



THE INFORMED PATIENT

# The Biggest Blood Supply Risk: Tainted Platelets

*By Laura Landro*

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Hospitals and blood banks are adopting new measures to improve the safety of donated platelets—the tiny cells that make blood clot and heal injuries but that also present the No. 1 infection risk in the U.S. blood supply.



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A growing number of studies show that standard tests performed by blood banks before they ship platelets to hospitals miss the majority of contaminated platelets. Unlike other blood components such as red cells, which are refrigerated, platelets must be stored at room temperature to remain effective, but during storage periods that last up to five days bacteria can grow and multiply.

About 150 hospitals have adopted a new contamination test, made by Verax Biomedical Inc., that can be administered immediately before patients get a transfusion. Initially approved by the Food and Drug Administration in 2007, one barrier is cost: It adds about \$25 to \$30 to the average \$540 cost of a unit of platelets.

The infection risk from platelets beats that of HIV and hepatitis C, researchers say, since advances in testing and screening have all but eliminated the risk of contracting those viral infections through donated blood. The federal government is stepping up scrutiny: A congressional committee has asked the FDA to determine what further actions should be taken to reduce the risks and spread awareness among hospitals.

More than two million doses of donated platelets are transfused annually in the U.S. to prevent uncontrolled bleeding in trauma, cancer and surgical patients. Most are safe and well-tolerated. New safety standards adopted by blood banks in 2004 have reduced the average rate of fatalities from sepsis, or blood poisoning, to three a year from between seven to 11 annually. Still, hundreds of nonfatal sepsis cases and other adverse reactions are still linked to contaminated platelets. Experts say the rate may be much higher than reported because infections might have been attributed to other causes.

"The closer you can test product to the time of transfusion, the more likely you are to pick up dangerous bacteria," says Richard Benjamin, chief medical officer of the American Red Cross.





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In a study of over four million platelet units the Red Cross collected and distributed to hospitals from January 2007 to December 2011, it found 381 suspected septic reactions in platelets it distributed, 38 definite or probable cases and four deaths. That is a big improvement over the four deaths per million in a 2003 study, but even with a fatality rate of one in a million, says Dr. Benjamin, "that's not acceptable if it happens to be your grandmother or your child."

Six-year-old Jessica Rose Kohut died in 2009 while undergoing treatment for a rare form of cancer at All Children's Hospital in St. Petersburg, Fla. According to a lawsuit brought by her family—settled by the hospital for an undisclosed sum—the cause wasn't cancer, but septic shock from a contaminated platelet transfusion at its Tampa outpatient clinic.



SHOW CAPTION | MAUREEN MASSARI

“Improving safety standards will not bring her back, but it will give others a better fighting chance,” says her mother, Maureen Massari, who pleaded for wide use of the same-day test at a meeting of industry and government officials convened by the AABB, formerly called the American Association of Blood Banks, earlier this month in Bethesda, Md.

Platelets can become contaminated if the donor has even a low-grade blood infection, or when the skin isn’t properly cleaned, drawing surface bacteria into the platelets during collection. In 2004, the AABB began requiring accredited facilities to detect and limit bacteria, generally by taking cultures of donated platelets to measure bacteria growth within 24 to 48 hours.

But bacteria levels may be too low that early for detection, and studies show as many as 1 in 1,000 units that tested negative were actually contaminated. Hospitals, which may also operate their own blood banks, don’t typically culture products again, since getting results can take another day.

AABB President Darrell Triulzi says blood centers have taken other steps to improve safety, such as diverting some initial blood drawn from the donor into a separate pouch to capture any skin bacteria, and swirling blood bags to visually spot signs of contamination. Hospitals have also been cautioned to watch patients for signs of infection such as fever and chills after a transfusion, and administer antibiotics if need be.

While the FDA says the rapid test has "important value for bacterial detection," there are concerns about its sensitivity, a spokeswoman says, and some users have found it difficult to interpret, which could add "significant complexity to operations in transfusion services." Verax says its clinical studies show the test, which detects antibodies present on bacteria cells, is highly sensitive, adding its customer studies found the test was easy to use and interpret.

But the extra cost can be a barrier for some when the risk of infection is relatively low. John Hess, a pathology professor and medical director of the blood bank at University of Maryland Medical Center, says he spends about \$16 million a year on platelets, and calculates it would add \$500,000 a year to use the test. Given the risk, he says he doesn't believe the test is cost effective compared with other expenditures that could help save lives.

But Mindy Greene, administrative director of transfusion medicine at UMass Memorial Medical Center, which has a large cancer clinic, says after learning of deaths from tainted platelets, "we knew it was important for our patients that this never happen here, and we dug down deep and found the money." In tests of nearly 5,000 platelet units between August 2010 and January 2012, four that tested negative by standard cultures were shown to be positive using the Verax test and were confirmed positive by a second culture.

Ms. Massari says that after Jessica Rose's treatment for cancer "she was not only

surviving but thriving,” almost cancer-free and receiving low-dose chemotherapy and routine maintenance treatments. But during a checkup, because her platelets were low, a transfusion was ordered.

That sent her into septic shock and while antibiotics killed the bacteria, she suffered organ failure and after nine days suffered a massive stroke. Ten days after the transfusion Jessica died in her mother’s arms.

At the meeting in Bethesda, Ms. Massari told attendees: “Those concerned about the cost—please figure it out—you can simply hope it won’t happen again but we all know that it’s just a matter of time before someone else dies.”

A spokesman for All Children’s says it believes the blood products it is supplied with exceed industry safety standards, but “we welcome the opportunity to work with the blood-bank industry to improve the quantity quality and safety of the blood supply.”

## Essential Cells

### Vital for Some Patients, Donated Platelets Carry a Risk of Contamination

Severe trauma patients, cancer patients on chemotherapy, burn patients and those undergoing open-heart surgery and bone-marrow transplants need platelets.

To acquire platelets, blood is drawn from a donor and is sent to a separator, which spins the blood, forcing platelet cells to the bottom.

Platelets are stored in a plastic bag while the other blood components such as plasma and red cells are returned to the donor.

About 10% of platelet donations are collected by separating the cells from four to six whole blood donations and pooling them into a single dose.

Platelets are stored at room temperature for up to five days because refrigeration renders them ineffective, but bacteria can grow over that period.

A test for contamination has been approved by the FDA, but it adds \$25-\$30 to the average \$570 cost of a unit of platelets.