

Require West Nile Virus Seasonal Testing for All Donors

Ad Hoc Disease Transmission Advisory Committee

Purpose of Proposal

- Improve patient safety by reducing West Nile Virus (WNV) transmissions in transplant recipients.
 - Routine WNV NAT testing is not required by OPO's or living donor hospitals. This gap can lead to unintended donor-derived transmissions, sometime resulting in fatal outcomes
 - Most WNV carriers are asymptomatic – No approved treatments or vaccines are currently available
 - CDC requested DTAC consider seasonal WNV NAT testing requirements for living and deceased donors in alignment I with CDC and FDA recommendations
 - **A recent CDC investigation identified:**
 - 11 confirmed clusters of WNV transmissions
 - 87% (26/30) recipients infected
 - 77% (20/26) with encephalitis
 - 40% (8/20) with encephalitis died

Proposal

- Require seasonal WNV NAT testing for all potential living and deceased donors between **July 1 - Oct 31**
 - Timeframe aligns with the period of highest WNV activity in the U.S. during summer through fall months
 - Testing during this defined seasonal window has a higher pre-test probability than other seasons, reducing the likelihood of false positives and unnecessary organ non-use
 - Proposed seasonal testing requirement would **not** preclude OPOs and living donor hospitals from testing year-round

Proposal

- Require WNV testing by use of Nucleic Acid Test (NAT)
 - For living donors, NAT would have to be performed within seven days—or as close as possible—to the planned organ recovery date, with results available prior to organ recovery
 - For deceased donors, NAT results would be required to be available before organ implantation

Rationale

- **WNV Seasonal Testing (July 1 – Oct 31)**

- The virus is most active between the summer and fall months, making early detection through testing especially important during this period
- Testing during this defined seasonal window has a higher pre-test probability than other seasons, reducing the likelihood of false positives and unnecessary organ non-use

- **Nucleic Acid Testing**

- Licensed NAT assays are highly specific; therefore, the false positive rate of NAT testing is expected to be very low particularly if testing is performed during peak WNV activity

Member Actions

- Require OPOs to test all potential deceased donors between July 1 - October 31 for WNV using an FDA-licensed, approved, or cleared nucleic acid test (NAT).
 - WNV NAT test results must be available before organ implantation.
- Require living donor recovery hospitals to test all potential living donors with planned organ recovery between July 1 - October 31 for WNV using an FDA-licensed, approved, or cleared nucleic acid test (NAT), as close as possible, but within seven days prior to organ recovery.
 - WNV NAT test results must be available before organ recovery.

What do you think?

- Is the proposed requirement to have living donors tested for WNV within seven days, or as close as possible, to organ recovery an appropriate testing timeframe?

FAQs

- Why is the required testing window limited to July 1 – Oct 31?
- When will OPO's be required to enter WNV NAT test results into the OPTN computer system?
- Does entering WNV antibody test results instead of WNV NAT results meet the proposed policy requirement?
- Can OPOs perform WNV testing and enter WNV NAT test results outside of the required testing window?
- How will the OPTN computer system treat the WNV NAT response fields outside of the testing window (Nov 1 – June 30)?

Provide Feedback

Submit public comments on the OPTN website:

- August 27, 2025 – October 1, 2025
- **optn.transplant.hrsa.gov**

