



High School Drives Safety Report

In recent years, there has been a rapid increase in high school blood drives. Blood bank organizations like the American Red Cross have increasingly looked to 16 and 17-year olds as a critical resource for meeting our nation's blood supply needs. Donating blood is safe. But a major study published in the Journal of the American Medical Association (JAMA), in 2008, found that [teenage donors are significantly more likely to experience donation-related medical complications](#). Adverse reactions like fainting and bruising after donating blood occurred in 10.7% of 16 and 17-year olds, as compared with 2.7% of donors 20-years and older. While not evaluated in the study, major adverse reactions may also occur, including prolonged loss of consciousness, large hematomas, and arterial puncture. The study concludes:

A higher incidence of donation-related complications and injury occurs among 16- and 17-year-old blood donors compared with older donors. The increasing dependence on recruiting and retaining young blood donors requires a committed approach to donor safety, especially at high school blood drives.

Soon after the JAMA study was released, the New York Times published an article entitled, [High School Blood Drives Pose Extra Risks](#). The report suggested that parents may want to talk to school officials about safety precautions at blood drives.

The following recommendations are intended to assist parents, PTA's, school administrators, and high school blood drive coordinators, with ensuring that best safety practices are applied at your high school blood drive. It is your right, and responsibility to work with your mobile blood drive operator, to help keep your blood drive safe.

Recommendations for Parents, School Administrators, and High School Drive Coordinators

The Workers Committee for Blood Safety includes licensed nurses, phlebotomists, and blood drive staff with extensive experience with teen donors at high school blood drives. We fully support high school blood drives, and encourage teens to consider becoming blood donors.



Based on the medical literature and the experience of our members, we recommend that you reach an understanding with your mobile blood operator to address the following safety concerns as you plan your next blood drive: 1) assignment of licensed nurses to your blood drive; 2) adequate blood drive staffing; 3) enforcement and parental notification of height and weight eligibility requirements; 4) investigation of all major adverse reactions and injuries that may occur on drives; and 5) proper blood drive setup. Finally, we encourage you to be aware of your Red Cross region's safety record.

(1) Will a Registered Nurse (RN) and Licensed Nurses Be Assigned to your Blood Drive?

According to the American Association of Blood Banks (AABB), assigning extra or experienced staff to high school blood drives may ["mitigate the rate and impact of donor reactions."](#)

The Committee believes that one RN, and preferably a second licensed nurse should be present at every high school blood drive. RNs and LPNs have extensive medical training and greater experience to make medical assessments, and respond to donor reactions or injuries. A licensed nurse at your drive may be particularly important if the staff assigned to your drive lack adequate training, medical education, and experience.

During regulatory inspections in two other Red Cross Regions – the [Greater Alleghenies](#) Region, and the [Ozark- Arkansas](#) Region – the FDA cited Red Cross for failing to assure that personnel have necessary training,


and a thorough understanding of operations which they perform. In the Greater Alleghenies Region, these problems involved the failure to provide employees with proper and/or have proper written procedures for use certain equipment.  In the Ozark-Arkansas Region, the FDA observed that collections staff did not understand blood safety procedures for proper deferral of donors. 

Current Red Cross practices vary, in terms of assigning nurses to high school blood drives. In some locations, one or two nurses, regularly staff high school drives. In other locations, Red Cross does not assign any licensed nurses to high schools. Blood drive workers also report that some regions do not require that all blood drive staff maintain current CPR certification. We believe that Red Cross should adopt, publicize and enforce a consistent policy that reflects best safety practices.


Recommendation: Contact your blood drive operator and make sure that a minimum of one registered nurse (RN); and preferably, a second licensed nurse be assigned to your high school blood drive.

(2) Will Your High School Drive be Adequately Staffed?

Over the past year, the FDA has issued inspection reports in two Red Cross regions that cite understaffing at blood drives. In the [Heart of America](#) Region, and the [Connecticut](#) Region, FDA observed, “The personnel responsible for the collection of blood or blood components are not adequate in number to assure competent performance of their assigned functions, and to ensure that the final product has the safety purity, potency, identity, and effectiveness it purports or is represented to possess.”

In the [Heart of America](#) Region, FDA reported to Red Cross, “According to your staffing matrix, specific numbers of employees are required to be present at mobile blood drives. ARC Heart of America Region operation records reviewed during your inspection reveal blood drives are not staffed adequately and according to the firm’s matrix.” 

The FDA cited four examples of understaffed drives - two at high schools and two at churches. FDA indicated that each of these drives were understaffed based on the collection goal, the projected number of whole blood procedures, and the total number of hours scheduled for the drives. In addition, at five blood drives, including one at a high school, when the blood drive coordinators complained about inadequate staffing in blood drive sponsor surveys, Red Cross did not follow procedures for evaluating and/or investigating these staffing complaints.

In an inspection report issued to the Red Cross [Connecticut](#) Region, the FDA again stated that the blood drive staff, were not adequate in number to assure competent performance of their assigned functions. Based on a review of operational records, FDA identified examples of six mobile drives that were not staffed adequately. 

FDA did not specify whether these mobile drives took place at high schools or at other locations.

Finally, blood drive RNs and phlebotomists report that at high school blood drives, when one teen donor has an adverse reaction and passes out, it is not uncommon for other teens to follow with their own adverse reactions. Blood drive workers describe this phenomenon as, “dominos,” or “contagious fainting.” Under these circumstances, workers report that adequate staffing may help keep the blood drive from becoming too chaotic.

Recommendation: Regardless of size, every high school drive should have two additional staff assigned above the normal Red Cross staffing matrix. If more than 150 students intend to give blood at the drive, three additional staff should be assigned.

(3) Will Height and Weight Safety Requirements Be Enforced?

In addition to age, the medical literature has shown that donor gender, height and weight are key factors for assessing risk of adverse reactions. Low weight teens with less blood volume, are at greater risk of experiencing a loss of consciousness, which [may result in injury](#).

To address this problem, many blood collection operations, including Red Cross, have raised height and weight requirements for all high school students. While these new requirements represent a positive change, in practice, the policy is compromised. Students are asked their height and weight before they donate blood, but Red Cross [maintains a policy to not measure and weigh them](#) at the drive to determine whether they actually meet eligibility requirements.

Recommendation: Each student should be weighed and measured at the blood drive, to determine whether they meet the height and weight eligibility requirements.

In many states, 16-year olds are allowed to donate with written parental consent. The parental consent forms provide a great deal of useful information, but may not inform parents of the specific height and weight requirements. Without having been informed of these requirements, a parent may unknowingly provide written permission for their child to give blood even though their child should be ineligible to donate blood. Parents should also be aware if their child is on the borderline of meeting height and weight requirements. In these situations, a parent may want to consider waiting an additional year before their child becomes a blood donor.

Recommendation: Review the parental consent forms and determine if they provide all needed information. In particular, consider having the blood drive operator include the height and weight safety requirements with the consent form.

(4) When a Blood Donor Has a Reaction or Injury, Will Red Cross Do Proper Follow-Up?

Over the past year, FDA has issued inspection reports citing nine Red Cross regions across the country, indicating failures to properly report and/or investigate donor reactions and injuries. The Red Cross regions cited in these inspection reports include: [Arizona](#), [Great Lakes](#), [Greater Alleghenies](#), [Heart of America](#), [Indiana-Ohio](#), [Missouri-Illinois](#), [Northern Ohio](#), [Southeast Michigan](#), and [Tennessee](#).

Thorough and proper investigation of adverse reactions and injuries may help to ensure that a donor receives follow-up treatment. Investigations and reviews are also designed to determine whether the donor should be allowed to donate in the future based on medical assessment and the interest of donor safety.

FDA inspection observations that indicate that Red Cross did not report or thoroughly investigate all adverse reactions are as follows:

- In the Red Cross [Heart of America](#) Region, the firm received a complaint via email from a mother of a 16-year old donor who donated at a high school blood drive. According to the email, the mother states in part, “. . . my daughter had one finger pricked and they told her she was anemic so they said, that’s ok we will prick the other finger. After she gave blood, they sat her in a chair and she passed out and hit her head very hard on the floor . . . My daughter has a large bump on her head and her neck is quite swollen . . .” According to the FDA investigation and observation report: 1) when the donor failed the initial test, there was no documented justification for repeating the test; 2) the donor was determined eligible to donate even though the team supervisor reported having concerns regarding the donor’s ability to meet the weight and height eligibility requirements for donors less than nineteen years of age;

3) there was no Donor Reaction Injury Report (DRIR), or documentation of the adverse reaction on the Blood Donation Record (BDR) and; 4) during the FDA inspection, the team supervisor stated that a volunteer at the drive had told the supervisor that the donor had a loss of consciousness and had fallen on the floor, however, the team supervisor did not know the length of time in which the loss of consciousness occurred. 📍

- In the [Southeast Michigan](#) Region, the following incidents were not reported to the Red Cross Risk Management Officer as required: 1) A donor fell at the collection site, causing a cut to lip with some bleeding, went to the emergency room and had stitches placed in lower lip; 2) At collection site, donor experienced tetany of fingers and a swollen tongue with bluish color. The donor had a change of speech and was transported to the hospital via emergency medical service; and 3) Donor became dizzy and incontinent secondary to donation and was taken to the emergency room. 📍
- In the [Indiana-Ohio](#) Region, the Red Cross medical director review was not completed on three DRIRs and it was completed over three weeks after the reaction on nine others. One of the DRIRs missing the medical director review involved a donor under age 19 who experienced a twisted ankle during a “less than one minute” loss of consciousness with prolonged recovery. 📍
- In the [Tennessee Valley](#) Region, 49 of 110 DRIR forms were not completed and/or documented as required. 📍

Recommendation: If a donor has a serious adverse reaction, ask the blood drive supervisor whether a DRIR has been initiated and whether documentation of the reaction has been recorded in the donor’s BDR.

(5) Will Red Cross ensure that your blood drive is set up properly?

In four Red Cross regions, the FDA cited failures to provide privacy for examinations of individuals to determine suitability as blood donors. Privacy is important because donors must be truthful when questioned about their sexual and medical history. The lack of privacy during donor screening was cited in regions including Southern California 📍, Connecticut 📍, Badger-Hawkeye Region, and Heart of America 📍.

Another high school set-up consideration is including a floor mat station or adding mats to your canteen area. After the donor’s blood is drawn, we believe it is best that students be escorted to an area where they can sit down on floor mats for 10 to 15 minutes. If an adverse reaction occurs, injuries can be avoided that might otherwise happen if the donor is sitting up in a chair or standing in a canteen area. Directing students to sit on floor mats after donation, is a common sense approach to reducing the chance of injuries. Currently, Red Cross uses floor mats on some high school blood drives, but not others.

Recommendation: During the setup of your blood drive, review the layout and determine if screening areas protect the privacy of students when they are providing their donor history information. If privacy is not protected, talk to the blood drive supervisor about making changes in the setup.

Recommendation: If possible, set up a mat station in, or near the canteen area, where donors can sit down and relax for 10 to 15 minutes.

(6) What is Your Red Cross Region’s Record on Blood Safety and Blood Product Recalls?

For 18 years, the American Red Cross has been under a Federal Consent Decree that orders improvements in its

blood safety practices. Despite this court order, compliance problems have persisted. Since 2003, the FDA has fined Red Cross \$37 million for safety compliance violations. The most recent fines occurred in June 2010, when FDA [fined Red Cross \\$16 million](#). A portion of these fines was for the release of unsuitable blood products that had to be recalled. The FDA described these releases as preventable by Red Cross. Some of the regions with significant compliance problems are listed below.

Red Cross Region	FDA Recall Fines Issued in June 2010
Penn-New Jersey Region	\$2.8 million
Southwest Region	\$1.2 million
Carolinas Region	\$818,000
Tennessee Valley Region	\$789,000
Alabama Region	\$780,000
Heart of America	\$717,000
Badger-Hawkeye Region	\$636,000
New England Region	\$475,000
Greater Chesapeake and Potomac	\$461,000

Source: [FDA Class II Recalls and Associated Fines Issued June 17, 2010](#)

Many of the problems that led to the recall of these products involved errors made at blood drives, including: inadequate arm preparation that may have compromised sterility of blood products; errors made determining donor eligibility to give blood; and quality control associated with equipment used on blood drives. Other fines related to problems with blood component preparations, and failure to perform proper testing on blood. Examples of these violations are below.

- Red Cross regions including [Alabama](#), [Heart of America](#), [Penn-New Jersey](#), and [Tennessee Valley](#), were each fined hundreds of thousands of dollars for [inadequate arm preparation](#) at blood drives.
- The [Carolinas Region](#) of Red Cross was fined \$500,000 for [failing to perform syphilis testing properly](#) on blood products.
- The [Badger-Hawkeye](#), [Greater Chesapeake and Potomac](#), and [Penn-New Jersey](#) regions each received \$400,000 fines for [problems with blood component preparation](#).

Recommendation: Be aware of any safety compliance problems that Red Cross has in your area. If you want the facts, ask your Red Cross representative to provide you with: 1) copies of FDA Form 483 Inspection and Observation Reports issued to your blood region over the past three years; and 2) copies of the most recent FDA Adverse Determination Letters (ADLs) that list compliance violations and fines in your blood region.