OPTN Lung Transplantation Committee
Meeting Summary
November 18, 2021
Conference Call

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

Introduction

The Lung Transplantation Committee (the Committee) met via Citrix GoTo teleconference on 11/18/2021 to discuss the following agenda items:

1. Continuous Distribution Review Boards

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

1. Continuous Distribution Review Boards

The Committee reviewed the goal for the project to update Lung Review Board guidance being explaining what types of information exceptions should be based on. The Committee also reviewed the current guidance language and the differences that will be present for exceptions in composite allocation scores (CAS) when a goal-level score does not accurately reflect the candidate's expected waitlist survival, post-transplant survival, biological disadvantages, and patient access.

Summary of discussion:

Justification

The Committee discussed the suggested guidance including clinical rationale for why the score does not adequately reflect the candidate, clinical rationale for why the requested score is more appropriate, and literature if available. A member mentioned that for biological disadvantages the Committee considered values and appropriate percentages of a candidate's CAS, but from a transplant program's perspective, would it be possible for a program to request an exception for biological disadvantage if that program does not perform certain procedures which could disadvantage the candidate. The member noted the example of programs not performing "downsize" transplantation for candidates of short stature and the Chair explained that the candidate would be getting the points for stature regardless of the program performing those procedures. The Chair continued that as the field progresses there is the possibility of new data presenting itself to support new biological disadvantage categories. A member felt that it is a slippery slope if exception requests are opened to program specifics or practices and really should be centered on patient characteristics. Another member and the Chair agreed, but the member suggested that a program is going to ultimately be concerned about their patient's survival so would argue those disadvantages. A member stated that if a candidate is getting progressively sicker, you can submit exceptions for more than one category if needed.

Potential Areas for Specific Guidance

The Chair did not feel there was a need for a more delineated guidance for specific candidate symptoms (i.e. hemoptysis) like there currently is for pulmonary hypertension (PH), but acknowledged that there are specific symptoms that impact waitlist mortality. A member noted that contemporary PH

management is a fluid practice, and initially when an exception was requested a program could ask for the maximum lung allocation score (LAS) possible. The member continued with explaining that specific symptoms or treatments are a "mixed bag" based on the combination of diagnosis and/or clinical events so they suggested that outside of PH they should be left unspecified. A member also noted that the guidance given for PH was fully vetted and agreed that the others should be left to best judgement. Members agreed that "high likelihood/history of acceptance" by transplant program has nothing to do with the patient needing a transplant and should be left off entirely. The Chair stated that they would not necessarily limit the types of justifications that could be submitted, but that any exception needs to be justified. A member shared that it would put them in an uncomfortable position if anything in the list was granted an exception based on some criteria that was not fully vetted. Another member agreed that it should be kept open and general to be reviewed on a case by case basis.

Current Pulmonary Hypertension (PH) Guidance

The Committee was asked for feedback on whether or not the current PH guidance needed to be updated or was still relevant as is. A member suggested there should be criteria related to wedge pressure included to address instances where a candidate is not adequately diuresed and appears to be sicker than they are. The Chair asked if simply denying those requests based on that information is adequate. A member stated that optimal therapy includes optimal diuresis, so those requests should be denied if they are obviously not meeting that criteria. The Chair added that they felt uncomfortable with adding a new variable to the guidance since there may be cases where it is justified and a member agreed that the circumstances may be variable. It was asked if a possible solution would be to add language to target that as a reference/thing to consider and members felt that was an adequate solution.

The current guidance suggests requesting a lung allocation score (LAS) at the 90th percentile and in CAS they could use the 90th percentile for waitlist mortality and post-transplant survival. This could be using a score that puts the candidate ahead of 90% of candidates in each group, looking at combined waitlist mortality and post-transplant survival and finding the 90% percentile, or giving these candidates 90% of the available points outside of efficiency points. The Chair stated that regardless of what is decided, the intent behind the original exception should be retained which is that these candidates should be in the 90th percentile. A member asked if it was possible to send out and update the quartiles like what is currently done for LAS and get the score from that and it was stated that those updates could continue to be posted. A member noted that the 90th percentile should be kept to waitlist mortality and post-transplant survival so that candidates with other disadvantages such as sensitization or height would still get those points as an advantage. Members supported keeping the exceptions for PH to waitlist mortality and post-transplant survival in the 90th percentile and keeping the other goals separate from the PH exception. Members also discussed how exceptions at the goal level can be additive and dynamic as they are submitted by programs for candidates as their status changes.

Exception Requests in Practice

Members discussed the types of CAS exceptions and how they would be submitted at the goal level. A member expressed concern over having an extremely sick patient not being transplanted over others if it is solely points being requested, so would more support looking at the candidates as a whole and deciding based on percentiles would be preferred. A member mentioned that in continuous distribution waitlist mortality is weighted the same as post-transplant survival so all of those variables are equally as important. A member mentioned that a candidate really would not be able to get additional points for candidate biology since those are based on a medical reason such as blood type or height. A member stated that the level ground for severity of disease should be limited to waitlist mortality and post-transplant survival. The Chair agreed, but acknowledged that as the field changes there may be rationale

for other biological disadvantage goal requests within disease severity. They also mentioned that the CAS incorporates utility more than the LAS does so there will be shifts in practice. A member strongly suggested seeing data for the CAS in action prior to implementation so that the community can prepare for any shifts and adapt as needed. A member noted that with current system, they often felt that it would be nice to have consistency for why certain requests would fall at which percentiles. The Chair stated that it has been discussed previously and agreed that having general guidance would be helpful, but that ultimately it will come down to the review on a case by case basis. A member suggested looking at PH exception requests to see where those would fall within CAS especially if it is limited to 90th percentile of waitlist mortality and post-transplant survival. The Chair added it would also be helpful to see aggregate data on where candidates would fall in continuous distribution. A member noted that the quartiles for LAS actually change quite a bit between reports and another member and the Chair stated they have seen shifts in a few points, but nothing major. The member asked if it was possible for the quartiles to be more of a live thing instead of a fixed number. It was noted that more information would be gathered to see if that was a possibility.

Upcoming Meetings

- December 16, 2021
- January 20, 2022

Attendance

- **Committee Members**
  - Erika Lease, Chair
  - John Reynolds
  - Julia Klesney-Tait
  - Whitney Brown
  - Errol Bush
  - Pablo Sanchez
  - Karen Lord
  - Cynthia Gries
  - Denny Lyu
  - Nirmal Sharma
  - Marc Schecter
  - Staci Carter
  - Soma Jyothula
  - Kelly Willenberg
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
  - David Schladt
- **UNOS Staff**
  - Elizabeth Miller
  - Susan Tlusty
  - Krissy Laurie
  - Tatenda Mupfudze
  - Leah Slife
- **Other Attendees**
  - Laurel Avery
  - Samantha DeLair
  - Samantha Taylor