

## FACTS ABOUT BLOOD AND BLOOD BANKING

### How much blood is donated each year?

According to the National Blood Data Resource Center (NBDRC) about 13.9 million units (including approximately 695,000 autologous donations) of whole blood are donated in the United States each year. Approximately eight million volunteer blood donors provide blood for about 4.5 million patients per year.

Typically, each donated unit of blood, referred to as whole blood, is separated into multiple components, such as red blood cells, plasma, platelets, and cryoprecipitated AHF (antihemophilic factor). Each component generally is transfused to a different individual, each with different needs.

### Who needs blood?

The need for blood is great — on any given day, an average of 34,000 units of red blood cells are needed. Blood transfusions often are needed for trauma victims — due to accidents and burns — heart surgery, organ transplants, and patients receiving treatment for leukemia, cancer or other diseases, such as sickle cell disease and thalassemia. In 1999, 26.5 million units of blood components were transfused. And with an aging population and advances in medical treatments and procedures requiring blood transfusions, the demand for blood continues to increase.

### Who donates blood?

Fewer than 5 percent of healthy Americans eligible to donate blood actually donate each year. According to studies, the average donor is a college-educated white male, between the ages of 30 and 50, who is married and has an above-average income. However, a broad cross-section of the population donates every day. Furthermore, these “average” statistics are changing, and women and minority groups are volunteering in increasing numbers to donate. Persons 65 years and older compose 13 percent of the population\*, but they use 25 percent of all blood units transfused. Using current screening and donation procedures, a growing number of blood banks have found blood donation by seniors to be safe and practical.

Patients scheduled for surgery may be eligible to donate blood for themselves, a process known as **autologous** blood donation. In the weeks before non-emergency surgery, an autologous donor may be able to donate blood that will be stored until the surgical procedure.

### What are the criteria for blood donation?

To be eligible to donate blood, a person must be in good health and generally must be at least **17 years of age** (although some states permit younger people, with parental consent, to donate). Minimum weight requirements may vary among facilities, but generally, donors must weigh approximately **110 pounds**. Most blood banks have no upper age limit. All donors must pass the physical and health history examinations given prior to donation.

Volunteer donors provide nearly all blood used for transfusion in the United States. The donor's body replenishes the fluid lost from donation in 24 hours. It may take up to two months to replace the lost red blood cells. **Whole blood can be donated once every eight weeks (56 days)**. Two units of red blood cells can be donated at one time, using a process known as red cell apheresis. This type of donation can be made every 16 weeks.

### **Who should not donate blood?**

- Anyone who has ever used intravenous drugs (illegal IV drugs)
- Men who have had sexual contact with other men since 1977
- Hemophiliacs
- Anyone with a positive antibody test for HIV (AIDS virus)
- Men and women who have engaged in sex for money or drugs since 1977
- Anyone who has had hepatitis since his or her eleventh birthday
- Anyone who has/had cancer
- Anyone who has had babesiosis or chagas disease
- Anyone who has taken Tegison for psoriasis
- Anyone with Cruetzfeldt-Jakob disease (CJD) or who has an immediate family member with CJD

### **Where is blood donated?**

There are many places where blood donations can be made. Bloodmobiles (mobile blood drives on specially constructed buses) travel to high schools, colleges, churches, and community organizations. People can also donate at community blood centers and hospital-based donor centers. Many people donate at blood drives at their places of work. Use the Online Locator or consult the yellow pages to locate a nearby blood center or hospital to donate.

### **What is Apheresis?**

**Apheresis**, an increasingly common procedure, is the process of removing a specific component of the blood, such as platelets, and returning the remaining components, such as red blood cells and plasma, to the donor. This process allows more of one particular part of the blood to be collected than could be separated from a unit of whole blood. Apheresis is also performed to collect red blood cells, plasma (liquid part of the blood), and granulocytes (white blood cells).

The apheresis donation procedure takes longer than whole blood donation. A whole blood donation takes about 10-20 minutes to collect the blood, while an apheresis donation may take about one to two hours.

### **What is the most common blood type?**

The approximate distribution of blood types in the US population is as follows. Distribution may be different for specific racial and ethnic groups:

<b>O Rh-positive</b>	<b>--- 38 percent</b>
<b>O Rh-negative</b>	<b>--- 7 percent</b>
<b>A Rh-positive</b>	<b>--- 34 percent</b>
<b>A Rh-negative</b>	<b>--- 6 percent</b>
<b>B Rh-positive</b>	<b>--- 9 percent</b>
<b>B Rh-negative</b>	<b>--- 2 percent</b>
<b>AB Rh-positive</b>	<b>--- 3 percent</b>
<b>AB Rh-negative</b>	<b>--- 1 percent</b>

In an emergency, anyone can receive type O red blood cells, and type AB individuals can receive red blood cells of any ABO type. Therefore, people with type O blood are known as “universal donors” and those with type AB blood are known as “universal recipients.” In addition, AB plasma donors can give to all blood types.

## What tests are performed on donated blood?

After blood is drawn, it is tested for ABO group (blood type) and Rh type (positive or negative), as well as for any unexpected red blood cell antibodies that may cause problems in the recipient. Screening tests are also performed for evidence of donor infection with **hepatitis viruses B and C, human immunodeficiency viruses (HIV) 1 and 2, human T-lymphotropic viruses (HTLV) I and II and syphilis**. The specific tests performed are listed below:

- Hepatitis B surface antigen (HBsAg)
- Hepatitis B core antibody (anti-HBc)
- Hepatitis C virus antibody (anti-HCV)
- HIV-1 and HIV-2 antibody (anti-HIV-1 and anti-HIV-2)
- HIV p24 antigen
- HTLV-I and HTLV-II antibody (anti-HTLV-I and anti-HTLV-II)
- Serologic test for syphilis
- Nucleic acid amplification testing (NAT)

*Note: NAT is still a research initiative, but nearly all blood collected in the US is being tested under the FDA's Investigational new drug (IND) application process.*

## How is blood stored and used?

Each unit of whole blood normally is separated into several components. **Red blood cells** may be stored under refrigeration for a maximum of 42 days, or they may be frozen for up to 10 years. Red cells carry oxygen and are used to treat anemia. **Platelets** are important in the control of bleeding and are generally used in patients with leukemia and other forms of cancer. Platelets are stored at room temperature and may be kept for a maximum of five days. **Fresh frozen plasma**, used to control bleeding due to low levels of some clotting factors, is usually kept in a frozen state for up to one year. **Cryoprecipitated AHF**, which contains only a few specific clotting factors, is made from fresh frozen plasma and may be stored frozen for up to one year. **Granulocytes** are sometimes used to fight infections, although their efficacy is not well established. They must be transfused within 24 hours of donation.

Other products manufactured from blood include albumin, immune globulin, specific immune globulins, and clotting factor concentrates. Commercial manufacturers commonly make these blood products.

## What fees are associated with blood?

While donated blood is free, there are significant costs associated with collecting, testing, preparing components, labeling, storing and shipping blood, recruiting and educating donors, and quality assurance. As a result, processing fees are charged to recover costs. Processing fees for the individual blood components vary considerably. Processing fees for one specific component may also vary in different geographic regions. Hospitals charge for any additional testing that may be required, such as the crossmatch, as well as for the administration of the blood.

## What is the availability of blood?

The blood supply level fluctuates throughout the year. For example, after the Sept. 11 attacks, the blood supply swelled to very high levels, due to the overwhelming response of volunteer donors. During the holidays and in the summer, levels tend to fall because donations decline while demand remains stable or even increases. In addition, recent policies being recommended by the Food and Drug Administration have eliminated donors who may be at risk for variant Creutzfeldt-Jakob disease — commonly known as “mad cow” disease. These elimination, or deferral, policies have reduced the number of people who are eligible to donate.

## **What can you do if you aren't eligible to donate?**

While a given individual may be unable to donate, he or she may be able to recruit a suitable donor. Blood banks are always in need of volunteers to assist at blood draws or to organize mobile blood drives. In addition, monetary donations are always welcome to help ensure that blood banks can continue to provide safe blood to those who are in need.

*\*United States Census 2000*

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## **DONOR SCREENING AND DEFERRAL**

### **The Donation Process**

#### **Education**

When prospective donors enter a blood bank, they are asked to read educational materials such as the AABB pamphlet titled "An Important Message to All Blood Donors." These materials contain information on the risks of infectious diseases transmitted by blood transfusion, including the signs and symptoms of AIDS. Prospective donors are asked to acknowledge in writing that they have read and understood these materials, have been given the opportunity to ask questions, and have provided accurate information. The prospective donors can elect to leave at this point without donating. (Self-deferral can occur at any point in the donation process when a donor voluntarily chooses not to complete the process.)

#### **Health History**

Prospective donors who do not self-defer, proceed to the next step – giving a detailed health history. The history is designed to ask questions that protect the health of both the donor and the recipient. To ensure that every donor is asked the same questions, the AABB recommends use of a uniform donor history questionnaire. However, donor centers often create their own questionnaires using the same general guidelines. In addition to questions about transfusion-transmissible diseases, prospective donors are asked questions to determine whether donating blood might endanger their health. If a prospective donor responds positively to any of these questions, he or she will be "deferred" or asked not to donate blood. The health history also is used to identify prospective donors who have been exposed to, or who may have diseases, such as human immunodeficiency virus (HIV), hepatitis or malaria. These individuals are further evaluated and those at high risk of disease are deferred.

#### **Physical Examination**

The next step in the donation process is an abbreviated physical examination that includes checking the blood pressure, pulse and temperature. A few drops of blood are taken from a finger to ensure that anemia is not present. Abnormalities found in any part of the physical examination may be a cause for deferral. Donors also must meet the weight requirement of 110 pounds.

#### **The Actual Donation**

A prospective donor who passes successfully through these steps proceeds to the actual whole blood donation process, which takes about 20 minutes. The donor lies down or sits in a reclining chair. The skin covering the inner part of the elbow joint is cleansed. A new, sterile needle connected to plastic tubing and a blood bag is inserted into an arm vein. The donor is asked to squeeze repeatedly his or her hand to

help blood flow from the vein into the blood bag. Typically, one unit of blood, roughly equivalent to a pint, is collected. After the blood is collected, it is sent to the laboratory for testing and component preparation. The donor is escorted to an observation area for light refreshments and a brief rest period.

Adult males have about 12 pints of blood in their circulation and adult females have about nine pints. The donor's body replenishes the fluid lost from donation in about 24 hours. The red blood cells that are lost are generally replaced in a few weeks. Whole blood can be donated once every eight weeks.

### **The Deferral Process**

Individuals disqualified from donating blood are known as “deferred” donors. A prospective donor may be deferred at any point during the collection and testing process. Whether or not a person is deferred temporarily or permanently will depend on the specific reason for disqualification (e.g., a person may be deferred temporarily because of anemia, a condition that is usually reversible). If a person is to be deferred, his or her name is entered into a list of deferred donors maintained by the blood center, often known as the “deferral registry.” If a deferred donor attempts to give blood before the end of the deferral period, the donor will not be accepted for donation. Once the reason for the original deferral no longer exists and the temporary deferral period has lapsed, the donor may return to the blood bank and be re-entered into the system.

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## WHOLE BLOOD AND BLOOD COMPONENTS

### **Background**

Blood may be transfused as whole blood or as one of its components. Because patients seldom require all of the components of whole blood, it makes sense to transfuse only that portion needed by the patient for a specific condition or disease. This treatment, referred to as “blood component therapy,” allows several patients to benefit from one unit of donated whole blood. Blood components include red blood cells, plasma, platelets, and cryoprecipitated antihemophilic factor (AHF). Up to four components may be derived from one unit of blood.

**Whole blood** is a living tissue that circulates through the heart, arteries, veins, and capillaries carrying nourishment, electrolytes, hormones, vitamins, antibodies, heat, and oxygen to the body's tissues. Whole blood contains red blood cells, white blood cells and platelets suspended in a fluid called plasma.

If blood is treated to prevent clotting and permitted to stand in a container, the red blood cells, weighing the most, will settle to the bottom; the plasma will stay on top; and the white blood cells and platelets will remain suspended between the plasma and the red blood cells. A centrifuge may be used to hasten this separation process. The platelet-rich plasma is then removed and placed into a sterile bag, and it can be used to prepare platelets and plasma or cryoprecipitated AHF. To make platelets, the platelet-rich plasma is centrifuged, causing the platelets to settle at the bottom of the bag. Plasma and platelets are then separated and made available for transfusion. The plasma may also be pooled with plasma from other donors and further processed, or fractionated, to provide purified plasma proteins such as albumin, immunoglobulin (IVIG) and clotting factors.

**Red blood cells** are perhaps the most recognizable component of whole blood. Red blood cells contain hemoglobin, a complex iron-containing protein that carries oxygen throughout the body and gives blood its red color. The percentage of blood volume composed of red blood cells is called the “hematocrit.” The average hematocrit in an adult male is 47 percent. There are about one billion red blood cells in two to three drops of blood, and, for every 600 red blood cells, there are about 40 platelets and one white cell.

Manufactured in the bone marrow, red blood cells are continuously being produced and broken down. They live for approximately 120 days in the circulatory system and are eventually removed by the spleen.

Red blood cells are prepared from whole blood by removing the plasma, or the liquid portion of the blood. They can raise the patient's hematocrit and hemoglobin levels while minimizing an increase in volume.

Patients who benefit most from transfusions of red blood cells include those with chronic anemia resulting from disorders such as kidney failure, malignancies, or gastrointestinal bleeding and those with acute blood loss resulting from trauma or surgery. Since red blood cells have reduced amounts of plasma, they are well suited for treating anemia patients who would not tolerate the increased volume provided by whole blood, such as patients with congestive heart failure or those who are elderly or debilitated.

Improvements in cell preservative solutions over the last 15 years have increased the shelf life of red blood cells from 21 to 42 days. Red blood cells may be treated and frozen for extended storage (up to 10 years).

**Plasma** is the liquid portion of the blood — a protein-salt solution in which red and white blood cells and platelets are suspended. Plasma, which is 90 percent water, constitutes about 55 percent of blood volume. Plasma contains **albumin** (the chief protein constituent), **fibrinogen** (responsible, in part, for the clotting of blood), **globulins** (including antibodies), and other clotting proteins. Plasma serves a variety of functions, from maintaining a satisfactory blood pressure and volume to supplying critical proteins for blood clotting and immunity. It also serves as the medium of exchange for vital minerals such as sodium and potassium, thus helping maintain a proper balance in the body, which is critical to cell function. Plasma is obtained by separating the liquid portion of blood from the cells. Plasma is usually not used for transfusion purpose but is fractionated (separated) into specific products such as albumin, specific clotting factor concentrates and IVIG (intravenous immune globulin).

Fresh frozen plasma is plasma frozen within hours after donation to preserve clotting factors, stored for one to seven years, and thawed before it is transfused. It is most often used to treat certain bleeding disorders when a clotting factor or multiple factors are deficient and no factor-specific concentrate is available. It can also be used for plasma replacement via a process called **plasma exchange**.

**Cryoprecipitated AHF** is the portion of plasma that is rich in certain clotting factors, including Factor VIII, fibrinogen, von Willebrand factor and Factor XIII. Cryoprecipitated AHF is removed from plasma by freezing and then slowly thawing the plasma. It is used to prevent or control bleeding in individuals with hemophilia and von Willebrand's disease, which are common, inherited major coagulation abnormalities. Its use in these conditions is reserved for times when viral-inactivated concentrates containing Factor VIII and von Willebrand factor are unavailable and plasma components must be used. It may also be used as hemostatic preparation [fibrin sealant or fibrin glue] in surgery.

**Platelets** (or thrombocytes) are very small cellular components of blood that help the clotting process by sticking to the lining of blood vessels. Platelets are made in the bone marrow and survive in the circulatory system for an average of 9-10 days before being removed from the body by the spleen. The platelet is vital to life, because it helps prevent both massive blood-loss resulting from trauma and blood vessel leakage that would otherwise occur in the course of normal, day-to-day activity. Units of platelets are prepared by using a centrifuge to separate the platelet-rich plasma from the donated unit of whole blood. The platelet-rich plasma is then centrifuged again to concentrate the platelets further.

Platelets may also be obtained from a donor by a process known as apheresis, or plateletpheresis. In this process, blood is drawn from the donor into an apheresis instrument, which, using centrifugation, separates the blood into its components, retains the platelets, and returns the remainder of the blood to the donor. The resulting component contains about six times as many platelets as a unit of platelets obtained from whole blood. Platelets are used to treat a condition called thrombocytopenia, in which there

is a shortage of platelets, and in patients with abnormal platelet function. Platelets are stored at room temperature for up to five days.

**White blood cells** are responsible for protecting the body from invasion by foreign substances such as bacteria, fungi, and viruses. The majority of white blood cells are produced in the bone marrow, where they outnumber red blood cells by two to one. However, in the blood stream, there are about 600 red blood cells for every white blood cell. There are several types of white blood cells; Granulocytes and macrophages protect against infection by surrounding and destroying invading bacteria and viruses, and lymphocytes aid in the immune defense.

Granulocytes can be collected by apheresis or by centrifugation of whole blood. They are transfused within 24 hours after collection and are used for infections that are unresponsive to antibiotic therapy. The effectiveness of white blood cell transfusion is still being investigated.

**Plasma derivatives** are concentrates of specific plasma proteins that are prepared from pools (many units) of plasma. Plasma derivatives are obtained through a process, known as fractionation, developed during World War II, and are heat-treated and/or solvent detergent- treated to kill certain viruses, including HIV and hepatitis B and C. Plasma derivatives include:

- Factor VIII Concentrate
- Factor IX Concentrate
- Anti-Inhibitor Coagulation Complex (AICC)
- Albumin
- Immune Globulins, including Rh Immune Globulin
- Anti-Thrombin III Concentrate
- Alpha 1-Proteinase Inhibitor Concentrate

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## AUTOLOGOUS (self-donated) BLOOD AS AN ALTERNATIVE TO ALLOGENEIC (donor-donated) BLOOD TRANSFUSION

“**Autologous**” transfusions refer to those transfusions in which the blood donor and transfusion recipient are the same.

“**Allogeneic**” transfusions refer to blood transfused to someone other than the donor.

### **Preoperative Donation**

The most common autologous donation is the preoperative donation of blood for possible transfusion back to the donor during elective surgery. For example, a person might give one unit of blood each week for up to six weeks before surgery, because blood can be stored in its liquid form for up to 42 days. Patients can make autologous donations up until 72 hours prior to their surgery. This is to allow the body enough time to replenish its blood supply before the surgical procedure.

A significant amount of iron is removed with each autologous donation. When appropriate, iron supplements are prescribed for patients making autologous donations to help increase red blood cell count.

Autologous donation is most often employed in surgery on bones, blood vessels, the urinary tract, and the heart, when the likelihood of transfusion is high. According to the National Blood Data Resource Center

autologous blood accounted for 4.7 percent of all donated blood in 1999. Potential autologous blood donors are medically stable patients who are free of infection. There is no age limitation for autologous donation. Many children and elderly patients have successfully completed autologous donations; however, some patients may not be good candidates. The physician and patient should make the decision regarding autologous donation and transfusion jointly.

The process of donating autologous blood stimulates the bone marrow to produce new blood cells. Given adequate time for recovery, the collected cells may be wholly or partially replaced prior to surgery.

If blood loss during surgery is less than anticipated, transfusion of autologous blood may not be medically necessary. Although the risk of a complication from autologous blood is low, some residual risk persists making automatic transfusion of autologous units unwise. Forty-four percent of autologous donations are unused by the autologous donor. These units are generally discarded since current standards do not allow transfusion of these units to another patient for safety reasons. In emergency situations, however, these units may be used for another patient provided that there is medical approval for the crossover and the unit has been fully screened. Due to the special handling and separate storage requirements, autologous donations cost more to process.

### **Blood Dilution (Hemodilution)**

Blood dilution, or hemodilution, is the removal of one or more units of blood just before surgery for transfusion to the patient during or at the end of the operation. Hemodilution is used to decrease the loss of red blood cells during surgery. In this procedure, blood is drawn from a patient prior to surgery, and the patient is immediately given intravenous fluids to compensate for the amount of blood removed. Since the number of red blood cells in the person's circulatory system has been diluted, fewer red blood cells will be lost from bleeding during the operation. After surgery, the patient's own blood is reinfused. However, the patient must be able to accommodate the anemia that the procedure causes.

### **Perioperative Blood Collection**

In perioperative blood collection, blood lost by the patient during surgery is recovered and recycled throughout the surgery. Most perioperative blood collection programs use machines in which shed blood is collected and the red blood cells are concentrated and washed prior to transfusion. This procedure is widely used for surgical procedures, such as cardiac, vascular, orthopedic, urologic, trauma, gynecologic, and transplant surgery, in which the anticipated blood loss is 20 percent or more of the patient's estimated blood volume and there is no contamination of the area by bacteria or cancer cells. This procedure is generally not used in cancer surgery or surgery of the lower gastrointestinal tract.

### **Postoperative Blood Collection**

In postoperative blood collection, blood that is lost in the early postoperative period is collected from a drainage tube at the surgical site and transfused to the patient, either washed or unwashed. Postoperative collection is used primarily in cardiac and orthopedic surgery. In most cases, though, the volume of salvaged red cells is small.

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## **TESTING OF DONOR BLOOD FOR INFECTIOUS DISEASE**

The AABB and its members are committed to ensuring a safe blood supply for everyone who may need transfusions. An important step in ensuring safety is the screening of donated blood for infectious

diseases. Today, nine tests for infectious diseases are conducted on each unit of donated blood. Tests for hepatitis B and syphilis were in place before 1985. Since then, tests for human immunodeficiency virus (HIV-1 and HIV-2), human T-lymphotropic virus (HTLV-I and II) and the hepatitis C virus (HCV) have been added. The following tests are performed on each unit of blood:

### **Hepatitis B Surface Antigen (HBsAg)**

The hepatitis B virus, which mainly infects the liver, has an inner core and an outer envelope (the surface). The HBsAg test detects the outer envelope identifying an individual infected with the hepatitis B virus. Hepatitis B can cause inflammation of the liver, and in the earliest stage of the disease, infected people may feel ill or even have yellow discoloration of the skin or eyes, known as **jaundice**. Fortunately, most patients recover completely and test negative for HBsAg within a few months after the illness. A small percentage of people become chronic carriers of the virus, and in these cases, the test may remain positive for years. Chronically infected people can develop severe liver disease as time passes, and need to be followed carefully by an experienced doctor.

### **Antibodies to the Hepatitis B Core (Anti-HBc)**

The anti-HBc test detects an antibody to the hepatitis B virus that is produced during and after infection. If an individual has a positive anti-HBc test, but the HBsAg test is negative, it may mean that the person once had hepatitis B, but has recovered from the infection. Of the individuals with a positive test for anti-HBc, many have not been exposed to the hepatitis B virus. This kind of test result is called a **false positive**, and although the individual may be permanently deferred from donating blood, it is unlikely that the person's health will be negatively affected. (Note: This antibody is not produced following vaccination against hepatitis B. Hepatitis B vaccination, by itself, will rarely cause the HbsAg test to be positive for a few days after the shots.)

### **Antibodies to the Hepatitis C Virus (Anti-HCV)**

This test is used to screen donors for the hepatitis C virus (HCV). It works by detecting antibodies manufactured by the body in reaction to portions of the virus called **antigens**. HCV causes inflammation of the liver, and up to 80 percent of those exposed to the virus develop chronic infection. Eventually, up to 20 percent of people with HCV may develop cirrhosis of the liver or other severe liver diseases. As in other forms of hepatitis, individuals may be infected with the virus, but may not realize they are carriers since they do not have any symptoms. Because of the risk of serious illness, people with HCV need to be followed closely by a physician with experience evaluating this infection.

### **Antibodies to the Human Immunodeficiency Virus, Types 1 and 2 (Anti-HIV-1, -2)**

This test is designed to detect antibodies directed against antigens of the HIV-1 or HIV-2 viruses. HIV-1 is much more common in the United States, while HIV-2 is prevalent in Western Africa. Donors are tested for both viruses because both are transmitted by infected blood, and a few cases of HIV-2 have been identified in US residents. Both of these viruses can cause acquired immunodeficiency syndrome, or AIDS.

### **HIV-1 p24 Antigen**

This test screens for antigens of the HIV-1 virus. The extra safety added by doing this test derives from its ability to detect HIV-1 infection a week earlier than the antibody test. Thus, the HIV-1 infection can be identified sooner, and the risk of getting HIV-1 from a blood transfusion has decreased. HIV-1 p24 antigen testing may be discontinued in the future when we know more about the performance of a new kind of testing called nucleic acid amplification testing or NAT (described below). The new tests are believed to identify HIV infection even sooner than p24 testing, and it may make it unnecessary.

## **Antibodies to Human T-Lymphotropic Virus, Types I and II (Anti-HTLV-I, -II)**

This test screens for antibodies directed against portions of the HTLV-I and HTLV-II viruses. Both of these viruses are relatively uncommon in the United States, but do occur more frequently in certain populations. HTLV-I is more common in Japan and the Caribbean. The infection can persist for a lifetime, but rarely causes major illnesses in most people who are infected. In rare instances, the virus may, after many years of infection, cause nervous system disease or an unusual type of leukemia. HTLV-II infections are usually associated with intravenous drug usage, especially among people who share needles or syringes. Disease associations with HTLV-II have been hard to confirm, but the virus may cause subtle abnormalities of immunity that lead to frequent infections, or rare cases of neurological disease.

## **Syphilis**

This test is done to detect evidence of infection with the *spirochete* that causes syphilis. Blood centers began testing for this shortly after World War II, when syphilis rates in the general population were much higher. The risk of transmitting syphilis through a blood transfusion is exceedingly small (no cases have been recognized in this country for many years) because the infection is very rare in blood donors, and because the spirochete is fragile and unlikely to survive blood storage conditions.

## **Nucleic Acid Amplification Testing (NAT)**

NAT employs new forms of testing technology that directly detect the genetic material of viruses like HCV and HIV. Because NAT detects the genetic material of a virus, instead of waiting for the body's response — the formation of antibodies, as with many current tests — it offers the opportunity to reduce the window period during which an infecting agent is undetectable by traditional tests, thus further improving blood safety.

NAT has yet to be approved by the FDA for donor screening in the U.S. however, because of the promise that this technology holds for improving the safety of the blood supply blood collection organizations are already using NAT for HIV and HCV under the FDA's Investigational New Drug (IND) application process.

## **Confirmatory Testing**

All of the above tests are referred to as **screening tests**, and are designed to detect as many infections as possible. Because these tests are so sensitive, some donors may have a false positive result, even if the donor were never exposed to the particular infection. In order to sort out true infections from false positive test results, screening tests that are reactive may be followed up with more specific tests called **confirmatory tests**. Thus, confirmatory tests help determine whether a donor is truly infected.

If the test result from a donated unit of blood is abnormal for any of these disease markers, the unit is discarded and the donor is notified. The donor's name is then added to a donor deferral list and is prohibited from donating blood indefinitely.

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## TRANSFUSION-TRANSMITTED DISEASES

### **Viruses**

## **Human Immunodeficiency Virus (HIV)**

Transfusion transmission of HIV, the virus that causes AIDS, has been almost completely eradicated, since blood banks began interviewing donors about at-risk behaviors and a blood test became available in early 1985. The HIV antibody tests, used on every blood donation since then, have undergone continuous improvement, and in 1996 blood centers added yet another HIV test called the HIV antigen assay (HIV-1). This new test makes the blood supply even safer, because it can detect HIV about one week sooner than the antibody test. Used in combination, these tests reduced the risk of getting HIV from a single blood transfusion to between 1 in 450,000 and 1 in 660,000. Starting in 1999 Nucleic acid amplification (NAT) testing has been used to directly detect the genetic material of the HIV virus in blood, and current estimates are that fewer than 1 in 1,900,000 blood components is capable of transmitting HIV. Transfusion medicine specialists are continually researching new technologies to further reduce the transmission of HIV. Examples of technologies on the horizon include methods to kill viruses in donated blood (called viral inactivation) and blood component substitutes.

## **Hepatitis**

Hepatitis was the first documented transfusion-transmitted disease. Many of the current practices for diminishing risk in transfusion medicine are based on the experiences of controlling the transmission of hepatitis.

Hepatitis viruses, which infect the liver, fall primarily into two groups: viruses with a chronic course that can readily be transmitted by blood transfusion (hepatitis B and C) and viruses that cause only acute disease and are rarely transmitted by transfusion (hepatitis A and E).

## **Hepatitis B Virus (HBV)**

Transmission of hepatitis B virus (HBV) is rare because of routine testing of blood for the HBsAg and hepatitis B core antibody, donor screening and deferral for risk of HBV infection, and the use of only altruistic volunteer blood donors. HBV is a major cause of acute and chronic hepatitis. Each year in the US, an estimated 300,000 persons are infected with HBV. More than 10,000 patients require hospitalization, and an average of 350 die from the disease. There is an estimated pool of 750,000–1,000,000 chronically infected HBV carriers in the US. Approximately 25 percent of carriers have active hepatitis that can progress to cirrhosis of the liver. An estimated 4,000 people die each year from hepatitis B-related cirrhosis, and more than 800 die from hepatitis B-related liver cancer. The number of HBV infections in the US is falling because hepatitis B vaccinations of health care professionals and school-age children has become nearly universal.

Screening blood donors for HBV began in 1969 and became mandatory in 1972. By the mid-1970s, testing and an all-volunteer blood donor supply reduced the rate of post-transfusion hepatitis B to between 0.3 and 0.9 percent. From 1982 to 1985, an average of 3.0 percent of hepatitis B cases in the US were related to blood transfusion. During the period from 1986 to 1988, the percentage of reported cases related to blood transfusion declined to 1.0 percent, possibly as a consequence of the donor screening questions that were instituted to identify persons at increased risk for HIV infection. In 2000, the frequency of post-transfusion hepatitis B developing after a blood transfusion was estimated at 1 in 137,000 screened units of blood.

## **Hepatitis C Virus (HCV)**

Hepatitis C, formerly known as non-A, non-B hepatitis, was discovered in the late 1980s, and all blood donations have been screened for it since 1990. Acute hepatitis C virus (HCV) is a relatively mild infection, and most people are unaware they have become infected; however, HCV becomes chronic in 80 percent of those infected. In the general population, 1.8 percent of the population has some evidence of HCV-infection. While the rate of new HCV infections is falling rapidly due to behavior changes and

blood screening, HCV is an important source of serious chronic liver disease, which often develops decades after the initial exposure to the virus.

Antibody screening was started in 1990, and the test has undergone significant improvement since. In 1999, NAT testing was added in the US. After more than 10 years of testing for HCV, the risk of HCV transmission through transfusion is less than 1 per 1,000,000-screened units of blood.

### **Hepatitis A Virus (HAV)**

Hepatitis A (HAV) infection is rarely transmitted through blood transfusion; it is usually spread by contaminated food and water. About 23,000 cases are reported annually in the US, but epidemiologists estimate that the virus infects 150,000 Americans each year. Hepatitis A is very prevalent in the developing world, including Mexico and parts of the Caribbean. Because HAV antibodies are present in approximately 20 percent of the population, many with no history of hepatitis, it is assumed that many people experience unrecognized infection. There have been occasional reports in the US of transfusion-transmitted HAV, but little can be done to prevent this rare occurrence. A vaccine recently developed for HAV has replaced immune globulin as a pre-exposure prophylactic measure for people at a high risk for acquiring this infection, although the latter remains useful after exposure.

### **Human T Lymphotropic Virus I, -II (HTLV-I, -II)**

HTLV-I and -II are viruses that are not related to HIV. HTLV-I is found mainly in Southwestern Japan and Caribbean islands. The virus can cause blood or nervous system diseases in a small number of infected people (less than 5 percent lifetime risk). HTLV-II is endemic in the Americas (including the US), and also may infrequently cause nervous system disease or slightly increased susceptibility to infections. Both of these viruses, although rare, were found in the US blood donor population in the 1980s. Few people have gotten HTLV as a result of transfusion, but because of the small transfusion risk that existed in the 1980s, tests to detect HTLV-I antibodies were developed and quickly implemented; these tests also detected many, but not all, HTLV-II infections. Tests specifically designed to detect both viruses are now available and are used by blood centers to screen every donation.

### **Cytomegalovirus (CMV)**

Cytomegalovirus (CMV) is a virus belonging to the herpes group that is rarely transmitted by blood transfusion. According to the Centers for Disease Control and Prevention (CDC), about 50 to 85 percent of adults in the United States are infected with CMV by the age of 40. CMV infection is usually mild, but it may be serious or fatal in those who are immunocompromised. Particularly at risk are low-birth weight infants and bone marrow and organ transplant patients. If a patient is at high risk of getting CMV diseases, blood that tests negative for CMV can be transfused. Alternatively, blood that has been filtered to decrease the number of white blood cells — the cells that carry CMV — will protect patients from getting a CMV infection from transfusion.

## **Parasitic Infections**

### **Malaria**

Between 1958 and 1998, the CDC recorded 103 cases of transfusion-transmitted malaria. These cases were most likely caused by donations from people who felt well and were not aware that they were carrying malaria. Although exceedingly rare, malaria can cause serious consequences, including fatalities. There is no practical test available to screen donors so AABB requires blood centers to temporarily defer blood donations from people who have visited malarial areas in the past year or who emigrated from a malarial area within the past three years.

## **Babesiosis**

Babesiosis is a parasitic infection carried by the white-footed mouse and transmitted by tick bites. It appears primarily in the northeastern US, in coastal areas that are home to the white-footed mouse. Cases also have been identified in the Upper Midwest and Pacific Northwest. About 30 transfusion-associated cases have been reported in the US. While babesiosis is often quite mild, some patients, including those without a spleen, the elderly, or the immunocompromised, may be at risk of serious illness. There are no useful tests available for screening blood donors, although testing strategies are being developed and discussed. The AABB requires that all donors be asked if they have a history of babesiosis. Those individuals with a history of the disease are permanently deferred from donating blood.

## **Chagas' Disease**

A Brazilian doctor, Carlos Chagas, discovered Chagas' disease almost 100 years ago. This disease is caused by a parasite that infects as many as 18 million people worldwide. Once infection is established, it is life-long. Each year, several thousand South and Central Americans die of heart and digestive problems caused by the disease. Up to 20percent of infected people never exhibit symptoms. This infection is rare in the US, but because of recent global population shifts, individuals from countries where this disease is common now reside in the US. To date, there have been only five cases of transfusion-transmitted Chagas' disease reported in North America. The AABB requires that blood centers permanently prohibit blood donation from anyone who has had Chagas' disease, and tests are being developed and screening strategies discussed.

## **Lyme Disease**

Although transfusion-related cases have not been reported, public health agencies and the AABB are monitoring this disease because of the remote chance that it could affect transfusion safety. Lyme disease is associated with the bite of certain species of the deer tick, and can cause an illness that affects many systems within the body. Donors with a history of Lyme disease can donate, provided they have undergone a full course of antibiotic treatment and no longer have any symptoms.

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## **CREUTZFELDT-JAKOB DISEASE (CJD)**

CJD is a rare degenerative and fatal nervous system disorder. It is diagnosed in about one person per million per year in the US and worldwide. There are three forms of CJD that can affect humans: sporadic CJD has no known risk factors and accounts for 85 percent of CJD cases; hereditary CJD occurs only in individuals with a family history of the disease and/or tests positive for specific genetic mutations; and acquired CJD is transmitted by exposure to brain or nervous system tissue. Acquired CJD accounts for less than 1 percent of CJD cases and can occur in individuals who have received injections of human pituitary gland growth hormone, or who have had their brain's outer lining (dura mater) repaired with dura mater from someone else who had CJD.

Individuals who will develop CJD can remain without symptoms for decades and then progress rapidly to dementia, severe loss of coordination and death. Scientists believe abnormal brain proteins that have undergone a peculiar shape change can cause other brain proteins to do the same and cause CJD.

Currently, there is no screening test for the disease, and while blood transfusions have never been shown to transmit any form of the disease, as a precaution the Food and Drug Administration (FDA) prohibits blood donation by individuals who may be at risk. These include potential donors who have received

injections of human-derived pituitary hormone, those with a family history of CJD, or those who have had surgeries that involved transplanted dura mater.

### **variant Creutzfeldt-Jakob disease (vCJD)**

Similar to CJD, vCJD, commonly known as the human form of “mad cow” disease, is a similar, rare degenerative and fatal nervous system disorder. There is reason to believe that vCJD occurs when humans eat beef contaminated with bovine spongiform encephalopathy (BSE or “mad cow”). This new form of CJD has appeared only in residents of the United Kingdom, France, and a single individual in Hong Kong. There have been no cases of vCJD infection in humans or of BSE in cattle in the US. Currently, there is no screening test in humans for the disease.

Even though there is no evidence that vCJD has ever been transmitted through a blood transfusion, the FDA, requires donor deferral policies for anyone who potentially could have been exposed to the disease, by eating contaminated beef products in areas of the world where BSE has been found. These policies are changing as we learn more about vCJD and BSE.

These current FDA *recommendations* will be put in place over the next year.

### **The FDA recommends that the following donors be deferred indefinitely due to vCJD risk:**

#### **Phase I**

- Donors who spent a total of three months or more in the United Kingdom (UK) from the beginning of 1980 through the end of 1996;
- Donors who have spent a total of five years or more in France from 1980 to the present;
- Current or former US military personnel, civilian military employees and their dependents who resided at US military bases in Northern Europe (Germany, UK, Belgium, and the Netherlands) for a total of six months or more from 1980 through 1990, or elsewhere in Europe (Greece, Turkey, Spain, Portugal, and Italy) from 1980 through 1996.

#### **Phase II**

- Donors who have received any blood or blood component transfusions in the UK between 1980 and the present;
- Whole blood, but not source plasma, donors, who have lived cumulatively for five years or more in Europe from 1980 to the present, (which includes the aforementioned deferral periods applied to the UK and France). Unless deemed unsuitable for other reasons, these donors, although deferred from whole blood collection, remain eligible to serve as source plasma donors;
- Donors who have injected bovine insulin since 1980, unless it is possible to obtain confirmation that the product was not manufactured after 1980 from cattle in the UK.

### **Other organizations have slightly different policies summarized here:**

#### **Department of Defense (DoD)**

The DoD implemented its set of new donor deferral rules in October. All active-duty military personnel, civil service employees, and these two groups' family members will be deferred indefinitely due to vCJD risk if they are:

- Donors who traveled or resided in the UK for a cumulative total of three months or more at any time from 1980 through the end of 1996;
- Donors who have received a blood transfusion in the UK at any time from 1980 to the present;

- Donors who have traveled to or resided anywhere in Europe for a cumulative total of six months or more at any time from 1980 through the end of 1996;
- Donors who traveled to or resided anywhere in Europe for a cumulative total of five years or more at any time from Jan. 1, 1997, to the present.

### **American Red Cross (ARC)**

The ARC implemented its set of new donor deferral rules in October 2001. All ARC donors will be deferred indefinitely due to vCJD risk if they are:

- Donors who have lived in the UK for a cumulative total of three months since 1980;
- Donors who have lived in any European country or a combination of countries (including the UK) for a cumulative total of six months since 1980;
- Donors who have received blood transfusions in the UK since 1980.

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## HIGHLIGHTS OF TRANSFUSION MEDICINE HISTORY

**1628** English physician William Harvey discovers the circulation of blood. Shortly afterward, the earliest known blood transfusion is attempted.

**1665** The first recorded successful blood transfusion occurs in England: Physician Richard Lower keeps dogs alive by transfusion of blood from other dogs.

**1667** Jean-Baptiste Denis in France and Richard Lower in England separately report successful transfusions from lambs to humans. Within 10 years, transfusing the blood of animals to humans becomes prohibited by law because of reactions.

**1795** In Philadelphia, American physician Philip Syng Physick, performs the first human blood transfusion, although he does not publish this information.

**1818** James Blundell, a British obstetrician, performs the first successful transfusion of human blood to a patient for the treatment of postpartum hemorrhage. Using the patient's husband as a donor, he extracts approximately four ounces of blood from the husband's arm and, using a syringe, successfully transfuses the wife. Between 1825 and 1830, he performs 10 transfusions, five of which prove beneficial to his patients, and publishes these results. He also devises various instruments for performing transfusions and proposed rational indications.

**1840** At St. George's School in London, Samuel Armstrong Lane, aided by consultant Dr. Blundell, performs the first successful whole blood transfusion to treat hemophilia.

**1867** English surgeon Joseph Lister uses antiseptics to control infection during transfusions.

**1873-1880** US physicians transfuse milk (from cows, goats, and humans).

**1884** Saline infusion replaces milk as a "blood substitute" due to the increased frequency of adverse reactions to milk.

**1900** Karl Landsteiner, an Austrian physician, discovers the first three human blood groups, A, B, and C. Blood type C was later changed to O. His colleagues Alfred Decastello and Adriano Sturli add AB, the fourth type, in 1902. Landsteiner receives the Nobel Prize for Medicine for this discovery in 1930.

**1907** Hektoen suggests that the safety of transfusion might be improved by crossmatching blood between donors and patients to exclude incompatible mixtures. Reuben Ottenberg performs the first blood transfusion using blood typing and crossmatching in New York. Ottenberg also observed the mendelian inheritance of blood groups and recognized the "universal" utility of group O donors.

**1908** French surgeon Alexis Carrel devises a way to prevent clotting by sewing the vein of the recipient directly to the artery of the donor. This vein-to-vein or *direct* method, known as anastomosis, is practiced by a number of physicians, among them J.B. Murphy in Chicago and George Crile in Cleveland. The procedure proves unfeasible for blood transfusions, but paves the way for successful organ transplantation, for which Carrel receives the Nobel Prize in 1912.

**1908** Moreschi describes the antiglobulin reaction. The antiglobulin is a direct way of visualizing an antigen-antibody reaction that has taken place but is not directly visible. The antigen and antibody react with each other, then, after washing to remove any unbound antibody, the antiglobulin reagent is added and binds between the antibody molecules that are stuck onto the antigen. This makes the complex big enough to see.

**1912** Roger Lee, a visiting physician at the Massachusetts General Hospital, along with Paul Dudley White, develops the Lee-White clotting time. Adding another important discovery to the growing body of knowledge of transfusion medicine, Lee demonstrates that it is safe to give group O blood to patients of any blood group, and that blood from all groups can be given to group AB patients. The terms "universal donor" and "universal recipient" are coined.

**1914** Long-term anticoagulants, among them sodium citrate, are developed, allowing longer preservation of blood.

**1915** At Mt. Sinai Hospital in New York, Richard Lewisohn uses sodium citrate as an anticoagulant to transform the transfusion procedure from direct to indirect. In addition, Richard Weil demonstrates the feasibility of refrigerated storage of such anticoagulated blood. Although this is a great advance in transfusion medicine, it takes 10 years for sodium citrate use to be accepted.

**1916** Francis Rous and J.R. Turner introduce a citrate-glucose solution that permits storage of blood for several days after collection. Allowing for blood to be stored in containers for later transfusion aids the transition from the vein-to-vein method to direct transfusion. This discovery also allows for the establishment of the first blood depot by the British during World War I. Oswald Robertson is credited as the creator of the blood depots.

**1927-1947** The MNSs and P systems are discovered. MNSs and P are two more blood group antigen systems — just as ABO is one system and Rh is another.

**1932** The first blood bank is established in a Leningrad hospital.

**1937** Bernard Fantus, director of therapeutics at the Cook County Hospital in Chicago, establishes the first hospital blood bank in the United States. In creating a hospital laboratory that can preserve and store donor blood, Fantus originates the term "blood bank." Within a few years, hospital and community blood banks begin to be established across the United States. Some of the earliest are in San Francisco, New York, Miami, and Cincinnati.

**1939/40** The Rh blood group system is discovered by Karl Landsteiner, Alex Wiener, Philip Levine, and R.E. Stetson and is soon recognized as the cause of the majority of transfusion reactions. Identification of the Rh factor takes its place next to the discovery of ABO as one of the most important breakthroughs in the field of blood banking.

**1940** Edwin Cohn, a professor of biological chemistry at Harvard Medical School, develops cold ethanol fractionation, the process of breaking down plasma into components and products. Albumin, a protein with powerful osmotic properties, plus gamma globulin and fibrinogen are isolated and become available for clinical use. John Elliott demonstrates the efficacy of albumin in transfusion.

**1940** The United States government establishes a nationwide program for the collection of blood. Charles R. Drew develops the "Plasma for Britain" program — a pilot project to collect blood for shipment to the British Isles. The American Red Cross participates, collecting 13 million units of blood by the end of World War II.

**1941** Isodor Ravdin, a prominent surgeon from Philadelphia, effectively treats victims of the Pearl Harbor attack with Cohn's albumin for shock. Injected into the blood stream, albumin absorbs liquid from surrounding tissues, preventing blood vessels from collapsing, a finding associated with shock.

**1943** The introduction by J.F. Loutit and Patrick L. Mollison of acid citrate dextrose (ACD) solution, which reduces the volume of anticoagulant, permits transfusions of greater volumes of blood and permits longer term storage.

**1943** P. Beeson publishes the classic description of transfusion-transmitted hepatitis.

**1945** Coombs, Mourant, and Race describe the use of antihuman globulin (later known as the "Coombs Test") to identify "incomplete" antibodies.

**1947** The American Association of Blood Banks (AABB) is formed to promote common goals among blood banking practitioners and the blood donating public.

**1949-1950** The US blood collection system includes 1,500 hospital blood banks, 46 community blood centers, and 31 American Red Cross regional blood centers.

**1950** Audrey Smith reports the use of glycerol cryoprotectant for freezing red blood cells.

**1950** In one of the single most influential technical developments in blood banking, Carl Walter and W.P. Murphy, Jr., introduce the plastic bag for blood collection. Replacing breakable glass bottles with durable plastic bags allows for the evolution of a collection system capable of safe and easy preparation of multiple blood components from a single unit of whole blood. Development of the refrigerated centrifuge in 1953 further expedites blood component therapy.

**1951** The AABB Clearinghouse is established, providing a centralized system for exchanging blood among blood banks. Today, the Clearinghouse is called the National Blood Exchange.

**Mid-1950s** In response to the heightened demand created by open-heart surgery and advances in trauma care patients, blood use enters its most explosive growth period.

**1957** The AABB forms its committee on Inspection and Accreditation to monitor the implementation of standards for blood banking.

**1958** The AABB publishes its first edition of *Standards for a Blood Transfusion Service* (now titled *Standards for Blood Banks and Transfusion Services*).

**1959** Max Perutz of Cambridge University deciphers the molecular structure of hemoglobin, the molecule that transports oxygen and gives red blood cells their color.

**1960** The AABB begins publication of *TRANSFUSION*, the first American journal wholly devoted to the science of blood banking and transfusion technology. In this same year, A. Solomon and J.L. Fahey report the first therapeutic plasmapheresis procedure — a procedure that separates whole blood into plasma and red blood cells.

**1961** The role of platelet concentrates in reducing mortality from hemorrhage in cancer patients is recognized.

**1962** The first antihemophilic factor (AHF) concentrate to treat coagulation disorders in hemophilia patients is developed through fractionation.

**1962** In the US, there were 4,400 hospital blood banks, 123 community blood centers and 55 American Red Cross blood centers, collecting a total of five to six million units of blood per year.

**1964** Plasmapheresis is introduced as a means of collecting plasma for fractionation.

**1965** Judith G. Pool and Angela E. Shannon report a method for producing Cryoprecipitated AHF for treatment of hemophilia.

**1967** Rh immune globulin is commercially introduced to prevent Rh disease in the newborns of Rh-negative women.

**1969** S. Murphy and F. Gardner demonstrate the feasibility of storing Platelets at room temperature, revolutionizing platelet transfusion therapy.

**1970** Blood banks move toward an all-volunteer blood donor system.

**1971** Hepatitis B surface antigen (HBsAg) testing of donated blood begins.

**1972** Apheresis is used to extract one cellular component, returning the rest of the blood to the donor.

**1979** A new anticoagulant preservative, CPDA-1, extends the shelf life of whole blood and red blood cells to 35 days, increasing the blood supply and facilitating resource sharing among blood banks.

**Early 1980s** With the growth of component therapy, products for coagulation disorders, and plasma exchange for the treatment of autoimmune disorders, hospital and community blood banks enter the era of transfusion medicine, in which doctors trained specifically in blood transfusion actively participate in patient care.

**1981** First Acquired Immune Deficiency Syndrome (AIDS) case reported.

**1983** Additive solutions extend the shelf life of red blood cells to 42 days.

**1984** Human Immunodeficiency Virus (HIV) identified as cause of AIDS

**1985** The first blood-screening test to detect HIV is licensed and quickly implemented by blood banks to protect the blood supply.

**1987** Two tests that screen for indirect evidence of hepatitis are developed and implemented, hepatitis B core antibody (anti-HBc) and the alanine aminotransferase test (ALT).

**1989** Human-T-Lymphotropic-Virus-I-antibody (anti-HTLV-I) testing of donated blood begins.

**1990** Introduction of first specific test for hepatitis C, the major cause of “non-A, non-B” hepatitis.

**1992** Testing of donor blood for HIV-1 and HIV-2 antibodies (anti-HIV-1 and anti-HIV-2) is implemented.

**1996** HIV p24 antigen testing of donated blood begins. Although the test does not completely close the HIV window, it shortens the window period.

**1997** U.S. Government issues two reports suggesting ways to improve blood safety, including regulatory reform.

National Blood Data Resource Center founded by AABB to collect, analyze and distribute data on all aspects of blood banking and transfusion medicine.

**1998** HCV lookback campaign — a public health effort to alert anyone who may have been exposed to the hepatitis C virus (HCV) through blood transfusions before July 1992 so they can receive medical counseling and treatment if needed.

**1999** Blood community begins implementation of Nucleic Acid Amplification Testing (NAT) under the FDA’s Investigational New Drug (IND) application process. NAT employs a testing technology that directly detects the genetic materials of viruses like HCV and HIV.

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