OPTN Lung Transplantation Committee
Meeting Summary
August 20, 2020
Conference Call

Erika Lease, MD, Chair
Marie Budev, DO, Vice Chair

Introduction

The Lung Transplantation Committee met via Citrix GoTo teleconference on 08/20/2020 to discuss the following agenda items:

1. Multi-Organ Policy Review Workgroup Update
2. Transplant as a Result of COVID-19
3. Biological Disadvantages/Equity Rating Scales

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

1. Multi-Organ Policy Review Workgroup Update

The Chair of the Multi-Organ Policy Review Workgroup (WG Chair) presented an update on the workgroup's progress.

Summary of discussion:

The WG Chair outlined the proposed recommendations for lung-liver allocation:

- Lung-liver candidates with a lung allocation score (LAS) greater than 35 should also receive the liver if the lung-liver candidate is within 500 nautical miles (nm)
- For candidates within 500 nm with LAS less than 35, the liver should be allocated alone to Status 1A, 1B, Model for End-Stage Liver Disease (MELD)/Pediatric End-Stage Liver Disease (PELD) 35 or higher candidates prior to allocating to other lung candidates
- If there are no candidates with LAS greater than 35 or Status 1A/1B, MELD/PELD 35 or higher, then the organ procurement organization (OPO) determines the next steps and allocates according to organ-specific policies

The Chair said that, logistically, the liver is often already allocated by the time it is determined whether the lung is suitable for transplant. The Chair asked if there will be guidance about how an OPO should handle the situation if an offer is made for a liver, and then an offer is made for a lung, and then it turns out that a lung-liver candidate is the most suitable recipient. The WG Chair said that the offer made for the liver could not be pulled back. However, the proposed policy language would require the liver to be allocated with the lung out to 500 nm, whereas the current policy requirement only extends to the donation service area (DSA).

The WG Chair said that other committees seem to support the proposed changes. The workgroup sees a need for clarification because there is no consistency across OPOs as to whether the liver is offered. The workgroup plans to address heart-kidney and lung-kidney allocation in the future.

A member asked how one would determine if a heart-liver candidate is sicker than a lung-liver candidate, and why heart-liver candidates would be prioritized over lung-liver candidates. The WG Chair

said that the workgroup prioritized heart-liver candidates because they are a larger population than lung-liver candidates. The member noted that heart candidates have left ventricular assist devices (LVAD) as a mechanical support option, whereas lung candidates do not have good mechanical support options like LVAD for heart or dialysis for kidney. The member it seems like the heart-liver candidates would get all the offers before the lung-liver candidates, who are often sicker, so it may make more sense to prioritize the lung-liver candidates.

Next steps:

The WG Chair will share the Lung Committee's feedback with the workgroup.

2. Transplant as a Result of COVID-19

The Chair led the Committee in a discussion of lung transplants as a result of COVID-19. In the U.S., there have been at least five lung transplants performed due to COVID-19 related lung damage. Currently, nothing in the candidate listing indicates if a patient is listed due to COVID-19. The Chair proposed adding two new diagnosis codes in diagnosis group D: "COVID-19: Acute Respiratory Distress Syndrome (ARDS)" and "COVID-19: pulmonary fibrosis." The Chair asked the Committee for feedback.

Summary of discussion:

Members agreed that the OPTN needs to collect this information, especially since there are a lot of unknowns regarding when to transplant, and what recovery looks like. Members agreed with pursuing an expedited approach with this policy.

Members discussed whether the proposed diagnosis codes adequately capture the populations of candidates impacted by COVID-19. Members agreed with including these candidates in diagnosis group D, and agreed that multiple diagnosis codes are appropriate, rather than one general "COVID" code.

The member said there are three groups of patients: (1) people with mild to moderate lung disease who get COVID-19 and recover, (2) people who have underlying fibrosis and get COVID-19 and never recover, and (3) people who have fulminant lung damage as a result of COVID-19. The Chair said the proposed diagnosis codes would not capture candidates who had chronic obstructive pulmonary disease (COPD) or idiopathic pulmonary fibrosis (IPF) that was later exacerbated by COVID-19 infection. The Chair asked if the Committee would advocate listing these candidates differently than by their underlying diagnosis.

A member asked how a transplant program would list a candidate who has COPD, gets COVID-19, and recovers. The member asked how the Committee can ensure that programs are not gaming the system, and suggested that the Committee develop a clear definition to ensure that programs list candidates appropriately. A member suggested following a similar approach as for influenza patients, for whom transplant programs must consider whether they had pre-existing lung disease and the viral infection worsened their condition, or if their condition is really a product of viral infection. A member recommended defining the acute COVID/ARDS and COVID/pulmonary fibrosis diagnosis codes as pertaining to patients with no prior history of lung disease. Members agreed that if the candidate has underlying lung disease, then that disease should be listed as the candidate's primary diagnosis, and acuity and likelihood of mortality will be reflected in the candidate's LAS.

The Chair asked how to list a candidate who has very mild COPD but is infected with COVID-19, and has primarily COVID-related lung failure. A member said that this is no different from an influenza patient that does not recover and goes on to transplant. A member noted that any patient who gets ARDS is on ECMO so they are extremely sick, so their underlying condition does not reflect their medical urgency in their current state. A member agreed, that in some cases it is not the underlying condition that led them to need a transplant, but it was the COVID-19 infection. SRTR staff noted that in influenza cases, if a

candidate had asthma but developed ARDS, then the candidate would be listed for ARDS. The diagnosis categories are designed based on risk of mortality.

A member asked how to list a candidate who has COPD, recovered from COVID-19, but is now in a worse state because of COVID-19 infection. Members said that the candidate would still be in diagnosis group A but with worse clinical data indicating the progression of their disease. The Chair noted that if a transplant program feels that a candidate's listing with a diagnosis of COPD does not reflect the extent of the candidate's illness, then the program can request an exception from the Lung Review Board. A member noted that a secondary diagnosis could always be reported as well.

A member asked if the LAS would be the same for COVID and non-COVID patients. The Chair affirmed that the candidates would have the same scores under the COVID diagnosis codes as if they were listed for ARDS or pulmonary fibrosis. SRTR staff said that if the number of candidates listed due to COVID-19 is large enough, they will be able to analyze the predictive power of the diagnosis. A member noted that COVID-19 candidates will get more medical urgency points if they are on extracorporeal membrane oxygenation (ECMO) or another form of mechanical ventilation, so they will be stratified differently from other candidates based on the severity of their disease.

A member asked if there are granular data on prior post-viral etiologies that led to transplant that could inform this discussion. The Chair said that from an OPTN standpoint, these data are not available because candidates are listed with a diagnosis of ARDS, rather than the cause of ARDS.

A member said that since the goal is primarily to capture COVID-19 data, it might be best to add a dropdown menu under the ARDS and pulmonary fibrosis diagnoses to ask whether or not the diagnosis is COVID-19 related. The member noted that this data is not collected for other viruses like influenza and it is not clear how long the OPTN would need to collect data on COVID-19. The Chair said that Lung Committee leadership walked through several options with UNOS staff and felt that the proposed diagnosis codes would be the clearest way to collect this data, as well as easiest to implement.

The Lung Committee voted to approve this policy change (15-yes, 0-neutral/abstain, 0-no).

Next steps:

The proposal will go to the Policy Oversight Committee and the Executive Committee for approval and release for a special public comment period from 08/31/2020 to 10/01/2020. Following public comment, the Lung Committee will vote on the proposal and seek approval from the OPTN Board of Directors during their meeting on 10/08/2020.

3. Biological Disadvantages/Equity Rating Scales

The Chair and UNOS staff outlined an approach for incorporating biological disadvantages into an equity rating scale accounting for sensitization, blood type, and candidate size. This rating scale was described in detail during the 08/13/2020 Continuous Distribution Data Workgroup meeting.[1]

Summary of discussion:

An attendee asked how a five-year-old candidate would score on this rating scale. UNOS staff said the candidate would likely receive a lot of points because the candidate would be very short. The candidate would also receive points based on blood type and sensitization, points for being a pediatric candidate, and points based on waitlist mortality and post-transplant survival. The attendee said this is an

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[1] OPTN Continuous Distribution Data Workgroup Meeting Summary, August 13, 2020.
https://optn.transplant.hrsa.gov/media/4046/20200813_lung_continuousdistributiondataworkgroup_meeting-summary.pdf

interesting surrogate for how children under age 12 are currently prioritized over older donors, since their pool of potential donors is smaller largely based on the criteria accounted for by this rating scale. The attendee said this might be an adequate surrogate for current policy that pushes organs to younger candidates over adolescents as long as the weighting is comparable to the current system.

A member asked whether the dataset represents all potential donors or just the donors whose lungs were transplanted. The member explained that if there were ten potential donors for small children, but there was only one small child on the waiting list who received a transplant, then it would look like there was only one donor size-matched for the recipient. UNOS staff affirmed that the dataset only represents those that were transplanted, and said that looking at all solid organ donors, whether or not the lungs were recovered, could possibly adjust for that effect. The member said the proposed approach is probably the right starting point, since solid organ donors that do not donate lungs, but it may be important to pay attention to this moving forward. Because the recipient pool is small, it is possible that the data overestimates the number of incompatible donors based on height and it may need to be adjusted over time.

A member agreed that size matters per diagnosis, since the restriction or obstruction affects the size of the lungs that can be accepted for that candidate, and asked if the OPTN collects data about chest cavity size or just height. UNOS staff affirmed that the OPTN only collects height, so this approach uses height as a proxy for chest cavity size.

A member asked if these data have been broken out by sex. Transplant programs take sex into account when evaluating donor-recipient pairs, since female lungs are smaller than male lungs by 20% on average. The member asked if this will affect women differently than men, outside of the height difference. UNOS staff did not look at the data by sex, and asked if the Committee would expect there to be different number of height-compatible donors for women and men of the same height. The member affirmed that since women have smaller chest cavities, it seems likely that a short woman would have fewer potential donors than a short man, even if they are the same height. An attendee said that UNOS staff have to identify what proportion of male donors could match with a male candidate, and what proportion of female donors could match with that male candidate, and then figure out those proportions for a female candidate. UNOS staff will have to convert these proportions to height ranges, and then reconstruct the rating scale. A member noted that age of the donor also plays a factor, since an older donor tends to have more space in the chest cavity than a younger donor.

UNOS staff said that height was selected for the rating scale to avoid the more complicated approach of developing a height-matching equity rating scale, as it can get very complicated very quickly with all of these different factors. UNOS staff asked if the proposed approach for incorporating height is better than the current system, with the idea that it could be improved over time. Members agreed that the proposed rating scale is better than the current system and an appropriate place to start for incorporating height into the continuous distribution framework.

Next steps:

UNOS staff will evaluate how sex impacts the probability of available donors by height.

Upcoming Meetings

- September 10, 2020 – Continuous Distribution Data Workgroup
- September 17, 2020 – Lung Committee

Attendance

- **Committee Members**
  - Erika Lease, Committee Chair
  - Marie Budev, Committee Vice Chair
  - Alan Betensley
  - Whitney Brown
  - Staci Carter
  - Ryan Davies
  - June Delisle
  - Cynthia Gries
  - Julia Klesney-Tait
  - Jasleen Kukreja
  - Denny Lyu
  - Dan McCarthy
  - John Reynolds
  - Marc Schecter
  - Nirmal Sharma
  - Kelly Willenberg
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Yoon Son Ahn
  - Katie Audette
  - Melissa Skeans
  - Maryam Valapour
- **UNOS Staff**
  - James Alcorn
  - Rebecca Brookman
  - Julia Chipko
  - Craig Connors
  - Rebecca Goff
  - Elizabeth Miller
  - Amanda Robinson
  - Janis Rosenberg
  - Darren Stewart
  - Kaitlin Swanner
  - Susan Tlusty
  - Sara Rose Wells
- **Other Attendees**
  - Jarrod Dalton
  - Mindy Dison
  - Kurt Shutterly
  - Stuart Sweet