

OPTN Lung Transplantation Committee

Meeting Summary

May 20, 2021

Conference Call

Erika Lease, MD, Chair

Marie Budev, DO, Vice Chair

Introduction

The Lung Transplantation Committee met via Citrix GoTo teleconference on 05/20/2021 to discuss the following agenda items:

1. COVID-19 6-month Report
2. Multi-organ transplant cutoffs by Composite Allocation Score (CAS)
3. Lung Review Board Timelines and Operations

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

1. COVID-19 6-month Report

UNOS Research staff presented the results from the COVID-19 Related Organ Failure in Thoracic Candidate Listings (Lung and Heart) report.¹ In order to capture the impact COVID-19 has on lung and heart candidates in the United States, the OPTN added a set of COVID-19 diagnoses to UNetSM in October 2020. The objective was to capture the number and demographic characteristics of lung candidates and recipients with a COVID-19 diagnosis. From March 13, 2020 to April 30, 2021, there have been 129 candidates added to the lung wait list with COVID-19 listings occurring in nine of the eleven OPTN Regions.

2. Multi-organ transplant cutoffs by Composite Allocation Score (CAS)

The Committee reviewed cutoff curves comparing different CAS across organ types versus the percent transplanted to help inform possible cutoff scores to utilize for multi-organ allocation as it relates to lung while lung is in continuous distribution and other organ types are not. The Committee previously discussed possibly utilizing the lowest CAS to determine this cutoff, which was a score of seven out of 100 on the cutoff curve. However, the majority of these candidates had a CAS occurring from 32 to 36 with another increase at 50 which represents the pediatric candidates.

Summary of discussion:

The Chair reiterated how difficult it is to receive organ offers for multi-organ candidates currently and supported selecting a score on the lower end of the cutoff curve so that most of these candidates are captured. The Vice Chair stated that often the candidates with the lower scores are further away and that those candidates should not be penalized for distance. A member agreed and suggested targeting a score that would capture 80 percent of multi-organ candidates since that would be a good compromise, and that would be a CAS of around 30. The Chair asked what a CAS of 28 would include and it was clarified that those percentages would likely capture more of the heart offers. It was also clarified that

¹ COVID-19 Related Organ Failure in Thoracic Candidate Listings (Lung and Heart). OPTN Thoracic Committee, Descriptive Data Request, Submitted May 20, 2021.

the initial discussion proposed that heart would offer to every multi-organ candidate on the wait list before other candidates which heart leadership was supportive of. The Vice Chair asked for feedback from members regarding liver and heart since not all lung transplant programs perform them. A member stated having the same process across organ types and those patients being captured in the same way would be easier to think through regarding the allocation process. Members agreed that a uniform approach across the organ types utilizing a CAS of 28 for heart, liver, and kidney would be a good option. A member stated that a CAS of 28 may be difficult for kidney since those kidneys would be pulled 99 percent of the time. The Vice Chair stated that those lower score candidates have to travel further distances and wait longer and also mentioned that there is a plan to refine multi-organ allocation with the development of the OPTN Ad-Hoc Multi-Organ Transplantation Committee. The member thought that there should be more of a compromise for kidney offers and the Vice Chair noted that the pool of candidates is very small and they should be advocated for. The Chair suggested proposing a CAS of 28 as the cutoff which leaves room for negotiation if needed. The Committee supported proposing a CAS of 28 as a cutoff for all organ types for multi-organ allocation as it relates to lung and would revise that score depending on the feedback received by the OPTN Heart, Liver, and Kidney Transplantation Committees.

3. Lung Review Board Timelines and Operations

The Committee reviewed the possible new process which would include exceptions being awarded at a goal level (ex: medical urgency, biological disadvantage) and have a maximum score of 100. The Committee was asked for feedback on review board exception timelines.

Summary of discussion:

The Length of Time Exceptions are Valid

The Committee discussed the different categories of exception requests and how long the exception score should be valid (expire in six months or indefinite). The Chair asked for clarification on the difference between the Lung Allocation Score (LAS) and Estimated Value exception in the current system and it was clarified that the Estimated Value exceptions substitute a specific values (such as creatinine) and these exceptions are rarely pursued. The Chair stated that the majority of exceptions are medical urgency followed by candidate biology which are circumstances that generally do not change and supported having the exceptions being indefinite. The Vice Chair supported having these exceptions being indefinite since those patients are very sick and it will be unlikely that an update would be needed in six months. A member noted that they would want the medical urgency exceptions to expire since there may not be the right incentive if there is no renewal in the instance that the patient's status improves. For example, if an exception request is approved for a patient who is currently experiencing hemoptysis and the patient no longer is experiencing hemoptysis. The Chair and SRTR staff noted that there is an increased risk of mortality if the patient had hemoptysis in the last year, so it may be appropriate to leave the exception indefinitely. The member mentioned that if a patient is well enough to survive six months without a transplant, it should be considered if whether or not they should have priority over more urgent candidates. A member also stated that if the exception has been granted appropriately, it should be indefinite. It was clarified that medical urgency exception expiration feedback can be requested when the Continuous Distribution of Lungs proposal is out for public comment. The Committee supported leaving all categories as indefinite exception scores, but wanted to gather more feedback.

Retrospective versus Prospective Reviews

Currently, most of the Lung Review Board exceptions are done prospectively with only pediatric priority 1 and overrides being done retrospectively. It was mentioned that from a UNOS IT standpoint, it would

conserve resources if there was only one type of review (either retrospective or prospective) in Continuous Distribution. Members noted that lung has operated primarily in prospective reviews and mentioned that retrospective reviews can cause anxiety for transplant teams should an offer be made before the exception is approved. The Vice Chair stated that with all of the changes being made in Continuous Distribution, it may be better to leave these exceptions as prospective which is an easier process to understand. Members stated that these reviews tend to happen quickly, but asked if the timeframe for review could be shortened from seven days if only prospective reviews are utilized. It was clarified that exception request reviews are completed in three days on average, but the Committee could pursue shortening the seven day timeframe. A member asked if the exception score is locked in or could it be increased if the patient becomes more unstable. It was clarified that once an exception application is submitted you cannot update a calculated LAS score, but that can be changed with the implementation of Continuous Distribution. Members discussed updating the process so that new values can be added if a candidate's information changes while the exception is still under review and how changes in a patient's values would affect an already approved exception score. Committee feedback was requested on the role of Lung Review Board alternates and the Vice Chair stated that acting as an alternate functions as a learning experience. A member mentioned that it is also beneficial to have alternates as a back-up if the primary is unavailable.

The Committee supported having all Lung Review Board exceptions being prospective and shortening the timeframe for review from seven to five days with the cases being sent to alternates at three days.

Other Review Board Operations

The Chair and Vice Chair agreed that the auto-decline for exceptions that receive a tie from reviewers or lack of quorum upon the initial review disadvantages patients. The Chair noted that in the cases where there is a tie, some reviewers felt the exception was valid. A member suggested that in the event of a tie, if there is a question on whether or not it was adjudicated properly, using alternates as a tie-breaker. Members discussed that there are a number of ways to utilize alternates as a tie-breaker, but also it could be a complicated process. The Vice Chair mentioned that in some cases the alternates may not have the experience level to be a tie-breaker. A member asked if the Lung Review Board Chair would be appropriate to act as a tie-breaker since they have a higher experience level and should be able to act objectively. The Committee requested feedback on whether or not previous Chairs would be comfortable breaking ties and how often ties occur.

The Committee also discussed future educational opportunities for Lung Review Board members and opportunities for structural or procedural improvements.

Upcoming Meetings

- May 27, 2021 (Updating Mortality Models Subcommittee)
- June 10, 2021 (Committee)

Attendance

- **Committee Members**
 - Erika Lease, Chair
 - Marie Budev, Vice Chair
 - Alan Betensley
 - Denny Lyu
 - Marc Schechter
 - John Reynolds
 - Julia Klesney-Tait
 - Nirmal Sharma
 - Whitney Brown
 - Kelly Willenberg
 - June Delisle
 - Jasleen Kukreja
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Katie Audette
 - Melissa Skeans
 - Andrew Wey
 - Maryam Valapour
- **UNOS Staff**
 - James Alcorn
 - Rebecca Goff
 - Elizabeth Miller
 - Janis Rosenberg
 - Susan Tlusty
 - Sara Rose Wells
 - Krissy Laurie
 - Leah Slife
 - Tatenda Mupfudze
- **Other Attendees**
 - Stuart Sweet
 - Jennifer Schiller
 - Masina Scavuzzo