OPTN Lung Transplantation Committee
Meeting Summary
April 13, 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 4/13/2023 to discuss the following agenda items:

1. Welcome and agenda
2. Discussion: Promoting efficiency of lung allocation
3. Provide feedback: Organ Offer Acceptance Limits Project
4. 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. Discussion: Promoting efficiency of lung allocation

The Committee discussed feedback they have received since the implementation of continuous distribution of lungs. There is mixed feedback on higher versus lower offer volume. Some transplant programs have reported higher offer volume for programs with the most medically urgent candidates. Some transplant programs with only outpatient candidates reported seeing lower offer volume, while other transplant programs reported an uptick in higher sequence offers. Some transplant programs are receiving more Donation after Cardiac Death (DCD) and multi-organ offers, and some transplant programs are observing more out-of-sequence allocation.

Transplant programs have also reported that more donor information needs to be available at the time of offer, particularly if needed to justify farther travel to recover lungs..

Staff provided an overview of system tools for managing offers.

Tools for transplant programs include:

- Donor acceptance criteria
- OPTN Waiting List update utility
- Reports in OPTN Waiting List
    - Pediatric priority 1 expiring data report
    - Lung Composite Allocation Score: 28 day report
    - Lung Composite Allocation Score: Missing/expired data report
    - Lung Composite Allocation Score: Points report

- Review feedback on exception requests

Tools for organ procurement organizations (OPOs) include:

- Notification limits

OPTN Policy 2.11.D Required Information for Deceased Lung Donors requires inclusion of an arterial blood gas (ABG) within two hours, bronchoscopy results, a chest x-ray, human leukocyte antigen (HLA) typing, a sputum gram stain, and lung laterality for lung offers. Hepatitis and Human Immunodeficiency Virus (HIV) infectious disease testing is required to run a match and SARS-CoV-2 testing is required pre-transplant by OPTN Policy 2.9 Required Deceased Donor Infectious Disease Testing. Transplant program members have said that ABGs are often old at time of offer, SARS-CoV-2 testing should be required at the time of offer, and computerized tomography (CT) scans should be a requirement at the time of offer.

The Committee discussed options that could address the increased offer volume seen since implementation:

- Provide more options for screening offers via acceptance criteria
    - E.g., "opt-in" to offers from geographically isolated areas like Hawaii, Alaska, and Puerto Rico
- Explore updates to OPO notification limits
- Request development of offer filters for lung
- Offer filters are applied at the time the OPO makes an offer, whereas acceptance criteria are applied when an OPO runs a match
- Review/update required donor information policy/system requirements and monitoring
- Increase weight on placement efficiency in allocation score

Summary of discussion:

The Chair stated that she has received five offers today and all the ABGs are over four hours old, so compliance with OPTN Policy 2.11.D Required Information for Deceased Lung Donors is not adequate. She stated tracheal aspirate should be available with the bronchoscopy. She estimates 15% of her offers do not have either tracheal aspirates or nasopharyngeal swabs included. She noted she routinely has the chest x-ray, but often gets offers with no HLA typing available. She stated she always has the sputum gram stain, but echocardiograms are also needed even if not required by policy. She stated this will be a deciding factor for certain donors.

The Past Chair stated it is frequent that chest x-rays were last done 24 hours ago, which is not a reasonable timeframe. She stated the list of requirements in OPTN Policy 2.11.D Required Information for Deceased Lung Donors is outdated.

A member asked if policy requires ventilator settings or gases on ventilators. The Chair stated OPTN Policy 2.11.D Required Information for Deceased Lung Donors requires, "Arterial blood gases and ventilator settings on 5 cm/H20/PEEP including PO2/FiO2 ratio and preferably 100% FiO2, within 2 hours prior to the offer." The member responded this does not align with what she would ask for. The Chair agreed and stated when evaluating offers she sees that donors are overventilated with high tidal volumes. She agreed lung protective statuses six to eight mL/kilo would be necessary for any donor management. A member noted this is evident in the literature, but not understood by the OPO community. She stated this needs to be messaged to the community. The Chair agreed and encouraged members to reach out to their local OPOs to form protocols.

A member stated lung measurements and serology results are needed. He also suggested defining recruitment maneuvers for OPOs. He explained this is variable across OPOs and is a growing problem with broader distribution. He said lung dynamic mechanics like dynamic compliance, static compliance, plateau pressures and peak expiratory pressures would be instrumental in making decisions. The Chair said to keep in mind OPOs are variable, so any proposed policy must be feasible for all of them. That may limit the measurements that can be required by policy, but these can be requested. The Past Chair suggested educating the OPO community on why transplant programs ask for this additional information.

A member said that a consensus on an antibiotic plan for a donor should be required by policy. The Chair noted the Committee must factor in what the OPO can afford. A member stated her OPO will ask for an acceptance before performing an echocardiogram. She explained this can push out recovery timelines since it depends on availability of an echocardiogram technician at the donor hospital.

A member noted some offers come with a set operating room time. She stated that there should be a minimum timeframe set before the transplant program has to go to the operating room.

The Past Chair said the enormous sequence offers that have started since continuous distribution of lungs implementation needs to stop. She voiced concern over retaining transplant coordinators. The Chair noted she has had eight offers in the last 12 hours that she oversees, and this is resulting in offer fatigue.

A member stated the filter in the OPTN Computer System for distance willing to travel for DCD donors has gone away since implementation. Staff explained that the local versus import distinction went away from the donor acceptance criteria. Staff will follow up on this.

Members agreed that mandating notification limits for OPOs is the Committee's priority.

3. Provide feedback: Organ Offer Acceptance Limits Project

The Committee received a presentation from the OPTN OPO Committee on their aim to modify OPTN Policy 5.6.C: Organ Offer Acceptance Limit to only allow a transplant hospital to have one organ offer acceptance for each organ type for any one candidate. This would eliminate the scenario where a transplant program can be primary for offers from two different donors and wait to determine which organ to accept for their candidate.

The presenter concluded that concurrent acceptance events most frequently occur for liver; the majority of candidates that concurrently accept organs are highly medically urgent; lungs concurrently accepted are most frequently transplanted with acceptor; the majority of livers concurrently accepted are transplanted with another candidate and for lungs and livers declined by concurrent acceptors the most frequently occurring refusal reason is, "Candidate transplanted or pending transplant."

The presenter asked which of the following options the Committee prefers:

- Modify OPTN Policy 5.6.C: Organ Offer Acceptance Limit to only allow a transplant hospital to have one organ offer acceptance (primary offer)
- Add timeframe prior to scheduled donor organ recovery to make a decision if there is more than one offer for a candidate
- Exceptions to the one organ offer acceptance based on medical urgency status
- Organ specific requirements
- Exception for DCD donors

Data Summary:

Multiple acceptance events between March 15, 2021 and September 15, 2022 occurred 811 times for liver, 62 times for lung, and four times for heart. Concurrent acceptors for lungs tended to have relatively high lung allocation scores (65.52% had a LAS of 50 or greater).

The outcomes of lungs that were concurrently accepted were 34.68% "transplanted with acceptor," 33.87% "organ not recovered," 25.81% "transplanted with another candidate," 3.23% "recovered for transplant but not transplanted," and 2.42% "recovered not for transplant." The most common refusal code for recovered lungs concurrently accepted and then declined was, "candidate transplanted or pending transplant" (38.89%), followed by "organ size" (13.89%). On average, concurrently accepted recovered lungs were declined around 5 hours before cross clamp during this time period. Out of sequence allocation is generally not needed for lungs.

The presenter noted that on average, lungs are declined around 5 hours before cross clamp and 12 hours before for those transplanted to another candidate. On average, livers are declined around 1.5 hours before cross clamp and 2 hours before for those transplanted to another candidate. Out of sequence bypass codes are utilized 16% of the time for livers concurrently accepted then declined that is almost double the national rate for all accepted livers. The cold ischemic time for transplanted livers that were declined by the concurrent acceptor was slightly longer than those that were transplanted with the concurrent acceptor (6 vs. 5.72 hours).

Summary of discussion:

The Chair asked if this behavior of multiple acceptances is specific to a particular center or geographic region. The presenter responded he does not have that data. A member asked how many multiple acceptances were for DCD lung donors. The presenter responded that 11.29% lungs concurrently accepted were from DCD donors. Members stated an exception would need to be made for DCD because transplanting lungs from these donors is less likely.

The Vice Chair stated he has concerns because the rate of concurrent acceptances for lung is relatively low. He also noted that concurrent acceptances tend to happen for high LAS candidates. He emphasized that the non-utilization rate is low for concurrently accepted lungs. He stated transplant programs who are more aggressive may be a lot more likely to transplant DCD lungs, so this exception may be a moot point. The presenter responded that he is concerned that late declines lead to OPOs scrambling to place organs, and this hinders the efficiency of the process. He also noted donor families are negatively impacted. He agreed exceptions for higher CAS candidates and DCD donors seems reasonable.

A member stated he has concerns with a one offer acceptance limit because while asking an OPO for a CT scan he has been marked as accepting an offer. He has been told by OPOs this is because they need an acceptance to close out a multi-organ list, which then closes him off from other offers. The presenter encouraged the member to clarify this with his OPO because this is not an acceptance. The Chair agreed that certain OPOs and transplant programs may exhibit behavior that makes this an issue. She encouraged the presenter to look at if the data is specific to certain transplant programs and OPOs.

A member stated that she has accepted more than one offer for very sick patients, but she has communicated this with the OPO when doing so and emphasized that the OPO should have a strong back-up. The member asked if the proposal could use different approaches for different organs. The presenter agreed this policy should be relaxed for sicker candidates. He stated that it will be simpler to have this policy universal for all organs.

A member commented policy should allow for concurrent acceptances with a specified timeframe to mitigate limited operating room availability. The presenter stated this will not prevent transplant

programs from using the provisional yes tool. The member responded that they are often pushed to accept to get test results. A member stated there is a lot of variability in lung transplant and it is more unpredictable than other organs. Members emphasized that this should be a policy for the organ group that is taking advantage of concurrent acceptances. The presenter responded that they are attempting to be as uniform as possible.

4. Next steps and closing comments

The Chair thanked members for their attendance and thoughtful comments.

Summary of discussion:

There was no further discussion by the committee.

Upcoming Meetings

- May 18, 2023, teleconference, 5 pm ET

Attendance

- **Committee Members**
  - Marie Budev
  - Erika Lease
  - Brian Armstrong
  - Cynthia Gries
  - Dennis Lyu
  - Edward Cantu
  - Errol Bush
  - Matthew Hartwig
  - Nirmal Sharma
  - Pablo Sanchez
- **HRSA Representatives**
  - Marilyn Levi
  - Jim Bowman
- **SRTR Staff**
  - David Schladt
  - Maryam Valapour
  - Nicholas Wood
- **UNOS Staff**
  - Kaitlin Swanner
  - Taylor Livelli
  - Beth Overacre
  - Kate Breitbeil
  - Chelsea Weibel
  - Darby Harris
  - Holly Sobczack
  - Krissy Laurie
  - Tatenda Mupfudze
  - Samantha Weiss
  - Sara Rose Wells
  - Susan Tlusty
- **Other Attendees**
  - Brian Keller
  - David Erasmus
  - Ernestina Melicoff-Portillo
  - Katja Fort Rhoden
  - Thomas Kaleekal
  - Kurt Shutterly
  - PJ Geraghty
  - Siddhartha Kapnadak