

## **OPTN Operations and Safety Committee**

### **Meeting Summary**

**August 28, 2025**

**Conference Call**

**Kim Koontz, MPH, Chair**

**Steven Potter, MD, Vice Chair**

### **Introduction**

The OPTN Operations and Safety Committee (the Committee) met via WebEx teleconference on 08/28/2025 to discuss the following agenda items:

1. Welcome
2. Public Comment Presentation: *Require West Nile Virus Seasonal Testing for All Donors* Proposal (OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC))
3. Project Update: Re-evaluation of Deceased Donor Testing Requirements
4. Open Forum
5. Closing Remarks/Adjourn

The following is a summary of the Committee's discussions.

#### **1. Welcome**

The Chair welcomed the members. The Committee reviewed the agenda, dates for the open public comment period, the schedule for upcoming OPTN regional meetings, and updates on OPTN directives.

#### **2. Public Comment Presentation: *Require West Nile Virus Seasonal Testing for All Donors* Proposal (OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC))**

The Committee received a presentation on the public comment proposal *Require West Nile Virus Seasonal Testing for Donors*.

#### Presentation summary:

The purpose of the proposal is to improve patient safety by reducing West Nile Virus (WNV) transmissions in transplant recipients. Currently, organ procurement organizations (OPOs) and living donor hospitals are not required to routinely test donors for WNV. Most WNV carriers are asymptomatic, and there are no approved treatments or vaccines for WNV. There have been cases of unintended transmission to transplant recipients, which in severe cases led to death.

The proposal would require WNV nucleic acid testing (NAT) for all potential living and deceased donors between July 1 through October 31 each year to align with peak WNV activity in the United States during the summer and fall months. 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.

#### Summary of discussion:

No decisions were made. The Committee's feedback will be provided to DTAC.

A member asked the presenter for the estimated time of expected WNV NAT results, and if there will be policy to address re-testing if presumed a false positive. The presenter said that the turn-around time for testing is typically a few hours. The proposed policy does not address false positives, but a previous guidance document developed by the DTAC may assist members in handling any concerns for false positives. The presenter expected false positive rates to be low based on anecdotal conversations with OPO members currently performing WNV testing on deceased donors.

A member said their OPO has WNV NAT in-house testing, and their turnaround time is typically 5-6 hours so their OPO can accommodate the new policy, but the policy may impose a burden on OPOs who do not have these capabilities within their organization. The member asked if the policy would accommodate rapid donor cases, perhaps requiring the OPO to disclose if WNV testing has not yet resulted.

The presenter appreciated feedback regarding test turnaround times. The proposed policy does not address rapid donor cases, but the presenter offered to discuss that further with DTAC. Contractor staff noted that the system provides the option to report tests as pending. The member noted that the policy requires the test to be resulted prior to organ implantation which could still be a potential barrier. Machine perfusion can help to preserve organs while test results are pending but there are still time constraints.

The Chair agreed that in rush cases where there are time constraints from the donor family, there could be challenges getting the test results back in time. Kidneys could be placed on pumps, but it could be challenging to transplant a liver from those donors. The Chair asked if WNV impacts various organ systems differently. The presenter said that in terms of WNV transmission rates, there does not appear to be a predilection for any particular organ, so all recipients are at increased risk. The presenter said the committee's intent was to be cautious since there are not any treatments or vaccines available for WNV that could be used to mitigate the risks of transmission.

#### Next steps:

The Committee's feedback will be summarized and posted on the corresponding public comment page on the OPTN website.

### **3. Project Update: Re-evaluation of Deceased Donor Testing Requirements**

The Committee reviewed progress to date on the project to re-evaluate deceased donor testing requirements.

#### Presentation summary:

A co-chair of the Workgroup presented an overview of the project. The purpose of the project is to re-evaluate policies related to donor testing requirements to determine if any requirements are outdated, and to better understand processes related to donor testing to propose modifications to current policy. The Workgroup finalized their recommendations, which include changes to policy, updates to guidance, new data collection, and other system changes to support compliance with the policy. Outreach to organ-specific committees is ongoing. The data collection recommendations will be presented to the OPTN Data Advisory Committee, and the full proposal will be presented to the committee on an upcoming meeting.

#### Summary of discussion:

No decisions were made.
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There were no questions or comments.

Next steps:

The Committee will review the final recommendations from the Workgroup and the cross-committee feedback at an upcoming meeting.

**4. Open Forum**

There were no open forum requests for this meeting.

**5. Closing Remarks/Adjourn**

The Committee reviewed the dates for upcoming committee meetings and the public comment period. The Committee will receive updated meeting invitations with call information using a new meeting platform. Contractor staff will send out the meeting slides for reference.

**Upcoming Meetings**

- September 25, 2025 (Teleconference)
- October 23, 2025 (Teleconference)

## **Attendance**

- **Committee Members**
  - Kim Koontz, Chair
  - Amanda Bailey
  - Bridget Dewees
  - Anja DiCesaro
  - Kaitlyn Fitzgerald
  - Laura Huckestein
  - Annemarie Lucas
  - Megan Roberts
  - Norihisa Shigemura
  - Elizabeth Shipman
  - Jillian Wojtowicz
- **UNOS Staff**
  - Tory Boffo
  - Betsy Gans
  - Carlos Martinez
  - Carly Rhyne
  - Kaitlin Swanner
  - Niyati Upadhyay
  - Joann White
- **Other attendees**
  - Stephanie Pouch