

OPTN Ad Hoc Disease Transmission Advisory Committee

Meeting Summary

December 20, 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 12/20/2021 to discuss the following agenda items:

1. 6 month lower respiratory testing (LRT) report
2. Lung multi-drug resistance (MDR) Question
 - The following is a summary of the Committee's discussions.

1. 6 month lower respiratory (LRT) report

The Committee reviewed the 6 month monitoring report of the policy to require lower respiratory NAT testing for SARS-CoV-2 on all lung donors prior to transplant.

Data summary:

- Compliance with the lower respiratory testing requirement remains high.
 - Since implementation (5/27/21), 99.8% (N=1238/1240) of transplanted lung donors had LRT. The majority (99.1%) had LRT results reported in DonorNet on or before the day of lung transplant.
- Since implementation, 76 donors had a positive LRT.
 - 47.4% (N=36/76) of these donors had a negative upper respiratory test reported in DonorNet. LRT in these cases prior to transplantation may have prevented SARS-CoV-2 transmission to potential lung transplant recipients.
 - One donor with a positive LRT had lungs transplanted; comments in DonorNet indicate that this was believed to be a false positive based on results of confirmatory tests.
 - Non-lung organs are being recovered and transplanted from donors with a positive LRT.
- Lung utilization decreased from 17.9% in May to 14.8% in September, then increased to 16.6% in November.

Summary of discussion:

Overall the Committee reviewed that since implementation of the policy there has been an avoidance of reported transmission of COVID-19 positive lungs into recipients, with the potential to avoid transmission through the testing of LRT. The Committee discussed the impact of false positives on the results of the [monitoring report](#), specifically for Table #7 of the report. However, there are limitations to knowing if a reported test is a false positive due to the methods of data collection. A member noted multiple donors in the report with some tests that are positive and some negative, and expressed concern about the ability to understand the accuracy of the different testing methods. A member of the CDC countered that a CDC paper describes discordant results being an issue regarding test selections, test platforms flagged by FDA as having false positive or negative results. Another member agreed,

noting it's also expected to have some conversion in test positivity due to the etiology of the disease. The presenter noted that the available data precludes the ability to determine true positives or true negatives.

Next steps:

The policy will be assessed again at 9 months post-implementation.

2. Lung Multi Drug Resistance Definition

Data summary

The Lung Committee's Updating Mortality Models Subcommittee had a question come up related to data field to include specific microhistory/multi-drug resistant (MDR) organisms since they may preclude transplant transfer additional risk. In addition to PAN-R field which is already captured, Subcommittee supported including *Burkholderia cenocepacia* and *Mycobacterium abscessus*

- Possible data definitions for MDR/PAN resistant infection that would be effective for data entry?
- CF Registry: multidrug resistance defined as resistance to all antibiotics tested in two or more antibiotic classes in a single culture using the most resistant strain identified (which is only captured for *Pseudomonas* in CF registry)
- Current definition Unet: 'if the candidate has a history of pan-resistant bacterial lung infection prior to listing'
- Options: collect *B. cenocepacia* and *M. abscessus* only and remove question about MDR GNRs or – include question about MDR GNRs with CF registry definition understanding data may be less reliable
- Ultimate goal: identify candidates for whom it affects their waiting list mortality, to include in update to mortality models used for lung scores

Summary of Discussion

The Committee discussed options for more detailed definitions based on the specificity and accuracy that could be obtained, versus the challenges with more detailed definitions requiring higher degrees of expertise. There may be variation in expertise from lab to lab. The Committee also discussed how the modeling is being constructed. The modeling will be used for updating mortality risk and allocation prioritization associated. The takeaway from that discussion was to avoid getting too in the weeds with an overly specific definition when the people inputting the data may not be subject matter experts, so keeping a more general definition would be preferable.

Next Steps

The Committee will review a proposed definition to share with the Lung Committee by email, which defines MDR as at least one agent in three or more antimicrobial categories.

Upcoming Meeting

- January 24, 2022

Attendance

- **Committee Members**
 - Ann Woolley
 - Charles Marboe
 - Debbie Levine
 - Dong Lee
 - Gary Marklin
 - Gerald Berry
 - Helen Te
 - Kelly Dunn
 - Lara Danziger-Isakov
 - Raymund Razonable
 - Ricardo La Hoz
 - Sam Ho
 - Sarah Taimur
- **HRSA Representatives**
 - Marilyn Levi
 - Raelene Skerda
- **UNOS Staff**
 - Amelia Devereaux
 - Anne McPherson
 - Cole Fox
 - Courtney Jett
 - Elizabeth Miller
 - Sandy Bartal
 - Sarah Booker
- **CDC Staff**
 - Pallavi Annambhotla
 - Sridhar Basavaraju
- **FDA Staff**
 - Brychan Clark
 - Scott Brubaker