OPTN Heart Transplantation Committee
Meeting Summary
September 21, 2021
Conference Call

Shelley Hall, MD, Chair
Richard Daly, DO, Vice Chair

Introduction

The Heart Transplantation Committee met via Citrix GoTo teleconference on 09/21/2021 to discuss the following agenda items:

1. Ad Hoc Multi-Organ Transplantation (MOT) Committee – "Metabolic Disease Diagnoses Categories"
2. Lung Transplantation Committee presentation: Establish Continuous Distribution of Lungs
3. Membership and Professional Standards Committee (MPSC) presentation: Enhance Transplant Program Performance Monitoring System
4. For consideration: Potential emergency policy actions to address transplant hospital capacity?

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

1. Ad Hoc Multi-Organ Transplantation (MOT) Committee – "Metabolic Disease Diagnoses Categories"

The Committee was asked for feedback on whether or not it was appropriate to omit the "metabolic disease" diagnosis category from the proposed eligibility criteria in simultaneous heart-kidney (SHK) allocation.

Summary of discussion:

The Chair has not seen a patient who would fall within the heart-kidney classification and shared that this policy language is a reflection of what exists in the simultaneous liver-kidney (SLK) policy, but it may not apply to heart. A member asked about how it may apply to patients with combined amyloid and would need a heart-kidney transplant on that basis. Another member noted that there are a number of those cases being done with success compared to non-amyloid heart transplants. An attendee stated that based on the recently published SLK data there were two candidates listed under the metabolic disease category and suggested it be included for heart. A member agreed and mentioned that there are a few rare mutations where you would want it as an option for multi-organ transplant. The Committee supported leaving the "metabolic disease" diagnosis category for SHK eligibility criteria.

2. Lung Transplantation Committee presentation: Establish Continuous Distribution of Lungs

The Lung Transplantation Committee Chair presented the Lung Committee's public comment proposal *Establish Continuous Distribution of Lungs.* The proposal is part of a larger effort to align all organs in a smarter allocation system and aims to align lung with community, ethical, and regulatory goals and medical advancements. Continuous distribution will move allocation from classification groups with hard boundaries to consider individual candidates holistically and the attributes in the proposal are based on feedback provided from the many aspects (community exercises, modeling, etc.).

Summary of discussion:

The Chair mentioned that there is a heavy emphasis in the discussions with the MOT Committee that heart-kidney allocation criteria match liver-kidney allocation and wanted to know if the cutoffs presented would need to match across organ types. The Lung Chair felt that those criteria could be re-reviewed and that the cutoff of a composite allocation score (CAS) of 28 is not necessarily what needs to happen in the future when all organs are in continuous distribution. The Chair also noted that some of the attributes proposed for lung will not apply to heart, such as height, and the Lung Chair clarified each organ will be deciding which factors should be included in their continuous distribution.

A member mentioned that they have a hard time seeing how travel efficiency weighting is the same as the weighting for candidate biology and the Lung Chair clarified that clear data related to placement efficiency is not available, but wanted to give credit for travel in the CAS. The Lung Chair also stated that lungs that are flying will fly longer distances, but less often, and will be pulled by factors such as medical urgency and high sensitization so those factors will add together to place those candidates higher on the match. The Vice Chair asked for clarification on travel when driving versus flying with having a hard cutoff at 75 nautical miles noting that 80 nautical miles is very different than a thousand nautical miles. The Lung Chair clarified that there is a steep curve for sensitization, but it is a linear curve for travel so 80 nautical miles would get more points than a thousand nautical miles, but the Lung Committee needed an idea of where centers would be driving versus flying. A member asked if there was any plan in the future to correlate travel with cold ischemic time and the Lung Chair stated that the data for cold ischemic time in lungs is mixed so did not find to be a good reference. The Chair noted inclusion of travel was also to acknowledge the rising costs for traveling. The Lung Chair shared that feedback from organ procurement organizations (OPO) included concern over inefficiencies in the system they are facing, but stated these are system inefficiencies that should not necessarily be incorporated in the allocation system.

A member inquired if a pediatric candidate would be likely to accept an offer for adult lungs and the Lung Chair clarified that currently age limits can be set for the donors. While pediatric donors preferentially go to pediatric recipients, the presenter pointed out that an 18-year-old donor is not very different from a 17-year-old donor. The Lung Chair acknowledged that a pediatric program would likely not accept lungs from a 60-year-old donor, but the pediatric points should be placing most pediatric candidates at the top of a match for pediatric donor offers.

3. Membership and Professional Standards Committee (MPSC) presentation: Enhance Transplant Program Performance Monitoring System

An OPTN Membership and Professional Standards Committee (MPSC) member presented the public comment proposal *Enhance Transplant Program Performance Monitoring System*. The MPSC currently uses one metric to identify underperforming transplant programs, which is one-year post-transplant patient and graft survival. The proposed metrics aim to create a more holistic review of transplant program performance, identify real time patient safety concerns, continue to expand support and collaboration with transplant programs, and promote equitable access and increase the number of transplants.

Summary of discussion:

The Chair asked if program volumes are taken into account or if that was left to CMS minimums, and the presenter clarified that the only volumes taken into account for this proposal are the number of transplants and associated hazard ratios. The MPSC member also noted that it is helpful for a program to keep their volumes up even if they are flagged.

The Vice Chair expressed concern over not having enough granularity regarding offer acceptance filters and without it patients may be disadvantaged. The presenter mentioned that the new offer acceptance filters are available in the data portal for members to try out and those seem much more granular, however, it was clarified that the new filters are being rolled out in stages with kidney having those available first. The MPSC member also explained that there is no competition among programs, more simply, a program's observed needs to match their expected and it only matters that programs are doing what they are supposed to be doing. The presenter continued that programs should be honest with themselves about which organs they are likely to accept. The presenter noted that continued education may be helpful because turning down an organ that is not expected to be utilized only adds incrementally to a program's denominator, but if one of those is accepted it adds to the numerator and essentially cancels out the offers that were declined. A member mentioned that offer acceptance is the impetus to give more flexibility in some of the offer acceptance filters since qualities such as the type of donor and donor height/weight cannot be specified, so the changes in performance monitoring may give the Committee capacity to add more flexibility.

Another member expressed concern for the addition of another metric that adds another element of stress to the system and asked for clarification on the overall goal of the addition. The MPSC member stated that the OPO community is experiencing difficulty and to not hold transplant programs accountable for a minimal threshold is not appropriate. A member mentioned that what acceptance percentage is based on may be less of an issue, but this metric could potentially push programs to take risks they might not normally take which could be detrimental to patients. The MPSC member clarified that programs have the most control over this metric and noted that the heart community performs very well in the current system. Another member stated this is creating another layer of regulation, which is stressful even if it seems like heart programs should still perform well. The Chair mentioned that the reality is that the transplant metrics are changing and the community requested the change. The Committee was encouraged to submit their thoughts through public comment so they can be heard and considered.

4. For consideration: Potential emergency policy actions to address transplant hospital capacity?

The Chair requested the Committee's feedback regarding the consideration of a potential emergency policy action to address transplant hospital intensive care unit (ICU) capacity. Currently, many programs have seen an influx of COVID-19 patients, which is leading to 60-100 percent capacity in transplant hospital ICUs. The Committee was asked if they are experiencing capacity issues and if they should pursue some type of emergency policy action to allow for more leniency in where transplant candidates are being hospitalized.

Summary of discussion:

A member asked if this would be a policy change or if this would be a statement put out with an allowance for such exceptions. It was clarified that what might be considered is flexibility around how the policy language is written around the heart statuses without using exception language. A member asked for clarification on whether or not the transplant would still occur at the transplant hospital and the Chair stated that the transplant candidates would be laterally transferred to the transplant hospital. The member also asked if the satellite hospital would be considered equivalent to the transplant hospital and suggested surveying other programs to see how likely this is to be an option. A member stated that their program has been hit harder by the Delta variant, so they are experiencing capacity hardships and another member agreed, but stated this may be difficult to define and suggested any action be temporary. The Chair also stated that the candidates would still need to be ill enough and qualify for the given status. A member asked if the patient needs to be at the transplanting hospital currently, and it was clarified that when listing a candidate you have to indicate that they are at the

transplanting hospital. Another member suggested looking into how these situations were handled for natural disasters such as post-Hurricane Katrina.

Upcoming Meetings

- October 6, 2021 (Virtual In-Person)
- October 19, 2021

Attendance

- **Committee Members**
  - Shelley Hall, Chair
  - Rocky Daly, Vice Chair
  - Adam Schneider
  - Amrut Ambardekar
  - Cindy Martin
  - Cristina Smith
  - David Baran
  - Jose Garcia
  - Hannah Copeland
  - Jennifer Carapellucci
  - Jonah Odim
  - Jondavid Menteer
  - Kelly Newlin
  - Mike Kwan
  - Arun Krishnamoorthy
  - Nader Moazami
- **HRSA Representatives**
  - Raelene Skerda
- **SRTR Staff**
  - Katie Audette
  - Yoon Son Ahn
  - Monica Colvin
- **UNOS Staff**
  - Chris Reilly
  - Keighly Bradbrook
  - Sara Rose Wells
  - Eric Messick
  - Krissy Laurie
  - Laura Schmitt
  - Leah Slife
  - Sally Aungier
  - Sharon Shepherd
  - Susan Tlusty
  - Elizabeth Miller
- **Other Attendees**
  - Erika Lease
  - Richard Formica