OPTN Lung Transplantation Committee
Meeting Summary
October 27, 2023
Chicago, IL

Marie Budev, DO, Chair
Matthew Hartwig, MD, Vice Chair

Introduction

The Lung Committee (the Committee) met in Chicago, IL on 10/27/2023 to discuss the following agenda items:

1. DCD Lung Transplant Collaborative Learning Congress Debrief
2. Continuous Distribution of Lungs: 6-month monitoring report
3. Lung Review Board Operations
4. Lung Allocation Efficiency Project
5. Update Data Collection for Lung Mortality Models Implementation Overview
6. Six Minute Walk Project
7. Vice Chair Nominations Process
8. Open Forum

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

1. DCD Lung Transplant Collaborative Learning Congress Debrief

The OPTN's DCD Lung Transplant Collaborative participants convened for a Learning Congress on September 26-27, 2023, in San Antonio, Texas to mark the end of the collaborative's active engagement period. The Committee reviewed participant takeaways, stakeholder keys for success, and feedback regarding lung allocation collected at the Learning Congress.

Summary of discussion:

Members highlighted the importance of considering donor hospital limitations. A member commented that it would be useful to organ procurement organizations (OPOs) for the committee to identify additional key information to collect from donor hospitals, as donor hospital data is inaccessible. Given that donor hospitals are not under OPTN purview, the Chair proposed exploring ways to connect with donor hospitals to address barriers during donation.

Next steps:

OPTN support staff will post materials from the Learning Congress to the OPTN website.

2. Continuous Distribution of Lungs: 6-month monitoring report

The Committee reviewed the 6-month monitoring report for Continuous Distribution (CD) of Lungs.[1] This analysis compares the pre-policy era (Sept 6, 2022-Mar 8, 2023) to the post-policy era (Mar 9, 2023-

[1]Samantha Weiss and Chelsea Weibel, "Lung Continuous Distribution Six Month Monitoring Report," OPTN, October 27, 2023, accessed November 11, 2023, https://optn.transplant.hrsa.gov/media/4feooi1h/data_report_lung_cd_6month_20231027.pdf.

Sept 8, 2023). The report included small sample sizes. Data are subject to change as data lag allowed by OPTN policy has not fully passed, thus, general trends described in the report may change.

Data summary:

Overall, the number of candidates ever on the waiting list increased from 2,468 in the pre-policy era to 2,611 in the post-policy era. The total number of candidates removed from the waiting list for death or too sick decreased from 111 pre-policy to 82 post-policy. Deaths per 100 patients years on the waiting list decreased by 27.5% in the post-policy era. The overall number of transplants performed increased from 1387 pre-policy to 1543 post-policy.

Medical Urgency:

This section of the analysis only contains data for the post-policy era as there was no data for this metric in the pre-policy era.

- Change in points from listing to removals
    - For 57% of registrations, medical urgency points did not change
    - Median: 0.00
    - Mean: 1.92

Pediatrics:

- Number of pediatric donors donating to pediatric recipients decreased from 9 to 4
- Number of adult donors donating to pediatric candidates increased from 4 to 11
- Pediatric candidates received more offers in sequence 1

Blood type

- The proportion of candidates with blood type O removed for death or too sick increased from 57.7% to 64.6% post-policy
- Median time to transplant decreased for all blood types, except O
- Number of transplants increased for all blood types, except O

Modify Lung Allocation by Blood Type was implemented on September 27, 2023 to address inequity of organ offers across blood types. In addition to the previously defined policy eras, the Committee compared data from pre-CD (February 15, 2023-March 8, 2023), post-CD (September 5, 2023-September 26, 2023) and post-CD + blood type modification (September 29, 2023-October 20, 2023). Due to their small size, these samples may not be representative of the entire waiting list. There were no significant trends identified.

CPRA

- Proportion of candidates for whom CPRA is 0 or not reported decreased from 83.7% to 71.4% in the post-policy era, indicating an increase in CPRA data entry
- Median time to transplant decreased for candidates with CPRA values 1-19 (113 days to 39 days) and 20-79 (149 days to 57 days)
    - Could not be determined for candidates with CPRA value of 80+ in the pre-policy era due to sample size

Height

Pediatric candidates were removed from this analysis, given their allocation advantages in CD.

- Removals for death or too sick decreased for all, except candidates 5’2” to 5’5”
- Median time (in days) to transplant:

- Decreased from 93 days to 58 days for candidates <5’2”
- Increased from 46 days to 55 days for candidates 5’2” to 5’5”
- Was similar for the groups with candidates 5’5” to 5’7” (39 to 40), 5’7” to 5’10” (30 to 29) and >5’10” (27 to 24)

Efficiency

- Median distance increased from 195 nautical miles (NM) to 353 NM
- Utilization rate increased slightly for both DCD and non-DCD donors
- Median number of programs notified before final acceptor increased from 4 to 10
- Median number of programs notified after the final acceptor increased from 8 to 11

Multiorgan

- Number of Lung/Liver transplants increased from 6 to 10
- Median sequence number increased for Lung/Kidney (3 to 11) and Lung/Liver (3 to 9) recipients

The Committee also reviewed recommendations from the OPTN Ad Hoc Multi-Organ Transplantation Committee to improve allocation efficiency for Lung/Liver candidates.

Geography

- Removals for death/too sick and median time to transplant increased in 3, 4, 8 and declined or remained stable in 8 remaining regions
- Number of transplants decreased for Regions 3 & 8

Summary of discussion:

Decision #1: The Committee requested that candidates with an exception request for medical urgency be analyzed separately in future monitoring.

Decision #2: The Committee requested post-transplant survival data stratified by age in future monitoring.

Decision #3: The Committee requested to review composite allocation score (CAS) sub-score at transplant excluding blood type points in future monitoring.

Decision #4: The Committee requested distinction between candidates with a CPRA value of 0 and those with CPRA not reported in future monitoring.

Decision #5: The Committee requested data for candidates with high CPRA values combined with height, gender or diagnosis group in future monitoring.

Decision #6: The Committee requested data for height stratified by diagnosis group in future monitoring.

Decision #7: The Committee was interested in defining a point earlier on the match run where OPOs can move to abdominal allocation to improve efficiency for lung multi-organ allocation.

Decision #8: The Committee will continue monitoring geographical access concerns for Regions 3 and 8.

Medical Urgency

Members were concerned about the percentage of candidates that had an increase in their medical urgency points from listing to removal, indicating some degree of deterioration in their condition, though the median change in medical urgency points was 0 points. In reference to the mean change in

points, a member noted that a difference of 2 medical urgency points is clinically significant. Potential confounding factors within data structure were explained. To better understand the impact of CD, the Committee requested that candidates with an exception request for medical urgency be analyzed separately.

Blood type

Prior to the ABO policy implemented September 2023, candidates with blood type O were getting sicker before being prioritized for transplant. The Committee requested to review CAS sub-score at transplant excluding blood type points in future monitoring. The Committee will review additional monitoring data for *Modify Lung Allocation by Blood Type* in the coming months.

CPRA & Height

The Committee discussed the need to evaluate how CPRA and height interact. Members were particularly concerned that short-statured females with high CPRAs may have inequitable access to the donor pool. It was noted that data for height groups <5'2" and 5'2" to 5'5" are conflated with high CPRA values and potentially certain diagnoses. The Committee discussed shifting the distribution of points to further advantage short-statured candidates. Height data stratified by diagnosis group would aid future decision-making.

Members emphasized that it is difficult to draw conclusions from the CPRA analysis due to small sample sizes driven by missing data. The Chair commented that the incentive to enter CPRA data and number of points assigned for CPRA are minimal. Another member agreed, stating points for CPRA do not overcome the offers lost for registering candidates as having unacceptable antigens. If non-reporting continues, the Committee may wish to adjust the CPRA point system to further incentivize data entry.

Efficiency

The Committee discussed the importance of monitoring the number of programs notified before and after the final acceptor. These metrics are indicative of the increased workload experienced by transplant programs in CD. Additionally, the Vice Chair commented that the number of unique programs that must review these offers may drive an increase in allocation time. An OPO representative noted that standardization of OPO offer management would help to mitigate these issues.

Members expressed concerns that OPOs are offering more lungs that may not be suitable for transplant. A Region 8 representative commented that it seems her program has reviewed more offers from DCD donors under CD. Though outside of OPTN purview, the Committee identified CMS OPO performance metrics as a driving factor in the number of offers sent.

Multiorgan

The Committee was interested in defining a point earlier on the match run where OPOs can move to abdominal allocation to improve efficiency for Lung/Liver candidates. Members discussed potentially giving more points to lung MOT candidates on the lung match run. The Committee also discussed raising the CAS threshold for required offer notifications, which could be defined by CAS sub-score, percentage of the match or sequence number, or a time constraint. An OPO representative explained that OPOs may be required to send upwards of 100 lung offers, in some cases, prior to initiating liver allocation. Raising the CAS threshold would reduce the number of primary offers sent.

The Chair stated, at her program, it seems Heart-Lung candidates are getting much sicker prior to transplant. Data for the change in medical urgency points for multiorgan candidates would be useful in assessing this potential issue.

Geography

The Committee discussed the need to continue monitoring geographical access concerns for Regions 3 and 8. A Region 8 representative expressed concerns about the strain of traveling for every suitable organ offer.

Next steps:

The Committee will review additional monitoring data in the coming months, including the 1-year monitoring report for Continuous Distribution of Lungs.

3. Lung Review Board Operations

The Lung Review Board (Review Board) Chair provided an overview of exception request concerns identified by the Review Board. The Review Board Chair clarified that exception requests for pulmonary hypertension (PH) should be submitted under medical urgency and post-transplant outcomes.

Summary of discussion:

The Chair shared that anecdotally, colleagues in the lung transplant community observed inconsistencies in Lung Review Board decisions. The Review Board Chair reviewed steps already taken and identified potential process improvements to standardize Review Board decisions. It was discussed that the community's understanding of exception requests also determines whether exceptions are requested appropriately. If sufficient data become available, additional guidance on typical clinical characteristics of candidates at certain percentiles would help in this realm.

A member proposed automating PH exception requests to streamline the process. Per the Review Board Chair, this solution has been explored previously and is not an option.

4. Lung Allocation Efficiency

The Committee reviewed the following potential solutions to decrease the number of organ offers sent after the final acceptor: lung offer filters and related data collection; system enhancements; require HLA typing prior to organ offer; OPO notification limits.

The Committee received updates on OPTN efforts related to efficiency, including:

- Expeditious: Organ Usage through Placement Efficiency Task Force
- MPSC OPO Performance Metrics Workgroup
- Match Efficiency project: Design changes in OPTN Donor Data and Matching System

Summary of discussion:

Decision #1: The Committee supported future implementation of offer filters for Donor positive Hepatitis B and Hepatitis C tests.

Decision #2: The Committee supported data collection for history of anaphylaxis to peanut and/or tree nut, although it affects a small percentage of donors.

Decision #3: The Committee supported data collection for previous coronary artery bypass grafting (CABG) but emphasized the need to clearly define the data field.

Decision #4: The Committee will explore Glasgow Coma Scale (GCS) as potential data collection; however, it may not be appropriate for use as a filter.

Decision #5: The Committee supported pursuing data collection for death due to asthma or airway burns.

Decision #6: The Committee supported exploring an offer filter for smoking history, which is currently collected in terms of whether the donor has ever used cigarettes for more than 20 pack years.

Decision #7: The Committee supported implementing a function that would allow OPOs to bypass candidates who will only accept bilateral transplant if one of the lungs is not available.

Decision #8: The Committee was interested in a modification that could allow transplant programs to opt in or out of offers from Hawaii, Alaska, and Puerto Rico.

Decision #9: The Committee recommended requiring HLA typing prior to organ offer in policy for DBD donors, but not for rapid DCD donors. The Committee recommends that the OPTN Histocompatibility Committee continues to assess this issue.

Decision #10: The Committee recommends continuing to assess options for optimizing offer volume.

Decision #11: The Committee requested data for offer volume by region.

Lung Offer Filters and Related Data Collection

The Committee endorsed several potential lung offer filters and new data collection elements to reduce the number of unwanted offers received by transplant programs. The Committee supported future implementation of offer filters for Donor positive Hepatitis B and Hepatitis C tests. Some members supported data collection for history of anaphylaxis to peanut and/or tree nut, although it affects a small percentage of donors. Members acknowledged that this would not significantly reduce offers, but providing the option to filter is worthwhile as some programs decline these organs.

The Committee supported data collection for previous CABG but emphasized the need to clearly define the data field. The Chair noted that this will would be helpful in assessing offers from DCD donors, which her program typically receives every couple of months. Members agreed that chest surgery is too broad to be useful in decision-making.

The Committee will explore GCS as potential data collection; however, it may not be appropriate for use as a filter. Members agreed that GCS could be useful in assessing DCD donors and is the most familiar tool among those presently available. There were concerns about the utility of GCS as an offer filter. It was discussed that GCS scores are not reliably indicative of donor outcomes. Members were concerned that suitable offers may be filtered out.

The Committee supported pursuing data collection for death due to asthma or airway burns. Members agreed that lung programs would not accept lungs from donors with these causes of death. The Committee was not interested in data collection for drowning for use as potential offer filters. A member commented that programs may accept lungs from drowned donor depending on water type, therefore, suitable offers could be filtered out.

The Committee supported exploring an offer filter for smoking history, which is currently collected in terms of whether the donor has ever used cigarettes for more than 20 pack years. Members noted that in combination with other factors, smoking history could be useful in decision-making for organ acceptance.

System Enhancements

The Committee discussed two system enhancements to reduce unwanted offers and allow programs to tailor offers received. Members supported implementing a function that would allow OPOs to bypass candidates who will only accept bilateral transplant if one of the lungs is not available. The Committee was interested in a modification that could allow transplant programs to opt in or out of offers from Hawaii, Alaska, and Puerto Rico. Members discussed the benefit for certain programs to receive offers

from isolated areas while still filtering offers from across the continental U.S. The Chair noted this function is impactful for a limited number of programs. The Committee planned to re-visit the topic of offers from isolated areas at a later time.

Require HLA typing

The Committee recommended requiring HLA typing prior to organ offer in policy for DBD donors, but not for rapid DCD donors. There were no concerns identified to requiring HLA typing for DBD donors. For rapid DCD donors, there was concern about the risk for nonuse due to time constraints. A member commented that it was highly unlikely that programs would accept organs from rapid DCD donors without crossmatch. Members agreed lack of HLA typing is a safety concern. The Committee recommends that the OPTN Histocompatibility Committee continues to assess this issue, and recommended adding a system notification for transplant programs to report if a match was run without HLA typing data.

OPO Notification Limits

The Committee recommends continuing to assess options for optimizing offer volume. Members discussed reducing the limit for primary lung offers from 1000 NM to within 500 NM. This method may increase the number of out-of-sequence offers. Members proposed other solutions to explore, including notification limits by sequence number.

Placement Efficiency

The Committee will continue to monitor concerns surrounding the weight of placement efficiency ratings. Members discussed the importance of creating balance in CD. A Region 8 representative vocalized concerns about the sustainability of increased logistical burdens on transplant programs, urging members to consider the impact of CD at the regional level. The Committee requested data for offer volume by region.

Next steps

OPTN staff will add The Promote Efficiency of Lung Allocation Workgroup will review and vote on the draft proposal for this project in their November meeting. If approved, the proposal will be submitted for Winter 2024 Public Comment. The Committee will communicate their feedback to OPTN Histocompatibility Committee.

5. Update Data Collection for Lung Mortality Models

The Committee received a brief update about the implementation of *Update Data Collection for Lung Mortality Models*.

Summary of discussion:

There was no additional discussion.

Next Steps:

OPTN staff will provide an overview of this project's implementation via webinar on November 15, 2023. Additional education and outreach efforts include updating the learning module "UNet for Lung Continuous Distribution" and the supplemental oxygen FAQ webpage.

6. Six Minute Walk Project

This project aims to standardize performance of the six-minute walk test (6MWT), given that 6MW distance impacts CAS sub-scores. The 6MW Workgroup (the Workgroup) met on 10/19/2023 to review

the 6MW draft proposal for Winter 2024 Public Comment. The Committee was asked to provide feedback on the following items:

- Should an oxygen titration test prior to the 6MWT be required by policy?
    - Should this be required every time a program conducts the 6MWT or only when the candidate is first registered on the waiting list?
- Proposed data definition changes

If an oxygen titration test were required by policy, potential policy language may state:

Six-minute walk distance (feet) ~~obtained while the candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.~~ Transplant hospitals must conduct an oxygen titration test at least once in every six month period following registration for each candidate on the lung waiting list to determine a candidate's oxygen needs for completing the six-minute walk test. The final amount of supplemental oxygen from the oxygen titration test must be documented in the candidate's medical record.

The proposed data definition for "six-minute walk distance" states:

Enter the total exertional distance on a flat surface the candidate is able to walk in six minutes in feet. Refer to Guidance for Conducting the Six-Minute Walk Test for Lung Allocation for additional information on conducting the test. ~~The distance walked is a measure of functional status.~~ The normal range is between 0 and 3000, although a value ~~outside of~~ greater than this range may be entered. Enter the Test Date when this information was obtained. These fields must be updated every 6 months from the time the candidate was added to the waiting list. If they are incomplete or expired, the least beneficial value will be used to calculate the candidate's lung composite allocation score.

Summary of discussion:

Decision #1: The Committee supported requiring an initial oxygen titration test in policy for candidates age 12 and older. Decision #2: The Committee requested inclusion of feet/meter conversion in guidance.

The Committee supported requiring an initial oxygen titration test in policy for candidates age 12 and older. Members agreed this requirement aligns with goals to standardize the 6MW test. It was discussed that this requirement could apply only to candidates age 12 and older as 6MW distance does not impact CAS sub-scores for candidates under 12 years of age.

Members did not support requiring an oxygen titration test every 6 months in policy as changes in supplemental oxygen needs vary by candidate. The Committee also considered the potential logistical impact for transplant programs and candidates. Members agreed that it is important to reinforce the benefits of performing an oxygen titration test in guidance.

The Committee requested inclusion of feet/meter conversion in guidance. A member commented that her program was cited for inaccurate conversion between feet and meters for 6MW reporting. Including the conversion in guidance would standardize data entry and could be referenced during site surveys. Members proposed adding a conversion tool to the OPTN computer system, however, agreed that guidance was sufficient.

Next Steps:

The Committee will review and vote on an updated draft proposal at their November meeting. If approved, the Committee will submit the proposal for Winter 2024 Public Comment.

7. Vice Chair Nominations Process

The Committee received an update regarding Vice Chair Nominations.

Summary of discussion:

There was no additional discussion.

8. Open Forum

The Chair gave members an opportunity for open discussion.

Summary of discussion:

There was no additional discussion.

Upcoming Meeting(s)

- TBD

Attendance

- **Committee Members**
  - Marie Budev
  - Matthew Hartwig
  - David Erasmus
  - Katja Fort Rhoden
  - Stephen Huddleston
  - Soma Jyothula
  - Thomas Kaleekal
  - Brian Keller
  - Julia Klesney-Tait
  - Erika Lease
  - Ernestina Melicoff Portillo
  - Serina Priestley
  - Jaclyn Russe
  - Wayne Tsuang
  - Brian Armstrong - virtual
  - Errol Bush - virtual
  - Edward Cantu - virtual
  - Siddhartha Kapnadak - virtual
  - Pablo Sanchez - virtual
  - Lara Schaheen - virtual
- **HRSA Representatives**
  - Marilyn Levi
  - James Bowman
- **SRTR Staff**
  - David Schladt
  - Maryam Valapour
  - Katie Audette
  - Nick Wood
- **UNOS Staff**
  - Kaitlin Swanner
  - Taylor Livelli
  - Susan Tlusty
  - Chelsea Weibel
  - Samantha Weiss
  - Leah Eminoski Nunez
  - Carson Yost
  - Holly Sobczak
  - Krissy Laurie
  - Sharon Shepard
  - Roger Vacovsky
  - Carlos Martinez
- **Other Attendees**
  - Kate Breitbeil