

OPTN Organ Procurement Organization Committee

Meeting Summary

January 23, 2025

Conference Call

PJ Geraghty, MBA, CPTC, Chair

Lori Markham, RN, MSN, CCRN, Vice Chair

Introduction

The OPTN Organ Procurement Organization Committee (the Committee) met via WebEx teleconference on 01/23/2025 to discuss the following agenda items:

1. Deceased Donor Lung Testing
2. Establish Comprehensive Multi-Organ Transplantation (MOT) Allocation Policy
3. 3-Month Monitoring Report – Modify Organ Offer Acceptance Limit

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

1. Deceased Donor Lung Testing

Presentation Summary

Modifying Lung Donor Data Collection

Purpose of proposal

- Promote efficiency of lung allocation by updating data collection on lung donors
- Streamline communication and information sharing between Organ Procurement Organizations (OPOs) and lung transplant programs as transplant programs consider lung offers.

The following proposed changes are intended to provide additional information needed to make informed decisions on lung offers.

Proposed changes to the OPTN Donor Data and Matching System include adding peak inspiratory pressure (PIP) as well as smoking history for cigarettes, marijuana, and vaping. This smoking history would be input by the OPO using one of the following options: packs per day, cigarettes per day, or unknown then followed by the number of years the donor smoked. The requirement of the OPO to enter if the donor smoked greater than twenty pack-years would be removed because the OPTN Donor Data Matching System would calculate that automatically using the newly added information. Lastly the OPTN Donor Data Match System would be modified to allow OPOs to indicate if lung diagnostic testing such as a bronchoscopy or a computed tomography (CT) scan was complete, pending, or unable to be completed.

Proposed changes to the Deceased Donor Registration (DDR) would add cigarette smoking history and remove the greater than twenty pack years cigarette use.

Proposed changes to the OPTN Waiting List would add Acceptable donor predicted Total Lung Capacity (pTLC) range and remove the greater than twenty pack years cigarette use.

Proposed changes to the Lung Offer Filter would allow programs to filter out lung offers that exceed specific cigarette pack quantities of their choosing.

These proposed changes mean the OPOs will be required to provide additional data and that may require staff training, adjustments to existing workflows, and increased staff time spent on each lung offer. Additionally, lung transplant programs will need to ensure staff are educated on the new features in the OPTN Waiting List and Lung Offer Filters.

Questions for the OPO Committee

- Will this new and updated data collection provide transplant programs with useful, granular information about potential lung donors?
- Do OPOs foresee challenges or burden related to this data collection?
- Could the data fields, response options, or data definitions be clearer?
- Do patients and donor family members support efforts to streamline communications between transplant programs and OPOs to place organs more efficiently?

Summary of Discussion:

No decisions were made regarding this agenda item.

The Committee discussed what the vaping and marijuana fields would look like. The vaping field and marijuana fields are designed to be very similar with options for if the patient is a current user, former user, has never used, or their vaping/marijuana history is unknown. If the donor is or was a smoker the system would then require the frequency of use with options such as every day, every week, less than every week, and unknown. The Chair noted that while this system might not be the best assessment of quantity given the differences in the amount an individual might smoke per day, this was likely the best format possible for capturing accurate data. The Vice Chair noted there is a space for free text in the OPTN Donor Data Matching system where details like that could be added.

The Chair asked if the pTLC would be a calculated field and the presenter confirmed it would be automatically calculated so there should be no additional burden on OPO coordinators.

The Committee discussed the new required field for completion of diagnostic tests in the OPTN Donor Data and Matching System. These diagnostic tests include angiography, bronchoscopy, cardiac catheterization, chest x-ray, CT scans, magnetic resonance imaging (MRI), epicardiogram, electrocardiogram (EKG), and ultrasounds. OPOs would be required to enter answers for bronchoscopy and chest CT scans, the rest of the diagnostic testing fields would be optional. This requirement was designed to address the constant communication back and forth between OPOs and transplant centers regarding testing, which is further complicated as many of these tests are performed by third parties. Having all the information about diagnostic tests in a single place would increase efficiency for OPO coordinators and transplant centers.

One member raised concerns that the proposal noted the workgroup supported adding diagnostic test status requirements for all diagnostic testing in the OPTN Donor Data Matching System. The member felt that putting all that on OPO coordinators would result in a large increase in workload. While only bronchoscopies and chest CT scans would be required now, they were concerned that in the future that could change as this proposal would enable requirements for all diagnostic testing questions. Another member felt that these changes would create efficiency and eliminate follow-up questions that can cause delays.

Next steps:

There are no next steps for this agenda item.

2. Establish Comprehensive MOT Allocation Policy

Presentation Summary

Purpose

- This policy proposal aims to promote equity in access to transplant among multi- and single-organ candidates and to facilitate consistent and efficient allocation.
- It will standardize the order in which OPOs allocate organs across match runs for highly prioritized candidate groups.

Twenty current and past OPTN Ad Hoc MOT committee members participated in a values prioritization exercise to help build clinical consensus on organ allocation priorities across match runs. These participants compared sixteen sets of candidates and determined which candidates should receive priority. Many factors went into this prioritization exercise such as candidate waitlist mortality and outcomes, post-transplant survival rates, candidate access and time without an offer, and match run efficiency.

Allocation Plan

The policy proposal will standardize allocation for donors with more than one organ available by inserting multi-organ allocation tables in policy. These tables include approximately fifty high priority candidate groups across all organ types. The OPO will enter donor information, run the applicable matches, and the system will generate a donor-specific allocation plan based on the applicable allocation table. The OPTN Ad Hoc MOT Committee has requested the development of a system solution to help guide the user through the proposed multi-organ allocation tables, with the goal of streamlining the allocation process.

The multi-organ allocation tables incorporate classifications in existing organ-specific policies. For example, the order of heart classifications within the multi-organ allocation tables follows existing heart policy. This policy proposal would not change the order of priority set in organ-specific policies. Additionally, lung allocation would use Composite Allocation Scores (CAS) as lungs are allocated through a continuous distribution system.

Details

The MOT Committee is focusing specifically on six multi-organ allocation tables which cover around ninety-six percent of donors to multi-organ recipients using data from July 2021 to December 2023. For the four percent of donors not covered by the tables they can still be allocated according to current OPTN policy.

Priority is largely based on medical urgency with some groups prioritized to promote access to transplants such as highly sensitized kidney patients and people who are prior living donors. Priority was also determined in a way to maximize utilization of organs and to try to avoid non utilization of organs, particularly pancreata.

Questions for the OPO Committee

- Does the community support the standardization of allocation order across match runs?
- Do the proposed tables cover appropriate donor and candidate groups?

- Do the proposed tables appropriately prioritize candidate groups?
- What potential barriers to operationalization does the community anticipate?
- What contingencies should be considered when developing the policy and system solutions?
- Does the combination of multi-organ allocation tables along with more flexibility to place any remaining organs after completion of the allocation tables support allocation efficiency?

Summary of Discussion:

No decisions were made regarding this agenda item.

One member asked what happens when a case is started, and an organ looks like it will not be transplantable, and allocation is started on other organs but then the organ that looked like it could not be transplanted becomes viable. They wanted to know if OPOs will have to restart the allocation process under those circumstances. The presenter answered that once a primary offer has been made it cannot be rescinded so the OPO would need to continue the allocation process as normal and treat the now viable organ as a single organ allocation.

Another member asked if the MOT allocation process would all be done through a single match run. The presenter answered that there would still be multiple match runs but that the allocation plan would be a single plan that would guide users between match runs. A staff member noted the system has yet to be built and so they do not know exactly what it will look like yet.

Next steps:

There are no next steps for this agenda item.

3. 3 Month Monitoring Report – Modify Organ Offer Acceptance Limit

Presentation Summary

Background

- In 2018, changes to OPTN policy established limits on the number of concurrent organ offer acceptances for any one candidate per organ type.
- The practice of having multiple primary organ offer acceptances can lead to late declines, which can cause logistical issues for OPOs.
- May 29, 2024, the Modify Organ Offer Acceptance Limit policy was implemented. This policy reduced the number of primary organ offer acceptances from two to one for any one candidate per organ type.

Data and Methods

The monitoring report used heart, liver, and kidney donor data from pre-policy February 2024 to May 2024 and post policy May 2024 to August 2024 as well as heart, liver, and lung candidates and transplant recipient data. The report compared median ischemic times across eras using Mood's median-test. For waitlist mortality rates, active and inactive waiting times were included in the patient years calculation. Candidates who received any previous transplant and multi-organ transplant candidates were excluded from the analyses.

For lungs, utilization rate is defined as the percentage of lungs that are transplanted based on all possible lungs from every deceased donor with at least one organ recovered for the purpose of transplant. Lung recipients' medical urgency status was based on the medical urgency component of their composite allocation score (CAS). This component is derived from the area under an estimated one-year survival curve for each patient and represents the estimated number of days in the upcoming year a patient is expected to survive on the waiting list without a transplant. This component also includes points from approved medical urgency exception requests.

The Monitoring Request

1. The non-use rate (organs recovered with the intent to transplant but not transplanted)
2. The utilization rate
3. The proportion of organs with a final acceptance allocated out of sequence or through the expedited liver process.
4. The number of acceptances refused after cross-clamp
5. Medical urgency status at transplant for recipients
6. Distribution of cold ischemic time at transplant for recipients
7. Pre-transplant mortality rates

An organ was considered to have been allocated out of sequence if one of the following refusal codes was used after an offer:

- Reason does not fit the other bypass reasons available.
- Potential recipient bypassed due to transportation logistics, including distance in relation to ischemic time or weather conditions.
- Potential recipient bypassed due to urgent donor organ placement.
- Potential recipient bypassed because of offer(s) made during an expedited placement attempt.
- Expedited Liver Placement, Reason does not fit the other bypass reasons available.

Results

4,381 donors were recovered during the pre-policy period. 4,226 were recovered during the post-policy period. Of those donors that were recovered during the pre-policy period 1,198 were heart donors, 3,069 were liver donors, and 954 were lung donors. Of those donors that were recovered in the post-policy period 1,279 were heart donors, 3,096 were liver donors, and 927 were lung donors.

- For utilization and non-use rates compared to the pre policy era in the post policy era there was an increase in utilization rates for donor after brain death (DBD) and donor after circulatory death (DCD) heart donors and DCD liver donors.
- For the percentage of accepted organs allocated out of sequence in the pre policy era compared to the post policy era there was a decrease for hearts, livers, and lungs.
- There was no significant difference in the proportion of transplants by medical urgency for either heart, liver, or lung transplants between the pre and post policy eras.
- There was no significant difference in transplants by medical urgency status and age between the pre and post policy eras.
- There was no significant difference in the distribution of cold ischemic time between the pre and post policy eras.

- There was no significant difference in mortality rates by age between the pre and post policy eras.
- There was no significant difference in the mortality rates by medical urgency status between the pre and post policy eras.

Liver Committee Concerns regarding Single Offer Acceptance Policy

The OPTN Liver and Intestinal Organ Transplantation committee has three possible scenarios they are concerned about under this new policy for Status 1 and Model for End-Stage Liver Disease (MELD) 37 or higher patients.

1. There is a young DCD donor with a delay of the initial operating room (OR) time and then the candidate dies waiting for the liver.
2. There is a non-ideal donor where the OR time is set with no delay, and the candidate receives a transplant but with increased risk due to quality.
3. There is an ideal donor where there is no OR time set, and the candidate dies waiting for the liver.

The Liver Committee would like to add the following items to future analysis in this monitor report.

- How many candidates are waiting at the end of each month with a MELD 37-40 or as a Status 1A/1B?
- How many of these patients become too sick to transplant/die with an accepted offer?
- How many had a provisional yes on the same day as too sick to transplant/death?
- Time from first acceptance offer to transplant.
- How many times did DCD get accepted and donor not expire?
- Number of declines for other offers because accepted; how many offers were declined because of Yes?
 - How many of those offers were pre-transplant?
- Intra-operative liver declines
 - How many had bedside biopsy before donor OR?

Summary of Discussion:

No decisions were made regarding this agenda item.

The Vice Chair told the Committee that Committee Leadership had spoken with Liver Committee Leadership and been told that anecdotally liver transplant centers are seeing higher MELD and Status 1 patients being negatively impacted by this policy. Liver Committee Leadership would like the OPO Committee to consider an exception to the policy for high MELD/Status 1 patients.

The Vice Chair noted that the data monitoring report is only a three-month timeframe and so it would be hard to draw conclusions from the report. While it does show that there is an increase in organ utilization, more data is needed before making any decisions. The Committee leadership agreed to share the Liver Committee's questions and see if there was anything else missing that might be beneficial to submit as an addition to the monitoring request.

The Committee felt that after the policy they had noticed a drop in late liver declines at their various OPOs. One member noted that a transplant center holding two organs based on OR times that might be a few hours apart with the intention of canceling one of those offers really disrupts the OPO's workflow when a transplant center could instead hold one organ and if the timing is not right, release it and take a different offer.

The Vice Chair noted that one concern they had with the additional research items was the "time from first acceptance offer to transplant" because there will be extended time there that does not accurately reflect the process due to OR delays because an organ team, like heart, backs out. The Chair felt this timeframe could be long for a multitude of reasons, not all related to multiple acceptances, such as the donor not arresting, a liver biopsy being bad, or a problem with transportation. Another member added that machine perfusion could add time to this item as well. The Committee debated changing that item to time from cross-clamp to OR time but decided against it because there are a lot of variables in that timeframe beyond the OPOs control. Instead, they decided to remove that question from the additional research items in the event they submit these items as an addition to their data monitoring request.

Next steps:

- Wait to see if the Liver Committee is going to submit these questions as part of their own data request.

Upcoming Meeting

- February 27, 2025

Attendance

- **Committee Members**
 - PJ Geraghty
 - Lori Markham
 - Rachel Markowski
 - Sharyn Sawcazak
 - Theresa Daly
 - Dan DiSante
 - Ann Rayburn
 - Dough Butler
 - Clint Hostetler
 - Judy Storfjell
 - Ross Walton
 - Shane Oakley
 - Stephen Gray

- **SRTR Staff**
 - Jonathan Miller
 - Katie Siegert

- **UNOS Staff**
 - Kaitlin Swanner
 - Kelly Poff
 - Ethan Studenic
 - Alina Martinez
 - Kevin Daub
 - Sarah Roache
 - Sara Langham

- **Other**
 - Matt Hartwig
 - Zoe Stewart