‘Premium’ plasma
Isn’t ‘regular’ blood safe enough?

You’ve probably heard the horror stories about people who go into the hospital for minor surgery and leave with AIDS or hepatitis from a contaminated blood transfusion. One recent response to the frightening prospect of blood-borne illness: brand-name blood.

The American Red Cross and V.I. Technologies, a biotech firm better known as Vitex, recently placed full-page ads in major Sunday newspapers urging people to “ask your physician for it by name!” It’s PLAS+SD, the first blood-plasma product bearing a brand name and backed by an ambitious marketing campaign. The Red Cross, which supplies roughly half the nation’s blood, has an exclusive agreement to supply Vitex with plasma—the liquid part of the blood, rich in antibodies and clotting compounds—then to distribute the finished product nationwide. The new plasma gets washed in chemicals that destroy any viruses that cause AIDS (by far the deadliest risk from blood) or hepatitis C (by far the most common transfusion risk). The price of the Red Cross’ premium plasma: roughly 2½ times the price of regular.

Meanwhile America’s Blood Centers, a group of nonprofit blood banks that supply the rest of the nation’s blood, has developed a competing product: donor-retested plasma. This plasma is quarantined for several months until the donor is retested for any delayed signs of the worrisome viruses—indicators that might have eluded the first test. Donor-retested plasma costs about 60 percent more than regular. The chance of getting the AIDS or hepatitis C virus from either premium plasma: virtually zero.

But despite all the hubbub about the new plasma, a third, quieter innovation called nucleic-acid testing (NAT) is actually more important. The new test can detect the virus itself, not just the telltale signs of the virus, which can take weeks or months to appear. So NAT should radically shrink the old testing loophole—the chance of missing a delayed sign of the virus—that created the need to retest the donors or destroy the viruses in the first place. By the time this issue of CONSUMER REPORTS is published, virtually all blood in the U.S. will be screened with the new test.

Moreover, washing and retesting are technically feasible only for plasma. But plasma accounts for only about one of every seven units (pints) of blood transfused in the U.S. (Most of the other units contain either red cells, which transport oxygen, or platelets, which help stop bleeding.) In contrast, NAT can spot viruses in any component of the blood and can thus help protect everyone who gets a transfusion.

The new blood and the new test raise two crucial questions: How safe is the U.S. blood supply? And is either of the premium plasmas worth the price?

Dramatic Improvement

In the 1970s high rates of hepatitis from transfusions triggered a sweeping re-examination of blood banks’ procedures. Most important, the banks stopped collecting blood from paid donors, who were more likely than unpaid donors to be sick.

The advent of AIDS in the early 1980s forced further reforms. The riskiest donors—intravenous drug abusers and gay men—were asked not to donate or were screened out by questionnaires, interviews, or physical exams. And new tests were developed to detect the AIDS virus in donor blood. The payoffs were huge.

In 1984, the year before blood banks got an AIDS-virus test, 714 transfusion recipients were infected with the disease, according to a 1997 government report.

Over the next 12 years, a total of just 38 cases of AIDS were linked to transfusions of blood that had tested negative for the virus—and the vast majority of those cases occurred in the early years.
before the test was refined.

That change reflects an impressive improvement in the blood supply. In 1983 the AIDS virus was present in as many as 1 in 100 units of blood. Today the odds are an estimated 1 in 676,000. Hepatitis C contamination has fallen from a similarly high prevalence to about 1 in 103,000 units. (Routine surgery typically requires about two units of blood; complicated cases may require more.)

Dr. F. Blaine Hollinger, chairman of the Food and Drug Administration's Blood Products Advisory Committee (a group of outside experts), says that even the above estimates of the AIDS and hepatitis C risk from transfusions may paint an overly pessimistic picture of blood safety. Not everyone exposed via transfusion to various blood-borne illnesses gets sick, Hollinger notes. Some who do may live for years and die of other things first, perhaps from the serious condition that necessitated the transfusion in the first place. And the introduction of nucleic-acid testing should make the already tiny risk much tinier.

While those viruses are the two most significant contaminants of blood, there are additional risks. The blood may carry other viruses as well as bacteria and parasites, although those pathogens are all either less serious or less common than AIDS or hepatitis C. In addition, you could develop a rare, potentially deadly allergic reaction. And due to human error—despite written checklists and bar-coded IV bags—you could receive dangerously incompatible blood.

A study published last year in the Journal of the American Medical Association provides further perspective on the risks. It suggests that the chance of dying in a hospital from a serious, unexpected reaction to a drug you've been given—even without considering overdoses and other drug-dispensing errors—may be hundreds of times greater than the average chance of getting the virus for hepatitis C or AIDS from a contaminated transfusion. (For more perspective on various risks, see the chart on page 61.)

So why “premium”?

Donated blood is tested not only for AIDS and hepatitis C but also for syphilis, various other hepatitis strains, and two viruses that cause a type of leukemia. Until now those tests generally worked by detecting antibodies that the donor's body makes to combat a particular virus. Blood centers are worried that some persons who give blood are incubating a disease early in the course of infection, not detectable by the antibody tests that blood bankers use," says Hollinger. "If I get hepatitis C, for example, I may not start making antibodies for several months." The premium plasmas were designed to close that "window."

With the donor-retested product, blood banks freeze the plasma, wait out the window for 16 weeks, then retest the donor for viruses. Only if the second test finds no problem with the donor do the banks finally release the plasma.

But nucleic-acid testing greatly reduces the need for donor retesting, since NAT can detect the actual virus, not antibodies to the virus. In as little as eight hours, the blood bank could know whether a specimen of any blood component carries the AIDS or hepatitis C virus.

However, even that test isn't absolutely foolproof. So donor-retested plasma "still offers a minuscule layer of extra safety," says Dr. Celso Bianco, president of America's Blood Centers.

NAT screening will add $3 to $5 to the cost of each blood product, or an estimated $100 million a year to the cost of the U.S. blood supply. "It's way off the scale from a cost-effectiveness point of view," since blood is already so safe, says Dr. Michael P. Busch, vice president for research at Blood Centers of the Pacific, an institution based in the San Francisco area. "But ask Joe Public, 'Would you spend an extra $3 to be sure the blood you get is free of AIDS?' " What's more, adds Busch, if a new blood-borne virus threatens the supply, it will be easy to add a test for it to the NAT procedure.

PLAS-SD attacks the window problem differently. The plasma is treated with a solvent and a detergent (the "SD") that destroy any viruses for AIDS or hepatitis C. Clearly, NAT screening reduces the value of this new plasma, too. But Dr. Richard Davey, chief medical officer of the American Red Cross, says, "We still like PLAS-SD, because it destroys the viruses, so you don't have to worry about the tests."

But certain other pathogens aren't destroyed. Already, Vitex has recalled 30 lots of the plasma—about 90,000 units—contaminated with high levels of parvovirus B19, which causes a common, mild childhood illness but can be deadly to adults with poor immunity and to the fetuses of pregnant women. No one got
Recalls

Vehicles and equipment

1991-96 Chevrolet and GMC light trucks, apart-utility vehicles, and vans

Airbag system (ABS) could malfunction, resulting in increased stopping distances.

Models: Approx. 1.1 million 1991-96 4-wheel-drive vehicles, including Chevrolet Blazer and S-10, and GMC Jimmy and Sonoma. Also subject to corrective action are about 2.4 million 2-wheel-drive vehicles, including ‘93-’96 Chevrolet Blazer and GMC Jimmy, ’94-’96 Chevrolet S-10 and GMC Sonoma, and ’93-’96 Chevrolet Astro and GMC Safari. According to General Motors, braking problems are much less likely to occur in the 2-wheel-drive vehicles because of a combination of plastic inner tubing and steel outer tubing. What to do: Have dealer replace sensor switch in ABS system of 4-wheel-drive vehicles. With 2-wheel-drive models, dealer will modify computer-control unit in ABS system.

Household products

Casse Ariva and Turnabout infant safety seat/carrier

When used as carrier, handle could release unexpectedly, causing child to fall.

Products: 670,000 child safety seats made 3/1995 to 9/96/7 including the following models: Ariva—02-486, 02-729, 02-731, 02-732, 02-733, 02-751, 02-756, 02-757. Turnabout—02-627, 02-726, 02-756, 02-760, 02-761, 02-762, 02-763, 02-764, 02-765. Manufacturer date and model no. are on seat shell. Seats were sold at juvenile-product, mass-merchant, and discount department stores as stand-alone product for about $30 to $80, and with a stroller for about $140.

What to do: Stop using seat as infant carrier and call Cosco at 800 221-6736 for free repair kit. Information is also available on company’s web site. www.coscorc.com. Note: Consumers may continue to use the product to restrain child in car or in conjunction with stroller.

Pool dive sticks (various brands)

In shallow water, child could be impaled on hard plastic implements. Child could also grab face or eye on stick when attempting to retrieve it.

Products: 19 million cylindrical or shark-shaped dive sticks sold since 1979 at grocery, drug, pool, and discount department stores for $4 to $7 per set. Toys were sold under various brand names, which may or may not appear on sticks themselves. Recall includes, but is not limited to, 9 million dive sticks distributed by Florida Pool and sold at Wal-Mart; 2 million sticks distributed by Poolmaster and sold at various stores under brand names. 897,000 sticks distributed by JM Industries, identifiable by words “Made in USA.” Dive sticks are colorful pool toys that sink to the bottom and stand upright so child can swim or dive to retrieve them. Cylinder-shaped items measure 4 to 6 inches long and about 1 inch in diameter. Shark-shaped ones are about 7 inches long and have gill-shaped bottom. Most were sold in packages of three or six; some came with other pool diving gear.

What to do: Wal-Mart is offering free repair kit for Florida Pool dive sticks. Owners of Poolmaster sticks can call 800 235-2636 for replacement. JM Industries dive sticks can be returned to place of purchase for replacement. Return all other sticks to place of purchase for refund or repair. To report an injury or ask questions, call the CPSC hotline at 800 638-2772.

For more information


See if you can use your own blood for transfusions.

Transfusions save nearly 10,000 lives a day: trauma and burn victims, surgery patients who lose lots of blood, cancer patients who undergo blood-depleting chemotherapy and radiation, and people with deadly anemias and clotting disorders. On average, that benefit far outweighs the extremely small risk of getting a serious disease from tainted blood.

Due to the higher cost of the premium plasmas and the introduction of NAT, most hospitals so far have not chosen to stock the new plasmas. So if you’re among the minority of transfusion recipients who do need plasma, you probably won’t be automatically offered a choice between regular and premium. Hospitals generally will order a premium plasma if your doctor asks for it. However, our medical consultants are wary of PLAS+SD because it combines the blood of so many donors. The labeling warns against using PLAS+SD in pregnant women because of possible risk. People with suppressed immunity, such as chemotherapy or AIDS patients, should also be especially concerned about the risk, we think.

Donor-restricted plasma might be useful as an extra safety measure if you’re one of the few people who need lots of plasma, usually for a severe clotting disorder that requires multiple transfusions. For everyone else, there’s no particular need for premium plasma—even thoughinsurance will generally cover the extra cost, which could run to hundreds ofdollars. If you or your family has the luxury of planning your procedure, the safest options are to reduce or eliminate the need for other people’s blood by using your own—or, better yet, to see if you can avoid the transfusion altogether. Consider these possibilities:

Avoid the transfusion. “In many ways, the best transfusion is the transfusion not given,” says the Red Cross’ Davey. New drugs that stimulate blood-cell production may help some patients do without a transfusion. Other patients may not actually need the blood they’re given.

“Plasma is one of the most misused items,” says Bianco of America’s Blood Centers. Many times an electrolyte solution will do as well as plasma to make up lost blood volume, without the risks. But some hospitals are three times as likely as others to transfuse patients during coronary-bypass surgery. The implication: Some of those transfusions aren’t needed.

If you’re facing elective surgery, ask how low your hematocrit (ratio of the blood count) can go before your surgeon orders a transfusion. Most people don’t need one until their hematocrit drops to 25 percent or lower, depending on the clinical circumstances.

Autologous transfusion. You may be able to bank your own blood—which includes all the components you may need—weeks before a planned operation. That option, which eliminates all risk of transfusion-borne infection or adverse reactions to a stranger’s blood, is generally best of all when you may need a transfusion. But some individuals may not be healthy enough or strong enough to give blood.

Hemodilution. Just before surgery, some blood is withdrawn and saved. The missing blood is replaced with intravenous solutions. If you need blood during or after surgery, you’ll first get your own blood back. The technique is not practical for all operations or all patients, and it may still expose you to strangers’ blood if you need more than the amount withdrawn. Other methods allow just your red cells to be removed before surgery and then stored for subsequent use, if necessary.

Cell salvage. Blood lost during surgery can be collected, washed, filtered, and returned to you during or after the operation. Most hospitals, particularly large ones, can perform this technique. As with hemodilution, cell salvage may not be practical in all operations, and it may not eliminate the need to receive standard transfusions.