). Working Group members found it challenging at times to balance the need for granular and objective data providing more information for analysis and discovery, and to reduce misinterpretation, with the desire for a simple system with low resource needs, that could be used for surveillance-type reporting and that was consistent with current data collection methods. A compromise was reached in which reporting centers are required simply to select the most appropriate standardized category/subcategory, while also having the option to provide additional, more-granular data. Examples of the definitions are provided in **Table 1**. A complete list of definitions and the workings of the database can be found in the Donor Hemovigilance System Definitions, a resource on the AABB Donor Hemovigilance website.¹¹

Validation:

Three blood collection facilities — Coffee Memorial Blood Center, Bonfils Blood Center, and Blood Systems, Inc. — representing small, medium, and large-sized blood collectors, piloted the initial roll-out between 2009 and 2011 to ensure that the methods of data entry, including manual and automated electronic submission, accurately captured and recorded

Table 1: Donor Reactions	
Reaction Type	Reaction Category
Vasovagal	Prefaint, no Loss of Consciousness (LOC), uncomplicated or minor
	LOC, any duration, uncomplicated
	LOC, any duration, complicated
	Injury
Local Injury related to needle	Nerve Irritation
	Hematoma/Bruise
	Arterial Puncture
Apheresis Related	Citrate
	Hemolysis
	Air Embolus
Allergic	Local
	Systematic
	Anaphylaxis
Other	Other

the intended data elements. The ability of Donor HART™ to verify and validate the data has been confirmed and is described elsewhere.¹⁰

4. Results

Reporting Centers:

Seven blood collection facilities (including one hospital) reported some 2012 donation data to the AABB US DHV program using Donor HART™, however, only five facilities reported denominator data that were sufficiently complete for rates to be calculated and the results included in this report. Additional facilities beyond the seven described have begun providing data into the pre-production/training environment and others are known to have begun adoption of the common definitions.

Data Elements:

The AABB US DHV Program has, through the Donor HART™ software, the ability to collect many data elements about the donor, the adverse reaction, and the donation. Entry of all attributes for every donor and donor reaction, however, is not required. Blood collection facilities are encouraged to report as many attributes as they have readily available in order to maximize the utility of reporting. In **Table 2**, reported attributes are listed by the percentage reported by the five initial reporting facilities. Age, donation history (first-time/repeat donor), donation type (autologous, allogeneic, etc.), gender, and procedure type (manual whole blood collection, apheresis, etc.) were reported by all five facilities. Some attributes of the donor or the collection procedure were

reported by fewer facilities, while other attributes, such as device software, were not reported by any of the reporting facilities.

Variable	Percentage of Facilities Reporting
Age	100%
Blood Pressure	40%
Collection Site	80%
Donation History	100%
Donation Type	100%
Ethnicity	80%
Gender	100%
Height	20%
Procedure Type	100%
Pulse	60%
Race	40%
Sponsor Group Type	60%
Weight	60%
Device Manufacturer	20%
Device Model	20%
Device Software	0%
Container Manufacturer	0%
Container Kit Type	0%

Donor Information:

Data were reported for 1,171,906 individual donations. The system does not capture the number of unique donors because the aggregate univariate denominator data are reported using donations, not donors. There were more donations from male (52.1%) than from female donors (47.9%) in the analysis cohort. Most donations were from donors who had donated previously (85.4%) with only 14.6% from first-time donors. Nearly 99% of donations were allogeneic donations. The remaining donation types reported included autologous, directed, and therapeutic (data not shown). Donations were predominantly whole blood donations (75.5%). Apheresis procedures were reported and included 14.2% double red cell collections, 5.4% platelet collections, 1.6% platelet and plasma combined col-

lections, and 1.2% platelet and red cell combined collections. All other automated combinations made up the remaining 1.7% collections reported.

Donor Demographics:

Overall, 61% of donations came from donors more than 40 years old (**Figure 1**). More donations came from donors who were between the ages of 50 and 59 (23%) at the time of donation than from any other single age cohort.

Basic Reaction Rates:

Reaction rates are listed in **Table 3**. The overall reaction rate was 13.41 per 1,000 donation procedures. Vasovagal type reactions were the most common, at a rate of

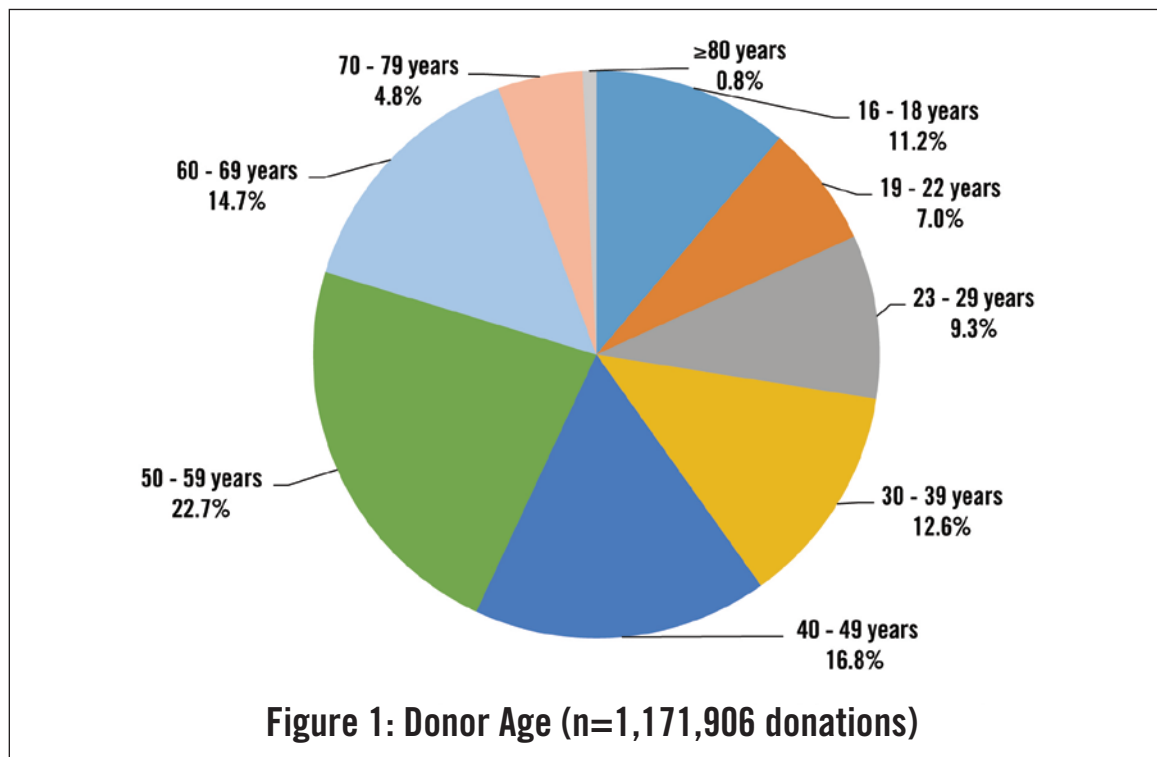
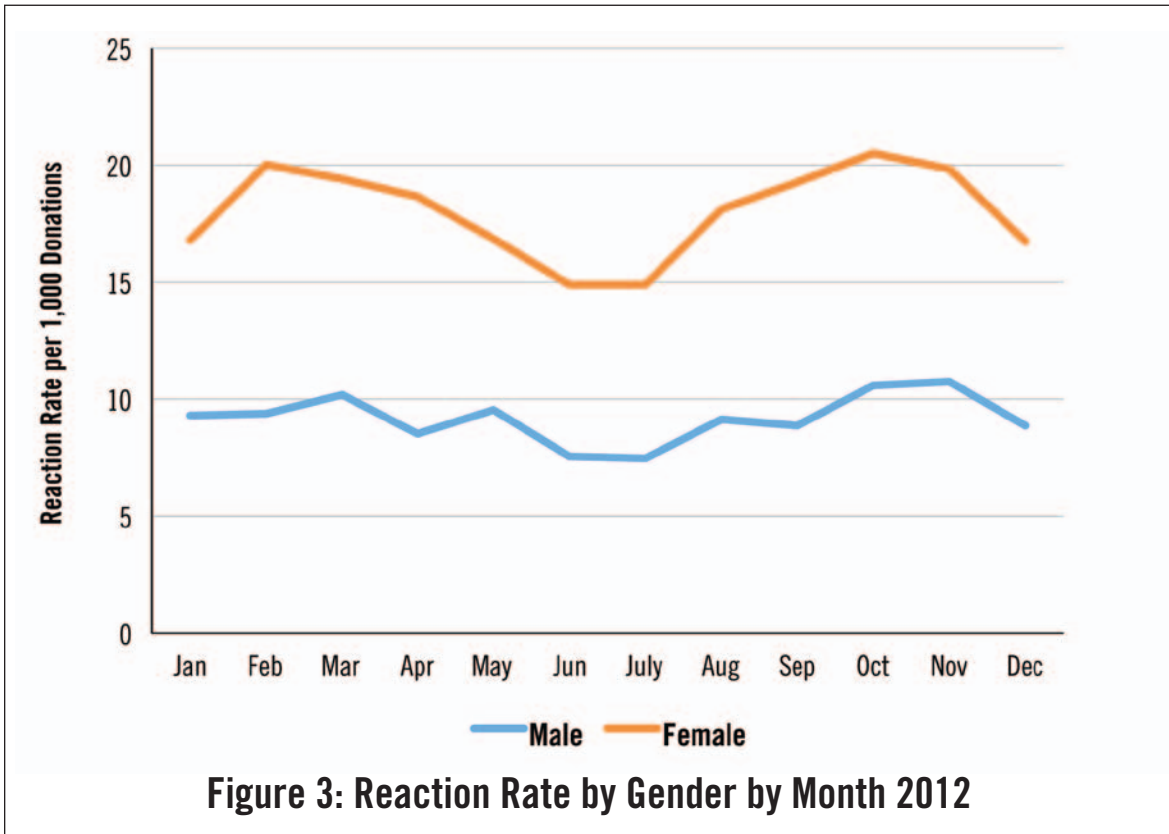
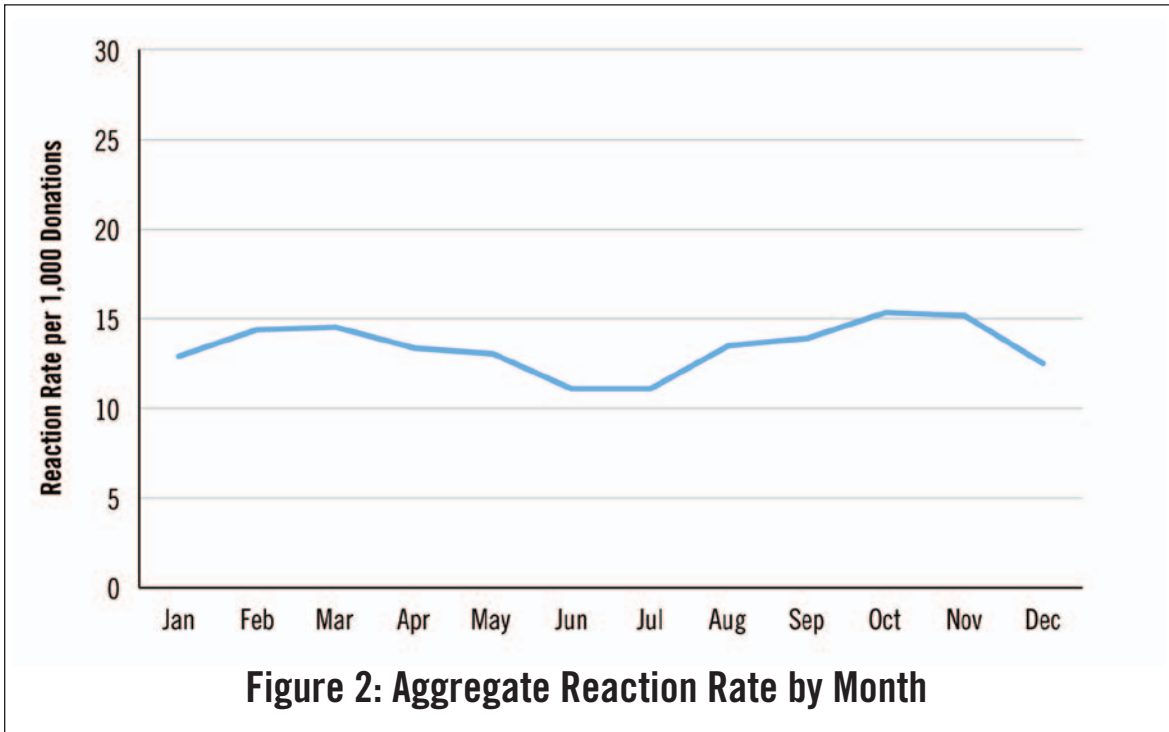
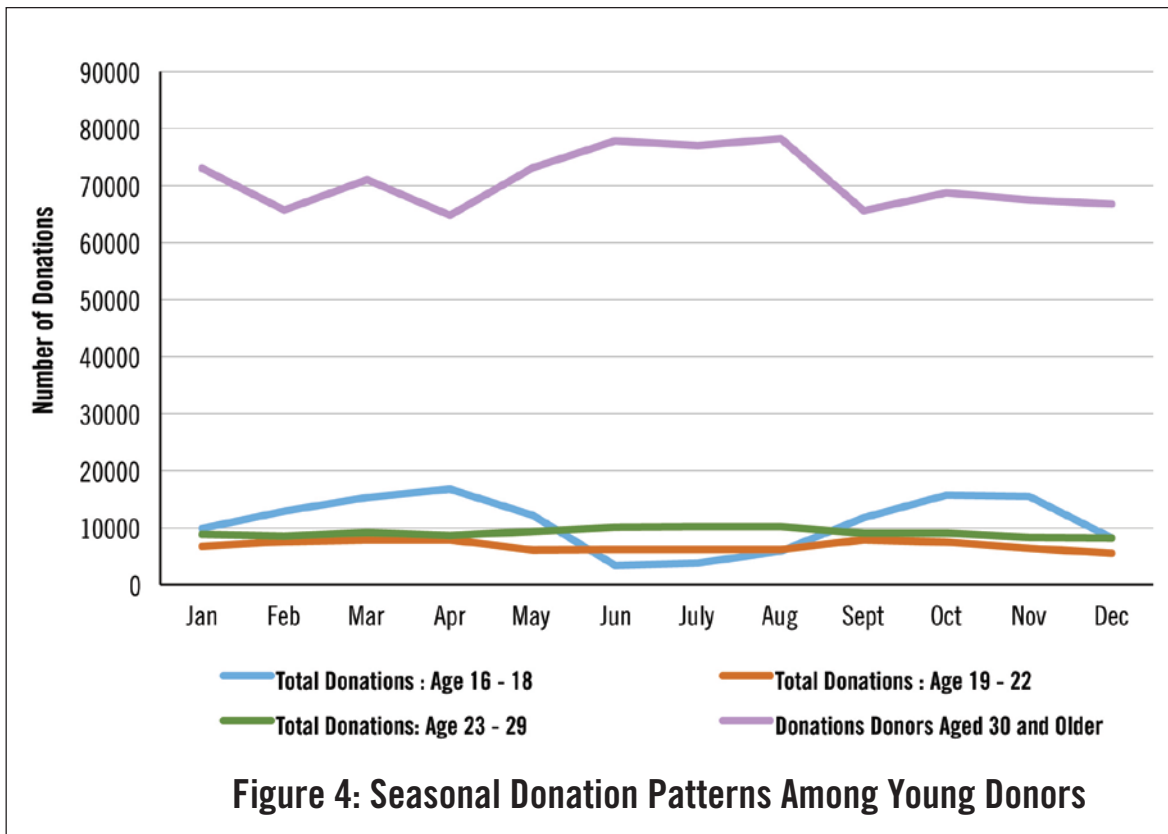


Table 3: Reaction Rates				
	Reaction Rate	Odds Ratio	Lower 95% CI	Upper 95% CI
Overall Reaction Rate	13.41			
Vasovagal	9.65			
Prefaint, No LOC, uncomplicated or minor	7.33	1.00	1.00	1.00
LOC, any duration, uncomplicated	1.87	0.25	0.24	0.27
LOC, any duration, complicated	0.40	0.05	0.05	0.06
Injury	0.06	0.01	0.01	0.01
Local Injury Related to Needle	2.48			
Nerve Irritation	0.23	0.10	0.09	0.12
Hematoma/Bruise	2.23	1.00	1.00	1.00
Arterial Puncture	0.03	0.01	0.01	0.02
Apheresis Related	0.83			
Citrate	0.05	0.06	0.05	0.08
Hemolysis	0.00	0.01	0.00	0.01
Air Embolism	0.00	0.00	0.00	0.01
Infiltration	0.77	1.00	1.00	1.00
Allergic	0.22			
Local	0.18	1.00	1.00	1.00
Systematic	0.04	0.20	0.14	0.28
Anaphylaxis	0.00	0.00		
Other	0.23			

9.65 per 1,000 donations. Most of these were categorized as “Prefaint” with no actual loss of consciousness (LOC). The second most common type of reaction was a symptomatic hematoma or bruise; these reactions were reported to occur at a frequency of 2.23 per 1,000 donations. More-severe reactions were much less commonly reported.

The blood donor adverse reaction rate was lower during the summer months. This can be seen in both the aggregate (Figure 2) and gender (Figure 3) analyses. The seasonal effect was somewhat larger in donations from female donors. In addition, the proportion of donations from younger donors varied across the calendar year (Figure 4). The reduced frequency of



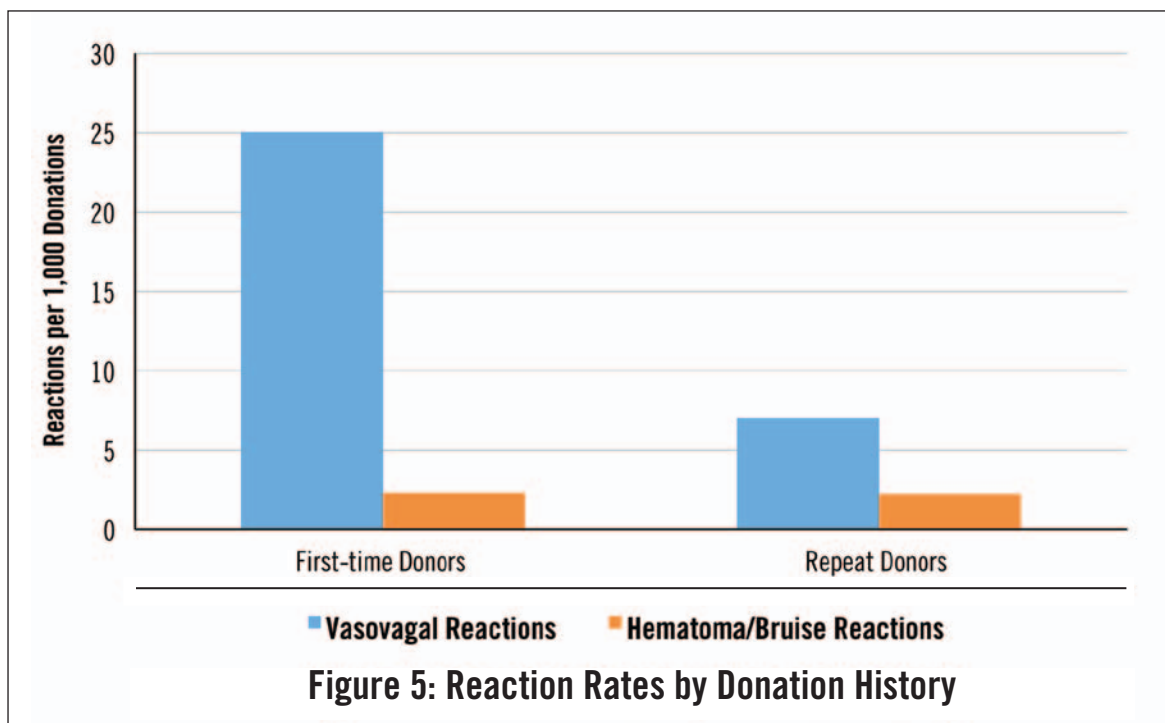


blood collection drives at high schools and college campuses was compensated with increasing donations from donors 30 years old and older.

Reactions By Age And Gender:

While 52.1% of collections were from male donors, only 35% of reactions occurred in males. Female donors were twice as likely ($p < 0.001$) to experience an adverse reaction to donating blood. First-time donations accounted for only 14.6% of the donations, but for 31.3% of adverse reactions, for a rate of 28.7 reactions per 1,000 donations. Twenty-four percent of donations were obtained using automated collections, while only 16.4% of reactions were reported from these

procedures. Overall, first-time donors (Figure 5) and younger donors (Table 4) were more likely to experience an adverse reaction. Donors aged 16 to 18 years contributed 11.2% of the donations reported (Figure 1), but accounted for 24.8% of adverse reactions and had a reaction rate of 29.7 per 1,000 donations ($p < 0.001$ as compared to donors aged 30 and older). Donors in the 19 to 22 year old group contributed 7.0% of donations, but had 11.6% of reactions ($p < 0.001$ as compared to donors aged 30 and older). This younger-donor effect extended to donations from donors aged 23 to 29, who experienced proportionately more reactions (12.9%) than their contribution to collections (9.3%; $p < 0.001$ as compared to donors aged 30 and older). On the other end of the age spectrum, the very oldest donors



Age	Reaction rate for all reaction types per 1,000 Donations (all: p<001)*	% of Reactions by Donor Age Group
16 - 18 years	29.7 (2.28)	24.8%
19 - 22 years	22.2 (1.69)	11.6%
23 - 29 years	17.2 (1.30)	12.9%
30 - 39 years	12.0 (0.91)	11.4%
40 - 49 years	9.3 (0.70)	12.6%
50 - 59 years	8.7 (0.65)	14.7%
60 - 69 years	9.3 (0.70)	10.1%
70 - 79 years	9.0 (0.67)	3.2%
≥ 80 years	12.3 (0.93)	0.7%

* Relative risk ratio as compared to mean reaction rate for overall population (13.41 per 1,000).

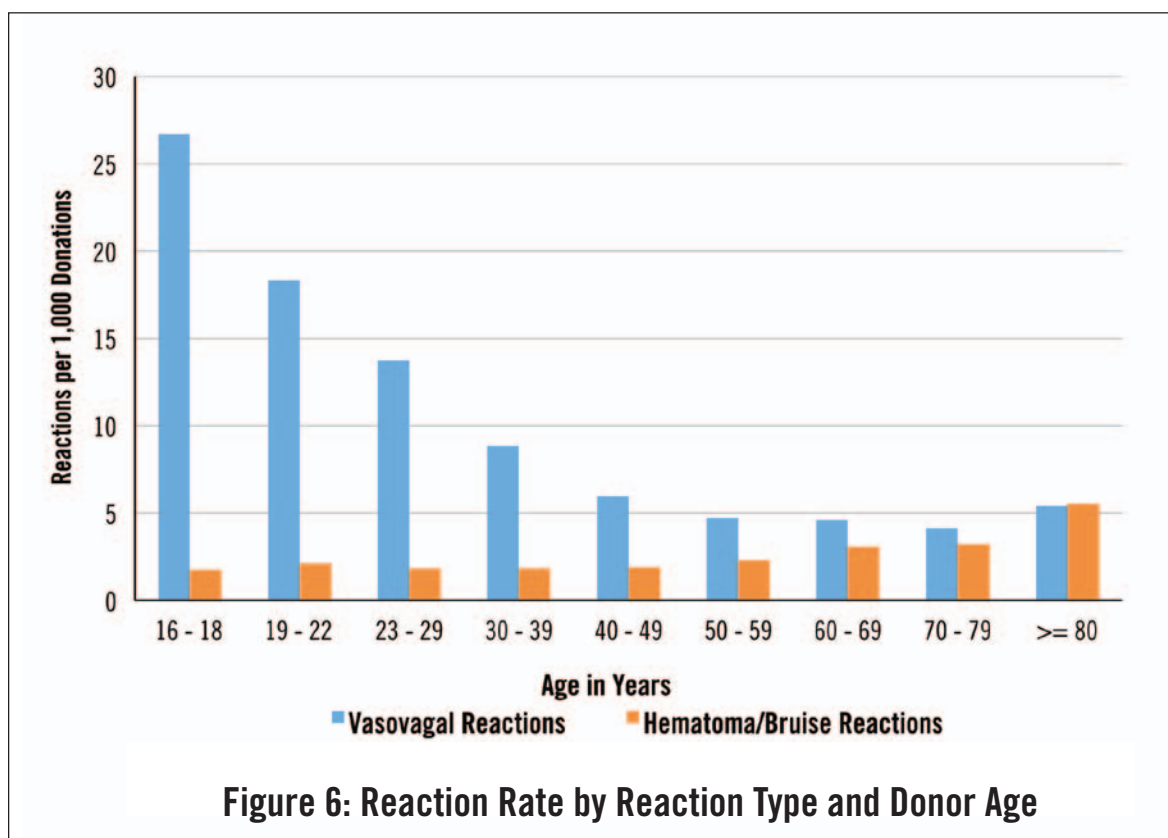
(aged 80 and older) experienced a rate of reactions no different from that of donors aged 30 to 39 years ($p=0.807$ when compared).

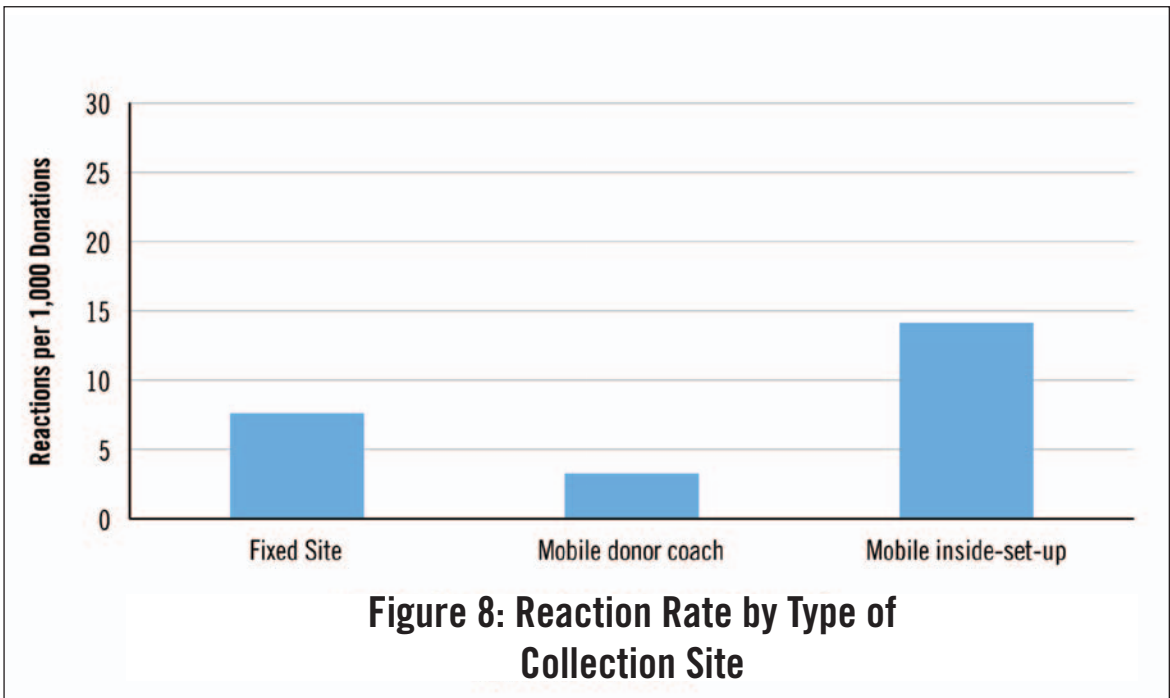
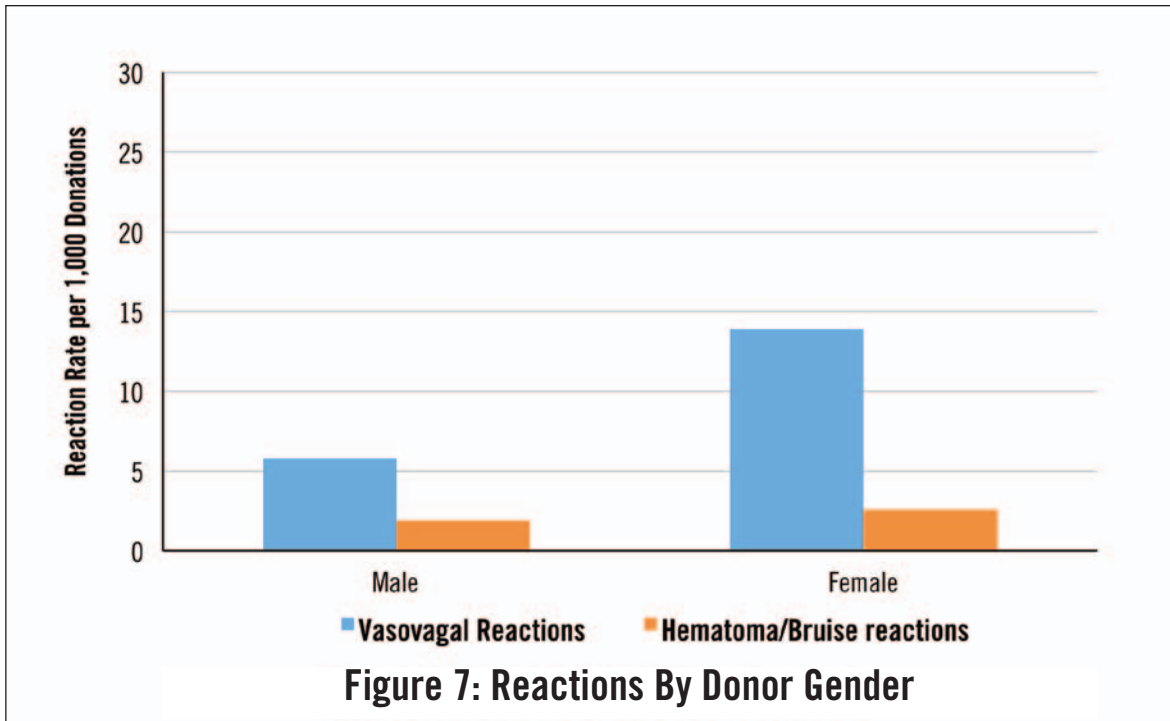
Figure 6 compares the reaction rate per thousand donations of VVRs and hematoma/bruise reactions by age group. In general, vasovagal reaction rates decreased as donors aged, dropping to between 4.1 and 5.9 per 1,000 in donors aged 40 and older. Conversely, hematoma/bruise reactions showed a slow and steady rise from 1.7 per 1,000 donations in the group aged 16 to 18 to 5.5 per 1,000 in donors aged 80 and older. Female donors were 2.4

times more likely to experience VVRs (13.9 versus 5.8 per 1,000 donations, $p<0.001$) and 1.3 times more likely than are male donors (2.6 versus 1.9 per 1,000 donations, $p<0.001$) to have had hematoma/bruise reactions (**Figure 7**).

Reaction Rates By Collection Site And Location:

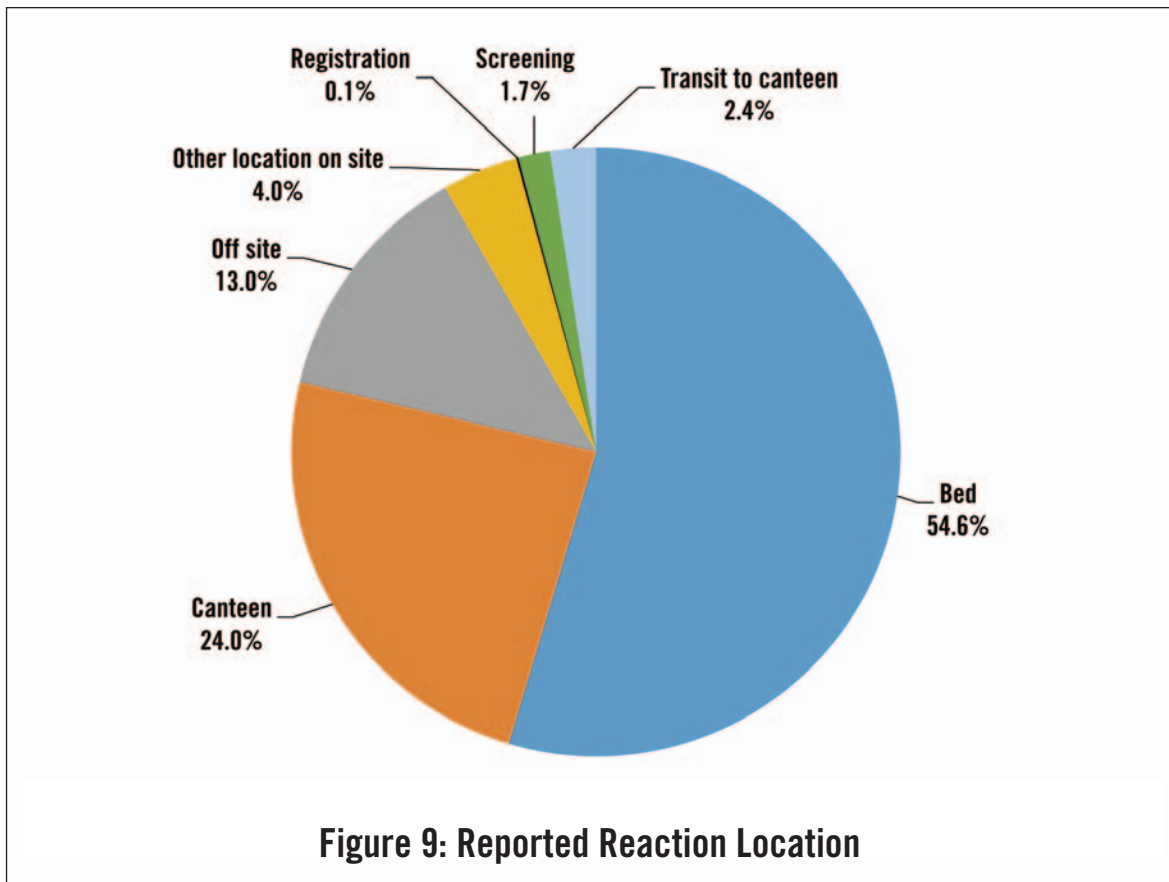
Reaction rates by the type of collection site are reported in **Figure 8**. Facilities reported the lowest overall reactions rates in mobile collection sites that used donor coaches, but the highest reaction rates at





mobile collection sites requiring setups inside the building of the mobile location (14.1 versus 3.3 per 1,000, $p < 0.001$). Once the donation process had begun, reactions at the collection bed (55%), the canteen (24%), or off-site (13%) together make up nearly 92% of all reactions

(**Figure 9**), however, a small number of reactions also occurred at registration (<1%), screening (2%), transit to canteen (2%), or at other on-site locations (4%), such as the rest room. Univariate denominator reporting limits the ability to analyze the collection site location reactions rates further.



5. Discussion

Reasons For DHV:

Whether they are remunerated or not, donors choose to give blood for a variety of reasons. Most donors make the choice to donate without detailed knowledge of physiology or of the technology involved, information that would be necessary to making a personal assessment of the safety or risk of the donation procedure. Blood donors are generally not familiar with current Good Manufacturing Practices or with the sophisticated quality systems in place in most donor centers, and many have never heard the term “continuous improvement” in relation to the blood collection procedures. Most importantly, donors trust that the donor centers hold patient and donor welfare as the highest priority and act as key stewards of the blood supply.

Participation in a DHV program is an effective way for blood collectors to monitor performance. Important questions such as: How many donors faint? How many have sequelae from venipuncture? How many are injured? In order to properly care for donors and prevent adverse reactions, it is important to know the answers to these questions. Simply caring for these donors is not sufficient. Future donors must have a better experience than that of past and current donors. Donors that have experienced injuries or adverse reactions from a blood donation expect subsequent changes to be made to reduce the pos-

sibility of future reactions or injuries on future donations. Recruitment of future potential donors might rely on education and marketing efforts articulating in pragmatic terms the ways in which blood collection facilities are constantly trying to make donation safer, more convenient, and a more satisfactory process overall.

Globally, people are becoming increasingly educated and with this progress comes the need for improvement in blood donation procedures along with metrics that demonstrate those advances. Changes in donor center collection practice should, therefore, be based on evidence supporting the potential for improvement. Historically, decisions in health care have not always been based on evidence; it is therefore important to provide evidence based support for blood donation process improvement.¹² Continuous improvement implies that we develop hypotheses about why certain donors react and how to prevent reactions and introduce interventions to assess those theories. Meaningful and high quality data must be sufficient to support rational hypothesis generation. If there is insufficient detail or the data are not stratified, rational hypothesis generation becomes quite difficult.

Active participation in national and international DHV programs is a simple but direct way for donor centers to demonstrate their commitment to continuous improvement in donor outcomes to stakeholders,

including donors, patients, transfusion medicine colleagues, and the community. Participation in DHV implies an effort to improve the donor care and safety infrastructure and a desire for national and international comparisons to determine best practices.

The cycle of continuous improvement in risk reduction begins with collecting data from the entire donation process, followed by analyzing these data, developing a risk reduction concept or strategy, implementing that strategy, and then monitoring to see if the idea was successful. At a minimum, some degree of risk reduction can be accomplished by monitoring the activities of other centers and implementing any of those interventions that are likely to be successful locally; however, some degree of monitoring one's own process is necessary to evaluate the effectiveness of the intervention. Collecting data specific to the adverse reaction, the donation, and the donor, as well as denominator data about the donor population, is essential for both strategies, because blood donor adverse events are multifactorial. Making assumptions about causes and designing interventions require an understanding of the data from all sources. Of course, not all hypotheses are ultimately found to be correct, and not all ideas work to increase donor safety or satisfaction. Without data expressed within the proper context, however, it is difficult to overcome incorrect initial assumptions.

For those interested in DHV, the first steps toward implementation are the adoption of current DHV definitions and standard data elements for routine use in operations and the determination of how much data from each of the four key categories

(donor, donation, reaction, and denominator) is collected within their facility. Organizations initiating DHV programs should begin to consistently capture the associated data elements in a format that can readily be re-used for operational, donor suitability, or DHV purposes (all of which are key requirements of data liquidity). Few facilities have all of the data elements readily available in electronic format; however, that deficit should not be a barrier to participation in DHV. In a system of continuous quality improvement, data must be rigorously obtained and analyzed. If data are not currently available, a commitment of time will be required to collect what is necessary for analysis. All facilities will likely take similar steps as they institute DHV (**Table 5**), proceeding from basic internal data gathering (Step I) through advanced benchmarking and data mining (Step IVb). Ideally, any collection facility in the world should be able to work through Steps I-III; those in the United States are encouraged to engage in Steps IVa or IVb.

Donor center resources are limited, therefore, successful vigilance systems must provide true value to those facilities that collect and submit data. The creation of new computer systems by individual facilities to capture DHV data may not be feasible. The AABB US DHV Program and the Donor HART™ software were designed to provide value to blood collection facilities and to other donor vigilance stakeholders. Data can be entered or uploaded and the data requirements are quite flexible with few mandatory data elements. Blood collection facilities should consider joining this national effort if they have not already done so.

Table 5: Implementation of DHV Activities		
Step	Description	Benefits
I	Internal data collection	<ul style="list-style-type: none"> • Basic data gathering and research
II	Internal mapping to or adoption of external vocabulary	<ul style="list-style-type: none"> • Ability to compare your data to others on the basis of internationally accepted vocabularies
III	Externally shared minimal data elements	<ul style="list-style-type: none"> • Minimal common surveillance data that can be shared and compared internationally • Surveillance detail summarized in AABB annual report
IVa	Externally shared benchmarking data (e.g., Donor HART™ Lite)	<ul style="list-style-type: none"> • Data incorporated into the AABB DHV annual report • DHV dashboard
IVb	Externally shared benchmarking with extended data mining capability	<ul style="list-style-type: none"> • Shared process improvement expertise to improve donor outcomes • Increased data liquidity on blood establishment computer systems (donor demographics, business analytics, etc.)

DHV As An International Concern:

The International Haemovigilance Network (IHN) formally defines hemovigilance as "... a set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence."¹³

Over the years, the AABB US DHV Working Group has worked closely with international groups (the ISBT and the IHN) with the intention of developing a single

international DHV vocabulary and an associated ontology. Arriving at common definitions of reactions is an important and challenging first step for comparing rates internationally and for assessing the impact of continuous-improvement measures adopted by various blood collection facilities throughout the world. International groups continue to work actively to harmonize simple, standardized definitions of reactions and to create a single list of attributes for numerator and denominator data.

Ideally, the vocabulary and associated ontology used by the ISBT and AABB US DHV programs will merge. A minimum dataset (MDS) that could be supplied by any international participant is being drafted. Participants who are willing and

able to provide additional and optional data would be able to do so within the standardized environment.

Plasma Protein Therapeutics Industry:

The Plasma Protein Therapeutics Association (PPTA) has participated in the AABB US DHV Working Group since its inception. The PPTA's Medical Policy Committee contributed to the common nomenclature and definitions incorporated in Donor HART™. While fully supporting the work of the AABB US DHV Working Group and Donor HART™, the PPTA determined that a source plasma-specific system would better serve its community. PPTA has developed a set of defined terms that relate specifically to source plasma collection. The donation type is limited to plasmapheresis, while the reaction types, categories, signs, and symptoms are harmonized as much as possible with those of the DHV program. The PPTA-developed definitions provide the foundation for a consensus-based approach for monitoring reactions in the plasma collection environment, called PlasmaVigilance.

Data Elements:

Most US blood collection facilities have data from all four categories (donor, donation, reaction, and denominator) in electronic format but may lack ready access to those data (i.e., poor data liquidity¹⁴) or they lack a structured data model format (ontology) for organizing those data sufficiently for subsequent analysis. Blood establishment computer systems (BECS), designed principally to protect recipient safety through high-quality manufacturing standards, are critical to

the successful collection, manufacturing, storage, and disposition of blood components. These BECS, however, are not designed for the data analysis required to support DHV goals. Time and resource limitations, therefore, restrict the extent to which facilities are able to collect and analyze data. Donor HART™ improves the liquidity of a collection facility's raw data and allows data analysts to spend more time actually analyzing data and less time simply collecting raw data on a spreadsheet. Blood centers, aware of the limitations of traditional BECS, are moving toward improved data liquidity as pressures increase to augment productivity or "do more with less," which ultimately will benefit all key stakeholders, from national and international policy makers to center leaders, managers, employees, and business analysts, as well as the blood donor or recipient.

Certain data elements are consistently reported in the 2012 dataset, including donor age, donor gender, donation history, donation type, and procedure type. Some elements are frequently, but not uniformly reported by all reporting organizations (e.g., collection site and ethnicity) or are only intermittently reported (e.g., donor race, pulse, and weight). Feedback suggests that these intermittently reported elements are not captured by facilities, are not currently stored electronically due to the manual nature of specific data collection, or are not stored at all (e.g., weight) because donor suitability is determined by other means. Data elements related to devices and kits are currently not reported, although these data can be found in most BECS, which suggests that most centers do not routinely view these data from a DHV point of view, but only from the manu-

facturing, quality control, or regulatory perspective.

How Collection Facilities Use Donor HART™:

Findings from the AABB US DHV Program are used to inform participant stakeholders and the greater blood collection community of opportunities to improve donor safety, to recruit donors safely, and to retain repeat donors who remain healthy. Current participants are using the data collected in Donor HART™ to measure process improvement, assess the impact of changes in practice, and to inform traditional business functions of a blood center. Examples include assessing post-implementation effectiveness of activities designed to prevent adverse donor reactions (e.g., implementation of prehydration stations, restriction of blood donations on the basis of total blood volume, introduction of salty snacks and/or oral electrolyte replacement, and introduction of muscle tension activities on the donor bed), assessing the impact of operational changes on donors (e.g., increasing the collection volume from 450 mL to 500 mL, implementing mobile double red cell collections, or increasing postdonation monitoring of high-risk groups such as high school students), and using quality assurance and industry benchmarking to evaluate performance.

Additional benefits of participating in DHV and Donor HART™ include the availability of denominator data for determining statistical sampling size for

auditors and ready access to descriptive donor base statistics and graphics for use in marketing and/or recruitment. Moreover, management review is easier with participation, because all data and figures are quickly and easily available for senior management, medical affairs, and quality teams to review on a regular basis.

Denominator Data And Donor Demographics:

The 2012 AABB DHV database represents adverse events from almost 10% of all US donations, with representation from approximately 12% of all non-hospital collection facilities.¹⁵ Most facilities report denominator data categorically, and therefore the following demographic comparisons were possible. Donors were slightly more likely to be male (52.1%) than female (47.9%). Repeat donors provided 85.4% of the donations, with 61% of donations coming from donors at least 40 years old. Given the decline in blood component demand since 2009, these numbers likely reflect an overall drop in donations from young first-time donors. Whole blood donation was the dominate form of donation (75.5%), followed by double red blood cell apheresis (14.2%) and apheresis donations containing platelets (8.2%). The seasonal variability in overall donations from donors less than 22 years old, especially those from the 16 to 18 year old group, emphasizes that, while young donors are an important group of donors, other donor groups are critical to meeting daily patient needs many months of the year.

Basic Reaction Rates:

The overall reported reaction rate was 13.41 per 1,000 donations (**Table 3**), including both serious and non serious reactions. This finding is consistent with the national rate of 1.3 serious adverse events per 1,000 donations estimated in 2011.¹³

Currently, there is debate whether national and international hemovigilance systems should capture adverse reactions with mild manifestations. Capturing all reactions allows for analysis of the full spectrum of adverse events, however, the benefit in capturing even the mildest of symptoms may not justify the extra resources required to capture and analyze those data. From a surveillance or a resource perspective, the best course may be to focus on collecting data on “moderate” to “severe” reactions (reactions with significant donor incapacity or sequelae). If we can demonstrate objectively that even the milder forms of adverse reactions decrease over time, donors may derive more satisfaction, thus become more likely to continue to donate. DHV should explain the spectrum of reactions, including symptoms, and the ways in which the data are captured in order to put reported rates into perspective.

It is important to note that there is wide variation in reaction rates across all facilities, even among collection sites within the same organization. Variation may be due to geography (e.g., relative altitude), overall donor population health, or phlebotomist skill. It is hypothesized that the causes of much of the variability are the differences in the identification, interpretation, and documentation of adverse events by frontline staff. Simple

and objective definitions of adverse events (e.g., VVRs with LOC) and the capture of associated signs and symptoms should be the goal of all national and international comparison studies, rather than the use of subjective classification systems (e.g., mild, moderate, or severe).

Donations from donors less than 30 years old were more likely to be associated with an adverse reaction than donations from donors of at least 30 years old. Overall, donations from donors less than 30 years of age accounted for more reactions than predicted by the number of donations from this age group, whereas donations from donors aged 30 or more accounted for fewer reactions than predicted by their number of donations. For example, first-time donors accounted for 14.6% of donations but 31.3% of all adverse reactions (28.7 reactions/1,000 donations), primarily because of their greater prevalence of VVRs. Overall, the total adverse reaction risk in younger donors is attributed to the risk of VVRs. There is an increasing rate of hematoma/bruises as donors age (**Figure 7**), with donors aged 80 or older having higher rates of hematoma/bruises than of VVRs, a finding that parallels the structural changes in skin with age.¹⁶

Reaction Rates By Location And Collection Site:

Reaction rates appear to vary by type of collection site (**Figure 8**). This finding may be largely artifactual and may be due to variations in donations by donor age and gender.¹⁷ Unfortunately, the one-dimensional denominator data used here prevent further detailed analysis. But, an objective analysis of the different environmental factors in fixed sites, mobile

donor coaches, and mobile inside-set-ups could provide insights into how to continue to reduce donor reaction rates. Could lighting, the general arrangement of beds, overall flow and layout, the ratios of donors to phlebotomists, continual proximity of phlebotomists to donors, and the overall collection area size, for example, be modified to demonstrate reproducible reductions in VVRs, especially in our most vulnerable age group (16-18 year old donors), who frequently donate in large, poorly lit, and uncontrolled spaces inside schools?

Few donor reactions occur before the venipuncture. During phlebotomy, there is a steady increase in donor reactions until a significant peak is reached at the time the needle is removed that is associated with donor total blood volume, gender, and age.^{17,18} The peak at the time of needle removal is partially due to the removal of the needle when a reaction begins. Injury is not very common from reactions occurring while the donor is recumbent. Injuries, including falls and their consequences, are more likely to occur because of reactions that occur once the donor has assumed the upright position and left the donation chair. When donors are questioned about symptoms several weeks after donation or at the time of their next donation, the actual rate of reported reactions is considerably higher than that determined by staff at the time of donation.¹⁹ In 2012, 81% of all reported reactions occurred either on the donation bed, in transit to the canteen, or in the canteen, and an additional 6% occurred on-site, either in screening, at registration, or in

another location (often the rest room). Of most concern are the 13% of reactions that occurred off-site, reactions that also frequently result in injury to the donor.

Future Directions:

A number of projects are under review by the AABB US DHV Program. As stated earlier, efforts to harmonize AABB and ISBT DHV definitions are ongoing. An international survey of practices for the prevention and management of donor iron depletion revealed wide variation in practices and has enhanced awareness of this issue.²⁰ The AABB US DHV Program, the IHN, and the ISBT intend to develop indicators to guide management and to allow relevant comparisons of iron stores related to blood donation.

Another project is the development of a Donor HART™ Lite version of Donor HART™ for blood collection organizations that would like to participate in DHV with a minimal and predefined commitment of data or resources. Numerators would include categorization of the adverse reaction and a small number of variables that apply to the donor, such as age, gender, or intended procedure/donation type. Some denominator data would be required to generate rates. Other data elements could be added later when the blood center is ready for more complete data submission and analysis. Donor HART™ Lite is expected to be available to participants in calendar-year 2014.

How To Participate:

To join the AABB US DHV Program, blood collection facilities must first complete an enrollment form to provide basic information, including point(s) of contact, the general size of the blood center, and a static IP address (for security purposes). The blood center can download the user manual and adopt the national definitions for donor reactions (the preferred process) or, at a minimum, can map local definitions to the national standards, recognizing that Donor HART™ will accept a minimal dataset.

The facility will be issued a training user ID and can then access the Donor HART™

training site to explore and train staff on the software. Meanwhile, facility leadership can sign the AABB US DHV Program Participation Agreement. When training is complete, the facility will receive a user-site ID and can begin submitting data and generating reports with the facility's own data. Blood collection facilities that submit a year's worth of donor reaction and denominator data may be involved in annual report generation and may be eligible to participate in interventions and studies developed to improve donor safety and health.

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