

CRITICAL NATIONAL NEED IDEAS

Title: Strengthening the National Blood Supply

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One of our Nation's most valuable natural resources to be conserved is: BLOOD. To maintain the health of a Nation, the blood supply should be safe and adequate. The following areas should be considered to meet this challenge:

- 1. Develop a method to utilize the blood units that are currently discarded because they are outdated – this is a low-risk, high reward area;**
- 2. All types of deferrals:**
 - a. unacceptable hematological parameters - low risk, high reward**
 - b. the Gay Men sector as well as AIDS/HIV individuals – high risk, high reward**
 - c. Travelers who have visited countries that are known to have certain communicable diseases – high risk, high reward**
- 3. Motivating, encouraging qualified citizens to participate actively in donating blood - low risk, high reward**

Outdated Blood Units:

The U.S. Department of Health and Human Services recently reported that more than 1 million donated blood units were discarded in 2006 solely because they were outdated and, in the December 2009 issue of TRANSFUSION, the American Red Cross reported that between the years 2001 and 2006, on the average, 7 million units of blood were collected each year. Why can't outdated blood be utilized?

The terrorist attack of 9/11 showed the interest of the American public to rise to the occasion. During a short period of time, every blood collecting agency was overwhelmed with the response. However, because of the nature of this tragic situation, the need for blood was minimal. Over the entire country, storage of the blood units became a major problem. The result was that tens of thousands of unit of outdated units had to be discarded. Unfortunately, most of these units were burned.

Since it is unusual that many blood units become outdated simultaneously under normal conditions, an individualized freeze-dried blood service could salvage each unit collected. This would eliminate blood unit mixing and maintain the integrity of the whole blood unit concept.

DEFERRALS

Being deferred by a blood collecting unit has a defeating personal effect. It is documented that a large percentage of deferrals never return to donate blood again. Often a deferral can result because of hematological parameter. As an example, iron deficiency, low hematocrit level, and insufficient hemoglobin. These hematological levels have a range of values, but on most cases, the blood will not be acceptable for direct transfusion. These donors, when deferred, usually do not return to donate blood again. They are LOST. Using an individualized freeze-dried process, these hematological parameters can be normalized to those of outdated blood. They should not be discarded. This could turn into a low-risk, high reward situation.

The situation is unique with HIV/AIDS. The following headline appeared, “**GAY MEN STILL BANNED FROM DONATING BLOOD,**” in the Dayton Daily News, May 2007, p.A27.

“The FDA reiterates its policy on its website Wednesday: Red Cross calls this policy ‘unwarranted.’” (Associated Press).

WASHINGTON – “Gay men remain banned for life from donating blood, the government said Wednesday, leaving in place – for now – a 1983 prohibition to prevent the spread of HIV through transfusions,

The Food and Drug Administration reiterated its long-standing policy on the website Wednesday, more than a year after the Red Cross and two other blood groups criticized as ‘medically and scientifically unwarranted.’

‘I am disappointed, I must confess,’ said Dr. Celso Bianco, executive vice president of the America’s Blood Centers, whose members provide nearly half of the Nation’s blood supply.

Before giving blood, all men are asked if they have had sex, even once, with another man since 1977. Those who say they have are permanently banned from donating. The FDA said these men are at increased risk of infection of HIV.

In March 2006, the Red Cross, the International Blood Association, AABB and the America’s Blood Centers proposed replacing the lifetime ban with a one year deferral following male – to – male contact. New and improved tests, which can detect HIV positive donors within just 10-21 days of infection, make the lifetime ban unnecessary, the blood groups told the FDA. In a paper posted Wednesday, the FDA said it would change its policy given data that show doing so wouldn’t pose

‘significant and preventable’ risk to the blood recipients. Anyone who has used intravenous drugs or has been paid for sex also is permanently barred from donating.”

The restrictions imposed in this article exclude a potentially large group of individuals. Since it is considered that the HIV/AIDS virus is on the red cell membrane, research and development are needed to remove the attached virus from the membrane and recover the hemoglobin from the interior of the red cell. This is a high risk and high reward process. More importantly, the process would restore the dignity and usefulness of the gay community to society.

It is not commonly known that traveling to certain countries defers people from donating blood. Between 2000 and 2006, the American Red Cross reported 542,048 blood deferrals due to malaria alone, Traveling to any country where malaria is a common disease excludes blood donation. Each year about 90,000 travelers to Mexico are deferred because of malaria. Practically all of our service personnel serving overseas will also be deferred because of malaria. Since the malaria parasite enters the red cell, it is possible to reverse the process and render the red cell malaria free...suitable for an individualized freeze-dried process.

MOTIVATION:

In the United States, only about 5% of all eligible people donate blood on a regular basis. This certainly may be another source of the current blood donation crisis. The American Association Blood Banks (AABB) is quite aware of this situation. In the August issue of AABB News, they cite many new and novel approaches to recruit more donors and recall previous donors. With the proper situation, donors do come forward. This was shown in the 911 incident. Awards including T-shirts, flashlights, dinner coupons and free gasoline cards appear to have a one-time appeal. We believe that the motto, “Every unit of blood collected, every unit of blood used,” would be a realistic goal for this individualized freeze=dried blood service. This approach would also be important to our military personnel in distant battlefields.

This concept is illustrated in the attached diagram.

FUNDING:

With the current economic situation, it is proposed that a stimulus approach be used for this Critical National Need project. To achieve the goals to Strengthen the National Blood Supply as well as jump-start the economy, the efforts of small businesses should be given serious consideration. Many problems sited in this White Paper could be achieved within three years. The goal that is proposed is a CONSORTIUM of small businesses, all working together with a common goal. Contrary to the usual practice, it is suggested that all interested groups should be funded at some level. This concept would bring in ideas which are never considered when a proposal is turned down.

In order to keep current on all aspects of the research, the CONSORTIUM of companies should meet three times a year in an open forum. Travel allowances should be included in the budgets to make these meetings possible. Funding should be \$15,000,000 for a three year period.

It has been a common practice to discard all blood units that are considered “outdated”. To date, very little if any effort has been given to solving this problem. Just refer to the “lost samples” of the 911 crisis. This was a shock to the donors who wanted to alleviate a “crisis.” However, no process was available to save tens of thousands of blood units. Instead, they were burned.

In addition, since the ban on blood donations from Gay men, as well as restrictions on travelers to certain countries, research and development funds are limited or non-existent. These are high risk and high reward areas.

These problems have been put “on the back burner” by most funding agencies. It appears that the TIP program is most appropriate for funding in this Area of Critical National Need.