OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Meeting Summary

OPTN Lung Transplantation Committee
Meeting Summary
September 15, 2022
Conference Call

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

Introduction

The Lung Transplantation Committee (the Committee) met via Citrix GoTo teleconference on 9/15/2022 to discuss the following agenda items:

1. Welcome and agenda
2. Continuous distribution and public comment update
3. Public comment presentation: *Redefining Provisional Yes and the Approach to Organ Offer and Acceptance*
4. Public comment presentation: *Enhancements to OPTN Donor Data and Matching System Clinical Data Collection*
5. Next Steps and Closing Comments

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

1. Welcome and agenda

The Chair welcomed the Committee members.

Summary of discussion:

There was no further discussion by the Committee.

2. Continuous distribution and public comment update

UNOS staff updated the Committee on the live educational playlist for continuous distribution that includes the courses:

- LUN102 Basic Principles of Continuous Distribution of Lungs
- LUN103 Unacceptable Antigens & CPRA in Lung Continuous Distribution

Additional products will be released on 9/28 that include:

- Lung Composite Allocation Score (CAS) Data Report
- Additional educational offerings
- Guide to Calculating the Lung Composite Allocation Score

The Committee reviewed current public comment feedback on the three OPTN Lung Transplantation Committee proposals in fall 2022 public comment, including three opposed votes and comments from regional meetings. . One comment recommended increasing pediatric representation on the review board for pediatric cases. Another comment expressed concern about perceived expansion of multi-organ policies potentially pulling more kidneys away from kidney-alone candidates. Regarding the Update Data Collection for Lung Mortality Models proposal, a commenter asked that the Committee provide an estimate of how long it would take to update the models to make useful calculations, that

the Committee consider whether leaving the data fields optional would introduce bias, , and explore whether it is possible to use retrospective data collection via automated interfaces to obtain the desired data.

Summary of discussion:

A Committee member asked if the guide has all the coefficients. UNOS Staff responded it has all the formulas, the rating scales, the weightings, and how all those pieces fit together.

3. Public comment presentation: *Redefining Provisional Yes and the Approach to Organ Offer and Acceptance*

The Operations and Safety Committee produced a concept paper with a three-tiered framework that aims to outline requirements for transplant programs and improve transparency across OPOs and transplant programs. A member of the Operations and Safety Committee explained this concept paper is in response to the high number of offers due to the high number of provisional yes responses, which overwhelms transplant programs and does not result in final acceptance.

The Operations and Safety Committee is looking for feedback on the three-tiered framework and associated responsibilities, time limit on offers within each tier, and the number of offers that can be sent within each tier.

A member of the Operations and Safety Committee explained the Tiered Framework:

- Tier III

Transplant programs evaluate organ offers to see if the offer immediately meets any of their program's refusal reasons. This would streamline how notifications are sent and notify OPOs of offers that are turned down. A transplant program would receive an electronic offer and provide a response.

- Tier II

In addition to the requirements in Tier I, transplant programs assess the candidate's medical suitability and notify OPOs of any additional information needed for testing or evaluation. This Tier would include additional back up offers, one offer for each organ available, and a one-hour time limit on offers.

- Tier I

In addition to the requirements in Tier I and Tier II, transplant programs assess histocompatibility and confirm candidate availability for transplant. There would be primary and back up offers with one offer sent for each organ available. This would include a one-hour time limit on the first offer and 30 minutes for subsequent offers.

Summary of discussion:

- Redefining Provisional Yes

The Chair highlighted that a lot of time is wasted asking for information from OPOs that is already required, such as a bronchoalveolar lavage (BAL) or a bronchoscopy, and asked if this is addressed in the proposal. Another member asked how this differs from our current system. A member vocalized this tier system works well for kidneys but poses complications for lungs. He explained this is because offers should be sent to a very limited number of candidates to not waste any time, so Tier III notifications should be limited to ABO identical candidates within 250 nautical miles. He expressed concern that programs would take too long in accepting these offers, which would limit the number of candidates that could serve as backups. He asked if sequences would still be included within the tiers. The presenter stated that reinforcing the minimum requirements to make sure a good offer is provided has

not yet been discussed by the Committee, but she will take this back to them. She explained the committee is trying to balance between overburdening programs while not leading to organ discard.

The member suggested requiring all tests be done by the OPO before the organ is offered, and a common list of tests that are required can be laid out in this proposal. A member agreed and stated there is inefficiency when going through the list. He stated for a lung transplant to have an efficient allocation there must be a chest x-ray in six hours, potentially a CT scan, etc. to assess organ quality. However, the data presented is often 24-48 hours old. He explained this tiered system does not necessarily work for lung because tier III needs to be expanded to include provisions for accepting the organ, such as emphysema shown on a CT scan. Another member emphasized this is kidney centric because lung is so dynamic, and an acceptance cannot be made as updated information causes a lot to change. A member explained the provisional yes is essential to the lung community, and tier III is already conducted by transplant centers, a balance just needs to be found so centers are not receiving an overwhelming amount of offers.

The Chair stated transplant centers have tight lists that are consistently monitored so when an organ is offered these candidates are ready to go for transplant. A member noted 70% of all matches occur in sequence numbers less than 10. Since most lungs are placed early in the allocation process, lung may not have the same challenges as other organs in trying to place organs far down the match run.. Members voiced concern that going two programs at a time down the list may delay allocation. A member stated tier II would serve as the new provisional yes for lung transplant centers and that could be very problematic for the lung community.

4. Public comment presentation: *Enhancements to the OPTN Donor Data and Matching System Clinical Data Collection*

The Vice Chair of the OPTN Organ Procurement Organization Committee presented on a new proposal that aims to streamline communication of donation after circulatory death (DCD) donor information and provide easily accessible information.

The following data elements are proposed to be added:

- Withdrawal of life sustaining medical support, date/time
- Cessation of circulation, date/time
- Flush time (In Situ), date/time
- Oxygen saturation (SpO2)

The rationale for this proposal is that data are not currently collected on these elements in the OPTN Donor Data and Matching System. This would reduce phone calls between OPOs and transplant programs, provide a snapshot of DCD donor progression, allow for improved organ offer evaluation, and improve efficiency of organ placement.

The proposal includes implementation in the OPTN Donor Data and Matching System and OPOs may have to update electronic donor records to allow for updated DCD information.

The Vice Chair of the OPTN Organ Procurement Organization Committee asked for feedback on:

- Are there additional data fields that could improve offer evaluation for DCD donors?
- Should a validator question, such as “controlled DCD?” be included, to reduce administrative burden and streamline data reporting?
- Will the proposed data collection be burdensome for OPOs to report? How can implementation be eased for OPO members?

- Should a new, separate page be created within the donor summary in the OPTN Donor Data and Matching System to report DCD progression information, including vitals such as heart rate, blood pressure, and oxygen saturation?

Summary of discussion:

The Chair stated the International Society for Heart Lung Transplant (ISHLT) developed a DCD database about seven years ago that was a wealth of information on data from transplant centers' individual cases, and this proposal may help all centers report data back to the ISHLT and revive that database. The Chair asked about having separate categories for controlled and uncontrolled DCDs. The presenter stated this is a possibility that could be captured based on the Maastricht classifications 1-4.

A member stated normothermic regional perfusion is becoming more common for heart procurement from DCDs and these donors go into a new sequence not seen before after a pulmonary bypass. He asked how the OPTN Organ Procurement Organization Committee plans to capture that data. The Vice Chair of the OPTN Organ Procurement Organization Committee stated that is not addressed in this proposal currently, but the committee is looking at that and is not opposed to it, they just want to make sure it is completely approved by the community and ethically sound.

A member stated standardizing this data collection is very helpful for placement and transplant teams, as well as for research in the future that examines what type of candidates will expire in the timeframes set, what kinds of organs are safe, and how to use out of body perfusion. The member stated not having the information as an attachment in the pdf will be very helpful for data storage and organ placement. The member noted there are offers that seem perfect, but these donors are over-breathing the ventilator and do not expire, so having that information would be helpful. The Vice Chair of the OPTN Organ Procurement Organization Committee responded that these fields will not address that, but OPOs could address those in the Donor Highlights section as needed.

5. Next Steps and Closing Comments

UNOS staff noted the October meeting was moved up to October 13, 2022. The Chair thanked the members for their comments and participation.

Summary of discussion:

There was no further discussion by the Committee.

Upcoming Meetings

- September 22, 2022, Updating Mortality Models Subcommittee, 4PM-5PM EST, teleconference
- October 13, 2022, 5PM-6PM EST, teleconference

Attendance

- **Committee Members**
    - Marie Budev
    - Erika Lease
    - Brian Armstrong
    - Cynthia Gries
    - Dennis Lyu
    - Edward Cantu
    - Errol Bush
    - John Reynolds
    - Kelly Willenberg
    - Lara Schaheen
    - Maryam Valapour
    - Matthew Hartwig
    - Pablo Sanchez
- **HRSA Representatives**
    - Marilyn Levi
- **SRTR Staff**
    - David Schladt
- **UNOS Staff**
    - Kaitlin Swanner
    - Taylor Livelli
    - Holly Sobczack
    - Joann White
    - Kayla Temple
    - Ross Walton
- **Other Attendees**
    - PJ Geraghty
    - Kimberly Koontz