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,

blood collection facilities are urged to consult legal counsel when addressing consent issues regarding minors.

In summary, it is vital to remember that consent is *not* a simple signature on a form, but a broader process that involves education of the donor and, in some cases, the parent. Providing adolescent donors (and parents) with information regarding the donation process and possible consequences meets an essential requirement of informed consent.

Recommendations

Blood collection facilities should consider the following:

- Consulting state statutes regarding age and consent requirements.
- Becoming familiar with the literature specific to adolescent/minor consent and assent.[7,8]
- Providing information to both donors and parents as part of the consent process. (Some facilities provide a parental consent form that functions as both informational brochure and consent documentation, when applicable.)
- Incorporating information specific to increased rates of reactions among groups such as young and first-time donors into the informed consent process.
- Incorporating statements concerning the release of information to parents about medical care for reactions and positive test results, as applicable.

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