Blood Centers *of the* Pacific

Update

Newsletter for Hospitals

June 2004

2004 West Nile Virus Blood Testing at BCP

Background

Nucleic Acid Testing (NAT) for West Nile Virus (WNV) has been performed at Blood Centers of the Pacific since July 1, 2003. The WNV test, currently in use under an Investigational New Drug study, is performed in minipools of 16 donors, similar to HIV and HCV NAT. Nationwide WNV testing during the 2003 epidemic has resulted in a significant increase in blood safety. Approximately 1,000 viremic donors were identified and transfusion of at least 1,500 WNV positive units was prevented. However, data from retrospective and prospective studies from 2003 indicate that minipool NAT may not detect the very low viral levels during early and late stages of WNV infection. Indeed, lookback studies have identified cases of WNV transmission resulting from transfusion of these low level viremic donations missed by minipool NAT.

Testing individual donations (IDT) for WNV would improve detection of infected donors compared to minipool testing. Unfortunately, IDT also yields many more false positive results, which leads to unnecessary donor deferrals in non-epidemic periods and regions. Furthermore, due to the complex nature of NAT testing, nationwide, year-long IDT NAT is currently not yet feasible operationally. The goal for the 2004 WNV season, therefore, has been to maximize blood safety given current operational constraints and an epidemic that rapidly changes temporally and geographically. A Task Force of key individuals at Blood Systems Laboratory and Blood Systems, Inc, with input from the FDA and CDC, was formed to develop the best strategy for WNV testing in the 2004 season. The Task Force established a consensus algorithm that has since been adopted by other major blood centers.

IDT NAT Algorithm

The key features of the algorithm are subregionalization of blood centers, continuous monitoring of reactive rates, subregion-specific conversion from minipool to IDT NAT as the WNV epidemic arrives, and reversion to minipool NAT as the epidemic wanes. This will focus finite testing capacity on areas with the highest WNV rates. Starting on June 7, 2004, Blood

have been divided into 1-5 distinct geographic zones, depending on donation volume. BCP comprises 3 zones: (1) Shasta Blood Center, (2) North Bay Center, and (3) Bay Area. Donor sample tubes are uniquely identified by zone and separately shipped to the testing lab. Reactive rates for each zone are continuously monitored at the testing laboratory.

On Trigger

IDT NAT will commence in a zone when one of the following criteria is met: (1) 2 Initial Reactives in a rolling 7-day period AND a minipool Initial Reactive rate of at least 1:1000; or (2) 3 Initial Reactives in 1 day.

Product retrieval is performed based on Initial Reactive results. Specialized sample tubes are used for WNV NAT so that donor samples can be stored at the testing lab and retrieved for retrospective testing. When a zone meets the On Trigger, retrospective IDT NAT will be done on all saved samples collected in that zone between the collection date of the On Trigger index samples and the date that IDT begins. Any positive donors identified during retrospective testing will be contacted for follow up, and recipient tracing will be performed as appropriate.

If the number of zones meeting the On Trigger exceeds testing capacity, then an Executive Task Force will be convened to prioritize testing. Blood centers that are prioritized to minipool NAT will be notified. These centers may decide to cease plasma production until capacity allows IDT NAT in order to minimize the risk of transfusing minipool NAT breakthrough viremic units.

Off Trigger

IDT NAT will stop and minipool NAT will resume in a zone when there are no IDT Initial Reactive in 7 consecutive days AND the IDT Initial Reactive rate is less than 1:1000.

There is no increase in cost to hospitals for IDT NAT testing during 2004.

As of the third week of June, 2004, WNV positive birds and mosquitoes are present in several counties in southern California, and human cases have been reported in Ohio, Arizona, New Mexico, and, recently, in southern California. Epidemiological studies have predicted significant numbers of human infections in California, Arizona, and New Mexico this season. BCP reminds physicians to notify the Blood Center of any cases of diagnosed WNV infection in a blood donor or recipient so that component retrieval can be performed.

We believe that the above WNV testing algorithm will improve safety for all transfusion recipients. Nevertheless, all patients and physicians should remember that the benefits of a medically indicated blood transfusion far outweigh the risks, and that an inadequate blood supply poses the greatest risk of all.

References

CDC website:
www.cdc.gov/ncidod/dvbid/westnile/index.htm

CDC Arbonet:
westnilemaps.usgs.gov

CA website:
www.westnile.ca.gov/maps.htm