

OPTN Ad Hoc Disease Transmission Advisory Committee

Meeting Summary

January 25, 2021

Conference Call

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

Lara, MD, MPH, Vice Chair

Introduction

The Ad Hoc Disease Transmission Advisory Committee (DTAC) met via Citrix GoToMeeting teleconference on 01/25/2021 to discuss the following agenda items:

1. Expansion of the HOPE Act 6 Month Monitoring Report
2. COVID-19 Testing in Research Report
3. DTAC COVID-19 Resource

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

1. Expansion of the HOPE Act 6-Month Monitoring Report

The DTAC reviewed a data analysis of the results of expanding the HOPE Act.

Data summary:

The HOPE Act in 2015 was modified to allow transplantation of HIV+ donors into HIV+ recipients for kidney and liver transplantation. In June 2019 the Board approved a modification to the variance expanding it to all solid organs. The analysis reviewed transplants that resulted from the variance from 2016 to 2020. The presenter noted that the report time period overlaps with COVID-era data collection.

The report showed transplant volumes growing for kidney and liver but no transplants for other organs. The presenter highlighted that this change expanded the donor pool to allow transplantation of HIV+ organs safely. It may take time for more programs to get more involved and comfortable transplanting organs from HIV+ donors.

Summary of discussion:

A DTAC member asked whether the increase of numbers involved new programs that never participated before – perhaps the policy change made programs more aware of this possibility? The presenter responded that majority seemed to be participating already. The DTAC discussed how it may make time for the number of transplants from this variance to grow as transplant programs and OPOs become more comfortable and knowledgeable transplanting HIV+ donors.

Another member asked: how many of the transplants were true positive HIV donors? The presenter identified that the OPTN is unable to determine that. If the field said positive it was counted as positive, but doesn't imply confirmatory testing. The OPTN does not collect that determination in order to be able to count them. Another member estimated 50% for a true positive date based on data from John Hopkins. The DTAC discussed whether the number of transplant reflected more candidates listed or donors converted. The presenter identified that it could be a conversion issue or could reflect a growing pool in identifying potential donors.

It was also noted that all transplants that occurred because of this variance would not have occurred otherwise, successfully expanding the number of transplants.

Next steps:

The DTAC will continue monitoring the impact of the expansion of the HOPE Act variance.

2. COVID-19 Testing in Research Report

The DTAC reviewed data they previously requested regarding COVID-19 testing in DonorNet®.

Data Summary:

The presenter specified that COVID tests could be entered as free text, an attachment or in discrete fields. The analysis reviews the 85% of COVID tests entered in discrete fields. The presenter noted that donors may have multiple tests. The analysis reflects data as of January 1, 2021, for a period from April 21 to December 11, 2020.

From 24 donors that had positive COVID tests, 44 transplants occurred. Each of the donors that had a positive test also tested negative as well. Test results showed one positive among lung donors where organs were recovered. For lung donors from the time period analyzed, 30.1% received lower respiratory test (e.g. BAL bronchoalveolar lavage). 86.4% received upper respiratory (percentages add to more than 100% because donors may have received multiple tests).

Discussion:

UNOS staff noted that use of these discrete fields becomes mandatory on January 27th. While an average of 85% use the discrete fields in DonorNet now, once the fields become mandatory OPOs will have to answer for every donor whether test was performed, then report results using these fields. The presenter clarified that 'pending results' were donors waiting for test results back; at any point there may be some donors that fall in this category.

The DTAC identified that tracheal aspirate is labeled as upper respiratory in DonorNet but is generally considered to be a lower respiratory test. A member questioned whether the 30% of lung donors getting lower respiratory tests may be a higher proportion if tracheal aspirate was included; UNOS staff agreed to follow up. Note: in follow up, tracheal aspirate was only identified as an upper respiratory test in 14 cases that staff was able to identify (as attachments to donor records), indicating that the percentage of lung donors at 30% does not shift because of the classification of tracheal aspirate as an upper respiratory test. Tracheal aspirate has been corrected in DonorNet to be identified as a lower respiratory test.

A member asked whether any donors are not getting COVID testing and it was verified that testing is being completed for all donors. The presenter clarified that many of the tests were performed post-mortem and there was patient safety follow up indicating that no evidence of positive results. For a handful of donors with no testing, the OPTN Executive Committee followed up and it was determined that testing was performed, the error was in documenting the test. The presenter also clarified that data on the type of platforms being used (from different manufacturers) is not available.

A member suggested dividing the analysis by active and resolved infection; the presenter assented. Another member asked if the presenter could stratify the data analysis based on donors with two specimens tested, with an upper test positive and a lower negative. The presenter identified that this information is available in the donor record and the data could be stratified that way.

A member noted that a requirement to perform lower respiratory tests on all lung donors would be potentially onerous for members. An OPO member assented, saying that access to lower respiratory tests can be limited and many platforms don't take lower respiratory fluids to be analyzed.

3. DTAC COVID-19 Resource

The DTAC discussed the resource they are developing for the community regarding COVID-19.

Discussion:

The COVID-19 resource was developed with a workgroup that had representation from AST, ASTS, AOPO and HRSA for the purpose of having all the important stakeholders weigh in. The purpose is to have a quick reference based on current data regarding a topic important to everyone in the community. The DTAC discussed whether the resource would be appropriate as policy and agreed it wouldn't be. The resource was never intended to be policy, and given the limitations of current data and the changing nature of the COVID-19 era, a policy change is neither the intent nor appropriate.

The DTAC discussed the feasibility of COVID-19 testing within 72 hours of transplant. An OPO member noted that the 72 hour limit could lead to repeat testing, but is feasible. A member noted that time of transplant can be interpreted different ways. The workgroup identified that because of the lack of consensus on time of transplant, time of transplant wouldn't be further specified but left to community discretion.

The DTAC discussed the feasibility of lower respiratory tests for all lung donors. A member noted not everyone is able to get the lower respiratory test based on the platforms available. Another member noted the limited data does not support lower respiratory tests for all lung donors being an appropriate element of the resource at this time, but the DTAC could re-review as more data becomes available.

HRSA identified that the document should be reflective of being a summary of evidence in the framing of its content.

Next Steps:

The document will be reviewed to ensure its reflection as a summary of evidence.

Upcoming Meetings

- January 29, 2021 (teleconference)
- February 22, 2021 (teleconference)
- March 19, 2021 (teleconference)

Attendance

- **Committee Members**
 - Ann Woolley
 - Avi Agarwal
 - Charles Marboe
 - Debbie Levine
 - Gary Marklin
 - Heather Stevenson-Lerner
 - Helen Te
 - Jason Goldman
 - Kelly Dunn
 - Lara Danziger-Isakov
 - Marian Michaels
 - Meenakshi Rana
 - Raymund Razonable
 - Ricardo La Hoz
 - Saima Aslam
 - Stephanie Pouch
- **HRSA Representatives**
 - Christopher McLaughlin
- **CDC Staff**
 - Ian Kracalik
 - Jefferson Jones
 - Pallavi Annambhotla
 - Rebecca Free
 - Sridhar Basavaraju
- **UNOS Staff**
 - Abigail Fox
 - Amber Wilk
 - Cassandra Meekins
 - Courtney Jett
 - Craig Connors
 - David Klassen
 - Kristine Althaus
 - Laura Cartwright
 - Leah Slife
 - Nicole Benjamin
 - Roger Brown
 - Sandy Bartal
- **FDA Staff**
 - Brychan Clark
 - Scott Brubaker