**OPTN Lung Transplantation Committee**
**Meeting Summary**
**January 21, 2021**
**Conference Call**

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

**Introduction**

The Lung Transplantation Committee met via Citrix GoTo teleconference on 01/21/2021 to discuss the following agenda items:

1. Public Comment Presentation: *Clarify Multi-Organ Allocation Policy*
2. Sorting/Tiebreakers
3. Clinical Value Update Schedule

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

**1. Public Comment Presentation: *Clarify Multi-Organ Allocation Policy***

The Vice Chair (VC) of the Organ Procurement Organizations (OPO) Committee presented the proposal *Clarify Multi-Organ Allocation Policy*, which would establish when OPOs allocating according to the heart or lung match run would be required to offer the liver and kidney from the same donor.

Summary of discussion:

A member asked which candidate would get the lung offer if there is a lung candidate with a lung allocation score (LAS) of 90, and a lung-liver candidate within 500 nm who has an LAS of 35. The OPO VC explained that the OPO still has to follow the lung match run, so the policy would not prioritize a lung-liver or a lung-kidney candidate over a lung-alone candidate higher on the match run based on LAS.

The Chair asked if a lung-liver candidate with an LAS of 36 might receive a liver over someone with a higher Model for End-Stage Liver Disease (MELD) score. The OPO VC affirmed that the lung-liver candidate would be offered the liver, even if there is a liver-alone candidate with a MELD score of 40. The Vice Chair noted that this could result in the lung pulling the other organ, which is rare currently, especially for lung-liver candidates. The lung-liver candidate would be prioritized over liver-alone candidates but there would be no change in the lung candidate priority.

A member asked what would happen in the case of a young cystic fibrosis patient who needs a liver transplant, and has a very low LAS but a very high MELD score. The OPO VC explained that the OPO would still follow the match run. The member asked what would happen if the LAS is below 35 but the candidate is dying of liver failure, and if the liver could pull the lung. The OPO VC said that the liver could pull the lung if the MELD score was high enough. The way that the proposal is written is that the OPO would have to allocate the liver along with a lung if the candidate has an LAS greater than 35. The OPO VC noted that this is the first phase of a broader effort to improve MOT policy, so eventually the organ-specific committees will be able to work on eligibility criteria.

A member asked why is there a threshold of 35. The OPO VC said current policy says that the OPO only has to offer the second organ within the Donation Service Area (DSA), so this proposal essentially expands the DSA to 500 nautical miles (nm). The threshold was intended to provide some sort of cut-off

within that area. The Vice Chair explained that the workgroup that developed this proposal initially considered an LAS threshold of 40 or higher, but decided that a lung-liver patient with an LAS of 35 is pretty sick. Lung-liver candidates are a small population, so the waitlist mortality data for this population were not very helpful in terms of informing what the thresholds should be.

A member said it would be great if the physician could choose whether the patient should receive organ offers based on their MELD score or their LAS, depending on the patient's more urgent need. The member recommended making sure that there is a safety net for the liver to pull the lung if need be. The OPO VC agreed to share that feedback with the workgroup but has not observed a situation in which a liver pulled a lung. The Chair said that for candidates listed for lung-liver, the issue has generally been that the lung is driving their illness but they can't get the liver, which is presumably why the proposal was framed in this way.

A member asked if there is a downside to removing the LAS threshold. The OPO VC said this proposal still allows OPOs the discretion to offer organs to lung-liver candidates outside of 500 nm as long as they are not bypassing other patients. The workgroup did not have the expertise to get into safety nets and eligibility criteria but did have broad representation from the relevant organ-specific committees. A member said that the OPTN is trying to eliminate arbitrary thresholds in policy, since there is not much difference in candidate status on either side of the threshold. The member suggested eliminating the threshold since it is unlikely that a candidate with a low LAS will pull a liver. The OPO VC said the workgroup had considered including more constraints, so that if there was no lung-liver candidate with an LAS of 35 within 500 nm, the OPO would have to check if there was a liver candidate with a MELD of 35 or higher on the waiting list before looking for lung-liver candidates beyond 500 nm, but the workgroup felt like that was too complicated. Future work in MOT may be able to address this further.

A member said that currently, the median LAS is approximately 36.5 so this policy would only apply to the top 50% of lung candidates. The member said the threshold should probably not be lower than 35. The Vice Chair said the workgroup looked at some data on lung-liver recipients and their LAS at transplant was around 35, which is why it was selected as the threshold.

A member said that using LAS excludes the 0-11 age group since those candidates do not use LAS. It is extremely rare to have a MOT candidate in that age group, but the OPO Committee may want to consider adding a note on that age group in the policy for it to be complete.

Next steps:

The Lung Committee's feedback will be posted on the OPTN public comment website.

**2. Sorting/Tiebreakers**

The Committee discussed how to handle sorting and tiebreakers in continuous distribution.

Summary of discussion:

The Committee reviewed current OPTN policy on sorting and tiebreakers for candidates ages 12 and over and candidates under the age of 12:

Current (ages 12+)

- LAS (highest to lowest)
- Total active waiting time (longest to shortest)
- LAS variable update date and time (earliest to most recent approval)
- LAS exception date (earliest to most recent approval)
- (earliest registration)

Current (ages <12)

- Pediatric priority waiting time (longest to shortest)
- Total waiting time (longest to shortest)
- (earliest registration)

The Vice Chair asked if this includes waiting time at other centers if the candidate is registered on the waiting list at multiple centers. UNOS staff explained that it is based on the time that the candidate was registered at each center, so the candidate might have a different waiting time at each center if registered at different times. However, if a candidate moves closer to another transplant center, the transplant center could do a wait time transfer, which would preserve the longest time the candidate has been registered but would not match times between two centers.

UNOS staff noted that in practice, only the first two criteria are really ever used for candidates over the age of 12, because there are rarely ties with LAS, and any ties can generally be broken based on waiting time. UNOS staff asked if the Committee is comfortable with using waiting time as the only tiebreaker, and whether it should be based only on active waiting time, or on total waiting time. Currently, only active waiting time is used for candidates ages 12+ while total waiting time is used for candidates under the age of 12. It may be appropriate to have a consistent policy across all ages.

The Chair said that pediatric candidates should get total waiting time to give them the benefit of the doubt, and using total waiting time for adults would be okay to keep the policy consistent. The Vice Chair asked the pediatric members to comment on inactive time for young candidates, since adults can be inactivated for months. A member said inactive time is variable for younger candidates, but if they are inactivated, they continue to accrue time if they are ages 0-11. Changing the tiebreaker to only active time would be a change for the candidates ages 0-11, but the member was not sure how many candidates would be affected in terms of how many candidates are on the list for a long time in an inactive state. An attendee agreed, noting that it is unlikely to have a tie in the 0-11 age group group given the small population, so using active time only would be acceptable for 0-11 candidates if that is the preferred approach for adults. A member agreed that it would be good to have consistency in the policy to avoid confusion. Pediatric candidates for other organs like heart do not accrue waiting time while inactive, so lung is unique in that way currently. Members agreed that active time is appropriate for adults since they can be inactive for long periods of time.

Next steps:

The Committee agreed to use active waiting time as the tiebreaker for lung candidates of all ages.

**3. Clinical Value Update Schedule**

The Committee discussed changes to the clinical value update schedule for continuous distribution.

Summary of discussion:

Currently, the clinical values used to calculate LAS must be updated every six months, except for values obtained via right heart catheterization. For candidates with an LAS greater than 50, the values for assisted ventilation and supplemental oxygen ($O_2$) must be updated every 14 days, and current partial pressure of carbon dioxide ($PCO_2$) must be assessed every 14 days and reported if performed in the last 14-day interval. Since the LAS construct will be replaced with the composite allocation score in continuous distribution, the Committee needs to consider how these requirements should be updated for the continuous distribution.

The Committee reviewed principles for why clinical values might need to be updated more frequently for patients with an LAS greater than 50:

- The candidate has greater access by being near the top of the list
- The candidate is not stable and therefore their clinical values might be changing rapidly
- Do not want to overburden centers with excessive updates by including too many candidates

The Chair recommended keeping the six-month update for clinical values except for those obtained via right heart catheterization. The Committee agreed with this approach. The Chair asked if there are other clinical values that should be updated more frequently than every six months. Members did not identify any clinical values that should be updated more frequently.

The Chair proposed removing the requirement to update current $PCO_2$ more frequently. The Chair also recommended continuing to require more frequent updates for assisted ventilation and supplemental $O_2$ for the most medically urgent candidates, but only requiring updates every 28 days instead of every 14 days. The Committee supported these recommendations. A member said that it is a big burden to update clinical values when a center has 40-50 candidates with an LAS over 50, and trusted that most centers will update the data for their sicker patients as needed.

The Chair asked the Committee how to identify the candidates who need to have assisted ventilation and supplemental $O_2$ updated more frequently and suggested the following options:

- Highest waitlist urgency candidates (top x% or less than x days expected survival without transplant)
- Highest candidate-based scores (total score except for placement efficiency points)
- Clinical markers of high-LAS patients
    - Patients who are on extracorporeal membrane oxygenation (ECMO)
    - Patients who are ventilated/have high oxygen requirement

A member said that programs should be required to update the score if there is a major change. The Chair said that is the expectation, and the Committee just needs to establish how often policy should require these changes. The member said that the fear of being audited and not documenting appropriately is enough to keep centers motivated to do the right thing without the added burden of a policy requirement. The Chair said that is why she suggested basing this more on clinical markers, so that the data collection is tied to changes in patient care, for example, if the patient is extubated. The Committee agreed that these clinical values should be updated more frequently for patients on ECMO and continuous mechanical ventilation, and patients with high oxygen requirements.

### *Patients with High Oxygen Requirements*

The Committee discussed how to define patients with high oxygen requirements. A member said that the Committee would have to consider the technology and which high flow system is being used. The Vice Chair said these patients are very sick so the Committee needs to be thoughtful about defining this threshold. A member suggested defining high oxygen as 26 liters or 100% fraction of inspired oxygen ($FiO_2$). A member said when a patient is on a device other than nasal cannula, she converts them over to $FiO_2$. The member suggested using a 60-70% $FiO_2$ as a threshold as well as the appropriate liter conversion. The Chair said that the current system only accepts one or the other. Since a lot of clinicians convert to $FiO_2$ once the liter flow gets high, it might be difficult to establish a standard threshold that will not miss patients.

A member suggested defining these patients as inpatients who require some sort of support that they cannot get as an outpatient. A member said that heated high flow meets that criteria, and centers would probably enter the $FiO_2$ and maintain the source documentation for calculating $FiO_2$, but it would be great if UNOS could do that calculation for everyone so it is consistent. The Chair agreed that the Committee needs to change how the oxygen information is collected but said that is a different topic.

The Chair suggested defining the threshold as patients who are intubated and require high flow not available at home. A member thought this could get confusing since there are so many devices that could qualify as high flow. The Vice Chair suggested that it might be better to use the broader term "high flow" since it is difficult to define precisely.

A member said that some clinicians opt to use a lower $FiO_2$ and a higher flow so the $FiO_2$ doesn't have to be defined as 100%; it could be 80% or some other reasonable number. The Chair suggested "receiving more than 26 liters or more than 100% $FiO_2$," since the sickest patients will almost certainly meet one of these criteria. A member agreed with this approach but suggested slightly lower thresholds, like 20 liters or 80% $FiO_2$. A member suggested making sure those are equivalent so that whatever threshold is selected for liters is about equal to $FiO_2$. The member said the conversion can vary based on device, so the Committee should be cautious.

UNOS staff asked if the oxygen threshold would vary depending on whether a device was high flow or low flow. The Chair said there are different devices on the market that will effectively provide different levels of oxygenation so liter flow measurements cannot necessarily be compared across devices. UNOS staff said it would be helpful to identify standard high flow or low flow devices. The Chair said there are other complicating devices, so the Committee members will have to think through this since they are not all equivalent.

A member said that since the goal is just to figure out who needs more frequent documentation, the Committee can probably come to a consensus on that. The member suggested defining the threshold as any oxygen flow that can only be met in the hospital. A member said that will depend on what is available to the patient based on where they live, not how sick they are. A member suggested using 70% for FiO2 and the associated liter flow. The Committee agreed with this approach.

Next steps:

These Committee decisions will be included in the continuous distribution of lungs policy proposal:

- Clinical values must be updated every six months, except for values obtained via right heart catheterization
- For certain patients, assisted ventilation and supplemental $O_2$ should be updated every 28 days
    - Patients on ECMO
    - Patients on continuous mechanical ventilation
    - Patients on 70% FiO2 (or associated liter flow)

**Upcoming Meetings**

- February 18, 2021 (Committee)
- February 25, 2021 (Subcommittee)

**Attendance**

- **Committee Members**
  - Erika Lease, Committee Chair
  - Marie Budev, Committee Vice Chair
  - Alan Betensley
  - Whitney Brown
  - Ryan Davis
  - June Delisle
  - Cynthia Gries
  - Julia Klesny-Tait
  - Jasleen Kukreja
  - Denny Lyu
  - John Reynolds
  - Marc Schecter
  - Nirmal Sharma
  - Kelly Willenberg
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Yoon Son Ahn
  - Katie Audette
  - Ajay Israni
  - Melissa Skeans
- **UNOS Staff**
  - James Alcorn
  - Julia Chipko
  - Rebecca Goff
  - Robert Hunter
  - Elizabeth Miller
  - Amanda Robinson
  - Janis Rosenberg
  - Leah Slife
  - Kaitlin Swanner
  - Susan Tlusty
  - Sara Rose Wells
  - Karen Williams
- **Other Attendees**
  - Masina Scavuzzo
  - Kurt Shutterly
  - Stuart Sweet