OPTN Lung Transplantation Committee
Meeting Summary
February 27, 2023
Detroit, Michigan/Conference Call

Erika Lease, MD, Chair
Marie Budev, DO, Vice Chair

Introduction

The OPTN Lung Committee (the Committee) met in Detroit, Michigan, on 02/27/2023 to discuss the following agenda items:

1. Welcome & Introductions
2. Continuous Distribution of Lungs
3. Lung Committee Project Work
4. Policy Oversight Committee Update
5. Review NASEM Projects Idea
6. Update on Implementation of Lung-Kidney eligibility Criteria and Kidney-After-Lung Safety Net
7. Public Comment Presentation: Identify Priority Shares in Kidney Multi-Organ Allocation
8. Overview of other Public Comment Items
9. Open Forum

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

1. Welcome & Introductions

Staff welcomed the Committee, and Committee members introduced themselves.

Summary of discussion:

There were no further discussions.

2. Continuous Distribution of Lungs

The Committee heard an implementation update on the Continuous Distribution (CD) of Lungs. Additionally, the Committee heard an overview of the analysis of the lung composite allocation score (CAS) and reviewed the monitoring plan.

Summary of discussion:

Implementation update

A member asked if offers made before the implementation of CD will maintain their allocation based on the lung allocation score (LAS). Staff confirmed that nothing will change with offers before implementation; organ procurement organizations (OPOs) will continue following the match run.

A member asked what is meant by donor acceptance criteria. Staff replied that currently, there's an option to specify different donor acceptance criteria for local and non-local. Continuous distribution will be one national allocation sequence; therefore, the criteria listed for local will be in effect for all donors. Some programs may already have the same criteria in place for local and non-local donors.

The Committee discussed CAS exception requests submitted ahead of implementation. A member asked what are the submitters writing the exceptions for. A member replied that exceptions are written for pneumothoraxes and pulmonary fibrosis, to name a few conditions. Another member added that from the reviewers' perspective, some exception request narratives are detailed while others are scarce. Sometimes it's difficult to understand the percentage requested and the total points the patient will receive. A member replied that a percentile breakdown chart is available while reviewing cases.

Another member asked if any of the denied exceptions were previously approved. The Vice Chair stated that this is an essential question because those granted exceptions before in the other system, and a potential cause for denial could be that some of the narratives are sparse. The Review Board members plan to develop a templated narrative to help programs write narratives for exceptions.

A member asked how many exceptions were submitted for LAS. Staff replied that there were about 40 approved LAS exceptions as of January 31st. A member noted that in the interim exception request period, centers are submitting a paragraph, and there is no additional information, and asked if this will continue to happen with continuous distribution. A member replied that the Review Board will be a template for programs to utilize where they will need to enter additional information to help justify their request for an exception, allowing for additional data.

Another member asked what is being done to resolve the percentage vs. percentile issue. Staff explained that webinars were hosted to provide more education, resources have been updated, and the "Scoring and Exceptions Under Lung Continuous Distribution" module will be updated to make it clearer. Staff is open to suggestions to best handle resolving this issue.

Managing Organ Offers

Staff explained the system notification limits on organ offers. For lung, within 1,000 nautical miles (nm), there are no system limits on organ offers, but OPOs may set their own limits in terms of the number of candidates or number of transplant programs that will receive offers at a time. Beyond 1,000 nm, system limits kick in, so that OPOs may only offer to three transplant programs pre-cross clamp and five transplant programs post-cross clamp. A member shared that OPOs sometimes send 250 offers at once, which can be overwhelming for donor coordinators and programs. The members asked if direction could be given to OPOs to limit offers to 1000 nautical miles or limit the number of offers offered at one time. Staff replied that they would follow up on this question. A member stated that there should be some best practices for the OPOs to limit offers initially. A member asked if there will be a difference in the volume of offers received now versus the volume of organ offers when CD is implemented. A member responded that, currently, more offers are coming through, although they have not been of the best quality.

Regarding managing organ offers, a member asked if there is an automated system that determines which transplant programs OPOs will offer organs to first for programs beyond 1000 nm. A member replied that it's based on the match run and the candidate's CAS. The OPO still follows the match run but there is an offer limit so that OPOs are not offering organs to every program at the same time. A member stated that within the CAS, the placement efficiency attribute is 10% of the overall score so there should be a good distribution of candidates based on distance from the donor hospital.

Staff noted that OPOs control organ offer notification limits by the number of candidates or by the number of programs. A member expressed that sending organ offers by the number of programs does not seem effective when sending notifications about organ offers. Staff explained that if an offer has already gone to the transplant program, the system will allow notification for another candidate at the same transplant program but then stops before it goes to the next candidate. A member asked if this will reduce efficiency since programs have 30 minutes to respond to an offer. Limiting the number of

organ offers is less concerning than the number of calls given to centers that will never get an organ. The member suggested creating a limit for organ offers based on the number on the match around which most organs are placed, with some percentage of additional offers as a buffer to maximize efficiency and reduce the amount of resources needed to review and respond to organ offers.

A member stated that in the new system, the pre-cross clamp limits might protect programs from receiving a large number of offers compared to the old system. A member replied that the distribution of non-local transplant programs within the first round of offers is unknown. The member communicated concerns about centers at different cut-offs in the sequence that may feel they don't have an opportunity to get that organ.

A member mentioned that there are concerns about how much burden changes donor coordinators will be faced with when CD lungs is implemented and asked if there is a plan to follow up with centers. The staff replied that there is no formal mechanism for collecting feedback at this time, but that members can always contact member.questions@unos.org or use the "Contact Us" form on the OPTN website.

Staff updated the Committee that staff was preparating a notification to be sent to OPOs to ask them to review the system notification limits that they set. A member asked how many OPOs are setting their own limits. Staff replied that every OPO is bound to their system limits that are programmed, though 11 OPOs don't have notification limits within 1,000 nautical miles. Another member asked if the communication just asks OPOs to review their notification limits or if it includes suggestions on managing organ offers when CD is implemented. Staff replied that the communication asks them to review their notification limit.

Webinar feedback

A member stated that patients had many questions about placement efficiency points. A member asked if the OPTN STAR file will still include the lung allocation score following lung CD implementation. Staff replied that they would follow up on this question.

Lung CAS Analysis Review

A member asked if there is a correlation between pediatric donors and height. The presenter replied yes, it does advantage small pediatric candidates because of their height. A member noted that short women need to have more points since pediatric candidates are already given additional points. The presenter replied that someone with a height of 140 cm and 200 cm is more likely to be compatible with donors, so they don't need additional points. At the same time, patients with a low proportion of compatible donors need those extra points.

The Chair asked if a monitoring dashboard would be available to review data in real time. The presenter replied that there is not yet a date set for when the dashboard will be available; however, staff indicated that the dashboard would be accessible within the next few months post-implementation. The member asked what information would be included in the dashboard. The presenter replied that the information would consist of counts and any information that can be monitored in real-time such as calculated waiting list survival and post-transplant survival days. The member asked if the number of deaths would be included in the dashboard. The presenter responded yes. A member asked how data is collected regarding device type for perfused lungs. The presenter replied that they would double-check.

Members voiced that blood type O, and multi-organ candidates are subpopulations of interest and should be closely monitored. A member asked when will the monitoring report be available. The presenter replied that the report would be available for three months, six months, and annually thereafter for three years, and the dashboard will be available at some point as well. A member asked if

it is possible to monitor offers that are more subsequently accepted. The presenter replied that they would look into this.

A member inquired if it would be worth having a listening webinar to understand how programs are adjusting to the new system. The Chair asked the OPTN to hold a listening session about two weeks following implementation. The Chair asked how education on lung CD is going for each program. A member replied that their coordinators participated in webinars and town halls to prepare for the implementation.

3. Lung Committee Project Work

The Committee heard an overview of the Six-Minute Walk project. This project aims to standardize the six-minute walk procedure through clinical guidance, policy changes, and updates to the data definition for the six-minute walk variable. The rationale is to ensure the six-minute walk is performed the same way for all lung candidates. It will help ensure that lung candidates are appropriately prioritized for lung transplant based on their estimated waitlist and post-transplant survival. The Committee also discussed the removal of heart-lung registration and other potential changes to heart-lung policy.

Summary of discussion:

Six-minute walk

A member asked if there is a patient representative on the subcommittee. The presenter replied yes. Another member suggested including a respiratory therapist on the subcommittee. Staff asked the Committee to provide recommendations for respiratory therapists who may be interested in participating on the subcommittee.

Heart-lung allocation

The Chair noted that the heart-lung registration has no value because some programs and OPOs do not use it. A member asked if it would impact pediatric candidates if the heart-lung registration was removed. A member replied that there might be some challenges around this. A member asked how the system would operate if the heart-lung registration was removed. The presenter replied that the system would work the same way as it works for most multi-organ combinations. For example, for heart-kidney candidates, the heart match run will indicate if the OPO has to offer the kidney with the heart. The Committee expressed concerns about access to heart-lung transplant for heart statuss 4 and 5 candidates, and that there appears to be geographic variation in access to heart-lung transplantation. Members noted that the degree of illness for congenital heart-lung candidates is not well accounted for in the heart allocation statuses. The Chair mentioned that their program must work closely with their local OPO to get offers for these candidates. A member noted that it should be considered in heart allocation if a patient requires a heart-lung transplant. A member shared that getting the patient transplanted is tough when a patient doesn't meet typical heart allocation status criteria, particularly because heart allocation policy has stringent requirements for exception requests. There is a concern that heart-lung candidates may become too sick for transplant if they cannot get organ offers until they reach heart status 1. A member said that the way multi-organ allocation is established, in heart-lung, the heart is the driving organ, but there are times when the lung needs to be the driving organ. The sickest organ should be able to drive the other organ.

Next steps:

The six-minute walk workgroup will be scheduled in the upcoming weeks. The Committee will continue to have discussions about potential changes to heart-lung registration and policy.

4. Policy Oversight Committee Update

The Committee heard an update from the Policy Oversight Committee (POC).

Summary of discussion:

A member asked about the importance of benefit scoring. The presenter explained that some projects are policy, and some are guidance documents. Implementing a policy rather than a guidance document may take more effort and resources. This is important to take into consideration for each project during project approval. The presenter commented that benefit scoring is relatively new for POC, and improvements are continuously being considered.

Next steps:

The Committee will provide POC with an update on the post-implementation of the CD lung.

5. Review NASEM Projects Idea

The Committee discussed project ideas aligned with the NASEM report. The six-minute walk project is aligned to improve equity recommendations, and the heart-lung project would support the CD of hearts project.

Summary of discussion:

Regarding helping transplant programs say yes to organ offers, the Chair asked if the Committee could consider developing a standardized document for OPOs that includes information about brain-dead donors and DCD that would be useful to programs. A document exists; however, it is not followed by OPOs consistently, and it is an important topic that needs to be addressed.

Another member expressed that it may take additional time to condition the lungs, and other organs trump the lung – compared to other organs, lungs are not prioritized for recovery. The member asked if this issue could be addressed. A member explained that with a low PF ratio, OPOs will not offer those organs. Some techniques could be used to manage the organs, but these options are not considered, which results in the lung organs not being offered. The Committee discussed what incentives could be introduced for OPOs to allow more time for conditioning of donor lungs. Members noted that donor recovery centers may provide an opportunity to plan more strategically by providing more time (up to 5 to 7 days) to condition lungs that otherwise would not be offered.

Another member inquired if it may be helpful to incorporate an educational component to help donor families understand why additional time may be needed to allocate organs. A member mentioned that programs are experiencing staff turnovers. In addition to this challenge, donor coordinators may not have much experience managing organ donors.

The Committee discussed challenges around the time constraints of accepting an organ. A member suggested including guidance for OPOs on the process of setting operating room (OR) time. Often, programs receive calls from the OR that organ procurement is set at a specific time, and there may not be a local procurement surgeon available. Members emphasized the challenge of setting OR times at the donor hospital. A member asked the Committee to consider how to incentivize community hospitals and health systems to set OR times that make sense. Community hospitals are strongly incentivized to set OR times at 2:00 am to avoid canceling elective cases. However, it's a disincentive for organ recovery and makes it very hard to place organs. Programs are being charged with the utilization of organs, and it's challenging to get a donor OR time promptly.

A member stated that there's variability in how donors are managed. Some successful countries have standardized protocols that are followed. The member indicated that understanding how to care for

complex patients takes expertise. The hospital-based organ recovery model is essential because there's an opportunity to foster groups of people with expertise in managing donors. Having a standardized document may help with the issue of donor management variability.

A member noted it would be helpful if the OPO could take on some post-death work. For example, a member said that staff are trained to perform a bronchoscopy at their local OPO. OPOs could own some of this work, which would help with some utilization issues. A member asked if it is known when the gamut of donor testing is completed. Members agreed that this should be monitored. Another member inquired if there is a list of all the items that must be done before the organ offer is sent. The Committee reviewed OPTN *Policy 2.11.D Required Information for Deceased Lung Donors*, which lists the information that OPOs are required to provide.

A member stated that OPOs had sent out a lung offer before the HLA typing of the donor was available. The member inquired if it has been specified that in the new system, OPOs cannot run the list until the HLA is available. Staff confirmed that this policy did not change in continuous distribution. The member said that this will be a problem because it will affect the composite allocation score (CAS).

A member asked if the OPTN Contractor is working on getting better variables for the social economic position (SEP) into the system. Staff replied that they hadn't gotten data yet but are working on getting it in the next few months. The Chair asked why primary care doctors or pulmonologists are not referring patients, and whether it could be related to education, time, or not having a relationship with the transplant center. A member replied that every population is a little different. The most disadvantaged population is chronic obstructive pulmonary disease (COPD) because they are cared for in the community. It is a challenge to capture what percentage of this population is not being referred due to low health literacy or might be of a lower socioeconomic status.

A member noted that kidney transplantation has United States Renal Data System (USRDS) data, which is a system that contains information about kidney candidate disparities and access to the list. The Committee discussed potential approaches for using data to better understand any disparities in access to lung transplantation and for helping other providers to make appropriate referrals for lung transplantation. A member suggested developing a tool that providers could use to enter patient information and see if the patient met the criteria for referral. Members suggested that datasets (e.g. perhaps via Medicare) that include patient-level information on supplemental oxygen use could provide more information on the broader population of potential candidates for lung transplant.

6. Update on Implementation of Lung-Kidney eligibility Criteria and Kidney-After-Lung Safety Net

The Committee discussed multi-organ exceptions in CD. Lung-kidney and lung-liver policy in CD requires OPOs to offer a kidney or a liver along with lungs to a candidate with a CAS of 25 or greater.

Summary of discussion:

A member stated that the Committee should consider how to handle exception requests for multi-organ candidates because they have access issues, and currently, there are no best practices for this. A member noted that the safety net criteria would be implemented in July 2023, which will help determine who is listed as multi-organ versus who may use the safety net. Staff shared that for lung candidates who are registered for multiple organs, the match run will identify the other organs they need. Lung multi-organ candidates with a CAS of 25 or higher will show up as a required share. When the eligibility criteria are implemented, the lung-kidney candidates must meet these criteria to show up in the system as required share. The Committee discussed that transplant programs may submit exception requests under the patient access attribute if they feel that their multi-organ candidates do

not have adequate access to transplant but do not have justification for submitting an exception under another goal, like medical urgency.

7. Public Comment Presentation: Identify Priority Shares in Kidney Multi-Organ Allocation

The Committee heard a presentation on the public comment concept paper, *Identify Priority Shares in Kidney Multi-Organ Allocation.* This concept paper provides background on multi-organ policies and the impact on kidney-alone patients.

The Ad Hoc Multi-Organ Transplantation Committee requests feedback on the following concepts:

- Required kidney shares
- Limit kidney multi-organ allocation
- Offering kidneys to candidates of equal priority
- Organ offer acceptance and required shares
- Balancing direction vs. flexibility for organ procurement organizations

Summary of discussion:

A member asked about the proportion of multi-organ kidney transplants compared to kidney-alone transplants. The presenter replied that kidney multi-organ transplants have been increasing but not as much as kidney alone transplants. As the kidney waiting list continues to increase andkidney alone transplants have increased, there's a gradual increase with multi-organ kidney transplants. Another member asked whether high quality kidneys should be offered to a multi-organ candidate over a kidney alone candidate. A member responded yes, that multi-organ candidates should have the opportunity for the best quality kidney and should not be penalized for needing more than one organ. Another member said that kidney alone candidates with high calculated panel reactive antibody (CPRA) should be prioritized over multi-organ candidates. A member stated that the biggest argument for a kidney transplant is the longevity of the graft. The member said that long graft survival as indicated by a low Kidney Donor Profile Index (KDPI) is not essential for multi-organ candidates since graft survival is more limited for multi-organ recipients. A member stated that multi-organ candidates should receive priority since it is such a small number of candidates.

A member said that these decisions should be based on waiting list mortality and if there is not a mortality risk to giving priority to multi-organ candidates, then there is no need to change this approach. Staff explained that there was a 2020 article[1] that compared donors where two kidneys were allocated. One kidney went to a multi-organ recipient, and the other to a kidney-alone recipient. The study found that there is a higher mortality risk for the next candidate on the kidney waiting list who would have received the kidney if it had not gone to the multi-organ candidate.

Another member asked why kidney-pancreas candidates should be prioritized over a lung-kidney candidate. Staff explained that often kidney-pancreas candidates compete for lower KDPI, high-quality kidneys so the concept paper is looking for feedback on access to transplant for kidney-pancreas candidates, since many low KDPI kidneys are offered to multi-organ candidates off of other organ match runs before OPOs reach the kidney-pancreas match run. A member said that type 1 diabetic

[1] Scott G. Westphal, Eric D. Langewisch, Amanda M. Robinson, et al., "The impact of multi-organ transplant allocation priority on waitlisted kidney transplant candidates," American Journal of Transplantation no. 6 (2021): 2161-2174, DOI: 10.1111/ajt.16390.

kidney-pancreas candidates should receive priority over other multi-organ candidates due to high waitlist mortality.

Next steps:

The Committee's feedback on the Multi-Organ Transplantation Committee concept paper will be posted to the OPTN website.

8. Overview of other Public Comment Items

The Committee heard an overview of the other public comment projects that are out for the Winter 2023 public comment cycle.

Summary of discussion:

In liver CD, a member asked for the population density attribute to be further explained. A member explained that population density attempts to account for rural areas with limited access to liver transplant hospitals and patient access. Members were surprised that the Liver & Intestine Committee do not intend to incorporate post-transplant survival into their allocation score at this stage, given that post-transplant survival was identified as an allocation goal for continuous distribution.

9. Open Forum

The Committee welcomed any questions or discussion.

Summary of discussion:

A member asked regarding the six-minute walk project, how often will six-minute walk be evaluated. The staff replied that it had not been determined yet. Another member asked when the first lung six-minute walk workgroup meeting is. Staff answered on April 6, 2023.

Upcoming Meeting

- March 16, 2023

Attendance

- **Committee Members**
  - Marie Budev
  - Erika Lease
  - Errol Bush
  - Edward Cantu
  - Cynthia Gries
  - Matthew Hartwig
  - Stephen Huddleston
  - Soma Jyothula
  - Julia Klesney-Tait
  - Karen Lord
  - Dennis Lyu
  - Lara Scaheen
  - Serina Priestley
  - Marc Schecter
  - Scott Scheinin
  - Nirmal Sharma
  - Nicholas Wood
  - Pablo Sanchez
  - Brian Armstrong
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - David Schladt
  - Maryam Valapour
  - Katherine Audette
- **UNOS Staff**
  - Kaitlin Swanner
  - Taylor Livelli
  - Tatenda Mupfudze
  - Susan Tlusty
  - Holly Sobczak
  - James Alcorn
  - Krissy Laurie
  - Rebecca Murdock
  - Sara Rose Wells