

Monday, October 17th at 10:30 a.m.**AABB 2005****Oral Presentation****WEST NILE VIRUS RNA PERSISTENCE FOLLOWING SEROCONVERSION OF VIREMIC BLOOD DONORS: IMPLICATIONS FOR BLOOD SAFETY (S1-030B)**

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Background:

Screening donors for West Nile virus (WNV) RNA based on nucleic acid amplification technology (NAT) has led to detection of viremic donors who have been followed to define the time course of seroconversion (SC) and RNA clearance. Persistence of WNV RNA after SC has important implications for donor deferral policies and possible risk of transmission from units screened only by NAT.

Methods:

349 WNV confirmed viremic donors (230 in 2003, 119 in 2004) were offered enrollment into weekly follow-up for 4 weeks followed by monthly sampling; 291 enrolled (182 in 2003; 109 in 2004). Samples were routinely tested for RNA by single TMA (Gen-Probe/ Chiron) and for IgM and IgG antibodies (Focus). Persistence of sporadic, low-level RNA was investigated by performing 5 additional replicate (rep) TMAs (total 6-rep TMA) on 180 serial follow-up samples from 56 donors in 2003 and on 88 samples collected 40 days post-index for 69 donors in 2004. Window periods (WP) were derived using interval censored longitudinal regression analysis.

Results:

Based on 2003 follow-up cases, time from the index RNA+/IgM- donation to IgM SC was 3.4 days (95% CI for mean WP: 2.9, 4.0); time to IgG SC was 7.6 days (6.6, 8.6); time to TMA reversion by single TMA was 14.6 days (11.6, 17.7); and time to loss of detectable RNA by 6-rep TMA was 21.5 days (17.4, 25.5). Time from RNA reversion by single TMA to 6-rep TMA was 6.1 days (4.2, 8.0). The 99% inclusion bound for loss of RNA by 6-rep TMA was 38.7 days post-index (assuming normal distribution). One 2003 donor had RNA detected by 1 of 6 TMA reps at 49 days, while two 2004 donors had RNA detected on 1 of 6 TMA reps on days 40 and 62 and a third donor had detectable RNA (1-2 of 6 TMA reps) at 57, 83, and 104 days.

Conclusion:

Low-level WNV RNA is detectable by replicate TMA for a mean of 21 days following index donation. Statistical WP calculations indicate that 99% of cases are estimated to clear RNA by 6-rep TMA at 39 days, and follow-up studies indicated that 121 of 125 donors (97%) did so. The four outliers had RNA last detected at 40, 49, 62 and 104 days. Given the relative lengths of detectability windows (6.9 days for minipool NAT and 6.1 days for 6-rep vs. single TMA), and detection nationwide of at least 934 minipool NAT cases in 2003 and 2004, we estimate that in the past two years 825 low-level RNA+/seropositive units were donated ($934 \times 6.1/6.9$) resulting in the production of 1,196 (825×1.45) components that were likely transfused. Since there have been no reported cases of post-transfusion WNV infection from units with RNA that was undetectable by single rep NAT, these data suggest that very low-level WNV viremia in the presence of WNV antibody is not infectious