

**OPTN Thoracic Committee
Meeting Minutes
October 17, 2019
Chicago, IL**

**Ryan Davies, MD, Chair
Erika Lease, MD, Vice Chair**

Introduction

The Thoracic Committee met in Chicago, IL on 10/17/2019 to discuss the following agenda items:

1. Continuous Distribution of Lungs: Road-mapping future Workgroup activities
2. Lung Subcommittee- Continuous Distribution of Lungs
3. Heart Subcommittee- Adult Heart Allocation Policy Considerations
4. Update of Pediatric Heart Workgroup activities
5. Continuous Distribution of Lungs Concept Paper: Post-public comment review
6. Thoracic Committee Charge Discussion
7. Policy Oversight Committee Update

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

1. Continuous Distribution of Lungs: Road-mapping future Workgroup activities

Committee members received information about Analytic Hierarchy Process (AHP), Discrete Choice Analysis (DCA), and other activities, related to continuous distribution.

Summary of discussion:

There was a question asking whether travel mode and ischemic are co-dependent attributes in terms of weighting. There was concern about redundancy in the modeling, and the questioner cautioned against counting variables twice. Staff explained that while the inputs to the two attributes are related, they are used to measure different aspects of the system; therefore, they are not counted twice. There was also concern about weighting certain attributes because of member bias and imperfect understanding of the impact of each attribute (e.g. importance of 1 hour versus 3 hour ischemic time). This member advocated not counting ischemic time, because post-transplant outcomes are already factored into the LAS.

Another member asked how different regions with varying populations can be factored into the modeling, and how the OPTN might ensure the principles are applied uniformly despite regional variances of opinions. Clarification was provided saying that the Committee would be responsible for considering all these factors, and discerning the best way to weigh each factor.

One member opined that donor characteristics are very important, and that they were concerned that this was not going to be accounted for under the new system. Staff clarified that the attributes listed are the ones under the current system, though there are others that physicians taken under consideration when determining an organ offer. Another member stated that the Committee should first start with these variables, and then modify over time. Other members supported this, and agreed that this system should not determine how to make offers. However, the Committee is aware that any historical data incorporates decision-making behavior.

Another member opined that the primary answer should be post-transplant outcomes, and that the Committee should strive to standardize outcomes across the U.S. However, there may be difficulties in doing this, because there is such variability in regional and center practices. Other members supported focusing on organ offers, because even if you try to take donor characteristics into consideration, there is too much regional and center variability. A member suggested focusing the modeling on each output, such as waitlist mortality or post-transplant outcomes, in order to determine the impact of each.

Next steps:

The Committee will continue their discussions about the continuous distribution of lungs throughout the next coming months. The goal is to submit a public comment proposal next Fall 2020.

2. Lung Subcommittee- Continuous Distribution of Lungs

Sub-committee members were asked to review identified attributes related to the concept paper. Members were also asked to consider what, if any, additional information is needed to consider the attributes as final and ready for inclusion in the proposed composite allocation score.

Summary of discussion:

The Subcommittee considered the following attributes to include in the composite allocation score:

Medical Urgency:

Recommendations were made to split the LAS into its two components (WLAUC and PTAUC) for the purpose of developing the composite allocation score. This will facilitate the comparison of WLAUC with Lung Pediatric Priority levels. It will also allow comparison of medical urgency across organs. The OPTN could maintain an LAS for members even if the LAS were split. Also, either the Subcommittee could keep the same weighting between WLAUC and PTAUC or reweigh them. Furthermore, the OPTN can continue to report the LAS if this is helpful to members. The Subcommittee agreed to consider LAS in its two components during the development of the continuous distribution proposal. The Subcommittee agreed to discuss the weighting of WLAUC and PTAUC when the AHP is performed. They also agreed to the proposed data requests:

1. Request 1: For a historical cohort, using unacceptable antigens reported for waiting list registrations, calculate each registration's CPRA using the kidney CPRA calculator. Calculate lung offer rates per active patient year on the waiting list, by CPRA group. The relationship between lung offer rates and CPRA, particularly the degree of nonlinearity, will be used to help inform development of a sensitization ratings scale for Continuous Distribution of lungs.

2. Request 2: After the coefficients of the lung allocation score (LAS) are updated by the SRTR, if deemed necessary after deciding upon a precise approach for developing the rating scale, examine the relative importance of differences in waiting list urgency measure. Examine the waiting list mortality rate and/or use Kaplan-Meier to estimate survival curves for a historical cohort by different waiting list urgency measures. The net increase in the waiting list mortality rate AND/OR KM survival estimates could be different by waiting list urgency measure. It is hypothesized that the waiting list mortality rate difference increases or becomes greater as the waiting list urgency measure increases. It should show increasing waiting list mortality rate by increasing waiting list urgency measure; not necessarily linear.

3. Request 3: After the coefficients of the lung allocation score (LAS) are updated by the SRTR, if deemed necessary after deciding upon a precise approach for developing the rating scale, examine the relative importance of differences in post-transplant survival measure. Examine the

estimated 1 year post-transplant survival for historical candidates by different post-transplant survival measures. The net increase in the posttransplant survival could be different by post-transplant survival measures. It should show increasing 1 year post-transplant survival by increasing post-transplant measure; not necessarily linear.

4. Request 4: After the coefficients of the lung allocation score (LAS) are updated by the SRTR, determine how pediatric priorities (Priority 1 and Priority 2) align with the waiting list mortality piece and post-transplant survival piece of LAS. Calibrate pediatric priority 1 and 2 to align with the waiting list urgency measure and post-transplant survival measure in LAS. Calculate the waiting list mortality rate and 1-year posttransplant survival for pediatric priority 1 and 2 candidates to determine how they align in the waiting list urgency measure and post-transplant survival measure.

HLA Matching:

The Subcommittee discussed this attribute and agreed not to pursue DR matching or a scale for HLA matching at this time, because there 1) there isn't consensus yet as to the impact of 0-ABDR lung matches on post-transplant outcomes; and 2) this isn't part of the current system.

schemic time:

The Subcommittee discussed the options for this attribute and developed a new data request to inform the choice. The Subcommittee requested analysis about which option is more closely correlated with post-transplant outcomes: straight-line distance, estimated travel distance, or estimated transit time. The SRTR will build the rating scale for transplant outcomes upon the option that is most closely correlated with post-transplant outcomes. This is the SRTR data request that was developed:

1. Data Request 1: Building on the results of request LU2019_01, in which SRTR estimated travel time and assigned mode, the committee requests the follow-up analyses below.

- Associations of ischemic time with each of the following: straight-line distance between donor and recipient, travel distance, travel time, and travel mode. Since data request LU2019_01 showed little variation in mode assignment per travel cut point, this analysis will be based on the 60- minute cut point.
- Impact of ischemic time, straight-line distance between donor and recipient, travel distance, travel time, and travel mode on 1-year posttransplant outcomes. Analyses will be adjusted for LAS or LAS-defining factors, and each will be modeled separately.

Size matching and height:

The Subcommittee agreed that while size matching holds promise for the future, the OPTN will not include size matching at this time. However, the Subcommittee wants to include priority points dependent upon the size of candidates (the theory is that smaller candidates are harder to match and therefore need priority for smaller donors.) During the discussion of size matching, some Subcommittee members mentioned that there wasn't universal agreement on how to measure size. The Subcommittee did not specify how to calculate candidate size for priority points.

Highly Sensitized:

The Subcommittee agreed to continue allowing lung allocation policy to priority highly sensitized lung candidates, because public comment from 2017 and 2018 indicate that this is a current and growing issue for the lung transplant community. The Subcommittee also agreed to recommend using the CPRA calculator to identify highly sensitized candidates. Transplant programs currently have the ability, but are not required, to enter enough information to determine a CPRA score. The Subcommittee would keep this voluntary for those programs who seek priority for highly sensitized candidates. Lastly, the Subcommittee agreed with the idea that if a center enters an unacceptable antigen that is used for screening then the candidates would receive boost points through CPRA.

Pediatrics:

Many members expressed a desire to keep age issues as close to current policy as possible. In other words, pediatric candidates should continue to get priority for pediatric donors. The Subcommittee initially said that they agreed to group candidates aged 0-18 together and not pursue age matching. However, one member suggested prioritizing pediatrics ages 12-17 for adult donors. In the end, the Subcommittee agreed not to pursue age matching at this time.

Prior Living Donors:

The Subcommittee agreed that this doesn't happen frequently, but that prior living donors should be prioritized. One suggestion was to prioritize prior lung donors more than other living donors.

Placement Efficiency:

UNOS staff asked Subcommittee members to bring ideas for other definitions of placement efficiency to a future meetings.

Next steps:

The Subcommittee will continue their discussion on the attributes to include in the composite allocation score in subsequent meetings.

3. Heart Subcommittee- Adult Heart Allocation Policy Considerations

Subcommittee members met on September 26, 2019 and were presented information related to an initial review of submitted exception requests. Subcommittee members indicated their preference to develop guidance documents for submitting and reviewing exception requests. At the October 17th meeting, members were asked to identify and clarify the information they believe will help regional review board members make informed decisions about submitted exception requests.

Summary of discussion:

In terms of status 2 IABP, Subcommittee members agreed that this status was meant for patients that required a balloon pump in order to get them out of an acute shock state. The policy was not meant to make balloon pumps a bridge to transplant. Part of the challenge is that the criteria listed "within 7 days" are the same criteria needed for any temporary support. Ideally, the transplant centers would determine the course of treatment for patients in cardiogenic shock, because it may prove difficult for the Subcommittee to determine which patients do or do not qualify. On the other hand you may list contraindications to other devices, such as mechanical support devices, which can show that the

candidate needed a balloon pump. Committee members also reinforced the fact that initially, the IABP criteria had been crafted in a particular way as to discourage IABP usage because in theory candidates on balloon pumps should have higher mortality rates when kept on the device for a long period of time. However, one member questioned this point, and noted that it may not be entirely bad that a candidate is put on a balloon pump in order to prevent having LVAD complications and higher mortality rates later on.

Another challenge for RRBs is that centers may not agree with the IABP criteria currently found in policy and thereby submit exception requests, which is a concern of Committee leadership. Also, Subcommittee leadership noted that some of the IABP exceptions they reviewed were submitted because of candidates that did not want durable VADs. Many members agreed, but noted that the purpose of the RRB is to determine whether an exception candidate has an equivalent mortality risk as other non-exception candidates for a particular status and criteria.

Another concern for RRBs is that they are unable to speak to each other about exception cases, and that they may be hesitant to deny a case because of the new policy changes. There has also been concern about which region is reviewing other regions, which may incorporate bias. The Subcommittee briefly touched upon a national heart review board, but no decision was made. Another member noted that broader access to organs may have the effect of altering center behavior practices (e.g. centers may not move a candidate onto an LVAD).

One member stated that from their point of view, centers are concerned that if they move their candidates off of an IABP (status 2) and onto an LVAD (status 3), that their candidate will not get transplanted. There was concern then that many candidates are being listed as status 2 IABP by exception out of fear of not getting transplanted, and that this may disadvantage those candidates who qualify by the criteria. Furthermore, the Subcommittee Chair stated that in their review of the status 2 exceptions, many candidates listed for IABP by exception showed no improvement in their hemodynamics after having received the IABP.

The Subcommittee discussed the differences between initial exceptions, exception extensions, and extensions. The Subcommittee also reviewed the data collection required for each (extension, exceptions, and extension exceptions). The members discussed how the terminology used for the exceptions and extensions likely leads to confusion among users, and may be an area for them to address. It was noted that when the Chair and Subcommittee Chair reviewed the narratives, it was a challenge for them to distinguish between the various forms when looking for documentation of contraindication to VADs. Both of the members thought it might be interesting to see how many words or sentences are included in the narratives, because this can point to members only providing bare minimum data or explanation.

Subcommittee members also expressed concern that the RRBs are taking too long to retrospectively review exceptions. For example, by the time a RRB reviews and either approves/denies the exception requests the patient may have already been transplanted. However, according to the data, the median number of days RRB's take to review the exception forms is about 3 days. In looking at the data further, members agreed that there are a large number of exceptions forms for status 2 exception. Subcommittee members were interested in assessing the percentage or number of candidates at each center who were listed using standard criteria, or by exception. For example, if such data showed a high volume of candidates listed using standard criteria, then perhaps the policy language and exception pathways are working well. Also, the data might show how many candidates had to transition from standard criteria to an exception in order to be transplanted.

The Subcommittee began discussing possible solutions to address the above issues. One possible solution would be to create a guidance document for both RRBs and transplant centers to use for IABP exception requests. Though the Subcommittee acknowledged that the intent would not be to dictate medical care for these patients, many members agreed that guidance may help in curbing the influx of exceptions being submitted and approved. For example, members agreed that it is difficult to define right heart failure (RHF) and to determine what qualifies as RHF. It may also prove difficult to determine the contraindications of a durable VAD. The Subcommittee agreed to provide guidance and to create a template containing suggested elements to include in an exception narrative for proving a contraindication to a durable VAD including RHF, thrombotic risk, contraindication to oral anticoagulants, surgical procedures (e.g. mechanical heart valve), chronic infection, not meeting the hemodynamics to prove an IABP is necessary, and small left ventricle. The Subcommittee agreed to further discuss whether IABP candidates should either be on inotropes or have a contraindication to inotropes in order to extend an exception.

The Subcommittee was supportive of having a national webinar for the thoracic community. This national webinar would cover exception cases, guidance and education related to submitting or reviewing exception cases.

Next steps:

The Subcommittee will continue their discussions as to the development of a guidance document, exception template and possibly a national webinar at subsequent meetings.

4. Update of Pediatric Heart Workgroup activities

The Committee Chair gave a brief update as to current activities so far, and the project's next steps.

Summary of discussion:

There were no questions or comments from Committee members.

Next steps:

The Committee Chair opened the Workgroup up to members of the full Committee. The next Pediatric Heart Workgroup meeting will occur on October 22, 2019.

5. Continuous Distribution of Lungs Concept Paper: Post-public comment review

The Committee reviewed public comment feedback and potential post-public comment changes to consider as the project moves forward.

Summary of discussion:

Committee members encouraged providing an opportunity to have outside organizations be involved in workgroups or listen into Committee calls. Staff has asked for input from these societies in the past and will continue to look for ways to incorporate their input.

6. Thoracic Committee Charge Discussion

As part of the contract deliverables pertaining to the governance and operations plan for OPTN committees, all committees were tasked with reviewing their current charges and modifying as necessary. The Committee discussed separating the OPTN Thoracic Committee into two Committees: OPTN Heart Committee and OPTN Lung Committee. Members voted to approve charges for both the Heart and Lung Committees.

Summary of discussion:

Overall, members were supportive of splitting the Thoracic Committee into separate Lung and Heart Committees. Members stated the benefits of separate Committees would include adequate resourcing for each Committee, and the ability for OPTN regions to have both a lung and a heart representative. Other benefits include each Committee focusing on their respective projects, and which would likely increase the efficiency and effectiveness of each Committee. The downside to splitting the Thoracic Committee would be a perceived decrease in participation and collaboration between the members. In the end, the Thoracic Committee voted unanimously (18,0,0) to split and approved separate charges.

Next Steps

The Lung and Heart charges will be put forward to the BOD for consideration and approval in December 2019.

7. Policy Oversight Committee Update

The Policy Oversight Committee (POC) has identified and recommended to the Executive Committee strategic policy priorities for the OPTN committee project portfolio. These will be used to guide the OPTN in selecting committee projects that deliver the greatest benefit to the transplant community. The Committee Vice Chair provided an overview of these priorities. Members were asked to provide feedback. The Committee also discussed potential enhancements for heart-lung listings and matches.

Summary of discussion:

During the discussion, a Committee member commented that physicians have decision fatigue, which may delay the organ placement, and therefore increase the risk that the donor may become unstable. Other members supported determining which organs are not being used, and then targeting the reasons why these organs are being turned down. There was also concern surrounding OPO practices (e.g. not performing certain labs when requested), competing incentives by outside regulatory agencies (e.g. post-transplant outcomes), the varying criteria transplant centers have in place when determining organ offers, and performing transplants during the night. One member opined that there may be issues surrounding the number of operating rooms available, and that certain OPOs will manage their donors in a particular way (lack of standardization). Many members supported looking at how to improve the relationships between transplant centers and OPOs, especially with broader sharing. Another member supported monitoring OR turndowns, because of a perceived increase in organ discard regardless of organ donor quality. For example, OPTN should collect more granular data in order to determine practice behaviors, such as mandating the specific reason an organ is turn-downed. However, other members stated that centers may react to their increase scrutiny by narrowing their acceptance criteria. A member suggested that candidates have a standardized score for organ quality ("high value organ"), though this might result in decrease in organ utilization. Another member stated that policies should drive increases in acceptance behaviors, especially for thoracic organs which tend to be more focused on transplant outcomes. One suggestion was to look into incentivizing the development of organ recovery centers, if such institutions should decrease organ discard rates, and increase in post-transplant outcomes. There would be some benefits, including controlling organ procurement costs through greater efficiencies (such as not sending multiple teams to procure an organ). There was some concern that in certain circumstances it is impermissible to move donors across state lines, so getting the organ donor to a particular recovery center may prove difficult. It was clarified that the OPTN OPO Committee is trying to address some of these issues.