# Man dies after receiving blood from suspect batch

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An elderly man died after a transfusion of blood that was part of a batch that was later quarantined, federal officials said Friday.

The American Red Cross reported that the unidehtified man died in a Georgia hospital, but declined to give details, citing medical confidentiality and the ongoing investigation.

Several other patients who received blood from the suspect batch experienced problems, from bacterial infections to an allergic reaction, said Dr. Jessie Goodman, director of the FDA Center for Biologics Evaluation and Research.

Two of those incidents were in Georgia, said Chris Hrouda, chief executive of Red Cross Blood Services Southern Region in Atlanta.

"We have two reported adverse reactions in Georgia patients prior to [the fatality]. Neither of them . . . resulted in death," Hrouda said.

The American Red Cross, which collected and distributed the blood, and the federal Food and Drug Administration say there is no proof that the blood caused the "adverse events."

The man who died after receiving the transfusion suffered from heart disease and experienced "cardiac or pulmonary" failure, officials said. He died Jan. 28 after receiving two units of blood the same day, the Red Cross and the FDA reported Friday.

The Red Cross issued a regional quarantine of thousands of units of blood two days after the man died, after 120 blood bags were found to contain unidentified matter.

"It is not yet clear whether the events are related to or unrelated to the possible presence of particulates," the FDA said in a statement Friday. "Adverse events in the transfusion setting can occur for many reasons, including reasons related to and unrelated to the transfusion. FDA has no indications of a heightened risk of adverse events related to transfusions at this time."

The quarantine initially affected much of the blood supply in Georgia, North Florida and parts of South Carolina and later spread to parts of Tennessee, Kentucky, Illinois and Missouri.

Hospitals canceled elective surgeries as they reserved dwindling blood supplies for emergencies. Some new blood was made available this week, somewhat easing the crunch.

Ten days after a Red Cross worker found strange white particles in bags of blood, authorities still have not determined what caused the suspected contamination that led to the quarantine.

The Centers for Disease Control and Prevention in Atlanta said Friday that its test results would not be released until today or next week.

The CDC earlier ruled out infectious agents commonly used in bioterrorism, but is testing for possible industrial contaminants.

Both the FDA and Red Cross officials said tests confirmed that some of the particles are clumps of platelets, cells that allow blood to clot.

"We don't know what is the cause of this phenomenon," Hrouda said. "Why are they there? These are abnormal. Why are they there in such quantities and in such size?"

The FDA and the CDC continue to test for possible chemical contaminants and other materials that might explain the other types of particles.

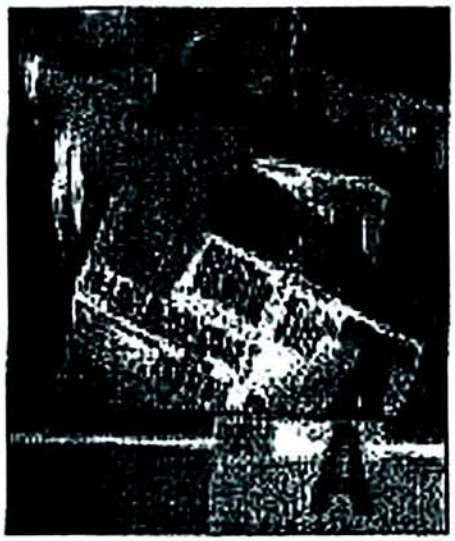
"Any particulate matter, even platelets, which are human cells and normally circulate in our blood, could be of concern," Goodman said. "Platelets could encourage clotting or other phenomena in the blood."

Baxter Healthcare Corp., the leading manufacturer of bags in which blood is stored and distributed, has said all along that the matter in the bags is harmless blood products, such as fibrin, a blood protein. The company, based in the Chicago suburb of Deerfield, Ill., tested four of its bags of blood and then tested 20 more. The company said nothing unusual was found.

The FDA said Friday it has received reports of particles in blood bags made by manufacturers other than Baxter.

Terumo Medical Corp., the nation's second-largest manufacturer of blood bags, said in a statement issued Friday that there have been three reports of particulate matter discovered in blood packaged in Terumo bags, which were not quarantined.

"Most likely the particulate matter is blood-derived in nature," the statement read.



CURTIS COMPTON / Staff

The Red Cross has quarantined blood since unidentified matter was discovered.

There have been no reported adverse reactions related to those units of blood, according to the company statement.

Jeffrey Miripol, Terumo vice president and general manager, speaking Friday from its North American headquarters in Somerset, N.J., said the particulate matter is probably a naturally occurring, biological product, such as "platelet material, cellular material, fibrin, clot material or lipemic materials."

The FDA advised any blood collection agency that detects particles in blood to quarantine the supply. It also recommended "enhanced visual inspection" measures that include placing blood bags on a flat surface at room temperature and, after 10 minutes, looking for any debris.

The white material — which has been divided into four groups, ranging from flakes to clumps to oily slicks — was discovered Jan. 29.

"We are continuing to look into everything," Hrouda said. "The temperature of the products, the processing steps, every potential variable is being considered."

FDA investigators are still on site at the Atlanta office, he said. "The final answers are going to have to come from the FDA and CDC."

Some metro area hospital officials expressed concern about the ongoing quarantine, especially with Atlanta playing host to the NBA All-Star Game and related events this weekend and the heightened national terrorism alert announced Friday.

But the area's main trauma center said it is prepared.

"Just as Grady Health System prepared for the Olympics, we also have a plan in place to deal with emergencies this weekend," said Dr. Curtis Lewis, Grady hospital chief of staff.

— Staff writers Patricia Guthrie and Bo Emerson contributed to this article.

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