

# New Rules May Shrink Ranks of Blood Donors

*HIV Risk Eases, but Concern Over Other Threats Grows; A Problem With Pregnancies*

By LAURA LANDRO

**F**AST-EMERGING threats to the blood supply—including infectious diseases from abroad and newly recognized risks of transfusion—are raising safety concerns and threatening to shrink the supply of eligible blood donors.

The chances of getting HIV or hepatitis C from donated blood have been all but eliminated thanks to sophisticated screening. But regulators and blood banks are adding new protections in an effort to quell the latest threats.

Among the most sweeping are changes that could affect 10% to 20% of female donors—as many as a million women who donate certain



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blood components. Scientists have only recently come to understand that certain antibodies in the blood of women who have ever been pregnant can cause a reaction known as transfusion-related acute lung injury, or TRALI. While rare,

TRALI has emerged as the leading cause of transfusion-related deaths, associated with 50-100 fatalities annually.

In addition, the Food and Drug Administration recently approved a new standard donor-screening form to better ferret out risk factors that could lead to a transmissible infection, with more direct and detailed questions about travel, relationships and lifestyle, such as intravenous drug use.

Last month, the FDA, which continues to seek new donor-screening tests for infectious diseases, approved a test for Chagas disease, a potentially fatal blood-borne illness linked to a parasite that affects as many as 11 million people in Latin America. Chagas is of increasing concern in the U.S. because of the rise in immigration from those countries.

Amid these concerns, there is growing debate about lifting bans on gay men, which could increase the pool of donors. Last year, transfusion-

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# Rules May Deter Blood Donors

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medicine experts, researchers and blood centers, including the American Red Cross, recommended that the FDA ease restrictions gay men, who are primary carriers of HIV, to reflect improvements in HIV testing.

With more than 15 million units of blood donated annually in the U.S., the supply is still adequate—for now. But according

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to the Department of Health and Human Services, the margin between blood supply and demand has never been smaller. Only about 5% of donors in the U.S. who are eligible to give blood actually do so, but a growing number have been deferred for a year or more in recent years because of travel histories to high-risk areas or risk-related behavior.

"There's an endless barrage of emerging or expanding pathogens, and it's a constant juggling act" between retaining donors and curbing risk, says Michael Busch, a transfusion medicine specialist and director of the nonprofit Blood Systems Research Institute in San Francisco.

Increasingly, researchers believe TRALI can occur when certain antibodies, produced by pregnant women to prevent rejection of the foreign male blood cells in their fetus, react with a transfusion recipient's cells, allowing fluid to enter the lungs.

The nonprofit group AABB (formerly the American Association of Blood Banks) is recommending that blood centers have plans in place to reduce the risk of TRALI from plasma donations by this November and in platelet donations by November 2008. Many centers will comply by shifting to predominantly male donors for plasma used for transfusion. The highest risk of TRALI is from plasma products and platelets, versus whole blood; plasma is the liquid portion of blood which carries cells and helps in blood clotting, and platelets help prevent massive blood loss from trauma and blood-vessel leakage.

American Red Cross Chief Medical Officer Richard Benjamin says his organization is already beginning the shift to 95% male plasma donors from 50% in some parts of the country for transfusion. "We need female donors," Dr. Benjamin says. So the group will use plasma from women "for the manufacture of other blood products where there is no risk." The Red Cross is also developing ways to screen donors for the presence of antibodies and will divert women who test positive to donating only whole blood.

Adding new screening tests will boost the cost of blood collection. Brian Custer, an investigator for Blood Systems Research, estimates that the new Chagas-disease test adds \$5 to \$7 to the cost of screening a unit

of donated blood, bringing the total cost to about \$54 this year.

The total cost of testing the blood supply for seven known high-risk infectious agents each year in the U.S. is approximately \$600 million, with about 60% coming from tests that weren't in place a decade ago—including tests for HIV and West Nile Virus, according to James AuBuchon, chairman of the pathology department at Dartmouth Hitchcock Medical Center in Lebanon, N.H. "The increase in costs is relatively minor to keep the blood supply safe," Dr. AuBuchon says.

The FDA says it must err on the safe side, even if it reduces the supply of donors. "For every deferral we put into place, we do a very careful consideration of how it will impact the donor pool," says Alan Williams, head of the division of blood applications at FDA's biologics center.

The FDA is under growing pressure to ease the policy that effectively bans blood donations from men who have had sex with other men even once since 1977. Last March, AABB, the American Red Cross and America's Blood Centers told the FDA that because of new tests that can quickly detect HIV, the policy is "medically and scientifically unwarranted" and recommended that it be changed to allow men who have abstained from sex with another man for a period of one year.

But the FDA says data show that men who have sex with men account for 25% of donors found positive for HIV, even though only a fraction of those admit to homosexual contact. The FDA says the policy is based on "the well-documented association of this behavior with risk of transfusion transmissible infection."