

## **OPTN Lung Transplantation Committee**

### **Meeting Summary**

**June 16, 2022**

**Conference Call**

**Erika Lease, MD, Chair**

**Marie Budev, DO, Vice Chair**

### **Introduction**

The Lung Transplantation Committee (the Committee) met via Citrix GoTo teleconference on 6/16/2022 to discuss the following agenda items:

1. Multi-Organ Allocation Threshold in Continuous Distribution
2. Updating Mortality Models
3. Next Steps and Closing Comments

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

#### **1. Multi-Organ Allocation Threshold in Continuous Distribution**

The Committee was informed that the composite allocation score (CAS) threshold of 28 that they chose for heart-lung, lung-liver, and lung-kidney candidates in continuous distribution would capture a smaller percentage of those candidates than what was originally intended.

The original intent of the Committee was to choose a threshold that captured about 95 percent of those who previously received lung multi-organ transplants. Based on recent analysis, it was found that the CAS threshold of 28 would only capture about 76 percent of MOT recipients; however, a CAS threshold of 26 would capture about 90 percent and a threshold of 25 would capture about 95 percent of multi-organ transplant (MOT) recipients.

Given the original intent of the CAS threshold, the Committee was asked to discuss revising the CAS threshold for heart-lung, lung-liver, and lung-kidney candidates in continuous distribution.

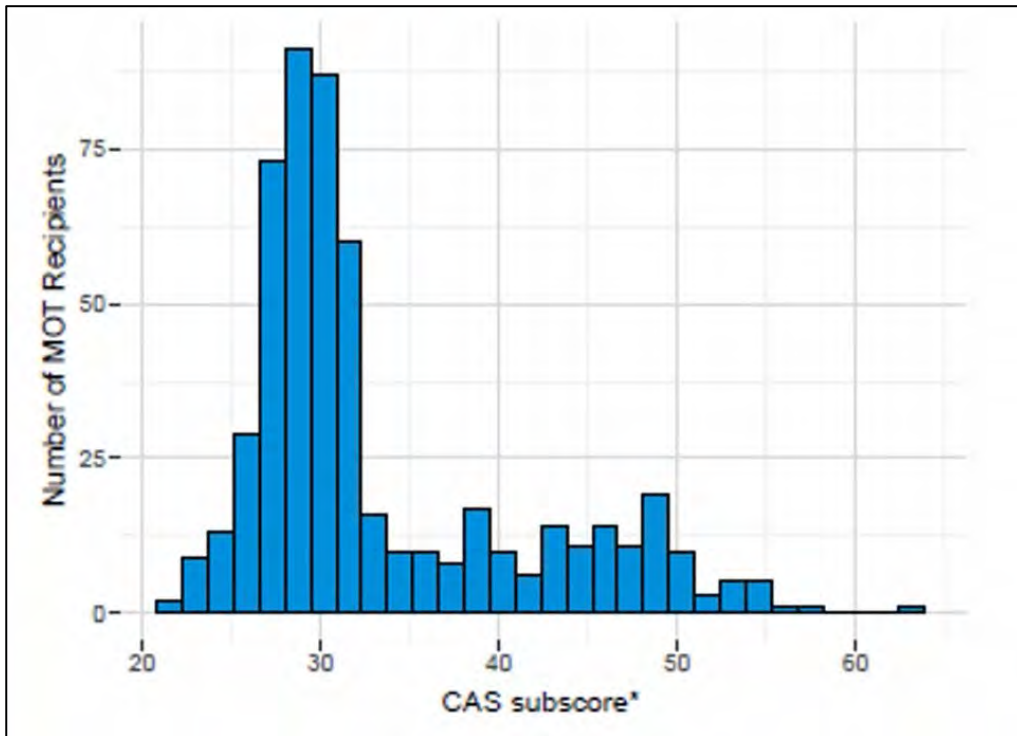
#### Summary of discussion:

A member stated that a score of 25 seems like a low score. The Chair explained that Figure 1 is showing the distribution of the CAS and the threshold of 25 is relatively on the lower side; however, this is only for the MOT candidates.

A member inquired if this data looks at all the patients in the past few years who have had MOT transplants with lung and calculates a CAS for them. So, this shows the distribution over the past however many years of actual patients and, if the Committee wants to capture 95 percent of lung MOT recipients, they need to reset the CAS threshold to 25 instead of 28. The Chair stated that that is correct.

A member stated that the MOT patients look to be the least sick in the graph of the distribution. The Chair clarified that this is the distribution only for MOT candidates, not all candidates. Staff stated that the distribution for all lung candidates is not radically different.

Figure 1: Distribution of the CAS Sub-score among MOT recipients who received their MOT transplant from a lung match. Uses distance to allocated organ.



A member stated, based on converting the lung allocation score (LAS) to a CAS, it appears these dual organ patients are low scoring lung severity patients. Staff clarified that CAS includes other components than just solely LAS, so it is not comparable with LAS.

The Chair also stated that the distribution includes what the recipient’s placement efficiency score would be. Staff stated that they used distance to the organ that the patient was allocated and that allowed them to get a sense of what the patient’s placement efficiency would be. The two components that this distribution does not include are calculated panel reactive antibodies (CPRA) and prior living donors because those variables were not being collected.

A member mentioned that this graph is hard to interpret because there is not a standard that is comparable. The member suggested that it may be helpful to include standard LAS patients with their different risk profiles compared to the CAS. The member noted that this seems nuanced because the Committee wants to understand where these MOT patients are going to sit on a continuum of risk with the non-MOT patients.

The Chair emphasized that, when the Committee looked at data for the CAS threshold of 28, the distribution was still on the lower end; however, the Committee didn’t want to disadvantage the MOT patients, who make up a very small number of lung transplants each year. The Chair also emphasized that the Committee wanted to capture 95 percent of those MOT candidates in the CAS threshold, and that was supported by the OPTN Heart Transplantation, Liver and Intestinal Organ Transplantation, and Kidney Transplantation Committees. The Chair explained that the Committee is not rehashing the intent of the CAS threshold, they would just be revising the threshold to better align with their current intent. Once all the other organs transition to continuous distribution, the Committee will have a better way to make these comparisons.

A member agreed and stated that this should be an easy adjustment for the Committee since they are not really changing anything.

Staff stated that if the Committee approves changing the CAS threshold to 25, then this proposal can go out for August 2022 Public Comment, to the Board of Directors in December 2022, and can be included in the implementation of lung continuous distribution.

A member mentioned that, generally, the good quality hearts have a lot of cold ischemic time by the time they can be allocated to heart-lung candidates, so there may still be some struggle with heart-lungs until the Committee comes up with a better system.

A member noted that heart is going to start transitioning to continuous distribution last. The member stated that data has been requested to look specifically at heart-lung, Status 3, and Status 4 candidates. Staff stated that they will reach out to those who are working on that and will follow-up when they have more information.

The Committee reviewed the proposed modifications to policy language and voted on sending this proposal to public comment in August 2022. The Committee unanimously supported sending this proposal to public comment.

## **2. Updating Mortality Models**

The Committee finalized data collection for the following items in the Updating Mortality Models proposal, which is slated to go out for August 2022 Public Comment:

- Supplemental oxygen (O2)
- Assisted ventilation
- Exacerbations – distinct definitions based on diagnosis: ILD, CF, COPD
- Microbiology
- Massive hemoptysis
- Data element removals
- Serial data collection
- Policy language

The Committee was also informed that six-minute walk will be addressed in a separate proposal.

### Summary of discussion:

The following is a summary of the Committee's discussion:

#### *Supplemental oxygen (O2)*

Staff inquired if the drop-down list of delivery devices for supplemental O2 should include an option for extracorporeal membrane oxygenation (ECMO). The Chair stated that ECMO would not be included because capturing whether a patient is on ECMO is not about oxygen delivery; however, it would be important for the transplant coordinator to enter the patient's oxygen delivery device as continuous mechanical ventilation or nasal cannula. Staff clarified that ECMO will be included in assisted ventilation and excluded as an option for supplemental O2, but if ECMO patients are also on a ventilator then the coordinator can select continuous mechanical ventilation.

A member inquired about the device that should be selected if a patient is on high flow or a reservoir. The Chair stated that all the options for oxygen delivery devices, except ECMO, would be available.

Staff inquired if there needs to be any limits on what can be selected in the supplemental O2 or assisted ventilation fields. Members agreed that coordinators should be allowed to input any combination.

### *Assisted Ventilation*

A member inquired if information will still be collected on the ventilation settings, but not ECMO settings. The Chair stated that that is correct –ECMO settings will not be collected in this proposal and the ventilation settings will be the fraction of inspired oxygen (FiO2), whether the patient is ventilated or just requires oxygen.

The Chair stated that effectively, even if patients on ECMO are not mechanically ventilated, they will get the 100 percent score for mechanically ventilated until the Committee changes that in the future.

A member stated that the more common scenario for ventilation and ECMO is using high flow O2 with venovenous (VV) ECMO. The member inquired if the Committee plans to add this into the data collection. The Chair stated that if the patient was on high flow O2, then the response would be “ECMO – VV not mechanically ventilated” and then high flow would be input under the oxygen delivery devices, along with the patient’s settings.

A member inquired if liters per minute (L/min) or percent would be collected for patients on high flow. The Chair stated that both L/min and percent could be entered, and the patient would get the benefit from the highest score, regardless of entering both.

### *Exacerbations*

A member inquired if the Committee wanted to specify in the chronic obstructive pulmonary disease (COPD) definition that it required treatment. The Chair stated that they had presumed that but would be alright with including it in the COPD definition.

A member inquired if the Committee should standardize the definitions for COPD, interstitial lung disease (ILD)/idiopathic pulmonary fibrosis (IPF), and cystic fibrosis (CF). A member inquired if the standardized definition will be based off society guidelines or does something else needed to be added, for example adding treatment to the COPD definition. The Chair emphasized that the COPD definition is based on the American Thoracic Society (ATS) definition.

A member stated that they thought about standardizing the definition for IPF. The member noted that there are recommendations from the International Society for Heart and Lung Transplantation (ISHLT) regarding when physicians should refer patients for transplant and clear definitions of rapid decline. A member stated that they were referring to the new ATS guidelines.

The Chair inquired if the Committee was considering using the ATS guidelines for the ILD/IPF or COPD definition. A member stated that the definition of ILD is challenging. The way it is currently written allows physicians to make the call if a patient has an exacerbation, whether the patient is in-patient or out-patient. The member stated that that is a simple definition; however, patients who have recurrent exacerbations or one severe exacerbation do poorly. The member stated that, if the intent of these definitions is to capture data that will potentially optimize the composite allocation score (CAS) for these patients in the future, then the definitions are missing the clinical phenotype of recurrent exacerbations that gets worse with ILD. A member inquired if the Committee should keep the ILD/IPF definition open-ended or define it even more.

The Chair stated that they understand wanting to get the best data possible, but they would caution the Committee against making the ILD/IPF definition too strict because that could potentially cause confusion. The Chair mentioned that they would like to be able to rely on a center to determine and document if a patient is having an exacerbation.

A member stated that, since the Committee is collecting this data for future iterations of the CAS, they would like to use hard definitions. The member noted that there could be an ability to game the system

if centers know that they can label their patient as having an exacerbation and that will increase the patient's CAS. The member suggested clarifying the definitions because, as the ILD/IPF definition is now, it may lead to junky data that is not very helpful.

A member noted that the ILD/IPF definition includes "leads to a significant decline in lung function" and inquired if that would also include an increase in supplemental O2 use. A member agreed with that point and suggested including "sudden worsening in exercise capacity" or "increase in oxygen needs from baseline" since the classic indicators of ILD progression are already captured.

A member also inquired what would be considered a "significant decline" for the ILD/IPF definition. The member suggested changing the language to "a delta change decline in lung function, supplemental O2 use, exercise, endurance, or six-minute walk".

A member stated that, looking through ATS guidelines, exacerbations is not clearly defined. The Chair inquired if the Committee is recommending adding "sudden acceleration of disease or acute injury that leads to a significant decline in lung function, an acute increased need for oxygen, hospitalization, or requiring treatment" to the ILD/IPF definition or would the Committee only want to capture those patients that have to be hospitalized.

A member mentioned that they aren't sure how this additional information in the definition is going to be helpful aside from capturing the hard data since patients experiencing IPF exacerbations rarely go home afterwards.

Staff mentioned that the Committee can also include the ILD/IPF exacerbation definition as a public comment question, which would allow the community to provide feedback and give the Committee more time to refine the definition before the proposal goes to the Board of Directors. Members liked the idea of including it as a question.

A member also noted that defining COPD and CF is important because they are markers of disease severity that centers use when determining whether to list a patient for transplant. A member mentioned that sometimes, when patients are experiencing ILD/IPF exacerbations, there isn't the chance to do pulmonary function tests (PFT) or capture the drop in the patient's forced vital capacity (FVC) or first forced expiratory volume (FEV1). A member stated that that makes sense, but one would think that pulmonary hypertension and oxygen would drive the patient's score up.

The Chair inquired how the Committee would feel about adding "required treatment" to the CF exacerbation definition, like what was added to COPD. Members agreed that sounded reasonable.

### *Microbiology*

The Committee was asked to discuss the timeframe that should be captured for history of infection: should the Committee collect history of infection within the last 12 months or more than 12 months ago?

A member stated that they look within the last 12 months and the longer the period is that the organism has not grown the more comfortable they feel. The member emphasized that it is at least a year though.

A member also suggested adding "*Scedosporium/Pseudallescheria* species complex" to the list of organisms.

The Chair mentioned that they agree the timeframe needs to be at least the last 12 months. A member stated that that timeframe makes sense if centers are routinely checking cultures. The Chair stated that transplant centers are graded on whether they collect their cultures.

A member inquired if the Committee had talked about grouping the timeframes. For example, zero to 12 months and then if ever. The Chair stated that in the mockup it includes history of infection within less than a year or more than a year. Committee members thought that that was reasonable.

A member inquired if it is important for the surgeon to know that the infection had been 24 or 36 months ago. The Chair stated that with some of the slow growing organisms, even at a year without infection it still makes them a little nervous to say the patient is completely clear; however, members agreed that as long as the patient is a year post-infection, then they are comfortable performing transplants.

#### *Serial Data Collection*

Members stated that they agree with the PFT serial data collection.

#### *Policy language*

A member stated that, at a previous meeting, the Committee talked a lot about the FiO<sub>2</sub> and liter flow for patients that are on heated high flow. The member stated that the Committee had determined that they would allow higher liter flows to be entered and inquired how the Committee is going to interpret that. The Chair stated that, when both L/min and percent are entered, the percent will be reconverted back to L/min and the patient will use whichever one gets them the highest score until the Committee gets more data.

The Committee voted on sending this proposal to public comment in August 2022. The Committee unanimously supported sending this proposal to public comment.

### **3. Next Steps and Closing Comments**

The Committee recognized those members rolling off the Committee and thanked them for all their contributions.

#### **Upcoming Meeting**

- July 21, 2022

## Attendance

- **Committee Members**
  - Erika Lease, Chair
  - Marie Budev, Vice Chair
  - John Reynolds
  - Julia Klesney-Tait
  - Errol Bush
  - Cynthia Gries
  - Denny Lyu
  - Nirmal Sharma
  - Marc Schechter
  - Kelly Willenberg
  - Staci Carter
  - Soma Jyothula
  - Dan McCarthy
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
  - David Schladt
- **UNOS Staff**
  - Kaitlin Swanner
  - Rebecca Brookman
  - Krissy Laurie
  - Sara Rose Wells
  - Tatenda Mupfudze
  - Susan Tlusty
  - Holly Sobczak
  - James Alcorn
  - Janis Rosenberg
- **Other Attendees**
  - Laurel Avery
  - Dave Weimer
  - Matt Hartwig
  - Stephen Huddleston
  - Serina Patrick