

OPTN Ad Hoc Disease Transmission Advisory Committee

Meeting Summary

November 2, 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 11/02/2021 to discuss the following agenda items:

1. DTAC-Pediatric Proposal Language Review and Vote
2. HOPE Act Variance Extension
3. Require Lower Respiratory Testing for SARS-CoV-2 in Lung Donors 4-month data report
4. Recipient Outcomes from donors with a positive COVID-19 Lower Respiratory Test data report

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

1. DTAC-Pediatric Proposal Language Review and Vote

Committee Vice Chair reviewed the scope of the problem the proposal is looking to address, and policy analyst reviewed the policy language with the committee.

Review of problem:

- OPTN policy currently requires HIV, HBV HCV testing upon hospital admission for transplant for all candidates, in line with 2020 PHS Guideline
- Risk of overdrawing blood volume for pediatric candidates is greater than for other candidates, while the risk of HIV, HBV, HCV transmission for this population is lower
- While risk is not zero and pretransplant testing is still needed, current timing requirement is not necessary or appropriate

Solution:

- Remove timing requirement for candidates under 11, so while they still need the pre-transplant testing, they don't have to get it right before getting transplanted

Summary of discussion:

Members had no questions or concerns. One member mentioned that this is a step forward to protect vulnerable patients.

Vote to send the proposal to January 2022 public comment: 12 yes, 0 no, 0 abstain.

2. HOPE Act Variance Extension

Policy associate reviewed the current state of the research variance and why it may need to be extended.

Current state of HOPE Act Research Variance:

- OPTN has sent letter to Secretary of HHS to remove research requirement from HIV-positive transplants
 - Cannot remove until after a response from the Secretary, possible change of federal regulations, public comment, and Board approval
- Current HOPE Act research variance set to expire January 1, 2022
 - Extending the current variance would allow HIV-positive transplants to occur in meantime
- 35 deceased donor kidney, 26 deceased donor liver, 5 living donor kidney, 4 living donor liver, and one deceased donor heart program approved
- Over 300 HIV-positive transplants have occurred since inception in 2015, with no patient safety concerns identified

Extending Research Variance:

- Does not alter the current OPTN HOPE Act variance requirements or participation
- HIV-positive transplantation would be able to continue while standard of care requirements are developed
 - Removal of the existing variance would mean no HIV-positive organs could be transplanted until new requirements are developed
 - The OPTN BOD can end a variance if/when a permanent policy is developed for HIV-positive transplantation

Summary of discussion:

Members had no questions or concerns.

Vote to send the proposal to December 2021 Board of Directors meeting: 12 yes, 0 no, 0 abstain.

3. Require Lower Respiratory Testing for SARS-CoV-2 in Lung Donors 4-month data report

Research analyst presented on the 4-month post-implementation monitoring report for the policy to require lower respiratory SARS-CoV-2 testing for lung donors.

Data summary:

Based on the first 4 months of data post-policy:

- Compliance with the LRT requirement remains high
 - 99% of lung donors had LRT results reported on/before the day of transplant
- 34 recovered donors had a positive LRT test result
 - 20/34 had at least 1 negative upper respiratory test

Summary of discussion:

One member raised a concern that there was a decrease in DCD lungs over a 5 month period, and wasn't sure if it was an issue related to access to testing or a systemic system-wide issue, as there was also a decrease in donors and lung donors overall. One member said that they had a similar concern looking at the donation rate overall, and that it might be related to the fact that the last two months have had overwhelming hospital utilization rates in certain areas of the country, and said that it may be useful to look at the donation rates by area of the country.

The original member stated that it may also be related to number of listed patients, and that in their area there were fewer listed patients for lungs last year and the waiting lists are very short. They cited that one of their nearby programs has a seven-day average waiting time currently, and that they're able to choose non-DCD organs and be extremely particular in organ selection. The member said that the

analysis should look at the number of lung patients on the waiting list to see if that plays a part in the donation utilization rate.

One member mentioned that the national donation rate in general has gone up significantly in the past year, by about 20% on average.

Another member mentioned that there have been no transmissions since implementation of the policy, as compared to three transmissions in a short period of time before implementation, and that compliance with the policy is near 100%.

A different member asked if DCD donations in general have decreased recently, or if it was only lung DCD donors. Research staff will add this analysis to the next month's monitoring report. The member also mentioned that their lung transplant list is also significantly shorter now, but that in the past they did have an issue of not having enough beds in the hospital during a COVID surge, and that there may be multiple factors at play related to COVID in why lung transplants in general might be decreased.

Next steps:

Research staff will add the number of lung waitlisted patients, number of DCD donors for all organs, and a breakdown of lung transplants by region to next month's monitoring report.

4. Recipient Outcomes from donors with a positive COVID-19 Lower Respiratory Test data report

Research analyst presented on a committee data request to evaluate recipient outcomes from donors who have had a positive lower respiratory test for COVID-19.

Data summary:

18 kidney recipients, 11 liver, 6 heart, 1 heart-kidney, and 1 pancreas recipient received organs from donors with a positive LRT for COVID-19. Research reviewed this data stratified by OPO/region, donor age, cause/mechanism/circumstance of death, donor history of certain illnesses, donor history of drug/alcohol/cigarette use, donor KDPI, LV ejection fraction, LDRI, most recent positive test time from admission, and sequence of final acceptor numbers. Research also reviewed recipient age, medical urgency criteria, days from listing to transplant, transplant hospitalization length of stay, and death/graft failures.

Summary of discussion:

One member asked the OPO committee member if they were aware of differences in practices for pursuing donors with known COVID-19, since only 11 OPOs procured these organs. The OPO member said that those OPOs must be located near transplant programs who are willing to accept these organs, and that the transplant program willingness to accept organs is likely driving the OPOs pursuing these organs.

Another member pointed out that this also included only seven of the eleven OPTN regions, and that there may be a geographic difference in offer/acceptance practices due to the scope of the pandemic during this time period.

Members asked if the donor-specific factors mirrored the national patterns for transplanted organs, and the general consensus from different specialists is that these ranges were well within normal for organ quality, neither high nor low, even with the small numbers.

One member pointed out that some people are still likely hesitant to accept these organs, and that their use isn't widespread yet.

Another member requested more detail on the recipients, but the chair clarified that the data request can only include aggregated information of the data elements already submitted in the usual course of transplant, since this is not within the bounds of medical peer review.

Members asked if they could also look at donors with positive upper respiratory tests, especially with so much unknown currently about COVID, especially about the infectious course and if there's a higher risk for non-lung recipients with positive upper respiratory or lower respiratory testing.

Upcoming Meetings

- November 22, 2021, 12 PM EST, Teleconference
- December 20, 2021, 12 PM EST, Teleconference
- January 4, 2021, 3 PM EST, Teleconference

Attendance

- **Committee Members**
 - Ann Woolley
 - Debbie Levine
 - Dong Lee
 - Gary Marklin
 - Helen Te
 - Jason Goldman
 - Kelly Dunn
 - Lara Danziger-Isakov
 - Michelle Kittleson
 - Ricardo La Hoz
 - Sam Ho
 - Stephanie Pouch
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **CDC Staff**
 - Ian Kracalik
 - Rebecca Free
- **FDA Staff**
 - Brychan Clark
 - Scott Brubaker
- **UNOS Staff**
 - Amelia Devereaux
 - Cole Fox
 - Courtney Jett
 - Darby Harris
 - Sandy Bartal
 - Sarah Booker
 - Susan Tlusty