



**STATEMENT OF  
AMERICAN ASSOCIATION OF BLOOD BANKS  
AMERICA'S BLOOD CENTERS  
AMERICAN RED CROSS**

**BEFORE THE BLOOD PRODUCTS ADVISORY COMMITTEE**

**March 13, 2003**

**West Nile Virus Testing**

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The U.S. blood banking organizations have taken significant steps in response to the 2002 mosquito-borne West Nile Virus epidemic. The organizations have worked with CDC and FDA to conduct the case investigations that established that WNV was transfusion-transmitted. As this new scientific knowledge was acquired, the organizations communicated to both their membership and to the general public that WNV could be transmitted by transfusion. The communications indicated that the risk was small but real and that the benefits of necessary transfusions outweighed the small risks due to WNV.

In 2002, several actions were taken to minimize the risk of transfusion-transmitted WNV. An increased emphasis was put on the need to obtain post-donation information from donors and to retrieve and quarantine units that were donated by persons with a high index of suspicion of WNV infection. At the end of the 2002 mosquito transmission season, a voluntary market withdrawal of frozen plasma products intended for transfusion was initiated for components derived from collections during the WNV transmission season in states with human cases of WNV. This action resulted in the withdrawal of over 150,000 such components. At the November 6 FDA WNV workshop, the blood organizations indicated their full support for the development of WNV screening tests that would be put into place for the 2003 transmission season.

Currently, the blood organizations are planning for the introduction of such testing by the target date of July 1, 2003. Planning includes participation in preparing and submitting INDs to FDA, modification of laboratory space for installation and validation of additional equipment where

needed, staff training, and revisions of blood center computer systems. The blood organizations are fully committed to implementing such testing as soon as reagents and systems are available.

Although several other actions are under consideration by FDA and others to minimize WNV transfusion risk in 2003, the blood organizations believe that blood donor screening by minipool NAT will be the most significant intervention to decrease WNV transfusion risk.

A review of initial data from WNV transfusion-transmission cases revealed that, in retrospect, a few donors reported symptoms compatible with WNV infection days to weeks prior to infection. However, the most current CDC data indicated that only 3 of 14 implicated donors reported pre-donation symptoms and in at least one case, these symptoms were much earlier than the donation, suggesting that these non-specific symptoms might have been coincidental with another condition and not due to WNV. The CDC data also indicates that while fever was reported as the most consistent symptom for implicated donors, 3.7 % of non-implicated donors reported fever three weeks before to three weeks after donation. Based on the available data, it appears that the sensitivity and specificity of additional pre-donation donor questioning would be low. It would be expected to be even lower once WNV MP-NAT is in place. Furthermore, it is anticipated that questioning about fever or other symptoms in the 7-14 days before donation will be non-specific and result in deferral of large numbers of donors. The committee is reminded that this was found to be the case when a new question concerning symptoms of diarrheal illness to prevent *Yersinia enterocolitica* infection was piloted a decade ago. Actions that decrease the available blood supply should be taken with extreme caution since blood shortages are frequent. Thus, the blood organizations are concerned about the potential impact of adding an additional donor-screening question. We recommend that appropriate information about the impact on blood availability be obtained before making a decision on this measure. With regard to post-donation information, the blood organizations agree with the need to emphasize that donors report such information promptly to blood centers. The current FDA guidance on this issue should remain unchanged since the guidance is consistent with procedures currently used by blood centers for other post-donation information and is based upon medical director evaluation of the information and a decision on appropriate action.

Blood centers will continue to conduct investigations of possible transfusion-transmitted WNV cases, as this will be important to evaluate the efficacy of donor screening. The blood organizations will work with the CDC and their local state health departments to coordinate these investigations.

Blood centers are actively stockpiling FFP and other frozen plasma products in anticipation of the onset of WNV clinical cases in 2003. In accordance with opinions expressed by CDC scientists, the current plan is to stockpile such components in a specific geographic area until the first human WNV case is reported in that area. These components would be available for use throughout the country and would be used preferentially in place of frozen plasma products collected in regions with WNV clinical cases prior to the onset of WNV donor screening. This frozen stockpile of units should be considered safe for transfusion and should not require retrospective WNV testing after such screening is introduced.

While it is possible to put such a program in place for frozen components, it is not possible to duplicate this program for liquid components with limited shelf life. If mosquito-borne WNV human cases occur in a geographic region prior to implementation of WNV donor screening, it would not be possible to cease blood collections in that region. The blood supply is too fragile to implement such a strategy. Lack of available blood would be a greater risk than the very small risk of WNV transfusion-transmission that would exist at the onset of the mosquito transmission season, when very few mosquito-borne cases are expected. This point was made repeatedly and eloquently by FDA during last year's epidemic. The blood organizations will encourage their members to work with local and state health departments to ascertain whether a significant early epidemic is occurring in a specific county or region.

The blood organizations are committed to minimizing the risk of WNV transfusion transmission in 2003 while maintaining an adequate blood supply. We believe that both tasks can be accomplished if testing is introduced at or near the July 1 target date. If, however, such testing is significantly delayed and if there is an unexpectedly large early season WNV outbreak, the blood organizations will work with FDA to reconsider appropriate policies.

America's Blood Centers (ABC) is an international network of community-based blood centers that collects nearly half of the U.S. blood supply and about 25% of the Canadian blood supply. The largest provider of blood components and services, America's Blood Centers' members are located in 45 states, serving more than 125 million people at 450 blood donation sites. For 40 years, America's Blood Centers' members have been committed to serving the needs of their local communities by saving lives through volunteer blood donation.

The American Red Cross (ARC) is an independent, non-profit organization dedicated to saving lives, easing suffering and restoring hope at home and around the world. The Red Cross, through its 36 Blood Services regions, supplies approximately half of the nation's blood for transfusion needs. Its primary focus is providing high quality blood and blood products to the patients who need them, but ARC is also a large supplier of human allograft tissue including heart valves, skin, bone and associated connective tissues. Additionally, the Red Cross is engaged in research and other efforts to support donation and processing of such human derived products as umbilical cord blood and bone marrow for use in treatment of malignancies and other serious diseases.

The American Association of Blood Banks (AABB) is the professional society for over 8,000 individuals involved in blood banking and transfusion medicine and represents approximately 2,000 institutional members, including blood collection centers, hospital-based blood banks, and transfusion services as they collect, process, distribute, and transfuse blood and blood components and hematopoietic stem cells. Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in this country. For over 50 years, the AABB's highest priority has been to maintain and enhance the safety and availability of the nation's blood supply.