



Ensuring the Safety of the U.S. Blood Supply

Ensuring the safety of the nation's blood supply is the top priority for America's Blood Centers and the entire blood community. Multiple layers of safety are in place to protect those that rely on blood transfusions. To maintain the highest degree of safety, all U.S. blood centers are regulated by the Food and Drug Administration (FDA) and must adhere to following donor eligibility policies and safeguards:

1. A donor history questionnaire (DHQ)

All prospective donors who visit a U.S. blood center must complete an FDA-required donor history questionnaire (DHQ) before each donation. During this process all prospective donors are asked the same series of eligibility questions to ensure they can safely donate. These questions cover a wide range of topics, including a prospective donor's current and past health status, medication and travel history, and behaviors that are associated with higher risks of transfusion-transmissible infections, including nonsterile tattoos/piercings, accidental needle sticks, etc. Only those individuals who meet strict DHQ guidelines can donate.

2. Temporary and permanent donor deferral history

Information on prospective donors who were temporarily or permanently deferred from donating is recorded by blood centers as required by the FDA. This allows blood collectors to review the donation history of all prospective donors during each donation attempt and ensure those who have a history of deferrals are not able to donate blood for patient transfusion. Any new deferrals are also recorded following completion of the DHQ.

3. Processing and testing of every donation

Every blood donation undergoes sophisticated laboratory processing and testing as required by the FDA. More than 12 tests are performed on every donation to identify the blood type and make sure the blood is safe for transfusion. This includes testing to identify the presence of Hepatitis B, Hepatitis C, HIV Types 1 and 2, HTLV Types I and II, Syphilis, Chagas Disease, West Nile Virus and, in certain geographical areas, Babesiosis. These tests are highly effective in identifying potentially infected blood and blood products before they are distributed to hospitals for patient transfusion. In addition, all donated blood is held in quarantine and not released to hospitals until all infectious disease testing is confirmed negative.

4. Rigorous quality standards

After the testing process, donated blood components are stored according to Current Good Manufacturing Processes (cGMPs) until they are needed for patient transfusion. Red blood cells can be stored for up to 42 days, plasma can be frozen and stored for up to 12 months, and platelets, depending on the manufacturing process, must be used within 7 days.

5. Local and national monitoring

The FDA closely monitors the safety of the blood supply and transfusions through such mechanisms such as the U.S. Department of Health and Human Services' (HHS) Transfusion Transmissible Infectious Monitoring System (TTIMS). This system allows for the collection and evaluation of scientific data on blood borne illnesses. TTIMS and other data sources continue to assist the FDA in providing the best science-backed guidance to U.S. blood centers.

The blood community's commitment to the safety of the blood supply, together with strict regulation by the FDA and sophisticated testing of all donations, ensures that blood and blood products remain safe and available for the millions of patients who rely on them every year.

