OPTN Lung Transplantation Committee
Meeting Summary
October 21, 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 10/21/2021 to discuss the following agenda items:

1. Continuous Distribution Public Comment Feedback and Post-Public Comment Changes

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

1. Continuous Distribution Public Comment Feedback and Post-Public Comment Changes

The Committee reviewed and discussed the feedback received on the Establish Continuous Distribution of Lungs public comment proposal. Overall, the proposal was generally supported and themes from the feedback included requests for a robust and careful monitoring plan, concerns over logistics, inclusion of a sliding scale for pediatric weighting, and concern over post-transplant outcome weighting and timeframe (one versus five year). The Committee considered the feedback received and discussed possible changes to the proposal.

Summary of discussion:

1-year versus 5-year Post-Transplant Outcomes

The Chair noted that when the Committee started working on continuous distribution the feedback initially received was to lengthen the timeframe for post-transplant outcomes, so it was interesting to see that the public comment feedback was focused on keeping the timeframe the same at 1-year. The Chair acknowledged that the data used for post-transplant outcomes could be better, but the prediction for 1-year is just as good as the 5-year and felt the proposal should still include 5-year post-transplant survival. SRTR staff explained that many centers may be more familiar with the 3-year metrics used for program specific reports (PSRs), which is a completely different report that looks at program performance and mentioned that the post-transplant survival included in the proposal is really reflective of who a candidate is, but donor information is not available at the time of allocation. A member stated that 1-year is not consistent with what the community would want, but suggested that a smaller jump in timeframe (i.e. 3-year) may be easier for the community to digest. SRTR staff continued that there is not much gain in going to a 3-year versus a 5-year and SRTR analysis showed similar C-statistic between 1-year (60.6%) and 5-year (59.3%) in post-transplant models. A member suggested that maybe these numbers are why initially waitlist mortality and post-transplant survival was given the ration of 2:1 since the prediction of post-transplant survival is really no better than flipping a coin. The Chair mentioned that this allows for an opportunity to consider what type of data could be collected to improve those predictions including donor characteristics. The Vice Chair stated that the Committee will be looking at the impacts early on and should be able to see trends before the 5-year mark. Members shared that stakeholder organizations and the community felt that the post-transplant outcomes should be longer

than 1-year and agreed that continuous distribution allows for easier adjustment if needed. The Chair felt that regarding the initial support for a longer post-transplant outcome, that this proposal should stretch further to a 5-year to really see an impact and SRTR staff mentioned that a 3-year post-transplant may not be long enough to really see a change. A member stated that if the Committee wanted to consider a 3-year option, they would want to see modeling before making that decision. A member asked if programs have an idea of how they are performing at the 5-year mark and SRTR staff explained that the PSRs are not the same as the post-transplant outcomes that are being considered as part of continuous distribution which effects allocation and not performance. The Committee supported keeping the proposal at a 5-year post-transplant survival.

1:1 versus 2:1 Waitlist Mortality and Post-Transplant Survival Weighting

The Chair understands that why there may be concern over moving from a 2:1 to a 1:1 ratio, but the data supports moving to a 1:1 ratio and that there really is not a strong, justifiable argument to go to keep a 2:1 ratio. A member noted that one of the comments supporting having the ratio remain at 2:1 came from their Region, but they felt that the data supports a 1:1 and the community expressed support for a 1:1 ratio through the analytic hierarchy process (AHP) exercise. Another member supported 1:1 and felt it could be closely evaluated. An additional member explained that it may be an emotional response to maybe worry about those sickest patients even though the data supports a 1:1. An opposing member noted that it may be too much to move to a 5-year post-transplant survival and a 1:1 ratio, but has come to terms with the proposed change. The Committee supported leaving a 1:1 ratio for waitlist mortality and post-transplant survival.

Pediatric Weighting

A member explained that this is an area that the Committee talked about extensively and that the 20% weighting is where the Committee landed based on all the information provided. They noted that this is a small percentage of patients, but that it is a vulnerable population and felt that 20% is the right weight. The Committee continued to support a pediatric weighting of 20%.

Pediatric Donors

The Committee discussed the feedback received regarding pediatric donor allocation and the concern that pediatric candidates would not have access to pediatric donor lungs. The Chair stated that with the pediatric weighting, pediatric candidates are effectively going to be at the top of a match and would have access to pediatric donors. A member explained that while it may be hard to disagree with the comment, the pediatric weighting is a significant bump, but size can be an issue so it should be monitored closely. Another member explained that while the specific language for pediatric donor allocation is being removed, in practicality pediatric candidates would get those offers before any adult candidate. The previous member thought that since that priority was fought for historically it is likely just perception, but still wanted to keep a close eye on it. The Vice Chair also pointed out that the smaller pediatric candidates would also get the points for height. A member asked for clarification on whether or not the increased transplant rate in the model for pediatrics was due to transplanting older donor lungs into pediatric candidates since no one is doing that in reality. SRTR staff noted that the denominator is so small with pediatrics that the models use multiple years to increase the size of the cohort. A member mentioned that the number of pediatrics has gone down by 10-20% in the last decade and that a pediatric program is not going to accept a donor over 50 years old. The Chair also pointed out that a program can set donor acceptance to limit the age of the donor. Currently, pediatric and adolescent candidates do not see adult offers so in a way they will have more access to donors, but it will be at the program's discretion on what is accepted. It was mentioned that there are differences in long term survival in pediatric candidates who accept older donor lungs, as in older donor organs do not

always do well in younger recipients. The Chair clarified that behavior in donor acceptance cannot be modeled and members agreed that the takeaway is that pediatric candidates will be at the top of a match so they will have access to pediatric and adolescent donors so we should see that those donors are going to those candidates. The Committee supported keeping the same allocation for pediatric donors as initially proposed.

Transition for Pediatric Priority

The Committee considered the feedback regarding the possibility of a sliding scale for pediatric weighting. It was clarified that if a candidate is registered under the age of 18, they would not lose the pediatric points when they turn 18. The Chair agreed that they liked the idea of a sliding scale in theory, however, in practice it is not something the Committee could legally justify since pediatrics are designated as under the age of 18 commonly and by National Organ Transplant Act (NOTA). The Chair also noted there is a risk of entering a slippery slope when trying to decide what age to end the sliding scale and that opens things up to age discrimination. A member agreed that continuous distribution should align with an established cutoff for pediatric age, but acknowledged that some consider adolescence from ages 13 to 25. Another member felt that it was an interesting idea, but agreed that it would be difficult to establish differing cutoffs for a sliding scale. UNOS staff added that it is possible for the Committee to establish a sliding scale but that it would need to be data driven and would take time to develop so could be considered as a future revision of continuous distribution. A member expressed concern over programs preemptively listing candidates while they are still under the age of 18 and inactivating them just so they could get the pediatric boost in points. They also asked if there were possible ways to prevent that type of behavior by programs. Members suggested closely monitoring the data and looking at inactive time after a pediatric listing to see if this is something that really would occur. A member noted that they cannot speak for all pediatric programs, but they felt that pediatric candidates are being listed when they need a transplant and would not think that programs would list a candidate only to inactivate them for prolonged periods, but supported monitoring that. It was clarified that the current pediatric waitlist is very small and should be able to monitor candidates who have extensive inactive time.

The Committee discussed whether or not the pediatric points should expire after a designated period of time. Some members did not feel strongly on whether or not the points should expire, but a member felt that if they are allowed to be listed preemptively and keep the points it may create inequities in the system due to lack of access as a younger patient. A member asked how what kind of scenarios would lead to a pediatric patient being inactive for a long period of time and another member stated it could be due to change in clinical status and felt that if a candidate is inactive for a year they really should be delisted and reevaluated. A member asked if the Committee had the ability to expire the pediatric points after a certain time and stated that if that is out of scope at this time, that it be monitored as is and evaluated if a problem is identified. A member noted that it would be reasonable based on trends in current pediatric weighting time, that if a pediatric listed candidate is not transplanted in 12 months after turning 18 years old that the points expire. A member pointed to the pediatric wait list having less than 20 candidates listed that the risk of programs gaming the system is low and that the policy should be generous and allow them to keep their pediatric priority. A member expressed interest in looking into candidates that are listed between ages 18-20 as well as inequities in access to transplant as a pediatric minority due to misdiagnosis. It was suggested that this is a larger discussion for the Committee to consider in the future and if a sliding scale for pediatric points is developed, there needs to be clinical justification for it.

Prior Living Donor Weighting

The Vice Chair mentioned that during an OPTN Patient Affairs Committee meeting it was interesting to hear the feedback that priority would be given to a donor over someone else was a negative. A member noted that their Region's feedback was that 5% weighting was not enough. The Committee supported leaving the prior living donor weighting at 5%.

Efficiency

The Chair shared feedback expressed by the OPTN Organ Procurement Organization (OPO) Committee regarding concerns they had, but that those concerns were out of scope for this proposal and were aimed at more general inefficiencies in organ allocation. A member added that there have been discussions over possible additional costs to members and whether or not there will be reimbursement. The Chair stated that there has been discussion on collecting better cost to member data, but is unsure on where that stands. It was clarified that the OPTN does not regulate cost and does not have any authority there and there has been hesitation by some members to share that information. The Committee supported keeping a 5% weight for proximity efficiency and 5% weight for travel efficiency.

Exception Process

The Chair reminded the Committee that lung has never had retrospective reviews, so having only prospective reviews would not be a change for lung programs. A member asked how retrospective reviews work in practice and the Chair clarified that in heart you would list a candidate at the higher status before receiving an approved exception which could lead to transplantation before approval or at a denied status exception. It was also clarified that the change for the lung exception would be the removal of the override option for pediatric priority 1. A member felt that all reviews should move to prospective reviews since the turnaround for exception review is fast and pediatrics should not be disadvantaged in the new system. The Chair also felt that the exceptions once granted should not expire since programs are doing this in the interest of their very sick patients. The Committee continued to support having no expiration on granted exceptions with all prospective reviews.

The Committee reviews the ability for programs to apply for an exception based on efficiency or if that should be removed as an option. The Chair mentioned that it is hard to imagine how a program would make an argument for a prospective exception for placement efficiency, so it seems reasonable to remove that as an option. The Committee supported revising the proposal to remove placement efficiency as an option for exception requests.

UNOS staff walked through the implementation challenges between the proposed nine reviewers plus alternates with three from pediatric programs versus 12 or more reviewers with pediatric representation with random selection of nine reviewers for each case. The Vice Chair supported the proposed 12 reviewers since it allows for more flexibility and there may be high case volumes initially. The Committee supported changing the proposal to include 12 reviewers on the Lung Review Board with nine reviewers assigned to each case.

The proposal includes review board alternates being notified of an open case after three days of a case review and either the primary or alternate is able to vote on the case. A potential issue that was identified was that this could result in opposing decisions and conflicting reasons to why. The proposed alternate approach would be that once the case is reassigned to an alternate, only the alternate can vote. A member asked if it is appropriate to have in house alternates and the Vice Chair explained that the reasoning was to have representation from certain program demographics. Another member asked if the alternate is typically a more junior staff member and the Vice Chair stated that it does not have to be. The Vice Chair asked if there was a way to identify programs that always need to be reassigned and

if there was a mechanism to address that. It was clarified that the review board chair has the opportunity to intervene, but it something the Committee could discuss. The Committee supported revising to reassign to another available reviewer (not necessarily from the same program).

The Committee discussed whether or not there is a need to have any exceptions expire when a candidate turns 12 years old. A member clarified that in the current system the under age 12 exception goes away when the candidate turns 12 due to now utilizing a lung allocation score (LAS). The Chair expressed that like adult exceptions, programs are likely submitting these requests in the best interest of their sickest patients. The Vice Chair mentioned that maybe the proposal mirror the current system and those candidates have an exception that expires with the need to reapply for an exception if needed. A member also noted that to meet criteria for pediatric priority 1, the candidate only needs to be on oxygen so this is a low number of exceptions. The Chair asked if in the current system programs essentially need to relist their candidates when they turn 12 years old and a member clarified that the transition happens automatically. It was explained that the default would be that the exception does not expire similarly to the adult exceptions, so that if they would expire, there needs to be justification for that. The Committee supported not having the exceptions expire for pediatric candidates who received exceptions under 12 years old.

Pediatric Eligibility for Blood Type Incompatible Lungs

This currently requires a candidate to be listed as priority 1 and a member felt that it was reasonable to leave as is since most programs are only going to do incompatibles in their really sick pediatric candidates since they are worried about waitlist mortality. The Committee agreed to keep the same as the public comment proposal to require the candidate be listed as priority 1 and not as an exception candidate.

Exception Appeals

The Committee was asked for feedback on whether or not quorum is required on an appeal with the proposed option of not requiring quorum for either the initial exception or the appeal. The Committee supported not requiring quorum on exception appeals.

Multi-Organ Transplant

The Chair mentioned that they presented the proposal to both the OPTN OPO Committee and Liver Committee and while the OPO Committee expressed concerns over lung-liver allocation, the Liver Committee was supportive. They continued by disagreeing with the feedback that OPOs need more discretion in allocation and felt that the majority of feedback included the need for less discretion for consistency. Members noted that in the majority of cases a heart would pull the lung and a member felt that the Committee should advocate for the lung. Another member expressed that a major issue is the inconsistency so this will help with that and the Vice Chair added that this is still a stop gap which will evolve with the OPTN Ad-Hoc Multi-Organ Transplantation Committee. The member asked if there was a timeframe for when these processes will be updated and the Vice Chair stated it is a high priority and being worked on currently. A member asked what would be involved in giving more priority to the lungs and it was clarified that there is support from the public comment for revision but the Committee felt that it would need to be supported by the relevant OPTN Committees like the initial proposal. A member expressed concern over setting this in place and then being locked in, but it was discussed that continuous distribution will be more flexible and can be adjusted as needed. The Committee supported leaving multi-organ allocation as initially proposed and expressed wanting to discuss lung multi-organ allocation with the Multi-Organ Committee.

Upcoming Meetings

- October 22, 2021
- November 18, 2021

Attendance

- **Committee Members**
  - Erika Lease, Chair
  - Marie Budev, Vice Chair
  - John Reynolds
  - Julia Klesney-Tait
  - Whitney Brown
  - Errol Bush
  - Pablo Sanchez
  - Jasleen Kukreja
  - Karen Lord
  - Dan McCarthy
  - Cynthia Gries
  - Denny Lyu
  - Nirmal Sharma
  - Marc Schecter
- **HRSA Representatives**
  - Jim Bowman
  - Raelene Skerda
- **SRTR Staff**
  - Katie Audette
  - David Schladt
  - Maryam Valapour
- **UNOS Staff**
  - Elizabeth Miller
  - Janis Rosenberg
  - Susan Tlusty
  - Sara Rose Wells
  - Krissy Laurie
  - Tatenda Mupfudze
  - Holly Sobczak
  - Leah Slife
  - Darby Harris
  - Darren Stewart
  - James Alcorn
  - Rebecca Murdock
- **Other Attendees**
  - Dave Weimer