OPTN Lung Transplantation Committee
Meeting Summary
May 5, 2021
Conference Call

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

Introduction

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

1. OPTN Histocompatibility Committee Calculated Panel Reactive Antibody (CPRA) Project
2. ABO Incompatibility
3. Lung Waiting Time
4. Multi-Organ Allocation in Continuous Distribution
5. Lung Review Board Exception Requests

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

1. OPTN Histocompatibility Committee Calculated Panel Reactive Antibody (CPRA) Project

The Histocompatibility (Histo) Committee Chair presented their Committee project for the addition of three major loci, the use of the National Marrow Donor Program human leukocyte antigen (HLA) typing data, and the use of a genotype calculation instead of a haplotype calculation. The anticipated impact would include more accurate depictions of a candidate's likelihood of compatibility with potential deceased donors and the additional loci will most significantly impact minority candidates. The Histo Committee requested the Committee's feedback on whether or not there should be one weight for CPRA across all organs or if there should be organ specific weighting and if there are any concerns about using one set or racial/ethnic weights for kidney, pancreas, and lung.

Summary of discussion:

The Chair asked if the Histo Committee is anticipating that transplant programs would enter data on antigens into Waitlist[SM] along with mean fluorescence intensity (MFI) and the system would calculate CPRA. The Histo Committee Chair clarified that any patients that have discernable antibodies that a program is unwilling to accept a donor for would enter those as unacceptable antigens (UA) and those would be used to create the candidate's CPRA. The Histo Committee Chair also mentioned that MFI values would be different for each program and it would be their discretion as to which of those antibody specificities are chosen as unacceptable to be entered into the system and only the information that is entered can be used for the CPRA calculation.

A member noted that the comparison between kidney and heart ethnic weights showed very similar results and asked if that comparison was available for lung. It was clarified that the modeling has started using the lung cohort and this meeting intended to get the Committee's preliminary feedback. Members agreed that if the results for lung are similar to other organs, it makes sense to have one weight, but they would need to see the results from the modeling. The Histo Committee Chair also suggested comparing the ethnic weighting of heart versus lung to more quickly compare results. HRSA staff asked about the possible impact of the slight differences seen in the heart and kidney comparison regarding

allocation. It was clarified that none of the candidates changed more than two percent and that while one to two percent differences could make a large difference under the current system, under continuous distribution the impact would be incremental and would change the composite allocation score (CAS) overall. HRSA staff also noted that separate weights for each organ would require significantly more development and ongoing maintenance.

The Vice Chair asked if there was any information available for how many antibodies are currently entered in Waitlist[SM] and the Chair clarified that information is not available since it is at the program's discretion and there is a range of clinical practice.

The Committee requested a follow-up review of the modeling results specific to lung, and would support one weight if the results showed that there are only slight differences between organs to make the new CPRA system easier to implement and maintain.

2. ABO Incompatibility

The Committee reviewed options for match run screening and allowable points for blood type biological disadvantage for ABO incompatibility eligible pediatric candidates as lung moves into continuous distribution.

Summary of discussion:

The Chair clarified that this applies to the youngest of pediatric candidates (less than one year) and is a small group of candidates. A member noted that not all programs perform ABO incompatible transplants and supported keeping a system in place that is the same as what is being done now. The Committee did not support adjusting the ABO points for candidates who qualify for ABO incompatibility transplants since the population is small and very young, and this is the option that provides the most benefit to the patient.

3. Lung Waiting Time

The Committee previously discussed calculating wait time based only on a candidate's active wait time for both adult and pediatric candidates, which differs from current practice which counts active and inactive wait time for pediatric candidates. A leadership group of OPTN organ committees focused on standardizing continuous distribution across organs recommended including active and inactive wait time for all candidates.

Summary of discussion:

The Vice Chair asked for clarification on why pediatric candidates are currently treated differently than adults and the Chair clarified that the intent was to give pediatrics the benefit while avoiding instances where adult candidates take advantage of the inclusion of inactive wait time. However, this is only used as a tie-breaker in the current proposed plan. The Chair asked why the leadership group thought that including inactive wait time would encourage active waitlist management and it was clarified that changing a candidate's status to inactive may be avoided if they would lose wait time and would instead keep the candidate active and turn down organ offers during that time. The Chair noted that the opposite could occur where a candidate is listed with an inactive status preemptively to accrue wait time before the true need for transplant, but recognized that this would be a small risk in practice. SRTR staff noted that this may not be a concern in lung, but may inflate the wait list for other organ programs. A member mentioned that the Lung Allocation Score (LAS) begins at age 12, so for younger pediatric candidates the wait time accrual is still one of the determining factors for ordering on the match run. It was clarified that in continuous distribution, waiting time will not affect candidates under 12 years old as significantly because of the inclusion of the other attributes that make up a candidate's CAS. The

Committee supported including both active and inactive statuses since the impact of wait time to standardize practice across organ types and will not be as significant of an impact in continuous distribution.

4. Multi-Organ Allocation in Continuous Distribution

The Committee revisited the options for lung-kidney and lung-liver multi-organ allocation while lung is in continuous distribution which is a point based system and the other organ types still use the current system. The Committee's initial preferred option which was modeled after heart-lung would likely not be able to be implemented in time for continuous distribution, so they discussed a more temporary option which would require an organ procurement organization (OPO) to offer through a certain point on the lung wait list, then allow offers off of the kidney and liver waitlists.

Summary of discussion:

Members noted that the presented option does not improve the current system, and does not address concern about dual organ recipients having less access to organ offers. The Chair clarified that this solution does not necessarily improve what is currently in place, but the goal is to not move backwards. It was noted that the OPTN Ad Hoc Multi-Organ Committee will be working on improving multi-organ allocation moving forward and this is an interim solution. A member asked if there was a way to get a more immediate fix to prioritize multi-organ candidates at the OPO level without working out all of the details and it was clarified that there is not really an avenue to fix one aspect without looking at how every aspect would be affected. The Vice Chair noted that the Committee's concerns will be addressed with the new Multi-Organ Committee, but that it is a process that will happen over time. The Committee supported moving forward with this option as an interim solution.

5. Lung Review Board Exception Requests

The Committee discussed a 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 new process would also mean the removal of LAS exceptions, diagnosis exceptions, estimated value exceptions, or adolescent exceptions.

Summary of discussion:

The Vice Chair noted that it an improvement for programs to no longer have to resubmit for pulmonary hypertension LAS exceptions. SRTR staff asked what would happen with diagnoses exceptions and it was clarified that they would go away in lieu of the goal exceptions. The Vice Chair asked for clarification on how combined diagnoses would be treated since they are currently not adequately represented, and it was suggested that those candidates could be entered as exceptions for waitlist mortality and/or post-transplant survival and explain their reasoning in the narrative. The Vice Chair stated that these updates would require that the Lung Review Board members to be familiar with the literature and waitlist and post-transplant mortality. It was also clarified that diagnosis exceptions are rarely used in the current system. Members supported moving to this type of process, but noted that there is a significant need for guidance and education for both the transplant programs and Lung Review Board members.

Upcoming Meetings

- May 20, 2021 (Committee)
- May 27, 2021 (Updating Mortality Models Subcommittee)

Attendance

- **Committee Members**
  - Erika Lease, Chair
  - Marie Budev, Vice Chair
  - Alan Betensley
  - Denny Lyu
  - Cynthia Gries
  - Marc Schecter
  - John Reynolds
  - Julia Klesney-Tait
  - Nirmal Sharma
  - Whitney Brown
  - Staci Carter
  - Kelly Willenberg
  - Kenneth McCurry
  - Daniel McCarthy
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
  - Melissa Skeans
  - Andrew Wey
  - Maryam Valapour
- **UNOS Staff**
  - James Alcorn
  - Julia Chipko
  - Rebecca Goff
  - Elizabeth Miller
  - Janis Rosenberg
  - Susan Tlusty
  - Sara Rose Wells
  - Krissy Laurie
  - Leah Slife
  - Courtney Jett
  - Kaitlin Swanner
  - Tatenda Mupfudze
  - Darren Stewart
  - Nicole Benjamin
- **Other Attendees**
  - Pete Lalli