

OPTN Ad Hoc Disease Transmission Advisory Committee

Meeting Summary

November 28, 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 11/28/2022 to discuss the following agenda items:

1. NASEM Report Recommendations
2. New Project Ideas
3. Chagas Policy Language Clarification Vote
4. New Project/Manuscript Support

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

1. NASEM Report Recommendations

Staff gave an overview of the National Academies of Sciences, Engineering, and Medicine (NASEM) Report, stating, the NASEM Ad Hoc Committee on A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution issued a report "Realizing the Promise of Equity in the Organ Transplantation System" in February 2022.¹ The OPTN Board of Directors responded to the NASEM report in April 2022, and the NASEM committee leadership presented the report's recommendations to the Board of Directors in June 2022.

The recommendations fell into the categories of improving equity, using more donated organs, and improving the system and system performance. Staff explained how the OPTN has worked to incorporate these recommendations.

Summary of discussion:

The Chair encouraged members to contribute new ideas that align with NASEM recommendations. She noted the Committee is working on projects that align with these recommendations already. The Past Chair stated organ utilization is a complex topic because it is difficult to balance the amount of organ offers with the number of organs accepted. He stated it is important to make sure a donor is adequately screened because even though donor-derived transmission events are rare, they result in a high mortality rate. He asked members how to maximize organ utilization with a cost-effective system. He stated he favors the safety of the system over the cost. A member agreed and stated it is very expensive to treat recipients that have a donor-derived transmission, so screening appropriately would help reduce this cost.

¹ "Realizing the Promise of Equity in the Organ Transplantation System," National Academies of Science, Engineering, and Medicine, accessed November 19, 2022, <https://www.nationalacademies.org/our-work/a-fairer-and-more-equitable-cost-effective-and-transparent-system-of-donor-organ-procurement-allocation-and-distribution>.

2. New Project Ideas

The Committee members discussed new project ideas based on the NASEM report recommendations.

Summary of discussion:

A member stated that continuous distribution will cause broader organ distribution, so the Committee's work on endemic diseases and geographic transmissible diseases will become even more important. The Chair agreed. The member stated coccidioidomycosis is another disease that falls into this category.

The member stated after examining trends through the Committee's closed session case reviews, fungal Candida donor-derived transmissions are severe and often result in anastomotic breakdown, mycotic aneurysm rupture, and death. He stated there are about 160 donors and 394 recipients of which there were 26 proven or probable transmissions of Candida species adjudicated by the Committee. He noted this is valuable work for the Committee to better patient safety. A member asked if the recipients received the correct anti-fungal medication. The Chair responded that these questions would be considered as part of a project for the Committee.

The Chair stated the Advisory Committee on Blood and Tissue Safety and Availability recent recommendations will likely require additional work from the Committee on the HIV Organ Policy Equity (HOPE) Act. She also noted a member suggested a focus on co-infections between hepatitis B and hepatitis C for future Committee work.

3. Chagas Policy Language Clarification Vote

Members voted on updated policy language for Chagas listed below:

Infectious disease testing using an FDA licensed, approved, or cleared screening test for Chagas 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.

Chagas screening antibody testing results must be available pre-transplant. Within 72 hours of receipt of a positive Chagas screening antibody test, the host OPO must submit a sample for confirmatory testing. Confirmatory testing requires submission through the CDC or at least two different tests performed that are FDA licensed, approved, or cleared antibody diagnostic tests.

The intent of these revisions is to clarify that Chagas screening antibody testing results must be available pre-transplant.

Summary of discussion:

The Committee unanimously approved sending this policy language to January 2023 public comment, with 19 Committee members on the call.

4. New Project/Manuscript Support

Members discussed a manuscript that evaluates Gram-negative multi drug resistant organism (MDRO) transmissions from 2012-2021. The Vice Chair stated the work that has been done on this highlighted kidney transplant recipients related to allograft loss, death, and anastomotic ruptures when transmissions occurred. This also showed implications of the lack of donor antibiotic information. The Vice Chair asked for volunteers to support this work.

UNOS staff asked for volunteers for work on the Candida donor-derived transmission events and extensive review of these cases.

Summary of discussion:

Centers for Disease Control and Prevention (CDC) staff asked what members think will come out of this work. The Vice Chair stated that the Committee will not be able to recommend antibiotics but understanding antibiotic reporting and delays in information sharing may be crucial. She stated that the susceptibilities that were done were dependent on what labs were conducting testing, and there is interest from the community in adjunctive molecular testing for these cases. The Past Chair stated these transmissions are due to infection control issues or antimicrobial stewardship issues.

CDC staff asked if fungal blood cultures of donors is needed. The Past Chair stated the fungal blood culture isolator has a better sensitivity for intracellular fungi, but it does not have a better performance to detect *Candida*. In general, fungal cultures always suffer from inadequate sensitivities, so new assays are being pursued. CDC staff noted they have investigated several *Candida* transmissions and are interested in participating noting that the output of this work must go through the CDC.

The Past Chair stated that the blood cultures for *Candida* are negative but the presentation in the recipient is highly suspicious of a transmission. He stated there may be better diagnostic performance by certain tests and this may be discovered by reviewing these cases. A member stated in some of these cases there is a theme of inconsistency between center action. He hopes the Committee can educate the community to prevent transmission.

A member stated these projects will serve as a steppingstone for information sharing with the community and potential policy work in the future. The Chair stated the Committee will target recognition of this risk and what will impact modification of outcomes.

Upcoming Meeting

- December 6, 2022, 3PM 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
 - Lorenzo Zaffiri
 - Michelle Kittleson
 - Marty Sellers
 - R. Patrick Wood
 - Ricardo La Hoz
 - Sarah Taimur
 - Sam Ho
 - Stephanie Pouch
- **HRSA Representatives**
 - Marilyn Levi
 - Jim Bowman
- **FDA Staff**
 - Scott Brubaker
- **CDC Staff**
 - Ian Kracalik
 - Sridhar Basavaraju
 - Rebecca Free
 - Pallavi Annambhotla
- **UNOS Staff**
 - Lee Ann Kantos
 - Amelia Devereaux
 - James Alcorn
 - Joel Newman
 - Emily Womble
 - Sandy Bartal
 - Susan Tlusty
 - Taylor Livelli