OPTN Lung Transplantation Committee
Meeting Summary
May 18, 2023
Conference Call

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

Introduction

The Lung Transplantation Committee (the Committee) met via Citrix GoTo teleconference on 5/18/2023 to discuss the following agenda items:

1. Welcome and agenda
2. Lung Continuous Distribution: One Month Monitoring
3. Lung Continuous Distribution Metrics
4. Promoting Efficiency of Lung Allocation
5. Kidney-After-Lung Safety Net Implementation Update
6. Next steps and closing comments

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

1. Welcome and agenda

The Chair welcomed Committee members and presenters.

Summary of discussion:

There was no further discussion by the Committee.

2. Lung Continuous Distribution: One Month Monitoring

Staff presented a monitoring report that focused on one month pre and post implementation of *Establish Continuous Distribution of Lungs.* The monitoring report included small sample sizes which limited stratification. Data are subject to change and general trends presented may change as more data are collected.

Data Summary:

The monitoring report focused on pre- (February 7, 2023 to March 8, 2023) and post- (March 9, 2023 to April 8, 2023) policy eras. Number of candidates waiting on the OPTN Waiting List jumped to 1,226 from 1,204 in the post policy era. Diagnosis Group A fell from 61 to 56 candidates, Diagnosis B increased from 15 to 16 candidates, Diagnosis Group C jumped to six from five candidates, and Diagnosis group D fell from 212 to 208 candidates in the post policy era. The number of OPTN Waiting List removals for death or too sick to transplant was 14 in the first month of continuous distribution of lungs. This ranged from 12 to 29 under the lung allocation score (LAS). There were 77 exception requests in the first month of continuous distribution of lungs, while the maximum under the LAS was 32 per month. However, under LAS, a single registration could only have one exception but in the new system, a single registration can have up to four exceptions. From March 9, 2023 to May 5, 2023 there were 160 total exception requests submitted.

There were 230 transplants under the first month of continuous distribution of lungs. Number of transplants ranged from 177 to 264 under the LAS. The median distribution of distance under the LAS was 198 nautical miles and the median under continuous distribution of lungs is 208 nautical miles. The first month of continuous distribution of lungs had a utilization rate of 32.40% compared to a range of 27.53% to 38.93% under the LAS. The non-use rate in the first month of continuous distribution of lungs was 9.26% compared to a range of 7.05%-10.62% under the LAS.

Summary of discussion:

A member asked if this could be broken up by death by brain death (DBD) donors versus donor after circulatory death (DCD) donors. Staff responded there is not currently enough data but that will be included in the two-month report. The Chair also asked to see if these organs were not utilized after ex vivo lung perfusion (EVLP) use. The Chair asked when the three-month data will be available, and staff responded it would be three months from March 9, 2023.

A member asked if there are pediatric data. He commented the 20 points for pediatric candidates may be too much. Those data are not yet available.

3. Lung Continuous Distribution Metrics

Data Summary:

SRTR staff showed a dashboard that display metrics from the pre-policy era and from implementation of continuous distribution of lungs through May 1, 2023. The median transplant program at acceptance pre and post implementation of continuous distribution of lungs jumped from four to 10. The median offer number at acceptance was between six and eight prior to implementation and has been trending upward to around 14 to 15. The median number of transplant programs notified about potential donor lungs jumped to 30 from 18 to 20 under the LAS.

Summary of discussion:

A member asked if this information could be sent to members and staff agreed. A member stated the implementation of the composite allocation score (CAS) has resulted in an increase in DCD organ offers. Many of these offers are from donors that are far away and whose reflexes are intact, which makes it hard to go out and evaluate those donors. It may be helpful to look at the data by DBD and DCD. The Chair stated these increased offers may include more offers of lower quality organs to more centers. A member stated the burden on the system is astronomical and lung transplants have not increased at the same rate. The Chair agreed this is placing burden on transplant coordinators.

4. Promoting Efficiency of Lung Allocation

Staff explained the Committee will form a Workgroup to explore possible solutions to promoting efficiency of lung allocation, which could include:

- Changes to organ procurement organizations (OPOs) offer notification limits
- Changes to donor acceptance criteria
- Offer filters for lung
- Changes to required lung donor testing outlined in *OPTN Policy 2.11.D*

Summary of discussion:

A member asked the timeline to implement these changes. Staff responded this is dependent on the solution. Notification limits could be a simpler fix, but other solutions may require the public comment process. The Chair commented this is an urgent matter burdening all transplant programs. The member

responded a limit on number of offers OPOs can send out makes a lot of sense. There should be a second wave of offers if needed, but the first wave needs to be limited.

The Chair noted transplant programs are now able to make the decision to turn down an organ instead of the OPOs making that decision, but it is at expense of burn out for transplant teams. Members agreed. A member stated that OPOs do not want to make that call and want to provide as many opportunities for transplant programs as possible. For marginal donor organs, OPOs don't want to take the chance that someone could die without that transplant.

5. Kidney-After-Lung Safety Net Implementation Update

The OPTN Board of Directors approved eligibility criteria for lung-kidney and heart-kidney allocation and safety net in June 2022. Kidney-after-lung/kidney-after-heart safety net will be retroactive. More information can be found here.

90 consecutive days of eligible criteria will enable a candidate to remain eligible until removal without the need to enter data within a 30-day range. There are 39 active kidney candidates as of May 5, 2023 with a prior thoracic transplant. Kidney listing was no greater than 365 days from that transplant for these candidates.

On June 29, 2023, transplant programs can begin entering data for candidates in the OPTN Waiting List for candidates who need simultaneous lung-kidney or heart-kidney transplants. Transplant programs can also begin entering safety net data for prior hear or lung recipients who are registered for a kidney in the OPTN Waiting List.

On September 21, 2023, the criteria for required shares goes into effect for simultaneous lung-kidney and heart-kidney candidates. Candidates who meet the criteria will show up as required shares on the lung and heart match.

Summary of discussion:

A member asked if a candidate has to have been registered on the kidney waiting list while also registered as a lung candidate in order to qualify for the safety net. Staff responded that a candidate could be registered for a lung and a kidney, but if a transplant program decides to move forward with a lung only transplant and the candidate is still registered for a kidney, they still qualify for the safety net if they do not get a kidney at the same time they received a lung transplant.

A member commented a candidate with higher creatinine that receives a lung-only transplant and has renal disease will have a higher priority the first-year post transplant. He asked if the candidate must have proven renal disease months prior to lung transplant or if it is impending for candidates, are transplant programs able to register afterwards as well. The Chair responded if kidney transplant is warranted after lung only transplant, transplant programs are able to show abnormal creatine or glomerular filtration rate in the 365 day timeline. It does not need to be known prior to lung transplant. Staff noted policy will state, "The candidate is registered on the kidney waiting list prior to the one-year anniversary of the candidate's most recent lung transplant date." The candidate could be almost one year out from a lung transplant and if kidney function begins to plummet, the candidate could be eligible for the safety net.

A member asked if a transplant program should still apply for the safety net if a recipient needs dialysis a few months after transplant and dialysis may restore kidney function. Staff responded policy will state:

On a date that is at least 60 days but not more than 365 days after the candidate's lung transplant date, at least one of the following criteria is met:

- The candidate has a measured or estimated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 20 mL/min.
- The candidate is on dialysis.

The member asked how long a candidate will need to have a GFR less than or equal to 20 to be eligible. Staff responded that there are timelines listed in the policy, so a candidate will have safety net priority for 30 days upon qualifying, and once a candidate meets the criteria for 90 consecutive days, then the candidate will retain safety net priority until removed from the kidney waiting list.

The previous heart or lung recipients who qualify for the kidney after lung or kidney after heart safety net will get the same priority in kidney allocation that the kidney after liver candidates receive. Staff shared that outreach to kidney programs on this policy change is being discussed.

6. Next steps and closing comments

The Chair asked members to send their protocols for the six-minute walk test to allow the Six-Minute Walk Workgroup to gauge if identifying oxygen needs ahead of the six-minute walk test would be a significant change from what most transplant programs are doing. The Chair thanked members for their participation.

Summary of discussion:

A member stated the question is how to standardize desaturation studies for the six-minute walk test, so it would be helpful to hear how members are doing this.

Upcoming Meetings

- June 15, 2023, teleconference, 5 pm ET

Attendance

- **Committee Members**
  - Marie Budev
  - Erika Lease
  - Cynthia Gries
  - Dennis Lyu
  - Errol Bush
  - John Reynolds
  - Jackie Russe
  - Julia Klesney-Tait
  - Matthew Hartwig
  - Marc Schecter
  - Laura Schaheen
  - Pablo Sanchez
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - David Schladt
  - Maryam Valapour
  - Nicholas Wood
  - Katherine Audette
- **UNOS Staff**
  - Kaitlin Swanner
  - Taylor Livelli
  - Beth Overacre
  - Chelsea Weibel
  - Holly Sobczack
  - Laura Schmitt
  - Tatenda Mupfudze
  - Samantha Weiss
  - Sara Rose Wells
  - Susan Tlusty
- **Other Attendees**
  - Brian Keller
  - David Erasmus
  - Ernestina Melicoff-Portillo
  - Katja Fort Rhoden
  - Siddhartha Kapnadak