OPTN Lung Transplantation Committee
Meeting Summary
October 22, 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 10/22/2021 to discuss the following agenda items:

1. Recap of the October 21, 2021 Meeting
2. Continuous Distribution Public Comment Feedback and Post-Public Comment Changes
3. Waitlist Survival Calculation Refit Update

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

1. Recap of the October 21, 2021 Meeting

The Committee reviewed the decisions made in the prior day's meeting including changes to the Lung Review Board and removing placement efficiency as a goal allowed as an exception request. A member brought up that good points were raised regarding lung priority in heart-lung allocation, but agreed that keeping as is may be the best course right now and offered that exceptions could be requested if needed.

Revisiting Blood Type Incompatibility (ABOi) for Pediatrics

It was clarified that in the current system if a pediatric candidate is priority 1 including by exception, they would have access to ABOi offers and that the Committee supported removing the by exception access in the discussion in the prior day's meeting. With the additional clarification the Committee supported allowing for exception candidates to have access to ABOi offers by having an equivalent waitlist score of 1.9073 (priority 1) or higher.

2. 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:

Decimal Precision

The feedback from public comment included keeping decimal precision around four or five decimal places to ensure candidates have differing composite allocation scores (CAS) to avoid ties and other feedback felt that two decimal places were sufficient for understanding the scores. The Committee

supported the decision made by the Committee during the last meeting regarding precision for the different values.

Clinical Values at Listing

Feedback was requested from the Committee regarding whether or not clinical values should be less than six months old and specifically discussed cardiac index at rest, pulmonary artery (PA) mean pressure, and PA systolic pressure at rest. As proposed, there is no recency requirement for clinical values, but due to the significant resources needed to change this, it was recommended that the requirement stay the same as the current system. The Committee was asked if there was a clinical need for not having the recency requirement. The Chair felt that data from within the last six months should be entered but realizes there are circumstances where those values may be slightly older than six months. Members felt that all data should be recent, but agreed that programs are typically updating the values as needed. The Committee supported requiring values to be less than six months old except for cardiac index at rest, PA mean pressure, and PA systolic pressure at rest.

Calculated Panel Reactive Antibodies (CPRA)

The public comment feedback on the inclusion of CPRA was highly supported by the community. The Chair asked if the OPTN Histocompatibility Committee was still working on the ability to upload data from histocompatibility labs and it was clarified that their current proposal going to the OPTN Board of Directors in December 2021 will make data collection more consistent which will better enable uploading of these data. The Vice Chair commented that there is a lack of consistency and understanding of this in programs and was glad that the Committee is at the point that CPRA could be included. A member asked for clarification on why the weighting for CPRA was chosen and the Chair clarified that the community feedback supported a 15% weight for candidate biology and since there are three attributes within that it made sense to divide by three. However, as more information comes in the weighting could be reevaluated. It was also clarified that the modeling included data on height and blood type, but not CPRA since that data is not available yet. The Committee supported keeping the 5% weighting for CPRA as initially proposed.

Additional Feedback from Public Comments

The Chair clarified that extracorporeal membrane oxygenation (ECMO) bridge to transplant is hard to capture since it is not captured at the listing point. A member asked if ECMO bridge to transplant is incorporated at all and the Chair stated that it is not because it is only considered mechanical ventilation at 100% so the first step would be to collect that specific data so it could be incorporated in the future.

Additional Changes

Some additional revisions that occurred as minor post-public comment changes for structure and clarity included reverting to a longer explanation for partial pressure of carbon dioxide (PCO_2), reconciling changes from the lung allocation score (LAS) updates, updating terminology, correcting errors and references, and showing that the current Lung Review Board guidelines will be removed. The Committee was comfortable with the additional changes that were outlined.

Post-Implementation Monitoring and Future Updating

The Chair noted that post-implementation monitoring is outlined in the proposal and additionally trends can be identified in the days and weeks post-implementation. The proposed monitoring plan includes a review at three months, 6 months, one year, and 2 years. A member asked if there would be reporting available to programs similarly to what was issued prior to the most recent LAS update so that programs could see the effect CAS would have on their waitlists. It was clarified that something would be

available, but the specifics of what that would look like has not been decided yet and would rely on Committee input.

When reviewing the waiting list metrics that would be monitored, the Chair suggested changing the number of heart-lung candidates to all multi-organ candidates and members agreed. A member asked if the a shift in wait time for geographic areas could be monitored and it was clarified that the proposed metrics aim at monitoring whether or not candidates are disadvantaged based on where they live. A member mentioned that two concerns coming from the Midwest are which organs from the Midwest are going to go to the coasts and as those organs leave the region are smaller centers going to see an increase in costs. Another member asked how efficiency would be monitored post-implementation and the Chair also suggested that center volume pre- and post-implemented be evaluated. It was added that utilization is evaluated which may get at the efficiency monitoring being requested. The Chair noted that in terms of efficiency there are still limitations in the data such as cost, so distance is the metric being used. They continued with possibly looking at the number of programs an offer is made to before it is accepted to address inefficiency concerns from organ procurement organizations (OPO). A member felt that this would be important from a transplant program perspective as well. Another member suggested looking at a percent of change in transplant rates by small, medium, and large programs in geographic areas. The Chair stated that those data would not likely be very reliable early on. Bringing the discussion back to efficiency monitoring, a member suggested tracking the time from the first offer to the time the organ is placed. The Chair asked if that be sufficiently captured in the time from first electronic offer to cross clamp and they felt it would. It was also add that there is a proposal from the OPTN Organ Procurement Organizations Committee that will strengthen that data in the future.

A member asked if it was possible to get a comparison of program metrics pre- and post-implementation. The Chair suggested that the previous six months to one year of benchmark reports be retained for comparison for programs. UNOS staff offered to follow-up with Research staff on how to retain that information on the data services portal.

Transition Plan

The Chair stated that they would stand by what the Committee previously discussed and allow for exceptions prior to implementation and that would be the only aspect needed. A member asked if there will be a calculator available ahead of time to see if programs can anticipate a need for a CAS exception and it was clarified that there will be a calculator available.

Committee Vote

Does the Committee approve to send the Establish Continuous Distribution of Lungs proposal to the OPTN Board of Directors meeting in December 2021?

The Committee voted 12 yes, 0 abstain, and 0 no.

3. Waitlist Survival Calculation Refit Update

SRTR staff presented three different models of how to handle the waitlist calculation component of the LAS for patients who are ventilated. The reason for this is due to when the LAS was recently updated it was realized that the SRTR and the OPTN are calculating this differently. SRTR sets the oxygen and six minute walk values to zero for ventilated patients while the OPTN is giving credit for being on a ventilator and multiplying the amount of oxygen the patient is using. It was suggested that this may have been due to patients not being transplanted while on a ventilator when the decision was made back in 2005.

The three options presented are using the values as entered by the program, setting the values to zero, The Committee reviewed the different effects on the model that each of the options would have. It was noted that as oxygen increases so does a candidate's LAS and the average ventilated patient will get a similar LAS, but it does depend on what the oxygen level is.

Summary of discussion:

A member asked where the specific oxygen numbers come from and the Chair clarified that it is the liters of oxygen. Another member stated that liters are not the same across all devices and the Chair added that part of the Updating Mortality Models Subcommittee work is to update those fields to be more accurate.

A member asked for a clinical explanation for why the effect of the amount of oxygen is different for ventilation and SRTR staff clarified that the reasoning is that if a patient is on six liters of oxygen via nasal cannula that is different that someone receiving the same amount via a ventilator sine there is an additional level of respiratory failure. Another member expressed concern over patients on ECMO being disadvantaged and it was stated that ECMO is entered as mechanical ventilation and 100% oxygen. SRTR staff explained that the OPTN calculation gives patients an LAS in the 90s and what is being presented today is SRTR modeling. A member added that conceptually if someone is on a lot of oxygen, they are intubated and are much sicker so there is a larger jump in LAS, but once the patient is ventilated there are smaller increases because they are already ventilated and very sick. SRTR staff agreed and further explained that in early stages there is more of a progression in severity of illness, but once the patient is at the sickest the delta becomes less. A member described the added risk in addition to oxygenation amounts for patients when they are placed on a ventilator and how that should be considered. SRTR staff explained that that jump in score when a patient is put on a ventilator incorporates that risk. Another member stated that a patient on 100% oxygen that is not ventilated is much different than a patient who is ventilated on 100% oxygen in terms of risk for mortality and felt that if an organ becomes available it should go to the patient on ECMO. SRTR staff and a member felt that both patients are very sick with high risk for mortality and should be ranked high on a match.

A member asked if this is for SRTR to use for modeling, could they not just mimic what the OPTN is doing. SRTR staff agreed that the two should be aligned, but that the OPTN score is so high that it could be potentially disadvantaging people who are very sick and not on a ventilator. The member asked if this is something that would be done prior to continuous distribution implementation and it was clarified that there is an opportunity to incorporate any changes with the work the Updating Mortality Models Subcommittee is doing since any change for the OPTN is part of policy and system programming and would require public comment. It was also suggested that the Committee may need more analysis to make a decision.

HRSA staff asked if the amount of time a patient is on a ventilator makes a difference and the Vice Chair stated that long-term ventilation does mean something different. SRTR staff also added that the way LAS is constructed the interaction of variables does not change over time. The Chair did not think that data is collected and if the patient was ventilated pre-listing we would not know for how long. HRSA staff suggested that it may beneficial to collect updates on ventilation status and the Chair clarified that if a patient is on a ventilator they will have an LAS over 50 which requires updating every 14 days.

Next Steps:

The Committee will submit a formal request for additional modeling to help inform any decision which will further be discussed by the Updating Mortality Models Subcommittee and full Committee.

4. Upcoming Committee Work

An update was given on the current ongoing Committee work and upcoming projects. The Updating Mortality Models Subcommittee is still ongoing and the Committee will begin working on updating Lung Review Board Guidance in continuous distribution. Other upcoming work would include implementation education and training planning for continuous distribution and post-implementation review of the recent LAS update. The Vice Chair asked if the Lung Review Board has seen an increase in the number of exceptions post-implementation and it was clarified that a drastic increase has not been communicated.

The Committee was also reminded of the upcoming Vice Chair opening and to apply if interested.

Upcoming Meeting

- November 18, 2021

Attendance

- **Committee Members**
  - Erika Lease, Chair
  - Marie Budev, Vice Chair
  - John Reynolds
  - Julia Klesney-Tait
  - Whitney Brown
  - Errol Bush
  - Dan McCarthy
  - Cynthia Gries
  - Denny Lyu
  - Nirmal Sharma
  - Marc Schecter
  - Staci Carter
- **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
  - James Alcorn
  - Rebecca Murdock
  - Rebecca Goff
- **Other Attendees**
  - Dave Weimer