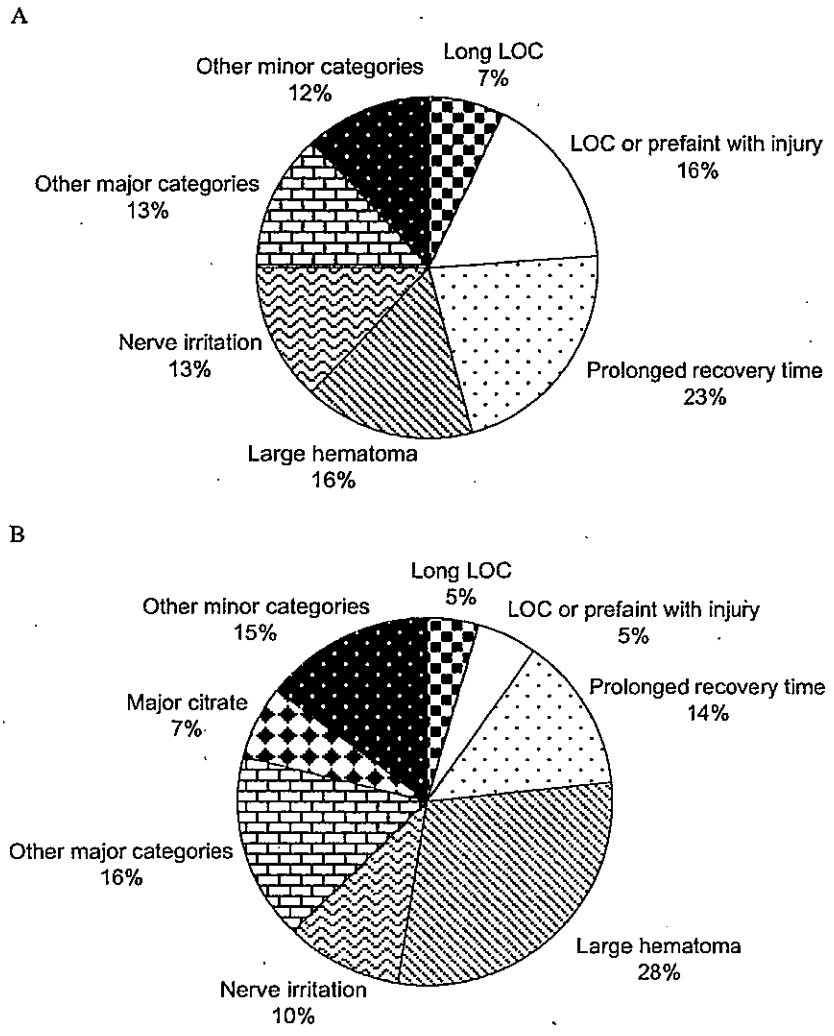

Fig. 6. Outside medical care reported after WB (A) and automated PLT and R2 collections (B). (A) WB (1,903 cases of outside medical care in 6,014,472 total WB collections; 3.2 per 10,000). (B) Automated (PLT, R2; 198 cases of outside medical care in 677,777 total automated collections; 2.9 per 10,000).

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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ASSOCIATION BULLETIN #08-04

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

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

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

Background

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

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

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

Donor Adverse Reactions

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

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

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

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

- **Blood drive environment and set-up.** Although few published data or information are available on best practices for drive set-up, the working group recognized the importance of adequate ventilation, electrical outlets, and physical space for managing adverse reactions. Specific actions discussed include:
  1. Procedures for site selection to ensure acceptable conditions that support operation and guidance on discontinuing operations if the conditions become unsuitable.
  2. Controlled donor flow and adequate staff or volunteer availability.
  3. Existence of a donation environment that can accommodate progressive recovery strategies.
  4. Donor escorts, especially from the chair/bed to the postdonation area (canteen).
  5. Predonation area for hydration and nutrition.
  6. Postdonation canteen/refreshment area.
  7. At the canteen site, adequate staff or volunteers who are trained in recognizing donation reactions.
  8. Separate areas for recovering donors who may feel anxious or sick.

  Additional practices and information relating to the listed strategies are contained in the appended reports.
- **Staff supervision and phlebotomist skills.** Training and supervision of collection staff are critical to the success of all blood drives and the safety of the donor. For high school drives, in particular, providing extra or experienced staff may mitigate the rate and impact of donor reactions. Blood collection facilities should regularly review collections staffing, training, and performance regarding managing reactions.
- **Interventions.** Various field practices are currently in place to prevent donor reactions, specifically in young donors. Although they are evolving practices, the following practices should be considered and evaluated by blood collection facilities.

  1. Donor Size/Age Criteria. The current eligibility requirement of a minimum weight of 110 lb and a whole blood collection limit of 10.5 mL/kg are sufficient to protect most donors. These criteria are based on the assumption that they would prevent drawing more than 15 percent of a donor's blood volume. Some blood collection facilities are considering changing those criteria to require that eligible donors have an estimated blood volume greater than 3500 mL. Other practices include raising the minimum weight to 120 lb for young donors or collecting a smaller volume of blood from young donors.

  2. Distraction Strategies. Distraction techniques such as audiovisual entertainment have been reported to be effective at putting donors at ease during collection, based on reductions in self-reporting of reactions.

  3. Hydration. In a few studies, donors who received water (500 mL, 30 minutes before donation) reported significantly fewer reactions. Blood

collection facilities may want to provide donors less than 20 years of age with beverages and encourage them to consume 500 mL of fluid within 30 minutes before phlebotomy.

4. Applied Muscle Tension (AMT). AMT is the repeated, rhythmic contraction of the large muscles of the arms and legs and has been shown to reduce presyncopal reactions in young donors. This technique is also easy to learn and safe to use.

5. Automated Collection Procedures. Automated two-unit red cell collections have a favorable safety profile compared to whole blood collections in young and first-time donors. The lower risk of reactions may be attributed in part to the saline (volume) replacement. Expansion and further study of apheresis red cell donation programs in high schools and colleges is recommended.

6. Postreaction Instructions. Under current standards, blood collection facilities must have a process for treating donor adverse events and providing for emergency care as necessary (BB/TS Standard 5.3.2.1). It is advisable to include information for both donors and families. This issue is addressed in more detail below under Donor Education.

Donor Injuries Resulting from Reactions

As it is a rare occurrence, there is no published information on injuries resulting from blood donor reactions. Available data come from injury claims at large collection programs. Current estimates predict approximately one serious injury per 200,000 donations. Injuries can occur when a donor has a syncopal reaction and collapses to the floor, causing facial or other fractures and lacerations. Reducing these syncopal reactions should, in turn, reduce these types of injuries. Other environmental and operational practices, including the use of additional staff and training in the management of reactions in the recovery area, are evolving. Reinforcement of canteen observation and escort policies and donor education about reaction recognition are also recommended. Placing recovering high school donors on floor mats to prevent falls and injury is another practice being evaluated. An accurate assessment of the impact of these measures awaits further collection of information on injury rates.

Donor Education

Predonation information, consent for donation and understanding how to manage postdonation issues are critical to providing a satisfying donation experience and ensuring that the donor returns for future donation. Because younger donors have different backgrounds, expectations, and legal issues relating to their donation, donor education and consent have special significance. Blood drives at high schools involve additional considerations for education, legal responsibility, and parent/guardian involvement.

Predonation anxiety is associated with increased rates of reactions. Addressing common donor fears and suggesting useful coping techniques allays donor anxiety and improves

attitudes toward self-efficacy (the belief that one has the capability to manage a situation) and future intention for blood donation. Predonation educational materials should be considered part of the consent process, in that information pertinent to the donation process, possible reactions, and interventions is imparted before the decision to donate. These materials will have greater impact if they are designed for the high school population, using age-appropriate language and graphics. They also may be presented in other adolescent-friendly formats, such as videos. Elements to be considered for inclusion in such materials include:

- A general statement that most donors have uneventful donations and most reactions, when they occur, are minor.
- A statement identifying which donors may be at increased risk for a reaction and why (for example, young, first-time, female, or low-weight donors may be especially at risk).
- A brief description of the donation process to inform first-time donors about the process and to alleviate anxiety about the unknown.
- Descriptions of possible techniques to prevent reactions and enhance coping skills, and a brief explanation of the possible benefits of adhering to these techniques.
- Statements describing blood collection facility policies on parent/guardian consent and confidentiality regarding test results, if applicable.

Blood collection facilities may want to consider targeting educational initiatives on adverse reaction prevention strategies, coping strategies to reduce reactions, responses to the management of delayed or prolonged donor reactions, and continuity of care after release from the donation site to the following groups:

- Chairpersons, drive sponsors, and high school officials.
- Training, recruitment and collection staff.
- High school students and their parents.
- School nurses.

Ideally, this information should be delivered close to the day of donation.

Postreaction Education and Care. Collection facilities must have a process for treating donor adverse events and providing for emergency care as necessary (BB/TS Standard 5.3.2.1). Measures to improve communication with parents/guardians or school nurses should improve the management of delayed reactions after leaving the site, and collection facilities may want to consider the following measures:

- Communication with parents/guardians if a donor experiences loss of consciousness or other reaction or injury, in accordance with state laws.
- Continuation of care for young donors who have had a reaction at the site or at home.

Consent and Confidentiality for Young Blood Donors

Informed consent practices for blood donation that successfully incorporate the principles of autonomy, veracity, beneficence, and non-maleficence have not been uniformly adopted. Consent to donate is not a simple signature on a form, but a broader process that involves education of the donor and, in some cases, the donor's parents/guardians. Moreover, consent for the collection of blood from 16- and 17-year-old minors, presents certain dilemmas and challenges. For example, state laws that allow 17-year-olds to consent to donate blood are generally silent on the minor's right to consent to subsequent medical treatment for an adverse reaction. States that allow 16-year-olds to donate often require parent/guardian permission/consent and, therefore, do not imply any emancipated status. Even though these states may recognize that minors have the decisional skills necessary to make informed health-care decisions, parents/guardians still have legal responsibility for their minor children.

Policies on notification of blood donors of test results must be carefully reviewed against state statutes relating to minors. In addition, minors are generally prohibited from participating in research without parent/guardian permission, although blood collection facilities may perform certain required or elective tests under research protocols that have been approved by an institutional review board.

Again, in providing adolescent donors (and parents/guardians) with information regarding the donation process and possible consequences (reactions), collection facilities are meeting an essential requirement of consent. Blood collection facilities may want to:

- Consult state statutes regarding age and consent requirements.
- Become familiar with the literature specific to adolescent/minor informed consent and assent.
- Provide information to both donors and parents/guardians as part of the consent process. Some facilities provide a parent/guardian consent form that functions as both informational brochure and consent documentation.
- Incorporate information specific to increased rates of reactions among certain groups such as young and/or first-time donors into the consent process.
- Incorporate statements regarding release of information to parents regarding medical care for reaction and/or positive test results, as applicable.

Summary and Conclusions

While most donations are uneventful, even a minor complication reduces the likelihood of a return donation. Serious injury following blood donation occurs infrequently among all donor age groups, but adolescent donors are disproportionately affected compared to older adults. Virtually all dimensions of the blood donation experience have some impact on the risk of complications. The working group has performed a comprehensive review of current views and practices involving adverse donation reactions in young donors. AABB believes that blood collection facilities may find this information useful in addressing the unique challenges presented by young donors and high school blood drives. Although zero risk may not be attainable even in adults, the rate of complications in minors calls for ongoing attention to a sustained operational effort that is continually focused on donation safety. AABB encourages blood collection facilities to continue to

monitor and report the effectiveness of interventions on blood donor reaction rates and injuries resulting from reactions. AABB's effort to establish a national hemovigilance program in the United States could provide not only a uniform reporting structure for adverse events after blood donation, but also the mechanism to monitor the effectiveness of efforts to prevent the rare but more medically serious donation-related complications.

Appendix 1.
Recommendations to Minimize the Risk of Reactions and Injuries among Adolescent Blood Donors

Contributing authors: Anne Eder, Hany Kamel, Christopher France, Diane Killion, Patsy Shipley, Pat Demaris, Nina Salamon, and Dan Waxman for the AABB Younger Donors Adverse Reaction Working Group, Robert Jones, MD, Chair

Objectives

1. To review published data and reported efficacy of methods to enhance the donor experience and/or reduce donor complications.
2. To identify the different approaches that could be employed at blood centers to reduce donor complications at high school drives.

Executive Summary

Young (16- and 17-year-old) donors now represent a significant and increasing proportion of the whole blood donations to blood centers in the United States, accounting for about 8% of the whole blood donations or 450,000 whole blood collections to the American Red Cross (ARC) in 2006. However, young age, total blood volume, and first-time donation status are known to be independent risk factors and leading determinants of donation-related complications.[1-6] Even minor reactions or temporary deferrals decrease the probability of return donation,[6-9] and efforts to improve the donation experience are crucial to sustain the blood supply. The increasing dependence on recruiting and retaining young blood donors requires a committed approach to donor safety, especially on high school blood drives.

A multidimensional view of the donation experience recognizes several aspects that influence the risk of complications after blood donation: inherent donor characteristics and predisposition toward reactions, blood center staff experience and skill, blood drive set-up and environmental features, and donor education before and after donation. Donor characteristics that correlate with higher syncopal complication rates after whole blood donation include young age, first-time donation status, low weight, low blood volume, female gender, and Caucasian race. While these may not all be independent predictors of reactions, an additive effect of risk factors has been observed in Caucasian high school students.[5] Several interventions (eg, asking the donor to drink 16 oz of water shortly before donation, or using applied muscle tension or distraction techniques) have been used to improve the donation experience and/or reduce donor complication rates. However, no single measure has been shown to prevent a majority of systemic reactions or to prevent the rare but more serious complications, such as syncope-related injury after whole blood donation.

Consequently, blood centers should consider all factors that affect a donor's experience and influence the risk of complications before deciding which safety measures should be enhanced or introduced at the blood center. The effectiveness of safety initiatives should be monitored continuously, the resultant data should be peer reviewed, and the conclusions should be published to further our understanding of the efforts to improve the donation experience.

The working group recommends that blood centers consider one or more of the measures in the following areas and develop monitoring programs to continually assess safety:

I. Predonation education
II. Drive set-up and environment
III. Staff supervision and phlebotomist skills
IV. Interventions
    A. Donor eligibility criteria
        1. Deferring young donors with blood volumes below 3500 mL
        2. Raising the minimum acceptable donor weight
        3. Collecting a smaller volume of blood from young donors
    B. Distraction strategies
    C. Water ingestion
    D. Muscle tension
    E. Automated red cell collection procedures with volume replacement
V. Postreaction instructions to donor and parents

This report summarizes the available evidence on these different approaches to improve the donation experience, identifying expected benefits and limitations, providing directions for additional development and study, and estimating the impact on the donor base, to offer consensus-derived recommendations in each area.

I. Predonation Education

Efforts to address common donor concerns and provide useful coping suggestions were associated with improved scores on questionnaires that assessed donor attitude, anxiety, self-efficacy (the belief that one has the capability to manage a situation), and intention toward blood donation.[10] There are no published studies that evaluate the effect of blood donation recruitment materials on complication or return donation rates.

Some unpublished data and anecdotal experience suggest that educational initiatives may be effective at reducing donor reactions and equipping the donor and staff to better handle reactions to reduce their severity.

Recommendations

Educational efforts may be reasonably expected to improve the donation experience and could result in greater participation and more effective preparation. Such efforts would not be expected to have an adverse impact on the donor base.

Educational initiatives should target the following groups:

- Chairpersons and sponsors of drives.
- High school students and their parents.
    - Educational material directed at donors should contain prevention strategies or anticipatory guidance and content that address coping strategies to reduce reactions.
    - Educational material should be delivered close to the day of donation.
- School nurses.

- School nurses should be informed of the pathophysiology of donation-related adverse reactions and the care of donors who experience complications.
- In advance of the drive, donor centers should discuss with school nurses or administrators how to handle delayed or prolonged donor reactions and ensure continuity of care after release from the donation site.

- Training recruitment and collection staff.

The optimal delivery method for student education is unknown but may include the following formats:

- An educational DVD. A video format ≤10-minutes meets the students in their world and offers school administrators the ability to provide the education at their convenience.
- Podcast, downloadable eBook, or similar application.
- Blood center Web site.

II. Drive Set-Up and Environment

Blood centers should have systems in place to process donors efficiently and to provide good donor care regardless of age. Scant data exist on best practices for drive set-up, and sponsor groups are often challenged to find enough space to accommodate a blood drive. Most blood centers require site clearance before a blood drive. It is important to tour the location where the drive is held to ensure adequate ventilation, electrical outlets, and space for handling adverse reactions. In a recent Blood Centers of America (BCA) survey of 26 blood centers, nine centers responded that the drive set-up for high school drives differs from the set-up for regular drives (Nina Salamon, personal communication).

Recommendations

Supportive evidence does not exist to recommend more controlled or restrictive requirements for drive site set-up. However, blood centers are encouraged to share their experiences to identify and implement processes that may lessen the likelihood of adverse reactions.

A predonation hydration station or other mechanism to provide fluids to donors before donation should be part of the drive planning or set-up. Donors should be allowed to leave the area with bottles of water, which may require obtaining permission from the school administrators before the drive.

Blood centers should consider the following aspects of drive set-up that may mitigate adverse reactions at high school blood drives:

- Procedures for site selection to ensure acceptable conditions to support operations and guidance on discontinuing operations if the conditions become unsuitable.
- Controlled donor flow and adequate staff or volunteer availability. Arrival and departure patterns of students should be evenly spaced to minimize commotion. Access to the donation area should be limited to student donors, designated volunteers, and staff.
- Progressive recovery strategies (eg, dangling legs over the side of the bed with appropriate attention) before having the donor stand up after donation.
- Escorting donors through the process—in particular, from the chair/bed to the canteen. Consider asking the volunteers to escort the donors back to class.

- Predonation canteen table for fluid and food (see Water Ingestion, below).
- Postdonation canteen/refreshment area:
- Designated area and donor flow should allow for adequate time in the canteen after donation.
- Have donors lie on gym mats on the floor during the recovery and refreshment period after donation.
- Inform donors of the importance of staying in the canteen for an allotted time (eg, about 15 minutes) or until they feel well. Emphasize to staff the importance of instructing donors to stay in the recovery area for sufficient recovery time.
- Additional staff or volunteers who are trained in recognizing prereaction signs and symptoms can be assigned to the refreshment area.
- Area for recovery. Wheel chairs should be available. Mobile screens can be used to separate or partition areas for students who may feel anxious or sick.

III. Staff Supervision and Phlebotomist Skills

Employees in the collections department are crucial to the mission and success of the blood center and the safety of the blood donor, regardless of donor age. In one study, phlebotomists exhibiting high scores on a standardized social skills test were associated with reduced donor reaction rates.[11] Phlebotomy training was somewhat significant in this study.

Some donor centers try to mitigate adverse reactions at high school blood drives by including staff who are well trained to recognize signs of reactions and to take steps to prevent them, and by increasing the number of staff or other supervisory personnel at high school drives.

Recommendations

Although donor centers often report having "extra" or "more experienced" staff on high school blood drives, there is no industry benchmark for a staffing model or skill-set requirements. The importance of hiring practices and staff training in interpersonal skills as well as technical skills is recognized. Blood centers are encouraged to continually evaluate their training programs and staff performance.

IV. Interventions

A. Donor Eligibility Criteria

1. Deferring young donors with blood volumes below 3500 mL.
    - Postdonation syncope may be a manifestation of the typical "vasovagal" attack, but can be a manifestation of hypovolemia.
    - One study of whole blood donations showed that a donor blood volume below 4775 mL is an independent risk factor for faint and prefaint reactions.2
    - The risk of reaction decreases substantially with increasing blood volume in the ranges assessed.2 Five percent of donors in this study had blood volumes of less than 3500 mL, which guarantees that their 525-mL donations would be more than 15% of their blood volumes.
    - Implementing an additional requirement for minimum total blood volume (>3500 mL) may reduce the risk of faint and prefaint reactions. A bivariate analysis indicates that the difference in reaction rates based on donor blood volume is larger at a younger age than the

difference for donors older than 30 years of age. An intervention applied to young donors (<23 years of age) with low blood volumes (<3500 mL) might reduce reactions.

- Preliminary unpublished data (Hany Kamel, personal communication) have indicated that donors younger than 23 years of age whose blood volume is <3500 mL represent 9% of donors younger than 23 and 1.6% of all donors. The rate of moderate and severe reactions in this group is 1.7% (compared to a 0.33% overall rate of moderate and severe reactions). A policy of excluding donors <23 years of age with blood volumes <3500 mL is estimated to eliminate 20% of moderate and severe reactions in this age group (9% of all reactions).

2. Raising the minimum acceptable donor weight.
   - Trouern-Trend et al1 reported a reaction rate of 0.46% in donors weighing <120 lb compared to a rate of 0.14% in the reference group of donors weighing 150 to 179 lb.
   - In high school students, Newman et al12 reported a reaction rate of 16.9% in donors weighing <130 lb compared to a rate of 8.2% in donors weighing 130 lb or more. Donors weighing <130 lb represented 4.1% of all donors (118/2894).
   - In one study,6 22 of 32 (69%) injured 16- and 17-year-old donors who received outside medical care for donation-related injuries weighed >130 lb; only 4 of 32 (12.5%) weighed less than 120 lb. Selection criteria based on donor-reported weight, therefore, would be expected to prevent only a small fraction of the injuries sustained by adolescent donors.
3. Collection of smaller volume of blood from young donors.
   - Two abstracts13,14 demonstrated equivalent overall safety profiles for 450-mL and 500-mL whole blood collections. In these studies, donors were not stratified by factors known to predispose to systemic reactions (eg, age, weight, experience, etc). It is possible that any beneficial effect of collecting smaller volumes from young and/or low-weight donors may have been masked.
   - Tomasulo et al15 measured the weight of whole blood units collected in a 450-mL bag, calculated the percentage of blood volume removed, and reported donor reaction rates in different donor groups. Female donors who had 14% to 16% of their blood volume removed were more likely to experience a reaction than those who had only 10% removed. The authors concluded that donors weighing 110 to 119 lb had an increased reaction rate, which was attributed to collection volume.

Recommendations (Donor Eligibility Criteria)

Studies have identified subgroups at higher risk that may benefit from having different selection criteria. The current eligibility requirement for minimum weight of 110 lb and to limit collection to 10.5 mL/kg is sufficient to protect most, but not all, donors. This requirement was based on the assumption that it would prohibit drawing more than 15% of a donor's blood volume. Recent data suggest that this assumption is not accurate[2] and a new standard approach may be needed to limit whole blood collection to no more than 15% of the total blood volume for adolescent donors. Although the reduction in reaction rates for a given change in selection criteria can be estimated by multivariate analysis, it is not known if implementation of a given policy will achieve the predicted results. Blood centers are encouraged to evaluate the potential effectiveness of different donor selection criteria in preventing reactions and injury.

B. Distraction of the Donor During Collection

It is widely recognized that distraction techniques are effective at putting donors at ease during collection. In a small study the use of audiovisual distractions reduced the self-reporting of vasovagal reactions.[16] Some examples of easy-to-implement audiovisual distractions for donor drives include allowing the use of MP3 players or providing headsets with music, encouraging applied muscle tension activities, and placing donor chairs back to back.

Recommendations

Blood centers should provide education to donors on permissible activities for distraction that may increase their sense of control during the donation. Blood centers should instruct staff on the importance of distraction as a possible way to reduce reactions.

C. Water Ingestion

To date, two studies have been published on the effects of predonation hydration on blood donor reactions. In a randomized controlled trial, 83 male and female first-time donors (median age = 19) consumed 500 mL of water 30 minutes before allogeneic whole blood donation.[17] Results indicated that the donors who received water reported significantly fewer presyncopal reactions (eg, faintness, dizziness, weakness) as compared to those who did not hydrate. This finding was later confirmed in a study of nearly 9000 high school donors (17-19 years of age) who consumed 473 mL of water 0 to 30+ minutes before phlebotomy.[12] Based on donor reactions recorded on the health history form, reaction rates were reduced 21% by predonation hydration (water = 9.9% reaction rate; no water = 12.5% reaction rate). Additional analyses indicated that reaction rates were lowest for those who consumed water within 10 minutes of the phlebotomy, with reaction rates increasing with longer lag times.

Although there are only two published studies on the effects of predonation hydration on donor reactions, additional laboratory research has demonstrated that acute water loading increases blood pressure, peripheral vascular resistance, and cerebral blood flow, and can serve as an effective prophylaxis against vasovagal reactions in healthy individuals undergoing orthostatic challenge.[18-20]

Table 1. Summary of Reductions in Donor Reactions Observed as a Function of Predonation Water Loading vs Standard Donation Control

Study	Water	Control	Change
Hanson and France[17] (2004)	0.48 (BDRI, log units)	0.91 (BDRI, log units)	↓47%
Newman et al[12] (2007)	9.9 % (donor reactions)	12.5% (donor reactions)	↓21%

Note: The BDRI, or Blood Donation Reactions Inventory, is a self-report measure of donor reactions such as faintness, dizziness, weakness, etc. Elevations on this scale predict donor non-return over and above the effect associated with reactions recorded on the donor record.

Recommendations

Based on existing evidence that predonation hydration can help prevent presyncopal reactions in both male and female donors, does not interfere with the donation process, and is perceived by collection staff as easy to implement, donors should be provided with 500 mL of water or fluid and encouraged to consume the water approximately 10 minutes before phlebotomy.

D. Muscle Tension

To date, four studies have been published on the effects of applied muscle tension (AMT) on blood donor reactions.[21-24] Although AMT exists in many forms, it typically involves repeated, rhythmic contraction of the large muscles of the arms and legs. In the first study to apply this technique in the context of blood donation, a brief video was used to teach AMT to a small group (n = 37) of relatively inexperienced donors (ie, 0 to 2 prior donations).[21] Compared to controls who did not view the video, donors who learned AMT reported significantly fewer presyncopal reactions (eg, faintness, dizziness, weakness) following donation. Furthermore, those who said they used AMT throughout the donation had the fewest reactions.

The beneficial effects of AMT were confirmed and extended in a larger study of 605 young donors (mean age = 22; mean prior donations = 3.5).[22] In this study donors were randomly assigned to 1) standard donation, 2) AMT predonation (placebo control), or 3) AMT during donation (intervention). In both AMT conditions the donors learned the muscle tensing technique from a brief video presentation. To control for positive expectancy effects, participants in the AMT predonation (placebo control) condition were instructed to practice AMT from the time they sat down in the donation chair until just before needle insertion. Overall, the results indicated that AMT had a beneficial effect for female, but not male, donors. Specifically, female donors assigned to the intervention condition reported significantly fewer presyncopal reactions, required fewer donation chair reclines, and were more likely to produce a full unit of blood than females in the placebo or standard donation conditions (the placebo and standard donation conditions did not differ).

In a separate sample of donors (n = 467), presyncopal reactions were attenuated for both male and female donors assigned to the AMT intervention instead of either placebo control or standard donation (which did not differ).[23] Most recently, 1209 donors (50% female, mean age = 22, mean prior donations = 2.2) were randomly assigned to either standard donation or one of five forms of muscle tensing.[24] Donors assigned to AMT viewed a brief video depicting repeated muscle tensing of the 1) full body (arms, legs, and abdomen), 2) lower body only (legs and abdomen), 3) upper body only (both arms), 4) upper body only with distraction (both arms, but instructed to attend to nondonation arm), or 5) donation arm only. When compared to standard donation, full body AMT replicated prior effects of significantly lower reports of presyncopal reactions and fewer donor chair reclines. Similar benefits were observed for lower body AMT, but not upper body AMT, suggesting that tension in the legs and lower abdomen are important components of the beneficial effects of AMT. Upper body AMT with distraction was also associated with a significant reduction in presyncopal reactions, suggesting that AMT benefits may also derive, at least in part, from distraction.

In addition to research in the blood donation context, AMT has been used for decades to successfully treat patients with syncope related to blood and injury phobia[25-29] as well as other

causes of vasovagal syncope.[30-34] Laboratory studies suggest that AMT may help prevent syncopal and presyncopal reactions by increasing blood pressure and cerebral blood flow and oxygenation.[31,35-39]

Table 2. Summary of Reductions in Donor Reactions Observed as a Function of Applied Muscle Tension vs Standard Donation Control

Study	Muscle Tension	Control	Change
Ditto et al[21] (2003)	4.9 (BDRI units)	6.3 (BDRI units)	↓22%
Ditto et al[22] (2003)	All donors = 0.43 (log BDRI)	0.47 (log BDRI)	↓8%
	Female donors = 0.44 (log BDRI)	0.55 (log BDRI)	↓20%
Ditto and France[23] (2006)	0.35 (log BDRI)	0.45 (log BDRI)	↓22%
Ditto et al[24] (2007)	0.42 (log BDRI)	0.52 (log BDRI)	↓19%

Note: The BDRI, or Blood Donation Reactions Inventory, is a self-report measure of donor reactions such as faintness, dizziness, weakness, etc. Elevations on this scale predict donor non-return over and above the effect associated with reactions recorded on the donor record.

Recommendations

Based on existing evidence that AMT is easy to learn, safe to use, and effective at reducing or averting presyncopal reactions in young donors, donor and staff instruction in this technique is recommended. Different approaches are possible but should be focused on tensing the large muscles of the legs and abdomen during donation. Further study is encouraged to evaluate the effectiveness of the intervention in reducing reactions and injuries after donation.

V. Automated Red Cell Collection

The safety of automated collection of Red Blood Cells (RBCs) has been compared to whole blood donation.[40,41] In the American Red Cross experience, the vast majority of adverse reactions to Whole Blood (WB) and 2-unit RBC donation were minor, systemic complications (eg, prefaint, citrate reactions).[40] The overall rate of complications was marginally greater for 2-unit RBCs than for WB collections (320.3 vs 274.5 per 10,000 collections; odds ratio, 1.17 (95% CI, 1.15 to 1.20).

Table 3. Risk Factors for Donation-Related Complications*

Demographic Characteristic	Reaction Rate (/1,000 donations)	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio† (95% CI)
Blood volume < 3500 mL‡	34.9	4.47 (4.10-4.88)	2.88 (2.57-3.23)
Age = 17-18 years‡	39.6	4.19 (3.94-4.45)	2.78 (2.59-2.98)
Age = 19-24 years‡	27.4	2.87 (2.68-3.06)	2.39 (2.23-2.56)
First-time donor‡	27.5	2.80 (2.66-2.94)	2.20 (2.07-2.33)
Race = Caucasian ethnicity‡	14.3	3.42 (2.63-4.46)	2.15 (1.64-2.82)
Blood volume = 3500-4000 mL‡	23.5	2.97 (2.77-3.17)	2.09 (1.90-2.31)

*Donor reaction rates and odds ratios of combined mild, moderate, and severe reactions by donor characteristics compared to donors without reactions.[2]

†Includes age group, gender, donation history, race/ethnicity, estimated blood volume, pulse, systolic blood pressure, and blood center as covariates.

‡Compared to the reference group: blood volume >4775 mL; age 25-65; repeat donor, and Black, non-Hispanic ethnicity.

However, the rate of major systemic complications (loss of consciousness, loss of consciousness with injury, prolonged recovery, major citrate) in 2-unit RBC donations was lower compared to the rate in WB donations; in particular, for donors <20 years [odds ratio, 0.41 (95% CI, 0.32 to 0.53)].[40] Blood Systems demonstrated that manual WB collections have a low incidence of moderate and severe reactions (47.1 per 10,000 collections, 0.47%).[41] Single-unit RBCs collected by apheresis have the same safety profile (37.44 per 10,000 collections, $p > 0.20$). Two-unit RBC collections by apheresis and plateletpheresis collections have a significantly lower reaction rate (15.65 per 10,000 collections, $p < 0.00005$; and 14.84 per 10,000 collections, $p < 0.00005$, respectively).[41]

Automated 2-unit RBC collections have a favorable safety profile compared to whole blood collections, with a lower risk of major systemic complications compared to whole blood donation. This benefit is most pronounced among young and first-time donors, providing a rationale for further study and for possibly expanding apheresis red cell donation programs in colleges and high schools.

The apparent safety advantage of 2-unit RBC collections may be attributed to the saline replacement during such procedures or to the more stringent criteria for such donations (the hematocrit, height, and weight criteria used to select donors for 2-unit RBC donations are designed to select donors with larger red cell or total volumes than whole blood donors of smaller stature). Further analysis is needed to tease out the true impact of volume replacement.

Recommendations

The available evidence supports further study of expanding apheresis red cell donation programs in high schools and colleges.

VI. Postreaction Instructions to Donors and Parents

Donor centers must have procedures for postreaction care of donors (Standard 5.3.2.1).[42] Measures to improve communication with parents/guardians or school nurses may decrease the likelihood of delayed reactions after leaving the site, and donor centers should consider the following aspects:

- Communication with parents/guardians that the donor experienced a loss of consciousness or other reaction or injury, in accordance with state laws.
- Blood centers should ensure that donors who have had a reaction receive continued care while they are still at the collection site and after they reach home.

Conclusions and Future Directions

Blood centers should recognize all the dimensions of the donation experience that affect the risk of complications and consider one or more of the measures discussed in this report to enhance safety on high school drives. Blood centers should also monitor the effectiveness of their efforts to gauge progress and further refine their policies and procedures to protect donors and ensure a good donation experience. Although most donations are uneventful, even a minor complication reduces the likelihood of return donation. Serious injury following blood donation occurs infrequently among all donor age groups, but adolescent donors are disproportionately affected compared to older adults. In one study, the risk of syncope-related injury among 16- and 17-year-donors was 5.9 per 10,000 donations compared to 0.4 per 10,000 donations by individuals 20 years or older (odds ratio, 14.46; 95% CI, 10.43-20.04).[6] Although the initiatives that have been defined in this report to reduce donor reactions are predicted to also prevent some injuries, the actual benefit of any specific action may be difficult to measure given the rarity of the occurrence of donor injuries. Currently, it is also impossible to compare reaction rates across donor centers because of inconsistent definitions of what constitutes a reaction, different reporting criteria, and variability in how individual phlebotomists recognize and report adverse reactions. AABB's effort to establish a national hemovigilance program in the United States will provide not only a uniform reporting structure for adverse events after blood donation but also the mechanism to monitor the effectiveness of efforts to prevent the rare, but more medically serious, donation-related complications. Although zero risk may not be attainable even in adults, the rate of complications in minors calls for ongoing attention to a sustained operational effort that is continually focused on donation safety.

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Appendix 2.
Recommended Initiatives Concerning Education and Consent for Adolescent Blood Donors

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I. Initiatives to Improve Education of Adolescent Donors, School Personnel, and Parents

A. Adolescent Donors

Objectives

1. To reduce reactions and injuries of high school donors by educating them about maneuvers to prevent common reactions and injuries resulting from such reactions.
2. To identify elements for inclusion in predonation materials designed to reduce anxiety and provide coping techniques, thereby reducing reactions and injuries.

Background

Although many aspects of blood collection (such as screening, labeling, and testing) are highly regulated and standardized across collection facilities, many other facets of the collection process are unregulated and vary widely, such as the multitude of materials supplied to donors for recruitment and educational purposes. Specific challenges arising from the collection of blood from an adolescent population, including the high rate of reactions, may be addressed by improvements in predonation education of the adolescent donor to allay anxiety associated with the blood donation process and to promote coping skills.

The association of predonation anxiety with increased rates of vasovagal reactions is well documented.[1-4] Labus et al[3] used the Medical Fears Survey to assess the association of anxiety with the likelihood of fainting in a group of 364 volunteer blood donors and found that high scores best predicted fainting in first-time and experienced female donors. Efforts to address common donor fears and provide useful coping suggestions through predonation education were associated with improved scores on questionnaires that assessed donor attitudes, anxiety, self-efficacy (the belief that one has the capability to manage a situation), and intentions toward blood donation.[5] Studies to evaluate the effect of educational materials on the frequency of reactions are under way.

Recommendations

Although no published studies evaluate the effectiveness of donor educational material in reducing reactions, studies associating anxiety and fear with an increased rate of reactions suggest that interventions, including education, to reduce anxiety should have a positive effect. Therefore, predonation educational materials can be considered part of the consent process, so that information pertinent to the donation process, possible reactions, and interventions is imparted before the adolescent makes the decision to donate.

Educational materials for high school donors will likely have a greater effect if they are designed with age-appropriate language and graphics. In addition, educational materials may be presented in adolescent-friendly formats such as videos. Regardless of the format, elements to be considered for inclusion in predonation materials for students include the following:

- A general statement to the effect that most donors have uneventful donations and that most reactions, when they occur, are minor.
- A statement identifying which donors may be at increased risk for a reaction (eg, young, first-time, female, or low-weight donors) and why.
- A brief description of the donation process to alleviate anxiety about the unknown for first-time donors.
- Descriptions of possible techniques to prevent reactions and enhance coping skills. Also, a brief explanation of the possible benefit of each technique may boost compliance. Common techniques that have been used include the following:
  - Predonation hydration.
  - Receiving adequate sleep.
  - Receiving adequate nutrition.
  - Avoiding alcohol before and after donation.
  - Using applied muscle tension.
  - Using distraction techniques.
  - Using progressive recovery techniques (eg, dangling legs).
  - Complying with postdonation instructions and spending adequate time in the canteen.
  - Avoiding strenuous physical activity after donation.
  - Acknowledging anxiety and alerting blood collection staff of anxious feelings.
  - Becoming informed and asking questions.
- Statements describing blood collection facility policies on parental consent and confidentiality regarding test results, if applicable.

B. Parents of Adolescent Donors

Objectives

1. To involve parents by educating them about ways to reduce donation risk for their adolescent children.
2. To involve parents by educating them about the handling and treatment of reactions and involving them in decision-making when reactions occur.

Background

Parents of adolescent blood donors are in a unique position both to participate with their children in the decision to donate blood and, if reactions occur, to provide any needed care after their children return home.

Recommendations

It may be helpful to provide parents with information about blood donation, possible adverse reactions, and parental involvement in the event of an adverse reaction, even if parental consent for the donation is not required. The following should be considered for parental educational materials:

- Materials should include the same informational elements as student educational materials.
- Materials may include specific statements regarding the confidentiality of donor information, as applicable.
- Materials may include general instructions for supporting donors after common reactions such as hematomas or vasovagal episodes.
- Materials may be provided to the parent with consent documents when such documents are required.

C. School Personnel

Objectives

1. To involve school personnel by educating them about ways to reduce donation risk for their adolescent students.
2. To involve school personnel by educating them about the handling and treatment of reactions and involving them in decision-making when reactions occur.

Background

As employees of the school district, school health personnel have responsibility for the health of students on campus and, therefore, may serve as integral partners with the blood collection facility in the care of student donors. These health personnel may be involved in donor reactions either during the blood drive or after the collections staff have left the collection site. In either case, school personnel may have specific responsibilities to the student and parent in cases of student injury. Education of school personnel about the general process of blood donation, the possible reactions, and appropriate interventions and treatment is likely to be well received. Articles specific to blood donation and reactions are needed in the school health literature.

Recommendations

Blood collection facilities are encouraged to communicate with school officials before high school blood drives to establish policies and delineate responsibilities for student care during and after the blood drive. It may be useful for blood collection facilities to develop educational materials that target school health personnel; elements for consideration include the following:

- A general statement to the effect that most donors have uneventful donations and that most reactions, when they occur, are minor.
- A statement about which donors may be at increased risk for a reaction (eg, young, first-time, female, or low-weight donors) and why.
- A brief description of the donation process.
- A description of signs and symptoms of common donor reactions.
- A brief description of the appropriate handling of common donor reactions.

- A statement delineating the responsibilities of blood center personnel and school health personnel.
- A statement regarding confidentiality and release of information to parents, if applicable.

II. Initiatives to Address Consent Issues Specific to Adolescent Donors

Objectives

1. To provide blood collection facilities with information specific to informed consent of minor/adolescent donors.
2. To consider addressing increased rates of reactions in this age group in the informed consent process.

Background

The ethical substance of informed consent incorporates the fundamental principles of autonomy, veracity, beneficence, and nonmaleficence. The application of informed consent principles for both blood donors and blood recipients has been thoroughly addressed through peer-reviewed journal articles[6-8] and AABB publications.[9,10] However, the collection of blood from 16- and 17-year-old minors presents particular dilemmas and challenges with regard to traditional notions of informed consent.

Many states have long allowed 17-year-olds to consent to donate by specific state statute, but these statutes are silent on the issue of the minor's right to consent to subsequent medical treatment for an adverse reaction. Therefore, the consent process should take into account applicable state law provisions.

States that allow 16-year-olds to donate often require parental permission/consent. This situation allows the process of donation but does not imply any emancipated status because of the requirement for parental permission. Although 16- and 17-year-olds are sometimes recognized by state law as having the decisional skills necessary for making informed health-care decisions, parents and guardians still have legal responsibility, absent state law provisions to the contrary. This ambiguity is often handled by including the additional concept of assent, the notion that minors should be involved in health-care decisions in age-appropriate and developmentally appropriate ways.[8]

Specific issues arise when applying this distinction to blood donation. Blood collection facilities have traditionally adhered strictly to practices of confidentiality in notification of blood donors, including minors, of positive test results. Such policies need to be reviewed by blood collectors with specific attention to state statutes. The research setting presents similar issues. Minors are generally prohibited from participating in research without parental permission; however, blood collection facilities may perform certain required or elective tests under research protocols that have been approved by an institutional review board, and such protocols address the requirements for consent applicable to minors. Because statutes governing informed consent are state specific,