

OPTN Ad Hoc Disease Transmission Advisory Committee

Meeting Summary

August 2, 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 08/2/2022 to discuss the following agenda items:

1. HOPE Act Expansion to Other Organs: 2-year post-implementation report
2. Pathogens of Special Interest Update
3. Monkeypox Discussion

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

1. HOPE Act Expansion to Other Organs: 2-year post-implementation report

- The first HIV positive to HIV positive heart transplant was performed in the last quarter
- There are now 2 heart transplant programs approved under the HOPE Act Expansion
- Most HOPE Act transplants are kidney and liver transplants

Data summary:

UNOS Staff gave a presentation on the HOPE Act expansion to other organs following 2 years since implementation. UNOS Staff noted that in March of 2016 there was a slight uptick in HIV positive donors. HIV positive donors have ranged from 0-8 per month and peaked in March of 2019. Most HOPE Act transplants are kidneys, with 271 kidneys, 71 livers, and 1 heart transplanted under the HOPE Act.

Summary of discussion:

A committee member inquired about the number of OPOs who have participated in this expansion. UNOS staff stated most OPOs have procured at least one donor. The Past Chair noted it would be interesting to see the specific data on which OPOs are performing transplants under the HOPE Act. A committee member asked the rate of HIV positive organ discard. UNOS staff agreed to follow-up on that but pointed out trends are hard to evaluate with such low numbers. UNOS staff also noted that UNOS has asked the Secretary to remove the HOPE Act variance.

2. Pathogens of Special Interest Update

The Ex-officio discussed edits to the Pathogens of Special Interest list since the Committee is required to review it annually.

The changes include:

- Removal of all language related to post-transplant recipient reporting requirements
- Addition of brief introduction to explain the use of the document
- Classification of diseases into categories, including both common and scientific names for all
- Clarification of language around inclusion/exclusion requirements and made consistent

- Addition of the following pathogens:
 - Blastomyces
 - Monkeypox
 - CVB3
- Modification of reporting requirements:
 - Amoebas- all amoebic infections must be reported, not just those involving encephalitis
 - Histoplasmosis- exclude reporting if only identified in respiratory culture
 - HBV- exclude reporting if only identified by surface antibody results

Summary of discussion:

CDC staff noted that coccidiomycosis can be diagnosed by serologic results as well. UNOS staff agreed but explained that these results do not need to be reported to the Committee. The Committee members stated opening an investigation with every positive serology is not necessary because they are reported to transplant centers, and the Committee will only need to receive reports of transmission. CDC staff asked if coccidiomycosis is routinely tested for. A Committee member responded in certain endemic areas this is tested for more routinely to make decisions regarding prophylaxis. The Committee members voted to approve this document with 17 members in favor, 0 members abstaining, and 0 members declining.

Next steps:

This document will be submitted to the OPTN Executive Committee on 9/19/22.

3. Monkeypox Discussion

The Past Chair explained that multiple OPTN committees and HRSA have requested that the Committee write a Summary of Evidence regarding monkey pox. He also noted that many members have reached out via OPTN member questions about a monkeypox resource. The Past Chair stated a Summary of Evidence is a better option than a Guidance Document because it does not have to go through the six-month policy cycle. The Past Chair gave an overview of a potential timeline that would allow for publication shortly after 9/19/22. Because of this, he emphasized the importance of Committee participants to meet these deadlines.

The Past Chair presented on potential collaborators and a potential outline for the Summary of Evidence. The outline will require committee members to collaborate on sections of the document including:

- Introduction/Methods
- Terms to know
- Routes of transmission, infectivity
- Safety of OPO Recovery Team and Transplant Programs
- Screening considerations
- Testing considerations
- Impact on living donor safety
- Risks of transmission
- Available Preventatives, Prophylactics, and Treatment

Summary of discussion:

OPO representative Committee members noted potential use/modifications to the uDRAI are being considered, while evaluating precautions with positive donors. They stated we need to think about transmission to staff as well as recipients and incorporate this guidance into the document.

A Committee member noted they have used European guidance on blood donation as current guidance. They noted they have struggled to define severity of illness and use this to dictate time until safe donation.

The Past Chair emphasized a focus on exposure, compatible clinical presentation, and prior diagnosis/severity as important points to include within screening considerations. A member suggested grouping incubation period and screening together in the document. A member suggested including specific guidelines regarding DCDs for hospital staff, and the possibility of respiratory secretions as a focus of the Safety of OPO Recovery Team and Transplant Programs. The Past Chair recommended a focus on what the Committee has learned along the way about potential donor derived transmission events under risk of transmission.

HRSA staff asked if FDA staff will be contributing, and UNOS staff noted stakeholders have all been contacted and invited.

Next steps:

Committee member assignments will be finalized on 8/5/22 by Committee leadership. Case reviews will be pushed to September because this was deemed higher priority.

Upcoming Meeting

- August 22, 2022, 12 PM- 1PM EST

Attendance

- **Committee Members**
 - Ann E. Woodley
 - Judith Anesi
 - Charles Marboe
 - Cindy Fisher
 - Dong Lee
 - Emily Blumberg
 - Gerald Berry
 - Helen Te
 - Jason D. Goldman
 - Kelly Dunn
 - Michelle Kittleson
 - Lorenzo Zaffiri
 - Sam Ho
 - R. Patrick Wood
 - Sarah Taimur
 - Stephanie Pouch
 - Raymund Razonable
 - Ricardo La Hoz
- **HRSA Representatives**
 - Marilyn Levi
 - Jim Bowman
 - Raelene Skerda
- **CDC Staff**
 - Rebecca Free
 - Pallavi Annambhotla
- **UNOS Staff**
 - Amelia Devereaux
 - Christine Chyu
 - Courtney Jett
 - David Klassen
 - Lee Ann Kontos
 - Samantha Weiss
 - Sandy Bartal
 - Susan Tlusty
 - Taylor Livelli