Blood mix-up, death probed

Red Cross mismatch at Piedmont downplayed in FDA report

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A Buford man who died in March at Piedmont Hospital had received blood improperly matched by the American Red Cross in Atlanta, new documents show. But nobody has determined whether the mix-up, involving an unusual blood type, killed 34-year-old Rodney English six days later.

The case, which provides a rare look at the complexities of blood transfusions, raises questions about why the government altered its findings in its investigation of Red Cross procedures — questions now part of a U.S. Senate Finance Committee probe.

Red Cross officials say they mismatched the blood. The U.S. Food and Drug Administration has acknowledged changing its inspection documents, effectively downplaying Red Cross responsibility. The FDA also says it deleted other questions it had raised about the Red Cross in Atlanta, some of which involved two other deaths after blood transfusions.

But the FDA, which has not blamed Piedmont or the Red Cross for English's death, has not fully explained the document changes.

The Senate Finance Committee, already examining the FDA's handling of safety issues involving Vioxx, Paxil and other prescription drugs, is looking into the report changes, committee staff said.

English, born with the crippling birth defect spina bifida, used a wheelchair most of his life. He was being treated at Piedmont for an infected pressure sore on his hip. Relatives say they aren't sure what happened after he received eight units of blood March 6 and 7. He went into a coma and died March 12, said Pam McDaris of Lilburn, English's aunt. There was no autopsy.

Family photo

Rodney English's death, six days after he got blood the Red Cross mismatched, may not have been caused by the mix-up.

What caused death?

Atlanta lawyer William Bird, who has been retained by the family, is investigating the case. Neither Piedmont, the Red Cross nor the FDA has identified English as the patient, but family members have said the hospital told them the investigation focused on him. No one has claimed responsibility for the death.

"This is a Red Cross story," said Piedmont spokeswoman Nina Montanaro. "Piedmont received a mislabeled unit of blood."

The Red Cross acknowledges failing to identify a rare antibody in English's blood. That caused the Red Cross to give him a mismatched unit March 6, six days before he died. But the Red Cross says it does not believe the problem caused the death.

Dr. Jerry Squires, chief medical officer of the Red Cross nationally, said fatal transfusion reactions generally occur quickly. "It's hard to tie those two events together, six days apart," he said.

Piedmont's Montanaro agrees. So does Dr. Louis Katz, president of America's Blood Centers, which represents 75 blood banks independent of the Red Cross. He said fatal reactions usually occur during transfusions, not several days after.

Experts say deaths from mistyped blood transfusions are extremely rare; fewer than two dozen people in the United States die annually from receiving the wrong type of blood.

Unusual blood type

The FDA routinely inspected the Red Cross after English died. Its initial report, dated June 10, contained several allegations about blood-testing methods involving his case. But a second version of the report was issued Sept. 2 dropping nearly all references to the death and the circumstances surrounding it.

The FDA also said in the June 10 report that the Red Cross had failed to properly investigate two other transfusion-related deaths since July 2003 — unnamed patients given blood from the Red Cross Blood Services Southern Region in Atlanta, which serves 140 medical centers in Georgia, North Florida and South Carolina.

The FDA also criticized the Red Cross for allowing blood donations from 11 people who had tested positive for hepatitis C and another virus that can cause a rare form of leukemia.

None of those allegations remained in the second version of the FDA report, issued four weeks after the Red Cross responded to the FDA's initial concerns. In a recent statement, the FDA only partially explained its changes, saying "concerns were raised about the appropriateness of some citations."

According to interviews and documents obtained last month by The Atlanta Journal-Constitution, English's case involves an unusual blood type, separate from the common blood types A, B, AB, O and Rh positive and negative.

The common blood types are based on the presence or absence of A, B and Rh antigens, substances on red blood cells. People who have an antibody, or allergy, to a particular antigen can experience serious side effects, even death, if they get the wrong blood.

But just as scientists have discovered planets beyond our solar system, researchers have found hundreds of other antigens on red blood cells, blood experts say. Most don't cause problems in most people. But patients who have received previous transfusions — such as English — or who have been pregnant can develop antibodies to some of the other antigens.

Antibody missed

When Piedmont and other hospitals order blood, they determine the patient's common blood type and screen for the general presence of any unusual antibodies. For the roughly 2 percent of patients who have these antibodies, hospitals generally ask the Red Cross or another blood bank to perform more complex testing required to identify the specific antibodies. The blood banks then select blood without the corresponding antigens.

Before hospitals use blood, they recheck to make sure it is the correct common blood type for the patient. But many hospitals, such as Piedmont, do not have the technology to make sure blood does not contain any of the other specific antigens, Montanaro said. They rely on blood banks for that testing, she said.

When Piedmont sent the Red Cross a blood sample from English on March 5, the Red Cross failed to detect an antibody he had recently developed to an antigen called Jk(b), according to Squires and Red Cross documents. That antigen was in one of the three units of blood given to him March 6, Squires and the documents say.

What occurred March 7, when English received five units of blood, is more complicated. Piedmont ordered the five units, and the Red Cross delivered them, before Piedmont supplied a fresh sample of English's blood the same day — a delay allowed in emergencies, both organizations say.

When the Red Cross tested the new sample, it found the antibody to Jk(b), according to the Red Cross documents. The Red Cross then retested the first sample and discovered the same antibody, which it had missed. It also tested the new sample against the five units just released — and initially found all of them incompatible.

'Best available' units

The Red Cross told Piedmont the five units were incompatible, but the hospital had already given English two of the units, the Red Cross documents say. Piedmont decided to transfuse the remaining three units anyway, the Red Cross says. Both parties now say those units were the best available at the time.

Dr. Linda Chambers, a senior medical officer of the Red Cross, explained that the five units initially tested incompatible because of a new complication: English's blood contained an "autoantibody" that can cause reactions in lab tests but usually doesn't cause transfusion problems for patients.

Those units also did not contain the Jk(b) antibody, so they were deemed "suitable" for English, Chambers said. Even though the Red Cross did not know about English's antibody to Jk(b) when it released the units, a separate test had shown a need for blood without several antigens including Jk(b), she said.

Chambers and Squires of the Red Cross say it is unlikely that either the mismatched unit from March 6 or the units initially considered problematic from March 7 caused English's death. Antibodies to antigens such as Jk(b) can cause reactions, but rarely fatal ones, they say.

An FDA warning letter to Piedmont on Aug. 3 — which addressed paperwork "deviations" surrounding the incident — called the March 12 death a "possible hemolytic transfusion fatality." Hemolysis is a breakdown of red blood cells.

The FDA, Piedmont and the Red Cross say patient privacy laws prevent them from disclosing English's full medical circumstances, which might help explain his death. McDaris, his aunt, said he was healthy except for the spina bifida and related pressure sore.

GA - 050 DAILY NEWSPAPER
ATLANTA JOURNAL - CONSTITUTION
Atlanta, GA
Morning Circulation - 397,097
Daily
NOVEMBER 3, 2004