

OPTN Ad Hoc Disease Transmission Advisory Committee

Meeting Summary

August 3, 2021

Conference Call

Ricardo La Hoz, MD, FACP, FAST, FIDSA, Chair

Lara Danziger-Isakov, MD, MPH, Vice Chair

Introduction

The Ad Hoc Disease Transmission Advisory Committee met via Citrix GoToMeeting teleconference on 08/03/2021 to discuss the following agenda items:

1. HOPE Act: Variance Data and 1 Year Evaluation to Include Other Organs
2. Discussion: HOPE Act and Current Variance
3. Closed Session: Confidential Medical Peer Review

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

1. HOPE Act: Variance Data and 1 Year Evaluation to Include Other Organs

UNOS Research scientist presented data on the OPTN HIV Organ Policy Equity (HOPE) Act variance and its May 2020 expansion to include all solid organs.

Background:

- The HIV Organ Policy Equity (HOPE) Act, enacted on November 21, 2013, allows for research on transplanted organs from HIV+ donors into HIV+ recipients
 - Prior to this milestone, individuals infected with HIV were not permitted to be organ donors in the US
- The HOPE Act gives HIV+ patients the opportunity for organ transplantation from donors (per guidelines published by The Secretary in 11/2015) who are also infected with HIV, increasing both the donor pool and the number of transplants
- In 11/2015, the OPTN modified policy and programming to allow HIV+ to HIV+ kidney and liver transplantation under an OPTN HOPE Act research variance
- In 6/2019, the OPTN Board of Directors approved a modification to expand the OPTN HOPE Act variance policy and programming to include all other solid organs
 - This change was implemented on May 21, 2020

Participating programs and transplants:

As of 7/9/2021 there were 68 kidney, liver, and heart programs (60 deceased donor and 8 living donor) among 35 unique centers. As of June 2021, 89% of centers with current HOPE Act approval listed at least one candidate willing to accept an HIV+ organ. To date, there have been zero candidates listed as willing to accept an HIV+ organ that was not a kidney or liver.

There have been 173 HIV positive donors recovered from February 2016 to July 2021. Some donors could represent HIV false positive donors but this is not discernible from OPTN data. 170 donors were deceased donors, and 3 living donors. Among the deceased donors, 164 donated at least one kidney and 65 donated a liver. 146 had at least one organ result in a transplant. All three living donors were kidney

donors. As of June 2021, 74% of centers with current HOPE Act approval have performed at least one HOPE Act transplant.

Since implementation of the modification to include additional solid organs to the OPTN HOPE Act variance, the number of transplants and donors per month have continued to increase for kidney despite the ongoing COVID-19 pandemic, but no growth was experienced for any other solid organs

OPTN HOPE Act Safety Review Workgroup Summary:

The Safety Review Workgroup reviewed the following:

- NIH criteria safety outcomes for review:
 - Rejection
 - Progression to AIDS, opportunistic infection
 - Virologic breakthrough, failure to suppress viremia
 - Resistant strain of infection
 - Malignancy
 - HIV associated organ failure
 - Graft failure
 - Death
- OPTN data analysis
 - Similar one year post-transplant graft survival for HOPE, non-HIV, and other HIV kidney and liver transplants
 - Four year post-transplant kidney survival was the same for HOPE transplant, non-HIV transplant, and other HIV transplants
- Protocol-specific Data and Safety Monitoring Board (DSMB) reports submitted to the OPTN
 - No DSMBs had safety concerns and all protocols were allowed to proceed following IRB reviews

The workgroup unanimously agreed to recommend to the Secretary of HHS that the research requirement for HOPE Act transplantation be removed and this become standard of care for HIV+ patients willing to accept HIV+ organs.

The OPTN is asking the Ad Hoc DTAC to approve a letter, once developed, to the Secretary of HHS advising the removal of the research criteria for their consideration.

2. Discussion: HOPE Act and Current Variance

DTAC Chair opened the floor to discussion of the HOPE Act presentation and on whether the committee supported the removal of the research criteria.

Summary of discussion:

One committee member asked whether there are barriers to HOPE Act transplantation in thoracic transplant. A UNOS staff member mentioned that while this data is not collected, programs have anecdotally reported that getting HOPE protocols running and maintaining them is a large amount of work on transplant programs. In addition, the OPTN does not collect data on candidate infectious disease status at listing, so the OPTN isn't able to determine the potential thoracic transplantation population size, just that there's only one program approved to participate. A committee member also mentioned that the requirement to join a research protocol is very restrictive, as the program needs to have recently performed at least five HIV+ transplants per organ type within a short timeframe. The committee member posed that it may be beneficial to allow transplant programs who have experience in other HIV+ transplants, not specific to the organ type, to decrease the barriers to transplantation.

A HRSA representative expressed concern that the HOPE Act put in place requirements to provide safeguards, with expertise in these transplants that go beyond general transplant program membership. He expressed concern that there is a difference between caring for HIV+ patients and transplanting HIV+ patients. UNOS staff mentioned that the committee developing policies for transplant safety would be step two of the discussion, and that currently programs will continue going through the existing variances while the committee can craft additional policies to ensure those safeguards. Another staff member mentioned that the letter would lay out the workgroup and committee recommendation, and highlight at a high level the necessary policy changes to remove this variance while maintaining patient safety, as well as that the variance has allowed us to get to this point since there haven't been adverse impacts. She then laid out that the DTAC would review the content of the letter and recommend it to the Board of Directors, which would then be reviewed by the BOD and sent to the Secretary. If the secretary approves the removal of the variance, the DTAC would be able to begin working on a policy proposal to carry through these aims.

Multiple committee members expressed support of removing the variance to allow HIV+ organ transplantation to occur outside of research protocols, and no committee members expressed concerns.

Next steps:

UNOS staff will work with committee leadership to draft a letter to the Secretary of Health and Human Services requesting removal of the research requirement for HIV+ organ transplantation.

3. Closed Session: Confidential Medical Peer Review

Summary of discussion:

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

Upcoming Meetings

- August 23, 2021, 12 PM EDT, Teleconference
- September 7, 2021, 3 PM EDT, Teleconference

Open Session Attendance

- **Committee Members**
 - Ann Woolley
 - Avi Agarwal
 - Charles Marboe
 - Debbie Levine
 - Gerald Berry
 - Helen Te
 - Jason Goldman
 - Lara Danziger-Isakov
 - Michelle Kittleson
 - Ricardo La Hoz
 - Sam Ho
 - Sarah Taimur
 - Stephanie Pouch
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
 - Raelene Skerda
- **CDC Staff**
 - Ian Kracalik
 - Pallavi Annambhotla
 - Rebecca Free
 - Sridhar Basavaraju
- **UNOS Staff**
 - Abby Fox
 - Amber Wilk
 - Anne McPherson
 - Courtney Jett
 - Emily Womble
 - Leah Slife
 - Sandy Bartal
 - Sarah Booker
 - Susan Tlusty

Closed Session Attendance

- **Committee Members**
 - Ann Woolley
 - Avi Agarwal
 - Charles Marboe
 - Debbie Levine
 - Gerald Berry
 - Helen Te
 - Jason Goldman
 - Lara Danziger-Isakov
 - Michelle Kittleson
 - Ricardo La Hoz

- Sam Ho
- Sarah Taimur
- Stephanie Pouch
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 - Sandy Bartal