

# Have You Given Blood Lately?

**E**very day, emergency rooms throughout the United States are challenged by large numbers of people who need blood, including victims of fires, floods, storms, and other disasters.

But it's not just accidents or disasters that prompt the need for blood. Blood is needed for many people ranging from those with life-threatening illnesses to others undergoing routine surgeries.

In fact, every two seconds, according to the American Red Cross, someone in America needs blood, such as

- Cancer patients undergoing chemotherapy
- People with sickle cell disease or other types of inherited anemia
- Organ transplant recipients
- People undergoing elective surgery
- Moms-to-be during and following labor and delivery

## FDA Oversight

"Blood products are often lifesaving or life-enhancing," says Jesse Goodman, M.D., Director of the Food and Drug Administration's Center for Biologics Evaluation and Research (CBER). "FDA strongly encourages people who are in good health to donate blood and to become regular blood donors."

FDA, through CBER, is responsible for ensuring the safety of the more than 14 million units of blood and blood components donated by

volunteers each year in the United States. FDA's standards and regulations regarding blood donations and processing help protect the health of both the donor and the recipient.

"Some people are concerned that they might get an infection by donating blood," says Goodman. "There is no risk that donors will acquire infectious diseases by giving blood. Donating blood is a safe procedure."

FDA's oversight of the blood industry includes:

- developing and enforcing quality standards
- monitoring reports of errors, accidents, and adverse events
- inspecting all blood facilities at least every two years
- inspecting "problem" facilities more often
- taking regulatory or legal actions if problems are found

## Five Layers of Safety

FDA's blood safety efforts focus on minimizing the risk of transmitting infectious diseases, while maintaining an adequate supply of blood for the nation. "While a blood supply with zero risk of transmitting infectious disease may not be possible, the blood supply is safer than it has ever been," says Goodman.

This safety record is based on five layers of overlapping safeguards:

- **Donor screening:** Donors are asked specific and direct questions about their medical history and other factors that may affect the safety of their blood. This "up-front" screening eliminates about 90% of ineligible (deferred) donors.



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- **Donor lists:** Blood establishments must keep current a list of deferred donors and share this information with other blood establishments to make sure blood is not collected from anyone on the list.
- **Blood testing:** After donation, each unit of donated blood undergoes a series of tests to detect several different infectious disease agents, including:
  - hepatitis B and C
  - human immunodeficiency viruses (HIV) 1 and 2
  - human T-cell lymphotropic viruses (HTLV) I and II, which can cause infections leading to leukemia
  - syphilis
  - West Nile virus
  - Cytomegalovirus (a member of the herpesvirus family) or Chagas disease (illness spread by a parasite) in certain instances
- **Quarantine:** Donated blood must be quarantined until it is tested and shown to be free of infectious agents.

- **Problems and deficiencies:** Blood centers must investigate manufacturing problems, correct all deficiencies, and notify the FDA when product deviations occur in distributed products.


If any one of these safeguards is breached, the blood product is considered unsuitable for transfusion and is subject to recall.

### Ongoing Safety Efforts

Emerging threats to the blood supply and other potential risks mean FDA's Blood Safety Team never stops looking for ways to improve blood safety. "We need to continually work to preserve the safety and integrity of blood and blood products," says Goodman.

FDA scientists are searching for

ways to detect bioterrorist agents in blood donations and working to produce sensitive donor screening tests to detect these agents. They are also working to improve blood donor testing kits to detect variable strains of HIV, West Nile virus, and hepatitis viruses. In addition, FDA's Blood Safety Team regularly looks at donor deferral issues to update eligibility requirements when appropriate.

As a member of a task force of blood services, associations, government agencies, and device manufacturers, FDA helps assure that blood facilities keep safe and adequate inventories at all times in case of a disaster, and have the means in place to determine the need for collecting and transporting blood if a disaster occurs. 

### For More Information

For more information about donor eligibility and giving blood, see

FDA's Center for Biologics  
Evaluation and Research  
[www.fda.gov/cber/faq/bldfaq.htm](http://www.fda.gov/cber/faq/bldfaq.htm)

American Red Cross  
[www.GiveLife.org](http://www.GiveLife.org)  
1-800-GIVE-LIFE (448-3543)

AABB (formerly known as the  
American Association of Blood  
Banks)  
[www.aabb.org/content](http://www.aabb.org/content)

America's Blood Centers  
[www.americasblood.org](http://www.americasblood.org)  
1-888-USBLOOD (872-5663)

To sign up for e-mail reminders,  
in English or Spanish, to schedule  
blood donations and other regular  
screening tests, see the College of  
American Pathologists' Web site at  
[www.MyHealthTestReminder.com](http://www.MyHealthTestReminder.com)

## The Process of Donating Blood

Blood is critically needed every day, yet only about 5% of the eligible U.S. population donates blood in any given year, according to the American Red Cross. Healthy individuals who meet donor eligibility requirements are urged to give blood.

The entire procedure takes about an hour and includes:

- Registering at the facility
- Answering questions about your health and travel history
- Getting a physical examination
- Donating the blood (about 10 minutes)
- Having a light refreshment to boost your energy level before leaving the facility

Source: American Red Cross

## Am I Eligible to Donate Blood?

To meet the basic requirements for giving blood, you must

- be healthy (feel well and be able to perform normal activities)
- be at least 17 years old
- weigh at least 110 pounds
- not have donated blood in the last 56 days

A number of conditions, which will be discussed with you at the donation site, make you temporarily or permanently ineligible to give blood, such as

- pregnancy
- past use of needles to take drugs that were not prescribed by a doctor
- being a male who has had sexual contact with another male since 1977
- getting tattooed in the last year
- living in or visiting certain countries during designated periods of time, for example, living a long time in a country where "mad cow disease" is found or visiting an area where malaria is found.

The rules for eligibility are less strict when making donations for your own use during surgery.

Source: FDA