# OPTN Ad Hoc Disease Transmission Advisory Committee
## Meeting Summary
## March 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 3/07/2023 to discuss the following agenda items:

1. Welcome and Agenda
2. Post Cross-Clamp Test Results Enhancement
3. DTAC Case Data: West Nile Virus
4. West Nile Virus Guidance vs. Policy
5. *Improve Deceased Donor Evaluation of Endemic Diseases* Public Comment Feedback
6. Closing Remarks and Adjourn

The following is a summary of the Committee'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. Post Cross-Clamp Test Results Enhancement

Staff gave an overview of a post cross-clamp test results enhancement that will provide a notification system that organ procurement organizations (OPOs) can initiate when test results that may affect recipients are obtained post cross-clamp. This is in response to culture reporting involving an inefficient and redundant process that is manually repeated for each organ transplanted. Also, culture reporting is not standardized throughout OPOs in the methodologies used for local and non-local transplant centers.

This enhancement will provide a means for transplant hospitals to acknowledge that they have received these notifications. They are directed to review updated test results. This will also provide an audit log allowing OPOs to see when notifications are sent, as well as if they have been acknowledged by transplant hospitals. This system enhancement will support OPTN Policy 15.4.

The pilot for this enhancement was conducted from 2020-2021 with five OPOs and 18 selected transplant hospitals. Development is set to begin in June 2023. This enhancement will not replace the OPTN Patient Safety Reporting Portal. Text message notifications, OPTN Donor Data and Matching System Mobile capability, and reporting for transplant centers are also being prioritized as additions to this enhancement.

Summary of discussion:

The Past Chair commended the efforts on this project. He voiced concern about the number of notifications centers would receive with this enhancement. He asked what would constitute acknowledgement of receipt of these results. Staff responded the responsibility for the transplant center will be to view the results and choosing the 'click to acknowledge' option.

The Vice Chair asked when the OPOs enter positive blood cultures if the center is prompted to open attachments. Staff responded they are working on an enhancement to allow centers to link directly to the test results instead of adding the extra step of locating the donor record.

The Past Chair asked about the feedback staff received on the time intervals for notifications, and staff responded that was decided by the Post Cross-Clamp Test Results Enhancement Workgroup. Staff explained that the regular practice of entering these positive test results will not change. The Chair asked if the notification is prompted by entering the results. Staff responded that the Post Cross-Clamp Test Results Enhancement Workgroup is discussing a future enhancement that will add that feature to the system.

A member asked how specific the information in these notifications will be and stated it would be helpful to clearly show what results need to be reviewed. Staff responded that the email notification will include the information that needs to be reviewed directly. The member noted it may be helpful to highlight exactly what needs to be reviewed instead of sorting through multiple page documents.

Staff stated the pilot phase has been completed, and this enhancement will now be rolled out nationally. He explained they will continue to test the enhancement and consider feedback from pilot programs.

**3. DTAC Case Data: West Nile Virus**

Data Summary:

The Committee has received 39 reports of potential West Nile Virus (WNV) 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 the month of September since 2008. The Committee has adjudicated seven of these donor derived infection 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.

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.

The Committee vocalized concern in a previous meeting when a data request showed that 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. After examination of these seven donors in the OPTN Donor Data and Matching System, it is likely these were attributable to data entry errors. This is predicted due to no documentation of positive NAT tests in the OPTN Donor Data and Matching System attachments. In one donor, organs were recovered, but not allocated.

Summary of discussion:

There was no further discussion by the Committee.

**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 updates needed for Identifying risk factors for West Nile Virus in living donors are:

- Updates to include deceased donors
- Updates to the summary section
- Updates to epidemiology figures

The updates needed for Recognizing seasonal and geographically endemic infections in living donors are:

- Revisiting the detailed information for each pathogen through the lens of what is currently know about donor-derived infections
- Updating Strongyloides and Chagas sections to align with the *Improve Deceased Donor Evaluation for Endemic Diseases* proposal if it is approved by the OPTN Board of Directors

The updates needed for Guidance for Identifying Risk Factors for Mycobacterium tuberculosis (MTB) During Evaluation of Potential Living Kidney Donors are:

- Updates to include changes in nomenclature
- Updates to testing guidance
- Updated report of donor-derived infections
- Refreshed epidemiology
- Addition of a section on deceased donors

The updates needed for Recognizing and testing for Chagas disease are:

- Updates to the donor screening section if the *Improve Deceased Donor Evaluation for Endemic Diseases* proposal if it is approved by the OPTN Board of Directors

The Chair asked if the Committee is in support of condensing these guidance documents into one guidance document for endemic diseases in deceased and living donors.

Summary of discussion:

The Chair noted that guidance can be worked on without ruling out policy for the future. Members agreed condensing these guidance documents is the best approach. A member noted the updates to endemic disease guidance for living donors will be helpful when dealing with living donors coming from other areas of the country.

A member commented the community does not understand why Strongyloides and Chagas would not be guidance as well. He emphasized the need for education on why these diseases are important to focus on. A member stated broader distribution emphasizes the need for these revisions.

CDC staff asked if there are any metrics on impact of guidance documents that the Committee has worked on in the past. Staff responded the Committee could look at the number of times a page is

accessed on the OPTN website. The Past Chair stated everyone at his center is aware of the guidance on endemic diseases for living donors.

**5. *Improve Deceased Donor Evaluation of Endemic Diseases* Public Comment Feedback**

Staff provided an overview of the public comment feedback the Committee has received on the *Improve Deceased Donor Evaluation of Endemic Diseases* proposal. Staff stated the Committee has received overall support of the proposal. There was sentiment that Chagas screening results required pre-transplant is too stringent of a requirement. There were also requests for guidance and education once the proposal is implemented.

OPTN members commented that travel history should be a factor for screening for Chagas. There was sentiment that universal testing should be required for Chagas as well.

OPTN members vocalized concern over cost and availability of testing for these endemic diseases as well as false positivity rates of available tests. There was concern over organs not being utilized when results are false positives.

Summary of discussion:

A member stated that results should not be required pre-transplant because recipient management is still possible when results are available post-transplant. She also noted that the data on donor derived transmissions does not warrant requiring results pre-transplant. The Past Chair stated the community has made it clear that this is not feasible, but he stated this could be important for heart transplantation. He also does not agree with testing all donors for Chagas. CDC staff asked if the Committee is comfortable removing this requirement for heart allocation.

A member commented that the heart is the first organ that gets transplanted, so that will be the least forgiving in terms of delaying allocation. He also noted families put time constraints on donors, which could further delay allocation. Members agreed. A member stated heart recipients can still be managed well if the donor tests positive for Chagas. She stated we can begin with requiring the test without a stringent timeframe, and that may facilitate testing becoming available sooner.

The Chair asked if this would impact equity across regions, specifically for regions that have higher proportions of donors born in endemic countries. The Vice Chair stated that if a screening result is positive, polymerase chain reaction (PCR) screening is easy to conduct while waiting for confirmatory results. The Past Chair stated that if the transplant community favors modifications to the proposal, then the Committee should consider changes after the close of public comment.

**6. Closing Remarks and Adjourn**

Staff gave an overview of reminders for the Committee. The Chair thanked the Committee for the thoughtful discussion.

Summary of discussion:

There was no further discussion by the Committee.

**Upcoming Meeting**

- March 20, 2023, 8:30am CT, in-person, Chicago, IL

**Attendance**

- **Committee Members**
  - Ann E. Woodley
  - Anil Trindade
  - Charles Marboe
  - Cindy Fisher
  - Gerald Berry
  - Jason D. Goldman
  - Judith Anesi
  - Kelly Dunn
  - Lara Danziger-Isakov
  - Michelle Kittleson
  - Marty Sellers
  - Ricardo La Hoz
  - R. Patrick Wood
  - Sam Ho
  - Sarah Taimur
  - Stephanie Pouch
- **HRSA Representatives**
  - Marilyn Levi
- **FDA Staff**
  - Brychan Clark
- **CDC Staff**
  - Sridhar Basavaraju
  - Rebecca Free
  - Carolyn Gould
  - Pallavi Annambhotla
- **UNOS Staff**
  - Lee Ann Kantos
  - Logan Saxer
  - Kevin Daub
  - Roger Vacovsky
  - Tamika Watkins
  - Sara Langham
  - Susan Tlusty
  - Laura Schmitt
  - Taylor Livelli