OPTN Ad Hoc Disease Transmission Advisory Committee
Meeting Summary
November 1, 2022
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 10/24/2022 to discuss the following agenda items:

1. Closed Session Case Review
2. DTAC Letter to the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA)
3. ***Vote:*** Send letter for public comment to the OPTN Executive Committee for approval
4. Strongy and Chagas Policy Language
5. ***Vote:*** Strongy and Chagas Policy Language

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

1. Closed Session Case Review

The Committee had a closed session review of potential donor-derived transmission events.

2. DTAC Letter to the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA)

The Chair provided a background of the need for public comment to the ACBTSA. She explained that on 10/29/2021, the OPTN Executive Committee sent a letter to the Department of Health and Human Services (HHS) Secretary recommending the Secretary remove the statutory research requirement for organ transplants from HIV positive organ donors to HIV positive transplant recipients. On 1/18/2022, the HHS Secretary acknowledged the request and notified the OPTN that HHS was consulting applicable HHS offices, agencies, and advisory committees/councils. On 8/26/2022, ACBTSA representatives met with Committee leadership including Ex-officio HRSA members to discuss potential forthcoming recommendations on the HIV Organ Policy Equity (HOPE) Act transplant variance. On 10/17/2022, ACBTSA published draft recommendations that will be discussed at their upcoming 11/17/2022 meeting.

ACBTSA recommendations include:

For the transplantation of organs from HIV-positive donors into HIV-positive recipients

Kidneys and Livers – remove statutory "NIH Research Criteria and IRB" requirement (with no special restrictions other than the applicable OPTN kidney and liver policies).

All other organs including thoracic organs – remove statutory "NIH Research Criteria" requirement BUT recommend the Secretary direct the OPTN to develop and implement the following new special policies:

1. OPTN organ-specific variance for each organ other than kidneys and livers
2. Additional organ-specific candidate criteria and transplant program requirements analogous (but not "identical") to the NIH Research Criteria developed specifically for the unique patient safety and outcomes monitoring characteristics of transplants other than kidneys and livers in HIV patients

3. Additional organ-specific OPTN outcomes monitoring for candidates of organs other than kidneys and livers on the Waiting List and recipients following transplantation
4. Each center/institution must have an IRB-approved protocol that will include measures of outcomes and safety
5. When multiple organs are transplanted simultaneously, the default approach will be to use the guidelines of the organ with more conservative policies

The OPTN should develop and implement the above-listed new special policies within 15 months of receiving this request from the Secretary of Health and Human Services

These criteria will be reviewed and re-evaluated 2 years after implementation.

The OPTN response voiced concerns in a call between Committee leadership and ACBTSA in August. The OPTN does not provide oversight of clinical studies and is not set up to be a primary organizer of a "quasi" research model. Collecting new research specific OPTN data elements would require the full policy development process and data changes would require the Office of Management and Budget (OMB) approval. Given the status of transplants done for other organs (two HOPE programs with one heart transplant performed), efforts may not be an effective use of resources and may lead to inequities between organs. If the ACBTSA believes it is unsafe to remove the research variance for all organs, the OPTN recommends keeping the status quo (NIH model) for non-kidneys and non-livers versus creating a new model for other organs.

Summary of discussion:

The Ex-officio asked for clarification on maintaining the "status quo" for non-kidney and non-liver organs. The Chair explained, in the letter, the OPTN asks for the research requirement removal for all organs, but if that is not feasible, the OPTN requests that the NIH model for the research requirement stay in place instead of proposing new OPTN oversight. She stated the timeline of creating an entirely new system could potentially delay things further. A member stated the research requirement is a barrier for organs, so we should ask for the removal for all organs. UNOS staff explained that is the overall message, but we state the model should stay the same if the Secretary is not willing to remove the research requirement for all organs.

3. Vote: Send letter for public comment to the OPTN Executive Committee for approval

The Committee voted on whether they support sending this letter for public comment to the OPTN Executive Committee for approval.

Summary of discussion:

The Committee unanimously approved sending the letter for public comment to the OPTN Executive Committee.

4. Strongy and Chagas Policy Language

After the 9/19/22 Committee meeting and input from CDC and leadership, the proposed policy language in Policy 2.9 Required Deceased Donor Infectious Disease Testing is as follows:

2. Infectious disease testing for all potential deceased organ donors using FDA licensed, approved, or cleared tests, as listed below:

Strongyloides antibody donor screening test

4. Infectious disease testing for Chagas disease using an FDA licensed, approved, or cleared test for T. cruzi antibody for all potential deceased donors whose donor history reflects the donor's birthplace was in a country classified as endemic for Chagas by the CDC. The OPTN maintains a list of countries

currently classified as endemic for Chagas by the CDC. T. cruzi antibody testing results must be available pre-transplant.

Within 72 hours of receipt of a positive T. cruzi antibody test, the host OPO must submit a sample for confirmatory testing. Confirmatory testing requires submission through the CDC or submission for at least two different tests that are FDA licensed, approved, or cleared antibody diagnostic tests.

The list of countries classified as endemic for Chagas by the CDC are listed below:

- Mexico
- Belize
- Costa Rica
- El Salvador
- Honduras
- Guatemala
- Nicaragua
- Panama
- Argentina
- Bolivia
- Brazil
- Chile
- Colombia
- Ecuador
- Guyana
- Suriname
- French Guiana
- Paraguay
- Peru
- Uruguay
- Venezuela

Summary of discussion:

A member asked if the timing of confirmatory testing relative to transplant would be specified. UNOS staff explained that Policy 15.1 requires the OPO, "Communicate any information regarding potential disease transmissions to the medical staff responsible for the recipient's clinical care at the transplant program as soon as possible, but no later than 24 hours after becoming aware of the potential disease transmission."

A member stated his OPO does not receive Chagas screening results pre-transplant, so he anticipates difficulties getting these results pre-transplant. The Chair explained that this will be a point the Committee will ask for feedback on in public comment. The Chair asked if an OPO has Chagas testing pending for a donor from an endemic country will the OPO offer the heart still. She explained she did not want to limit the number of hearts offered because the screening results are not available pre-transplant.

The member asked if a donor born in an endemic country who moves to the United States at three years of age need to be screened. The Chair responded it is difficult to differentiate this and put it into policy, so another feedback question will ask about an adequate differentiation in the proposal. The Ex-officio stated the SARS-CoV-2 testing policy was developed with OPOs to address barriers they faced with obtaining results pre-transplant. He stated transmission does occur and the heart recipient suffers when

results are not available pre-transplant. A member asked how much downside there is if results are not required pre-transplant. The Ex-officio stated there will be more donor derived events if the Committee does not require this.

5. *Vote:* Strongy and Chagas Policy Language

The Committee voted on whether the Committee votes to send this policy language to January 2023 public comment.

Summary of discussion:

The Committee unanimously approved sending this policy language to January 2023 public comment.

Upcoming Meeting

- November 28, 2022, teleconference, 12pm EST

Attendance

- **Committee Members**
  - Ann E. Woodley
  - Anil Trindade
  - Charles Marboe
  - Cindy Fisher
  - Dong Lee
  - Gerald Berry
  - Jason D. Goldman
  - Judith Anesi
  - Kelly Dunn
  - Lara Danziger-Isakov
  - Lorenzo Zaffiri
  - Michelle Kittleson
  - Marty Sellers
  - R. Patrick Wood
  - Ricardo La Hoz
  - Sarah Taimur
  - Sam Ho
  - Stephanie Pouch
- **HRSA Representatives**
  - Marilyn Levi
  - Jim Bowman
- **CDC Staff**
  - Ian Kracalik
  - Sridhar Basavaraju
- **UNOS Staff**
  - Lee Ann Kantos
  - Amelia Devereaux
  - Krissy Laurie
  - Sandy Bartal
  - Susan Tlusty
  - Taylor Livelli