



Church/Community Drives Safety Report

Safety Procedures at Church and Community Blood Drives: Recommendations for Blood Drive Coordinators

Blood donation is a great way to save lives and contribute a vital service to your community. Donating blood is safe. But, there are occasions when adults, and more frequently, teen donors, have adverse reactions that may involve fainting or bruising. Injuries are highly uncommon, but they can occur if a donor faints, loses consciousness, and sustains a fall. Major adverse reactions may also occur, including prolonged loss of consciousness, large hematomas, and arterial puncture

The Workers Committee for Blood Safety includes licensed nurses, phlebotomists, and blood drive staff with extensive experience with donor' safety and community blood drives. We encourage church and community organizations to sponsor blood drives, and we are providing blood drive coordinators with the following recommendation to make your blood drive safer.

If your organization is planning to sponsor a blood drive, we encourage you to talk to your mobile blood drive representative about safety protocols at your blood drive. The Committee recommends that you seek assurances on the following issues:

1. [assignment of a licensed nurse to your drive](#)
2. [adequate blood drive staffing](#)
3. [investigation of any adverse reaction or injuries to donors on your drive](#)
4. [proper blood drive setup](#)

Finally, we encourage you to be aware of your Red Cross region's safety record.

It is your right, and responsibility to work with your mobile blood drive operator, to help keep your blood drive safe. Ask your mobile blood drive representative:

(1) Will a Registered Nurse (RN) be at Your Blood Drive?

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

During regulatory inspections in two Red Cross Regions – the Greater Alleghenies Region, and the Ozark-Arkansas Region – the Food and Drug Administration (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 of 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 assignment of nurses to high school blood drives. Some locations regularly assign RNs; some locations regularly assign Licensed Professional Nurses (LPNs), and some locations do not assign any staff that have a medical degree, or a medical certificate or license. 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: Request that a RN be assigned to your blood drive. If a RN is unavailable, request that a LPN be assigned to your drive.

(2) Will Your Blood Drive Have an Adequate Number of Staff?

Red Cross workers have reported that donor safety errors may be linked to understaffing. 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, when the high school 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.

Recommendation: When you talk to your mobile blood drive representative, review your goal for number of people who will come to your blood drive to donate. Ask your representative about staffing requirements, based on the projected numbers. During the blood drive, if it seems understaffed, request that additional staff be sent to the drive, and report any problems in your Blood Drive Satisfaction Survey.

(3) 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, review, 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, review, and/ 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 experience 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.

(4) Will Red Cross ensure privacy for blood donors and an appropriate layout?

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.

In Connecticut, FDA Inspections cited Red Cross for operating mobile blood drives with environmental deficiencies. Problems cited include the [temperature at the drive site, inadequate lighting, lack of ventilation, and noise.](#)

Recommendation: During the setup of your blood drive, review the layout and determine if screening areas protect the privacy of donors 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.

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
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.