

# Have You Given Blood Lately?

Every day, hospitals throughout the United States are challenged by large numbers of people who need blood. These people include victims of fires, motor vehicle accidents, and other emergencies.

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

In fact, every two seconds, someone in America needs blood. This includes

- cancer patients undergoing chemotherapy
- people with sickle cell disease or other types of inherited anemia
- organ transplant recipients
- people undergoing elective surgery
- women during and following labor and delivery

"Blood products are often lifesaving or life-enhancing," says Karen Midthun, M.D., director of the Food and Drug Administration (FDA) 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 Oversight

FDA, through CBER, is responsible for ensuring the safety of the more than 15 million units of blood and blood components donated each year in the United States. FDA's standards and regulations regarding blood donor selection, blood donation, 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 Midthun. “Donating blood is a safe procedure.”

FDA’s oversight of the blood industry includes

- approving licenses for blood products
- approving devices used for blood collection and infectious disease testing
- developing and enforcing quality standards
- inspecting all blood facilities at least every two years
- inspecting “problem” facilities more often
- monitoring reports of errors and adverse events
- 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 Midthun.

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 ineligible donors.
- **Donor deferral lists.** Blood establishments must keep current a list of deferred donors. They must also check all potential donors against that list to prevent the use of blood from deferred donors.
- **Blood testing:** After donation, blood establishments are required to test each unit of donated blood for the following infectious disease agents:
  - Hepatitis B
  - Hepatitis C
  - Human immunodeficiency viruses (HIV) 1 and 2
  - Human T-cell lymphotropic viruses (HTLV) I and II
  - Treponema pallidum, which causes syphilis

In addition, FDA recommends that each unit of donated blood used for transfusion be tested for the West Nile virus.

- **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 FDA when product deviations occur in distributed products.

If a violation of any one of these safeguards occurs, 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 Midthun.

FDA scientists are working to develop sensitive donor screening tests to detect emerging diseases and bioterrorist agents in blood donations. They are also working to improve blood donor testing kits to detect variant strains of HIV, West Nile virus, and hepatitis viruses. In addition, FDA’s Office of Blood Research and Review regularly looks at donor deferral issues to update eligibility requirements when appropriate.

Also, FDA is a member of an interorganizational task force on domestic disasters and acts of terrorism that includes blood organizations, government agencies, and device manufacturers. As such, it works with others to help assure that blood facilities keep safe and adequate inventories at all times in case of a disaster.

### The Process of Donating Blood

Blood is critically needed every day, yet only a small percentage of the eligible U.S. population donates blood in any given year.

The entire procedure takes about an hour and includes

- registering at the donation site

- answering questions about your health and travel history
- getting a limited physical examination
- donating the blood (This takes about 15 to 20 minutes)
- having a light refreshment to boost your energy level before leaving the facility

### 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) and

- have a blood pressure within normal limits
- have a normal temperature
- be free from acute respiratory diseases
- be at least 16 years old
- have a normal blood hemoglobin level
- not have donated blood in the last 56 days

A number of conditions, which will be discussed with you at the donation site, may cause you to be temporarily or permanently ineligible to give blood. These conditions include

- not feeling well
- past use of needles to take drugs that were not prescribed by a health care professional
- being a male who has had sexual contact with another male since 1977
- getting tattooed in the last year (unless done under sterile conditions and at a state-licensed facility)
- living in or visiting certain countries during designated periods of time; for example, living for a period of time in a country where bovine spongiform encephalopathy (also known as mad cow disease) is found, or visiting an area where malaria is found.

The rules for eligibility are less strict when making donations before surgery for your own use (autologous donations).

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