

OPTN Ad Hoc Disease Transmission Advisory Committee

Meeting Summary

February 7, 2023

Conference Call

Lara Danziger-Isakov, MD, MPH, Chair

Stephanie Pouch, MD, MS, Vice Chair

Introduction

The Ad Hoc Disease Transmission Advisory Committee met via Citrix GoToMeeting teleconference on 2/07/2023 to discuss the following agenda items:

1. Welcome and agenda
2. VOTE: SARS-CoV-2 Summary of Evidence and Mpox Summary of Evidence Revisions
3. DTAC Case Data: West Nile Virus
4. West Nile Virus Screening
5. West Nile Virus Guidance vs. Policy
6. Closing Remarks and Adjourn

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

1. Welcome and agenda

The Chair welcomed Committee members. Staff presented an overview of the meeting agenda.

Summary of discussion:

There was no further discussion by the Committee.

2. VOTE: SARS-CoV-2 Summary of Evidence and Mpox Summary of Evidence Revisions

The Committee voted on revisions to the [Summary of Current Evidence and Information–Monkeypox in Donor Screening and Transplantation](#) that included:

- Changed Monkeypox to Mpox throughout
- Updated case numbers to show decline in cases
 - Added vaccine effectiveness
- Added a recent study that examines sample collection from multiple body sites

The Committee also voted on revisions to the [Summary of Current Evidence and Information– Donor SARS-CoV-2 Testing & Organ Recovery from Donors with a History of COVID-19](#) that included:

- Added importance of still screening lung donors
- Added Omicron subvariant XBB information
- Added success of Require Lower Respiratory SARS-CoV-2 Testing for Lung Donors Emergency Policy
- Simplified the 90-day suggestion of reinfection

- May not be pertinent with the variety of variants emerging
- Updated the considerations for living donor surgery as there is newer data that suggests the risk isn't as severe

Summary of discussion:

The Committee unanimously approved sending the documents to the OPTN Executive Committee for approval. A committee member commented that an additional revision to the SARS-CoV-2 Summary of Evidence included the removal of the 21-day horizon of recency of infection.

3. DTAC Case Data: West Nile Virus

The Committee reviewed OPTN data on West Nile Virus (WNV) and then reviewed data from the Centers for Disease Control and Prevention (CDC) on WNV. CDC staff explained that the sensitivity and specificity of screening assays in organ donors is unknown and screening requires laboratory and staffing resources. She explained that there is a need for timely results and WNV seasonal activity is variable and unpredictable from year-to-year. CDC staff also noted that most disease cases and transmission events have occurred during months of seasonal WNV activity. She argued that seasonal screening is more cost-effective than year-round screening and would result in the prevention of cases with high morbidity and mortality. She introduced the options of screening during predetermined season using historical data in a defined region, or a triggered approach using blood donation data, reported disease cases, or mosquito and non-human surveillance data.

Data Summary:

The Committee has received 39 reports of potential West Nile Virus transmission since 2008. There is a range of zero to nine reports per year and a median of three reports per year. Most reports have been received in September. The Committee has adjudicated seven of these reports as proven, one as possible, six as unlikely, and 25 as excluded. 30 cases were reported due to post-transplant recipient illness or testing, and nine cases were reported due to post-procurement donor results.

The OPTN data was pulled from 2016-2021. There is little seasonality in WNV serology testing across the country. Testing by month ranges from 87.1 percent to 88.4 percent. There is slightly more seasonality in Nucleic Acid Amplification Testing (NAT) testing. There is a range of 62.7 percent of donors tested in October to 69.2 percent in January from 2016 to 2021. There is higher use of WNV NAT testing than serology for deceased donors. There is significant regionality in utilization of WNV serology testing by region. Only 23.6 percent of the deceased donors in Region 5 did not have serology performed. There is significant regionality in utilization of WNV NAT testing by region with a range of 9.1 percent of donors not tested in Region 5 to 99.9 percent in Region 1. 47 out of 57 organ procurement organizations reported at least one NAT test result during this period.

24 organs were transplanted after an OPO had indicated a positive WNV NAT in the OPTN Donor Data and Matching System. There was no evidence of infection in any of the recipients.

CDC staff explained that from 2002 to 2022 there are 13 documented transmission events with 85 percent of recipients infected and 75 percent of recipients with neuroinvasive disease. She explained that there were 33 percent of deaths in recipients with neuroinvasive disease. All reported transmissions were from August to October during 2002 to 2022. She noted that screening might have prevented at least seven of 12 transmission events, including 11 neuroinvasive disease cases and two deaths. The U.S. Food and Drug Administration (FDA) recommends year-round screening using licensed NAT for WNV for donations of whole blood and blood components. She explained that 39 percent of OPOs were screening for WNV in 2019 and 2020, which is an increase from 11 in 2008.

Summary of discussion:

A member commented the regions that are testing for WNV are not what aligns with the Committee's expectation based on epidemiology. A member agreed that a much higher proportion of donors are being screen than expected.

A member asked if WNV NAT positive organs were used when the OPO was aware of the result prior to procurement. CDC staff noted this is discrepant with the Committee's adjudication of WNV cases that show detrimental outcomes. Members stated they would not use WNV positive organs. The Vice Chair requested information on assay, region, date, month, and when results were available regarding the use of WNV NAT positive organs. HRSA staff asked how long the cases were followed. Staff responded that 45-day follow-up is standard.

HRSA staff asked about the difference in time period from CDC data and OPTN data. The Chair explained that the CDC data outlined investigations of outbreak investigations and OPTN data involves OPTN Patient Safety events. The Past Chair agreed that targeted screening may be the best approach. The Past Chair noted it seems that OPOs are using positive organs and outcomes are less severe based on the OPTN data. He questioned how to use seasonality cutoffs. CDC staff questioned the use of WNV positive organs and questioned the accuracy of the data because it is opposite to the CDC's experience with WNV positive organs.

A member stated that WNV NAT testing can be sensitive and detect positivity in asymptomatic donors when donors are no longer able to transmit WNV, but it is still detectable in blood samples. HRSA staff asked if CDC has access to cases outside of OPTN data. CDC staff explained that they may be made aware of a case, but they will ask centers to report these to the OPTN. A member stated he does not agree with the use of WNV positive organs.

4. West Nile Virus Guidance vs. Policy

Staff explained the differences between guidance versus policy. She noted that guidance allows room for clinical decision-making and does not establish requirements, while policy sets requirements and allows for little clinical decision making. Staff explained that the Committee has four guidance documents on endemic diseases listed here:

- [Identifying risk factors for West Nile Virus in living donors](#)
- [Recognizing seasonal and geographically endemic infections in living donors](#)
- [Guidance for Identifying Risk Factors for Mycobacterium tuberculosis \(MTB\) During Evaluation of Potential Living Kidney Donors](#)
- [Recognizing and testing for Chagas disease](#)

The Chair asked if the Committee is in favor of consolidating these guidance documents and updating them to include living and deceased donor guidance.

Summary of discussion:

Members commented that due to the opposing data from the CDC that shows there is always transmission when WNV positive organs are utilized, it would be difficult to implement policy. CDC staff explained more information is needed on the utilization of WNV positive organs and whether those are true positives. Members agreed. Members noted there is likely not enough data to implement policy at this point.

5. Closing Remarks and Adjourn

The Chair stated that since the Committee does not have a consensus on guidance versus policy. The Committee will continue this discussion in their next open session.

Summary of discussion:

There was no further discussion by the Committee.

Upcoming Meeting

February 27, 2023, 12PM EST, teleconference

Attendance

- **Committee Members**
 - Ann E. Woodley
 - Anil Trindade
 - Charles Marboe
 - Cindy Fisher
 - Dong Lee
 - Gerald Berry
 - Helen Te
 - Jason D. Goldman
 - Judith Anesi
 - Kelly Dunn
 - Lara Danziger-Isakov
 - Michelle Kittleson
 - Marty Sellers
 - Ricardo La Hoz
 - R. Patrick Wood
 - Stephanie Pouch
- **HRSA Representatives**
 - Marilyn Levi
 - Jim Bowman
- **FDA Staff**
 - Scott Brubaker
 - Brychan Clark
- **CDC Staff**
 - Sridhar Basavaraju
 - Rebecca Free
 - Carolyn Gould
 - Pallavi Annambhotla
- **UNOS Staff**
 - Lee Ann Kantos
 - Logan Saxer
 - Emily Womble
 - Cole Fox
 - Sandy Bartal
 - Sara Langham
 - Susan Tlusty
 - Taylor Livelli