



**America's Blood
Centers**

It's About Life!

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**Statement before the TSE Advisory Committee on October 25, 2001
Anticipated Implementation of New Donor Deferral Policies**

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America's Blood Centers (ABC) is a national network of locally-controlled, non-profit community blood centers that collect half of the U.S. blood supply from volunteer donors. Collectively, we operate in 45 states and serve more than half of the nation's 6,000 hospitals. America's Blood Centers' total blood collections exceeded 6.7 million pints in the year 2000. America's Blood Centers thanks the FDA for the opportunity to participate in this public meeting.

On June 24, 2001, exactly four months ago, America's Blood Centers expressed before this Committee its concerns about the impact that donor deferral policies designed to address the theoretical risk of transmission of vCJD by transfusion of blood and blood products could have on an already limited blood supply. At the end of August, FDA issued its Draft Guidance recommending that individuals who lived 3 months or more in the United Kingdom and 5 years or more in the remainder of Europe be deferred from donating blood. FDA also recommended implementation of the expanded U.K. deferral policy in May 2002 and the pan-European deferral policy in October 2002. It has been estimated that these measures will reduce the donor base by as much as 5%.

ABC Comments on the Draft Guidance

ABC is submitting comments on the draft guidance. These comments address operational issues and do not alter the spirit of the guidance. The most important issues raised in the comments are the following:

- a) We asked that CBER eliminate recommendations to retrieve/quarantine/destroy all in-date products from donors with classical CJD because the transmission of CJD by blood and blood products is unlikely.
- b) We urged CBER to modify the proposed donor questions to assure simplicity, clarity and better donor comprehension.
- c) Finally, expressing major concerns about the complexity of two implementation dates, ABC asked that the guidance be implemented on a single date: October 31, 2002. A single implementation date in October 2002 would ensure that education for donors and blood center staff, training, literature, donor registration cards, and standard operating procedures would not have to be revised twice within a short period of time.

Position of ABC Member Centers regarding the FDA Draft Guidance

ABC member centers strongly believe that FDA made a diligent effort to balance safety and availability. Seventy three of the 74 member centers based in the United States plan to implement the FDA recommendations. Only one ABC member center plans to follow the Red Cross deferral strategy. Over 99% of the almost 7 million ABC collections will be performed according to the FDA-recommended criteria. ABC members want to reaffirm their support of FDA as the agency responsible for setting national blood safety guidelines. We strongly disagree with the more restrictive approach adopted by the American Red Cross because it may reduce the donor base by 8-9% without the benefit of additional protection. Both the FDA algorithm and the ARC algorithm achieve statistically identical protection from theoretical risk. The difference—and it is an important difference—is in the donor loss.

Tuesday, September 11, 2001

As we prepared ourselves for the potential of major blood shortages associated with the precautionary deferrals, our lives changed. Less than an hour after three airplanes hijacked by terrorists crashed into the World Trade Center in New York City and the Pentagon in Arlington, Virginia, thousands of Americans donated blood in anticipation of the needs of survivors. Blood centers soon were overwhelmed by the public response. By late Wednesday, blood centers' refrigerators were full, their staff exhausted, and their hospitals supplied with all their needs for days to come.

Within 24 hours of the attack, concerns about the availability of blood and blood products turned into concerns about excess collections, outdates, and potential shortages in the weeks ahead because many donors scheduled to give in the coming weeks had responded to the current crisis. Tragically, the need for blood was miniscule compared with the enormity of the attack. The New York Blood Center, a member of America's Blood Centers that provides most of the blood used in Greater New York City, distributed only 600 additional units of red blood cells in the 24 hours that followed the attack or an increase of 20% over their usual daily distribution. Ultimately, more than a quarter of a million people (259,714) donated blood to ABC centers from Tuesday, September 11 through Sunday, September 16. Overall, this represents nearly 3 times more blood than these centers would have collected in the same timeframe. As a group ABC members collected a ten-day supply of blood in only four days.

ABC has provided the Committee and the audience with reprints of a Commentary published in the October issue of the journal *Transfusion*. It summarizes our activities in the weeks following the terrorist attack. ABC worked closely with governmental agencies. FDA officials called us within hours of the attack to ask what was required to maintain an uninterrupted blood supply. The Armed Services Blood Program Office (ASBPO) of the Department of Defense was in continuous contact to offer assistance.

On Friday, September 14, the Assistant Secretary for Health convened a meeting with officials from ABC, the American Association of Blood Banks, the American Red Cross and government branches involved in the emergency, to evaluate the status of the blood supply and to provide the American public with a unified message about blood donations. We all agreed that the blood supply was sufficient to meet all anticipated short-term needs, and that the nation's focus must change to assure the long-term needs over the ensuing months. Unfortunately, later that day, ARC, rejecting what we thought was consensus, continued to issue calls for blood donations, promising that excess blood would be stored in a frozen blood reserve.

vCJD Deferrals and the Future

Blood services in the United States have changed with a single devastating event. We knew that the American population is willing to donate blood in a moment of national crisis. We saw it with the earthquake in San Francisco, the Gulf War, the Oklahoma City bombing and now the terrorist attack. We have documented that there is a strategic blood donor reserve, ready to be mobilized in times of extraordinary need. What we don't know is whether we can sustain such a response as the urgency decreases, but demand for blood increases. Our past experience led us to conclude that only a small portion of individuals donating during catastrophic events become regular donors.

ABC members do not believe that frozen blood is an effective solution. Frozen blood is extremely valuable for the maintenance of small rare blood repositories for patients with rare red cell phenotypes like patients with sickle cell disease and thalassemia. The process is too slow and cumbersome for management of large inventories in national emergencies. ABC agrees with Colonel Fitzpatrick from ASBPO: the best place to store blood is in the donor.

ABC members are working actively to transform today's good will and motivation to donate blood into a sustainable, continuous contribution to the lives of patients in need. We are investing in extensive market research to learn how these individuals can be persuaded to donate more often. We will launch a major Member Donation Initiative in a few weeks and continue it through the introduction of the vCJD deferrals to assure that hospitals and patients served by ABC centers have an adequate blood supply. We will also contribute to HHS efforts in data collection for monitoring the adequacy of the blood supply. Our initial monitoring system will be implemented in the next two weeks.

Thank you very much for the opportunity to present our point of view.

America's Blood Centers and the gift relationship

On September 11, less than an hour after three airplanes hijacked by terrorists crashed into the World Trade Center in New York City and the Pentagon in Arlington, Virginia, thousands of Americans donated blood in anticipation of the needs of survivors of this heinous crime. In the following days, overwhelmed by shock and grief, Americans continued to line up at the nation's blood centers wanting to give the "gift of life."

Thirty years ago, British sociologist Richard Titmuss wrote the definitive treatise¹ on why people give blood (and organs and tissue). He described how strangers overcome difficulties and pain to reach out to others and make the most personal and intimate gift of blood. Titmuss characterized this "gift relationship" as the very definition of altruism. On Tuesday, September 11, 2001, the world was reminded that Titmuss was right—blood donation is the ultimate gift relationship.

Blood centers soon were overwhelmed by the public response. People waited hours to donate and cried if they were deferred. By late Wednesday, September 12, blood centers' refrigerators were full, their staffs exhausted, and their hospitals supplied with all the blood needed for days to come. Logistic difficulties in New York and Washington were overcome quickly with the help of police, fire departments, the Department of Defense (DOD), the National Guard, and volunteer organizations.

The response by blood center staff members was overwhelming. They worked extended hours and were reassigned from every department to sustain blood collection, component preparation, and component distribution. Volunteers comforted donors, adding a human touch to the juice and cookies.

On Thursday, however, concerns about the availability of blood and blood components turned into concerns about excess collections, outdates, and potential shortages in the weeks ahead, because many donors scheduled to give in the coming weeks had responded to the current crisis.

Tragically, most of the victims were killed immediately or soon succumbed to their injuries. The need for blood was minuscule in comparison to the enormity of the attack. The New York Blood Center (NYBC), a member of America's Blood Centers (ABC) that provides most of the blood used in Greater New York City, distributed only 600 additional units

of RBCs in the 24 hours that followed the attack, a 20-percent increase over their usual daily distribution.

ABC and its members issued press releases asking people to call for appointments and to space their donations in the weeks ahead, so as to sustain the availability of blood and blood components to all patients in need.

Ultimately, according to a survey of ABC members conducted during the week after the terrorist attacks, more than a quarter-million people (259,714) donated blood to ABC sites from Tuesday, September 11, through Sunday, September 16. Overall, this represents nearly three times as much blood as ABC normally would have collected in the same time frame. As a group, ABC member institutions collected a 10-day supply of blood in only 4 days. Twenty-one centers (about one-third of the ABC members) shipped a total of 4,705 blood components to New York, New Jersey, or the District of Columbia during this period.

ABC

ABC is the national network of 75 locally controlled, community-based blood centers. Members are licensed by the FDA and are governed by community-based boards of directors. Together, ABC member institutions (Table 1) collect nearly 7 million donations or about half of the United States blood supply. They are located in 43 of the 50 states, including Hawaii and Alaska, and they provide blood services to hospitals in 45 states. Canada's HémaQuébec is our newest member, as ABC spreads its message of success through community control around the world. ABC's Washington office has experts in communications, government relations, regulatory affairs, transfusion medicine, and science and technology. ABC also has a \$90 million group services program that includes group purchasing and technical support. Members meet twice a year to share experiences and best practices. At the meetings, each of the 75 members has an equal vote, regardless of center size or location. National activities and organizational positions are coordinated through standing committees and carried out by the office staff. Elected officers guide the staff. An elected board of directors oversees the organization throughout the year. ABC staff and members are present at every public hearing held by federal agencies with interest or authority over transfusion medicine and its associated disciplines.

ABC maintains a website, www.americasblood.org, and publishes the widely read and respected weekly *ABC News-*

TRANSFUSION 2001;41:1181-1184.

COMMENTARY

TABLE 1. Members of ABC and the states where they operate

Center	State	Center	State
Blood and Tissue Center of Central Texas	Texas	Houchin Blood Services	California
Blood Assurance	Tennessee	Hoxworth Blood Center	Kentucky, Ohio
Blood Bank of Alaska	Alaska	Indiana Blood Center	Indiana
Blood Bank of Delaware/Eastern Shore	Delaware, Maryland	Inland Northwest Blood Center	Idaho, Washington
Blood Bank of Hawaii	Hawaii	Institute for Transfusion Medicine	Illinois, Pennsylvania, West Virginia
Blood Bank of the Redwoods	California	Lane Memorial Blood Bank	Oregon
Blood Center of Central Iowa	Iowa	Lifeflood/Mid-South Regional Blood Center	Arkansas, Tennessee
Blood Center of New Jersey	New Jersey	Lifeline/West Tennessee Regional Blood Center	Tennessee
Blood Center of Southeastern Wisconsin	Wisconsin	LifeShare	Ohio
Blood Centers of the Pacific Blood Systems	California	LifeShare Blood Centers	Louisiana, Texas
	Alabama, Arizona, Arkansas, California, Colorado, Louisiana, Mississippi, Montana, Nevada, New Mexico, North Dakota, South Dakota, Texas, Wyoming	LifeSouth Community Blood Centers	Alabama, Florida, Georgia
Bonfils Blood Center	Colorado	Manatee Community Blood Center	Florida
Carter BloodCare	Texas	Marathon County Blood Bank	Wisconsin
Cascade Regional Blood Services	Washington	Memorial Blood Centers of Minnesota	Minnesota, Wisconsin
Central California Blood Center	California	Michigan Community Blood Centers	Michigan
Central Florida Blood Bank	Florida	Miller Memorial Blood Center	New Jersey, Pennsylvania
Central Illinois Community Blood Bank	Illinois	Mississippi Blood Services	Mississippi
Central Jersey Blood Center	New Jersey	Mississippi Valley Regional Blood Center	Illinois, Iowa
Central Kentucky Blood Center	Kentucky	New York Blood Center	New Jersey, New York
Central Pennsylvania Blood Bank	Pennsylvania	Northern California Community Blood Bank	California
Coffee Memorial Blood Center	Texas	Northern Illinois Blood Bank	Illinois
Community Blood Bank of Northwest Pennsylvania	Pennsylvania	Northwest Florida Blood Center	Florida
Community Blood Bank of the Lancaster County Medical Society	Nebraska	Nueces County Medical Society Community Blood Center	Texas
Community Blood Center (Dayton)	Ohio	Oklahoma Blood Institute	Oklahoma
Community Blood Center (Appleton)	Wisconsin	Puget Sound Blood Center	Washington
Community Blood Center of Greater Kansas City	Arkansas, Kansas, Missouri	Rhode Island Blood Center	Rhode Island
Community Blood Center of the Ozarks	Missouri	Sacramento Medical Foundation Blood Centers	California
Community Blood Centers of South Florida	Florida	San Diego Blood Bank	California
Community Blood Services	New Jersey	Shepard Community Blood Center	Georgia, South Carolina
Community Blood Services of Illinois	Illinois	Siouxland Community Blood Bank	Iowa
Delta Blood Bank	California	South Texas Blood and Tissue Center	Texas
Florida Blood Services	Florida	Southeastern Community Blood Center	Florida, Georgia
Florida Georgia Blood Alliance	Florida, Georgia	Stewart Regional Blood Center	Texas
Gulf Coast Regional Blood Center	Texas	Suncoast Communities Blood Bank	Florida
Heartland Blood Centers	Illinois, Indiana	Texoma Regional Blood Center	Texas
HémaQuébec	Quebec, Canada	The Blood Center (New Orleans)	Louisiana
		The Blood Connection	South Carolina
		Virginia Blood Services	Virginia
		Western Kentucky Regional Blood Center	Kentucky

letter, with extensive coverage of events and of administrative, scientific, and regulatory issues relevant to transfusion medicine.

Most communications between ABC and its members are through the Internet, which proved critical during the crisis of the terrorist attacks, when telephone communications to New York City were ineffective early on. The ABC national office was immediately evacuated on Tuesday because of its proximity to the White House, but operations were run effectively from remote sites.

BLOOD FOR NEW YORK CITY

ABC members responded immediately with offers to provide blood to New York City through the NYBC. Although these efforts were hindered by air traffic shutdowns and the closing of roads and bridges into New York City, many blood centers found creative ways to send blood directly to their sister center, to blood centers in nearby New Jersey, and to the Washington, DC, area. Refrigerated trucks drove hours to reach the New Jersey branch of the NYBC. Volunteer pilot

groups, medical courier services, and military airplanes received permission to fly on Wednesday. Early on Tuesday, a crew of firemen—their truck carrying emergency supplies—stopped off at an ABC member center in the Midwest to pick up blood before heading east on a 2-day journey to New York.

The NYBC had substantial difficulties with e-mail and telephone systems when its Internet provider ceased operating after the World Trade Center collapsed. Phone lines were overwhelmed by potential blood donors. Blood center staff members used cellular phones, beepers, police escorts, and couriers to maintain blood services to New York City's hospitals. Internet services were reestablished only 3 days later.

LOGISTICS OF TESTING: CENTRALIZED LABS, NAT

The interruption of air traffic created a major obstacle for the many ABC members that ship donor samples for laboratory screening to other centers. This was particularly worrisome for specimens used for NAT for HCV and HIV, be-

cause of the constraints on the length of time between collection and testing of (short-lived) components. Members found alternative shipping methods, including over-the-road transportation involving hundreds of miles and thousands of specimens. In the end, it was unnecessary to transfuse any blood without complete testing.

Another concern was the availability of reagents and supplies for collections and testing. During the first 3 days after the attack, collections were twice or three times as high as normal. Manufacturers of testing reagents and collection bags managed increased deliveries by truck. To our knowledge, no donations were lost for lack of supplies.

INTERACTIONS WITH GOVERNMENTAL AGENCIES

ABC worked closely with governmental agencies. FDA officials called ABC within hours of the attack to ask what was required to maintain an uninterrupted blood supply, not just in New York City and Washington, but across the nation, where the need for blood did not diminish during the immediate emergency. Appropriate guidance for emergency collections was speedily posted on the FDA Internet site.

The Armed Services Blood Program Office of the DOD was in continuous contact with the ABC national office to discuss blood supplies, possible donations by military personnel, and logistical assistance. ABC maintained constant communication with the Department of Health and Human Services (HHS), through the Office of the Assistant Secretary for Health. On Friday, September 14, the Assistant Secretary convened a meeting in Washington with officials from ABC, the AABB, the American Red Cross (ARC), and government agencies involved in the emergency, to evaluate the status of the blood supply. At the meeting were representatives for HHS Secretary Tommy Thompson as well as representatives from the DOD, the CDC, the NIH, and the Office of Emergency Preparedness. Secretary Thompson issued an authoritative message, fully supported by ABC, that the blood supply was sufficient to meet all anticipated short-term needs, and that the nation's focus must change to ensure that long-term needs would be met over the ensuing months. HHS continues to monitor supply at the hospital level on a daily basis.

PUBLIC MESSAGES

The media provided superb coverage about the need for blood donations and later about the need to schedule donations in the coming weeks and months to preserve a robust supply. ABC members expanded and reinforced this message through their long-standing and collegial contacts with local and regional media. The national office coordinated interactions with the national media and issuance of press releases. Member centers reached rapid consensus on the contents of ABC press releases in advance. Despite the di-

versity of member centers, we spoke, and continue to speak, with a single voice during this crisis.

ABC members were provided with electronic access to relevant articles and broadcast messages being published around the country, to maintain a high level of awareness of hour-to-hour developments that might affect their critical role as stewards of the nation's blood supply.

EXPRESSIONS OF SYMPATHY FROM AROUND THE WORLD

ABC received messages of support, condolences, and offers of blood from many of our friends and partners around the world, including those in Australia, Brazil, Peru, Canada, Singapore, Mexico, Kyrgyzstan, Pakistan, France, Portugal, and Holland.

THE FUTURE

Weeks before the attack, the US transfusion community was preparing for major blood shortages associated with recommendations for the deferral of persons who lived for 3 months in the United Kingdom or for 5 years or more in the remainder of Europe, as a precautionary measure to address the theoretical possibility that vCJD is transmitted by transfusion. The FDA has recommended implementation of the expanded UK deferral policy in May 2002 and the pan-European deferral policy in October 2002. It has been estimated that these measures will reduce the donor base by as much as 5 percent. The ARC has chosen to adopt a more restrictive approach that may reduce the donor base by 8 to 9 percent. The FDA algorithm and the ARC algorithm achieve the same degree of protection from theoretical risk, about 90 percent. The difference is the donor loss. ABC members will adopt the recommendation of FDA, the organization charged with setting national blood safety guidelines.

Blood services in the United States have changed with a single devastating event. As we suspected, the population is willing to donate in a moment of national crisis. We have documented that there is a strategic blood donor reserve, ready to be mobilized in times of extraordinary need. What we don't know is whether we can sustain such a response as the urgency decreases, but the demand for blood increases. ABC members are working actively to transform today's good will and motivation to donate blood into a sustainable, continuous contribution to the lives of patients in need. We will launch a major Member Donation Initiative in a few weeks and continue it through the introduction of the vCJD deferrals to ensure that ABC sites have an adequate blood supply.

The tragedy of September 11 validates the ABC model for community-controlled blood centers collaborating under a national umbrella to effectively provide for the blood needs of patients. While we learned that we can improve our coordination and preparedness for disasters, we also learned that our greatest resources—our donors and our staff—are there when we need them.

COMMENTARY

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REFERENCE

1. Titmuss RM. The gift relationship: from human blood to social policy. London: Allen and Unwin, 1970.