

Meeting Summary

OPTN Disease Transmission Advisory Committee Meeting Summary August 1, 2023 Conference Call

Lara Danziger-Isakov, MD, Chair Stephanie Pouch, MD, Vice Chair

Introduction

The OPTN Ad Hoc Disease Transmission Advisory Committee (the Committee) met via Citrix GoToMeeting teleconference on 08/01/2023 to discuss the following agenda items:

- 1. LRT Monitoring Report
- 2. DTAC Data Sharing
- 3. General Updates

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

1. LRT Monitoring Report

The Committee heard an update on the Lower Respiratory SARS-CoV-2 Testing lower respiratory tract (LRT) for lung donors: 2 years post-implementation monitoring report. The policy was implemented in May 2021. The policy was developed in response to evidence that upper respiratory testing alone poses patient safety risks to lung recipients. The policy aims to minimize the risk of donor-derived SARS-CoV-2 transmission to lung recipients without undue impact on the utilization of lungs or other organs. Additionally, the update included information on site survey compliance monitoring metrics.

Data summary (as applicable):

In the two years since implementation:

- 600 donors (2%) had a positive LRT.
- 14 lungs were transplanted from seven LRT-positive donors.
 - Kidney non-use rates from LRT-positive donors similar to overall non-use rates
 - Liver non-use rates from LRT-positive donors lower than overall non-use rates
 - o Heart utilization from LRT-positive donors similar to overall utilization
- Lung utilization by month ranged from 14.1- 18.8%
- There are no statistically significant differences in six-month post-transplant outcomes from kidney, liver, or heart recipients from LRT-positive donors

Summary of discussion:

Decision #1: The Committee agreed that the data presented showed the policy change for <u>Lower Respiratory SARS-CoV-2 Testing for Lung Donors</u> was successful.

A member asked if there was any data on lung survival. The presenter replied there have been seven transplants from LRT-positive donors since policy implementation for lungs, and no graft failures or patient deaths have been reported. Another member asked if the graft survivals are death censored or pure-graft survival. The presenter replied death censored; she explained that if the death were caused

by graft failure, it would be counted as death but not otherwise. The Chair commented that initially, there was a significant concern that this would negatively impact the use of donors after cardiac rest. However, that has not been the case; instead, there has been a slight increase in organ utilization.

The presenter noted that most of the policy violations occurred in 2022 with only one violation in 2023. Another member asked if the policy violations get reported to the MPSC. The presenter replied that policy violations are reviewed through routine monitoring with the site survey team. Site survey monitors policy violations through weekly automated reports and conducts individual program outreach when they identify errors. The member further inquired how a case would be handled if it resulted in a recipient infection. The presenter replied that there would be a patient safety investigation, and it would be handled appropriately. Another member asked if the Lung Donors would be required indefinitely. The presenter replied that the site survey team follows up with the policy based on how the policy is written. For example, if the policy were to change or the team sees high levels of compliance, they may not need to actively monitor it as much.

2. DTAC Data Sharing

The Committee heard a presentation on DTAC data sharing. The Chair emphasized that data can be shared in aggregate when the correct approval process is used.

Summary of discussion:

Decision #2: There were no decisions made by the Committee.

There were no further discussions.

3. General Updates

Staff provided the Committee with general updates.

Summary of discussion:

There were no further discussions.

Upcoming Meeting

August 28, 2023, 12pm ET, teleconference

Attendance

• Committee Members

- o Anil Trindade
- o Anna Hughart-Smith
- o Charles Marboe
- o Chelsea Weibel
- o Cindy Fisher
- o Dong Lee
- o Gerald Berry
- o Helen Te
- o Isabel Griffin
- o Lara Danziger-Isakov
- o Maheen Abidi
- o Marty Sellers
- o Pallavi Annambhotla
- o R. Patrick Wood
- o Riki Graves
- o Sam Ho
- o Sarah Taimur
- o Scott Brubaker
- Stephanie Pouch

• HRSA Representatives

o Marilyn Levi

SRTR Staff

o First Name Last Name

• FDA

o Brychan Clark

UNOS Staff

- o Krissy Laurie
- o Laura Schmitt
- Sandy Bartal
- o Sarah Booker
- o Tamika Watkins
- o Taylor Livelli

Other Attendees